SUMMARY SHEET
SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

November 12, 2020

( ) ACTION/DECISION
(X) INFORMATION

I. TITLE: Healthcare Quality Administrative and Consent Orders.

II. SUBJECT: Healthcare Quality Administrative Orders and Consent Orders for the period of September 1, 2020 through September 30, 2020.

III. FACTS: For the period of September 1, 2020 through September 30, 2020, Healthcare Quality reports five Consent Orders totaling $11,650 in assessed monetary penalties. No Administrative Orders or Emergency Suspension Orders were executed during the reporting period.

Healthcare Quality Bureau	Facility, Service, Provider, or Equipment Type	Administrative Orders	Consent Orders	Emergency Suspension Orders	Assessed Penalties
Bureau of Facilities Oversight	Community Residential Care Facility	0	1	0	$5,000
	In-Home Care Provider	0	1	0	$750
Bureau of Healthcare Professionals	Ambulance Services	0	1	0	$2,500
Bureau of Radiological Health	Dental X-Ray	0	2	0	$3,400
TOTAL		**0**	**5**	**0**	**$11,650**

Submitted By:

Gwendolyn C. Thompson

Gwen C. Thompson
Director of Healthcare Quality

HEALTHCARE QUALITY ENFORCEMENT REPORT
SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

November 12, 2020

Bureau of Facilities Oversight

Facility Type	Total # of Licensed Facilities	Total # of Licensed Beds
Community Residential Care Facility	501	22,330

1. Legacy at Southpointe – Greenville, SC

Inspections and Investigations: The Department was notified of and later confirmed with the facility that it allowed a local news station to enter the facility in July 2020, which was in violation of the Governor's Order 2020-48 and regulatory requirements.

Violations: The Department found that the facility failed to comply with the visitation restrictions set forth in the Governor's Order 2020-48 and Section 1701 of Regulation 61-84, *Standards for Licensing Community Residential Care Facilities*, by allowing news media personnel to go inside of the facility.

Enforcement Action: The parties agreed to resolve the matter with a consent order. In September 2020, the parties executed a consent order imposing a civil monetary penalty of $5,000 against the facility. The facility was required to pay the full amount of the penalty within 30 days of executing the Consent Order.

Remedial Action: The facility has made the required payment.

Prior Enforcement Actions: None in the past five years.

Facility Type	Total # of Licensed Providers
In-Home Care Provider	741

2. Visit by an Angel LLC – North Charleston, SC

Inspections and Investigations: The Department notified the provider beginning in May 2020 that the provider was required to submit both a license renewal application and the license renewal fee in order to renew their license. The Department found that the provider repeatedly violated regulatory requirements by letting their license expire.

Violations: The Department found the provider failed to comply with Regulation 61-122, *Standards for Licensing In-Home Care Providers*, by continuously failing to submit the renewal application and fees within the specified timeframe. The provider repeatedly failed to timely submit a renewal application and pay the required fees.

Enforcement Action: The parties agreed to resolve the matter with a consent order after the Department notified the provider that their license was expired and no longer valid. In September 2020, the parties executed a consent order imposing a civil monetary penalty of $750 against the provider. The provider was required to pay the full amount of the penalty within 30 days of executing the Consent Order. The Department will reissue the provider's renewal license upon receipt of the full monetary penalty.

Remedial Action: The provider has made the required payment. The Department has reissued the provider's license.

Prior Enforcement Actions: None in the past five years.

Bureau of Healthcare Professionals

Provider Type	Total # of Licensed Providers
Ambulance Services	269

3. Med Atlantic – Ambulance Service Provider

Inspections and Investigations: The Department conducted an inspection in January 2020 and found that the provider was in violation of regulatory requirements.

Violations: The Department determined that the provider was in violation of Regulation 61-7, *Emergency Medical* Services, for operating an ambulance that belonged to another ambulance provider and used the ambulance not licensed to them for thirty transports.

Enforcement Action: The parties agreed to resolve the matter with a consent order. In September 2020, the parties executed a consent order imposing a civil monetary penalty of $2,500 against the facility. The provider was required to pay $500 of the assessed penalty within 30 days of executing the Consent Order. The remaining $2,000 of the penalty will be held in abeyance for twelve months.

Remedial Action: The provider has made the required payment.

Prior Enforcement Actions: None in the past five years.

Bureau of Radiological Health

Facility Type	Total # of Registered Facilities
Dental X-Ray	1,774

4. Acuity Orthodontics – Dental X-Ray Facility

Inspections and Investigations: The Department conducted a routine inspection in July 2019 and found that the registrant had repeatedly violated statutory and regulatory requirements.

Violations: The Department determined that the registrant violated the Atomic Energy and Radiation Control Act and Regulation 61-64, *X-Rays*, for repeatedly failing to conduct equipment performance testing on dental x-ray systems when testing was due.

Enforcement Action: The parties agreed to resolve the matter with a Consent Order. In September 2020, the parties executed a Consent Order imposing a civil monetary penalty of $1,700 against the registrant. The registrant was required to pay $255 of the assessed penalty within 30 days of executing the Consent Order. The remaining $1,445 of the penalty will be stayed. The Department may conduct unannounced follow-up inspections after execution of this Consent Order.

Remedial Action: The registrant has made the required payment.

Prior Enforcement Actions: None in the past five years.

5. Crews and Mills Dental Associates – Hampton, SC

Inspections and Investigations: The Department conducted a routine inspection in August 2019 and found that the registrant had repeatedly violated statutory and regulatory requirements.

Violations: The Department determined that the registrant violated the Atomic Energy and Radiation Control Act and Regulation 61-64, *X-Rays*, for repeatedly failing to conduct equipment performance testing on dental x-ray systems when testing was due.

Enforcement Action: The parties agreed to resolve the matter with a Consent Order. In September 2020, the parties executed a Consent Order imposing a civil monetary penalty of $1,700 against the registrant. The registrant was required to pay $255 of the assessed penalty within 30 days of executing the Consent Order. The remaining $1,445 of the penalty will be stayed. The Department may conduct unannounced follow-up inspections after execution of this Consent Order.

Remedial Action: The registrant has made the required payment.

Prior Enforcement Actions: None in the past five years.

SUMMARY SHEET
BOARD OF HEALTH AND ENVIRONMENTAL CONTROL
November 12, 2020

_____ ACTION/DECISION

__X__ INFORMATION

1. **TITLE:** Administrative and Consent Orders issued by the Office of Environmental Affairs.

2. **SUBJECT:** Administrative and Consent Orders issued by the Office of Environmental Affairs during the period September 1, 2020, through September 30, 2020.

3. **FACTS:** For the reporting period of September 1, 2020, through September 30, 2020, the Office of Environmental Affairs issued eighty-two (82) Consent Orders with total assessed civil penalties in the amount of one hundred fifteen thousand, eight hundred thirty dollars ($115,830.00). Also, three (3) Administrative Orders were reported during this period.

Bureau and Program Area	Administrative Orders	Assessed Penalties	Consent Orders	Assessed Penalties
Land and Waste Management				
UST Program	0	0	7	$9,760.00
Aboveground Tanks	0	0	0	0
Solid Waste	0	0	0	0
Hazardous Waste	0	0	0	0
Infectious Waste	0	0	0	0
Mining	0	0	0	0
SUBTOTAL	**0**	**0**	**7**	**$9,760.00**
Water				
Recreational Water	0	0	46	$50,790.00
Drinking Water	0	0	1	$1,000.00
Water Pollution	0	0	5	$18,780.00
Dam Safety	0	0	0	0
SUBTOTAL	**0**	**0**	**52**	**$70,570.00**
Air Quality				
SUBTOTAL	**0**	**0**	**0**	**0**
Environmental Health Services				
Food Safety	0	0	20	$17,500.00
Onsite Wastewater	3	0	0	0
SUBTOTAL	**3**	**0**	**20**	**$17,500.00**
OCRM				
SUBTOTAL	**0**	**0**	**3**	**$18,000.00**
TOTAL	**3**	**0**	**82**	**$115,830.00**

Submitted by:

Myra C. Reece
Director of Environmental Affairs

ENVIRONMENTAL AFFAIRS ENFORCEMENT REPORT
BOARD OF HEALTH AND ENVIRONMENTAL CONTROL
November 12, 2020

BUREAU OF LAND AND WASTE MANAGEMENT

Underground Storage Tank Enforcement

1) Order Type and Number: Consent Order 19-0176-UST
Order Date: September 4, 2020
Individual/Entity: **HMS Heath Springs, LLC**
Facility: Smalls Food Center Heath Spring
Location: 4517 Kershaw Camden Highway
Heath Springs, SC 29058-9566
Mailing Address: 3104 Commerce Drive
Richburg, SC 29729
County: Lancaster
Previous Orders: None
Permit/ID Number: 09579
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988, S.C. Code Ann. § 44-2-10 et seq. (2018) (SUPERB Act); and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs. 61-92, 280.34(c), 280.40(a), and 280.41(b)(1)(i)(B) (2012 and Supp. 2019)

Summary: HMS Heath Springs, LLC (Individual/Entity) owns and operates underground storage tanks (USTs) in Lancaster County, South Carolina. The Department conducted an inspection on May 3, 2020 and issued a Notice of Alleged Violation. The Individual/Entity has violated the SUPERB Act and South Carolina Underground Storage Tank Control Regulation as follows: failed to provide records to the Department upon request; failed to provide an adequate release detection method; and failed to conduct annual line tightness test or monitor lines monthly.

Action: The Individual/Entity is required to: submit line tightness test results for the 3,000-gallon kerosene UST by October 19, 2020. The Department has assessed a total civil penalty in the amount of one thousand, three hundred seventy-five dollars ($1,375.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand, three hundred seventy-five dollars **($1,375.00)** by October 19, 2020.

Update: No updates.

2) Order Type and Number: Consent Order 20-0033-UST
Order Date: September 4, 2020
Individual/Entity: **Pareshkumar Patel**
Facility: Gopinath Inc DBA Bluffton Market
Location: 1271 A May River Road

Bluffton, SC 29841
Mailing Address: Same
County: Beaufort
Previous Orders: None
Permit/ID Number: 11058
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. code Ann., § 44-2-10 et seq. (2018); and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs. 61-92.280.34(c), 61-92.280(a), 61-92.280.41(b)(1)(i)(B), 61-92.280.43(d), 61-92.280.44(A), 61-92.280.70(a) (2012 & Supp. 2019).

Summary: Pareshkumar Patel (Individual/Entity) owns underground storage tanks (USTs) located in Bluffton, South Carolina. The Department conducted an inspection on December 20, 2019. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Control Regulation as follows: failed to provide the Department with records upon request, failed to provide adequate release detection records upon request, failed to conduct an annual tightness test or have monthly monitoring of pressurized piping, failed to conduct proper release detection using an automatic tank gauge, failed to conduct annual test of automatic line leak detectors and/or sump sensors, and failed to maintain corrosion protection or appropriate release detection on a temporarily closed UST.

Action: The Individual/Entity is required to: submit either the most recent twelve (12) months of ATG records or current tank tightness test results for the regular unleaded UST; and pay a civil penalty in the amount of two thousand dollars **($2,000.00).**

Update: The Individual/Entity has completed all requirements of the Order and paid the civil penalty.

3) Order Type and Number: Consent Order 20-0048-UST
Order Date: September 4, 2020
Individual/Entity: **Quick Pantry of Orangeburg, LLC**
Facility: Quick Pantry 15
Location: 2198 Magnolia Street
Orangeburg, SC 29115
Mailing Address: 2182 Magnolia Street
Orangeburg, SC 29115
County: Orangeburg
Previous Orders: None
Permit/ID Number: 11583
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988, S.C. Code Ann. § 44-2-10 et seq. (2018) (SUPERB Act); and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs. 61-92, 280.70(a) (2012 and Supp. 2019).

Summary: Quick Pantry of Orangeburg, LLC (Individual/Entity) owns and operates underground storage tanks (USTs) in Orangeburg County, South Carolina. The Department conducted an inspection on January 9, 2020 and issued a Notice of Alleged Violation. The Individual/Entity has violated the SUPERB Act and South Carolina Underground Storage Tank Control Regulation as follows: failed to continue release

detection for a temporarily closed UST.

Action: The Individual/Entity is required to: submit evidence that the 8,000-gallon plus UST contains less than one (1) inch of residue or proof that a valid release detection method is in place for the 8,000-gallon plus UST. The Department has assessed a total civil penalty in the amount of two hundred dollars ($200.00). The Individual/Entity shall pay a civil penalty in the amount of two hundred dollars **($200.00)**.

Update: The Individual/Entity has completed all requirements of the Order and paid the civil penalty.

4) Order Type and Number: Consent Order 20-0071-UST
Order Date: September 4, 2020
Individual/Entity: **7-Eleven. Inc.**
Facility: 7-Eleven #40377
Location: 4900 Ashley Phosphate Road
North Charleston, SC 29405
Mailing Address: P.O. Box 711
Dallas, TX 75221
County: Charleston
Previous Orders: None
Permit/ID Number: 12675
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. code Ann., § 44-2-10 et seq. (2018); and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs. 61-92.280.20(c)(1)(ii) (2012 and Supp. 2019).

Summary: 7-Eleven, Inc. (Individual/Entity) owns and operates underground storage tanks (USTs) located in Charleston County, South Carolina. On June 4, 2020, the Department conducted an inspection and issued a Notice of Alleged Violation because a tank gauging stick was found in the drop tube of the 10,000-gallon regular tank. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Control Regulation as follows: failed maintain overfill prevention on an UST system.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of one thousand dollars ($1,000.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand dollars **($1,000.00)**.

Update: The Individual/Entity has paid the civil penalty.

5) Order Type and Number: Consent Order 19-0190-UST
Order Date: September 8, 2020
Individual/Entity: **HMS Lancaster, LLC**
Facility: Korner Kupboard Citgo
Location: 3068 Flat Creek Road
Lancaster, SC 29720
Mailing Address: 3104 Commerce Drive

Richburg, SC 29729
County: Lancaster
Previous Orders: None
Permit/ID Number: 09578
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988, S.C. Code Ann. § 44-2-10 et seq. (2018) (SUPERB Act); and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs. 61-92, 280.34(c), and 280.40(a)(2) (2012 and Supp. 2019).

Summary: HMS Lancaster, LLC (Individual/Entity) owns and operates underground storage tanks (USTs) in Lancaster County, South Carolina. The Department conducted an inspection on the May 3, 2020 and issued a Notice of Alleged Violation. The Individual/Entity has violated the SUPERB Act and South Carolina Underground Storage Tank Control Regulation as follows: failed to provide records to the Department upon request and failed to properly install, calibrate, operate, and maintain release detection equipment.

Action: The Individual/Entity is required to: submit the most current automatic tank gauge (ATG) print-out/record for the 3,000-gallon kerosene UST as proof of a valid release detection method by October 23, 2020. The Department has assessed a total civil penalty in the amount of three thousand, three hundred fifteen dollars ($3,315.00). The Individual/Entity shall pay a civil penalty in the amount of three thousand, three hundred fifteen dollars **($3,315.00)** by October 23, 2020.

Update: No updates.

6) Order Type and Number: Consent Order 20-0115-UST
Order Date: September 15, 2020
Individual/Entity: **Myrtle Beach Yacht Club**
Facility: Myrtle Beach Yacht Club
Location: 714 Highway 17 North
Little River, SC 29566
Mailing Address: Same
County: Horry
Previous Orders: None
Permit/ID Number: 12998
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988, S.C. Code Ann. § 44-2-10 et seq. (2018) (SUPERB Act); and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs. 61-92, 280.20(c)(1)(ii) (2012 and Supp. 2019).

Summary: Myrtle Beach Yacht Club (Individual/Entity) owns and operates an underground storage tank (UST) in Horry County, South Carolina. The Department conducted an inspection on the July 24, 2020 and issued a Notice of Alleged Violation. The Individual/Entity has violated the SUPERB Act and South Carolina Underground Storage Tank Control Regulation as follows: failed to equip a permitted or upgraded site with overfill prevention.

Action: The Individual/Entity has corrected all violations. The Department has

assessed a total civil penalty in the amount of one thousand dollars ($1,000.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand dollars **($1,000.00)**.

Update: The Individual/Entity has paid the civil penalty.

7) Order Type and Number: Consent Order 20-0125-UST
Order Date: September 28, 2020
Individual/Entity: **Adrian Smith**
Facility: Smith's
Location: 1050 Bill Davis Road
Manning, SC 29102
Mailing Address: Same
County: Clarendon
Previous Orders: None
Permit/ID Number: 02459
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988, S.C. Code Ann. § 44-2-10 et seq. (2018) (SUPERB Act); and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs. 61-92, 280.93(a) and 280.110(c) (2012 and Supp. 2019).

Summary: Adrian Smith (Individual/Entity) owns and operates underground storage tanks (USTs) in Clarendon County, South Carolina. The Department issued a Notice of Alleged Violation on May 19, 2020, as a result of a records review. The Individual/Entity has violated the SUPERB Act and South Carolina Underground Storage Tank Control Regulation as follows: failed to demonstrate financial responsibility for an UST system; and failed to submit evidence of financial assurance to the Department upon request.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of eight hundred seventy dollars ($870.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred seventy dollars **($870.00)** by November 12, 2020.

Update: The civil penalty is being paid in accordance with a promissory note.

BUREAU OF WATER

Recreational Waters Enforcement

8) Order Type and Number: Consent Order 20-040-RW
Order Date: September 1, 2020
Individual/Entity: **Myrtlewood Vacations, LLC**
Facility: Myrtlewood Villas
Location: 4801 Wild Iris Drive
Myrtle Beach, SC 29577

Mailing Address:	Same
County:	Horry
Previous Orders:	18-069-RW ($2,040.00)
Permit/ID Number:	26-1812B, 26-1813C, & 26-1814D
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Myrtlewood Vacations, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool, kiddie pool, and spa located in Horry County, South Carolina. The Department conducted inspections on May 29, 2020, and August 11, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the chlorine and pH levels were not within the acceptable range of water quality standards; there was no shepherd's crook; the emergency notification device was not operational; the pool rules sign was not completely filled out; the current pool operator of record information was not posted to the public; and, the log book provided was not properly bound and numbered and was not maintained on a daily basis.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of three thousand, two hundred dollars ($3,200.00). The Individual/Entity shall pay a civil penalty in the amount of three thousand, two hundred dollars **($3,200.00)**.

Update: The Individual/Entity has paid the civil penalty. This Order has been closed.

9)

Order Type and Number:	Consent Order 20-041-RW
Order Date:	September 1, 2020
Individual/Entity:	**Mid-America Apartment Communities, Inc.**
Facility:	Colonial Grand at Commerce Park
Location:	3785 Ladson Road Ladson, SC 29456
Mailing Address:	Same
County:	Berkeley
Previous Orders:	None
Permit/ID Number:	08-1042B
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Mid-America Apartment Communities, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Berkeley County, South Carolina. The Department conducted inspections on June 8, 2020, and July 10, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the deck was not clean; the chlorine and pH levels were not within the acceptable range of water quality standards; the life ring was deteriorated on the first inspection and the life ring was not United States Coast Guard approved on the second inspection; and, the bound and numbered log book was not maintained on a daily basis.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The

Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)** by October 3, 2020.

Update: The Individual/Entity has paid the civil penalty. This Order has been closed.

10) Order Type and Number: Consent Order 20-042-RW
Order Date: September 1, 2020
Individual/Entity: **The Pinnacle Condominium Association, Inc.**
Facility: Pinnacle Condominiums
Location: 2507 South Ocean Boulevard, North Myrtle Beach, SC 29582
Mailing Address: P.O. Box 1004, North Myrtle Beach, SC 29598
County: Horry
Previous Orders: None
Permit/ID Number: 26-A15-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: The Pinnacle Condominium Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Horry County, South Carolina. The Department conducted inspections on June 5, 2020, and July 13, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a ladder step was crooked; the chlorine and pH levels were not within the acceptable range of water quality standards; the facility address was not posted at the emergency notification device; and, the life ring rope was deteriorated.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The Individual/Entity has paid the civil penalty. This Order has been closed.

11) Order Type and Number: Consent Order 20-043-RW
Order Date: September 1, 2020
Individual/Entity: **Lexington Commons Homeowners Association**
Facility: Lexington Commons
Location: 1436 Autumn Creek Court, Rock Hill, SC 29732
Mailing Address: 1726 Hidden Creek Drive, Rock Hill, SC 29732-2717
County: York
Previous Orders: None
Permit/ID Number: 46-1022B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Lexington Commons Homeowners Association (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in York County, South Carolina. The Department conducted inspections on May 26, 2020, and June 29, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the depth marker tiles did not have the appropriate size letters and numbers; a ladder was missing a non-slip tread insert; there was debris in the skimmer baskets and a skimmer was missing a weir; the chlorine and pH levels were not within the acceptable range of water quality standards; the facility address was not posted at the emergency notification device; the bound and numbered log book was not maintained on a daily basis and was not maintained a minimum of three times per week by the pool operator of record on the first inspection; and, the cyanuric acid level was not maintained on a weekly basis in the bound and numbered log book on the second inspection.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The Individual/Entity has paid the civil penalty. This Order has been closed.

12)

Order Type and Number:	Consent Order 20-044-RW
Order Date:	September 1, 2020
Individual/Entity:	**HPI Broad River, LLC**
Facility:	Broad River Trace Apartments
Location:	551 Riverhill Circle Columbia, SC 29210
Mailing Address:	Same
County:	Richland
Previous Orders:	None
Permit/ID Number:	40-386-1
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: HPI Broad River, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Richland County, South Carolina. The Department conducted inspections on June 23, 2020, and July 10, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the waterline tiles were dirty; the chlorine level was not within the acceptable range of water quality standards; the cyanuric acid level was above the water quality standards acceptable limit; the bound and numbered log book was not maintained on a daily basis; and, the current pool operator of record information was not posted to the public.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The Individual/Entity has paid the civil penalty. This Order has been closed.

13) Order Type and Number: Consent Order 20-045-RW
Order Date: September 1, 2020
Individual/Entity: **Westfield Properties, LLC**
Facility: Beachcomber
Location: 1405 S. Ocean Boulevard
Myrtle Beach, SC 29577
Mailing Address: Same
County: Horry
Previous Orders: 18-232-RW ($680.00)
Permit/ID Number: 26-234-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J) & 61-51(K)(1)(c)

Summary: Westfield Properties, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Horry County, South Carolina. The Department conducted inspections on June 8, 2020, and July 16, 2020, and violations were issued for failure to properly operate and maintain, and for re-opening prior to receiving Department approval. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the lifeline floats were not properly spaced; there was debris in the skimmer baskets; the drinking water fountain and foot rinse shower were not operating properly; the pool equipment room was not locked; the gate did not self-close and latch; the chlorine level was not within the acceptable range of water quality standards; the main drain grates were not visible due to cloudy water; the emergency notification device was not operating properly on the first inspection; the emergency notification device that was provided on the second inspection was not approvable and was not within two hundred feet of the pool; the pool rules sign was not completely filled out; there were no "No Lifeguard On Duty – Swim At Your Own Risk" signs posted; the current pool operator of record information was not posted to the public; the bound and numbered log book was not available for review; and, the pool re-opened prior to receiving Department approval.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of two thousand dollars ($2,000.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand dollars **($2,000.00)**.

Update: The Individual/Entity has paid the civil penalty. This Order has been closed.

14) Order Type and Number: Consent Order 20-046-RW
Order Date: September 1, 2020
Individual/Entity: **AB Apartments SPE, LLC**
Facility: Atlantic at the Boulevard Apartments
Location: 2155 Morris Baker Boulevard
North Charleston, SC 29406
Mailing Address: Same
County: Charleston
Previous Orders: None

Permit/ID Number: 10-1341B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: AB Apartments SPE, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Charleston County, South Carolina. The Department conducted inspections on June 8, 2020, and July 9, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: there was debris in the skimmer baskets; the drinking water fountain and foot rinse shower were not operating properly; the chlorine level was not within the acceptable range of water quality standards; the pool rules sign was not completely filled out; and, the current pool operator of record information was not posted to the public.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The Individual/Entity has paid the civil penalty. This Order has been closed.

15) Order Type and Number: Consent Order 20-047-RW
Order Date: September 1, 2020
Individual/Entity: **Summit Hospitality I, LLC**
Facility: Hilton Garden Inn
Location: 108 Carolina Point Parkway
Greenville, SC 29607
Mailing Address: 13215 Bee Cave Parkway, Suite B-300
Austin, TX 78736
County: Greenville
Previous Orders: 19-167-RW ($680.00)
Permit/ID Number: 23-1182D
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Summit Hospitality I, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a spa located in Greenville County, South Carolina. The Department conducted inspections on June 10, 2020, and July 22, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the chlorine and pH levels were not within the acceptable range of water quality standards; the spa temperature was too high; the spa rules sign was not completely filled out; and, only one “No Lifeguard On Duty – Swim At Your Own Risk” sign was posted.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of one thousand, six hundred dollars ($1,600.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand, six hundred dollars **($1,600.00)**.

Update: The Individual/Entity has paid the civil penalty. This Order has been closed.

16) Order Type and Number: Consent Order 20-048-RW
Order Date: September 3, 2020
Individual/Entity: **Shellbrook Plantation HOA of SC, Inc.**
Facility: Shellbrook Plantation
Location: 1 Palm Springs Way
Simpsonville, SC 29681
Mailing Address: P.O. Box 1037
Mauldin, SC 29662
County: Greenville
Previous Orders: None
Permit/ID Number: 23-1113B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Shellbrook Plantation HOA of SC, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Greenville County, South Carolina. The Department conducted inspections on July 31, 2020, and August 7, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a ladder was missing bumpers; the waterline tiles were dirty; there was algae on the pool wall; the gate did not self-close and latch; the chlorine level was not within the acceptable range of water quality standards; the bound and numbered log book was not maintained on a daily basis; there were chlorine pucks in the skimmer baskets on the first inspection; there was a disinfectant chemical in the skimmer baskets on the second inspection; and, the recirculation and filtration system was leaking.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The Individual/Entity has paid the civil penalty. This Order has been closed.

17) Order Type and Number: Consent Order 20-052-RW
Order Date: September 3, 2020
Individual/Entity: **Smith Family Partners, LLC**
Facility: Bar Harbor Motor Inn
Location: 100 N. Ocean Boulevard
Myrtle Beach, SC 29577
Mailing Address: Same
County: Horry
Previous Orders: None
Permit/ID Number: 26-C96-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Smith Family Partners, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Horry County, South Carolina. The Department conducted inspections on June 16, 2020, and July 23, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a handrail was not tight

and secure; the water level was too high; skimmer lids were cracked; the chlorine and pH levels were not within the acceptable range of water quality standards; the life ring was deteriorated; the life ring beckets were loose and not in the appropriate position; a section of the perimeter fencing had an opening greater than four inches; and, the bound and numbered log book was not maintained on a daily basis.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The Individual/Entity has paid the civil penalty. This Order has been closed.

18) Order Type and Number: Consent Order 20-049-RW
Order Date: September 8, 2020
Individual/Entity: **Greenslake Association, Inc.**
Facility: Greenslake Condos
Location: 1100 Green Castle Drive
Goose Creek, SC 29445
Mailing Address: Same
County: Berkeley
Previous Orders: None
Permit/ID Number: 08-041-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Greenslake Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Berkeley County, South Carolina. The Department conducted inspections on June 23, 2020, and July 30, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: there was no lifeline on the first inspection; the lifeline floats were not properly spaced on the second inspection; a depth marker tile was broken; handrails were not tight and secure; ladders were not tight and secure; the bathrooms did not have soap or paper towels; there was no drinking water fountain; the pool equipment room was unlocked; a section of the perimeter fencing was not at least four feet tall; the life ring was not United States Coast Guard approved; and, the emergency notification device was not operating.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The Individual/Entity has paid the civil penalty. This Order has been closed.

19) Order Type and Number: Consent Order 20-050-RW
Order Date: September 8, 2020
Individual/Entity: **Port O'Call Horizontal Property Regime**
Facility: Port O'Call Condos I

Location:	9000 Palmetto Drive Isle of Palms, SC 29451
Mailing Address:	Same
County:	Charleston
Previous Orders:	None
Permit/ID Number:	10-185-1
Violations Cited:	S.C. Code Ann. Regs. 61-51(J) & 61-51(K)(1)(c)

Summary: Port O'Call Horizontal Property Regime (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Charleston County, South Carolina. The Department conducted inspections on June 18, 2020, and June 30, 2020, and violations were issued for failure to properly operate and maintain, and for re-opening prior to receiving Department approval. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a light in the pool wall was out of its niche; the fill spout was not stainless steel or equivalent; the fill spout was not co-located with a ladder or diving board; the gate did not self-close and latch; the life ring was deteriorated; the emergency notification device was not operating; the current pool operator of record information was not posted to the public; and, the pool was operating prior to receiving Department approval.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of one thousand, twenty dollars ($1,020.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand, twenty dollars **($1,020.00)**.

Update: The Individual/Entity has paid the civil penalty. This Order has been closed.

20)

Order Type and Number:	Consent Order 20-051-RW
Order Date:	September 8, 2020
Individual/Entity:	**Patrick Square Owners Association, Inc.**
Facility:	Patrick Square
Location:	145 Keller Boulevard Clemson, SC 29631
Mailing Address:	160 Thomas Green Boulevard Clemson, SC 29631
County:	Pickens
Previous Orders:	None
Permit/ID Number:	39-1065B
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Patrick Square Owners Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Pickens County, South Carolina. The Department conducted inspections on June 25, 2020, and August 4, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the foot rinse shower was not operating properly; the gate did not self-close and latch; the waterline tiles were dirty; there was algae on the pool floor; the chlorine level was not within the acceptable range of water quality standards; the disinfection equipment was not operating; and, the bound and numbered log book was not maintained on a daily basis.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The Individual/Entity has paid the civil penalty. This Order has been closed.

21) Order Type and Number: Consent Order 20-053-RW
Order Date: September 8, 2020
Individual/Entity: **Holy City Hospitality, LLC**
Facility: Cambria Hotel and Suites
Location: 84 Ripley Point Drive
Charleston, SC 29407
Mailing Address: Same
County: Charleston
Previous Orders: None
Permit/ID Number: 10-1349B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Holy City Hospitality, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Charleston County, South Carolina. The Department conducted inspections on June 5, 2020, and July 6, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the gate did not self-close and latch; the chlorine and pH levels were not within the acceptable range of water quality standards; the emergency notification device was not operating properly; the lifesaving equipment was not in its designated location; and, the log book was not properly bound or numbered.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The Individual/Entity has paid the civil penalty. This Order has been closed.

22) Order Type and Number: Consent Order 20-054-RW
Order Date: September 8, 2020
Individual/Entity: **VW SPE I, LLC**
Facility: Haddon Hall Apartments
Location: 1801 Haddon Hall Drive
Charleston, SC 29414
Mailing Address: Same
County: Charleston
Previous Orders: None
Permit/ID Number: 10-1165B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: VW SPE, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Charleston County, South Carolina. The Department conducted inspections on June 2, 2020, and July 8, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a skimmer was missing a weir; the chlorine level was not within the acceptable range of water quality standards; the emergency notification device was not operational; and, the bound and numbered log book was not maintained on a daily basis.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The Individual/Entity has paid the civil penalty. This Order has been closed.

23)	Order Type and Number:	Consent Order 20-055-RW
	Order Date:	September 10, 2020
	Individual/Entity:	**Ocean Blue Homeowner's Association, Inc.**
	Facility:	Ocean Blue
	Location:	2709 South Ocean Boulevard Myrtle Beach, SC 29578
	Mailing Address:	Same
	County:	Horry
	Previous Orders:	None
	Permit/ID Number:	26-1528D
	Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Ocean Blue Homeowner's Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a spa located in Horry County, South Carolina. The Department conducted inspections on June 22, 2020, and July 20, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the drinking water fountain was not operating; and, the chlorine and pH levels were not within the acceptable range of water quality standards.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The Individual/Entity has paid the civil penalty. This Order has been closed.

24)	Order Type and Number:	Consent Order 20-056-RW
	Order Date:	September 10, 2020
	Individual/Entity:	**The Reserve at Foster Creek**

Homeowners Association, Inc.

Facility: The Reserve at Foster Creek
Location: 7499 Hawks Circle
Hanahan, SC 29410
Mailing Address: 201 Sigma Drive, Suite 400
Summerville, SC 29486
County: Berkeley
Previous Orders: None
Permit/ID Number: 08-1021B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: The Reserve at Foster Creek Homeowners Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Berkeley County, South Carolina. The Department conducted inspections on May 26, 2020, and June 23, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a ladder was missing bumpers; a skimmer was missing a weir; the bathrooms were not accessible; the drinking water fountain was not operating properly; there were non-pool related items stored in the equipment room; and, the chlorine level was not within the acceptable range of water quality standards.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The Individual/Entity has paid the civil penalty. This Order has been closed.

25) Order Type and Number: Consent Order 20-057-RW
Order Date: September 11, 2020
Individual/Entity: **OTV Town Centre, LLC**
Facility: Hyatt Place Mount Pleasant
Location: 1600 Palmetto Grand Drive
Mount Pleasant, SC 29466
Mailing Address: Same
County: Charleston
Previous Orders: None
Permit/ID Number: 10-1328B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: OTV Town Centre, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Charleston County, South Carolina. The Department conducted inspections on May 26, 2020, and July 1, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: skimmers were missing weirs; the chlorine level was not within the acceptable range of water quality standards; and, the bound and numbered log book was not available for Department review on the first inspection and was not maintained on a daily basis on the second inspection.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The Individual/Entity has paid the civil penalty. This Order has been closed.

26)	Order Type and Number:	Consent Order 20-059-RW
	Order Date:	September 11, 2020
	Individual/Entity:	**Hunter's Glen Apartments, LLC**
	Facility:	Hunter's Glen Apartments
	Location:	854 Issaquenna Trail Central, SC 29630
	Mailing Address:	3859 Battleground Avenue, Suite 100 Greensboro, NC 27410
	County:	Pickens
	Previous Orders:	None
	Permit/ID Number:	39-023-1
	Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Hunter's Glen Apartments, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Pickens County, South Carolina. The Department conducted inspections on June 9, 2020, and July 17, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the lifeline was not in place; the chlorine level was not within the acceptable range of water quality standards; the emergency notification device was not operating; the pool rules sign did not have all of the required rules; only one "Shallow Water – No Diving Allowed" sign was posted; and, only one "No Lifeguard On Duty – Swim At Your Own Risk" sign was posted.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The Individual/Entity has paid the civil penalty. This Order has been closed.

27)	Order Type and Number:	Consent Order 20-058-RW
	Order Date:	September 14, 2020
	Individual/Entity:	**Sandcastle Plaza Owners' Association, Inc.**
	Facility:	Sandcastle Plaza Condos
	Location:	22 Folly Field Road Hilton Head Island, SC 29928
	Mailing Address:	Same
	County:	Beaufort
	Previous Orders:	None

Permit/ID Number: 07-1148B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Sandcastle Plaza Owners' Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Beaufort County, South Carolina. The Department conducted inspections on July 14, 2020, and August 6, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the gate did not self-close and latch; the pool rules sign was not completely filled out; the life ring was deteriorated; the disinfection equipment was missing; and, there were chlorine pucks in the skimmer baskets.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The Individual/Entity has paid the civil penalty. This Order has been closed.

28) Order Type and Number: Consent Order 20-060-RW
Order Date: September 15, 2020
Individual/Entity: **OYO Hotels, Inc.**
Facility: Palette Resort
Location: 703 South Ocean Boulevard
Myrtle Beach, SC 29577
Mailing Address: Same
County: Horry
Previous Orders: None
Permit/ID Number: 26-1628D
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: OYO Hotels, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a spa located in Horry County, South Carolina. The Department conducted inspections on June 19, 2020, and July 22, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the chlorine and pH levels were not within the acceptable range of water quality standards; and, the bound and numbered logbook was not maintained on a daily basis.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The Individual/Entity has paid the civil penalty. This Order has been closed.

29) Order Type and Number: Consent Order 20-061-RW
Order Date: September 15, 2020

Individual/Entity:	**Hartsville Ventures, LLC**
Facility:	Hampton Inn
Location:	203 E Carolina Avenue Hartsville, SC 29550
Mailing Address:	3722 Shipyard Boulevard, Suite C Wilmington, NC 28403
County:	Darlington
Previous Orders:	19-181-RW ($680.00)
Permit/ID Number:	16-1007B
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Hartsville Ventures, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Darlington County, South Carolina. The Department conducted inspections on June 8, 2020, July 10, 2020, and July 27, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the gate did not self-close and latch; the chlorine level was not within the acceptable range of water quality standards; there was debris in the skimmer baskets; a skimmer was missing a weir; the bound and numbered log book was not maintained on a daily basis and was not maintained a minimum of three times per week by the pool operator of record; the cyanuric acid level was not checked weekly; the disinfection equipment was not operating properly; and, the recirculation and filtration system was not operating properly.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of four thousand, eight hundred dollars ($4,800.00). The Individual/Entity shall pay a civil penalty in the amount of four thousand, eight hundred dollars **($4,800.00)**.

Update: The Individual/Entity has paid the civil penalty. This Order has been closed.

30)

Order Type and Number:	Consent Order 20-062-RW
Order Date:	September 15, 2020
Individual/Entity:	**CR Ladson Investco, LLC**
Facility:	Cypress River Apartments
Location:	9325 Blue House Road Ladson, SC 29456
Mailing Address:	Same
County:	Charleston
Previous Orders:	None
Permit/ID Number:	10-1229B
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: CR Ladson Investco, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Charleston County, South Carolina. The Department conducted inspections on July 14, 2020, and August 10, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: depth marker tiles were broken; the pool furniture was not at least four feet from the edge of the pool; skimmers were missing weirs; the chlorine and pH levels were not within the acceptable range of water quality standards; the main drain grates were not visible due to

cloudy water; the shepherd's crook handle was not the approved length; the current pool operator of record information was not posted to the public; and, the bound and numbered log book was not maintained on a daily basis.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The Individual/Entity has paid the civil penalty. This Order has been closed.

31) Order Type and Number: Consent Order 20-065-RW
Order Date: September 15, 2020
Individual/Entity: **Watermark Property Owners' Association**
Facility: Watermark
Location: 1400 Penshell Drive, Mount Pleasant, SC 29464
Mailing Address: 1352 Penshell Place, Mount Pleasant, SC 29464
County: Charleston
Previous Orders: None
Permit/ID Number: 10-1149B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Watermark Property Owners' Association (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Charleston County, South Carolina. The Department conducted inspections on May 22, 2020, and June 24, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: skimmers were missing weirs; the foot rinse shower was not operating; the pump room was not accessible; there was no pool rules sign; the emergency notification device was not operating; only one "Shallow Water – No Diving Allowed" sign was posted; only one "No Lifeguard On Duty – Swim At Your Own Risk" sign was posted; and, the bound and numbered log book was not available for review.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The Individual/Entity has paid the civil penalty. This Order has been closed.

32) Order Type and Number: Consent Order 20-063-RW
Order Date: September 17, 2020
Individual/Entity: **Foxfire Motel Properties, LLC**
Facility: Days Inn Beach Front
Location: 1403 South Ocean Boulevard

		Myrtle Beach, SC 29577
	Mailing Address:	Same
	County:	Horry
	Previous Orders:	18-048-RW ($2,040.00); 18-233-RW ($1,700.00); 19-192-RW ($2,720.00)
	Permit/ID Number:	26-H81-1
	Violations Cited:	S.C. Code Ann. Regs. 61-51(J) & 61-51 51(K)(1)(c)

Summary: Foxfire Motel Properties, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Horry County, South Carolina. The Department conducted inspections on June 16, 2020, and July 16, 2020, and violations were issued for failure to properly operate and maintain, and for re-opening prior to receiving Department approval. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the drinking water fountain was not operating properly; the chlorine and pH levels were not within the acceptable range of water quality standards; the emergency notification device was not operational; there was no pool rules sign; the current pool operator of record information was not posted to the public; a ladder was missing rungs and non-slip tread inserts; a skimmer lid was cracked; the gate did not self-close and latch; and, the pool was operating prior to receiving Department approval.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of three thousand, six hundred dollars ($3,600.00). The Individual/Entity shall pay a civil penalty in the amount of three thousand, six hundred dollars **($3,600.00)**.

Update: The Individual/Entity has paid the civil penalty. This Order has been closed.

33)	Order Type and Number:	Consent Order 20-064-RW
	Order Date:	September 17, 2020
	Individual/Entity:	**Bethelfields Homeowners Association, Inc.**
	Facility:	Bethelfields
	Location:	2513 Ivy Creek Ford York, SC 29745
	Mailing Address:	Same
	County:	York
	Previous Orders:	None
	Permit/ID Number:	46-1028C
	Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Bethelfields Homeowners Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a kiddie pool located in York County, South Carolina. The Department conducted inspections on June 12, 2020, and August 4, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: skimmers were missing weirs; the drinking water fountain was not accessible; the bound and numbered log book was not maintained on a daily basis; the cyanuric acid level was

not recorded weekly in the bound and numbered log book; skimmer baskets were floating; the chlorine and pH levels were not within the acceptable range of water quality standards; the emergency notification device was not operating; and, the recirculation and filtration system was not operating.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The Individual/Entity has paid the civil penalty. This Order has been closed.

34)

Order Type and Number:	Consent Order 20-066-RW
Order Date:	September 17, 2020
Individual/Entity:	**Riverside Glen Homeowners Association, Inc.**
Facility:	Riverside Glen
Location:	1 Valley Glen Court Greer, SC 29650
Mailing Address:	117 Glen Willow Court Greer, SC 29650
County:	Greenville
Previous Orders:	None
Permit/ID Number:	23-495-1
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Riverside Glen Homeowners Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Greenville County, South Carolina. The Department conducted inspections on June 29, 2020, and August 6, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: skimmers were missing weirs; the drinking water fountain was not operating; the chlorine and pH levels were not within the acceptable range of water quality standards; the pool rules sign did not have all of the required rules; the "No Lifeguard On Duty – Swim At Your Own Risk" signs did not have the appropriate size letters; and, the bound and numbered log book was not maintained on a daily basis.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The Individual/Entity has paid the civil penalty. This Order has been closed.

35)

Order Type and Number:	Consent Order 20-067-RW
Order Date:	September 17, 2020
Individual/Entity:	**Griffin Assets XVII, LLC**
Facility:	Cottages at Crowfield

Location:	1398 South University Drive Ladson, SC 29456
Mailing Address:	Same
County:	Berkeley
Previous Orders:	None
Permit/ID Number:	08-050-1
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Griffin Assets XVII, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Berkeley County, South Carolina. The Department conducted inspections on July 15, 2020, and August 10, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the chlorine level was not within the acceptable range of water quality standards; the cyanuric acid level was above the water quality standards acceptable limit; the facility address was not posted at the emergency notification device; the current pool operator of record information was not posted to the public; and, there were chlorine sticks in the skimmer baskets.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The Individual/Entity has paid the civil penalty. This Order has been closed.

36)

Order Type and Number:	Consent Order 20-068-RW
Order Date:	September 17, 2020
Individual/Entity:	**DLH Preserve at Spears Creek, LLC**
Facility:	The Preserve at Spears Creek
Location:	325 Spears Creek Church Road Elgin, SC 29045
Mailing Address:	41 Church Street Cortland, NY 13045
County:	Richland
Previous Orders:	None
Permit/ID Number:	40-1081B
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: DLH Preserve at Spears Creek, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Richland County, South Carolina. The Department conducted inspections on June 26, 2020, and August 10, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the chlorine and pH levels were not within the acceptable range of water quality standards; the bound and numbered log book was not maintained on a daily basis; there was no United States Coast Guard approved life ring; and, the recirculation and filtration system was leaking.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The Individual/Entity has paid the civil penalty. This Order has been closed.

37) Order Type and Number: Consent Order 20-069-RW
Order Date: September 17, 2020
Individual/Entity: **DLH Polo Commons, LLC**
Facility: Polo Commons Apartments
Location: 811 Polo Road
Columbia, SC 29223
Mailing Address: 41 Church Street
Cortland, NY 13045
County: Richland
Previous Orders: None
Permit/ID Number: 40-425-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: DLH Polo Commons, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Richland County, South Carolina. The Department conducted inspections on June 1, 2020, and August 11, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a ladder was missing bumpers; only one "No Lifeguard On Duty - Swim At Your Own Risk" sign was posted and the sign posted did not have the correct wording; only one "Shallow Water – No Diving Allowed" sign was posted; the waterline tiles were dirty; the emergency notification device was not operational; and, the bound and numbered log book was not maintained on a daily basis.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The Individual/Entity has paid the civil penalty. This Order has been closed.

38) Order Type and Number: Consent Order 20-070-RW
Order Date: September 21, 2020
Individual/Entity: **Magnolia Hospitality, LLC**
Facility: Best Western
Location: 11445 Ocean Highway
Pawleys Island, SC 29585
Mailing Address: Same
County: Georgetown
Previous Orders: 19-176-RW ($2,040.00)
Permit/ID Number: 22-114-1

Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Magnolia Hospitality, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Georgetown County, South Carolina. The Department conducted inspections on July 13, 2020, and August 4, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: there was a hose on the deck that presented a trip hazard; the chlorine level was not within the acceptable range of water quality standards; the life ring was deteriorated and was not hung in its designated location; the pool rules sign was not completely filled out; and, the bound and numbered log book was not maintained on a daily basis.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of one thousand, six hundred dollars ($1,600.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand, six hundred dollars **($1,600.00)** in installments. Payments are due October 2, 2020, October 23, 2020, and November 13, 2020.

Update: The Individual/Entity has paid the first and second installments of the civil penalty.

39)

Order Type and Number:	Consent Order 20-072-RW
Order Date:	September 21, 2020
Individual/Entity:	Harbour View, LLC
Facility:	Sleep Inn at Harbour View
Location:	909 Highway 17 North Little River, SC 29566
Mailing Address:	Same
County:	Horry
Previous Orders:	18-136-RW ($560.00)
Permit/ID Number:	26-P82-1
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Harbour View, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Horry County, South Carolina. The Department conducted inspections on May 29, 2020, and August 10, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a handrail was not tight and secure; a weir was broken; the gate did not self-close and latch; the chlorine and pH levels were not within the acceptable range of water quality standards; and, the bound and numbered log book was not maintained on a daily basis.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of one thousand, six hundred dollars ($1,600.00). The Individual/Entity shall pay a civil penalty in the amount of one hundred sixty dollars **($160.00)** and pay a suspended penalty in the amount of one thousand, four hundred forty dollars ($1,440.00) should any requirement of the Order not be met.

Update: The Individual/Entity has paid the civil penalty. This Order has been closed.

40) Order Type and Number: Consent Order 20-073-RW
Order Date: September 21, 2020
Individual/Entity: **Broad Creek Landing Horizontal Property Regime, Inc.**
Facility: Broad Creek Landing
Location: 40 Point Comfort Road
Hilton Head, SC 29928
Mailing Address: 1040 William Hilton Pkwy, Suite 200
Hilton Head, SC 29928
County: Beaufort
Previous Orders: None
Permit/ID Number: 07-212-2
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Broad Creek Landing Horizontal Property Regime, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a kiddie pool located in Beaufort County, South Carolina. The Department conducted inspections on June 18, 2020, and July 20, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the chlorine and pH levels were not within the acceptable range of water quality standards; the facility address was not posted at the emergency notification device; and, the cyanuric acid level was above the water quality standards acceptable limit.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The Individual/Entity has paid the civil penalty. This Order has been closed.

41) Order Type and Number: Consent Order 20-074-RW
Order Date: September 21, 2020
Individual/Entity: **BLVD Group, LLC**
Facility: Sea Aire
Location: 403 24th Avenue North
Myrtle Beach, SC 29577
Mailing Address: 407 30th Avenue North
Myrtle Beach, SC 29577
County: Horry
Previous Orders: 18-186-RW ($2,040.00)
Permit/ID Number: 26-171-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: BLVD Group, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Horry County, South Carolina. The Department conducted inspections on June 10, 2020, and July 15, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the life ring was deteriorated and the

beckets were loose; only one "Shallow Water – No Diving Allowed" sign was posted; there were no "No Lifeguard On Duty – Swim At Your Own Risk" signs posted; and, the bound and numbered log book was not available for review.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of one thousand, six hundred dollars ($1,600.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand, six hundred dollars **($1,600.00)**.

Update: The Individual/Entity has paid the civil penalty. This Order has been closed.

42)

Order Type and Number:	Consent Order 20-077-RW
Order Date:	September 21, 2020
Individual/Entity:	**Cannon Street Young Men's Christian Association**
Facility:	Berkeley Family YMCA
Location:	210 Rembert Dennis Boulevard
Mailing Address:	Same
County:	Berkeley
Previous Orders:	None
Permit/ID Number:	08-057-1
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Cannon Street Young Men's Christian Association (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Berkeley County, South Carolina. The Department conducted inspections on July 20, 2020, and August 12, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a ladder was not secured properly; skimmers were missing weirs and the skimmer baskets were broken; an entrance to the pool area was unlocked and unsupervised; the chlorine level was not within the acceptable range of water quality standards; the current pool operator of record information was not posted to the public; and, the bound and numbered log book was not maintained on a daily basis.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The Individual/Entity has paid the civil penalty. This Order has been closed.

43)

Order Type and Number:	Consent Order 20-078-RW
Order Date:	September 21, 2020
Individual/Entity:	**Knightsbridge Property Owners Association, Inc.**
Facility:	Knightsbridge
Location:	760 Knightsbridge Road Fort Mill, SC 29715

Mailing Address: Same
County: York
Previous Orders: None
Permit/ID Number: 46-144-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Knightsbridge Property Owners Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in York County, South Carolina. The Department conducted inspections on June 12, 2020, and July 14, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: there was debris in the skimmer baskets and the skimmers were missing weirs; the water level was too low; the drinking water fountain was missing; the pool equipment room was not locked to prevent unauthorized access; the flow meter was not operating properly; the gate did not self-close and latch; the chlorine and pH levels were not within the acceptable range of water quality standards; the facility address was not posted at the emergency notification device; the pool rules sign was not completely filled out; only one "No Lifeguard On Duty – Swim At Your Own Risk" sign was posted; the bound and numbered log book was not maintained at least three times per week by the pool operator of record; and, the recirculation and filtration system was leaking.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)** by October 11, 2020.

Update: The Individual/Entity has paid the civil penalty. This Order has been closed.

44) Order Type and Number: Consent Order 20-071-RW
Order Date: September 22, 2020
Individual/Entity: **Village Creek Condominium Association of Columbia, Inc.**
Facility: Village Creek Condos
Location: Kay Street
Columbia, SC 29210
Mailing Address: P.O. Box 2014
Lexington, SC 29071
County: Richland
Previous Orders: None
Permit/ID Number: 40-214-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Village Creek Condominium Association of Columbia, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Richland County, South Carolina. The Department conducted inspections on June 19, 2020, and July 30, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the bathrooms were not clean; the chlorine and pH levels were not within the acceptable range of water quality standards; the current pool operator of record

information was not posted to the public; there was algae on the pool floor and the pool floor was dirty; and, the bound and numbered log book was not maintained on a daily basis.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The Individual/Entity has paid the civil penalty. This Order has been closed.

45) Order Type and Number: Consent Order 20-075-RW
Order Date: September 22, 2020
Individual/Entity: **WW Multifamily, LLC**
Facility: Roseberry Apartments
Location: 137 Roseberry Lane
Columbia, SC 29223
Mailing Address: Same
County: Richland
Previous Orders: None
Permit/ID Number: 40-1177B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: WW Multifamily, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Richland County, South Carolina. The Department conducted inspections on June 1, 2020, June 25, 2020, and August 7, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the chlorine and pH levels were not within the acceptable range of water quality standards; and, the bound and numbered logbook was not maintained on a daily basis.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of two thousand, forty dollars ($2,040.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand, forty dollars **($2,040.00)**.

Update: The Individual/Entity has paid the civil penalty. This Order has been closed.

46) Order Type and Number: Consent Order 20-076-RW
Order Date: September 22, 2020
Individual/Entity: **Sea Cabin on the Ocean VII Oceanside Villas Horizontal Property Regime Council of Co-Owners, Inc.**
Facility: Oceanside Villas
Location: 1400 Palm Boulevard
Isle of Palms, SC 29451
Mailing Address: Same
County: Charleston
Previous Orders: None

Permit/ID Number: 10-198-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Sea Cabin on the Ocean VII Oceanside Villas Horizontal Property Regime Council of Co-Owners, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Charleston County, South Carolina. The Department conducted inspections on June 19, 2020, and July 22, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the drinking water fountain was missing; the gate did not self-close and latch; the chlorine level was not within the acceptable range of water quality standards; the life ring did not have a permanently attached rope; the pool rules sign was not completely filled out; only one "Shallow Water – No Diving Allowed" sign was posted; only one "No Lifeguard On Duty – Swim At Your Own Risk" sign was posted; the bound and numbered log book was not maintained daily on the first inspection, and, the chemical readings in the bound and numbered log book were entered in advance on the second inspection.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The Individual/Entity has paid the civil penalty. This Order has been closed.

47) Order Type and Number: Consent Order 20-079-RW
Order Date: September 22, 2020
Individual/Entity: **Gateway Fort Mill, LLC**
Facility: Willows at Fort Mill Apartments
Location: 3115 Drewsky Lane
Fort Mill, SC 29715
Mailing Address: Same
County: York
Previous Orders: 19-069-RW ($680.00)
Permit/ID Number: 46-1132B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Gateway Fort Mill, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in York County, South Carolina. The Department conducted inspections on June 11, 2020, and July 15, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a skimmer was missing a weir; there was debris in the skimmer baskets; a gate did not self-close and latch; the pH level was not within the acceptable range of water quality standards; the life ring rope was deteriorated; only one "No Lifeguard On Duty – Swim At Your Own Risk" sign was posted; the current pool operator of record information was not posted to the public; and, the lifeline with floats was not attached to the pool wall.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of one thousand, six hundred dollars

($1,600.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand, six hundred dollars **($1,600.00)**.

Update: The Individual/Entity has paid the civil penalty. This Order has been closed.

48) Order Type and Number: Consent Order 20-080-RW
Order Date: September 22, 2020
Individual/Entity: **Amber Oaks Farm Property Owners Association, Inc.**
Facility: Amber Oaks Farm
Location: Fews Chapel Road & Pennington Road
Greer, SC 29651
Mailing Address: 9500 Statesville Road
Charlotte, NC 28021
County: Greenville
Previous Orders: None
Permit/ID Number: 23-1137C
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Amber Oaks Farm Property Owners Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a kiddie pool located in Greenville County, South Carolina. The Department conducted inspections on June 4, 2020, and July 13, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the chlorine and pH levels were not within the acceptable range of water quality standards; the bound and numbered log book was not available for review; and, the current pool operator of record information was not posted to the public.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The Individual/Entity has paid the civil penalty. This Order has been closed.

49) Order Type and Number: Consent Order 20-081-RW
Order Date: September 24, 2020
Individual/Entity: **Sea Cabin on the Ocean III Horizontal Property Regime Council of Co-Owners, Inc.**
Facility: Sea Cabin on the Ocean III
Location: 1300 Ocean Boulevard
Isle of Palms, SC 29451
Mailing Address: Same
County: Charleston
Previous Orders: None
Permit/ID Number: 10-604-1 & 10-605-1

Violations Cited: S.C. Code Ann. Regs. 61-51(J) & 61-51(K)(1)(c)

Summary: Sea Cabin on the Ocean III Horizontal Property Regime Council of Co-Owners, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool and kiddie pool located in Charleston County, South Carolina. The Department conducted inspections of the pool and kiddie pool on June 19, 2020, June 22, 2020, July 1, 2020, and July 23, 2020, and violations were issued for failure to properly operate and maintain the pool, and on June 22, 2020, violations were issued for re-opening the pool and kiddie pool prior to receiving Department approval. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the main drain grates were not visible; the shepherd's crook was attached to a telescoping pole; the emergency notification device was not operational; one of the "Shallow Water – No Diving Allowed" signs posted was obstructed and one of the "Shallow Water – No Diving Allowed" signs posted did not have the correct wording on the first inspection; both of the "Shallow Water – No Diving Allowed" signs posted did not have the appropriate size letters on the second inspection; the bound and numbered log book was not maintained on a daily basis; the chlorine and pH levels were not within the acceptable range of water quality standards; skimmer baskets were floating; and, the pool and kiddie pool were operating prior to receiving Department approval.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of two thousand, two hundred ten dollars ($2,210.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand, two hundred ten dollars **($2,210.00)**.

Update: The Individual/Entity has paid the civil penalty. This Order has been closed.

50) Order Type and Number: Consent Order 20-085-RW
Order Date: September 25, 2020
Individual/Entity: **Meadow Lakes II Homeowners Association, Inc.**
Facility: Meadow Lakes II
Location: 1408 Jack White Road, Rock Hill, SC 29730
Mailing Address: 1739 Farrow Drive, Rock Hill, SC 29732
County: York
Previous Orders: 17-100-RW ($680.00)
Permit/ID Number: 46-109-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J) & 61-51(K)(1)(c)

Summary: Meadow Lakes II Homeowners Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in York County, South Carolina. The Department conducted inspections on July 28, 2020, and July 30, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the depth marker tiles did not have the correct depth; the skimmer lids were cracked and the skimmer baskets were floating; the gate did not self-close and latch; the emergency notification

devise was not operating; the pool rules sign was not completely filled out; the bound and numbered log book was not maintained on a daily basis; and, the pool was operating prior to receiving Department approval.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of two thousand dollars ($2,000.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand dollars **($2,000.00)** by October 5, 2020.

Update: The Individual/Entity has paid the civil penalty. This Order has been closed.

51)	Order Type and Number:	Consent Order 20-082-RW
	Order Date:	September 29, 2020
	Individual/Entity:	**Yacht Harbor Owners' Association, Inc.**
	Facility:	Yacht Harbor
	Location:	301 Yacht Harbor Court Isle of Palms, SC 29451
	Mailing Address:	4401 Leeds Avenue, Suite 120 North Charleston, SC 29405
	County:	Charleston
	Previous Orders:	None
	Permit/ID Number:	10-317-1
	Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Yacht Harbor Owners' Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a spa located in Charleston County, South Carolina. The Department conducted inspections on June 18, 2020, and July 22, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the deck was uneven with sharp edges; the heater exhaust pipe was damaged; the chlorine and pH levels were not within the acceptable range of water quality standards; the spa temperature was not monitored and recorded; the water level was too low; and, the fill spout was not stainless steel or equivalent.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)** by October 19, 2020.

Update: The Individual/Entity has paid the civil penalty. This Order has been closed.

52)	Order Type and Number:	Consent Order 20-083-RW
	Order Date:	September 29, 2020
	Individual/Entity:	**Golf Colony Resort I Homeowners' Association, Inc.**
	Facility:	Golf Colony Resort I
	Location:	Bay Tree Golf Course Highway North Myrtle Beach, SC 29582

Mailing Address:	P.O. Box 3559 North Myrtle Beach, SC 29582
County:	Horry
Previous Orders:	17-089-RW ($680.00)
Permit/ID Number:	26-894-1
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Golf Colony Resort I Homeowners' Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a spa located in Horry County, South Carolina. The Department conducted inspections on May 29, 2020, and July 23, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a handrail was not tight and secure; the gate did not self-close and latch; the pH level was not within the acceptable range of water quality standards; and, the spa rules sign was not completely filled out.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of one thousand, six hundred dollars ($1,600.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand, six hundred dollars **($1,600.00)**.

Update: The Individual/Entity has paid the civil penalty. This Order has been closed.

53)

Order Type and Number:	Consent Order 20-084-RW
Order Date:	September 29, 2020
Individual/Entity:	**Maitri Group, LLC**
Facility:	Sleep Inn
Location:	4715 Saul White Boulevard North Charleston, SC 29418
Mailing Address:	Same
County:	Charleston
Previous Orders:	None
Permit/ID Number:	10-1142B
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Maitri Group, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Charleston County, South Carolina. The Department conducted inspections on May 27, 2020, and June 25, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the depth marker tiles had been painted over; skimmers were missing weirs and the skimmer lids were cracked; there was no drinking water fountain; there were non-pool related items stored in the pump room; the pump room was not locked; the chlorine level was not within the acceptable range of water quality standards; the cyanuric acid level was above the water quality standards acceptable limit; the life ring was deteriorated and the rope was too short; the bound and numbered log book was not available during the first inspection; and, the bound and numbered log book was not maintained on a daily basis on the second inspection.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The

Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)** in installments due October 15, 2020, and December 15, 2020.

Update: The Individual/Entity has paid the first installment of the civil penalty.

Drinking Water Enforcement

54)

Order Type and Number:	Consent Order 20-021-DW
Order Date:	September 29, 2020
Individual/Entity:	**Michael Wilson, Individually and d.b.a. Diversified Signs & Graphics**
Facility:	Diversified Signs & Graphics
Location:	1123 James Harvey Road York, SC 29715
Mailing Address:	P.O. Box 1187 York, SC 29745
County:	York
Previous Orders:	None
Permit/ID Number:	4630062
Violations Cited:	S.C. Code Ann. Regs. 61-58.1.K(1)

Summary: Michael Wilson, Individually and d.b.a. Diversified Signs & Graphics (Individual/Entity) owns and is responsible for the proper operation and maintenance of a public water system (PWS) located in York County, South Carolina. On July 16, 2020, Department staff conducted an inspection at the facility, and it was determined that the PWS had been placed into operation prior to obtaining written approval to operate. The Individual/Entity has violated the State Primary Drinking Water Regulation as follows: failure to obtain written approval to operate from the Department prior to the operation of a PWS.

Action: The Individual/Entity is required to: submit the required documents to the Department to obtain written approval to operate. The Department has assessed a total civil penalty in the amount of one thousand dollars ($1,000.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand dollars **($1,000.00)**.

Update: The Individual/Entity has submitted the required documents and the Department has issued written approval to operate the PWS. The Individual/Entity has paid the civil penalty. This Order has been closed.

Water Pollution Enforcement

55)

Order Type and Number:	Consent Order 20-32-W
Order Date:	May 21, 2019
Individual/Entity:	**City of Sumter**
Facility:	Mayesville WWTF
Location:	3rd Street, Mayesville Sumter County, SC
Mailing Address:	303 East Liberty Street

Sumter, SC 29150
County: Sumter County
Previous Orders: 19-028-W ($1,400.00)
Permit/ID Number: 0069787
Violations Cited: Pollution Control Act, S.C Code Ann § 48-1-110 (d) (2008 & Supp. 2018); Water Pollution Control Permits, S.C. Code Ann Regs. 61-9.505.41 (a) (2011).

Summary: The City of Sumter (Individual/Entity) owns and is responsible for the proper operation and maintenance of a wastewater treatment facility (WWTF) located in Sumter County, South Carolina. On March 5, 2018, a Notice of Violation was issued as a result of violations of the permitted discharge limits for biochemical oxygen demand (BOD) it reported to the Department. The Individual/Entity has violated the Pollution Control Act and Water Pollution Control Permit Regulations as follows: failed to comply with the effluent discharge limits of the State Land Application Permit for BOD.

Action: The Individual/Entity is required to: continue to operate the WWTF under the current permit, submit quarterly reports of progress until the discharge is eliminated, and eliminate the discharge from the WWTF by connection to the Sumter/Pocotaligo WWTF by January 15, 2021.

Update: The Individual/Entity has started construction to connect to the Sumter/Pocotaligo WWTF.

56) Order Type and Number: Consent Order 20-028-W
Order Date: September 16, 2020
Individual/Entity: **South Carolina Distributors, Inc.**
Facility: South Carolina Distributors, Inc. WWTF
Location: Off County Road 120, Cherokee Falls
Cherokee County, SC
Mailing Address: 1406 Cherokee Falls Road
Cherokee Falls, SC 29702
County: Cherokee
Previous Orders: 20-007-W ($1,400.00)
Permit/ID Number: SCG570013
Violations Cited: Pollution Control Act, S.C Code Ann § 48-1-110 (d) (2008 & Supp. 2019); Water Pollution Control Permits, S.C. Code Ann Regs. 61-9.122.41 (a) and (d) (2011).

Summary: South Carolina Distributors, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a wastewater treatment facility (WWTF) located in Cherokee County, South Carolina. On April 13, 2020, a Notice of Violation was issued to the Individual/Entity as a result of Escherichia coli (E. coli) violations it reported to the Department. The Individual/Entity has violated the Pollution Control Act and Water Pollution Control Permit Regulations in that it failed to comply with the effluent discharge limits of the National Pollutant Discharge Elimination System Permit for E. coli.

Action: The Individual/Entity is required to: submit notification for the completion date of all corrective actions and demonstrate a six-month compliance confirmation monitoring period once corrective actions are complete. The Department has assessed a

total civil penalty in the amount of two thousand eight hundred dollars ($2,800.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand eight hundred dollars **($2,800.00)**.

Update: The Individual/Entity has completed the corrective actions and paid the civil penalty.

57) Order Type and Number: Consent Order 20-029-W
Order Date: September 16, 2020
Individual/Entity: **SC Pet Food Solutions, LLC**
Facility: SC Pet Food Solutions, LLC WWTF
Location: 1299 Duncan Road, Ward
Mailing Address: 601 North 13th Street
Monett, MO 65708
County: Saluda
Previous Orders: None
Permit/ID Number: ND0089419
Violations Cited: Pollution Control Act, S.C Code Ann § 48-1-110 (d) (2008 & Supp. 2019); Water Pollution Control Permits, S.C. Code Ann Regs. 61-9.505.41 (a) (2011).

Summary: SC Pet Food Solutions. LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a wastewater treatment facility (WWTF) located in Saluda County, South Carolina. On February 5, 2020, a Notice of Violation was issued to the Individual/Entity as a result of fecal coliform (FC) violations it reported to the Department. The Individual/Entity has violated the Pollution Control Act and Water Pollution Control Permit Regulations as follows: failed to comply with the effluent discharge limits of the National Pollutant Discharge Elimination System Permit for FC.

Action: The Individual/Entity is required to: submit notification for the completion date of all corrective actions and demonstrate a six-month compliance confirmation monitoring period once corrective actions are complete. The Department has assessed a total civil penalty in the amount of three thousand, seven hundred eighty dollars ($3,780.00). The Individual/Entity shall pay a civil penalty in the amount of three thousand, seven hundred eighty dollars **($3,780.00)**.

Update: The Individual/Entity has completed the corrective actions and paid the civil penalty.

58) Order Type and Number: Consent Order 20-030-W
Order Date: September 22, 2020
Individual/Entity: **Serrus Real Estate and Property Management**
Facility: Falls at Meehan Site
Location: Off Westinghouse Road
Anderson County, SC
Mailing Address: 7 Davis Keats Drive
Greenville, SC 29607
County: Anderson
Previous Orders: None

Permit/ID Number: SCR10U935
Violations Cited: Pollution Control Act, S.C Code Ann § 48-1-90 (A) (2019); Water Pollution Control Permits, S.C. Code Ann Regs. 61-9.122.41 (a) and (e) (2011).

Summary: Serrus Real Estate and Property Management (Individual/Entity) owns and is responsible for land disturbing activity at a site located in Anderson County, South Carolina. On November 20, 2019, an Inspection Report was issued to the Individual/Entity as a result of its failure to maintain sediment and erosion controls and unauthorized discharges of sediment associated with construction. The Individual/Entity has violated the Pollution Control Act and Water Pollution Control Permit Regulations as follows: discharged sediment into the environment, including waters of the state, in a manner other than in compliance with a permit issued by the Department, and failed to install and maintain storm water, sediment, and erosion control measures in accordance with the approved storm water pollution prevention plan (SWPPP).

Action: The Individual/Entity is required to: correct all deficiencies and bring the Site into compliance with the General Permit and SWPPP by October 22, 2020; submit an engineer's report certifying all stormwater and sediment control devices are installed and functioning properly by November 6, 2020, and submit a Notice of Termination forty-five (45) days after final stabilization of the site. The Department has assessed a total civil penalty in the amount of eleven thousand, two hundred dollars ($11,200.00). The Individual/Entity shall pay a civil penalty in the amount of eleven thousand, two hundred dollars **($11,200.00)**.

Update: The Individual/Entity has paid the civil penalty.

59) Order Type and Number: Consent Order 20-031-W
Order Date: September 22, 2020
Individual/Entity: **Orangeburg County**
Facility: Goodbys Creek Reg WWTF
Location: One mile south of U.S Hwy 301 and 176
Santee, SC
Mailing Address: P.O. Drawer 9000
Orangeburg, SC 29116
County: Orangeburg County
Previous Orders: None
Permit/ID Number: ND0086461
Violations Cited: Pollution Control Act, S.C Code Ann § 48-1-110 (d) (2008 & Supp. 2019); Water Pollution Control Permits, S.C. Code Ann Regs. 61-9.122.21(d) (2011).

Summary: Orangeburg County, (Individual/Entity) owns and is responsible for the proper operation and maintenance of a wastewater treatment facility (WWTF) located in Orangeburg County, South Carolina. On June 5, 2020, a Notice of Violation was issued as a result of the Individual/Entity's failure to comply with the reporting requirements of its State Land Application Permit. The Individual/Entity has violated the Pollution Control Act and Water Pollution Control Permits Regulations as follows: failed to submit a new NOI or permit application 180 days before the existing permit expires.

Action: The Individual/Entity is required to: continue to operate under the current permit until a new permit is issued by the Department. The Department has assessed a total civil penalty in the amount of one thousand dollars ($1,000.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand dollars **($1,000.00)**.

Update: The Individual/Entity has submitted an application for permit renewal and has paid the civil penalty.

BUREAU OF ENVIRONMENTAL HEALTH SERVICES

Food Safety Enforcement

60)	Order Type and Number:	Consent Order 2020-206-06-004
	Order Date:	September 2, 2020
	Individual/Entity:	**Panda Express**
	Facility:	Panda Express
	Location:	112 Loyola Drive Myrtle Beach, SC 29588
	Mailing Address:	1683 Walnut Grove Avenue Rosemead, CA 91770
	County:	Horry
	Previous Orders:	None
	Permit Number:	26-206-13768
	Violations Cited:	S.C. Code Ann. Regs. 61-25

Summary: Panda Express (Individual/Entity) is a restaurant located in Horry County, South Carolina. The Department conducted inspections on June 7, 2019, October 23, 2019, and January 3, 2020. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to keep equipment food contact surfaces and utensils clean to sight and touch.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25. The Department has assessed a total civil penalty in the amount of four hundred dollars ($400.00). The Individual/Entity shall pay a civil penalty in the amount of four hundred dollars **($400.00**).

Update: The Individual/Entity has completed all requirements of the Order and paid the civil penalty. This Order has been closed.

61)	Order Type and Number:	Consent Order 2020-206-04-015
	Order Date:	September 2, 2020
	Individual/Entity:	**Las Fogatas Mexican Restaurant**
	Facility:	Las Fogatas Mexican Restaurant
	Location:	145 Main Street Chesterfield, SC 29709
	Mailing Address:	Same

County: Chesterfield
Previous Orders: None
Permit Number: 13-206-01466
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Las Fogatas Mexican Restaurant (Individual/Entity) is a restaurant located in Chesterfield County, South Carolina. The Department conducted inspections on February 7, 2018, February 5, 2019, and January 7, 2020. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that refrigerated, ready-to-eat, time/temperature control for safety foods were discarded if the temperature and time combination exceeded seven (7) days or if the package was not properly date marked.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25. The Department has assessed a total civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred dollars **($800.00)**.

Update: The Department has entered into a payment plan with the Individual/Entity for the civil penalty.

62) Order Type and Number: Consent Order 2020-206-03-012
Order Date: September 8, 2020
Individual/Entity: **Hillview Restaurant**
Facility: Hillview Restaurant
Location: 2656 Ben Franklin Road
Leesville, SC 29070
Mailing Address: Same
County: Lexington
Previous Orders: 2015-206-03-124 ($1,200.00)
Permit Number: 32-206-05636
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Hillview Restaurant (Individual/Entity) is a restaurant located in Lexington County, South Carolina. The Department conducted inspections on May 30, 2019, February 4, 2020, and February 7, 2020. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain the premises free of insects, rodents, and other pests.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25. The Department has assessed a total civil penalty in the amount of five hundred dollars ($500.00). The Individual/Entity shall pay a civil penalty in the amount of five hundred dollars **($500.00)**.

Update: The Individual/Entity has completed all requirements of the Order and paid the civil penalty. This Order has been closed.

63) Order Type and Number: Consent Order 2020-206-04-022

Order Date: September 14, 2020
Individual/Entity: **Home 2 Suites by Hilton**
Facility: Home 2 Suites by Hilton
Location: 900 Woody Jones Boulevard
Florence, SC 29501
Mailing Address: P.O. Box 7537
Florence, SC 29502
County: Florence
Previous Orders: None
Permit Number: 21-206-02634
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Home 2 Suites by Hilton (Individual/Entity) operates a restaurant located in Florence County, South Carolina. The Department conducted inspections on May 7, 2018, March 21, 2019, and January 27, 2020. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to store poisonous or toxic materials so that they cannot contaminate food equipment, utensils, linens, and single-service and single-use articles.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25. The Department has assessed a total civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred dollars **($800.00)**.

Update: The Individual/Entity has completed all requirements of the Order and paid the civil penalty. This Order has been closed.

64) Order Type and Number: Consent Order 2020-206-04-030
Order Date: September 14, 2020
Individual/Entity: **Western Sizzlin**
Facility: Western Sizzlin
Location: 2688 David H McLeod Boulevard
Florence, SC 29501
Mailing Address: Same
County: Florence
Previous Orders: 2014-206-04-025 ($750.00);
2016-206-04-021 ($1,200.00)
Permit Number: 21-206-00658
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Western Sizzlin (Individual/Entity) is a restaurant located in Florence, South Carolina. The Department conducted inspections on January 8, 2018, July 11, 2018, February 13, 2019, and January 21, 2020. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to properly cool cooked time/temperature control for safety foods, failed to use effective methods to cool cooked time/temperature control for safety foods, and failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-

25. The Department has assessed a total civil penalty in the amount of two thousand, two hundred fifty dollars ($2,250.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand, two hundred fifty dollars **($2,250.00)**.

Update: The Individual/Entity has completed all requirements of the Order and paid the civil penalty. This Order has been closed.

65) Order Type and Number: Consent Order 2020-206-04-035
Order Date: September 14, 2020
Individual/Entity: **El Paso Grill LLC**
Facility: El Paso Grill LLC
Location: 611 East Maynard Street
Pageland, SC 2978
Mailing Address: Same
County: Chesterfield
Previous Orders: None
Permit Number: 13-206-01488
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: El Paso Grill LLC (Individual/Entity) is a restaurant located in Chesterfield County, South Carolina. The Department conducted inspections on March 13, 2018, March 11, 2019, and February 28, 2020. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to properly cool cooked time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25. The Department has assessed a total civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred dollars **($800.00)**.

Update: The Individual/Entity has completed all requirements of the Order and paid the civil penalty. This Order has been closed.

66) Order Type and Number: Consent Order 2020-206-06-016
Order Date: September 14, 2020
Individual/Entity: **Bellissimo**
Facility: Bellissimo
Location: 2608 Main Street, Unit I
Conway, SC 29526
Mailing Address: Same
County: Horry
Previous Orders: None
Permit Number: 26-206-12329
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Bellissimo (Individual/Entity) is a restaurant located in Conway, South Carolina. The Department conducted inspections on April 25, 2019, February 28, 2020, and March 6, 2020. The Individual/Entity has violated the South Carolina Retail Food

Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25. The Department has assessed a total civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred dollars **($800.00)**.

Update: The Individual/Entity has completed all requirements of the Order and paid the civil penalty. This Order has been closed.

67)

Order Type and Number:	Consent Order 2020-206-06-022
Order Date:	September 14, 2020
Individual/Entity:	**China Town**
Facility:	China Town
Location:	2608 Main Street, #G Conway, SC 29526
Mailing Address:	Same
County:	Horry
Previous Orders:	None
Permit Number:	26-206-12991
Violations Cited:	S.C. Code Ann. Regs. 61-25

Summary: China Town (Individual/Entity) is a restaurant located in Horry County, South Carolina. The Department conducted inspections on April 25, 2019, June 28, 2019, February 27, 2020, and March 6, 2020. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure written procedures were in place and made available to the Department when the facility uses time as a public health control.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25. The Department has assessed a total civil penalty in the amount of one thousand, six hundred dollars ($1,600.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand, six hundred dollars **($1,600.00)**.

Update: The Individual/Entity has completed all requirements of the Order and paid the civil penalty. This Order has been closed.

68)

Order Type and Number:	Consent Order 2020-206-01-008
Order Date:	September 17, 2020
Individual/Entity:	**Ingles #39 Deli**
Facility:	Ingles #39 Deli
Location:	4396 Highway 24 Anderson, SC 29626
Mailing Address:	P.O. Box 6676 Asheville, NC 28816
County:	Anderson
Previous Orders:	None

Permit Number: 04-206-02640
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Ingles #39 Deli (Individual/Entity) is a deli located in Anderson County, South Carolina. The Department conducted inspections on June 19, 2018, April 29, 2019, and March 3, 2020. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25. The Department has assessed a total civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred dollars **($800.00)**.

Update: The Individual/Entity has completed all requirements of the Order and paid the civil penalty. This Order has been closed.

69) Order Type and Number: Consent Order 2020-206-04-033
Order Date: September 17, 2020
Individual/Entity: **Subway #2308**
Facility: Subway #2308
Location: 2524 Highway 378
Gresham, SC 29546
Mailing Address: P.O. Box 2527
Spartanburg, SC 29304
County: Marion
Previous Orders: None
Permit Number: 33-206-00827
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Subway #2308 (Individual/Entity) is a restaurant located in Marion County, South Carolina. The Department conducted inspections on October 29, 2018, July 19, 2019, February 24, 2020, and March 4, 2020. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25. The Department has assessed a total civil penalty in the amount of one thousand, three hundred fifty dollars ($1,350.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand, three hundred fifty dollars **($1,350.00)**.

Update: The Individual/Entity has completed all requirements of the Order and paid the civil penalty. This Order has been closed.

70) Order Type and Number: Consent Order 2020-206-06-018
Order Date: September 17, 2020
Individual/Entity: **El Cerro Grande**
Facility: El Cerro Grande
Location: 892 Church Street

	Georgetown, SC 29440
Mailing Address:	Same
County:	Georgetown
Previous Orders:	2016-206-06-157 ($800.00)
Permit Number:	22-206-05573
Violations Cited:	S.C. Code Ann. Regs. 61-25

Summary: El Cerro Grande (Individual/Entity) is a restaurant located in Georgetown County, South Carolina. The Department conducted inspections on May 6, 2019, October 1, 2019, and February 18, 2020. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25. The Department has assessed a total civil penalty in the amount of one thousand dollars ($1,000.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand dollars **($1,000.00)**.

Update: The Individual/Entity has complied with all requirements of the Order and paid the civil penalty. This Order has been closed.

71)	Order Type and Number:	Consent Order 2020-206-06-021
	Order Date:	September 17, 2020
	Individual/Entity:	**Ramando's Fine Restaurant**
	Facility:	Ramando's Fine Restaurant
	Location:	2001 North Kings Highway Myrtle Beach, SC 29577
	Mailing Address:	Same
	County:	Horry
	Previous Orders:	None
	Permit Number:	26-206-00319
	Violations Cited:	S.C. Code Ann. Regs. 61-25

Summary: Ramando's Fine Restaurant (Individual/Entity) is a restaurant located in Horry County, South Carolina. The Department conducted inspections on March 20, 2018, March 4, 2019, and March 3, 2020. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25. The Department has assessed a total civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred dollars **($800.00)**.

Update: The Individual/Entity has completed all requirements of the Order and paid the civil penalty. This Order has been closed.

72)	Order Type and Number:	Consent Order 2020-211-01-001

Order Date: September 17, 2020
Individual/Entity: **Ingles #39 Market**
Facility: Ingles #39 Market
Location: 4396 Highway 24
Anderson, SC 29626
Mailing Address: P.O. Box 6676
Asheville, NC 28816
County: Anderson
Previous Orders: None
Permit Number: 04-211-00448
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Ingles #39 Market (Individual/Entity) is a grocery store located in Anderson County, South Carolina. The Department conducted inspections on April 29, 2020, March 2, 2020, and March 12, 2020. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25. The Department has assessed a total civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred dollars **($800.00)**.

Update: The Individual/Entity has completed all requirements of the Order and paid the civil penalty. This Order has been closed.

73) Order Type and Number: Consent Order 2020-206-04-031
Order Date: September 20, 2020
Individual/Entity: **Huddle House Restaurant**
Facility: Huddle House Restaurant
Location: 1141 Cottingham Boulevard
Bennettsville, SC 29512
Mailing Address: 147 Lake Thirteen Circle
Cheraw, SC 29520
County: Marlboro
Previous Orders: None
Permit Number: 34-206-00511
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Huddle House Restaurant (Individual/Entity) is a restaurant located in Marlboro County, South Carolina. The Department conducted inspections on September 25, 2019, October 4, 2019, and March 6, 2020. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that the permit holder was the person in charge or to designate a person in charge and ensure that a person in charge is present at the retail food establishment during all hours of operation and failed to provide a test kit or other device that accurately measures the concentration of MG/L of sanitizing solutions.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-

25. The Department has assessed a total civil penalty in the amount of four hundred dollars ($400.00). The Individual/Entity shall pay a civil penalty in the amount of four hundred dollars **($400.00)**.

Update: The Individual/Entity has completed all requirements of the Order and paid the civil penalty. This Order has been closed.

74) Order Type and Number: Consent Order 2020-206-04-024
Order Date: September 23, 2020
Individual/Entity: **Tijuanas Grill Mexican Restaurant**
Facility: Tijuanas Grill Mexican Restaurant
Location: 143 East Broadway Street
Johnsonville, SC 29555
Mailing Address: P.O. Box 674
Johnsonville, SC 29555
County: Florence
Previous Orders: None
Permit Number: 21-206-02845
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Tijuanas Grill Mexican Restaurant (Individual/Entity) is a restaurant located in Florence County, South Carolina. The Department conducted inspections on October 3, 2018, March 5, 2019, and February 19, 2020. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that refrigerated, ready-to-eat, time/temperature control for safety foods were discarded if the temperature and time combination exceeded seven (7) days or if the package was not properly date marked.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25. The Department has assessed a total civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred dollars **($800.00)**.

Update: The Individual/Entity has completed all requirements of the Order and paid the civil penalty. This Order has been closed.

75) Order Type and Number: Consent Order 2020-206-04-025
Order Date: September 23, 2020
Individual/Entity: **Teals Seafood**
Facility: Teals Seafood
Location: 68 Church Street
Cheraw, SC 29520
Mailing Address: Same
County: Chesterfield
Previous Orders: None
Permit Number: 13-206-00693
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Teals Seafood (Individual/Entity) is a restaurant located in Chesterfield County, South Carolina. The Department conducted inspections on March 1, 2018, March 1, 2019, and February 28, 2020. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods and failed to ensure that food employees clean their hands in a handwashing sink or approved automatic handwashing facility.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25. The Department has assessed a total civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred dollars **($800.00)**.

Update: The Individual/Entity has complied with all requirements of the Order and paid the civil penalty. This Order has been closed.

76)

Order Type and Number:	Consent Order 2020-206-04-026
Order Date:	September 23, 2020
Individual/Entity:	**Roger's Food and Beverage**
Facility:	Roger's Food and Beverage
Location:	202 West McGregor Street Pageland, SC 29728
Mailing Address:	Same
County:	Chesterfield
Previous Orders:	None
Permit Number:	13-206-01102
Violations Cited:	S.C. Code Ann. Regs. 61-25

Summary: Roger's Food and Beverage (Individual/Entity) is a restaurant located in Chesterfield County, South Carolina. The Department conducted inspections on April 19, 2018, March 14, 2019, and January 22, 2020. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that refrigerated, ready-to-eat, time/temperature control for safety foods were discarded if the temperature and time combination exceeded seven (7) days or if the package was not properly date marked.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25. The Department has assessed a total civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred dollars **($800.00)**.

Update: The Individual/Entity has completed all requirements of the Order and paid the civil penalty. This Order has been closed.

77)

Order Type and Number:	Consent Order 2020-206-04-034
Order Date:	September 25, 2020
Individual/Entity:	**Southern Delights**
Facility:	Southern Delights

Location:	175 15-401 Bypass Bennettsville, SC 29512
Mailing Address:	Same
County:	Marlboro
Previous Orders:	None
Permit Number:	34-206-00661
Violations Cited:	S.C. Code Ann. Regs. 61-25

Summary: Southern Delights (Individual/Entity) is a restaurant located in Marlboro County, South Carolina. The Department conducted inspections on August 21, 2018, January 30, 2019, and January 28, 2020. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that the handwashing sinks were accessible at all times.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25. The Department has assessed a total civil penalty in the amount of four hundred dollars ($400.00). The Individual/Entity shall pay a civil penalty in the amount of four hundred dollars **($400.00)**.

Update: The Individual/Entity has completed all requirements of the Order and paid the civil penalty. This Order has been closed.

78)

Order Type and Number:	Consent Order 2020-206-06-017
Order Date:	September 25, 2020
Individual/Entity:	**Subway #3224**
Facility:	Subway #3224
Location:	3400 South Fraser Street Georgetown, SC 29440
Mailing Address:	P.O. Box 1580 Springfield, OH 45501
County:	Georgetown
Previous Orders:	None
Permit Number:	22-206-06387
Violations Cited:	S.C. Code Ann. Regs. 61-25

Summary: Subway #3224 (Individual/Entity) is a restaurant located in Georgetown County, South Carolina. The Department conducted inspections on June 26, 2019, February 20, 2020, and February 28, 2020. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25. The Department has assessed a total civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred dollars **($800.00)**.

Update: The Individual/Entity has completed all requirements of the Order and paid the civil penalty. This Order has been closed.

79) Order Type and Number: Consent Order 2020-206-08-006
Order Date: September 25, 2020
Individual/Entity: **China Buffet**
Facility: China Buffet
Location: 2056 Bells Highway
Walterboro, SC 29488
Mailing Address: Same
County: Colleton
Previous Orders: None
Permit Number: 15-206-00693
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: China Buffet (Individual/Entity) is a restaurant located in Colleton County, South Carolina. The Department conducted inspections on October 30, 2018, June 26, 2019, and March 10, 2020. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that refrigerated, ready-to-eat, time/temperature control for safety foods were discarded if the temperature and time combination exceeded seven (7) days or if the package was not properly date marked.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25. The Department has assessed a total civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred dollars **($800.00)**.

Update: The Individual/Entity has completed all requirements of the Order and paid the civil penalty. This Order has been closed.

On Site Wastewater Enforcement

80) Order Type and Number: Administrative Order 20-105-OSWW
Order Date: September 10, 2020
Individual/Entity: **Russell D. Dominick and Logan D. Dominick**
Facility: Russell D. Dominick and Logan D. Dominick
Location: 126 Branch Street
Cowpens, SC 29330
Mailing Address: 1311 Bethesda Road
Spartanburg, SC 29302
County: Spartanburg
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: Russell D. Dominick and Logan D. Dominick (Individual/Entity) own property located in Spartanburg County, South Carolina. The Department conducted an investigation on August 11, 2020, and observed domestic wastewater discharging onto the surface of the ground. The Individual/Entity has violated the South Carolina Onsite

Wastewater (OSWW) Systems Regulation as follows: failed to ensure that no septic tank effluent, domestic wastewater, or sewage was discharged to the surface of the ground without an appropriate permit from the Department.

Action: The Individual/Entity is required to connect the residence to the available public sewer system within five (5) days to effectively stop the discharging of septic tank effluent, domestic wastewater, or sewage to the surface of the ground; or immediately vacate the residence to eliminate the flow of domestic wastewater to the OSWW system. The Department has assessed a total civil penalty in the amount of five thousand dollars ($5,000.00). The Individual/Entity shall pay a **suspended penalty** in the amount of five thousand dollars **($5,000.00)** should any requirement of the Order not be met.

Update: The Individual/Entity has connected the residence to public sewer. This Order has been closed.

81)

Order Type and Number:	Administrative Order 20-103-OSWW
Order Date:	September 17, 2020
Individual/Entity:	**Thomas Moore**
Facility:	Thomas Moore
Location:	131 Lakeshore Lane Seneca, SC 29678
Mailing Address:	531 Sitton Mill Road Seneca, SC 29678
County:	Oconee
Previous Orders:	None
Permit Number:	None
Violations Cited:	S.C. Code Ann. Regs. 61-56

Summary: Thomas Moore (Individual/Entity) owns property located in Oconee County, South Carolina. The Department attempted to conduct an investigation on August 5, 2020, after a complaint from Oconee County Codes Enforcement officer of multiple persons residing in a camper without a connection to an approved domestic wastewater treatment system. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: allowing a dwelling unit, building, business, or other structure to be occupied more than two hours per day without an approved method for the treatment and disposal of domestic wastewater.

Action: The Individual/Entity is required to remove the camper within five (5) days; connect the camper to an approved OSWW system within five (5) days; or immediately vacate the camper. The Department has assessed a total civil penalty in the amount of five thousand dollars ($5,000.00). The Individual/Entity shall pay a **suspended penalty** in the amount of five thousand dollars **($5,000.00)** should any requirement of the Order not be met.

Update: The Individual/Entity has provided a copy of the paperwork to evict individuals from the site.

82)

Order Type and Number:	Administrative Order 20-106-OSWW
Order Date:	September 17, 2020
Individual/Entity:	**Sam Dom Charleston Equity, LLC**

Facility: Sam Dom Charleston Equity, LLC
Location: 105 Assembly Street
Monks Corner, SC 29461
Mailing Address: P.O. Box 49422
Charlotte, NC 28277
508 Meeting Street
West Columbia, SC 29169
County: Berkeley
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: Sam Dom Charleston Equity, LLC (Individual/Entity) owns property located in Berkeley County, South Carolina. The Department conducted an investigation on August 10, 2020, and observed domestic wastewater discharging onto the surface of the ground. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that no septic tank effluent, domestic wastewater, or sewage was discharged to the surface of the ground without an appropriate permit from the Department.

Action: The Individual/Entity is required to: repair the OSWW system within five (5) days to effectively stop the discharging of septic tank effluent, domestic wastewater, or sewage to the surface of the ground; or immediately vacate the residence to eliminate the flow of domestic wastewater to the OSWW system. The Department has assessed a total civil penalty in the amount of five thousand dollars ($5,000.00). The Individual/Entity shall pay a **suspended penalty** in the amount of five thousand dollars **($5,000.00)** should any requirement of the Order not be met.

Update: The Individual/Entity has notified the Department the repairs were completed.

OFFICE OF OCEAN AND COASTAL RESOURCE MANAGEMENT

83) Order Type and Number: Consent Order AF-0000221
Order Date: September 17, 2020
Individual/Entity: **John and Cynthia Blount**
Location: 1101 Norris Drive
Pawleys Island, SC 29585
Mailing Address: 212 Larkton Place
Franklin, TN 37069
County: Georgetown
Previous Orders: None
Permit/ID Number: N/A
Violations Cited: S.C. Code Ann. §48-39-130(A) and S.C. Code Ann. Regs. 30-2(B); S.C. Code Ann. §48-39-290(B)(2)(a) and S.C. Code Ann. Regs. 30-13(N)(3)(a).

Summary: John and Cynthia Blount (Individual/Entity) are the current owners of certain property abutting the Atlantic Ocean located in Georgetown County. The

Department conducted an inspection on January 22, 2019. The Individual/Entity has violated the S.C. Coastal Zone Management Act and Coastal Division Regulations as follows: constructed an erosion control structure seaward of the setback line and in the beach/dune system critical area at the Site without a Department permit.

Action: The Individual/Entity is required to: submit a Corrective Action Plan (CAP) to address removal of the unauthorized erosion control structure. The Department has assessed a total civil penalty in the amount of three thousand dollars ($3,000.00). The Individual/Entity shall pay a civil penalty in the amount of three thousand dollars **($3,000.00).**

Update: The Individual/Entity has submitted the CAP to the Department, and it has been approved. The civil penalty has been paid.

84) Order Type and Number: Consent Order AF-0000226, -0000225
Order Date: September 17, 2020
Individual/Entity: **Brian and Konni McMurray**
Location: 1145 and 1159 Norris Drive
Pawleys Island, SC 29585
Mailing Address: 25 Cypress Point Drive
Pinehurst, NC 28374
County: Georgetown
Previous Orders: None
Permit/ID Number: N/A
Violations Cited: S.C. Code Ann. §48-39-130(A) and S.C. Code Ann. Regs. 30-2(B); S.C. Code Ann. §48-39-290(B)(2)(a) and S.C. Code Ann. Regs. 30-13(N)(3)(a).

Summary: Brian and Konni McMurray (Individual/Entity) are the current owners of certain properties abutting the Atlantic Ocean located in Georgetown County, South Carolina. The Department conducted inspections on January 22, 2019. The Individual/Entity has violated the S.C. Coastal Zone Management Act and Coastal Division Regulations as follows: installed two erosion control structures, sandbags, sand and other fill material seaward of the setback line, in the beaches, and beach/dune system critical areas without a Department permit.

Action: The Individual/Entity is required to: submit a Corrective Action Plan (CAP) to address removal of the unauthorized erosion control structures and sandbags. The Department has assessed a total civil penalty in the amount of ten thousand dollars ($10,000.00). The Individual/Entity shall pay a civil penalty in the amount of ten thousand dollars **($10,000.00).**

Update: The Individual/Entity has submitted the final CAP to the Department, and it has been approved. The civil penalty has been paid.

85) Order Type and Number: Consent Order AF-0000227
Order Date: September 17, 2020
Individual/Entity: **Christopher and Carol Lee**
Location: 1175 Norris Drive
Pawleys Island, SC 29585

Mailing Address:	3728 Mooreland Farms Road Charlotte, NC 28226
County:	Georgetown
Previous Orders:	None
Permit/ID Number:	N/A
Violations Cited:	S.C. Code Ann. §48-39-130(A) and S.C. Code Ann. Regs. 30-2(B); S.C. Code Ann. §48-39-290(B)(2)(a) and S.C. Code Ann. Regs. 30-13(N)(3)(a).

Summary: Christopher and Carol Lee (Individual/Entity) are the current owners of certain property abutting the Atlantic Ocean located in Georgetown County. The Department conducted an inspection on January 22, 2019. The Individual/Entity has violated the S.C. Coastal Zone Management Act and Coastal Division Regulations as follows: installed an erosion control structure, a brick wall structure, patio decking, sandbags, sand and other fill material seaward of the setback line, in the beaches and beach/dune system critical areas without a Department permit.

Action: The Individual/Entity is required to: submit a Corrective Action Plan (CAP) to address removal of the unauthorized erosion control structure, brick structure, sandbags, fill material and landscaping. The Department has assessed a total civil penalty in the amount of five thousand dollars ($5,000.00). The Individual/Entity shall pay a civil penalty in the amount of five thousand dollars **($5,000.00)** by October 17, 2020.

Update: The Individual/Entity has submitted the final CAP to the Department, and it has been approved.

* Unless otherwise specified, "Previous Orders" as listed in this report include orders issued by Environmental Affairs Programs within the last five (5) years.

SUMMARY SHEET
SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

November 12, 2020

(X) ACTION/DECISION
( ) INFORMATION

I. TITLE: Request for Placement of Oliceridine into Schedule II for Controlled Substances in South Carolina

II. SUBJECT: Placement of Oliceridine in Schedule II for Controlled Substances

II. FACTS:

Controlled substances are governed by the South Carolina Controlled Substances Act ("CSA"), Title 44, Chapter 53 of the South Carolina Code of Laws. Schedule II substances are listed in Section 44-53-210 of the South Carolina Code of Laws. Pursuant to Section 44-53-160, titled "Manner in which changes in schedule of controlled substances shall be made," controlled substances are generally designated by the General Assembly upon recommendation by the Department. Section 44-53-160(C) provides a process for the Department to expeditiously designate a substance if the federal government has so designated.

South Carolina Section 44-53-160(C) states:

> If a substance is added, deleted, or rescheduled as a controlled substance pursuant to federal law or regulation, the department shall, at the first regular or special meeting of the South Carolina Board of Health and Environmental Control within thirty days after publication in the federal register of the final order designating the substance as a controlled substance or rescheduling or deleting the substance, add, delete, or reschedule the substance in the appropriate schedule. The addition, deletion, or rescheduling of a substance by the department pursuant to this subsection has the full force of law unless overturned by the General Assembly. The addition, deletion, or rescheduling of a substance by the department pursuant to this subsection must be in substance identical with the order published in the federal register effecting the change in federal status of the substance. Upon the addition, deletion, or rescheduling of a substance, the department shall forward copies of the change to the Chairmen of the Medical Affairs Committee and the Judiciary Committee of the Senate, the Medical, Military, Public and Municipal Affairs Committee, and the Judiciary Committee of the House of Representatives, and to the Clerks of the Senate and House, and shall post the schedules on the department's website indicating the change and specifying the effective date of the change.

The United States Food and Drug Administration ("FDA") approved a new drug application for oliceridine for intravenous use on August 7, 2020. Oliceridine is chemically known as N-[(3- methoxythiophen-2-yl)methyl] ({2- [(9R)-9-(pyridin-2-yl)-6-oxaspiro [4.5]decan-9-yl]ethyl})amine fumarate. The Department of Health and Human Services ("HHS") provided the Drug Enforcement Administration ("DEA") with a scheduling recommendation to place oliceridine in schedule II of the Controlled Substances Act ("federal CSA"). In accordance with the federal CSA, as amended by the Improving Regulatory Transparency for New Medical Therapies Act, the DEA issued an interim final rule placing oliceridine, including its salts and salts of isomers, esters and ethers whenever the existence of such isomers, esters, ethers, and salts is

possible, in schedule II of the CSA, effective October 30, 2020 in *Federal Register*, Volume 85, Number 211, pages 68749-68753; https://www.govinfo.gov/content/pkg/FR-2020-10-30/pdf/2020-22762.pdf.

III. ANALYSIS:

Oliceridine, chemically known as N-[(3- methoxythiophen-2-yl)methyl] ({2- [(9R)-9-(pyridin-2-yl)-6-oxaspiro [4.5]decan-9-yl]ethyl})amine fumarate, is a new molecular entity with Central Nervous System ("CNS") depressant properties. On November 2, 2017, Trevena, Inc. ("Sponsor") submitted an intitial new drug application ("NDA") for oliceridine that was subsequently resubmitted on February 7, 2020. On August 7, 2020, FDA approved the NDA for oliceridine for medical use as an intravenous drug for the management of acute pain severe enough to require an intravenous opioid analgesic and for patients for whom alternative treatments are inadequate.

On July 27, 2020, DEA received from HHS a scientific and medical evaluation entitled ''Basis for the Recommendation to Control Oliceridine and its Salts in Schedule II of the Controlled Substances Act'' and a scheduling recommendation. This document contained an eight-factor analysis of the abuse potential, legitimate medical use, and dependence liability of oliceridine, along with a recommendation from HHS to control oliceridine and its salts under schedule II of the CSA. DEA reviewed the scientific and medical evaluation and scheduling recommendation provided by HHS, along with all other relevant data, and completed its own eight-factor review pursuant to 21 U.S.C. 811(c). DEA concluded that oliceridine meets the 21 U.S.C. 812(b)(2) criteria for placement in schedule II of the CSA.

The CSA lists the findings required to place a drug or other substance in any particular schedule (I, II, III, IV, or V). 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Assistant Secretary for Health of HHS and review of all available data, the Acting Administrator of DEA, pursuant to 21 U.S.C. 812(b)(2), finds that:

1) Oliceridine Has a High Potential for Abuse.

Oliceridine is a mu-opioid receptor agonist and produces behavioral effects that are similar to those of morphine, a schedule II opioid substance, in animals and humans. A self-administration study in animals demonstrated that oliceridine produced self-administration that was comparable to morphine. Additionally, a drug discrimination study in animals demonstrated that oliceridine generalized to morphine, indicating that it has mu-opioid receptor agonist properties. Results from a human abuse potential ("HAP") study showed that oliceridine produces positive subjective effects as well as adverse events such as euphoria, similar to that of morphine, a schedule II substance with a high potential for abuse. Lastly, clinical studies in healthy individuals indicate that oliceridine produces abuse-related adverse events such as euphoria and sedation. These data collectively indicate that oliceridine has a high potential for abuse similar to the schedule II substance morphine.

2) Oliceridine Has a Currently Accepted Medical Use in the United States.

FDA recently approved a NDA for oliceridine for the management of acute pain severe enough to require an intravenous opioid analgesic and for patients for whom alternative treatments are inadequate. Thus, oliceridine has a currently accepted medical use in treatment in the United States.

3) Abuse of Oliceridine May Lead to Severe Physical Dependence or Psychological Dependence.

Chronic administration of oliceridine in rats followed by drug discontinuation produced classic opioid withdrawal signs, similar to that of schedule II drug morphine. This study would indicate oliceridine's potential to cause physical dependence similar to that of morphine. Oliceridine also produces self-administration in rats and positive subjective responses in a HAP study. These results parallel those produced by morphine and suggest that oliceridine can also produce psychological dependence. These data collectively suggest that oliceridine abuse may lead to psychological and physical dependence similar to that of schedule II opioids.

IV. RECOMMENDATION:

The Acting Administrator of the Drug Enforcement Administration has concluded that oliceridine, including its salts and salts of isomers, esters and ethers whenever the existence of such isomers, esters, ethers, and salts is possible, warrants control in schedule II of the CSA.

Pursuant to South Carolina Code Section 44-53-160(C), the Department recommends the addition of oliceridine to Schedule II for controlled substances in South Carolina and the amendment of Section 44-53-210 of the South Carolina Code of Laws to include:

( ) Oliceridine N-[(3- methoxythiophen-2-yl)methyl] ({2- [(9R)-9-(pyridin-2-yl)-6-oxaspiro [4.5]decan-9-yl]ethyl})amine fumarate.

Submitted by:

Lisa Thomson
Bureau Director
Bureau of Drug Control

Gwen Thompson
Deputy Director
Healthcare Quality

Attachment:
Federal Register, Volume 85, Number 192, pages 68749-68753, October 2, 2020

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–715]

Schedules of Controlled Substances: Placement of Oliceridine in Schedule II

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Interim final rule, with request for comments.

SUMMARY: On August 7, 2020, the U.S. Food and Drug Administration approved a new drug application for oliceridine, chemically known as *N*-[(3-methoxythiophen-2-yl)methyl] ({2-[(9*R*)-9-(pyridin-2-yl)-6-oxaspiro [4.5]decan-9-yl]ethyl})amine fumarate. The Department of Health and Human Services provided the Drug Enforcement Administration (DEA) with a scheduling recommendation to place oliceridine in schedule II of the Controlled Substances Act (CSA). In accordance with the CSA, as revised by the Improving Regulatory Transparency for New Medical Therapies Act, DEA is hereby issuing an interim final rule placing oliceridine, including its isomers, esters, ethers, salts and salts of isomers, esters and ethers whenever the existence of such isomers, esters, ethers and salts is possible, in schedule II of the CSA.

DATES: The effective date of this rulemaking is October 30, 2020. Interested persons may file written comments on this rulemaking in accordance with 21 U.S.C. 811(j)(3) and 21 CFR 1308.43(g). Electronic comments must be submitted, and written comments must be postmarked, on or before November 30, 2020. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

Interested persons may file a request for hearing or waiver of hearing in accordance with 21 U.S.C. 811(j)(3) and 21 CFR 1308.44. Requests for hearing and waivers of an opportunity for a hearing or to participate in a hearing must be received on or before November 30, 2020.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–715'' on all correspondence, including any attachments.

- *Electronic comments:* The Drug Enforcement Administration encourages that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *http://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on *Regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.
- *Paper comments:* Paper comments that duplicate the electronic submission are not necessary and are discouraged. Should you wish to mail a paper comment *in lieu of* an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, VA 22152.
- *Hearing requests:* All requests for hearing and waivers of participation must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing and waivers of participation should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/LJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362–3261.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received are considered part of the public record. They will, unless reasonable cause is given, be made available by the Drug Enforcement Administration (DEA) for public inspection online at *http://www.regulations.gov.* Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify the confidential business information to be redacted within the comment.

Comments containing personal identifying information and confidential business information identified as directed above will generally be made publicly available in redacted form. If a comment has so much confidential business information or personal identifying information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to *http://www.regulations.gov* may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this document and supplemental information, including the complete Department of Health and Human Services (HHS) and DEA eight-factor analyses, to this interim final rule (IFR) are available at *http://www.regulations.gov* for easy reference.

Request for Hearing or Appearance; Waiver

Pursuant to 21 U.S.C. 811(a), this action is a formal rulemaking ''on the record after opportunity for a hearing.'' Such proceedings are conducted pursuant to the provisions of the Administrative Procedure Act (APA), 5 U.S.C. 551–559. 21 CFR 1308.41–1308.45; 21 CFR part 1316, subpart D. Interested persons may file requests for a hearing or notices of intent to participate in a hearing in conformity with the requirements of 21 CFR 1308.44 (a) or (b), and include a statement of interest in the proceeding and the objections or issues, if any, concerning which the person desires to be heard. Any interested person may file a waiver of an opportunity for a hearing or to participate in a hearing together with a written statement regarding the interested person's position on the

matters of fact and law involved in any hearing as set forth in 21 CFR 1308.44(c).

All requests for a hearing and waivers of participation must be sent to DEA using the address information provided above.

Background and Legal Authority

Under the Improving Regulatory Transparency for New Medical Therapies Act, Public Law 114–89, 2(b), 129 Stat. 698, 700 (2015), DEA is required to commence an expedited scheduling action with respect to certain new drugs approved by the U.S. Food and Drug Administration (FDA). As provided in 21 U.S.C. 811(j), this expedited scheduling is required where both of the following conditions apply: (1) The Secretary of the Department of Health and Human Services (the Secretary) has advised DEA that an application for a new drug has been submitted for a drug that has a stimulant, depressant, or hallucinogenic effect on the central nervous system, and that it appears that such drug has an abuse potential; and, (2) the Secretary recommends that DEA control the drug in schedule II, III, IV, or V pursuant to 21 U.S.C. 811(a) and (b). In these circumstances, DEA is required to issue an IFR controlling the drug within 90 days.

The law further states that the 90-day timeframe starts the later of (1) the date DEA receives the HHS scientific and medical evaluation/scheduling recommendation, or (2) the date DEA receives notice of the application approval by HHS. In addition, the law specifies that the rulemaking shall become immediately effective as an IFR without requiring DEA to demonstrate good cause therefor. Thus, the purpose of subsection (j) is to speed the process by which DEA schedules newly approved drugs that are currently either in schedule I or not controlled (but which have sufficient abuse potential to warrant control) so that such drugs may be marketed without undue delay following FDA approval.[1]

Subsection (j) further provides that the IFR shall give interested persons the opportunity to comment and to request a hearing. After the conclusion of such proceedings, DEA must issue a final rule in accordance with the scheduling criteria of subsections 21 U.S.C. 811(b), (c), and (d) and 21 U.S.C. 812(b).

On November 2, 2017, Trevena, Inc. (Sponsor) submitted an initial New Drug Application (NDA) to FDA for oliceridine that was subsequently resubmitted on February 7, 2020. FDA determined that oliceridine is a new molecular entity, and HHS determined that oliceridine has a depressant effect on the central nervous system. On August 7, 2020, FDA approved the NDA for oliceridine for medical use as an intravenous drug for the management of acute pain severe enough to require an intravenous opioid analgesic and for patients for whom alternative treatments are inadequate.

Determination To Schedule Oliceridine

On July 27, 2020, DEA received a scientific and medical evaluation document from HHS prepared by FDA related to oliceridine, titled: ''Basis for the Recommendation to Control Oliceridine and its Salts in Schedule II of the Controlled Substances Act.'' Pursuant to 21 U.S.C. 811(b), this document contained an eight-factor analysis of the abuse potential of oliceridine, along with HHS's recommendation to control oliceridine under schedule II of the CSA. Subsequently, on August 7, 2020, DEA received notification from HHS that FDA had approved an NDA for oliceridine (OLINVYK).

In response, DEA reviewed the scientific and medical evaluation and scheduling recommendation provided by HHS, along with all other relevant data, and completed its own eight-factor review document pursuant to 21 U.S.C. 811(c). DEA concluded that oliceridine met the 21 U.S.C. 812(b)(2) criteria for placement in schedule II of the CSA.

Pursuant to subsection 811(j), and based on HHS's recommendation, the NDA approval by HHS/FDA, and DEA's determination, DEA is issuing this IFR to schedule oliceridine as a schedule II controlled substance under the CSA.

Included below is a brief summary of each factor as analyzed by HHS and DEA, and as considered by DEA in its scheduling action. Please note that both the DEA and HHS analyses are available in their entirety under ''Supporting Documents'' in the public docket for this IFR at *http://www.regulations.gov,* under Docket Number ''DEA–715.'' Full analysis of, and citations to, the information referenced in the summary may also be found in the supporting and related material.

1. *Its Actual or Relative Potential for Abuse:* Oliceridine is a new molecular entity that has not been marketed in the United States or any other country. Thus, information about the diversion and actual abuse of oliceridine is limited. Oliceridine is currently not available for medical treatment, has not been diverted from legitimate sources, and individuals have not taken this substance in amounts sufficient to create a hazard to public health and safety. DEA notes that there are no reports for oliceridine in the National Forensic Laboratory Information System (NFLIS),[2] which collects drug identification results from drug cases submitted to and analyzed by Federal, State, and local forensic laboratories. There were also no reports in DEA's laboratory drug evidence data system of record, STARLiMS.[3]

According to the legislative history of the CSA, one of the criteria by which DEA should assess actual or relative potential for abuse is whether the substance in question ''is so related in its action to a substance already listed as having a potential for abuse to make it likely that it will have the same potential for abuse as such substance, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.'' [4] As stated by HHS, oliceridine is a high-affinity mu opioid agonist that produces behavioral effects similar to other mu opioid agonists, such as the schedule II opioid morphine. Moreover, in a rat drug discrimination study, oliceridine generalized to morphine, showing that oliceridine has opioid-like properties. In a clinical study investigating the abuse potential of oliceridine, HHS concluded that oliceridine produced subjective responses that were similar to those for morphine. Specifically, like morphine, oliceridine produced positive subjective responses and euphoria-related adverse events in clinical studies. Together, this

[1] Given the parameters of subsection (j), in DEA's view, it would not apply to a reformulation of a drug containing a substance currently in schedules II through V for which an NDA has recently been approved.

[2] NFLIS represents an important resource in monitoring illicit drug trafficking, including the diversion of legally manufactured pharmaceuticals into illegal markets. NFLIS is a comprehensive information system that includes data from forensic laboratories that handle more than 96 percent of an estimated 1.0 million distinct annual State and local drug analysis cases. NFLIS includes drug chemistry results from completed analyses only. While NFLIS data is not direct evidence of abuse, it can lead to an inference that a drug has been diverted and abused. *See* 76 FR 77330, 77332 (Dec. 12, 2011). NFLIS data were queried on July 28, 2020.

[3] On October 1, 2014, DEA implemented STARLiMS (a web-based, commercial laboratory information management system) to replace the System to Retrieve Information from Drug Evidence (STRIDE) as its laboratory drug evidence data system of record. DEA laboratory data submitted after September 30, 2014, are reposited in STARLiMS. STARLiMS data were queried on July 28, 2020.

[4] Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. Rep. No. 91–1444, 91st Cong., Sess. 1 (1970), reprinted in U.S.C.C.A.N. 4566, 4603.

evidence demonstrates that oliceridine is related in action and effect to the schedule II substance morphine, and can therefore be expected to have a similar potential for abuse.

2. *Scientific Evidence of Its Pharmacological Effects, if Known:* Oliceridine has high affinity for the mu-opioid receptor and does not bind to any other receptors that are typically associated with abuse, such as kappa and delta opioid receptors, cannabinoid receptors, GABAergic receptors, or other ion channels. According to HHS, general behavioral studies in animals indicate that oliceridine produces behavioral and motor effects similar to those of morphine, a schedule II substance. Additionally, oliceridine produces self-administration in rats. Furthermore, in a drug discrimination study used to predict subjective effects in humans, oliceridine mimicked the stimulus effects of morphine. In a human abuse potential (HAP) study, therapeutic and supratherapeutic doses of oliceridine produced euphoria, somnolence, and paresthesia. These adverse events are consistent with those of other schedule II opioids such as morphine. In other clinical studies, adverse events such as somnolence, sedation, anxiety, restlessness, and paresthesia were seen in subjects treated with oliceridine. As concluded by HHS, results from preclinical and clinical studies indicate that oliceridine has abuse potential similar to morphine.

3. *The State of Current Scientific Knowledge Regarding the Drug or Other Substance:* Oliceridine is a new molecular entity, chemically known as *N*-[(3-methoxythiophen-2-yl)methyl]({2-[(9*R*)-9-(pyridin-2-yl)-6-oxaspiro[4.5]decan-9-yl]ethyl})amine fumarate. It has a molecular formula of $C_{22}H_{30}N_2O_2S.C_4H_4O_4$. Oliceridine is a white to lightly-colored solid that is sparingly soluble in water. On August 7, 2020, FDA approved an NDA for oliceridine for medical use to manage acute pain severe enough to require an intravenous opioid analgesic and for which alternative treatments are inadequate. Thus, oliceridine has an accepted medical use in the United States. Oliceridine will be marketed as an intravenous medication formulated in vials containing 1, 2, or 30 mg of oliceridine.

4. *Its History and Current Pattern of Abuse:* There is no information available relating to the history and current pattern of abuse of oliceridine, since this drug is not currently marketed in any country. HHS notes that oliceridine produces abuse-related signals, such as euphoria and somnolence, and abuse potential similar to that of schedule II controlled substance morphine. DEA searched NFLIS and STARLiMS databases for oliceridine encounters. Consistent with the fact that oliceridine is a new molecular entity, these databases had no records of encounters of oliceridine by law enforcement.

5. *The Scope, Duration, and Significance of Abuse:* Oliceridine is currently not marketed in any country. Thus, information on the scope, duration, and significance of abuse for oliceridine is lacking. However, as stated by HHS, data from animal and human studies indicate that oliceridine has abuse potential similar to morphine. Therefore, upon marketing, oliceridine scope of abuse is expected to be similar to morphine.

6. *What, if any, Risk There is to the Public Health:* The extent of abuse potential of a drug is an indication of its public health risk. Data from the preclinical and clinical studies suggest that the abuse potential and physical or psychological dependence potential of oliceridine are similar to the schedule II substance morphine. Thus, oliceridine upon its availability for marketing would be expected to create a public health risk.

7. *Its Psychic or Physiological Dependence Liability:* Physical dependence for oliceridine was tested in an animal toxicity study. According to HHS, the animal toxicity study using rats demonstrated dose-dependent decreases in food consumption and body weight as well as classic opioid withdrawal signs from discontinuation of oliceridine. In a rat self-administration study as well as in clinical studies, oliceridine produced rewarding effects similar to morphine. Based on these studies, HHS stated that oliceridine may produce physical and psychological dependence.

8. *Whether the Substance is an Immediate Precursor of a Substance Already Controlled under the CSA:* Oliceridine is not an immediate precursor of any controlled substance, as defined in 21 U.S.C. 802(23).

Conclusion: After considering the scientific and medical evaluation conducted by HHS, HHS's scheduling recommendation, and its own eight-factor analysis, DEA has determined that these facts and all relevant data constitute substantial evidence of a potential for abuse of oliceridine. As such, DEA hereby schedules oliceridine as a controlled substance under the CSA.

Determination of Appropriate Schedule

The CSA outlines the findings required to place a drug or other substance in any particular schedule (I, II, III, IV, or V). 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Assistant Secretary for Health of HHS and review of all available data, the Acting Administrator of DEA, pursuant to 21 U.S.C. 812(b)(2), finds that:

1. Oliceridine Has a High Potential for Abuse

Oliceridine is a mu-opioid receptor agonist and produces behavioral effects that are similar to those of morphine (schedule II opioid substance) in animals and humans. A self-administration study in animals demonstrated that oliceridine produced self-administration that was comparable to morphine. Additionally, a drug-discrimination study in animals demonstrated that oliceridine generalized to morphine, indicating that it has mu-opioid receptor agonist properties. Results from a HAP study showed that oliceridine produces positive subjective effects as well as adverse events such as euphoria, similar to that of morphine, a schedule II substance with a high potential for abuse. Lastly, clinical studies in healthy individuals indicate that oliceridine produces abuse-related adverse events such as euphoria and sedation. These data collectively indicate that oliceridine has a high potential for abuse similar to the schedule II substance morphine.

2. Oliceridine Has a Currently Accepted Medical Use in the United States

FDA recently approved a NDA for oliceridine for the management of acute pain severe enough to require an intravenous opioid analgesic and for patients for whom alternative treatments are inadequate. Thus, oliceridine has a currently accepted medical use in treatment in the United States.

3. Abuse of Oliceridine May Lead To Severe Psychological or Physical Dependence

Chronic administration of oliceridine in rats followed by drug discontinuation produced classic opioid withdrawal signs, similar to that of schedule II drug morphine. This study would indicate oliceridine's potential to cause physical dependence similar to that of morphine. Oliceridine also produces self-administration in rats and positive subjective responses in a HAP study. These results parallel those produced by morphine and suggest that oliceridine can also produce psychological dependence. These data collectively suggest that oliceridine abuse may lead to psychological and physical

dependence similar to that of schedule II opioids.

Based on these findings, the Acting Administrator of DEA concludes that oliceridine warrants control in schedule II of the CSA. 21 U.S.C. 812(b)(2).

Requirements for Handling Oliceridine

Oliceridine is subject to the CSA's schedule II regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, dispensing, importing, exporting, research, and conduct of instructional activities and chemical analysis with, and possession involving schedule II substances, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, dispenses, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) oliceridine, or who desires to handle oliceridine, must be registered with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958 and in accordance with 21 CFR parts 1301 and 1312. Any person who currently handles or intends to handle oliceridine, and is not registered with DEA, must submit an application for registration and may not continue to handle oliceridine, unless DEA has approved the application for registration, pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312.

2. *Quota.* Only registered manufacturers are permitted to manufacture oliceridine in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303.

3. *Disposal of stocks.* Any person who does not desire or is not able to maintain a schedule II registration must surrender all quantities of currently held oliceridine, or may transfer all quantities of currently held oliceridine to a person registered with DEA in accordance with 21 CFR part 1317, in addition to all other applicable Federal, State, local, and tribal laws.

4. *Security.* Oliceridine is subject to schedule II security requirements and must be handled and stored pursuant to 21 U.S.C. 821 and 823 and in accordance with 21 CFR 1301.71–1301.93.

5. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of oliceridine must comply with 21 U.S.C. 825 and 958(e) and be in accordance with 21 CFR part 1302.

6. *Inventory.* Every DEA registrant who possesses any quantity of oliceridine must take an inventory of oliceridine on hand, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

Any person who becomes registered with DEA to handle oliceridine must take an initial inventory of all stocks of controlled substances containing oliceridine on hand on the date the registrant first engages in the handling of controlled substances, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

After the initial inventory, every DEA registrant must take a new inventory of all stocks of controlled substances (including oliceridine) on hand every two years, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

7. *Records and Reports.* Every DEA registrant must maintain records and submit reports for oliceridine, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1304, 1312, and 1317.

8. *Orders for oliceridine.* Every DEA registrant who distributes oliceridine is required to comply with order form requirements, pursuant to 21 U.S.C. 828, and in accordance with 21 CFR part 1305.

9. *Prescriptions.* All prescriptions for oliceridine or products containing oliceridine must comply with 21 U.S.C. 829, and be issued in accordance with 21 CFR parts 1306 and 1311, subpart C.

10. *Manufacturing and Distributing.* In addition to the general requirements of the CSA and DEA regulations that are applicable to manufacturers and distributors of schedule II controlled substances, such registrants should be advised that (consistent with the foregoing considerations) any manufacturing or distribution of oliceridine may only be for the legitimate purposes consistent with the drug's labeling, or for research activities authorized by the Federal Food, Drug, and Cosmetic Act, as applicable, and the CSA.

11. *Importation and Exportation.* All importation and exportation of oliceridine must be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

12. *Liability.* Any activity involving oliceridine not authorized by, or in violation of, the CSA or its implementing regulations, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Administrative Procedure Act

Public Law 114–89 was signed into law, amending 21 U.S.C. 811. This amendment provides that in cases where a new drug is (1) approved by HHS, and (2) HHS recommends control in CSA schedule II–V, DEA shall issue an IFR scheduling the drug within 90 days. Additionally, the law specifies that the rulemaking shall become immediately effective as an IFR without requiring DEA to demonstrate good cause. Therefore, DEA has determined that the notice and comment requirements of section 553 of the APA, 5 U.S.C. 553, do not apply to this scheduling action.

Executive Orders 12866, 13563, and 13771, Regulatory Planning and Review, Improving Regulation and Regulatory Review, and Reducing Regulation and Controlling Regulatory Costs

In accordance with 21 U.S.C. 811(a) and (j), this scheduling action is subject to formal rulemaking procedures performed ''on the record after opportunity for a hearing,'' which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the procedures and criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of Executive Order (E.O.) 12866 and the principles reaffirmed in E.O. 13563.

This IFR is not an E.O. 13771 regulatory action pursuant to E.O. 12866 and OMB guidance.[5]

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of E.O. 13132. The rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

[5] Office of Management and Budget, Executive Office of The President, Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017, Titled ''Reducing Regulation and Controlling Regulatory Costs'' (Feb. 2, 2017).

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) applies to rules that are subject to notice and comment under section 553(b) of the APA. Under 21 U.S.C. 811(j), DEA is not required to publish a general notice of proposed rulemaking. Consequently, the RFA does not apply to this IFR.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.,* DEA has determined that this action would not result in any Federal mandate that may result ''in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted for inflation) in any one year.'' Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. This action does not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. This rule does not result in: An annual effect on the economy of $100 million or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based companies to compete with foreign based companies in domestic and export markets. However, pursuant to the CRA, DEA has submitted a copy of this IFR to both Houses of Congress and to the Comptroller General.

List of Subjects

21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, DEA amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. Amend § 1308.12 by:
■ a. Redesignating paragraph (c)(18) through (c)(29) as (c)(19) through (c)(30);
■ b. Adding new paragraph (c)(18).

The addition to read as follows:

§ 1308.12 Schedule II.

* * * * *

(c) * * *

(18) Oliceridine (*N*-[(3-methoxythiophen-2-yl)methyl] ({2-[(9*R*)-9-(pyridin-2-yl)-6-oxaspiro [4.5]decan-9-yl]ethyl})amine fumarate) 9245

* * * * *

Timothy J. Shea,

Acting Administrator.

[FR Doc. 2020–22762 Filed 10–29–20; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[Docket ID: DOD–2020–HA–0050]

RIN 0720–AB83

TRICARE Coverage of National Institute of Allergy and Infectious Disease Coronavirus Disease 2019 Clinical Trials

AGENCY: Office of the Secretary, Department of Defense (DoD).

ACTION: Interim final rule with request for comments.

SUMMARY: The Assistant Secretary of Defense for Health Affairs (ASD(HA)) issues this interim final rule (IFR) with request for comments to temporarily modify the TRICARE regulation by adding coverage for National Institute of Allergy and Infectious Disease (NIAID)-sponsored clinical trials for the treatment or prevention of coronavirus disease 2019 (COVID–19).

DATES: *Effective date:* This interim final rule is effective on October 30, 2020 through the end of the President's national emergency regarding COVID–19 (Proclamation 9994, 85 FR 15337 (Mar. 18, 2020)). The ASD(HA) will publish a document announcing the expiration date.

Comment date: Comments are invited and must be submitted on or before November 30, 2020.

ADDRESSES: You may submit comments, identified by docket number and/or Regulation Identification Number (RIN) number and title, by any of the following methods:

- *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* The DoD cannot receive written comments at this time due to the COVID–19 pandemic. Comments should be sent electronically to the docket listed above.

Instructions: All submissions received must include the agency name and docket number or RIN for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Erica Ferron, Medical Benefits and Reimbursement Section, 303–676–3626, *erica.c.ferron.civ@mail.mil.*

SUPPLEMENTARY INFORMATION: *Expiration Date:* Unless extended after consideration of submitted comments, this IFR will cease to be in effect upon termination of the President's declared national emergency regarding COVID–19, in accordance with applicable law (50 U.S.C.1622(a)).

If the ASD(HA) determines it would be appropriate to make these changes permanent, the ASD(HA) will follow-up with final rulemaking. The ASD(HA) will publish a document in the **Federal Register** announcing the expiration date.

Date: November 12, 2020

To: S.C. Board of Health and Environmental Control

From: Bureau of Environmental Health Services

Re: Public Hearing for Notice of Final Regulation Amending R.61-56, *Onsite Wastewater Systems*; Repealing R.61-55, *Septic Tank Site Evaluation Fees;* R.61-56.1, *License to Construct or Clean Onsite Sewage Treatment and Disposal Systems and Self-Contained Toilets*; and R.61-56.2, *Licensing of Onsite Wastewater Systems Master Contractors*, Document No. 4979

I. Introduction

The Bureau of Environmental Health Services ("Bureau") proposes the attached Notice of Final Regulation amending R.61-56, *Onsite Wastewater Systems*; and repealing R.61-55, *Septic Tank Site Evaluation Fees;* R.61-56.1, *License to Construct or Clean Onsite Sewage Treatment and Disposal Systems and Self-Contained Toilets*; and R.61-56.2, *Licensing of Onsite Wastewater Systems Master Contractors*, and merging these regulations' requirements, as amended, into R.61-56. Legal authority resides in S.C. Code Sections 44-1-140(11), 44-1-150, 44-55-825, 44-55-827, and 48-1-10 *et seq*., which enable the Department of Health and Environmental Control ("Department") to promulgate regulations related to the disposal of sewage. The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these amendments.

II. Facts

1. Pursuant to R.61-56, the Department provides oversight for safe treatment and disposal of domestic wastewater to protect the health of families and communities. In accordance with R.61-55, R.61-56, R.61-56.1, and R.61-56.2, the Department issues onsite wastewater contractor licenses, permits to construct, and approvals to operate for individual onsite wastewater treatment systems (septic systems).

2. The Department is amending R.61-56, *Onsite Wastewater Systems*, to add new system standards, clarify and amend definitions, and clarify and update selected sections. The amendments will modernize the regulation and streamline permitting procedures to address needed updates in administering the Onsite Wastewater program.

3. The Department is also amending provisions of R.61-56.1 and R.61-56.2 and merging R.61-56.1 and R.61-56.2 into R.61-56 to improve efficiency and clarity for regulated entities and the public. This will entail repealing R.61-56.1 and R.61-56.2 and simultaneously adding their provisions, as amended, to R.61-56. The amendments include changes to licensing requirements for pumpers and haulers currently under R.61-56.1. The amendments will revise provisions currently contained in R.61-56.2 to implement a tiered licensing program to establish improved competency of onsite wastewater system contractors/installers. This approach includes new requirements for examination and continuing education. In addition, because R.61-56.1 and R.61-56.2 are being combined with R.61-56, previously separate enforcement provisions will also be consolidated and updated for clarity and to improve administration of the Onsite Wastewater program.

4. The revisions will expand existing site evaluation options and allow more streamlined permit processing by allowing an applicant to submit a proposed system layout from a licensed Professional Soil Classifier ("PSC") or other licensed person qualified by statute to practice professional soil classifying. Under this regulation, applicants desiring to install systems for a subdivision will be required to submit third-party soils work from a PSC or other licensed person qualified by statute to practice professional soil classifying.

That person would then have the option to either submit a proposed system layout under one of the system standards established within R.61-56 or give the soils report to a Registered Professional Engineer to design a specialized septic system through the 610 Standard. Outside of the subdivision context, applicants for conventional systems will retain the option to use a qualified third party or allow the Department to conduct a soil evaluation and prepare a system layout. The expanded options and enhanced involvement of third-party contractors will serve to streamline and expedite the permit process for the Department and the regulated community.

5. In the interest of efficiency, the Department is repealing R.61-55 and adding its provisions to R.61-56. The amendments related to R.61-55 include amendments to definitions and other changes as necessary to facilitate merging this regulation into R.61-56.

6. The Department has also made other corrections for clarity and readability, grammar, punctuation, codification, and regulation text improvement.

7. The Department had a Notice of Drafting published in the March 27, 2020, *State Register*.

8. The Bureau held twenty-two (22) stakeholder engagement meetings between August 2, 2017, and July 1, 2020, to solicit input, including open-invitation public meetings, in person and virtually, and individual interest group discussions. A total of three hundred and seventy-five (375) stakeholders attended. The Bureau utilized the Department's website and agency calendar to advertise these meetings, as well as mailed invitation cards and emailed invitations to identified stakeholders. The Bureau received favorable feedback from these meetings.

9. Appropriate Department staff conducted an internal review of the amendments on July 8, 2020.

10. The Department had a Notice of Proposed Regulation published in the August 28, 2020, *State Register*. The Department received public comments from 16 people by the September 28, 2020, close of the public comment period. One comment also included a petition with a list of signatories in support of the comment. Attachment B presents a summary of these public comments received and Department responses.

11. After consideration of all timely received comments, staff has made substantive changes to the regulatory text of the Notice of Proposed Regulation approved by the Board in the August 13, 2020, Board meeting and published in the August 28, 2020, *State Register*. Descriptions of the changes appear in Attachment B, Summary of Public Comments and Department Responses.

III. Request for Approval

The Bureau of Environmental Health Services respectfully requests the Board to find need and reasonableness of the attached amendment of R.61-56, *Onsite Wastewater Systems*; and the repeals of R.61-55, *Septic Tank Site Evaluation Fees;* R.61-56.1, *License to Construct or Clean Onsite Sewage Treatment and Disposal Systems and Self-Contained Toilets*; and R.61-56.2, *Licensing of Onsite Wastewater Systems Master Contractors*, for submission to the General Assembly.

Renee Shealy
Bureau Chief of Environmental Health Services

Myra C. Reece
Director, Environmental Affairs

Attachments:
A. Notice of Final Regulation
B. Summary of Public Comments and Department Responses

ATTACHMENT A

STATE REGISTER NOTICE OF FINAL REGULATION
FOR R.61-56, *Onsite Wastewater Systems*

November 12, 2020

Document No. 4979
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Sections 44-1-140(11), 44-1-150, 44-55-825, 44-55-827, and 48-1-10 et seq.

61-55. Septic Tank Site Evaluation Fees.
61-56. Onsite Wastewater Systems.
61-56.1. License to Construct or Clean Onsite Sewage Treatment and Disposal Systems and Self-Contained Toilets.
61-56.2. Licensing of Onsite Wastewater Systems Master Contractors.

Synopsis:

Pursuant to R.61-56, the Department of Health and Environmental Control ("Department") provides oversight for safe treatment and disposal of domestic wastewater to protect the health of families and communities. In accordance with R.61-55, R.61-56, R.61-56.1, and R.61-56.2, the Department issues onsite wastewater contractor licenses, permits to construct, and approvals to operate for individual onsite wastewater treatment systems (septic systems).

The Department amends R.61-56, Onsite Wastewater Systems, to add new system standards, clarify and amend definitions, and clarify and update selected sections. The amendments modernize the regulation and streamline permitting procedures to address needed updates in administering the Onsite Wastewater program.

The Department also amends provisions of R.61-56.1 and R.61-56.2 and merges R.61-56.1 and R.61-56.2 into R.61-56 to improve efficiency and clarity for regulated entities and the public. This entails repealing R.61-56.1 and R.61-56.2 and simultaneously adding their provisions, as amended, to R.61-56. The amendments include changes to licensing requirements for pumpers and haulers currently under R.61-56.1. The amendments revise provisions currently contained in R.61-56.2 to implement a tiered licensing program to establish improved competency of onsite wastewater system contractors/installers. This approach includes new requirements for examination and continuing education. In addition, because R.61-56.1 and R.61-56.2 are being combined with R.61-56, previously separate enforcement provisions are also consolidated and updated for clarity and to improve administration of the Onsite Wastewater program.

The revisions expand existing site evaluation options and allow more streamlined permit processing by allowing an applicant to submit a proposed system layout from a licensed Professional Soil Classifier ("PSC") or other licensed person qualified by statute to practice professional soil classifying. Under this regulation, applicants desiring to install systems for a subdivision will be required to submit third-party soils work from a PSC or other licensed person qualified by statute to practice professional soil classifying. That person would then have the option to either submit a proposed system layout under one of the system standards established within R.61-56 or give the soils report to a Registered Professional Engineer to design a specialized septic system through the 610 Standard. Subdivision permit applicants may incur additional costs for the third-party work performed under this process. Outside of the subdivision context, applicants

for conventional systems will retain the option to use a qualified third party or allow the Department to conduct a soil evaluation and prepare a system layout. The expanded options and enhanced involvement of third-party contractors serve to streamline and expedite the permit process for the Department and the regulated community.

In the interest of efficiency, the Department is also repealing R.61-55 and adding its provisions to R.61-56. The amendments related to R.61-55 include amendments to definitions and other changes as necessary to facilitate merging this regulation into R.61-56.

The Department has also made other corrections for clarity and readability, grammar, punctuation, codification, and regulation text improvement.

The Department had a Notice of Drafting published in the March 27, 2020, *South Carolina State Register*.

Instructions:

Repeal R.61-55, R.61-56.1, and R.61-56.2 in their entirety from the South Carolina Code of Regulations; replace R.61-56 in its entirety with this amendment.

Text:

~~Indicates Matter Stricken~~
Indicates New Matter

61-55. ~~Septic Tank Site Evaluation Fees.~~

~~SECTION I. PURPOSE~~

~~A major factor influencing the health of individuals where public sewer is not available is the proper treatment and disposal of human excreta and other domestic wastes. To this end and to protect the environment from contamination by untreated sewage, the Department of Health and Environmental Control has established and maintained a conscientious program of designing individual sewage treatment and disposal systems, evaluating sites for suitability for individual sewage treatment and disposal systems and approving the installations of such systems. This direct service program is conducted primarily by public health professionals working in county health departments. Funding for the program comes from state appropriations and the fees authorized by this regulation.~~

~~SECTION II. DEFINITIONS~~

~~The following definitions shall apply in the interpretation and enforcement of this regulation.~~

~~A. DEPARTMENT - The South Carolina Department of Health and Environmental Control.~~

~~B. HEALTH AUTHORITY - An authorized representative of the South Carolina Department of Health and Environmental Control.~~

~~C. INDIVIDUAL SEWAGE TREATMENT AND DISPOSAL SYSTEM - A system designed for the treatment and disposal of sewage by a septic tank and soil absorption trench. The term also includes alternatives to septic tanks and soil absorption trenches when such alternatives are approved by the Health Authority under the provisions of *R..61-56, Individual Sewage Treatment and Disposal Systems*.~~

~~D. PERMIT – A written statement issued by the Health Authority permitting the construction of an individual sewage treatment and disposal system under the provisions of *R.61-56, Individual Sewage Treatment and Disposal Systems.*~~

~~SECTION III. FEES~~

~~The Department shall charge a fee of $150.00 to evaluate the site of a proposed individual sewage treatment and disposal system. This fee shall be paid prior to the evaluation of any site for which an application for a permit has been made.~~

~~SECTION IV. OTHER~~

~~A. DESIGNATION OF USE~~

~~Funds derived from these fees shall be used only for the provision of services and accompanying expenses associated with Environmental Health programs.~~

~~B. UNCONSTITUTIONALITY CLAUSE~~

~~Should any chapter, paragraph, sentence, clause, or phrase of this regulation be declared unconstitutional or invalid for any reason, the remainder of this regulation shall not be affected thereby.~~[Repealed].

61-56. Onsite Wastewater Systems.

Statutory Authority: ~~1976~~ S.C. Code Sections 44-1-140(11), 44-1-150, 44-55-825, 44-55-827, and 48-1-10 et seq.

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Appendix K - System Standard 290/291 - Alternative Trench Width and Depth Systems with Fill Cap.
~~410 Appendix J~~ L - System Standard 370/371 - Shallow Placement ~~With~~ with Fill Cap for Sites ~~With~~ with Shallow Class IV Soil.
~~411 Appendix K~~ M - System Standard 380/381 - Double Aggregate Depth Wastewater Infiltration Trenches.
~~412 Appendix L~~ N - System Standard 420/421 - Mounded Infiltration System.
~~413 Appendix M~~ O - System Standard 431 - Mounded Fill System.
~~414 Appendix N~~ P - System Standard 601 - Elevated Infiltration System.
~~415 Appendix O~~ Q - System Standard 610 - Specialized Onsite Wastewater System Designs (~~Less Than~~ less than 1500 gpd ~~GPD~~).
~~416 Appendix P~~ R - Curtain Drain Standard.
Appendix S - Nonwater-Carried Sewage Treatment Systems.
Appendix T - Wastewater Combustion Systems.
Appendix U - Gray Water Subsurface Reuse Systems.
500. ~~Appendix Q -~~ Long-Term Acceptance Rate Standard ~~For~~ for Onsite Wastewater Systems.
501. ~~Appendix R -~~ Peak Sewage Flow Rate Standard.
~~600 Appendix S~~ 502. - Onsite Wastewater Pump System Standard.
~~700 Appendix T~~ 503. - Minimum Design Standards ~~For~~ for Tank Construction.
~~800 Appendix U~~ 504. - Fiberglass Reinforced Plastic Tanks Standard.
~~900 Appendix V~~ 505. - Thermoplastic Tanks Standard.
600. License to Clean Onsite Wastewater Systems, Self-Contained Toilets, and Other Sewage Holding Systems (i.e., Licensing of Pumper/Haulers).
601. Vehicles, Equipment, and Practices.
602. Records of Operation.
700. License to Construct or Repair Onsite Wastewater Systems (i.e., Licensing of Installers).
701. Continuing Education and Training.
702. Practice, Procedure, and Quality Control.
703. Bonding and Insurance Requirements: Tier 3 Installers.
704. Transition to Tiered Licensure.
800. Enforcement.
801. Severability Clause.

~~100 PURPOSES and SCOPE~~ 100. Purposes and Scope.

(1) A major factor influencing the health of individuals where public wastewater treatment facilities are not available is the proper onsite treatment and disposal of domestic wastewater. Diseases such as dysentery, cholera, infectious hepatitis, typhoid, and paratyphoid are transmitted through the fecal contamination of food, water, and the land surface largely due to the improper treatment and disposal of domestic wastewater. For this reason, every effort should be made to prevent such hazards and to treat and

dispose of all ~~human~~ domestic wastewater through the practical application of the ~~best and~~ most ~~cost affective~~ effective technology available.

(2) Safe treatment and disposal of domestic wastewater is necessary to protect the health of families and communities, and to prevent the occurrence of public health nuisances. Domestic wastewater can be rendered ecologically safe and public health can be protected if such wastes are disposed of so that:

~~A.~~(a) They will not contaminate any drinking water supply.

~~B.~~(b) They will not give rise to a public health hazard by being accessible to insects, rodents, or other possible carriers, which may come into contact with food or drinking water.

~~C.~~(c) They will not give rise to a public health hazard by being accessible to children or adults.

~~D.~~(d) They will not violate federal and state laws or regulations governing water pollution or sewage disposal.

~~E.~~(e) They will not pollute or contaminate any waters of the state.

~~F.~~(f) They will not give rise to a public health nuisance.

(3) Where the installation of an onsite wastewater system is necessary, the basic principles of design, construction, installation, operation and maintenance shall be followed.

~~101 DEFINITIONS AND REFERENCES~~ **101. Definitions and References.**

~~A. DEFINITIONS.~~ 101.1. Definitions.

~~ACCESSIBILITY~~Accessibility - S.C. Code Sections 44-55-1410 and 5-31-2010 authorizes county and municipal governments to determine if a wastewater treatment facility is accessible to properties. Where annexation or easements to cross adjacent property are required to connect to a wastewater treatment facility, the wastewater treatment facility shall not be considered accessible.

~~ALTERNATIVE SYSTEM~~Alternative System - A system incorporating design modifications of the proposed subsurface wastewater infiltration trench area (drain field) or absorption trench geometry for the purpose of achieving compliance with required setbacks and offset to the zone of saturation and/or restrictive horizons. No such system shall be utilized unless the Department has established a specific standard.

~~ALTERNATIVE INFILTRATION TRENCH PRODUCTS~~Alternative Infiltration Trench Products - Products specifically designed to replace or eliminate the aggregate typically utilized in subsurface infiltration trenches. Such products must be approved for use by the Department and must adhere to required equivalency values established herein.

~~APPLICANT~~Applicant - A property owner, general contractor or agent representing the property owner, or developer who seeks a permit to construct and operate an onsite wastewater system.

Bond - A sum of money set aside (Surety Bond) to insure completion of work under a contract.

~~CAMPGROUND~~Campground - An organized camp in which campsites are provided for use by the general public or certain groups.

~~CANAL~~Canal - An artificial waterway used for navigation, drainage, or irrigation.

Cleaning - The removal and transportation of septage from an onsite wastewater system, self-contained toilet, or other sewage holding system to an approved disposal location.

~~COLOR CHARTS~~Color Charts (Munsell System or equivalent) - Charts bearing various color chips established by a recognized color system which uses three elements—hue, value, and chroma—to make up a specific color notation. The notation is recorded ~~if~~ in the form of hue, value, and chroma (e.g., 10YR 5/6). The three attributes of color are arranged in the system in orderly scales of equal visual steps, which are used to measure and describe color accurately under standard conditions of illumination by comparing soil samples to color chips on various charts.

Construction - The installation, upgrade, or expansion of an onsite wastewater system.

~~CONVENTIONAL SYSTEM~~Conventional System - An onsite wastewater system that utilizes a network of conventional wastewater infiltration trenches installed in the naturally occurring soil for the treatment and disposal of domestic wastewater.

~~CRITICAL AREA~~Critical Area - S. C. Code Section 48-39-10(J) defines critical area as the following: 1) coastal waters; 2) tidelands; 3) beaches; 4) beach/dune systems which are the areas from the mean high-water mark to the setback line as determined in S. C. Code Section 48-39-280.

~~CURTAIN DRAIN~~Curtain Drain - A subsurface interceptor drain that is installed to collect and redirect ~~seasonal~~ groundwater as it flows through the soil profile to an appropriate discharge point.

~~DEPARTMENT~~Department - The South Carolina Department of Health and Environmental Control.

~~DITCH~~Ditch - A long narrow excavation~~,~~ intended for the ~~purposes~~ purpose of drainage and/or irrigation.

~~DOMESTIC WASTEWATER OR SEWAGE~~Domestic Wastewater - The untreated liquid and solid human body waste and the liquids generated by water-using fixtures and appliances, including those associated with food service operations. For the purposes of this regulation, domestic wastewater shall not include industrial process wastewater.

Dwelling - A self-contained unit used by one (1) or more households as a home, such as a house, apartment, mobile home, house boat, tiny house, park model RV, RV or camper, or other substantial structure that provides living facilities for one (1) or more persons, including permanent or semi-permanent provisions for living, sleeping, eating, cooking, and sanitation.

~~EFFLUENT~~Effluent - The liquid discharged from a septic tank, effluent pump station, or other sewage treatment device.

~~EMBANKMENT~~Embankment - A bank of soil with at least two (2) feet of vertical height from top to bottom.

~~ENVIRONMENTALLY SENSITIVE WATERS~~Environmentally Sensitive Waters - Outstanding resource waters (ORW), Shellfish Harvesting Waters (SFH), and Trout-Natural Waters (TN) as defined in R.61-68 and classified in R.61-69, and including lakes greater than forty (40) acres in size and the Atlantic Ocean, regardless of their classifications in R.61-69.

~~EXISTING SYSTEM~~Existing System - An onsite wastewater system, which has received final construction approval or has been serving a legally occupied ~~residence~~ dwelling or structure.

~~EXPANSIVE SOILS~~Expansive Soils - Soils containing significant amounts of expansible-layer clay minerals (smectites) as evidenced in the field by classifications of "Very Sticky," "Very Plastic" and where "Slickensides" are present when evaluated in accordance with the Field Book. Such soil horizons are considered to be restrictive for onsite wastewater systems.

~~FAILING ONSITE WASTEWATER SYSTEM~~Failing Onsite Wastewater System - An onsite wastewater system that is discharging effluent in an improper manner or has ceased to function properly.

~~FIBERGLASS REINFORCED PLASTIC~~Fiberglass Reinforced Plastic - A fibrous glass and plastic mixture that exhibits a high strength to weight ratio and is highly resistant to corrosion.

~~FIELD BOOK FOR DESCRIBING AND SAMPLING SOILS~~Field Book for Describing and Sampling Soils (Field Book) - A field guide published by the U.S. Department of Agriculture (USDA) Natural Resources Conservation Service (NRCS) for making or reading soil descriptions and for sampling soils, as presently practiced in the USA.

~~FINAL TREATMENT AND DISPOSAL~~Final Treatment and Disposal - Ultimate disposition of the effluent from a septic tank or other treatment device into the soil.

~~FLEXURAL MODULUS OF ELASTICITY~~Flexural Modulus of Elasticity - A measure of stiffness of a material.

~~FLEXURAL STRENGTH~~Flexural Strength - A measure of the ability of a material to withstand rupture when subjected to bend loading.

~~GEL COATING~~Gel Coating - A specially formulated polyester resin, which is pigmented and contains filler materials, the purpose of which is to provide a smooth, pore-free, watertight surface for fiberglass reinforced plastic parts.

Gleying - Bluish, greenish, or grayish colors in the soil profile that are indicative of markedly reduced conditions due to prolonged saturation. This condition can occur in both mottled and unmottled soils, and can be determined by using the gley page of the soil color charts.

Gray Water - Domestic wastewater that is generated by water-using fixtures and appliances such as sinks (excluding kitchen sinks), showers, and laundry but that does not come into direct contact with human excreta or solid organic matter.

Gray Water Subsurface Reuse Systems - A system designed to separately collect and treat gray water and subsequently dispose of gray water by reusing it as part of a subsurface irrigation system. This definition does not include any system designed to reuse gray water for any purpose, or by any means, other than subsurface irrigation. This definition also does not include any system that reuses or recirculates gray water within the confines of (i.e., via the plumbing within) a dwelling unit, building, business, or other structure.

~~GREASE TRAP~~Grease Trap - A device designed to separate and store the oil and grease component of wastewater discharged from facilities that prepare food.

~~GLEYING - Bluish, greenish, or grayish colors in the soil profile that are indicative of markedly reduced conditions due to prolonged saturation. This condition can occur in both mottled and unmottled soils, and can be determined by using the Gley page of the soil color charts.~~

~~INDUSTRIAL PROCESS WASTEWATER~~Industrial Process Wastewater - Non-domestic wastewater generated in a commercial or industrial operation that may or may not be combined with domestic wastewater.

License - The official document issued by the Department authorizing a person to be responsible for the construction, repair, or cleaning of onsite wastewater systems, self-contained toilets, and other sewage holding systems.

Licensed Onsite Wastewater System Installer (Installer) - A person authorized under this regulation to construct or repair onsite wastewater systems. The specific scope of activities authorized depends on the installer's tier of licensure, as follows:

(1) Tier 1 - May install all gravity-fed residential onsite wastewater systems. This level is not authorized to conduct repairs on existing onsite wastewater systems.

(2) Tier 2 - May install all Tier 1 systems plus pumps, grease traps, systems with curtain drains, elevated infiltration systems, mounded systems, and all commercial onsite wastewater systems, large onsite wastewater systems, and community onsite wastewater systems. This level is also authorized to conduct repairs on existing onsite wastewater systems.

(3) Tier 3 - May install all Tier 1 and 2 systems plus all Standard 610 - Specialized Onsite Wastewater Systems. This level is also authorized to conduct repairs on existing onsite wastewater systems.

~~LONG-TERM ACCEPTANCE RATE~~Long-Term Acceptance Rate (LTAR) - The long-term rate, typically expressed in gallons per day (gpd) per square foot of trench bottom area, at which a mature onsite wastewater system can continue to accept effluent without hydraulic failure occurring. This flow rate is a result of the interaction between unsaturated soil hydraulic conductivity and biomat resistance.

~~MOTTLING~~Mottling - Morphological features of the soil revealed as spots or blotches of different color or shades of color interspersed with the dominant matrix color.

~~NSF STANDARD~~NSF Standard #14 - A National Sanitation Foundation Standard relating to thermoplastics~~,~~ which have been tested and found satisfactory for potable water supply uses, ~~and for~~ drains, waste, and vent applications.

Nonwater-Carried Sewage Treatment System - A self-contained system for waste treatment (such as a biological, composting, or incinerating toilet) that stores, treats, and renders human urine and feces inert without the use of water and that is designed to not discharge into the soil, onto the soil surface, into bodies of water, or other external media.

~~ONSITE WASTEWATER SYSTEM~~Onsite Wastewater (OSWW) System - A system, generally consisting of a collection sewer, septic tank(s), and subsurface wastewater infiltration area, designed to treat and dispose of domestic wastewater through a combination of natural processes that ultimately result in effluent being transmitted through the soil, renovated, and ultimately discharged to groundwater. An onsite wastewater system shall also include an onsite wastewater system, as described above, for the treatment and disposal of gray water.

(1) Small Onsite Wastewater System - An individual system serving an individually deeded ~~residence~~ dwelling or business that generates less than fifteen hundred (1500) ~~gallons per day~~gpd of domestic wastewater. Management and maintenance of each system is the responsibility of the individual property owner.

(2) Large Onsite Wastewater System (General) - An individual system that treats and disposes of domestic wastewater discharges in excess of fifteen hundred (1500) ~~gallons per day~~gpd.

(a) Privately Owned Large System - A large onsite wastewater collection and treatment system that serves one (1) piece of deeded property such as a school, adult residential care facility, rental apartment complex, shopping center, campground, mobile home park, office complex, etc. Management and maintenance of the system is the responsibility of the individual property owner.

(b) Community (Cluster) System - A wastewater collection and treatment system that provides shared collection, treatment, and disposal of domestic wastewater from multiple parcels or multiple units of individually deeded property. Such a system might serve a small subdivision or a condominium complex. It is imperative with such systems that some form of common ownership and management be established and approved by the Department.

(c) Commercial Onsite Wastewater System - An onsite wastewater system generating domestic wastewater or sewage that serves a facility, other than a private dwelling, intended for the engagement of commerce.

~~OPERATION AND MAINTENANCE~~Operation and Maintenance - Activities including tests, measurements, adjustments, replacements, and repairs that are intended to maintain all functional units of the onsite wastewater system in a manner that will allow the system to function as designed.

Other Sewage Holding System - Components of a sewer system or holding tank not related to an onsite wastewater system, including grease traps.

~~PARENT MATERIAL~~Parent Material - The unconsolidated and chemically weathered mineral or organic matter from which the column of soils is developed by pedogenic processes.

~~PERCHED ZONE OF SATURATION~~Perched Zone of Saturation (Episaturation) - ~~A soil horizon that is a perched water table soil horizon that is intermittently saturated with water above a soil horizon that is not saturated with water.~~ A zone of saturation above an unsaturated zone.

~~PERMIT~~Permit - A written document or documents issued by the Department authorizing the construction and operation of an onsite wastewater system, nonwater-carried sewage treatment system, wastewater combustion system, or gray water subsurface reuse system under this regulation. The term "permit" includes the permit to construct and the approval to operate, both of which are required prior to operation of a system under this regulation. Upon installation of a permitted system and Department issuance of an approval to operate, ~~The~~the construction and operation permit ~~survives~~ remains in effect for the life of the onsite wastewater system that it authorizes.

~~PLASTICITY~~Plasticity - The degree to which "puddled" or reworked soil can be permanently deformed without rupturing. The evaluation is made in accordance with the Field Book by forming a roll (wire) of soil at a water content where the maximum plasticity is expressed.

~~PRIMARY TREATMENT~~Primary Treatment - The initial process to separate solids from the liquid, digest organic matter, and store digested solids through a period of detention and biological conditioning of liquid waste.

~~PROFESSIONAL SOIL CLASSIFIER~~Professional Soil Classifier ("PSC") - A person ~~with~~who, by reason of special knowledge of the physical, chemical, and biological sciences applicable to soils as natural bodies and of the methods and principles of soil classification as acquired by soils education and soil classification experience in the formation, morphology, description, and mapping of soils~~;~~, is qualified to practice soil classifying~~;~~ and ~~who~~ has been duly ~~registered~~licensed by the South Carolina ~~State Board of Registration for professional soil classifiers classifiers~~Soil Classifiers Advisory Council as a Professional Soil Classifier in South Carolina.

~~PUBLIC ENTITY~~Public Entity - Any organizations such as a city, town county, municipality, or special purpose sewer district.

~~PUBLIC WATER SYSTEM~~Public Water System - Any publicly or privately owned waterworks system that provides drinking water for human consumption~~,~~ as defined in R.61-58, State Primary Drinking Water Regulations.

~~PUMP CHAMBER~~Pump Chamber - A watertight, covered receptacle designed and constructed to receive and store the discharge from a septic tank until such time that the effluent is pumped to a final treatment and disposal site.

Pumping and Transporting Vehicle - A vehicle approved by the Department for the cleaning of onsite wastewater systems, self-contained toilets, and other sewage holding systems and the transporting of septage and sewage to an approved disposal site.

~~RECEPTOR~~Receptor - Any water well or surface water of the state, including estuaries.

~~REDOX DEPLETIONS~~Redox Depletions - Morphological features that are formed by the processes of reduction and translocation of iron and manganese oxides in ~~seasonally~~ saturated soils. These features may be revealed as spots, blotches, or streaks and are lighter shades of color compared with the dominant matrix color.

~~REDOXIMORPHIC FEATURES~~Redoximorphic Features - Morphological features that are formed by the processes of reduction, translocation, and oxidation of iron and manganese oxides in ~~seasonally~~ saturated soils. These include redox concentrations, redox depletions, and reduced matrices.

Registered Professional Engineer - A person licensed as a Professional Engineer by the South Carolina State Board of Registration for Professional Engineers and Surveyors who, by reason of special knowledge of the mathematical and physical sciences and the principles and methods of engineering analysis and design, acquired by professional education and practical experience, is qualified to practice engineering as attested by the person's license and registration as a Professional Engineer in South Carolina.

~~REMOTE SUBSURFACE WASTEWATER INFILTRATION AREA~~Remote Subsurface Wastewater Infiltration Area - A subsurface wastewater infiltration area that is not situated within the legal boundaries of the primary lot or tract that it serves.

~~REPAIR~~Repair - Any work performed on an existing onsite wastewater system for the purposes of correcting a ~~surface~~ system failure, malfunction, or ~~other~~ unauthorized discharge, enhancing system

performance, ~~relocating~~or relocation or replacement of the entire system or system components, provided there are no changes in use that would impact the existing system.

~~REPAIR OR REPLACEMENT AREA~~Repair or Replacement Area - ~~An area reserved for the installation of additional wastewater infiltration trenches.~~ An area identified on the permit to construct reserved for the installation of additional wastewater infiltration trenches.

~~RESTRICTIVE HORIZON~~Restrictive Horizon - A soil horizon that is capable of severely retarding the movement of groundwater or effluent~~,~~ and may be brittle and cemented with iron, aluminum, silica, organic matter, or other compounds. Restrictive horizons may occur as fragipans, iron pans, organic pans, or shallow rock formations~~,~~ and are recognized by their resistance in excavation and auger boring.

~~RESIN~~Resin - Any number of commercially available polyester products used in the manufacture of fiberglass reinforced products which serve to contribute mechanical strength, determine chemical and thermal performance, and prevent abrasion of fibers, and which must be physically and/or chemically determined to be acceptable for the environment, and free from inert filler materials.

Revocation - The permanent withdrawal of rights and privileges granted by a license or an onsite wastewater system permit or approval, as applicable.

Rippable Rock - The rippability of rock material is a measure of its ability to be excavated with conventional excavation equipment (e.g., rubber-tired backhoe or mini excavator).

~~SAPROLITE~~Saprolite - Soft, friable, thoroughly decomposed rock that has formed in place by chemical weathering, retaining the fabric and structure of the parent rock, and being devoid of expansive clay. Unconsolidated saprolite can be dug using a hand auger or knife. Consolidated saprolite cannot be penetrated with a hand auger or similar tool, and must be dug with a backhoe or other powered equipment.

~~SEALANT~~Sealant - A bonding agent specifically designed to bond joining sections of fiberglass reinforced plastic products to each other in such a manner ~~so as~~ to create a durable, long-lasting, watertight seal, which does not alter the structural integrity or strength of the two (2) joined fiberglass products.

Self-Contained Toilet - A single or multiple-unit toilet and holding tank combination.

Septage - The mixture of solids and liquids removed during cleaning of a septic tank, grease trap, any other part of an onsite wastewater system, self-contained toilet, or other sewage holding system which receives domestic sewage; this includes the liquid, solid, and semi-solid materials which settle to the bottom of transport containers.

~~SEPTIC TANK~~Septic Tank - A watertight, covered receptacle designed and constructed to receive the discharge of domestic wastewater from a building sewer, separate solids from the liquid, digest organic matter, store digested solids through a period of detention and biological conditioning of liquid waste, and allow the effluent to discharge for final treatment and disposal.

~~SERIAL DISTRIBUTION~~Serial Distribution - A method for effluent distribution on sloping terrain that utilizes drop boxes or earthen dams to affect total sequential flow from upper to lower wastewater infiltration trenches.

Sewage - Any liquid waste containing human, animal, vegetable, or chemical matter in suspension or solution from water closets, urinals, lavatories, bathtubs, laundry tubs or devices, floor drains, drinking fountains, or other water-using fixtures.

Site - The area or plot of land identified by a plat, deed, or other legal document specifying lot size and its boundaries that is submitted for evaluation by an applicant in an onsite wastewater system permit application.

~~SITE EVALUATION~~Site Evaluation - Evaluation of the soil, geology, zone of saturation, surface waters, topography, structures, and property lines of the proposed location of the onsite wastewater system. The evaluation can be conducted directly by certified Department personnel or the Department may conduct an evaluation through the review of information submitted by a ~~Professional Soil Classifier licensed in the State of South Carolina~~licensed person meeting the criteria of Section 102.1(2)(b) or (c).

Soils Report - A report prepared by a licensed person meeting the criteria of Section 102.1(2)(b) or (c) describing soil and site conditions for the purpose of designing an onsite wastewater system.

~~SOIL STRUCTURE~~Soil Structure - The aggregation of primary soil particles (i.e., sand, silt, and clay) into compound particles~~,~~ or clusters of primary particles~~,~~ which are separated from the adjoining aggregates by surfaces of weakness. In soils with platy structure, the aggregates are plate-like and overlap one another to severely impair permeability. A massive condition can occur in soils containing considerable amounts of clay when a portion of the colloidal material, including clay particles, tends to fill the pore spaces making the soil very dense.

~~SOIL TEXTURE~~Soil Texture - The relative proportions of the three soil separates (sand, silt, and clay) in a given sample of soil. The percentages of each separate are used to determine which class a particular sample falls into by plotting the intersection of these three values on the ~~United States~~U.S. Department of Agriculture (USDA) Natural Resource Conservation Service (~~USDA~~ NRCS) Textural Triangle.

~~SPECIALIZED ONSITE WASTEWATER SYSTEM DESIGN~~Standard 610 - Specialized Onsite Wastewater System Design (less than 1500 ~~GPD~~ gpd) - An onsite wastewater system that is certified to function satisfactorily and in accordance with all requirements of ~~R.61-56~~ this regulation by virtue of it having been designed by a Registered Professional Engineer (PE) licensed in ~~the State of~~ South Carolina with technical input from a ~~Professional Soil Classifier licensed in the State of South Carolina~~licensed person meeting the criteria of Section 102.1(2)(b) or (c). Such systems have limited application~~,~~ and can only be utilized when the required engineering design, certification, and technical soils documentation have been provided to and accepted by the Department.

~~STANDARD~~Standard - A group of requirements developed by the Department that specifies the minimum site conditions and design criteria necessary for the approval of a specific type of onsite wastewater system. ~~(i.e., alternative system) that differs from a conventional system.~~ A standard may also address minimum design criteria for certain components of onsite wastewater systems as well as methodologies for determining system sizing.

~~STICKINESS~~Stickiness - The capacity of soil to adhere to other objects. Stickiness is estimated in accordance with the Field Book at the moisture content that displays the greatest adherence when pressed between the thumb and forefinger.

Subdivision - Means all divisions of a tract or parcel of land into two (2) or more lots, building sites, or other divisions, for the purpose, whether immediate or future, of sale or building development, and includes all division of land involving a new street or a change in existing streets, and includes resubdivision. This definition shall apply whether the lots are to be sold, rented, or leased. This definition shall not apply when the division or partition of the land, or the conveyance of property is pursuant to a will, an intestacy statute, or an order by a probate judge.

~~SUBSURFACE WASTEWATER INFILTRATION AREA (DRAIN FIELD)~~Subsurface Wastewater Infiltration Area (Drain Field) - A specific area where a network of wastewater infiltration trenches or other devices of sewage application are installed to provide the final treatment and disposal of effluent.

Suspension - The temporary or indefinite withdrawal or cessation of rights and privileges granted by a license or onsite wastewater system permit or approval, as applicable.

Third-Party - A qualified person or entity, as determined by the Department, that is independent of the parties involved.

~~ULTIMATE TENSILE STRENGTH~~Ultimate Tensile Strength - A measure of the resistance of a material to longitudinal stress, measured by the minimum longitudinal stress required to rupture the material.

~~UPGRADE/EXPANSION~~Upgrade/Expansion - Any work performed on an existing onsite wastewater system for the purposes of increasing the capacity of the system above its original design and/or accommodating wastes of a different character than was originally approved.

Wastewater Characteristics - The physical, chemical, and biological parameters and characteristics of domestic wastewater. Physical characteristics include turbidity, color, odor, total suspended solids (TSS), temperature and fats, oils and grease (FOG). Chemical characteristics include the presence and extent of chemical oxygen demand (COD), total organic carbon (TOC), Total Kjeldahl Nitrogen (TKN), nitrogen, phosphorous, chlorides, sulfates, alkalinity, pH, heavy metals, trace elements, and priority pollutants identified by the U.S. Environmental Protection Agency (EPA). Biological characteristics include biological oxygen demand (BOD), oxygen required for nitrification and microbial population. High strength wastewater is characterized as meeting one (1) or more of the following levels: BOD > 350 mg/l, TSS > 100 mg/l, TKN > 100 mg/l, FOG > 30 mg/l.

Wastewater Combustion System - A self-contained system for wastewater treatment that uses water as a medium for transport and storage. It treats and renders wastewater inert using maceration and incineration.

~~WASTEWATER INFILTRATION TRENCH~~Wastewater Infiltration Trench - A trench installed in the naturally occurring soil that is utilized for the treatment and disposal of domestic wastewater. ~~A conventional trench is characterized by the following: (a) at least twenty-three (23) inches in depth; (b) thirty-six (36) inches in width; (c) filled with aggregate so that at least six (6) inches is beneath the distribution pipe, with at least five (5) inches on both sides of the pipe, and at least three (3) inches covering the pipe; and (d) at least nine (9) inches of backfill. Other trench configurations are specified in the attached Appendices of Standards for Onsite Wastewater Systems.~~

~~WASTEWATER TREATMENT FACILITY~~Wastewater Treatment Facility - An accessible publicly or privately owned system of structures, equipment, and related appurtenances ~~to~~ that treat, store, or manage wastewater.

~~ZONE OF SATURATION~~Zone of Saturation - Any zone in the soil profile that has soil water pressures that are zero or positive at some ~~times~~ time during the year. For the purpose of this regulation, the beginning of such a zone shall be utilized in determining all required vertical separations from the deepest point of effluent application. This zone~~, therefore,~~ shall be defined as the shallowest of those points at which either redox depletions of value four (4) or more and chroma two (2) or less appear or gleying is first observed; or, in the absence of other field identification methods, the maximum groundwater elevation as determined by wet season monitoring performed in accordance with criteria approved by the Department.

B. REFERENCES101.2. References.

(1) The following statutes referenced in this Regulation are those in force on the effective date of this Regulation:

(a) 1976 S.C. Code of Laws, Section 44-1-140(11), South Carolina Department of Health and Environmental Control (1976 Code as amended)

(b) 1976 S.C. Code of Laws, Section 1-23-10 et seq., South Carolina Administrative Procedures Act (1976 Code as amended)

(c) 1976 S.C. Code of Laws, Section 48-1-10 et seq., South Carolina Pollution Control Act (1976 S.C. Code as amended)

(d) 1976 S.C. Code of Laws, Section 48-39-10 et seq., South Carolina Coastal Tidelands and Wetlands (1976 S.C. Code as amended)

(e) Section 208, Federal Clean Water Act, 33 U.S.C. Section 1288

(f) 1976 S.C. Code of Laws, Section 48-39-280 et seq., South Carolina Coastal Tidelands and Wetlands (1976 Code as amended)

(g) 1976 S.C. Code of Laws, Section 44-55-1410 et seq., Water and Sewer Facilities in Counties (1976 S.C. Code as amended)

(h) 1976 S.C. Code of Laws, Section 5-31-2010 et seq., Additional Powers of Municipalities as to Sewage Collection and Disposal (1976 S.C. Code as amended)

(2) The following Departmental Regulations referenced in this Regulation are those in force on the effective date of this Regulation:

(a) Regulation 61-25, Retail Food Establishments
(b) Regulation 30-1, Coastal Division Regulations
(c) Regulation 61-9, Water Pollution Control Permits
(d) Regulation 61-58, State Primary Drinking Water Regulations
(e) Regulation 61-67, Standards for Wastewater Facility Construction
(f) Regulation 61-68, Water Classification and Standards
(g) Regulation 61-69, Classified Waters

(3) The following manufacturing and procedural standards referenced in this Regulation regulation are those in force on the effective date of this Regulation revision:

(a1) American Society of Agronomy (ASA)
(b2) American Society for Testing and Materials (ASTM International) C
(c3) American Society for Testing and Materials (ASTM International) D
(d4) Canadian Standard Association (CSA Group)
(e5) Crop Science Society of America (CSSA)
(f6) International Association of Plumbing and Mechanical Officials (IAPMO)
(g7) National Building Specification (NBS) Voluntary Product Standard PS 15-69
(h8) National Electrical Manufacturers Association (NEMA)
(i9) Soil Science Society of America (SSSA)

102. Onsite Wastewater System Site Evaluation and Fees.

102.1. Site Evaluations.

(1) An applicant for a permit to construct an onsite wastewater system, nonwater-carried sewage treatment system, wastewater combustion system, or gray water subsurface reuse system shall, at the time

an application for a permit to construct is submitted to the Department, pay to the Department the site evaluation fee set forth in Section 102.2.

(2) Soil evaluations shall be conducted only by:

(a) A certified Department staff member;

(b) A licensed Professional Soil Classifier; or

(c) Another licensed person qualified to practice professional soil classifying under S.C. Code Section 40-65-40(7), provided that the burden of documenting qualification under S.C. Code Section 40-65-40(7) is on the licensed professional. The licensed professional shall provide to the Department verification of qualification from the relevant licensing authority, and the Department will disallow a soil evaluation from any person not able to provide verification to the Department's satisfaction.

(3) Except as provided in Section 102.1(4) and 102.1(5), an onsite wastewater system layout in accordance with Section 400, Appendices of Standards for Permitted Systems, may be prepared by:

(a) A certified Department staff member;

(b) A Registered Professional Engineer licensed in South Carolina; or

(c) The same licensed person under Section 102.1(2)(b) or (c) who conducted the soil evaluation for the site.

(4) Only a Registered Professional Engineer may design a system and prepare a system layout for Standard 610/611 – Specialized Onsite Wastewater Systems, Standard 150 – Large and Community Onsite Wastewater Systems, nonwater-carried sewage treatment systems, wastewater combustion systems, and gray water subsurface reuse systems.

(5) The Department will not perform a soil evaluation or prepare a system layout for any subdivision or portion of a subdivision. Soil evaluations for any lots that are part of a subdivision must be conducted by a licensed person meeting the criteria of Section 102.1(2)(b) or (c). Proposed system layouts for any lots that are part of a subdivision must be prepared by a third-party Registered Professional Engineer or Professional Soil Classifier meeting the criteria under Section 102.1(3)(c). The Soils Report and proposed system layout must be submitted with the onsite wastewater system permit application for the purpose of the Department review and issuance of a permit to construct.

102.2. Fees.

The Department shall charge a fee of one hundred and fifty dollars ($150.00) to evaluate the site of a proposed onsite wastewater system, nonwater-carried sewage treatment system, wastewater combustion system, or gray water subsurface reuse system.

102.3. Other.

Funds derived from these fees shall be used only for the provision of services and accompanying expenses associated with the Department’s Bureau of Environmental Health Services programs.

~~102. General~~103. Onsite Wastewater Systems.

103.1. General.

~~102.1~~(1) Each dwelling ~~unit, building~~, business, or other structure occupied for more than two (2) hours per day shall be provided with an approved method for the treatment and disposal of domestic wastewater.

~~102.2~~(2) It shall be the responsibility of the property owner to ensure that a permit to construct and operate any new, upgraded, or expanded onsite wastewater system, nonwater-carried sewage treatment system, wastewater combustion system, or gray water subsurface reuse system is obtained from the Department prior to construction and operation of the system.

~~102.3~~(3) No person shall begin construction of a ~~building~~ dwelling, business, or other structure to be served by an onsite wastewater system, nonwater-carried sewage treatment system, wastewater combustion system, or gray water subsurface reuse system until a permit to construct and operate such a system is issued by the Department. ~~-~~Mobile or modular structures intended for occupancy shall not be moved onto the site until the permit to construct and operate an onsite wastewater system has been issued.

~~102.4~~(4) The ~~permit holder~~ property owner shall be required to properly operate and maintain in good working order all onsite wastewater system(s) and their parts~~, and operate as efficiently as possible, all facilities and systems which are installed pursuant to the permit~~ and to comply with all terms and conditions of ~~the~~a previously issued permit. System parts may include, but are not limited to, sealed watertight tanks, lid(s), piping, aggregate, pump, and pump components.

~~102.5~~(5) An onsite wastewater system serving more than one (1) piece of deeded property shall be considered as a community or cluster collection and treatment system and shall comply with the following:

~~(1)~~ (a) A permit activity will not occur that is inconsistent with a plan or plan amendment approved under section 208(b) of the Clean Water Act unless the Department finds such variance necessary to protect the public's health, safety, and welfare.

~~(2)~~ (b) ~~A~~If a public entity ~~shall~~ owns the system ~~and~~, the entity shall be responsible for the operation, maintenance, and replacement of all components unless otherwise approved by the Department. The Department may consider a request from a private entity or person; however, such proposals must be evaluated on a case-by-case basis. The Department will evaluate the capability of long-term, reliable system operation in its evaluation of a permit request.

~~(3)~~ (c) If the project is owned by a private entity or person, the Department shall require financial assurances for the operation, maintenance, and replacement of the tank(s) and subsurface wastewater infiltration area system and relevant collection/pumping components.

~~(4)~~ (d) Sufficient area meeting the minimum requirements for large onsite wastewater systems shall be provided for at least one hundred (100) percent repair or replacement of the primary subsurface wastewater infiltration area.

~~(5)~~ (e) The collection sewer and pumping portions of a community onsite wastewater system shall receive a separate Construction Permit under ~~R. 61-67.300.~~ R.61-67.300, Standards for Wastewater Facility Construction.

~~102.6 When the actual or estimated peak sewage flow will exceed fifteen hundred (1500) gallons per day, the Department may require that the design of the onsite wastewater system be prepared by a Registered Professional Engineer licensed in the State of South Carolina. A Registered Professional Engineer licensed in the State of South Carolina may also design all onsite wastewater systems where the sewage flow will~~

~~be less than fifteen hundred (1500) gallons per day. These designs shall include the Soils Report conducted by certified Department personnel or submitted by a Professional Soil Classifier licensed in the State of South Carolina and shall satisfy requirements of Regulation 61-56, Section 415, Appendix O – System Standard 610 – Specialized Onsite System Designs.~~

~~102.7~~ 103.2. Large (greater than 1500 gpd) and community onsite wastewater systems incorporating advanced treatment methods, including but not limited to aerobic pre-treatment, lagoons, surface or subsurface drip irrigation, low pressure pipe distribution and other maintenance intensive methods, shall be required to obtain a Land Application Permit under ~~R. 61-9.505.~~R.61-9, Water Pollution Control Permits.

~~102.8~~ 103.3. Facilities that generate industrial process or any other non-domestic wastewater shall not be granted a permit under this regulation unless the Department determines that the proposed discharge would not pose a significant environmental risk. In such a determination, the Bureau of Water ~~Department~~ would ~~assess the risk to public health and/or groundwater contamination~~determine if the waste may cause a violation of any drinking water standard under R.61-58, State Primary Drinking Water Regulations, or may otherwise adversely affect the health of persons regardless of whether or not the wastewater ~~were~~ is to be discharged continuously or intermittently to the onsite wastewater system. Plumbing appurtenances that facilitate the transport of such wastewater, including floor drains, trench drains, utility sinks, equipment drains, or any other conduit shall not be installed in facilities served by onsite wastewater systems unless specifically approved by the Department as a result of the above-described determination.

~~102.9~~103.4. Campgrounds.

(1) Onsite wastewater systems serving campgrounds shall comply with all applicable requirements of this regulation. Such campgrounds shall be provided with adequate toilet and bathing facilities, except in those cases where all campsites are furnished with individual sewer service connections, and each site is exclusively designated for use by camping units equipped to access such connections.

(2) Individual sewer service connections shall be part of an approved sewage collection system and shall be equipped with removable, tight fitting covers.

(3) Where individual sewer service connections are not furnished at all campsites, an approved sanitary dump station(s) shall be provided at a convenient location(s) within the campground at the ratio of one (1) dump station per one hundred (100) ~~unsewered~~ campsites or fractions thereof.

(a) A dump station shall consist of one (1) or more trapped four (4) inch sewer risers surrounded by a concrete apron having a diameter of at least two (2) feet and sloped to drain. Sewer risers must be equipped with removable, tight fitting covers.

(b) Each dump station shall be equipped with pressurized water to be used for washing the concrete apron. The water outlet shall be protected from back siphonage by a vacuum breaker installed at its highest point, or by other approved means. A sign shall be placed at this water outlet stating: THIS WATER IS FOR CLEANING PURPOSES ONLY.

~~103. APPLICATION, PERMIT, APPROVAL~~**104. Application, Permit, Final Inspection, and Approval.**

~~103.1~~104.1. Application.

(1) The applicant shall furnish, ~~on the application form provided~~ in a format as identified by the Department, ~~correct~~complete and accurate information necessary for determining the feasibility of an onsite wastewater system.

(2) The application shall include written permission from the property owner or their legal representative, using a form identified by the Department, for Department representatives to access the property.

(~~2~~3) A boundary plat, deed, or other legal document specifying the lot size ~~and its boundaries~~ shall be furnished by the applicant. The applicant shall provide a legal description that specifies lot boundary lengths for lots two (2) acres or smaller in size and upon request for any lot greater than two (2) acres in size. When a dwelling or facility is to be served by a remote ~~s~~subsurface wastewater infiltration area, the applicant must provide appropriate easement(s). An appropriate easement must allow ingress and egress for construction, operation, maintenance, replacement and repair and must run with the land.

(~~3~~4) Soil boring descriptions, backhoe pits, and soils classifications from specifically identified locations, including other tests or information, shall be required when deemed necessary by the Department.

(5) Backhoe pits shall be required above the Fall Line that separates the Piedmont area from the Coastal Plain as defined by the South Carolina Geological Survey.

(~~4~~6) Before a site evaluation of the lot is performed by the Department, the applicant ~~may~~shall be required to: clear and mark pertinent property boundary lines and corners; post an identification marker in the front center of the lot; place stakes at the corners of the proposed building; mark the proposed point of stub-out and septic tank as well as proposed drain field area; locate the proposed or existing well location; and identify the proposed location of any additional structures or facilities on the property that may influence the placement and configuration of the onsite wastewater system. A site sketch shall be included on the application or as a separate attachment that reflects the items above and any other items specified on the application. ~~Also, the~~The applicant may be required to clear underbrush from the property in order to facilitate the evaluation.

(7) The Department will not issue a permit if it determines that site conditions are unsuitable for the system layout or permit requested, or if issuance of the permit would otherwise be inconsistent with the requirements of this regulation. The Department also reserves the right to modify a proposed system layout submitted by a licensed person under Section 102.1(3)(c) when deemed appropriate.

~~103.2~~104.2. Permit.

(1) It shall be unlawful to construct, upgrade, expand, or operate an onsite wastewater system, nonwater-carried sewage treatment system, wastewater combustion system, or gray water subsurface reuse system unless the Department has issued a permit to construct and approval to operate for the specific construction and operation proposed. The system shall be constructed and operated in accordance with the permit, and the Department must authorize any changes prior to the construction and operation of the system. The applicant shall be required to make a written request ~~or submit a new application if the~~for any desired permit modifications ~~require another site evaluation~~. The applicant shall submit a new application with a new site evaluation fee for permit modifications that require an additional site evaluation. The Department may also require a permit to construct and approval to operate for the repair, relocation, or replacement of an onsite wastewater system or its components when deemed necessary, irrespective of whether any change in use impacting the existing onsite wastewater system would occur. The property owner or their legal representative shall notify the Department before relocating or replacing an onsite

wastewater system or its components so that the Department may determine whether a permit will be required.

(2) The ~~onsite wastewater~~permitted system shall be constructed and operated according to the specifications and conditions of the permit~~,~~ and in compliance with this regulation.

~~(3) In the case of repairs to existing onsite wastewater systems, the Department may authorize the best possible method of repair that, in the opinion of Department staff, may improve the operation of the system, regardless of site conditions.~~

~~(4)~~(3) Permits issued after the effective date of this regulation shall remain valid for a period of five (5) years from the date of issuance, provided the physical character of the property has not changed and the conditions of the original permit can be met. Exceptions may be granted for those permits addressed by other statutes.

~~103.3 Approval~~

~~(1) Any repair, extension or alteration for which a permit has been issued and all newly constructed onsite wastewater systems may be inspected in accordance with S.C. Code Section 44-55-825.~~

~~(2) The licensed system contractor shall also sign a statement that the onsite wastewater system was installed as specified in the Department issued permit.~~

104.3. Final Inspections and Approval.

(1) Except in the case of systems designed by a Registered Professional Engineer, all installers shall arrange with the Department in advance a time for a final inspection of an onsite wastewater system that is being installed. It shall be considered a violation of this regulation to cover a system that has not been subject to final Department inspection or installer self-inspection in accordance with this regulation.

(2) Final inspections of onsite wastewater systems to determine compliance with a Department-issued permit to construct shall be conducted by certified Department staff except as follows:

(a) Registered Professional Engineers licensed in South Carolina must conduct final inspections on all systems they design.

(b) Except as provided in 104.3(2)(a), Tier 3 installers may self-inspect systems they install. Tier 3 installers shall comply with Section 702.2 in its entirety.

(c) Except as provided in Section 104.3(2)(a), the Department may, in its discretion, direct Tier 1 and Tier 2 installers with no pending enforcement actions or prior Department findings of violation under Section 800 of this regulation to self-inspect systems they have installed using a process and form directed by the Department. Tier 1 and Tier 2 installers allowed to conduct self-inspections shall comply with Section 702.2 in its entirety. The Department reserves the right to withdraw any direction to Tier 1 and Tier 2 installers to conduct self-inspections at any time.

(3) Documentation of system installations, including certified as-built plans where required, shall be submitted in a Department-approved format within two (2) business days of completing the system installation or within two (2) business days of the installer self-inspection, where applicable.

(4) The licensed system installer shall also sign a statement certifying that the onsite wastewater system was installed as specified in the Department issued permit.

(5) Following final inspection and upon review of all required documentation, the Department will issue an approval to operate for a system installed in compliance with the issued permit to construct and all applicable requirements of this regulation. The Department will not issue an approval to operate if it determines that the system installation is inconsistent with the issued permit to construct or inconsistent with any requirement of this regulation.

~~200. MINIMUM SITE CONDITIONS~~**200. Minimum Site Conditions for Onsite Wastewater Systems.**

200.1. Soil texture, depth of soil to restrictive horizons, and depth to the zone of saturation shall meet minimum standards approved by the Department. These characteristics shall be determined using accepted methodologies in the field of soil science.

200.2. Soils exhibiting massive or platy structure, and soils which have been identified as having substantial amounts of expansible layer clay minerals or smectites, are unsuitable for onsite wastewater systems.

200.3. Where the estimated peak sewage flow will not exceed fifteen hundred (1500) gpd, the minimum vertical separation between the deepest point of effluent application and the zone of saturation shall be at least six (6) inches.

200.4. Where the estimated peak sewage flow will exceed fifteen hundred (1500) gpd, the depth to the zone of saturation shall be at least thirty-six (36) inches below the naturally occurring soil surface, and at least six (6) inches below the deepest point of effluent application.

200.5. Depth to rock and other restrictive horizons shall be greater than twelve (12) inches below the deepest point of effluent application.

200.6. Setbacks.

(1) The area of the lot or plot of ground where the onsite wastewater system is to be installed shall be of sufficient size so that no part of the system, excluding solid pipes, will be:

~~(1)~~ (a) Within five (5) linear feet of a building, or under a driveway or parking area;

~~(2)~~ (b) Within seventy-five (75) linear feet of a private well ~~(less than 1500 gpd sewage flow), one hundred (100) linear feet of a receptor (greater than 1500 gpd sewage flow), and within the Department's established minimum distance from a public well~~;

~~(3)~~ (c) ~~With in~~Within one hundred (100) linear feet of a public well;

~~(4)~~ (d) Within seventy-five (75) linear feet of the delineated critical area line (tidal waters of coastal waters and tidelands critical areas) as determined by the Department's coastal division; or within seventy-five (75) linear feet of the mean high water (within the banks) elevation (~~non-tidal~~nontidal waters, beach/dune systems and beach critical areas) of an impounded or natural body of water, including streams, ~~and~~ canals, and retention ponds;

~~(5)~~ (e) Within ten (10) feet of upslope and twenty-five (25) feet of down-slope curtain drains;

~~(6)~~ (f) Within twenty-five (25) feet of a drainage ditch or stormwater treatment system including any detention ponds (determined by maximum water elevation);

(g) Within fifteen (15) feet of piped drainage ditches;

(h) Within fifteen (15) feet of an inground pool;

(i) Within twenty-five (25) feet upslope of a basement; and within fifteen (15) feet of the sides of a basement, except that if foundation drains are present and the elevation of the foundation drain is at the same elevation or lower than the elevation of the trench bottom for the subsurface wastewater infiltration area or repair area, then a twenty-five (25) foot setback from the sides of a basement applies. These setbacks do not apply to a septic tank/pump chamber location or where trench installations are downslope of a basement;

~~(7)~~ (j)Within fifteen (15) feet of the top of the slope of embankments or cuts of two (2) feet or more vertical height when any part of the wastewater infiltration trench is to be placed higher in elevation than the invert of the cut or embankment;

~~(8)~~ (k) Within five (5) feet of a property line.

~~(9)~~ (2) Greater protective offsets shall be required when utilizing certain ~~alternative~~ system standards contained within this ~~Regulation~~ regulation.

(3) Prior to permitting the onsite wastewater system, jurisdictional determination of any affected wetlands may be required. Should any part of the proposed onsite wastewater system be located in wetlands, approval from the appropriate permitting agency(s) (e.g., U.S. Army Corps of Engineers, SCDHEC Ocean and Coastal Resource Management, etc.) shall be received, and proof of such provided to the Department.

200.7. In addition to the minimum space required in Section 200.6, minimum repair area shall be set aside as follows:

(1) Any new site meeting the minimum design criteria for an onsite wastewater system shall have a usable repair or replacement area equivalent to at least fifty (50) percent of the size of the original system. Where community onsite wastewater systems are utilized, there must be at least one hundred (100) percent repair or replacement area. ~~This area cannot be covered with structures or impervious materials.~~

(2) Usable repair or replacement area shall be demonstrated to include suitable soil conditions, and shall be free of impervious materials, buildings, or other improvements, setbacks, easements, and other encroachments that would prevent system construction. The undisturbed area between the wastewater infiltration trenches shall not be credited towards this requirement.

200.8. Multiple, individually owned remote subsurface wastewater infiltration areas may be considered for mass installation in a defined area where the wastewater infiltration trenches will be adjacently located to each other, provided that the combined peak wastewater loading is less than fifteen hundred (1500) gpd. In such cases, each subsurface wastewater infiltration area plot shall be sized such that there is sufficient area for one hundred (100) percent subsurface wastewater infiltration area replacement. Each plot shall be deeded, with all appropriate easements, as a lot in conjunction with the specific unit that it serves, and required protective offsets, as described in Section 200.6, shall apply to each individual remote subsurface wastewater infiltration area. A plan shall be prepared by a Registered Professional Engineer licensed in ~~the State of~~ South Carolina that illustrates the overall plan; specifies the route and identification of effluent sewers and/or force mains; specifies the entity responsible for perpetual maintenance of the sewer lines and

mass subsurface wastewater infiltration area; specifies the configuration and identification of the individual subsurface wastewater infiltration area parcels; and specifies the manner in which ingress and egress will be provided to the individual subsurface wastewater infiltration area parcels. When the combined peak wastewater loading of the adjacently loading subsurface wastewater infiltration area will exceed fifteen hundred (1500) gpd, the project shall be considered as a public (community) collection and treatment system, ~~then~~ and the onsite wastewater system must comply with the requirements in Section ~~102.5~~ 103.1(5).

~~201. MINIMUM REQUIREMENTS FOR PRIMARY TREATMENT~~ **201. Minimum Requirements for Onsite Wastewater System Primary Treatment.**

201.1. Septic Tanks.

(1) All persons or firms manufacturing septic tanks for use in South Carolina shall submit detailed plans for each size tank to the Department~~,~~ and shall receive written approval for such tanks prior to their installation in the state.

(2) The design and construction of each septic tank shall be in accordance with minimum standards contained within this ~~Regulation~~ regulation.

(3) No septic tank shall be installed which has a net liquid capacity of less than one thousand (1000) gallons. Such tanks shall be sufficient to serve dwellings of four (4) bedrooms or less. Two hundred fifty (250) gallons additional capacity shall be required for each bedroom over four (4).

(4) When multiple dwellings~~, including condominiums, apartments, and mobile homes,~~ share a common onsite wastewater system, each dwelling unit shall either have its own properly sized septic tank~~,~~ or it must discharge to a larger tank(s) that provides the combined total of the minimum septic tank capacities required for each contributing unit. Exception may be granted when a public entity, or private entity with financial assurances, is approved by the Department to provide operation and maintenance of the system. In such cases, the formula in Section 201.1(5) may be considered.

(5) Septic tanks serving establishments other than individual dwellings shall be sized according to actual peak flow data, when available, or by estimates of peak sewage flow, as set forth in standards established by the Department. For those septic tanks receiving peak flows less than fifteen hundred (1500) gpd, the net liquid capacity shall be calculated by multiplying 1.5 times the peak flow expressed in ~~gallons per day~~ (gpd). For those septic tanks receiving peak flows between fifteen hundred (1500) and forty-five hundred (4500) gpd, the net liquid capacity shall be calculated as follows:

Volume (V) = 1125 gal. plus (0.75 x Peak Flow(gpd)).

For those septic tanks receiving peak flows in excess of forty-five hundred (4500) gpd, the net liquid capacity shall be at least equal to the peak flow:

Volume (V) = Peak Flow (gpd)

(6) The minimum liquid capacity requirements shall be met by the use of a single septic tank or two (2) or more tanks installed in series. Septic tanks joined in series shall be interconnected by an upper effluent pipe(s) with a minimum diameter of four (4) inches and a lower sludge pipe(s) with a minimum diameter of twelve (12) inches. The upper connection(s) shall be installed level from tank to tank, and the lower sludge pipe connection(s) shall be installed level and shall be placed twelve (12) inches above the bottoms of the tanks. The lower sludge pipe connection(s) can be eliminated if the first tank in series contains at

least two-thirds (2/3) of the total required liquid capacity. There shall be no more than two (2) inches of fall from the inlet invert of the first tank to the outlet invert of the last tank in series.

201.2. Grease Traps.

(1) Any new food service facilities permitted under ~~R. 61-25~~ R.61-25, Retail Food Establishments, and served by an onsite wastewater system that is permitted after the effective date of this regulation shall be required to have a properly sized grease trap. This requirement ~~shall~~ may also apply to new facilities not requiring a food service permit under ~~R. 61-25~~ R.61-25. ~~where cooking operations are performed.~~ Exception may be granted in cases where a permitted retail food service establishment performs limited food preparation and/or cooking. ~~is permitted but does not perform any cooking or food preparation operations.~~

(2) ~~Existing food service establishments permitted under R. 61-25 prior to the effective date of this regulation shall not be required to immediately comply with this section, provided the facility does not experience an onsite wastewater system malfunction. Those existing establishments that experience a future malfunction as a result of problems associated with the accumulation of grease shall be required to comply with all portions of this section. Also, food service facilities that were permitted prior to the effective date of this regulation, were closed, and then reopened at any time thereafter, provided the facility was not experiencing a malfunction prior to closure and the original peak design flow will not be exceeded, shall not be required to immediately comply with this section provided the facility does not experience an onsite wastewater system malfunction.~~ Any existing food service establishment that does not have a grease trap, but experiences an onsite wastewater malfunction as a result of grease accumulation, shall be required to immediately comply with all portions of Section 201 as if it were a new food service facility.

(3) Any food service facility requiring a grease trap shall provide two (2) separate plumbing stub-outs, one serving the food preparation area and the other serving the restrooms. The stub-out from the restrooms shall discharge directly into the main building septic tank. The stub-out from the food preparation area shall discharge directly into the grease trap with the effluent then directed to the main building septic tank. In order to enhance grease separation while the liquids are hot, the grease trap shall be placed as close as possible to the source of wastewater. Garbage grinders shall not be allowed to discharge to such systems.

(4) All grease traps must be directly accessible from the surface~~,~~ and must be equipped with an extended outlet sanitary tee terminating six (6) to twelve (12) inches above the tank bottom. The minimum access opening shall be eighteen (18) inches in diameter.

(5) All grease traps serving facilities from which the peak sewage flow exceeds fifteen hundred (1500) gpd shall either be dual chambered or individual tanks in series. If dual chambered, both the dividing wall and the second chamber must be equipped with a sanitary tee terminating six (6) to twelve (12) inches above the tank bottom.

(6) It shall be the responsibility of the owner/manager to ensure that the grease trap(s) is cleaned by a licensed septage pumper at frequent intervals to prevent the carryover of grease into other parts of the onsite wastewater system.

(7) Determination of Minimum Net Liquid Capacity

(a) No grease trap used as part of an onsite wastewater system shall have a net liquid capacity of less than one thousand (1000) gallons. ~~Also, commercial~~ Commercial interior-type grease interceptors shall not be utilized in lieu of a properly sized exterior grease trap.

(b) Minimum net liquid capacities of grease traps shall be determined as follows:

NLC = GPD x LF x RF, where
NLC = Net Liquid Capacity of Grease Trap (gallons)
GPD = Total Maximum Estimated Sewage Flow (gpd)
LF = Loading Factor (the approximate portion of the total maximum daily flow generated in food preparation areas)
0.3 - Schools and Other Institutions
0.4 - Restaurants
0.5 - Retail Food Stores
RF = Minimum Retention and Storage Factor of 2.5 for Onsite Wastewater Systems

201.3. Other Primary Treatment Methods.

The Department, at its discretion, may consider other methods of primary treatment requested by a Registered Professional Engineer where conditions are warranted.

~~202. MINIMUM REQUIREMENTS FOR FINAL TREATMENT AND DISPOSAL SYSTEMS~~ **202. Minimum Requirements for Onsite Wastewater System Final Treatment and Disposal Systems.**

~~202.1 General~~

(1) All pipe utilized in onsite wastewater systems shall meet applicable ASTM standards. All piping utilized in the connection of a septic tank to a subsurface wastewater infiltration area, including that which is utilized in the connection of adjacent wastewater infiltration trenches, whether they be level or serially fed, shall be non-perforated Schedule 40 PVC pipe. Such pipe, excluding force mains, shall be a minimum of three (3) inches in diameter. The connecting pipe shall not be surrounded by aggregate.

(2) At least seven (7) feet of undisturbed earth shall exist between wastewater infiltration trenches.

(3) The aggregate used in onsite wastewater systems shall be a material approved by the Department~~,~~ and shall range in size from one-half (1/2) inch to two and one-half (2 1/2) inches. Fines shall be prohibited. Tire chips shall range in size from one-half (1/2) inch to four (4) inches in size, and wire strands shall not protrude more than one-half (1/2) inch from the sides.

(4) Drop boxes shall be utilized when deemed necessary by the Department. When required, they shall be surrounded and stabilized by at least two (2) feet of undisturbed or manually compacted earth, and the wastewater infiltration trenches shall be fed with non-perforated Schedule 40 PVC pipe. The invert of the drop box overflow pipe shall be at the same elevation as the top of the aggregate in the trenches fed by that box, and the top of the aggregate shall be level throughout the trench run. Other methods that affect serial distribution shall also overflow at the same elevation as the top of the aggregate.

(5) There shall be at least two (2) feet of earthen buffer between the septic tank and all portions of adjacent wastewater infiltration trenches. Where gravity flow is utilized, the invert elevation of the septic tank outlet shall be at the same elevation or higher than the top of the aggregate in the highest placed wastewater infiltration trench.

(6) To ensure proper operation and protection of onsite wastewater systems, the Department may require individual or combined installation of drainage swales, curtain or interceptor drains, protective barriers, or protective ground cover. Final approval of the permit may be withheld until such time as these improvements are completed.

(7) The bottom of each wastewater infiltration trench, including the distribution pipe contained within, shall be as level as possible, with an elevation differential not to exceed two (2) inches throughout the trench run.

(8) The required number, length, and configuration of wastewater infiltration trenches shall be determined by the Department, and shall be based upon the Standard for Determining Peak Sewage Flow Rates (Appendix R) (Section 501, Peak Sewage Flow Rate Standard) from Commercial and Recreational Establishments in conjunction with the Long-Term Acceptance Rate Standard for Onsite Wastewater Systems (Appendix Q) (Section 500, Long-Term Acceptance Rate Standard for Onsite Wastewater Systems). All systems shall be sized based upon the most hydraulically limiting, naturally occurring soil texture from the ground surface to twelve (12) inches below the bottom of the proposed wastewater infiltration trenches.

(9) The aggregate over the distribution pipe shall be covered with a strong, untreated pervious material to prevent infiltration of backfill material.

203. CONSTRUCTION CRITERIA **203. Onsite Wastewater System Construction Criteria.**

203.1. On sloping terrain, wastewater infiltration trenches shall be installed perpendicular to the direction of slope and parallel to the contours of the land.

203.2. Where deemed necessary by the Department, all required site alterations (swales, fill, shaping, etc.) shall be done prior to permitting the installation of the onsite wastewater system.

203.3. The area in which the onsite wastewater system is to be located shall be protected from surface water and roof or downspout drainage by the installation of drainage swales and small amounts of fill to achieve positive surface drainage.

203.4. Gross amounts of dirt, mud, and debris shall be removed from the septic tank before backfilling. All backfilling around the tank shall be tamped to facilitate stabilization.

203.5. If septic tank lids are of multi-part, slab-type construction, all joints shall be caulked or covered with heavy roofing paper or similar material.

203.6. All septic tanks of two-piece construction joined by tongue and groove shall be sealed with either bituminous mastic or other watertight caulking material placed in the groove in such quantity that the sealant is clearly visible around the entire tank after the two (2) pieces are joined.

203.7. When effluent pumping is required, all components of the pumping system shall adhere to standards contained within this Regulationregulation.

203.8. The Department may restrict, delay, or prohibit the installation or final approval of any onsite wastewater system when adverse soil or site conditions exist. These may include, but not be limited to, wet soil conditions in textural classesClass III and Class IV as described in the Long-Term Acceptance Rate Standard for Onsite Wastewater Systems approved by the Department.

204. EVALUATION OF ALTERNATIVE INFILTRATION TRENCH PRODUCTS **204. Evaluation of Alternative Infiltration Trench Products.**

The Department shall be responsible for the evaluation and approval of alternative infiltration trench products prior to their use in the ~~S~~state, unless otherwise regulated by statute. This evaluation shall include a review of available research data; a review of parameters relating to structure, geometry, and volume; and the establishment of required equivalency values for comparing the product to a conventional wastewater infiltration trench.

204.1. Application.

(1) All requests for approval of alternative infiltration trench products must be submitted in writing to the Department~~,~~ and must include the following:

(a) Complete description of the product and its intended use.

(b) Complete listing of materials used in the construction of the product, including specifications.

(c) Copies of all available literature pertaining to the product~~,~~ and a listing of all appropriate reference materials.

(d) Copies of any and all available research, testing, and monitoring data, to include records of performance and/or prior experience in actual field conditions.

(2) The Department will review the application~~,~~ and may seek other information, including additional evaluations.

204.2. Equivalency Value ~~For~~for Infiltrative Surface.

(1) The total infiltrative surface area surrounding the sides and bottom of a conventional wastewater infiltration trench (i.e., 5.33 sq.ft./lin.ft.) shall serve as the basis for all geometric comparisons to alternative infiltration trench products.

(2) The effective infiltrative surface area of a conventional trench shall include the total of both rectangular sidewalls, beginning at the top of the aggregate and extending to the trench bottom, in addition to the width of the trench bottom. Similarly, the effective infiltrative surface area of a product shall include the total of both immediately adjacent, rectangular sidewalls, beginning at the top of louvers, slits, holes or similar orifices, in addition to the rectangular width of the trench immediately beneath the product.

(3) The equivalency value (E) for any given product is determined by comparing the total effective surface area of the product, as defined above, with that of a conventional wastewater infiltration trench as follows:

(a) Total Infiltrative Surface Area for One (1) Foot of Conventional Trench:

Trench Sidewalls = 2 x ~~(1.16ft.H ÷ 1.0 ft.L)~~(1.16ft.H x 1.0 ft.L) = 2.33 sq.ft./lin.ft.
Trench Bottom = 1 x (3ft.W x 1ft.L) = 3.0 sq.ft./lin.ft.
Total Infiltrative Surface Area = 5.33 sq.ft./lin.ft.

(b) Equivalency Value (E) Shall Be Computed As Follows:

E = 5.33 sq.ft./ft ÷ Sum of Three Rectangular Interfaces Immediately Adjacent to Product (sq.ft./ft.)

(c) The Required Total Length of the Product Shall Be Calculated As Follows:

Length of Product (L) = E x Length of Conventional 36 in. Wide Trenches Required ~~By~~by DHEC Regulations and Standards

204.3. Other parameters to be evaluated for alternative infiltration trench products may include the following:

(1) Structural Integrity - Products must be of sound construction and able to adequately withstand the normal pressures and ~~stressed~~stresses associated with installation and use.

(2) Inertness - No product can be approved unless it will remain relatively unaffected for extended periods of time while in contact with typical domestic wastewater.

(3) Storage Volume - The effluent storage capacity of a product must closely approximate or exceed that of a comparable conventional system.

(4) Maintenance of Permeable Interfaces - A product shall have a direct interface with the effective infiltrative surface (undisturbed natural soil) or, if backfill is required, backfill material shall not create a permeability barrier and shall not hinder the downward or horizontal flow of effluent into the undisturbed natural soil.

(5) The unique characteristics of a given product may warrant the evaluation of other parameters not specifically mentioned in this section of the regulation.

(6) The design, construction, or installation methods used with any product shall not conflict nor violate any other requirements established by the Department.

204.4. Approval ~~For~~for General Use.

If warranted, the Department will issue a letter of approval for general use of the alternative infiltration trench product in accordance with equivalency values and other requirements determined herein. At least nine (9) inches of ~~backfill~~soil cover is required ~~unless a lesser amount is approved by the Department~~.

~~300. WASTEWATER TREATMENT FACILITY ACCESSIBILITY~~**300. Wastewater Treatment Facility Accessibility.**

300.1. Permits for new onsite wastewater systems shall not be issued where a wastewater treatment facility is accessible for connection.

300.2. Repairs to or replacement of failing onsite wastewater systems shall not be allowed where a wastewater treatment facility is accessible for connection.

~~301. DISCHARGE OF WASTE~~**301. Discharge of Waste.**

No septic tank effluent or domestic wastewater or sewage shall be discharged to the surface of the ground or into any stream or body of water in South Carolina without an appropriate permit from the Department.

~~302. ENFORCEMENT PROVISIONS~~

~~(1) This regulation is issued under the authority of Section 44-1-140(11) of the 1976 Code of Laws, as amended, and Section 48-1-10 et seq. of the 1976 Code of Laws, as amended. It shall be enforced in accordance with interpretations and public health reasons approved by the Department.~~

~~(2) The Department may temporarily suspend a permit for a violation of this regulation.~~

~~(3) The Department may revoke a permit for a violation of this regulation. The Department will revoke a permit when:~~

~~(a) the onsite wastewater system is malfunctioning and sewage is discharging to the ground or the groundwater, the holder of the permit has received notice that the system is malfunctioning, the Department has given notice that repairs must be made within a reasonable period of time, the holder of the permit has not made the repairs, and the system continues to discharge sewage to the ground or the groundwater; or~~

~~(b) the onsite wastewater system is malfunctioning and sewage is discharging to the ground or the groundwater, the holder of the permit has received notice that the system is malfunctioning, the Department has given notice that a wastewater treatment facility is accessible for connection.~~

~~(4) Following revocation under R.61-56.302.3.a, the holder of the revoked permit can obtain a repair permit and make the necessary repairs to the system. After the Department approves the repairs pursuant to Section 103.3 of this regulation, the holder of the permit will operate the onsite wastewater system under the terms of the new permit.~~

~~(5) In addition to the authority to suspend and revoke permits, the Department may seek enforcement and issue civil penalties in accordance with SC Code Ann. Sections 44-1-150 and 48-1-320, 330, and 340. The Department shall have the authority to assess and suspend civil penalties if the violations of this regulation are corrected in a period of time established by the Department.~~

~~(6) A Department decision involving the issuance, denial, renewal, modification, suspension, or revocation of a permit may be appealed by an affected person with standing pursuant to applicable law, including S.C. Code Title 44, Chapter 1 and Title 1, Chapter 23. Any person to whom an order or enforcement letter is issued may appeal it pursuant to applicable law, including S.C. Code Title 44, Chapter 1 and Title 1, Chapter 23.~~

~~303. REPEAL AND DATE OF EFFECT~~

~~This regulation shall become effective as provided in Section 12310 et seq. of the 1976 Code of Laws of South Carolina, as amended, and shall repeal Department of Health and Environmental Control R. 6156 of the Code of Laws of South Carolina, 1976; except that, Sections 200.6(2) and 200.6(4) shall become effective on January 1, 2009, and existing Sections V.E(b) and (c) shall remain in effect until that date.~~

~~304. CHANGES IN USE THAT IMPACT EXISTING ONSITE WASTEWATER SYSTEMS~~**302. Changes in Use That Impact Existing Onsite Wastewater Systems.**

If the use of a dwelling or facility is changed such that additions or alterations are proposed which increase wastewater flow, change wastewater characteristics, or compromise the integrity or function of the system, the onsite wastewater ~~s~~system shall be brought into full compliance with this regulation. Alterations that change the wastewater characteristics or increase wastewater flow will require the owner to ~~apply for~~submit an application and receive ~~an approval~~ a permit to construct for the upgrade/expansion prior to any alterations.

~~305 SEVERABILITY CLAUSE~~

~~Should any section, paragraph, sentence, clause or phrase of this regulation be declared unconstitutional or invalid for any reason, the remainder of this regulation shall not be affected thereby.~~

~~400~~
~~APPENDICES OF STANDARDS FOR ONSITE WASTEWATER SYSTEMS~~

400. Appendices of Standards for Permitted Systems.

Appendix A – System Standard 100/101 – Conventional with 14-Inch Aggregate Depth

(1) Site/Permitting Requirements

(a) The depth to the zone of saturation (ZOS) must be at least twenty-nine (29) inches below the naturally occurring soil surface and at least six (6) inches below the bottom of the proposed wastewater infiltration trenches at the deepest point of effluent application.

(b) The depth to any restrictive horizon must be greater than twelve (12) inches below the bottom of the proposed wastewater infiltration trenches at the deepest point of effluent application.

(c) The long-term acceptance rate for system sizing shall be based upon the most hydraulically limiting naturally occurring soil texture from the ground surface to twelve (12) inches below the bottom of the proposed wastewater infiltration trenches.

(d) There shall be a replacement area equivalent to at least fifty (50) percent in size of the original system area held in reserve for system repair. This area shall have a suitable configuration and shall meet the minimum soil and site conditions of this regulation.

(e) This system must not be used on sloping sites that require serial distribution unless it can be demonstrated that the entire wastewater infiltration trench installation (i.e., side wall to side wall and end to end) can meet the required textural limitations and the required offsets to the zone of saturation and restrictive horizons.

(2) Installation Requirements

(a) The wastewater infiltration trench aggregate shall be fourteen (14) inches in depth and shall be placed so as to provide six (6) inches of aggregate below the pipe, five (5) inches beside the pipe, and three (3) inches above the pipe. The aggregate shall be covered with at least nine (9) inches of soil.

(b) The wastewater infiltration trench width shall be thirty-six (36) inches.

(c) Where gravity flow from the septic tank to the subsurface wastewater infiltration area is utilized, the invert elevation of the septic tank outlet shall be installed at an elevation at least equal to or higher than the top of the aggregate in the highest wastewater infiltration trench(es).

(d) All tree and brush removal shall be done in a manner that minimizes the disturbance or loss of naturally occurring soil.

(3) Final Landscaping and Drainage

(a) Installation of drainage swales, ditches, curtain drains, and rain gutters may be required to divert or intercept water away from the onsite wastewater system location to a positive outfall. The septic tank and subsurface wastewater infiltration area shall be backfilled and shaped to promote surface water runoff.

(b) A barrier to preclude parking and vehicular traffic over the system area may be required.

(c) Following final landscaping, seeding, or sodding may be required to prevent erosion.

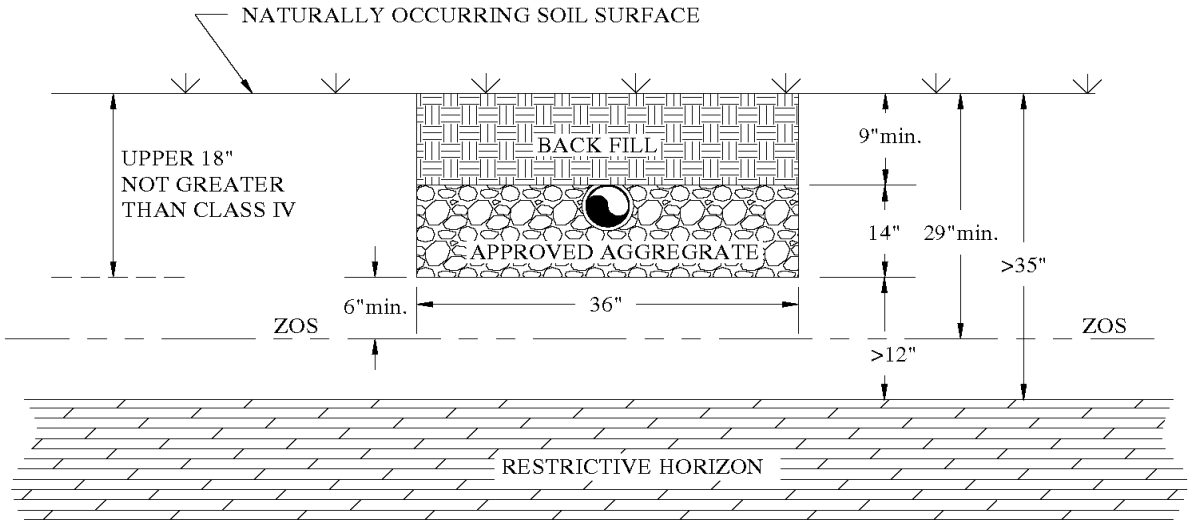
(d) Final approval shall be withheld until all landscaping and drainage improvements have been satisfactorily completed.

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
BUREAU OF ENVIRONMENTAL HEALTH SERVICES

CONVENTIONAL STANDARD
WITH FOURTEEN (14) INCH AGGREGATE DEPTH

PROGRAM 360/ CODE 100 / CODE 101 IF PUMPED

TYPICAL DESIGN ILLUSTRATION



NOT TO SCALE

03/09/2018

~~401. Appendix A – SYSTEM STANDARD 150 – LARGE (greater than 1500 GPD) AND COMMUNITY ONSITE WASTEWATER SYSTEMS~~ **Appendix B – System Standard 150 – Large (greater than 1500 gpd) and Community Systems**

~~401.1 SITE/PERMITTING REQUIREMENTS~~

(1) Site/Permitting Requirements

(a) ~~The Department may require that designs~~Designs for large and community onsite wastewater systems shall be prepared by a Registered Professional Engineer licensed in ~~the State of~~ South Carolina. Further, the Department may require whatever engineering and soils based submittals are deemed necessary to determine the feasibility and acceptability of any site for such a system.

(b) No part of the system, with the exception of solid pipe, may be located within one hundred (100) linear feet of a receptor.

~~(2)~~ (c) The depth to the zone of saturation (ZOS) shall be at least thirty-six (36) inches below the naturally occurring soil surface~~,~~ and at least six (6) inches below the deepest point of effluent application.

~~(3)~~ (d) The depth to any restrictive horizon must be greater than twelve (12) inches below the bottom of the proposed wastewater infiltration trenches.

~~(4)~~ (e) The ~~Long Term Acceptance Rate~~long-term acceptance rate for system sizing shall be based upon the most hydraulically limiting, naturally occurring soil texture from the ground surface to twelve (12) inches below the bottom of the proposed wastewater infiltration trenches.

~~(5)~~ (f) There shall be at least fifty (50) percent reserved subsurface wastewater infiltration area repair or replacement area available consisting of soils suitable for a large onsite wastewater system, except where public (community) systems are utilized, in which case there must be at least one hundred (100) percent repair or replacement area.

~~(6)~~ (g) Large (greater than 1500 gpd) and community onsite wastewater systems incorporating advanced treatment methods, including but not limited to aerobic pre-treatment, lagoons, surface or subsurface drip irrigation, low pressure pipe distribution, and other maintenance intensive methods, shall be required to obtain a Land Application Permit under ~~R. 61-9.505~~R.61-9.505.

~~(7)~~ (h) Efforts to circumvent the requirements of this standard by configuring remote, individually deeded, adjacently located subsurface wastewater infiltration areas in lieu of a community onsite wastewater system shall not be permitted. On a very limited basis, a few of these individual systems may be considered for mass installation where the wastewater infiltration trenches will be adjacent to each other in a defined area, provided that the combined peak wastewater loading is less than fifteen hundred (1500) gpd. In such cases:

~~(a)~~ (i) Each subsurface wastewater infiltration area plot shall be sized such that there is sufficient area for one hundred (100) percent subsurface wastewater infiltration area replacement.

~~(b)~~ (ii) Each plot shall be deeded with all appropriate easements as a lot in conjunction with the specific unit that it serves, and required protective offsets, as described in Section 200.6, shall apply to each individual remote subsurface wastewater infiltration area.

~~(c)~~ (iii) A plan shall be prepared by a Registered Professional Engineer licensed in ~~the State of~~ South Carolina that illustrates the overall plan; specifies the route and identification of effluent sewers and ~~forcemains~~force mains; specifies the entity responsible for perpetual maintenance of the sewer lines and mass subsurface wastewater infiltration area; specifies the configuration and identification of the individual subsurface wastewater infiltration area parcels; and specifies the manner in which ingress and egress will be provided to the individual subsurface wastewater infiltration area parcels.

~~(d)~~ (iv) When the combined peak wastewater loading of the adjacently located subsurface wastewater infiltration areas from the entire project will exceed fifteen hundred (1500) gpd, the project shall be considered as a public (community) collection and treatment system, and all requirements described in Section ~~102.5~~ 103.1(5) and this standard shall apply.

~~401.2 INSTALLATION REQUIREMENTS~~ (2) Installation Requirements

~~(1)~~ (a) Large (greater than 1500 gpd) and community onsite wastewater systems shall not be constructed in fill material~~,~~ and shall not be placed any closer to receptors than one hundred (100) feet.

~~(2)~~ (b) Conventional wastewater infiltration trenches installed in the naturally occurring soil and having a width of thirty-six (36) inches shall be utilized.

~~(3)~~ (c) Wherever possible, designs that favor long wastewater infiltration trenches, convex landscape positions, and rectangular subsurface wastewater infiltration area configurations shall be required.

~~(4)~~ (d) All tree/brush removal shall be done in a manner that minimizes the disturbance or loss of naturally occurring soil.

~~401.3 COMMUNITY OR CLUSTER COLLECTION AND TREATMENT ONSITE WASTEWATER SYSTEMS~~ (3) Community or Cluster Collection and Treatment Onsite Wastewater Systems

~~(1)~~ (a) An onsite wastewater system serving more than one (1) piece of deeded property shall be considered as a public (community) collection and treatment system.

~~(2)~~ (b) A permit activity will not occur that is inconsistent with a plan or plan amendment approved under Section 208(b) of the Clean Water Act, unless the Department finds such variance necessary to protect the public's health, safety, and welfare.

~~(3)~~ (c) A public entity shall own the system and shall be responsible for the operation, maintenance, and replacement of all components unless otherwise approved by the Department. The Department may consider a request from a private entity or person; however, such proposals must be evaluated on a case-by-case basis. The Department will evaluate the capability of long-term, reliable system operation in its evaluation of a permit request.

~~(4)~~ (d) If the project is owned by a private entity or person, the Department shall require financial assurances for the operation, maintenance, and replacement of the tank(s) and subsurface wastewater infiltration area system and relevant collection/pumping components.

~~(5)~~ (e) ~~Sufficient area meeting the minimum requirements for large onsite wastewater systems shall be provided for at least one hundred (100) percent repair or replacement of the primary subsurface wastewater infiltration area.~~There shall be an area equivalent to one hundred (100) percent in size of the original primary subsurface wastewater infiltration area held in reserve for system repair or replacement.

This area shall have a suitable configuration and shall meet all minimum requirements for large onsite wastewater systems.

~~(6)~~ (f) The collection sewer and pumping portions of a community onsite wastewater system shall receive a separate Construction Permit under ~~R. 61-67.300~~R.61-67.300.

~~(7)~~ (g) The ~~permit holder~~responsible party(s) on record shall be required to properly operate and maintain in good working order all system(s) parts~~, and operate as efficiently as possible, all facilities and systems~~ which are installed pursuant to the permit and to comply with all terms and conditions of the permit. System parts include, but are not limited to, sealed watertight tanks, lid(s), piping, aggregate, pump, and pump components.

~~402. Appendix B – System Standard 210/211 — Shallow Placement With 9 Inch Aggregate Depth~~
Appendix C – System Standard 210/211 – Shallow Placement with 9-Inch Aggregate Depth

~~402.1 SITE/PERMITTING REQUIREMENTS~~ (1) Site/Permitting Requirements

~~(1)~~ (a) There must not be a zone of saturation (ZOS) within twenty-four (24) inches of the naturally occurring soil surface.

~~(2)~~ (b) The depth to any restrictive horizon must be greater than twelve (12) inches below the bottom of the proposed wastewater infiltration trenches.

~~(3)~~ (c) The texture in the upper eighteen (18) inches of naturally occurring soil may either be Class I, Class II, Class III, or Class IV.

~~(4)~~ (d) The ~~Long-Term Acceptance Rate~~long-term acceptance rate for system sizing shall be based upon the most hydraulically limiting naturally occurring soil texture from the ground surface to twelve (12) inches below the bottom of the proposed wastewater infiltration trenches.

~~(5)~~ (e) Due to the decreased sidewall absorption area and the increased potential for ground water mounding near the surface, the Equivalency Factors for these systems shall be calculated by conventional wastewater infiltration trenches and increased by an additional factor of 0.09 times.

~~(6)~~ (f) There shall be a replacement area equivalent to at least fifty (50) percent in size of the original system area held in reserve for system repair. This area shall have a suitable configuration~~,~~ and shall meet the minimum soil and site conditions of ~~R. 61-56~~ this regulation.

~~(7)~~ (g) This system must not be used on sloping sites that require serial distribution unless it can be demonstrated that the entire wastewater infiltration trench installation (i.e., side wall to side wall and end to end) can meet the required textural limitations and the required offsets to the zone of saturation and restrictive horizons. ~~Level installations on slightly sloping sites can be considered if the above requirements can be met.~~

~~(8)~~ (h) This system cannot be considered for facilities with peak flow rates in excess of fifteen hundred (1500) ~~gallons per day~~ gpd.

~~402.2 INSTALLATION REQUIREMENTS~~ (2) Installation Requirements

~~(1) Serial distribution is restricted (see item 7. above).~~

~~(2)~~ (a) The wastewater infiltration trench aggregate shall be nine (9) inches in depth and shall be covered with at least nine (9) inches of backfill.

~~(3)~~ (b) The ~~maximum~~ wastewater infiltration trench width shall be thirty-six (36) inches~~; the minimum width shall be eighteen (18) inches~~.

~~(4)~~ (c) The maximum depth of the bottom of the wastewater infiltration trench shall be eighteen (18) inches below the naturally occurring soil surface unless it can be demonstrated that deeper placement can meet the required textural limitations and the offsets to the zone of saturation and restrictive horizons.

~~(5)~~ (d) Where gravity flow from the septic tank to the subsurface wastewater infiltration area is utilized, the invert elevation of the septic tank outlet shall be installed at an elevation at least equal to or higher than the top of the aggregate in the highest wastewater infiltration trench(es).

~~(6)~~ (e) All tree and brush removal shall be done in a manner that minimizes the disturbance or loss of naturally occurring soil.

~~402.3 FINAL LANDSCAPING AND DRAINAGE~~ (3) Final Landscaping and Drainage

~~(1)~~ (a) Installation of drainage swales, ditches, curtain drains, and rain gutters may be required to divert or intercept water away from the onsite wastewater system location to a positive outfall. The septic tank and subsurface wastewater infiltration area shall be backfilled and shaped to promote surface water runoff.

~~(2)~~ (b) A barrier to preclude parking and vehicular traffic over the system area may be required.

~~(3)~~ (c) Following final landscaping, seeding or sodding may be required to prevent erosion.

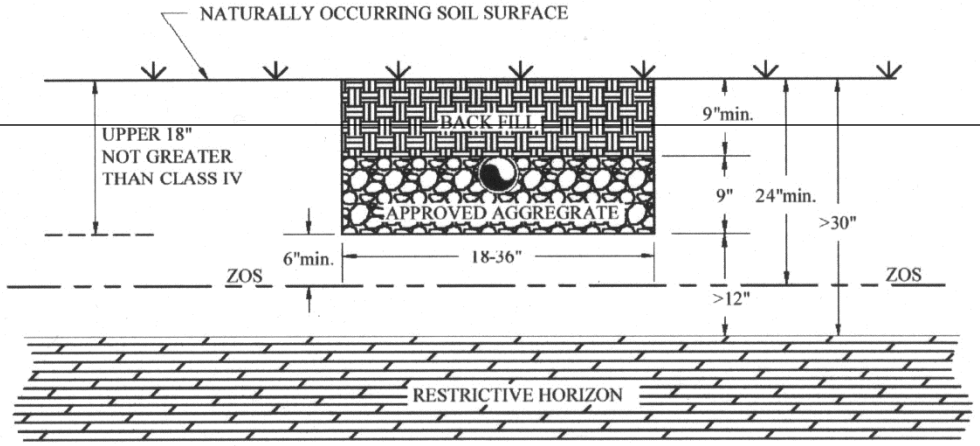
~~(4)~~ (d) Final approval shall be withheld until all landscaping and drainage improvements have been satisfactorily completed.

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
BUREAU OF ENVIRONMENTAL HEALTH

ALTERNATIVE SYSTEM
SHALLOW PLACEMENT WITH NINE (9) INCH AGGREGATE DEPTH

PROGRAM 362 / CODE 210 / CODE 211 IF PUMPED

TYPICAL DESIGN ILLUSTRATION



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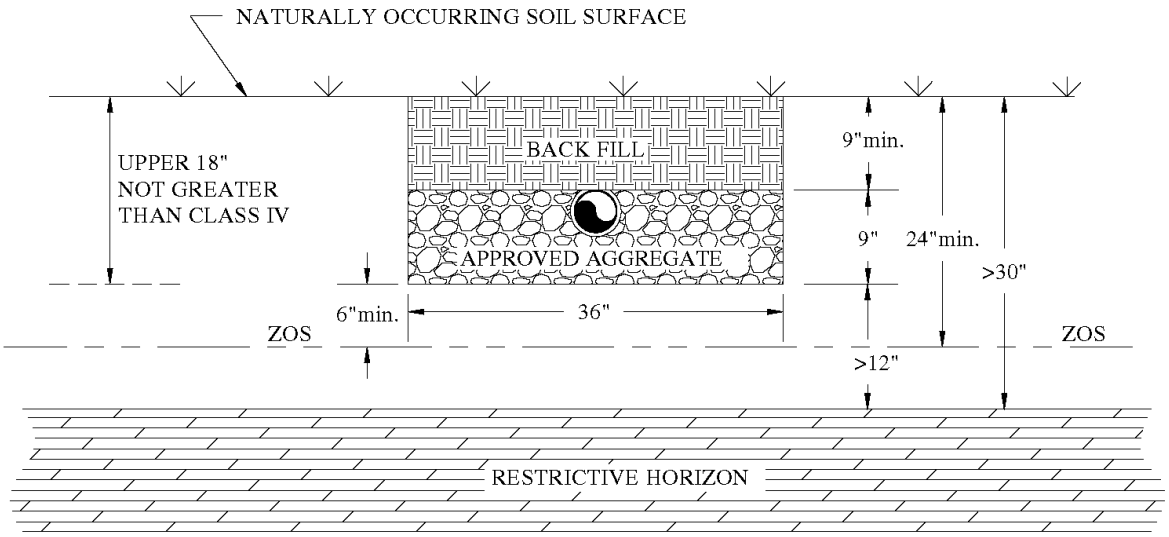
T.S. REV. 03/16/07

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
BUREAU OF ENVIRONMENTAL HEALTH

ALTERNATIVE STANDARD
SHALLOW PLACEMENT WITH NINE (9) INCH AGGREGATE DEPTH

PROGRAM 362 / CODE 210 / CODE 211 IF PUMPED

TYPICAL DESIGN ILLUSTRATION



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REV. 03/09/2018

~~403 Appendix C – SYSTEM STANDARD 220/221 – SHALLOW PLACEMENT WITH 6 INCH AGGREGATE DEPTH~~**Appendix D – System Standard 220/221 – Shallow Placement with Six (6)-Inch Aggregate Depth**

~~403.1 SITE/PERMITTING REQUIREMENTS~~ (1) Site/Permitting Requirements

~~(1)~~ (a) There must not be a zone of saturation (ZOS) within twenty-one (21) inches of the naturally occurring soil surface.

~~(2)~~ (b) The depth to any restrictive horizon must be greater than twelve (12) inches below the bottom of the proposed wastewater infiltration trenches.

~~(3)~~ (c) The texture in the upper eighteen (18) inches of naturally occurring soil may either be Class I, Class II, Class III, or Class IV.

~~(4)~~ (d) The ~~Long-Term Acceptance Rate~~long-term acceptance rate for system sizing shall be based upon the most hydraulically limiting naturally occurring soil texture from the ground surface to twelve (12) inches below the bottom of the proposed wastewater infiltration trenches.

~~(5)~~ (e) Due to the decreased sidewall absorption area and the increased potential for ground water mounding near the surface, the Equivalency Factors for these systems shall be calculated by conventional wastewater infiltration trenches and increased by an additional factor of 0.12 times.

~~(6)~~ (f) There shall be a replacement area equivalent to at least fifty (50) percent in size of the original system area held in reserve for system repair. This area shall have a suitable configuration~~,~~ and shall meet the minimum soil and site conditions of ~~R. 61-56~~ this regulation.

~~(7)~~ (g) This system must not be used on sloping sites that require serial distribution unless it can be demonstrated that the entire wastewater infiltration trench installation (i.e., side wall to side wall and end to end) can meet the required textural limitations and the required offsets to the zone of saturation and restrictive horizons. ~~Level installations on slightly sloping sites can be considered if the above limitations can be met.~~

~~(8)~~ (h) This system cannot be considered for facilities with peak flow rates in excess of fifteen hundred (1500) ~~gallons per day~~gpd.

~~403.2 INSTALLATION REQUIREMENTS~~ (2) Installation Requirements

~~(1) Serial distribution is restricted (see Section 403.1(7)).~~

~~(2)~~ (a) The wastewater infiltration trench aggregate shall be six (6) inches in depth and shall be covered with at least nine (9) inches of backfill.

~~(3)~~ (b) The ~~maximum~~ wastewater infiltration trench width shall be thirty-six (36) inches~~; the minimum width shall be eighteen (18) inches~~.

~~(4)~~ (c) The maximum depth of the bottom of the wastewater infiltration trench shall be fifteen (15) inches below the naturally occurring soil surface unless it can be demonstrated that deeper placement can meet the required textural limitations and the offsets to the zone of saturation and restrictive horizons.

~~(5)~~ (d) Where gravity flow from the septic tank to the subsurface wastewater infiltration area is utilized, the invert elevation of the septic tank outlet shall be installed at an elevation at least equal to or higher than the top of the aggregate in the highest wastewater infiltration trench(es).

~~(6)~~ (e) All tree and brush removal shall be done in a manner that minimizes the disturbance or loss of naturally occurring soil.

~~403.3 FINAL LANDSCAPING AND DRAINAGE~~ (3) Final Landscaping and Drainage

~~(1)~~ (a) Installation of drainage swales, ditches, curtain drains, and rain gutters may be required to divert or intercept water away from the onsite wastewater system location to a positive outfall. The septic tank and subsurface wastewater infiltration area shall be backfilled and shaped to promote surface water runoff.

~~(2)~~ (b) A barrier to preclude parking and vehicular traffic over the system area may be required.

~~(3)~~ (c) Following final landscaping, seeding or sodding may be required to prevent erosion.

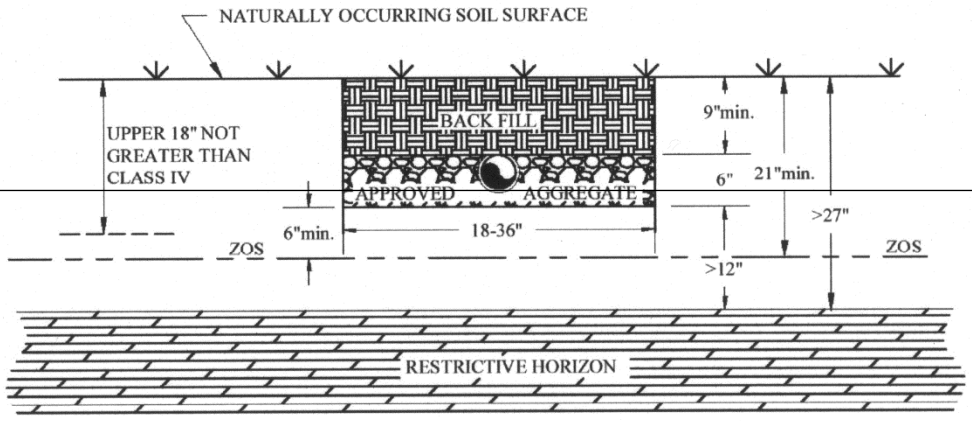
~~(4)~~ (d) Final approval shall be withheld until all landscaping and drainage improvements have been satisfactorily completed.

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
BUREAU OF ENVIRONMENTAL HEALTH

ALTERNATIVE SYSTEM
SHALLOW PLACEMENT WITH SIX (6) INCH AGGREGATE DEPTH

PROGRAM 362 / CODE 220 / CODE 221 IF PUMPED

TYPICAL DESIGN ILLUSTRATION



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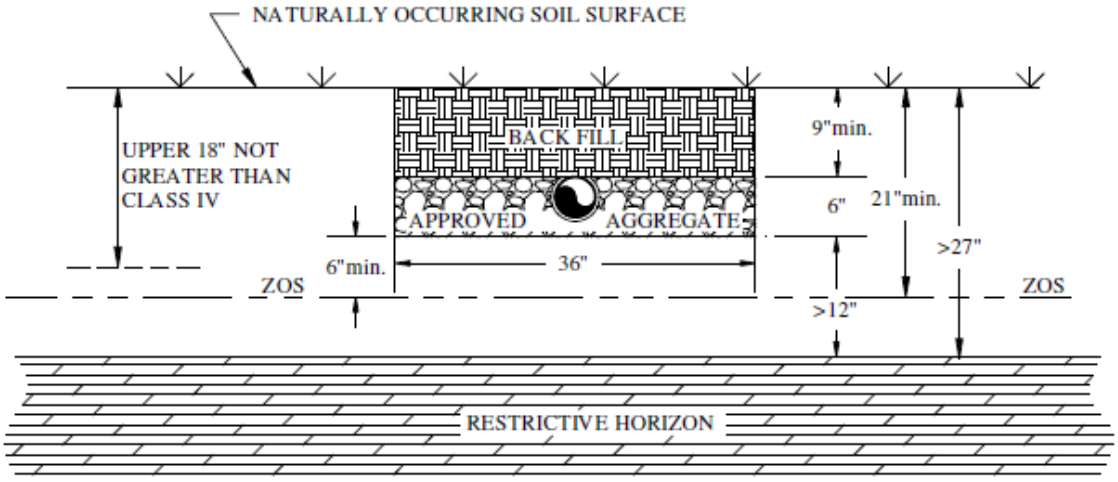
TLS REV. 03/16/07

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
BUREAU OF ENVIRONMENTAL HEALTH SERVICES

ALTERNATIVE STANDARD
SHALLOW PLACEMENT WITH SIX (6) INCH AGGREGATE DEPTH

PROGRAM 362 / CODE 220 / CODE 221 IF PUMPED

TYPICAL DESIGN ILLUSTRATION



NOT TO SCALE

Rev. 03/09/18

~~404 APPENDIX D – System Standard 230/231 Shallow Placement System WITH 14 INCH AGGREGATE DEPTH With Fill Cap~~**Appendix E – System Standard 230/231 – Shallow Placement with 14-Inch Aggregate Depth with Fill Cap**

~~404.1 SITE/PERMITTING REQUIREMENTS~~ (1) Site/Permitting Requirements

~~(1)~~ (a) There must not be a zone of saturation (ZOS) within twenty (20) inches of the naturally occurring soil surface.

~~(2)~~ (b) The depth to any restrictive horizon must be greater than twelve (12) inches below the bottom of the proposed wastewater infiltration trenches.

~~(3)~~ (c) The texture in the upper eighteen (18) inches of naturally occurring soil must be no more limiting than Class III.

~~(4)~~ (d) ~~This system must not be utilized on sites that require serial distribution. Level installations on slightly sloping sites can be considered if it can be demonstrated that the entire installation (i.e., side wall to side wall and end to end) will meet the required textural limitations and the required offsets to the zone of saturation and restrictive horizons.~~ This system must not be used on sloping sites that require serial distribution unless it can be demonstrated that the entire wastewater infiltration trench installation (i.e., side wall to side wall and end to end) can meet the required textural limitations and the required offsets to the zone of saturation and restrictive horizons.

~~(5)~~ (e) The ~~Long-Term Acceptance Rate~~long-term acceptance rate for system sizing shall be based upon the most hydraulically limiting naturally occurring soil texture from the ground surface to twelve (12) inches below the bottom of the proposed wastewater infiltration trenches.

~~(6)~~ (f) The total linear footage of wastewater infiltration trenches shall be the same as that required for conventional systems.

~~(7)~~ (g) There shall be a replacement area equivalent to at least fifty (50) percent in size of the original system area held in reserve for system repair. This area shall have a suitable configuration~~,~~ and shall meet the minimum soil and site conditions of ~~R. 61-56~~this regulation.

~~(8)~~ (h) This system cannot be considered for facilities with peak flow rates in excess of fifteen hundred (1500) ~~gallons per day~~gpd.

~~404.2 INSTALLATION REQUIREMENTS~~ (2) Installation Requirements

~~(1)~~ (a) The ~~maximum~~ wastewater infiltration trench width ~~must not exceed~~shall be thirty-six (36) inches~~; the minimum width shall be eighteen (18) inches~~.

~~(2)~~ (b) The maximum depth of the bottom of the wastewater infiltration trench shall be fourteen (14) inches below the naturally occurring soil surface unless it can be demonstrated that deeper placement can meet the required textural limitations and the offsets to the zone of saturation and restrictive horizons.

~~(3)~~ (c) The depth of the fill cap shall provide a minimum of twelve (12) inches ~~backfill~~of soil cover above the top of the wastewater infiltration trench aggregate. ~~(see attached illustration)~~

~~(4)~~ (d) Where gravity flow from the septic tank to the subsurface wastewater infiltration area is utilized, the invert elevation of the septic tank outlet shall be installed at an elevation at least equal to or higher than the top of the aggregate in the highest wastewater infiltration trench(es).

~~(5)~~ (e) The required fill cap must extend at least five (5) feet beyond the limits of the subsurface wastewater infiltration trenches~~,~~ and must taper to the original soil surface at a slope not to exceed 10 percent. ~~(see attached illustration).~~ On sloping sites, where serial distribution has been incorporated into the system design, on the lower side and ends of the wastewater infiltration trenches, the fill cap must extend to at least ten (10) feet beyond the limits of the wastewater infiltration trenches and must taper to the original soil surface at a slope not to exceed five (5) percent. The required property line setback shall be measured from the point at which the fill cap taper intersects with the natural soil surface. The fill cap must be installed prior to beginning trench installation when required on the construction permit.

~~(6)~~ (f) The required fill material must be soil texture Class I, Class II, or Class III and be devoid of extraneous debris such as organic matter, building materials, etc.

~~(7)~~ (g) The wastewater infiltration trench aggregate shall be fourteen (14) inches in depth.

~~(8)~~ (h) All tree/brush removal shall be done in a manner that minimizes the disturbance or loss of naturally occurring soil.

~~404.3 FINAL LANDSCAPING AND DRAINAGE~~ (3) Final Landscaping and Drainage

~~(1)~~ (a) The septic tank and fill cap area shall be backfilled and shaped to promote the runoff of surface water.

~~(2)~~ (b) Where natural surface drainage does not exist, a swale shall be constructed adjacent to the fill cap area to divert surface water away from the onsite wastewater system to a positive outfall. The installation of ditches, curtain drains, and rain gutters may be required to intercept and divert water away from the onsite wastewater system location.

~~(3)~~ (c) A barrier to preclude parking and vehicular traffic over the system area may be required.

~~(4)~~ (d) Following final landscaping, seeding or sodding may be required to prevent erosion.

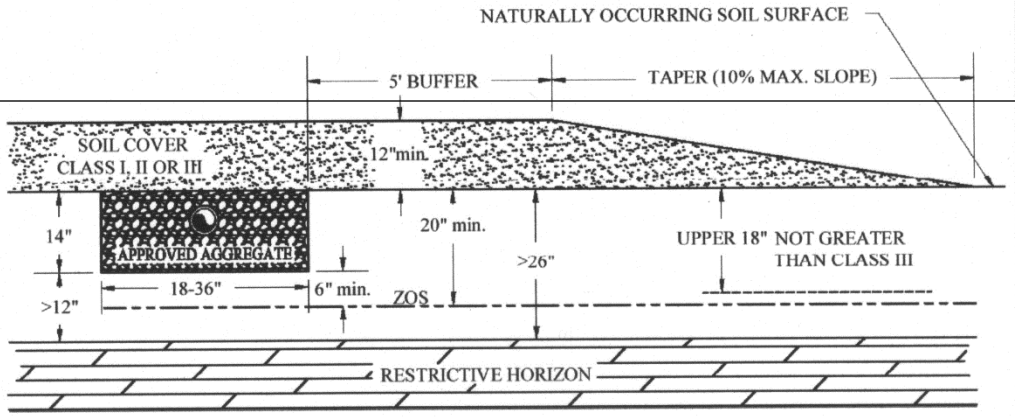
~~(5)~~ (e) Final approval shall be withheld until all landscaping and drainage improvements have been satisfactorily completed.

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
BUREAU OF ENVIRONMENTAL HEALTH

ALTERNATIVE SYSTEM
SHALLOW PLACEMENT SYSTEM WITH FILL CAP

PROGRAM 362 / CODE 230 / CODE 231 IF PUMPED

TYPICAL DESIGN ILLUSTRATION



NOT TO SCALE

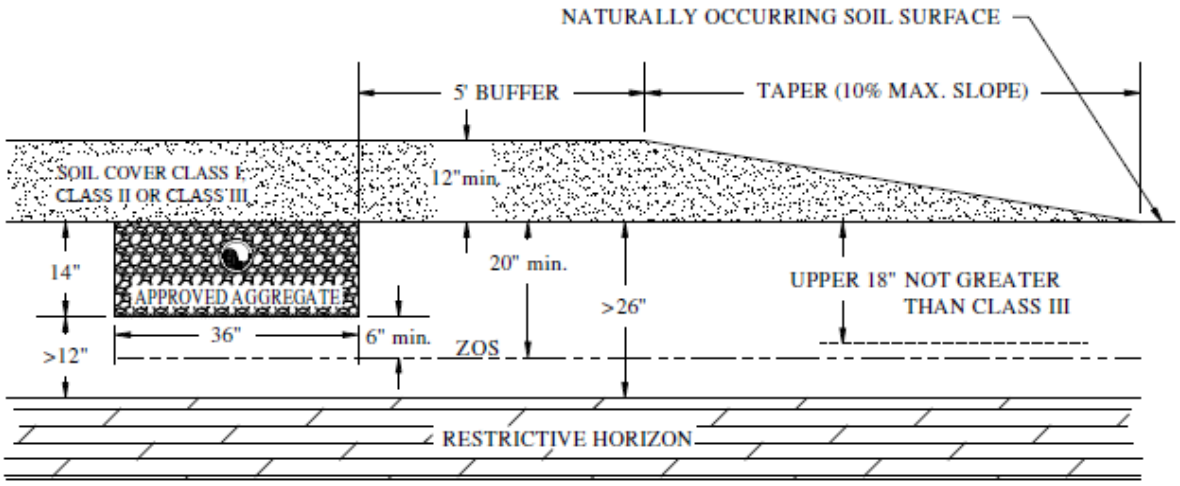
TLS REV. 03/16/07

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
BUREAU OF ENVIRONMENTAL HEALTH SERVICES

ALTERNATIVE STANDARD
SHALLOW PLACEMENT SYSTEM WITH FILL CAP

PROGRAM 362 / CODE 230 / CODE 231 IF PUMPED

TYPICAL DESIGN ILLUSTRATION



NOT TO SCALE

Rev. 03/09/18

~~405 Appendix E – SYSTEM STANDARD 240/241 – ULTRA SHALLOW PLACEMENT WITH 6-INCH AGGREGATE DEPTH WITH FILL CAP~~**Appendix F – System Standard 240/241 – Ultra-Shallow Placement with 6-Inch Aggregate Depth with Fill Cap**

~~405.1 SITE/PERMITTING REQUIREMENTS~~ (1) Site/Permitting Requirements

~~(1)~~ (a) There must not be a zone of saturation (ZOS) within twelve (12) inches of the naturally occurring soil surface.

~~(2)~~ (b) The depth to any restrictive horizon must be greater than twelve (12) inches below the bottom of the proposed wastewater infiltration trenches.

~~(3)~~ (c) The soil texture in the upper eighteen (18) inches of naturally occurring soil must be no more limiting than Class III.

~~(4)~~ (d) ~~This system must not be utilized on sites that require serial distribution. Level installations on slightly sloping sites can be considered if it can be demonstrated that the entire installation (i.e., side wall to side wall and end to end) will meet the required textural limitations and the required offsets to the zone of saturation and restrictive horizons.~~ This system must not be used on sloping sites that require serial distribution unless it can be demonstrated that the entire wastewater infiltration trench installation (i.e., side wall to side wall and end to end) meets the required textural limitations and required offsets to the zone of saturation and restrictive horizons.

~~(5)~~ (e) No part of this system can be installed within one hundred twenty-five (125) feet of the critical area line or tidal waters as determined by the Department; or within one hundred twenty-five (125) feet of the ordinary high water elevation within the banks of non-tidal, environmentally sensitive waters.

~~(6)~~ (f) The ~~Long Term Acceptance Rate~~long-term acceptance rate for system sizing shall be based upon the most hydraulically limiting naturally occurring soil texture from the ground surface to twelve (12) inches below the bottom of the proposed wastewater infiltration trenches.

~~(7)~~ (g) Due to the decreased sidewall area and the increased potential for ground water mounding near the surface, the Equivalency Factors for these systems shall be calculated by conventional wastewater infiltration trenches and increased by an additional factor of 0.12 times.

~~(8)~~ (h) There shall be a replacement area equivalent to at least fifty (50) percent in size of the original system area held in reserve for system repair. This area shall have a suitable configuration~~,~~ and shall meet the minimum soil and site conditions of ~~R. 61-56~~this regulation.

~~(9)~~ (i) This system cannot be considered for facilities with peak flow rates in excess of fifteen hundred (1500) ~~gallons per day~~gpd.

~~405.2 INSTALLATION REQUIREMENTS~~ (2) Installation Requirements

~~(1)~~ (a) The ~~maximum~~ wastewater infiltration trench width ~~must not exceed~~shall be thirty-six (36) inches~~; the minimum width shall be 18 inches~~.

~~(2)~~ (b) The maximum depth of the bottom of the wastewater infiltration trench shall be six (6) inches below the naturally occurring soil surface unless it can be demonstrated that deeper placement can meet the required textural limitations and offsets to the zone of saturation and restrictive horizons.

~~(3)~~ (c) The depth of the fill cap shall provide a minimum of twelve (12) inches backfill above the top of the wastewater infiltration trench aggregate ~~(see attached illustration)~~.

~~(4)~~ (d) Where gravity flow from the septic tank to the subsurface wastewater infiltration area is utilized, the invert elevation of the septic tank outlet shall be installed at an elevation at least equal to or higher than the top of the aggregate in the highest wastewater infiltration trench(es).

~~(5)~~ (e) The required fill cap must extend at least five (5) feet beyond the limits of the subsurface wastewater infiltration trenches~~,~~ and must taper to the original soil surface at a slope not to exceed of 10 percent. ~~(see attached illustration)~~ On sloping sites where serial distribution has been incorporated into the system design, on the lower side and ends of the wastewater infiltration trenches, the fill cap must extend to at least ten (10) feet beyond the limits of the wastewater infiltration trenches and must taper to the original soil surface at a slope not to exceed five (5) percent. The required property line setback shall be measured from the point at which the fill cap taper intersects with the natural soil surface. The fill cap must be installed prior to beginning trench installation when required on the construction permit.

~~(6)~~ (f) The required fill material must be soil texture Class I, Class II, or Class III, and be devoid of extraneous debris such as organic matter, building materials, etc.

~~(7)~~ (g) The wastewater infiltration trench aggregate shall be six (6) inches in depth.

~~(8)~~ (h) All tree/brush removal shall be done in a manner that minimizes the disturbance or loss of naturally occurring soil.

~~405.3 FINAL LANDSCAPING AND DRAINAGE~~ (3) Final Landscaping and Drainage

~~(1)~~ (a) The septic tank and fill cap area shall be backfilled and shaped to promote the runoff of surface water.

~~(2)~~ (b) Where natural surface drainage does not exist, a swale shall be constructed adjacent to the fill cap area to divert surface water away from the onsite wastewater system to a positive outfall. The installation of ditches, curtain drains, and rain gutters may be required to intercept and divert water away from the onsite wastewater system location.

~~(3)~~ (c) A barrier to preclude parking and vehicular traffic over the system area may be required.

~~(4)~~ (d) Following final landscaping, seeding or sodding may be required to prevent erosion.

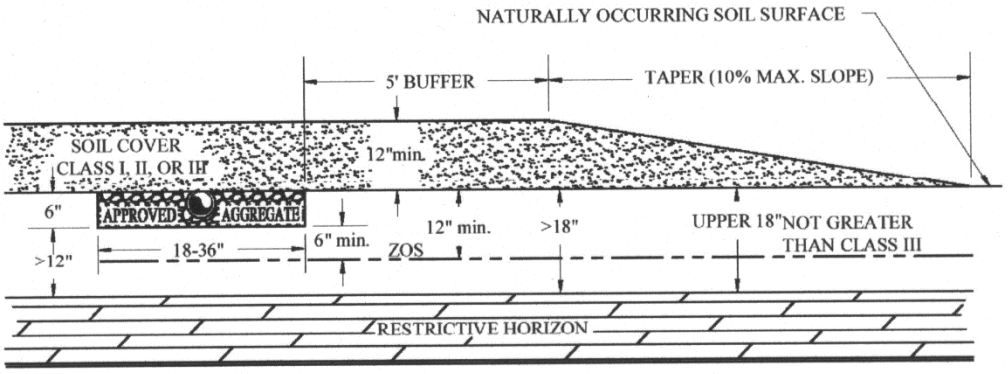
~~(5)~~ (e) Final approval shall be withheld until all landscaping and drainage improvements have been satisfactorily completed.

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
BUREAU OF ENVIRONMENTAL HEALTH

ALTERNATIVE SYSTEM
ULTRA-SHALLOW PLACEMENT SYSTEM WITH FILL CAP

PROGRAM 362 / CODE 240 / CODE 241 IF PUMPED

TYPICAL DESIGN ILLUSTRATION



NOT TO SCALE

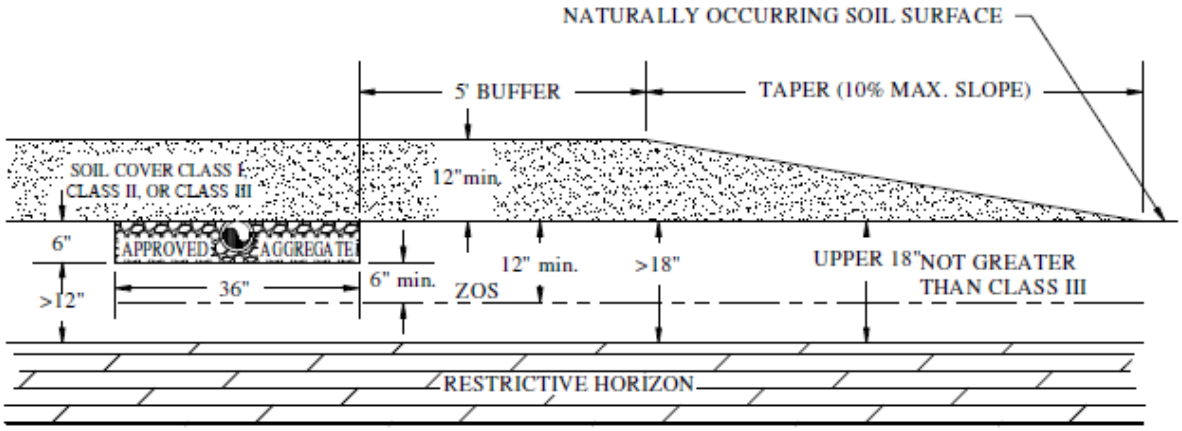
TLS REV. 03/16/07

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
BUREAU OF ENVIRONMENTAL HEALTH SERVICES

ALTERNATIVE STANDARD
ULTRA-SHALLOW PLACEMENT SYSTEM WITH FILL CAP

PROGRAM 362 / CODE 240 / CODE 241 IF PUMPED

TYPICAL DESIGN ILLUSTRATION



NOT TO SCALE

Rev. 03/09/18

406 APPENDIX F – System Standard 250/251 – Reservoir Infiltration System For Soils With Expansive Clay**Appendix G – System Standard 250/251 – Reservoir Infiltration System for Soils with Expansive Clay**

406.1 SITE/PERMITTING REQUIREMENTS (1) Site/Permitting Requirements

(1) (a) Rock formations must be greater than four (4) feet below the naturally occurring soil surface.

(2) (b) For standard installations (see Typical Design Illustration A), the wastewater infiltration trenches must penetrate the saprolite at least six (6) inches. Also, thereThere must be an offset greater than twelve (12) inches between the bottom of the trenches and any rock formations. (i.e., there must be greater than eighteen (18) inches of clean, unconsolidated saprolite below the expansive clay layer.)

(3) (c) If the unconsolidated saprolite layer is greater than sixty (60) inches below the naturally occurring soil surface (see Typical Design Illustration B), item 2.paragraph (1)(b) (above) shall apply and clean medium sand shall be added to the trenches so that the top of the aggregate will be twelve (12) inches below finished grade.

(4) (d) There must be no evidence of a zone of saturation (ZOS) in the unconsolidated saprolite layer.

(5) (e) The Long-Term-Acceptance-Ratelong-term acceptance rate shall not exceed 0.25 gpd/sq. ft.

(6) (f) There shall be a replacement area equivalent to at least fifty (50) percent in size of the original system area held in reserve for system repair. This area shall have a suitable configuration, and shall meet the minimum soil and site conditions of R. 61-56this regulation.

(7) (g) Sites to be considered for this system shall be evaluated using backhoe pits to describe the soil profile.

(8) (h) This system cannot be considered for facilities with peak flow rates in excess of fifteen hundred (1500) gallons per daygpd.

(a) (i) Clean, unconsolidated saprolite shall be defined as: Soft soft, friable, thoroughly decomposed rock that has formed in place by chemical weathering, retaining the fabric and structure of the parent rock, and being devoid of expansive clay. Unconsolidated saprolite can be dug using a hand auger or knife. Consolidated saprolite cannot be penetrated with a hand auger or similar tool, and must be dug with a backhoe or other powered equipment.

(b) (ii) Expansive clay shall be defined as soils containing significant amounts of expansible-layer clay minerals or smectites as evidenced in the field by classifications of Very Sticky and Very Plastic and Structure Grades of Weak or Structureless when evaluated in accordance with the Field Book. Such soils are considered to be unsuitable for onsite wastewater systems.

406.2 INSTALLATION REQUIREMENTS (2) Installation Requirements

(1) (a) The aggregate depth of approved aggregate shall be twenty-four (24) inches.

(2) (b) The depth of medium sand will vary between zero (0) and one hundred twenty (120) inches, depending upon the depth to the saprolite layer.

(3) (c) The trench width shall be thirty-six (36) inches.

~~(4)~~ (d) Where gravity flow from the septic tank to the subsurface wastewater infiltration area is utilized, the invert elevation of the septic tank outlet shall be installed at an elevation at least equal to or higher than the top of the aggregate in the highest wastewater infiltration trench(es).

~~(5)~~ (e) The backfill shall range from twelve (12) inches to thirty-six (36) inches for standard installations (see Typical Design Illustration A)~~,~~ and shall be twelve (12) inches where the depth to saprolite is greater than sixty (60) inches below the naturally occurring soil surface (see Typical Design Illustration B).

~~406.3 FINAL LANDSCAPING AND DRAINAGE~~ (3) Final Landscaping and Drainage

~~(1)~~ (a) On sites where there is evidence of a zone of saturation at the soil-expansive clay interface, a curtain drain must be placed upslope along a contour and must extend the entire length of the subsurface wastewater infiltration area. The curtain drain shall extend a minimum of six (6) inches into the expansive clay layer. The septic tank and subsurface wastewater infiltration area shall be backfilled and shaped to promote surface water runoff.

~~(2)~~ (b) Following final landscaping, seeding or sodding may be required to prevent erosion.

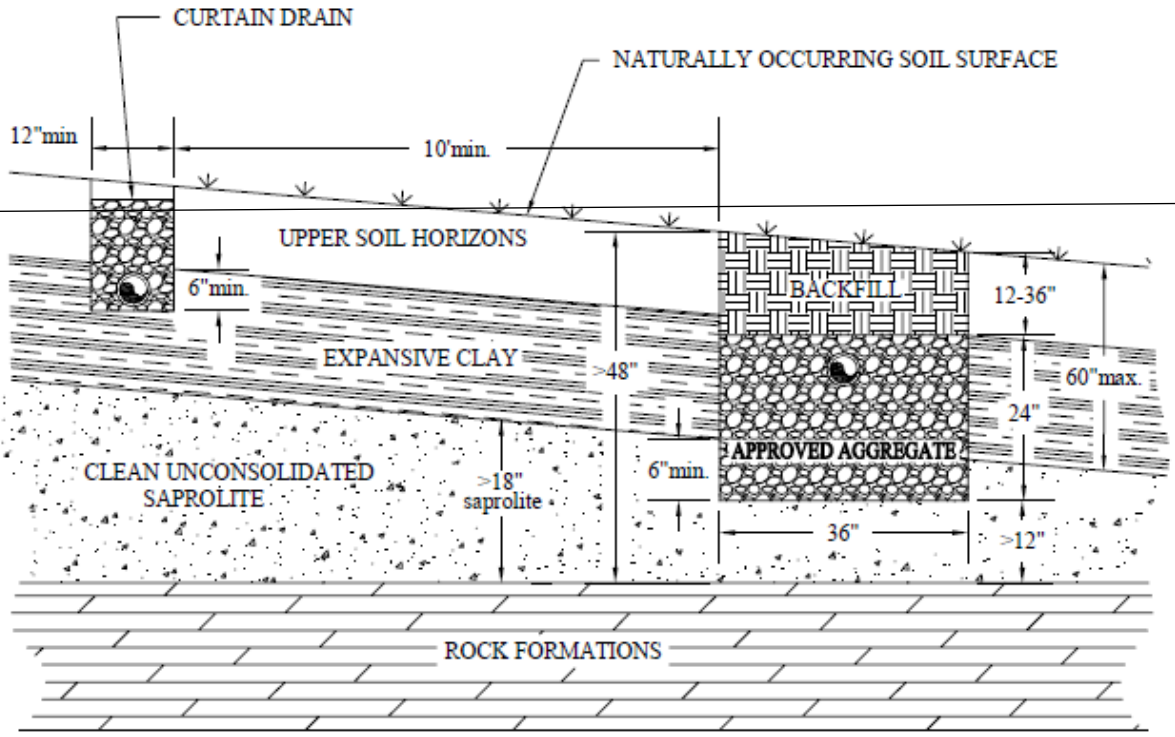
~~(3)~~ (c) Final approval shall be withheld until all landscaping and drainage improvements have been satisfactorily completed.

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
BUREAU OF ENVIRONMENTAL HEALTH

ALTERNATIVE SYSTEM
RESERVOIR INFILTRATION SYSTEM FOR SOILS WITH EXPANSIVE CLAY

PROGRAM 362 / CODE 250 / CODE 251 IF PUMPED

TYPICAL DESIGN ILLUSTRATION (A)
STANDARD INSTALLATION



NOTE: FOR SOILS WITH THICK EXPANSIVE CLAY HORIZONS
(i.e., DEPTH TO SAPROLITE > 60 INCHES BELOW NATURALLY OCCURRING SOIL SURFACE)
SEE TYPICAL DESIGN ILLUSTRATION (B)

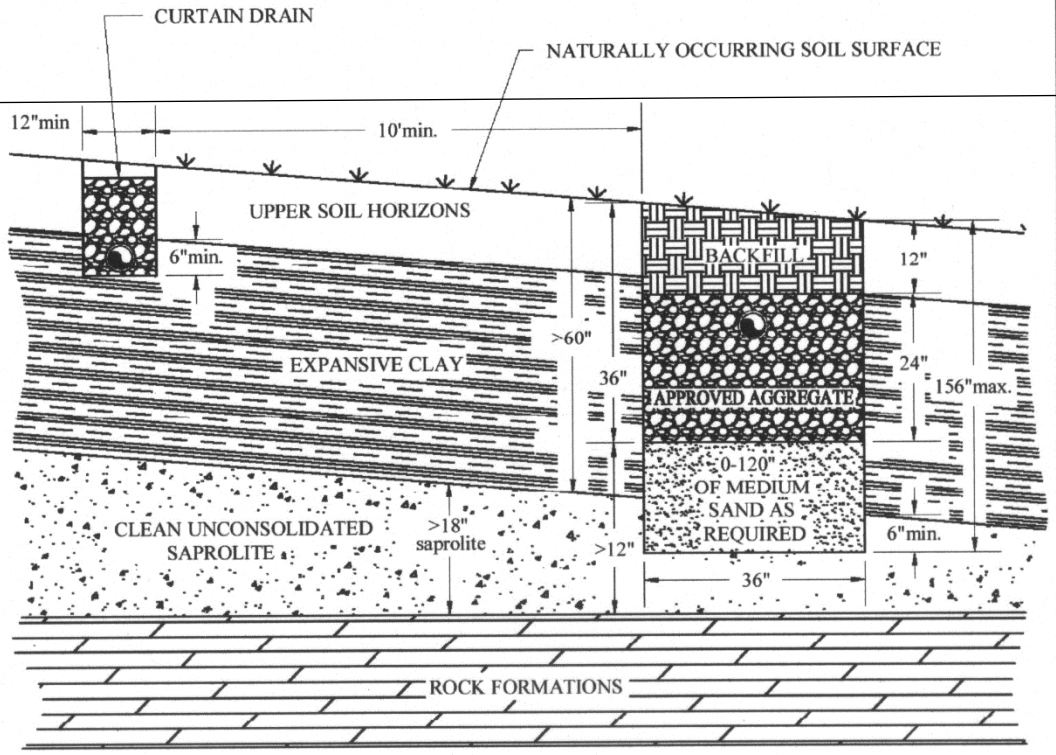
NOT TO SCALE

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
BUREAU OF ENVIRONMENTAL HEALTH

ALTERNATIVE SYSTEM
RESERVOIR INFILTRATION SYSTEM FOR SOILS WITH EXPANSIVE CLAY

PROGRAM 362 / CODE 250 / CODE 251 IF PUMPED

TYPICAL DESIGN ILLUSTRATION (B)
WHERE DEPTH TO SAPROLITE > 60in. BELOW SURFACE



NOTE: FOR SOILS WITH THINNER EXPANSIVE CLAY HORIZONS
(i.e., DEPTH TO SAPROLITE NOT >60in. BELOW NATURALLY OCCURRING SOIL SURFACE)
SEE TYPICAL DESIGN ILLUSTRATION (A)

NOT TO SCALE

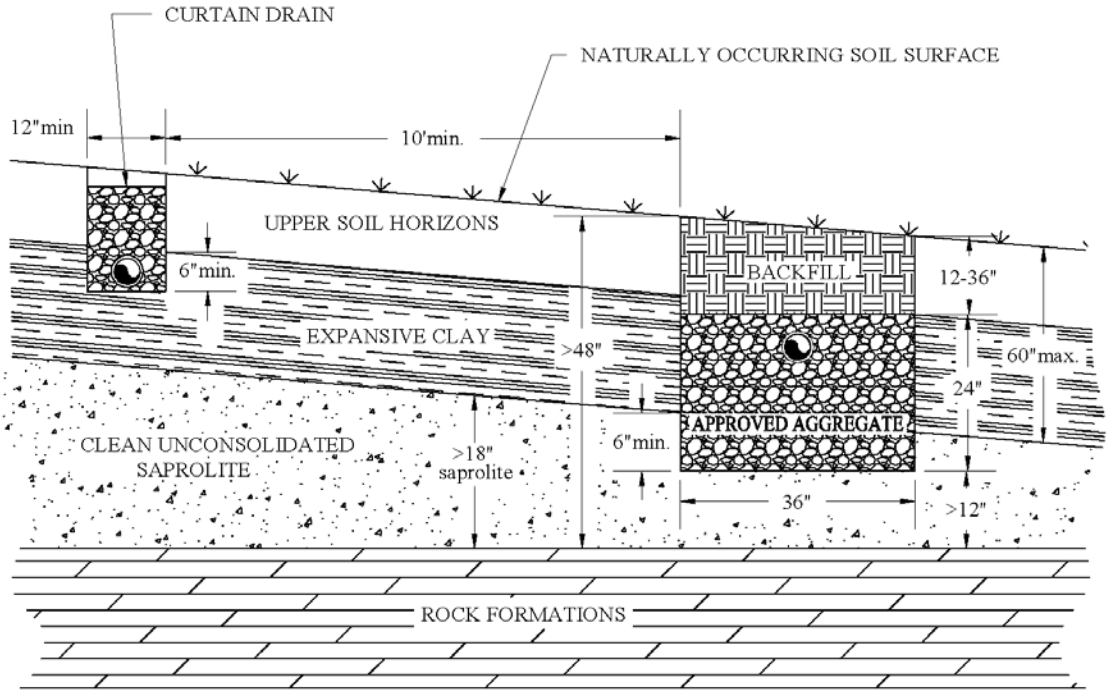
TLS REV. 03/16/07

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
BUREAU OF ENVIRONMENTAL HEALTH SERVICES

ALTERNATIVE SYSTEM
RESERVOIR INFILTRATION SYSTEM FOR SOILS WITH EXPANSIVE CLAY

PROGRAM 362 / CODE 250 / CODE 251 IF PUMPED

TYPICAL DESIGN ILLUSTRATION (A)
STANDARD INSTALLATION



NOTE: FOR SOILS WITH THICK EXPANSIVE CLAY HORIZONS
(i.e., DEPTH TO SAPROLITE > 60 INCHES BELOW NATURALLY OCCURRING SOIL SURFACE)
SEE TYPICAL DESIGN ILLUSTRATION (B)

NOT TO SCALE
REV. 03/09/18

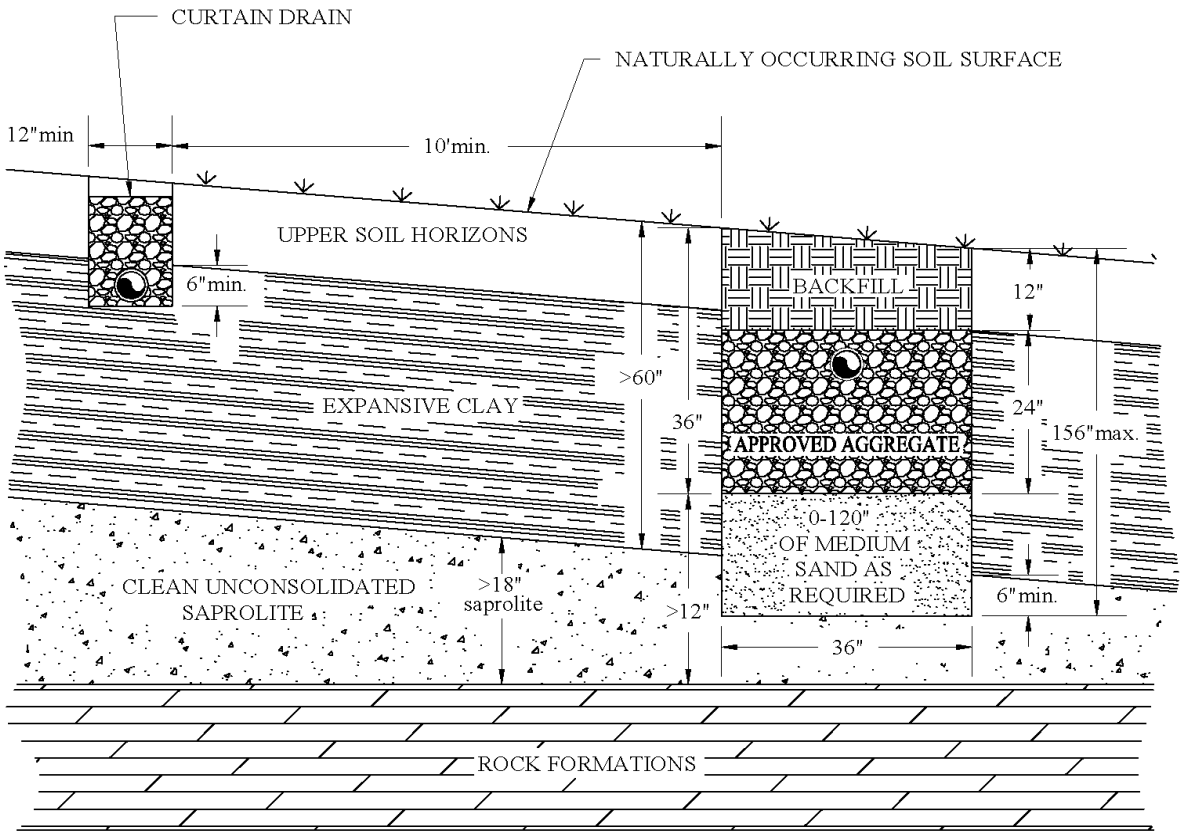
SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
BUREAU OF ENVIRONMENTAL HEALTH SERVICES

ALTERNATIVE SYSTEM
RESERVOIR INFILTRATION SYSTEM FOR SOILS WITH EXPANSIVE CLAY

PROGRAM 362 / CODE 250 / CODE 251 IF PUMPED

TYPICAL DESIGN ILLUSTRATION (B)

WHERE DEPTH TO SAPROLITE > 60in. BELOW SURFACE



NOTE: FOR SOILS WITH THINNER EXPANSIVE CLAY HORIZONS
(i.e., DEPTH TO SAPROLITE NOT >60in. BELOW NATURALLY OCCURRING SOIL SURFACE)
SEE TYPICAL DESIGN ILLUSTRATION (A)

NOT TO SCALE

REV.03/09/18

~~407 APPENDIX G – System Standard 260/261 – 9 INCH Shallow Placement System With Fill Cap~~**Appendix H – System Standard 260/261 – 9-Inch Shallow Placement System with Fill Cap**

~~407.1 SITE/PERMITTING REQUIREMENTS~~ (1) Site/Permitting Requirements

~~(1)~~ (a) There must not be a zone of saturation (ZOS) within fifteen (15) inches of the naturally occurring soil surface.

~~(2)~~ (b) The depth to any restrictive horizon must be greater than twelve (12) inches below the bottom of the proposed wastewater infiltration trenches.

~~(3)~~ (c) The texture in the upper eighteen (18) inches of naturally occurring soil must be no more limiting than Class III.

~~(4)~~ (d) ~~This system must not be utilized on sites that require serial distribution. Level installations on slightly sloping sites can be considered if it can be demonstrated that the entire installation (i.e., side wall to side wall and end to end) will meet the required textural limitations and the required offsets to the zone of saturation and restrictive horizons.~~ This system must not be used on sloping sites that require serial distribution unless it can be demonstrated that the entire wastewater infiltration trench installation (i.e., side wall to side wall and end to end) can meet the required textural limitations and the required offsets to the zone of saturation and restrictive horizons.

~~(5)~~ (e) The ~~Long Term Acceptance Rate~~long-term acceptance rate for system sizing shall be based upon the most hydraulically limiting naturally occurring soil texture from the ground surface to twelve (12) inches below the bottom of the proposed wastewater infiltration trenches.

~~(6)~~ (f) Due to the decreased sidewall absorption area and the increased potential for ground water mounding near the surface, the Equivalency Factors for these systems shall be calculated by conventional wastewater infiltration trenches and increased by an additional factor of 0.09 times.

~~(7)~~ (g) No part of this system can be installed within 125 feet of the critical area line or tidal waters as determined by the Department; or within 125 feet of the ordinary high water elevation within the banks of non-tidal, environmentally sensitive waters.

~~(8)~~ (h) There shall be a replacement area equivalent to at least fifty (50) percent in size of the original system area held in reserve for system repair. This area shall have a suitable configuration~~,~~ and shall meet the minimum soil and site conditions of ~~R. 61-56~~this regulation.

~~(9)~~ (i) This system cannot be considered for facilities with peak flow rates in excess of fifteen hundred (1500) ~~gallons per day~~gpd.

~~407.2 INSTALLATION REQUIREMENTS~~ (2) Installation Requirements

~~(1)~~ (a) The ~~maximum~~ wastewater infiltration trench width ~~must not exceed~~shall be thirty-six (36) inches~~; the minimum width shall be eighteen (18) inches~~.

~~(2)~~ (b) The maximum depth of the bottom of the wastewater infiltration trench shall be nine (9) inches below the naturally occurring soil surface unless it can be demonstrated that deeper placement can meet the required textural limitations and the offsets to the zone of saturation and restrictive horizons.

~~(3)~~ (c) Where gravity flow from the septic tank to the subsurface wastewater infiltration area is utilized, the invert elevation of the septic tank outlet shall be installed at an elevation at least equal to or higher than the top of the aggregate in the highest wastewater infiltration trench(es).

~~(4)~~ (d) The depth of the fill cap shall provide a minimum of twelve (12) inches backfill above the top of the wastewater infiltration trench aggregate ~~(see attached illustration)~~.

~~(5)~~ (e) The required fill cap must extend at least five (5) feet beyond the limits of the wastewater infiltration trenches~~,~~ and must taper to the original soil surface at a slope not to exceed 10 percent (see attached illustration). On sloping sites where serial distribution has been incorporated into the system design, on the lower side and ends of the wastewater infiltration trenches, the fill cap must extend to at least ten (10) feet beyond the limits of the wastewater infiltration trenches and must taper to the original soil surface at a slope not to exceed five (5) percent. The required property line setback shall be measured from the point at which the fill cap taper intersects with the naturally occurring soil surface. The fill cap must be installed prior to beginning trench installation when required on the construction permit.

~~(6)~~ (f) The required fill material must be soil texture Class I, Class II, or Class III, and be devoid of extraneous debris such as organic matter, building materials, etc.

~~(7)~~ (g) The wastewater infiltration trench aggregate shall be nine (9) inches in depth.

~~(8)~~ (h) All trees/brush removal shall be done in a manner that minimizes the disturbance or loss of naturally occurring soil.

~~407.3 FINAL LANDSCAPING AND DRAINAGE~~ (3) Final Landscaping and Drainage

~~(1)~~ (a) The septic tank and fill cap area shall be backfilled and shaped to promote the runoff of surface water.

~~(2)~~ (b) Where natural surface drainage does not exist, a swale shall be constructed adjacent to the fill cap area to divert surface water away from the onsite wastewater system to a positive outfall. The installation of ditches, curtain drains, and rain gutters may be required to intercept and divert water away from the onsite wastewater system location.

~~(3)~~ (c) A barrier to preclude parking and vehicular traffic over the system area may be required.

~~(4)~~ (d) Following final landscaping, seeding or sodding may be required to prevent erosion.

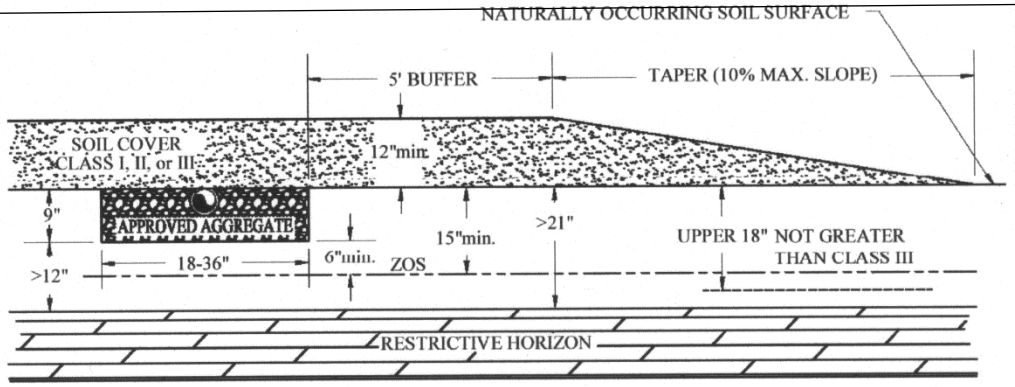
~~(5)~~ (e) Final approval shall be withheld until all landscaping and drainage improvements have been satisfactorily completed.

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
BUREAU OF ENVIRONMENTAL HEALTH

ALTERNATIVE SYSTEM
NINE INCH SHALLOW PLACEMENT WITH FILL CAP

PROGRAM 362 / CODE 260 / CODE 261 IF PUMPED

TYPICAL DESIGN ILLUSTRATION



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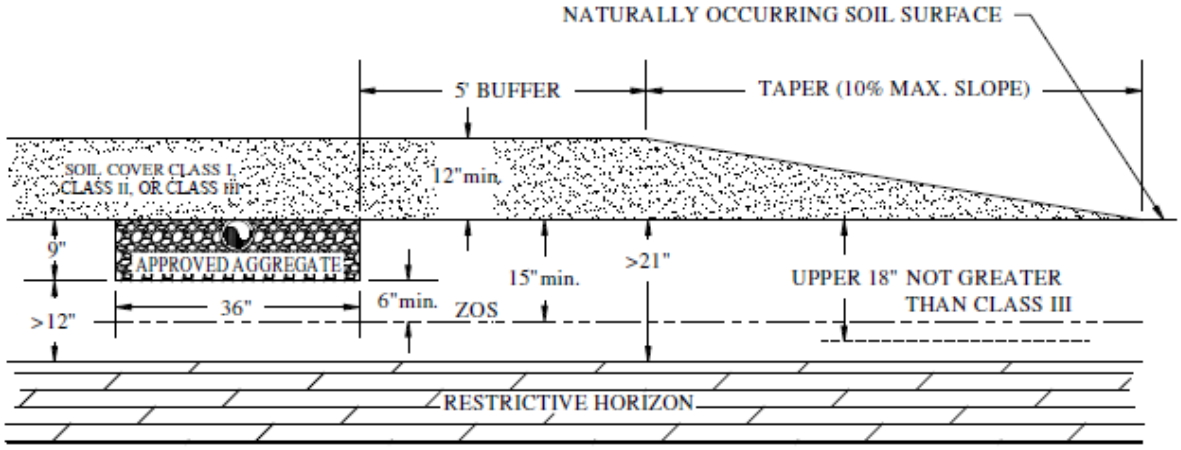
SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
BUREAU OF ENVIRONMENTAL HEALTH SERVICES

ALTERNATIVE STANDARD
NINE INCH SHALLOW PLACEMENT WITH FILL CAP

PROGRAM 362 / CODE 260 / CODE 261 IF PUMPED

TYPICAL DESIGN ILLUSTRATION



NOT TO SCALE

Rev. 03/09/18

~~408 APPENDIX H – SYSTEM STANDARD 270/271 – ALTERNATIVE TRENCH WIDTH AND DEPTH SYSTEMS~~**Appendix I – System Standard 270/271 – Alternative Trench Width and Depth Systems**

~~408.1 SITE/PERMITTING REQUIREMENTS~~ (1) Site/Permitting Requirements

~~(1) Lot size or suitable area must be too small to accommodate a conventional or alternative onsite wastewater system.~~

~~(2) This Standard and associated systems shall not be used to calculate minimum lot sizes in new subdivisions approved after the effective date of this standard.~~

~~(3)~~ (a) Soil conditions, the depth to rock and other restrictive horizons, the depth to the zone of saturation (ZOS), and the elevation differential between the septic tank outlet and the highest wastewater infiltration trench(es) must meet applicable standards for conventional or alternative onsite wastewater systems.

~~(4)~~ (b) There shall be a replacement area equivalent to at least fifty (50) percent in size of the original system area held in reserve for system repair. This area shall have a suitable configuration~~,~~ and shall meet the minimum soil and site conditions of ~~R. 61-56~~this regulation.

~~(5)~~ (c) This system cannot be considered for facilities with peak flow rates in excess of fifteen hundred (1500) ~~gallons per day~~gpd unless the trench width is three (3) feet and the aggregate depth is between fourteen (14) and twenty-eight (28) inches.

~~(6)~~ (d) The linear footage requirement for an alternative width and depth system shall be determined by first figuring the conventional (thirty-six (36) inch wide with fourteen (14) inch aggregate depth) linear footage requirements and then multiplying by the appropriate factor based on desired trench width and aggregate depth. (See table below system illustration for multiplication factors.)

~~**FACTORS (F) FOR MAINTAINING EQUIVALENT INFILTRATIVE SURFACE AREA**~~						
~~**TRENCH WIDTH (ft.)**~~	~~**AGGREGATE DEPTH (in.)**~~					
~~XXXXXXX~~	~~**6" ***~~	~~**9" ****~~	~~**14"**~~	~~**20"**~~	~~**24"**~~	~~**28"**~~
~~**1.5'**~~	~~2.39~~	~~1.94~~	~~1.39~~	~~1.10~~	~~0.97~~	~~0.87~~
~~**2.0'**~~	~~1.99~~	~~1.66~~	~~1.23~~	~~1.00~~	~~0.89~~	~~0.80~~
~~**2.5'**~~	~~1.71~~	~~1.46~~	~~1.10~~	~~0.91~~	~~0.82~~	~~0.75~~
~~**3'**~~	~~1.50~~	~~1.30~~	~~1.00~~	~~0.84~~	~~0.76~~	~~0.70***~~
~~**4'**~~	~~1.20~~	~~1.06~~	~~0.84~~	~~0.73~~	~~0.67~~	~~0.62~~
~~**5'**~~	~~1.00~~	~~0.89~~	~~0.73~~	~~0.64~~	~~0.59~~	~~0.55~~
~~**6'**~~	~~0.85~~	~~0.78~~	~~0.64~~	~~0.57~~	~~0.53~~	~~0.50~~
~~**7'**~~	~~0.74~~	~~0.68~~	~~0.57~~	~~0.52~~	~~0.49~~	~~0.46~~
~~**8'**~~	~~0.66~~	~~0.61~~	~~0.52~~	~~0.47~~	~~0.45~~	~~0.42~~
~~**9'**~~	~~0.59~~	~~0.55~~	~~0.47~~	~~0.43~~	~~0.41~~	~~0.39~~
~~**10'**~~	~~0.54~~	~~0.51~~	~~0.43~~	~~0.40~~	~~0.38~~	~~0.36~~

~~FACTORS (F) FOR MAINTAINING EQUIVALENT INFILTRATIVE SURFACE AREA~~						
~~TRENCH WIDTH (ft.)~~	~~AGGREGATE DEPTH (in.)~~					
~~XXXXXXX X~~	~~6" *~~	~~9" **~~	~~14"~~	~~20"~~	~~24"~~	~~28"~~
~~F = 5.34 ft²/ ft~~ ~~2 (SwD / 12) + TW~~ ~~* Factors reflect a 12 percent increase~~ ~~** Factors reflect a 9 percent increase~~ ~~*** Use system code 360/380~~	~~Where, 5.34 ft²/ft = total infiltrative surface area per linear foot of conventional type trench 36 in. wide, 14 in. deep~~ ~~SwD = Side Wall Depth (in.)~~ ~~TW = Trench Width (ft)~~					

~~408.2~~ ~~INSTALLATION REQUIREMENTS~~ (2) Installation Requirements

~~(1)~~ (a) Trench widths ~~shall always be kept as narrow as possible and~~ shall not exceed ten (10) feet.

~~(2)~~ (b) The aggregate depth shall be between six (6) inches and twenty-eight (28) inches when considering trench widths ranging from one and one-half (1½) to ten (10) feet (see chart). The aggregate depth may be increased to a maximum of forty-two (42) inches, provided the trench width does not exceed thirty-six (36) inches (Note: ~~in~~ In these cases, the equivalency formula should be utilized to determine the appropriate factor (F) when considering aggregate depths between twenty-eight (28) and forty-two (42) inches). All trenches shall be covered with at least nine (9) inches of backfill.

~~(3)~~ (c) Methods of construction which preclude vehicular compaction of the trench bottom must always be utilized.

~~408.3~~ ~~FINAL LANDSCAPING AND DRAINAGE~~ (3) Final Landscaping and Drainage

~~(1)~~ (a) Installation of drainage swales, ditches, diversion drains, or rain gutters may be required to divert or intercept water away from the onsite wastewater system location. The septic tank and subsurface wastewater infiltration area shall be backfilled and shaped to promote surface water runoff.

~~(2)~~ (b) A barrier to preclude parking and vehicular traffic over the area of the system may be required.

~~(3)~~ (c) Following final landscaping, seeding or sodding may be required to prevent erosion.

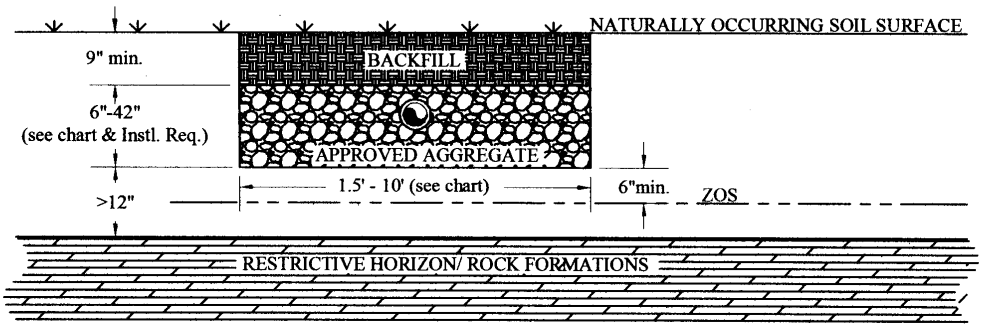
~~(4)~~ (d) Final approval shall be withheld until all landscaping and drainage improvements have been satisfactorily completed.

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
BUREAU OF ENVIRONMENTAL HEALTH

ALTERNATIVE SYSTEM
ALTERNATIVE TRENCH WIDTH & DEPTH SYSTEMS

PROGRAM 362 / CODE 270 / CODE 271 IF PUMPED

TYPICAL DESIGN ILLUSTRATION



NOT TO SCALE

FACTORS (F) FOR MAINTAINING EQUIVALENT INFILTRATIVE SURFACE AREA

TRENCH WIDTH (ft.)	AGGREGATE DEPTH (in.)					
	6" *	9" **	14"	20"	24"	28"
1.5'	2.39	1.94	1.39	1.10	0.97	0.87
2.0'	1.99	1.66	1.23	1.00	0.89	0.80
2.5'	1.71	1.46	1.10	0.91	0.82	0.75
3.0'	1.50	1.30	1.00	0.84	0.76	0.70***
4.0'	1.20	1.06	0.84	0.73	0.67	0.62
5.0'	1.00	0.89	0.73	0.64	0.59	0.55
6.0'	0.85	0.78	0.64	0.57	0.53	0.50
7.0'	0.74	0.68	0.57	0.52	0.49	0.46
8.0'	0.66	0.61	0.52	0.47	0.45	0.42
9.0'	0.59	0.55	0.47	0.43	0.41	0.39
10.0'	0.54	0.51	0.43	0.40	0.38	0.36

$$F = \frac{5.34 \text{ sqft.} / \text{ft}}{2\,(\text{SwD} / 12) + \text{TW}}$$

* Factors (F) reflect 12% increase
** Factors (F) reflect 9% increase
*** Use system code 360/380
(See notes in text)

Where, 5.34 sqft/ft = total infiltrative surface area per linear foot of conventional type trench (36in. wide, 14in. deep)
SwD = Side Wall Depth (in)
TW = Trench Width (ft.)

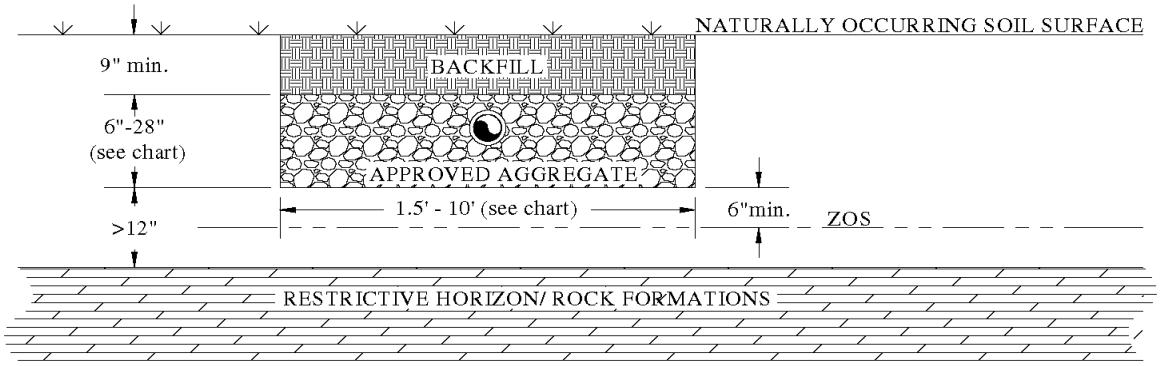
TLS REV. 05/15/07

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
BUREAU OF ENVIRONMENTAL HEALTH SERVICES

ALTERNATIVE STANDARD
ALTERNATIVE TRENCH WIDTH & DEPTH SYSTEMS

PROGRAM 362 / CODE 270 / CODE 271 IF PUMPED

TYPICAL DESIGN ILLUSTRATION



NOT TO SCALE

FACTORS (F) FOR MAINTAINING EQUIVALENT INFILTRATIVE SURFACE AREA

TRENCH WIDTH (ft.)	AGGREGATE DEPTH (in.)					
	6" *	9" **	14"	20"	24"	28"
1.5'	2.39	1.94	USE LTAR STANDRARD	1.10	0.97	0.87
2.0'	1.99	1.66	USE LTAR STANDARD	1.00	0.89	0.80
2.5'	1.71	1.46	USE LTAR STANDARD	0.91	0.82	0.75
3.0'	1.50	1.30	USE LTAR STANDARD	0.84	0.76	0.70 see system 360/380
4.0'	1.20	1.06	0.84	0.73	0.67	0.62
5.0'	1.00	0.89	0.73	0.64	0.59	0.55
6.0'	0.85	0.78	0.64	0.57	0.53	0.50
7.0'	0.74	0.68	0.57	0.52	0.49	0.46
8.0'	0.66	0.61	0.52	0.47	0.45	0.42
9.0'	0.59	0.55	0.47	0.43	0.41	0.39
10.0'	0.54	0.51	0.43	0.40	0.38	0.36

$$F = \frac{5.33 \text{ sqft.} / \text{ft}}{2 (SwD / 12) + TW}$$

* Factors (F) reflect 12% increase
** Factors (F) reflect 9% increase
(See notes in text)

Where, 5.33 sqft/ft = total infiltrative surface area per linear foot of conventional type trench (36in. wide, 14in. deep)
SwD = Side Wall Depth (in)
TW = Trench Width (ft.)

REV. 03/09/2018

~~409 APPENDIX I – SYSTEM STANDARD 280/281 – RESERVOIR INFILTRATION SYSTEM FOR SOILS WITH EXPANSIVE CLAY SHALLOW ROCK FORMATIONS~~**Appendix J – System Standard 280/281 – Reservoir Infiltration System for Soils with Expansive Clay Shallow Rock Formations**

~~409.1 SITE/PERMITTING REQUIREMENTS~~ (1) Site/Permitting Requirements

~~(1)~~ (a) Rock formations must be rippable ~~(see Section 409.1(9)(b))~~ to a depth greater than four (4) feet below the naturally occurring soil surface.

~~(2)~~ (b) The soil wastewater infiltration trenches must penetrate the saprolite at least six (6) inches, and there must be an offset greater than twelve (12) inches between the trench bottoms and any rock formations (i.e., there must be at least six (6) inches of clean, unconsolidated saprolite below the expansive clay layer, and medium sand may be added to the excavation to achieve an offset from rock that exceeds twelve (12) inches).

~~(3)~~ (c) There must be no evidence of a zone of saturation (ZOS) in the unconsolidated saprolite layer.

~~(4)~~ (d) The ~~Long-Term Acceptance Rate~~long-term acceptance rate shall not exceed 0.20-gpd/sqft.

~~(5)~~ (e) Effluent discharged to this system must receive a higher degree of treatment than that provided by a conventional septic tank~~.~~ (~~i.e.,~~ e.g., two (2) compartment septic tank or two (2) septic tanks in series).

~~(6)~~ (f) There shall be a replacement area equivalent to at least fifty (50) percent in size of the original system area held in reserve for system repair. This area shall have a suitable configuration~~,~~ and shall meet the minimum soil and site conditions of ~~R. 61-56~~this regulation.

~~(7)~~ (g) No part of this system can be installed within one hundred twenty-five (125) feet of the ordinary high water elevation within the banks of environmentally sensitive waters.

~~(8)~~ (h) Sites to be considered for this system shall be evaluated using backhoe pits to describe the soil profile.

~~(9)~~ (i) This system cannot be considered for facilities with peak flow rates in excess of fifteen hundred (1500) ~~gallons per day~~gpd.

~~(a)~~ (i) Clean, unconsolidated saprolite shall be defined as~~: Soft~~ soft, friable, thoroughly decomposed rock that has formed in place by chemical weathering, retaining the fabric and structure of the parent rock, and being devoid of expansive clay. Unconsolidated saprolite can be dug using a hand auger or knife. Consolidated saprolite cannot be penetrated with a hand auger or similar tool, and must be dug with a backhoe or other powered equipment.

~~(b) Rippable rock shall be defined as formations that can be readily dug with a standard rubber-tired backhoe.~~

~~(c)~~ (ii) Expansive clay shall be defined as soils containing significant amounts of expansible-layer clay minerals (smectites) as evidenced in the field by classifications of Very Sticky and Very Plastic and Structure Grades of Weak or Structureless when evaluated in accordance with the Field Books. Such soils are considered to be unsuitable for onsite wastewater systems.

~~409.2 INSTALLATION REQUIREMENTS~~ (2) Installation Requirements

~~(1)~~ (a) The ~~aggregate~~ depth of approved aggregate shall be at least twenty-four (24) inches.

~~(2)~~ (b) The trench width shall be thirty-six (36) inches.

~~(3)~~ (c) Where gravity flow from the septic tank to the subsurface wastewater infiltration area is utilized, the invert elevation of the septic tank outlet shall be installed at an elevation at least equal to or higher than the top of the aggregate in the highest wastewater infiltration trench(es).

~~409.3 FINAL LANDSCAPING AND DRAINAGE~~ (3) Final Landscaping and Drainage

~~(1)~~ (a) On sites where there is evidence of a zone of saturation at the soil-expansive clay interface, a curtain drain must be placed upslope along a contour and must extend the entire length of the subsurface wastewater infiltration area. The curtain drain shall extend a minimum of six (6) inches into the expansive clay layer. ~~Also, the~~ The septic tank and subsurface wastewater infiltration area shall be backfilled and shaped to promote surface water runoff.

~~(2)~~ (b) Final approval shall be withheld until all landscaping, drainage, and other requirements have been satisfactorily completed.

~~(3)~~ (c) Following final landscaping, seeding or sodding may be required to prevent erosion.

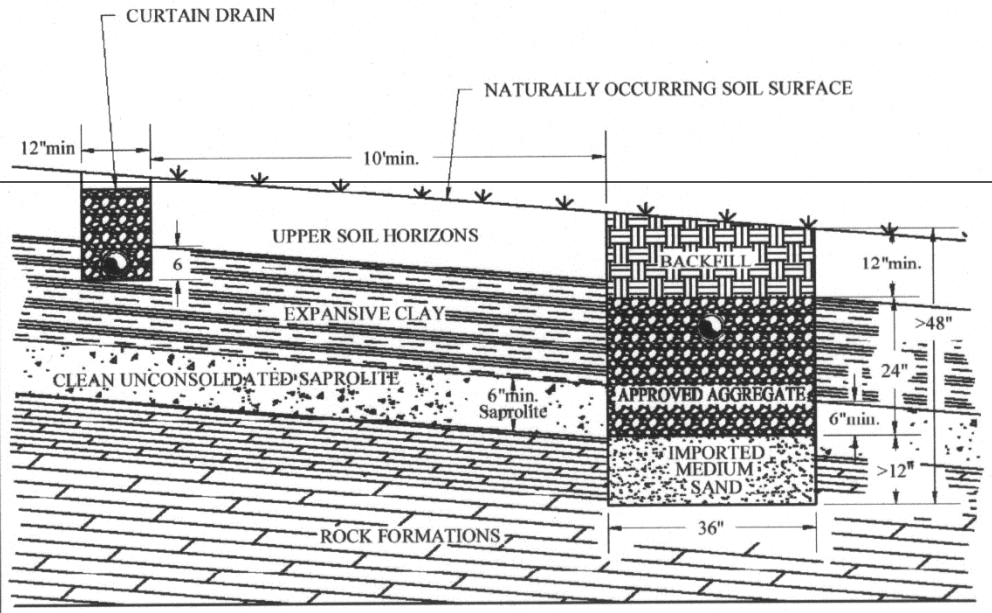
~~(4)~~ (d) Final approval shall be withheld until all landscaping and drainage improvements have been satisfactorily completed.

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
BUREAU OF ENVIRONMENTAL HEALTH

ALTERNATIVE SYSTEM
RESERVOIR INFILTRATION SYSTEM FOR SOILS WITH EXPANSIVE CLAY
OVER SHALLOW ROCK FORMATIONS

PROGRAM 362 / CODE 280 / CODE 281 IF PUMPED

TYPICAL DESIGN ILLUSTRATION



NOT TO SCALE

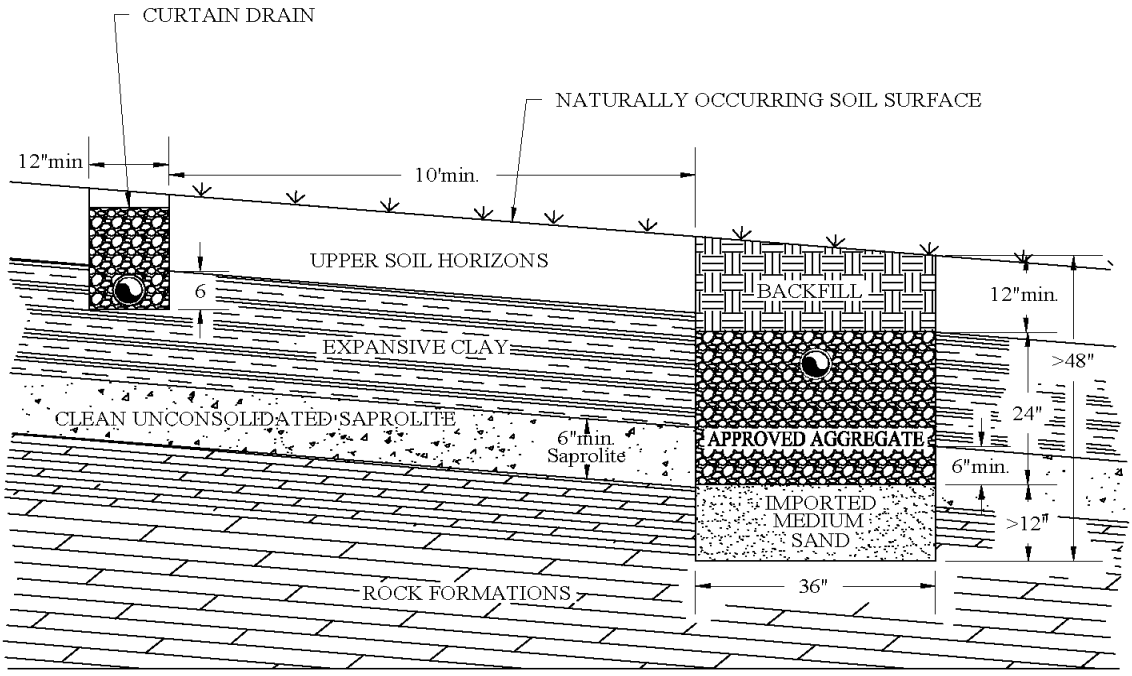
TLS REV 05/10/07

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
BUREAU OF ENVIRONMENTAL HEALTH SERVICES

ALTERNATIVE SYSTEM
RESERVOIR INFILTRATION SYSTEM FOR SOILS WITH EXPANSIVE CLAY
OVER SHALLOW ROCK FORMATIONS

PROGRAM 362 / CODE 280 / CODE 281 IF PUMPED

TYPICAL DESIGN ILLUSTRATION



NOT TO SCALE
REV. 03/09/19

Appendix K – System Standard 290/291 – Alternative Trench Width and Depth Systems with Fill Cap

(1) Site/Permitting Requirements

(a) The depth to any restrictive horizon must be greater than twelve (12) inches below the bottom of the proposed wastewater infiltration trenches.

(b) The texture in the upper eighteen (18) inches of naturally occurring soil must be no more limiting than Class III.

(c) Soil conditions, the depth to rock and other restrictive horizons, the depth to the zone of saturation (ZOS), and the elevation differential between the septic tank outlet and the highest wastewater infiltration trench(es) must meet applicable standards for alternative onsite wastewater systems.

(d) There shall be a replacement area equivalent to at least fifty (50) percent in size of the original system area held in reserve for system repair. This area shall have a suitable configuration and shall meet the minimum soil and site conditions of this regulation.

(e) This system cannot be considered for facilities with peak flow rates in excess of six hundred (600) gpd.

(f) The linear footage requirement for an alternative width and depth system shall be determined by first figuring the conventional (36-inch-wide with 14-inch aggregate depth) linear footage requirements and then multiplying by the appropriate factor based on desired trench width and aggregate depth as computed in the following table:

FACTOR (F) FOR MAINTAINING EQUIVALENT INFILTRATIVE SURFACE AREA			
TRENCH WIDTH (ft.)	**AGGREGATE DEPTH (in.)**		
	6" *	**9" ****	**# OF DISTRIBUTION PIPES**
	MULTIPLICATION FACTOR		
4'	1.20	1.06	1
5'	1.00	0.89	1
6'	0.85	0.78	2
7'	0.74	0.68	2
8'	0.66	0.61	2
9'	0.59	0.55	3
10'	0.54	0.51	3
* Factors reflect a twelve (12) percent increase ** Factors reflect a nine (9) percent increase			

(g) This system may only be installed on sites where the long-term acceptance rate (LTAR) for the system will be between 1.0 and 0.5 gpd per foot squared (gpd/ft^2). The bottom of the absorption field cannot be installed in Class IV soils (0.4 to 0.1 LTAR).

(h) The distribution pipes in the bed shall be at least eighteen (18) inches from the edge of the trench and located on three (3) foot centers.

(i) This system must not be used on sloping sites that require serial distribution unless it can be demonstrated that the entire wastewater infiltration trench installation (i.e., side wall to side wall and end to end) can meet the required textural limitations and the required offsets to the zone of saturation and restrictive horizons.

(j) The long-term acceptance rate for system sizing shall be based upon the most hydraulically limiting naturally occurring soil texture from the ground surface to twelve (12) inches below the bottom of the proposed wastewater infiltration trenches.

(2) Installation Requirements

(a) Trench widths shall not exceed ten (10) feet.

(b) Wide trenches should be installed by excavating from the sides. Heavy equipment, such as backhoes, may not be placed in the trenches in order to avoid soil compaction.

(c) The required fill cap must extend at least five (5) feet beyond the limits of the wastewater infiltration trenches and must taper to the original soil surface at a slope not to exceed ten (10) percent. On sloping sites, where serial distribution has been incorporated into the system design, on the lower side and ends of the wastewater infiltration trenches, the fill cap must extend to at least ten (10) feet beyond the limits of the wastewater infiltration trenches and must taper to the original soil surface at a slope not to exceed five (5) percent. The required property line setback shall be measured from the point at which the fill cap taper intersects with the naturally occurring soil surface. The fill cap must be installed prior to beginning trench installation when required on the construction permit.

(3) Final Landscaping and Drainage

(a) Installation of drainage swales, ditches, diversion drains, or rain gutters may be required to divert or intercept water away from the onsite wastewater system location. The septic tank and subsurface wastewater infiltration area shall be backfilled and shaped to promote surface water runoff.

(b) A barrier to preclude parking and vehicular traffic over the area of the system may be required.

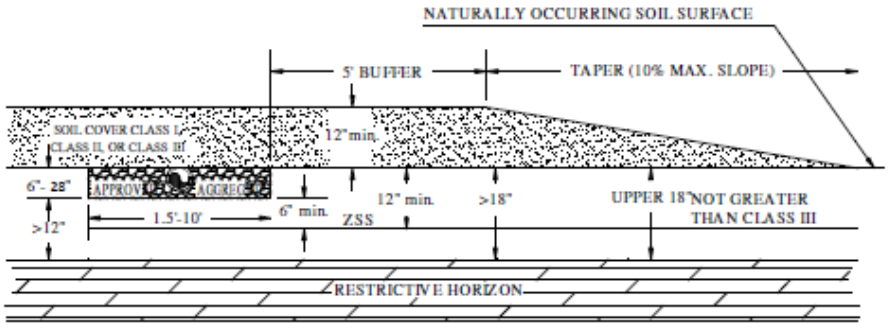
(c) Following final landscaping, seeding, or sodding may be required to prevent erosion.

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
BUREAU OF ENVIRONMENTAL HEALTH SERVICES

ALTERNATIVE STANDARD
ALTERNATIVE TRENCH WIDTH & DEPTH SYSTEMS

PROGRAM 362 / CODE 290 / CODE 291 IF PUMPED

TYPICAL DESIGN ILLUSTRATION



NOT TO SCALE

FACTORS (F) FOR MAINTAINING EQUIVALENT INFILTRATIVE SURFACE AREA

TRENCH WIDTH (ft.)	AGGREGATE DEPTH (in.)					
	6" *	9" **	14"	20"	24"	28"
1.5'	2.39	1.94	USE LTAR STANDRARD	1.10	0.97	0.87
2.0'	1.99	1.66	USE LTAR STANDARD	1.00	0.89	0.80
2.5'	1.71	1.46	USE LTAR STANDARD	0.91	0.82	0.75
3.0'	1.50	1.30	USE LTAR STANDARD	0.84	0.76	0.70 see system 360/380
4.0'	1.20	1.06	0.84	0.73	0.67	0.62
5.0'	1.00	0.89	0.73	0.64	0.59	0.55
6.0'	0.85	0.78	0.64	0.57	0.53	0.50
7.0'	0.74	0.68	0.57	0.52	0.49	0.46
8.0'	0.66	0.61	0.52	0.47	0.45	0.42
9.0'	0.59	0.55	0.47	0.43	0.41	0.39
10.0'	0.54	0.51	0.43	0.40	0.38	0.36

$$F = \frac{5.33 \text{ sqft. / ft}}{2\,(SwD / 12) + TW}$$

* Factors (F) reflect 12% increase
** Factors (F) reflect 9% increase
(See notes in text)

Where, 5.33 sqft/ft = total infiltrative surface area per linear foot of conventional type trench (36in. wide, 14in. deep)
SwD = Side Wall Depth (in)
TW = Trench Width (ft.)

Rev. 03/09/18

~~410 APPENDIX J – SYSTEM STANDARD 370/371 – SHALLOW PLACEMENT WITH FILL CAP FOR SITES WITH SHALLOW CLASS IV SOIL~~**Appendix L – System Standard 370/371 – Shallow Placement with Fill Cap for Sites with Shallow Class IV Soil**

~~410.1 SITE/PERMITTING REQUIREMENTS~~ (1) Site/Permitting Requirements

~~(1)~~ (a) There must not be a zone of saturation (ZOS) within twelve (12) inches of the naturally occurring soil surface.

~~(2)~~ (b) The depth to any restrictive horizon must be greater than twelve (12) inches below the bottom of the proposed wastewater infiltration trenches.

~~(3) This system must not be utilized on sites that require serial distribution. Level installations on slightly sloping sites can be considered if it can be demonstrated that the entire installation (i.e., side wall to side wall and end to end) will meet the required textural limitations and the required offsets to the zone of saturation and restrictive horizons.~~

~~(4)~~ (c) No part of this system can be installed within one hundred twenty-five (125) feet of the ordinary high water elevation within the banks of environmentally sensitive waters.

~~(5)~~ (d) This system may be considered for installation on contiguous lots in new subdivisions approved after the effective date of this standard provided a setback of at least seventy-five (75) feet is maintained between the system and all adjacent property lines. The seventy-five (75) foot setback shall be measured from the point at which the fill cap taper intersects with the naturally occurring soil surface.

~~(6)~~ (e) This system cannot be considered for facilities with peak sewage flow rates in excess of four hundred eighty (480) ~~gallons per day~~gpd. In addition, this system shall not be considered for facilities requiring grease traps.

~~(7)~~ (f) There shall be a replacement area equivalent to at least fifty (50) percent in size of the original system area held in reserve for system repair. This area shall have a suitable configuration~~,~~ and shall meet the minimum soil and site conditions of ~~R. 61-56~~this regulation.

~~(8)~~ (g) The ~~Long-Term Acceptance Rate~~long-term acceptance rate for system sizing shall be based upon the most hydraulically limiting naturally occurring soil texture from the ground surface to twelve (12) inches below the bottom of the proposed wastewater infiltration trenches.

~~410.2 INSTALLATION REQUIREMENTS~~ (2) Installation Requirements

~~(1) This system cannot utilize serial distribution.~~

~~(2)~~ (a) Effluent discharged to this system must receive a higher degree of treatment than that provided by a conventional septic tank (~~i.e.,~~e.g. two (2) compartment septic tank or two (2) septic tanks in series).

~~(3)~~ (b) Where gravity flow from the septic tank to the subsurface wastewater infiltration area is utilized, the invert elevation of the septic tank outlet shall be installed at an elevation at least equal to or higher than the top of the aggregate in the highest wastewater infiltration trench(es).

~~(4)~~ (c) The required fill cap must extend at least five (5) feet beyond the limits of the wastewater infiltration trenches, and it must taper to the original soil surface at a slope not to exceed ten (10) percent

~~(see attached sketch)~~. The required seventy-five (75) ~~feet~~foot property line setback shall be measured from the point at which the fill cap taper intersects with the naturally occurring soil surface.

~~(5)~~ (d) The required fill material must be soil texture Class I, Class II, or Class III and be void of extraneous debris such as organic matter, building materials, etc.

~~(6)~~ (e) The depth of the fill cap shall provide a minimum of twelve (12) inches backfill above the top of the wastewater infiltration trench aggregate.

~~(7)~~ (f) The wastewater infiltration trench width shall be thirty-six (36) inches**.**

~~(8)~~ (g) All tree and brush removal shall be done in a manner that minimizes the disturbance or loss of naturally occurring soil.

~~(9) The following criteria shall be utilized in the selection and design of these systems:~~

~~**Depth to ZOS (Inches)**~~	~~**Depth to Class IV Soil (Inches)**~~	~~**Amount of Imported Fill Cap/Aggregate Depth (Inches)**~~	~~**Extension Factor**~~
~~12~~	~~18~~	~~12/6~~	~~1.5~~
~~13~~	~~17~~	~~12/6~~	~~1.5~~
~~14~~	~~16~~	~~12/6~~	~~1.5~~
~~15~~	~~15~~	~~12/9~~	~~1.3~~
~~16~~	~~14~~	~~12/9~~	~~1.3~~
~~17~~	~~13~~	~~12/9~~	~~1.3~~
~~18~~	~~12~~	~~12/9~~	~~1.3~~
~~19~~	~~11~~	~~12/9~~	~~1.3~~
~~20~~	~~10~~	~~12/9~~	~~1.3~~

~~Note: refer to the design sketch (typical) for detail.~~

~~410.3 FINAL LANDSCAPING AND DRAINAGE~~ (3) Final Landscaping and Drainage

~~(1)~~ (a) The septic tank and fill cap area shall be backfilled and shaped to promote the runoff of surface water.

~~(2)~~ (b) Where natural surface drainage does not exist, a swale shall be constructed adjacent to the filled area to divert surface water away from the onsite wastewater system to a positive outfall. The installation of ditches, curtain drains, and rain gutters may be required to intercept and divert water away from the onsite wastewater system location.

~~(3)~~ (c) A barrier to preclude parking and vehicular traffic over the system area may be required.

~~(4)~~ (d) Following final landscaping, seeding or sodding may be required to prevent erosion.

~~(5)~~ (e) Final approval shall be withheld until all landscaping and drainage improvements have been satisfactorily completed.

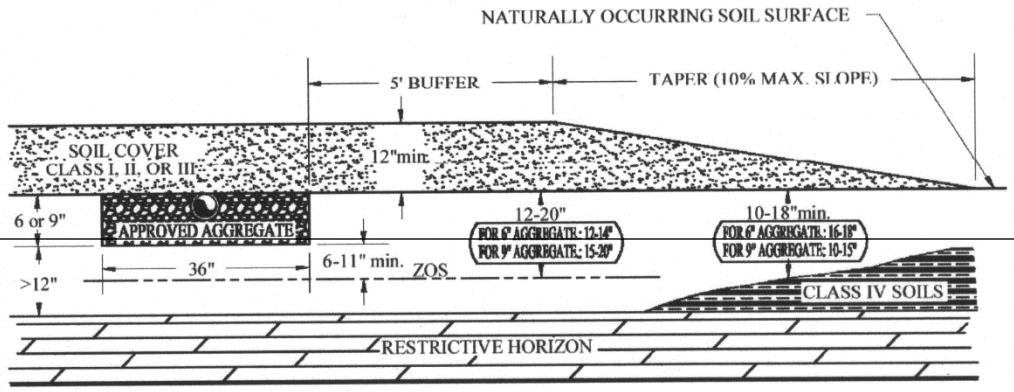
SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
BUREAU OF ENVIRONMENTAL HEALTH

ALTERNATIVE SYSTEM

SHALLOW PLACEMENT SYSTEM WITH FILL CAP FOR SITES WITH SHALLOW CLASS IV SOILS

PROGRAM 362 / CODE 370 / CODE 371 IF PUMPED

TYPICAL DESIGN ILLUSTRATION



Depth to ZOS (in)	Depth to Class IV Soil (in)	Amount of Imported Fill Cap / Aggregate Depth (in)	Extension Factor
12	18	12 / 6	1.5
13	17	12 / 6	1.5
14	16	12 / 6	1.5
---	---	---	---
15	15	12 / 9	1.3
16	14	12 / 9	1.3
17	13	12 / 9	1.3
18	12	12 / 9	1.3
19	11	12 / 9	1.3
20	10	12 / 9	1.3

NOT TO SCALE

TLS REV. 03/16/07

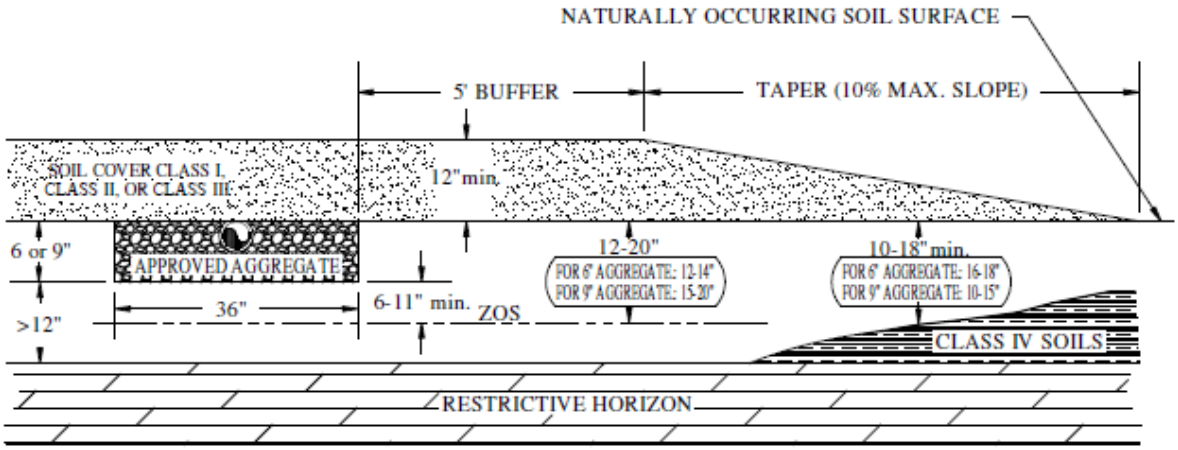
SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
BUREAU OF ENVIRONMENTAL HEALTH SERVICES

ALTERNATIVE STANDARD

SHALLOW PLACEMENT SYSTEM WITH FILL CAP FOR SITES WITH SHALLOW CLASS IV SOILS

PROGRAM 362 / CODE 370 / CODE 371 IF PUMPED

TYPICAL DESIGN ILLUSTRATION



NOT TO SCALE

Depth to ZSS (in)	Depth to Class IV Soil (in)	Amount of Imported Fill Cap / Aggregate Depth (in)	Extension Factor
12	18	12 / 6	1.5
13	17	12 / 6	1.5
14	16	12 / 6	1.5
---	---	---	---
15	15	12 / 9	1.3
16	14	12 / 9	1.3
17	13	12 / 9	1.3
18	12	12 / 9	1.3
19	11	12 / 9	1.3
20	10	12 / 9	1.3

Rev. 03/09/18

~~411 APPENDIX K – System Standard 380/381 – DOUBLE AGGREGATE DEPTH WASTEWATER INFILTRATION TRENCHES~~**Appendix M – System Standard 380/381 – Double Aggregate Depth Wastewater Infiltration Trenches**

~~411.1 SITE/PERMITTING REQUIREMENTS~~ (1) Site/Permitting Requirements

~~(1)~~ (a) Use of the double aggregate depth option must be restricted to soils that meet all textural limitations and required offsets to the zone of saturation (ZOS) and restrictive horizons.

~~(2)~~ (b) Systems incorporating the double aggregate depth option shall be loaded on the basis of the most hydraulically limiting naturally occurring soil texture from the ground surface to twelve (12) inches below the bottom of the proposed wastewater infiltration trenches.

~~(3)~~ (c) In order to maintain the same total absorptive area as that provided by conventional aggregate depth systems, the equivalent linear footage requirement for thirty-six (36) inch wide double aggregate depth trenches shall be determined by multiplying the conventional trench requirement by a factor of 0.7.

~~(4)~~ (d) There shall be a replacement area equivalent to at least fifty (50) percent in size of the original system area held in reserve for system repair. This area shall have a suitable configuration~~,~~ and shall meet the minimum soil and site conditions of ~~R. 61-56~~this regulation.

~~411.2 INSTALLATION REQUIREMENTS~~ (2) Installation Requirements

~~(1)~~ (a) The wastewater infiltration trench aggregate shall be twenty-eight (28) inches in depth~~,~~ and shall be placed so as to provide twenty (20) inches of aggregate below the pipe, five (5) inches beside the pipe, and three (3) inches above the pipe. The aggregate shall be covered with at least nine (9) inches of backfill.

~~(2)~~ (b) The wastewater infiltration trench width shall be thirty-six (36) inches.

~~(3)~~ (c) Where gravity flow from the septic tank to the subsurface wastewater infiltration area is utilized, the invert elevation of the septic tank outlet shall be installed at an elevation at least equal to or higher than the top of the aggregate in the highest wastewater infiltration trench(es).

~~411.3 FINAL LANDSCAPING AND DRAINAGE~~ (3) Final Landscaping and Drainage

~~(1)~~ (a) Installation of drainage swales, ditches, curtain drains, and rain gutters may be required to divert or intercept water away from the onsite wastewater system location. The septic tank and subsurface wastewater infiltration area shall be backfilled and shaped to promote surface water runoff.

~~(2)~~ (b) Following final landscaping, seeding or sodding may be required to prevent erosion.

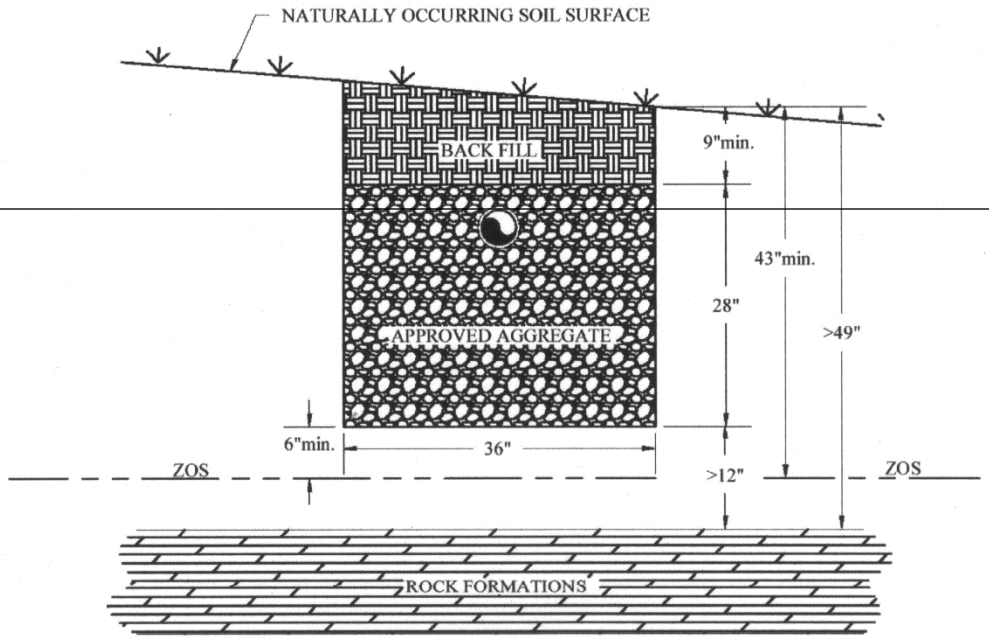
~~(3)~~ (c) Final approval shall be withheld until all landscaping and drainage improvements have been satisfactorily completed.

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
BUREAU OF ENVIRONMENTAL HEALTH

ALTERNATIVE SYSTEM
DOUBLE AGGREGATE DEPTH SOIL ABSORPTION TRENCHES

PROGRAM 360 / CODE 380 / CODE 381 IF PUMPED

TYPICAL DESIGN ILLUSTRATION



SCALE: 3/4"=1'

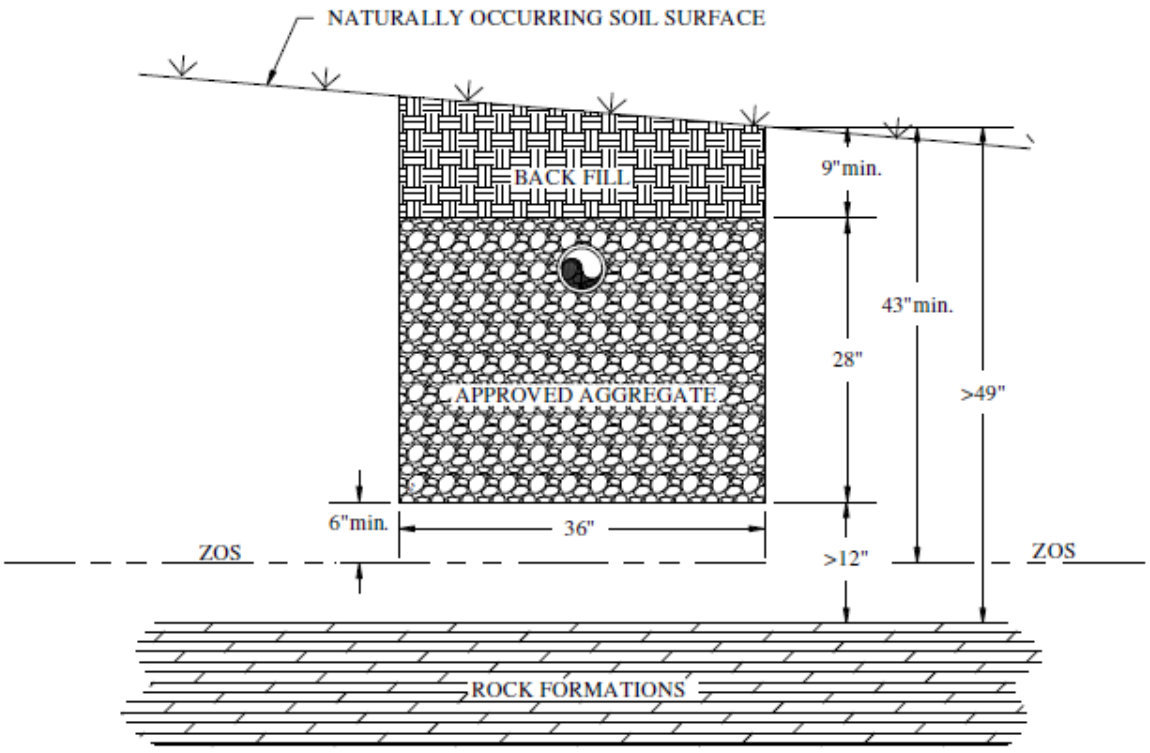
TLS REV. 03/16/07

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
BUREAU OF ENVIRONMENTAL HEALTH SERVICES

ALTERNATIVE STANDARD
DOUBLE AGGREGATE DEPTH SOIL ABSORPTION TRENCHES

PROGRAM 360 / CODE 380 / CODE 381 IF PUMPED

TYPICAL DESIGN ILLUSTRATION



NOT TO SCALE

Rev. 03/09/18

~~412 APPENDIX L – System Standard 420/421 – MOUNDED INFILTRATION SYSTEM~~**Appendix N – System Standard 420/421 – Mounded Infiltration System**

~~412.1 SITE/PERMITTING REQUIREMENTS~~ (1) Site/Permitting Requirements

~~(1)~~ (a) The texture in the upper twelve (12) inches of naturally occurring soil must be Class I or Class II.

~~(2)~~ (b) The soil texture in the permeable substratum must be no more limiting than Class II.

~~(3)~~ (c) There must not be a zone of saturation (ZOS) within six (6) inches of the naturally occurring soil surface.

~~(4)~~ (d) The depth to any restrictive horizon must be greater than twelve (12) inches below the bottom of the proposed wastewater infiltration trenches.

~~(5)~~ (e) There shall be a replacement area equivalent to at least fifty (50) percent in size of the original system area held in reserve for system repair. This area shall have a suitable configuration~~,~~ and shall meet the minimum soil and site conditions of ~~R. 61-56~~this regulation.

~~(6) Prior to permitting the onsite wastewater system, delineation of any affected jurisdictional wetlands may be required. Should any part of the proposed onsite wastewater system be located in jurisdictional wetlands, approval from the appropriate permitting agency(s) (i.e., US Army Corp. of Engineers, SCDHEC OCRM, etc.) shall be received, and proof of such provided to the Department.~~

~~(7)~~ (f) No part of this system can be installed within one hundred twenty-five (125) feet of the critical area line or tidal waters as determined by the Department; or within one hundred twenty-five (125) feet of the ordinary high water elevation within the banks of non-tidal, environmentally sensitive waters.

~~(8)~~ (g) This system cannot be considered for facilities with peak flow rates in excess of four hundred eighty (480) ~~gallons per day~~gpd. In addition, this system shall not be considered for facilities requiring grease traps.

~~(9) This system may not be installed on sites that flood.~~

~~(10)~~ (h) This system must not be utilized on sites that require serial distribution. Level installations on ~~slightly~~ sloping sites can be considered if it can be demonstrated that the entire installation (i.e., side wall to side wall and end to end) will meet the required textural limitations and the required offsets to the zone of saturation and restrictive horizons.

~~(11)~~ (i) The total linear footage of six (6) inch deep, thirty-six (36) inch wide wastewater infiltration trenches shall be increased by 100 percent over that which would be required for conventional trenches, as determined by the ~~Long-Term Acceptance Rate~~long-term acceptance rate of the permeable substratum.

~~(12)~~ (j) This system may be considered for installation on contiguous lots in new subdivisions approved after the effective date of this standard provided a setback of at least seventy-five (75) feet is maintained between the system and all adjacent property lines. The seventy-five (75) foot setback shall be measured from the point at which the fill cap taper intersects with the naturally occurring soil surface.

~~412.2 INSTALLATION REQUIREMENTS~~ (2) Installation Requirements

~~(1)~~ (a) Site Preparation

~~(a)~~ (i) The naturally occurring soil surface underlying the area of the wastewater infiltration trenches shall be thoroughly tilled and mixed with the imported medium sand to a depth of six (6) inches.

~~(b)~~ (ii) All tree and brush removal shall be done in a manner that minimizes the disturbance or loss of naturally occurring soil.

~~(2)~~ (b) Fill and System ~~(see ref. sketch)~~

~~(a)~~ (i) The fill cap and buffer shall be Class I, Class II, or Class III.

~~(b)~~ (ii) The depth of the fill cap shall provide a minimum of twelve (12) inches backfill above the top of the wastewater infiltration trench aggregate ~~(see ref. sketch)~~.

~~(c)~~ (iii) Where gravity flow from the septic tank to the subsurface wastewater infiltration area is utilized, the invert elevation of the septic tank outlet shall be installed at an elevation at least equal to or higher than the top of the aggregate in the highest wastewater infiltration trench(es).

~~(d)~~ (iv) The fill buffer shall be at least fifteen (15) feet in width.

~~(e)~~ (v) The fill taper shall be at least twenty (20) feet in width.

~~(f)~~ (vi) The required property line setback shall be measured from the point at which the fill cap taper intersects with the naturally occurring soil surface.

~~(g)~~ (vii) The total fill depth, excluding the taper zone, shall be at least eighteen (18) inches above the naturally occurring soil surface.

~~(h)~~ (viii) The wastewater infiltration trenches shall be installed in a Class I fill pad at least six (6) inches in depth, which extends five (5) feet beyond the trenches in all directions.

~~(i)~~ (ix) The wastewater infiltration trenches require a total aggregate depth of six (6) inches.

~~(j)~~ (x) The wastewater infiltration trench width shall be thirty-six (36) inches.

~~(k)~~ (xi) Infiltration trenches shall penetrate the permeable substratum and shall be at least two (2) feet in width containing USDA medium sand, washed concrete sand, or other material approved by the Department.

~~(l)~~ (xii) Effluent discharged to this system must receive a higher degree of treatment than that provided by a conventional septic tank (~~i.e.,~~e.g., two (2) compartment septic tank or two (2) septic tanks in series).

~~412.3 FINAL LANDSCAPING AND DRAINAGE~~(3) Final Landscaping and Drainage

~~(1)~~ (a) The septic tank and fill cap area shall be backfilled and shaped to promote the runoff of surface water.

~~(2)~~ (b) Where natural surface drainage does not exist, a swale shall be constructed adjacent to the filled area to divert surface water away from the onsite wastewater system to a positive outfall. The installation

of ditches, curtain drains, and rain gutters may be required to intercept and divert water away from the onsite wastewater system location.

~~(3)~~ (c) A barrier to preclude parking and vehicular traffic over the system area may be required.

~~(4)~~ (d) Following final landscaping, seeding or sodding may be required to prevent erosion.

~~(5)~~ (e) Final approval shall be withheld until all landscaping and drainage improvements have been satisfactorily completed.

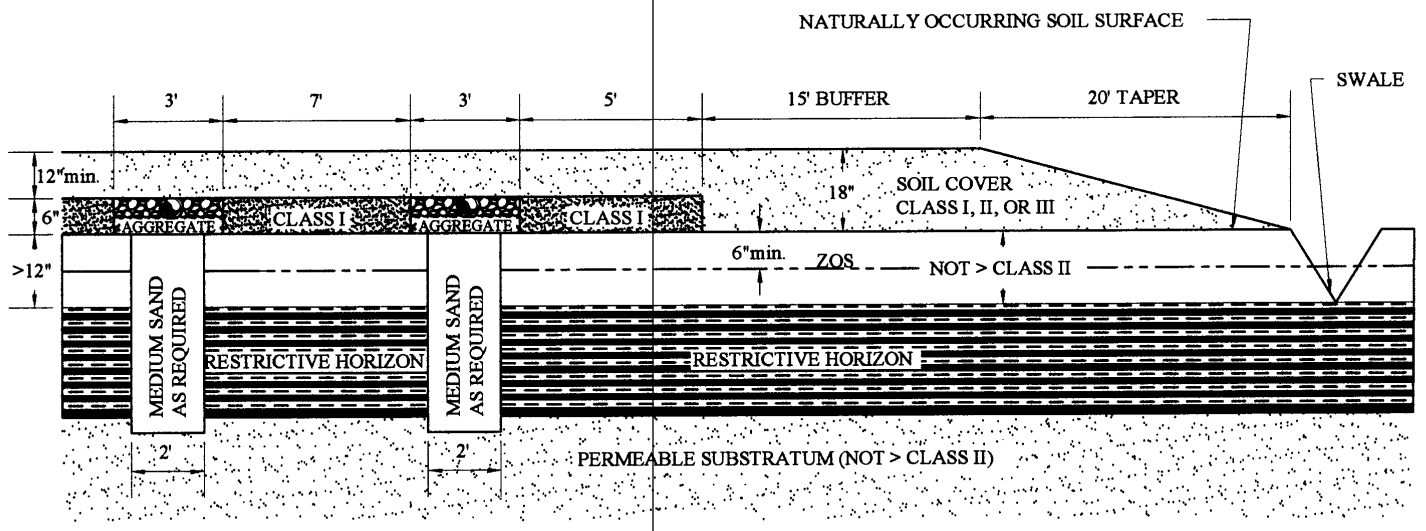
SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
BUREAU OF ENVIRONMENTAL HEALTH

ALTERNATIVE STANDARD

MOUNDED INFILTRATION SYSTEM FOR PERMEABLE SANDS UNDERLYING RESTRICTIVE HORIZONS

PROGRAM 362 / CODE 420 / CODE 421 IF PUMPED

TYPICAL DESIGN ILLUSTRATION



NOT TO SCALE

TLS REV. 09/28/06

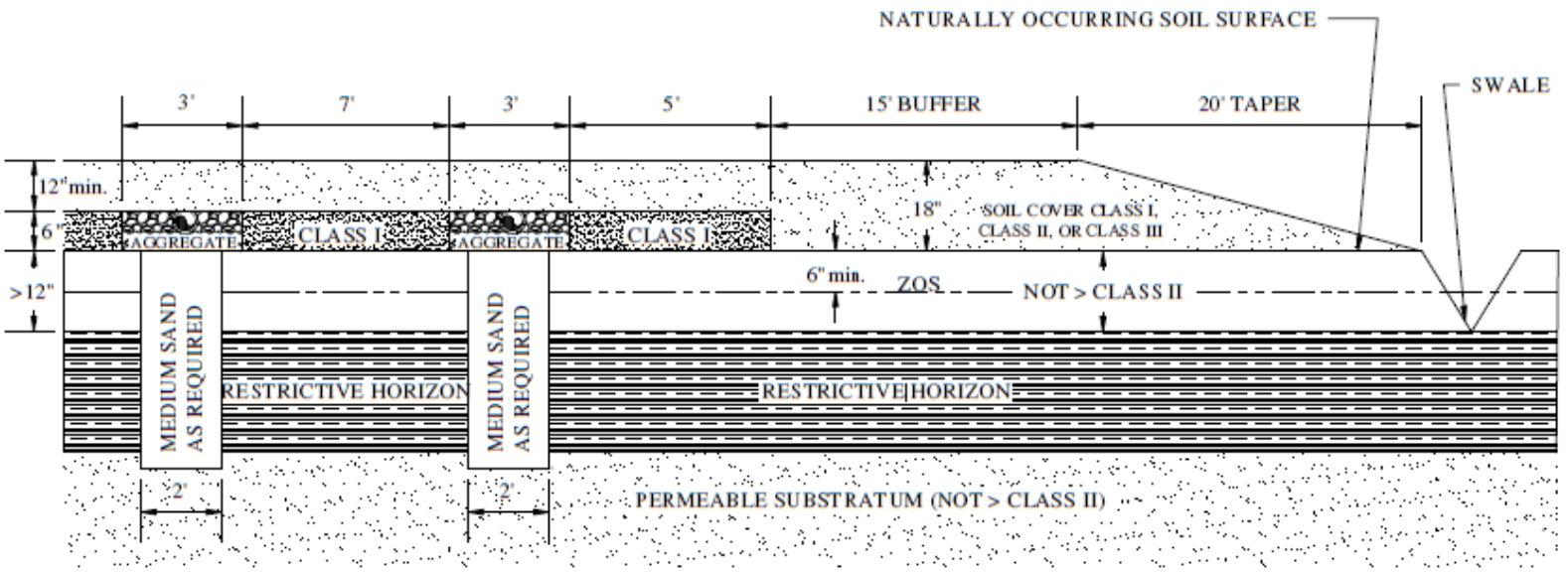
SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
BUREAU OF ENVIRONMENTAL HEALTH SERVICES

ALTERNATIVE STANDARD

MOUNDED INFILTRATION SYSTEM FOR PERMEABLE SANDS UNDERLYING RESTRICTIVE HORIZONS

PROGRAM 362 / CODE 420 / CODE 421 IF PUMPED

TYPICAL DESIGN ILLUSTRATION



NOT TO SCALE

Rev. 03/09/18

~~413 APPENDIX M - System Standard 431 MOUNDED FILL SYSTEM~~**Appendix O – System Standard 431 – Mounded Fill System**

~~413.1 SITE/PERMITTING REQUIREMENTS~~ (1) Site/Permitting Requirements

~~(1) This system shall not be used on sites that are subject to flooding.~~

~~(2)~~ (a) The texture in the upper eighteen (18) inches of naturally occurring soil must be Class I or Class II.

~~(3)~~ (b) The absorption bed within the mound shall be sized on the ~~Long-Term Acceptance Rate~~long-term acceptance rate of the most limiting texture in the upper eighteen (18) inches of naturally occurring soil.

~~(4)~~ (c) The linear footage of the absorption bed shall be determined in accordance with Standard 270.

~~(5)~~ (d) The absorption bed width shall be a minimum of five (5) feet and a maximum of 10 feet.

~~(6)~~ (e) Mounded fill systems must not be placed on sites with a slope in excess of three (3) percent.

~~(7)~~ (f) No part of this system can be installed within one hundred twenty-five (125) feet of the critical area line or tidal waters as determined by the Department; or within one hundred twenty-five (125) feet of the ordinary high water elevation within the banks of non-tidal, environmentally sensitive waters. Because of the long buffer, side slope, fill pad, and taper associated with this system, the one hundred twenty-five (125) foot setback shall be measured from the outer edge of the aggregate bed within the mound.

~~(8)~~ (g) There shall be a replacement area equivalent to at least fifty (50) percent in size of the original system area held in reserve for system repair. This area shall have a suitable configuration~~,~~ and shall meet the minimum soil and site conditions of ~~R. 61-56~~this regulation.

~~(9) Prior to permitting the onsite wastewater system, delineation of any affected jurisdictional wetlands may be required. Should any part of the proposed onsite wastewater system be located in jurisdictional wetlands, approval from the appropriate permitting agency(s) (i.e., US Army Corp. of Engineers, SCDHEC Ocean and Coastal Resource Management, etc.) shall be received and proof of such provided to the Department.~~

~~(10)~~ (h) This system cannot be considered for facilities with peak flow rates in excess of four hundred eighty (480) ~~gallons per day~~gpd. In addition, this system shall not be considered for facilities requiring grease traps.

~~(11)~~ (i) Effluent discharged to this system must receive a higher degree of treatment than that provided by a conventional septic tank (~~i.e.,~~e.g., two (2) compartment septic tank or two (2) septic tanks in series).

~~(12)~~ (j) This system may be considered for installation on contiguous lots in new subdivisions approved after the effective date of this standard provided a setback of at least seventy-five (75) feet is maintained between the system and all adjacent property lines. ~~-~~Because of the long buffer, side slope, fill pad, and taper associated with this system, the seventy-five (75) foot setback shall be measured from the outer edge of the aggregate bed within the mound.

~~413.2 INSTALLATION REQUIREMENTS~~ (2) Installation Requirements

~~(1)~~ (a) Site Preparation

~~(a)~~ (i) If present within eighteen (18) inches of the naturally occurring soil surface, organic material and restrictive horizons must be removed from beneath the mound and replaced with USDA medium sand, washed concrete sand, or an equivalent material approved by the Department. The replacement area must extend five (5) feet in all directions beyond the edges of the aggregate filled absorption bed.

~~(b)~~ (ii) The naturally occurring soil surface underlying the mound shall be thoroughly tilled and mixed with the imported mound fill material to a depth of six (6) inches.

~~(2)~~ (b) Mound/Absorption Bed Requirements

~~(a)~~ (i) Low Pressure Pipe Distribution (LPP) must be utilized to preclude localized hydraulic overloading of the imported fill material and to minimize the impact on the shallow zone of ~~seasonal~~ saturation.

(ii) Low Pressure Pipe Distribution (LPP) must be designed and installed in accordance with Department standards or equivalent designs. The size and layout of each distribution system will vary based on the size of the filter and the needed dosing.

(iii) Pump design shall be in accordance with Department standards.

~~(b)~~ (iv) There must be at least twenty-four (24) inches of medium sand placed between the naturally occurring soil surface and the bottom of the absorption bed. ~~Also, the~~ The bottom surface of the absorption bed must be placed at least twenty-four (24) inches above the zone of saturation.

~~(c)~~ (v) If the slope of the site in the proposed mound area is one (1) percent or less, then the mound shall be placed on a twelve (12) inch fill pad which must extend twenty (20) feet beyond the mound in all directions. If the slope of the site in the proposed mound area is greater than one (1) percent but less than or equal to three (3) percent, then the mound shall be placed on a twelve (12) inch deep fill pad which must extend twenty (20) feet beyond the mound area on the sides of the mound; forty (40) feet beyond the mound area on the down-slope side of the mound; with no fill pad required on the upslope side of the mound.

~~(d)~~ (vi) The mound and fill pad material shall be USDA medium sand, washed concrete sand, or other equivalent material approved by the Department.

~~(e)~~ (vii) The depth of the fill cap material above the absorption bed shall be nine (9) to fifteen (15) inches of soil texture Class II or Class III. Sod may be substituted for four (4) inches of this portion of the fill cap material. ~~(see attached illustration).~~

~~(f)~~ (viii) The depth of the fill cap material above the mound side-slope, the twelve (12) inch deep fill pad, and the taper shall be at least four (4) inches of soil texture Class II or Class III. Sod may be substituted for this portion of the fill cap material. ~~(see attached illustration).~~

~~(g)~~ (ix) A 1:2 maximum slope is required if the mound side-slope and taper are sodded.

~~(h)~~ (x) A 1:4 maximum slope is required if the mound side-slope and taper are mulched and seeded.

(3) ~~Final Landscaping And Drainage Requirements~~Final Landscaping and Drainage

(a) The septic tank and mound area shall be backfilled and shaped to promote the runoff of surface water.

(b) Where natural surface drainage does not exist, a swale shall be constructed adjacent to the filled area to divert surface water away from the onsite wastewater system to a positive outfall. The installation of ditches, curtain drains, and rain gutters may be required to intercept and divert water away from the onsite wastewater system location.

(c) A barrier to preclude parking and vehicular traffic over the system area may be required.

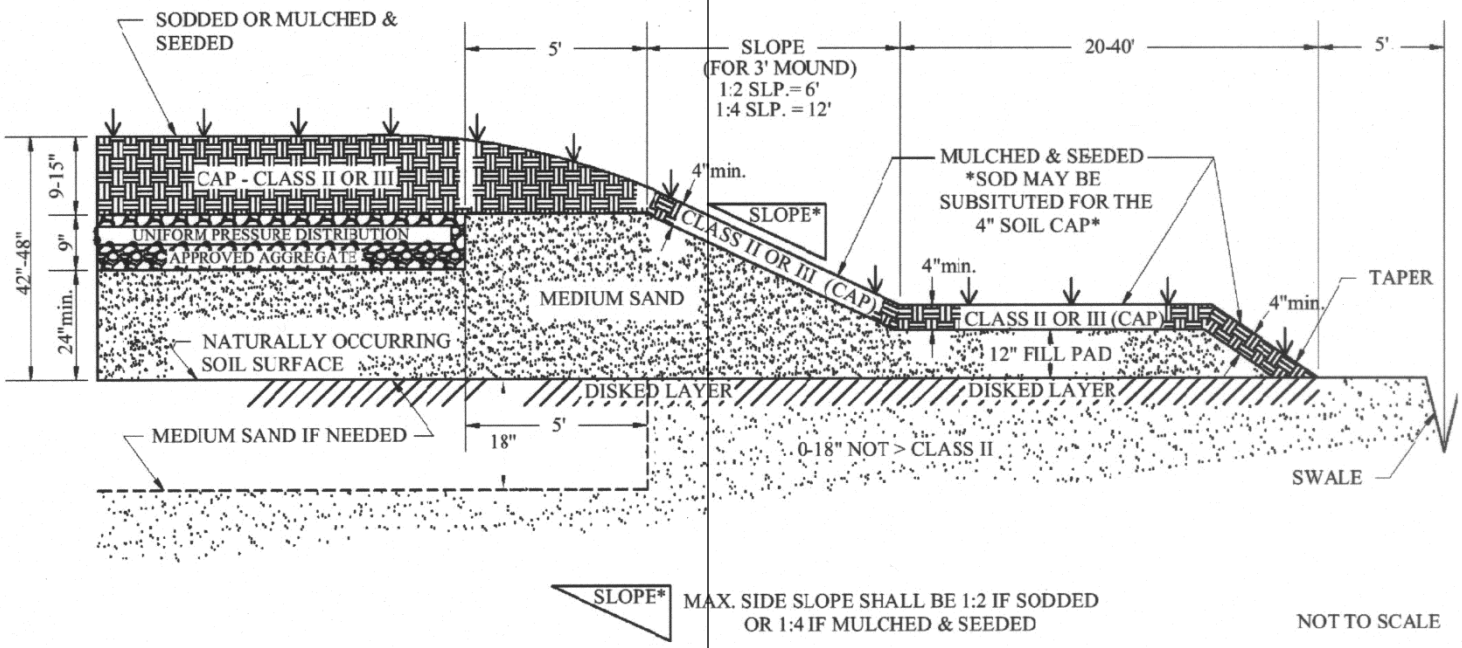
(d) Following final landscaping, seeding, or sodding may be required to prevent erosion.

(e) Final approval shall be withheld until all landscaping and drainage improvements have been satisfactorily completed.

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
BUREAU OF ENVIRONMENTAL HEALTH

ALTERNATIVE SYSTEM
MOUNDED FILL SYSTEMS
PROGRAM 362 / CODE 431

TYPICAL DESIGN ILLUSTRATION



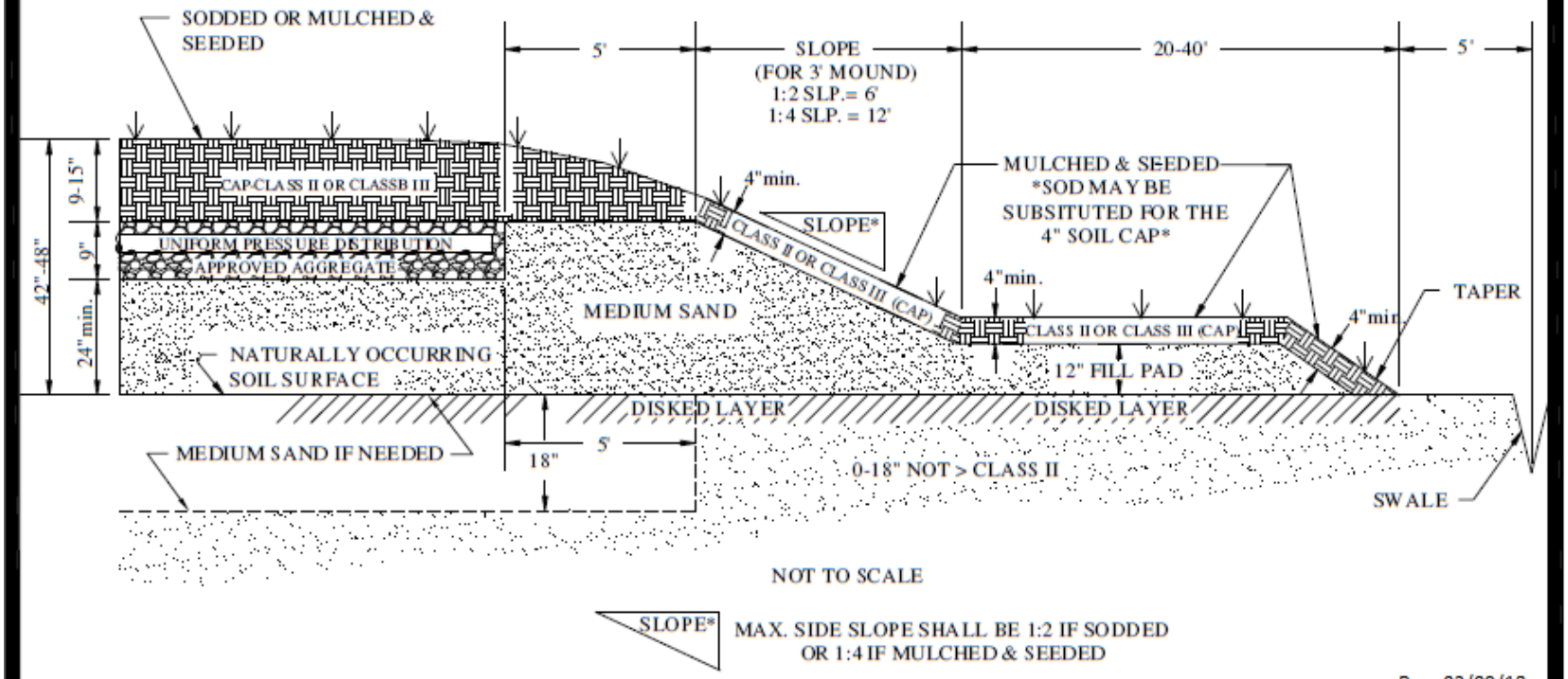
TLS REV. 03/16/07

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
BUREAU OF ENVIRONMENTAL HEALTH SERVICES

ALTERNATIVE STANDARD
MOUNDED FILL SYSTEMS

PROGRAM 362 / CODE 431

TYPICAL DESIGN ILLUSTRATION A

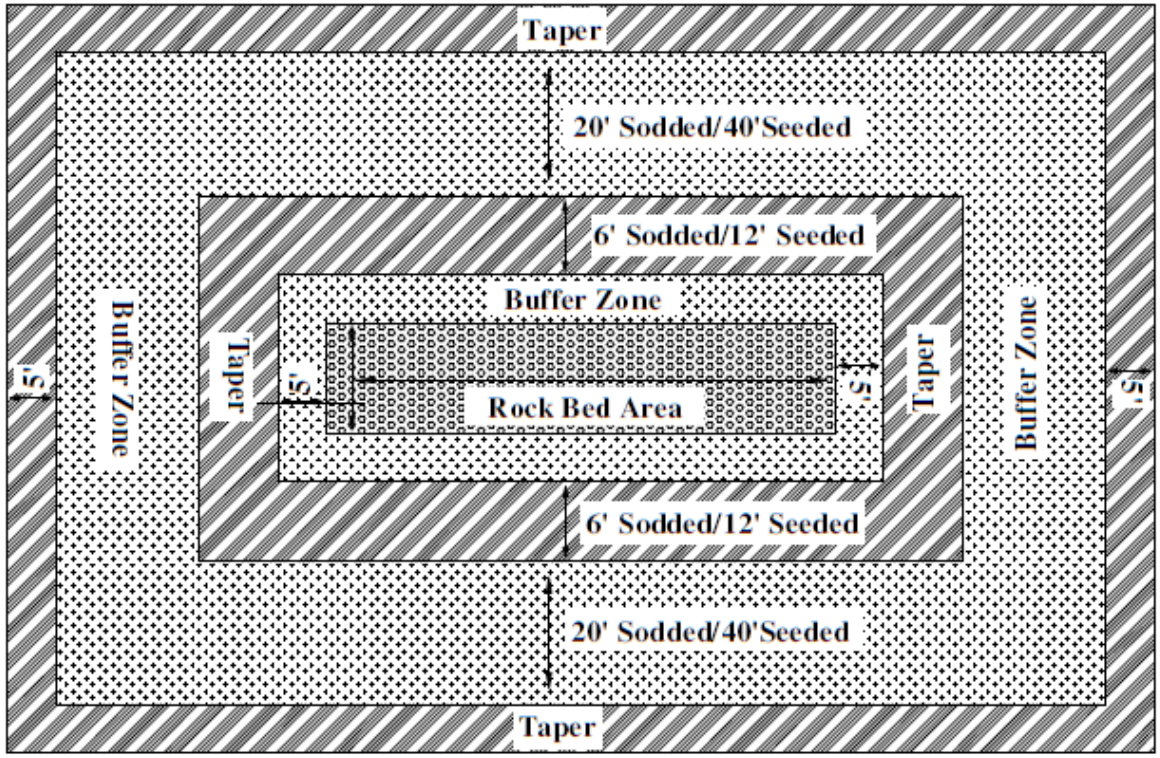


Rev. 03/09/18

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
BUREAU OF ENVIRONMENTAL HEALTH SERVICES

ALTERNATIVE STANDARD
MOUNDED FILL SYSTEMS
PROGRAM 362 / CODE 431

TYPICAL DESIGN ILLUSTRATION B



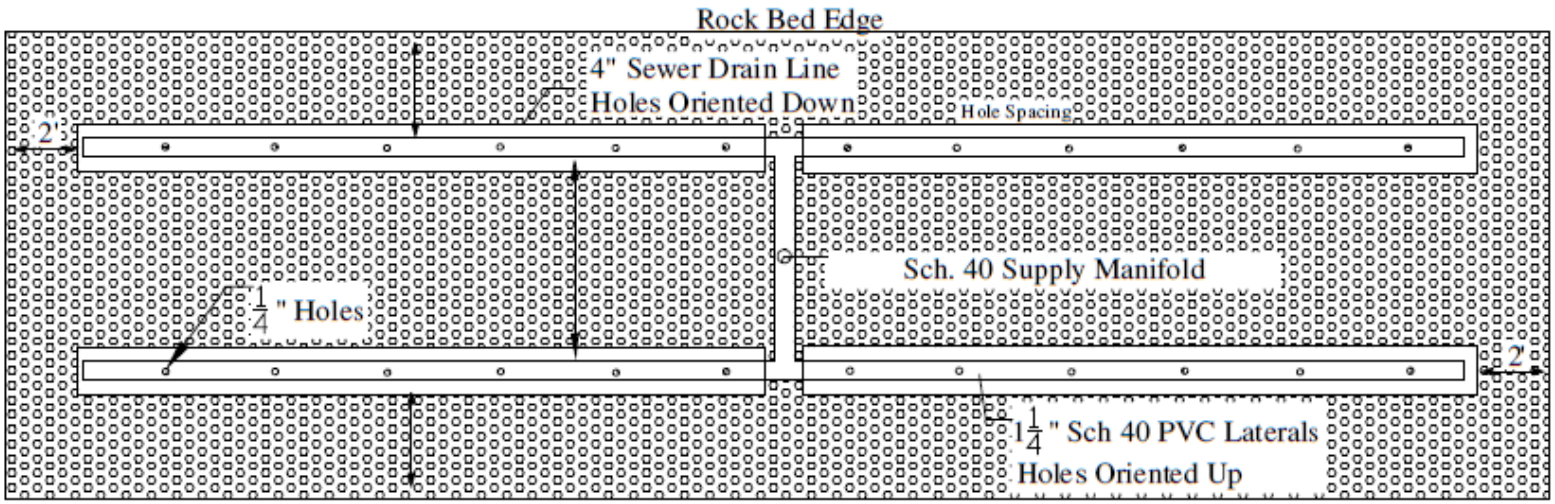
NOT TO SCALE

Rev. 03/09/18

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
BUREAU OF ENVIRONMENTAL HEALTH SERVICES

ALTERNATIVE STANDARD
MOUNDED FILL SYSTEMS
PROGRAM 362 / CODE 431

TYPICAL DESIGN ILLUSTRATION C



*Note: Cleanouts are required at the end of each lateral to extend to finishing grade with screw-on cleanout caps.

NOT TO SCALE

Rev. 03/09/18

~~414 APPENDIX N – SYSTEM STANDARD 601 – ELEVATED INFILTRATION SYSTEM~~**Appendix P – System Standard 601 – Elevated Infiltration System**

~~414.1 SITE/PERMITTING REQUIREMENTS~~ (1) Site/Permitting Requirements

~~(1)~~ (a) The texture in the upper eighteen (18) inches of naturally occurring soil must be Class I or Class II.

~~(2)~~ (b) The filter shall not be placed on slopes greater than three (3) percent.

~~(3)~~ (c) This system cannot be considered for facilities with peak flow rates in excess of four hundred eighty (480) ~~gallons per day~~gpd. ~~In addition, this~~This system shall not be considered for facilities requiring grease traps.

~~(4)~~ (d) There shall be a buffer of at least fifty (50) feet surrounding and separating the system from all adjacent property lines. This buffer shall be measured from the retaining wall.

~~(5)~~ (e) There shall be a replacement area equivalent to at least fifty (50) percent in size of the original system area held in reserve for system repair. This area shall have a suitable configuration~~,~~ and shall meet the minimum soil and site conditions of ~~R. 61-56~~this regulation.

~~(6) This system shall not be placed on sites that flood.~~

~~(7)~~ (f) No part of this system can be installed within one hundred twenty-five (125) feet of the critical area line or tidal waters as determined by the Department~~;~~ or within one hundred twenty-five (125) feet of the ordinary high water elevation within the banks of non-tidal, environmentally sensitive waters.

~~(8) Prior to permitting the onsite wastewater system, delineation of any affected jurisdictional wetlands may be required. Should any part of the proposed onsite wastewater system be located in jurisdictional wetlands, approval from the appropriate permitting agency(s) (i.e., US Army Corp. of Engineers, SCDHEC Ocean and Coastal Resource Management, etc.) shall be received, and proof of such provided to the Department. The absorption bed shall be sized on the most limiting soil texture class in the upper eighteen (18) inches of naturally occurring soil.~~

~~(9)~~ (g) The total bottom area of the filter must be increased by fifty (50) percent above that required for conventional trenches.

~~(10)~~ (h) This system may be considered for installation on contiguous lots in new subdivisions approved after the effective date of this standard provided a setback of at least seventy-five (75) feet is maintained between the system and all adjacent property lines. The seventy-five (75) foot setback shall be measured from the point at which the retaining wall intersects the naturally occurring soil surface.

~~414.2 INSTALLATION REQUIREMENTS~~ (2) Installation Requirements

~~(1)~~ (a) Site Preparation

~~(a)~~ (i) If present within eighteen (18) inches of the naturally occurring soil surface, organic material and restrictive horizons must be removed from beneath the filter and replaced with USDA medium sand, washed concrete sand, or an equivalent material approved by the Department.

~~(b)~~ (ii) The naturally occurring soil surface underlying the filter shall be thoroughly tilled and mixed with the imported filter material to a depth of six (6) inches.

~~(2)~~ (b) System Requirements

~~(a)~~ (i) The filter must be constructed to a height of at least thirty-six (36) inches above the original grade~~,~~ with the sewage effluent passing through at least twenty-four (24) inches of filter material.

~~(b)~~ (ii) The filter material shall be USDA medium sand, washed concrete sand, or other material approved by the Department.

~~(c)~~ (iii) The filter retaining wall shall extend at least four (4) inches above the surface of the filter material and shall penetrate the naturally occurring soil surface at least four (4) inches.

~~(d)~~ (iv) The filter retaining wall shall be constructed in accordance with the accompanying design illustrations.

~~(e)~~ (v) Effluent discharged to this system must receive a higher degree of treatment than that provided by a conventional septic tank (~~i.e.,~~e.g., two (2) compartment septic tank or two (2) septic tanks in series).

~~(f)~~ (vi) The top of the filter shall be capped with Class II or Class III soil~~,~~ and shall slope from center to edges in order to promote surface runoff.

~~(3)~~ (c) Distribution Requirements

~~(a)~~ (i) Low Pressure Pipe Distribution (LPP) must be utilized to preclude localized hydraulic overloading of the imported fill material and to minimize the impact on the shallow zone of saturation.

(ii) Low Pressure Pipe Distribution (LPP) must be designed and installed in accordance with Department standards or equivalent designs. The size and layout of each distribution system will vary based on the size of the filter and the needed dosing.

~~(b)~~ (iii) Pump design shall be in accordance with Department standards.

~~414.3 FINAL LANDSCAPING AND DRAINAGE REQUIREMENTS~~ (3) Final Landscaping and Drainage

~~(1)~~ (a) Fill material shall be placed around the outside of the filter to a depth of one (1) foot, and shall slope to original grade at a point five (5) feet from the retaining wall.

~~(2)~~ (b) The septic tank and filter area shall be backfilled and shaped to promote the runoff of surface water.

~~(3)~~ (c) Where natural surface drainage does not exist, a swale shall be constructed adjacent to the filter to divert surface water away from the onsite wastewater system to a positive outfall. The installation of ditches, curtain drains, and/or rain gutters may be required to intercept and divert water away from the onsite wastewater system location.

~~(4)~~ (d) Following final landscaping, seeding or sodding may be required to prevent erosion.

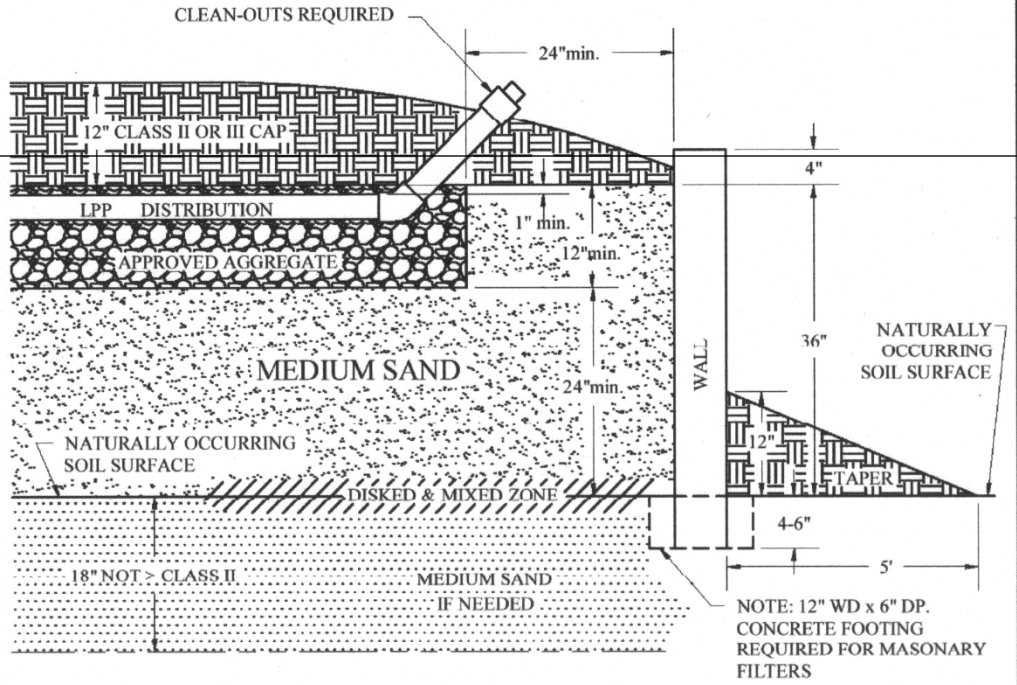
~~(5)~~ (e) Final approval shall be withheld until all landscaping and drainage improvements have been satisfactorily completed.

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
BUREAU OF ENVIRONMENTAL HEALTH

ALTERNATIVE SYSTEM
ELEVATED INFILTRATION SYSTEM

PROGRAM 362 / CODE 601

TYPICAL DESIGN ILLUSTRATION



SECTION A-A

NOT TO SCALE

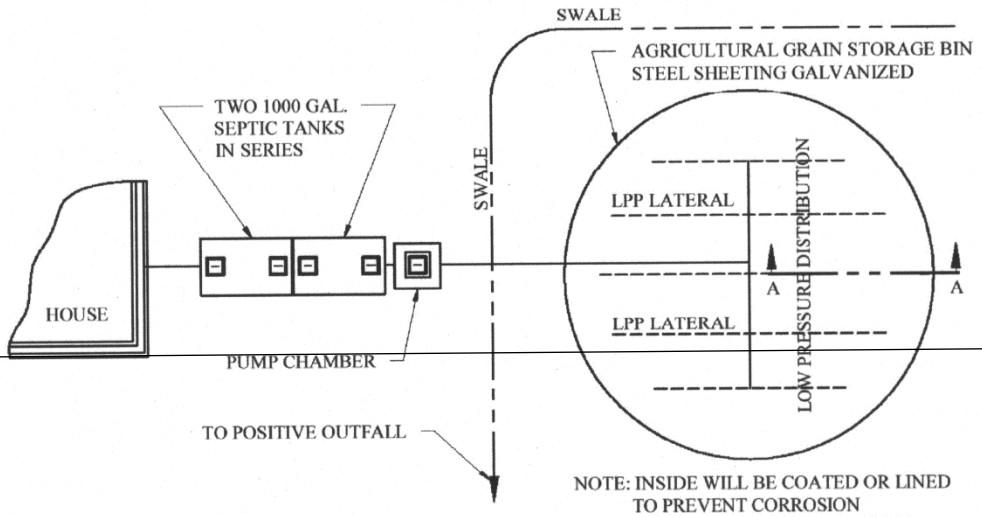
TLS REV. 03/16/07

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
BUREAU OF ENVIRONMENTAL HEALTH

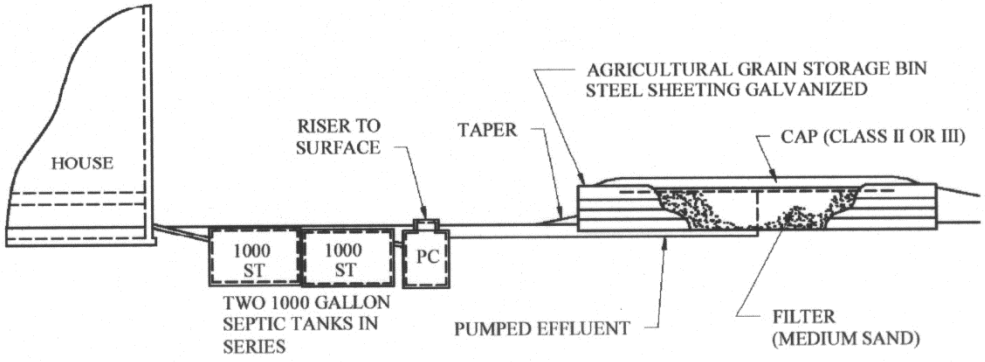
ALTERNATIVE SYSTEM
ELEVATED INFILTRATION SYSTEM

PROGRAM 362 / CODE 601

TYPICAL DESIGN ILLUSTRATION
CIRCULAR STEEL FILTER DETAILS



PLAN VIEW
NOT TO SCALE



ELEVATION
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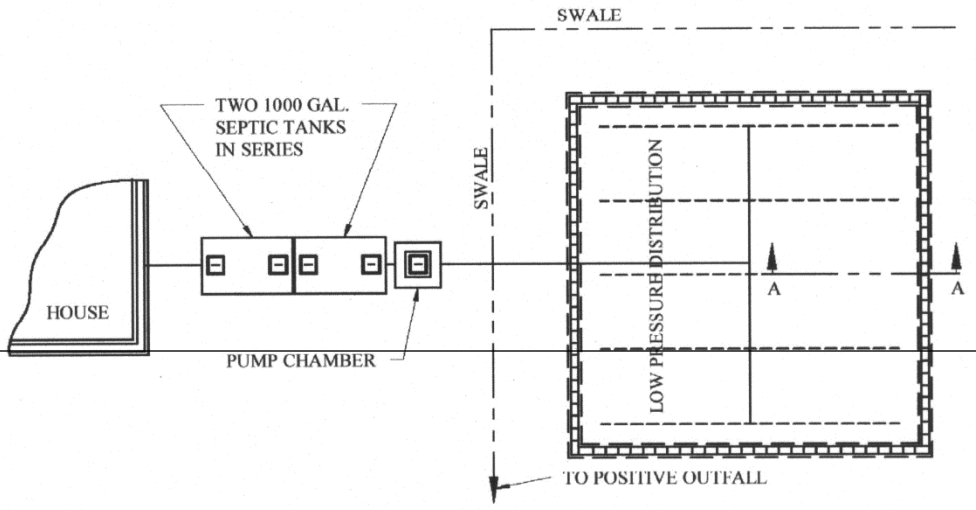
TYPICAL DESIGN ILLUSTRATION
SQUARE CONCRETE & BLOCK FILTER DETAILS



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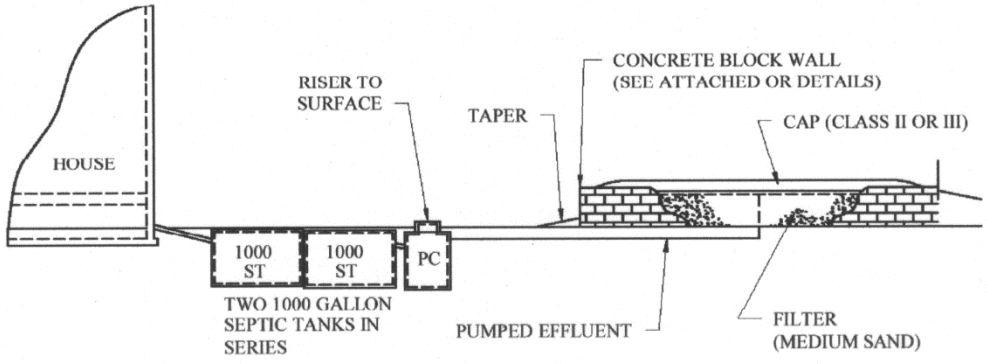

ELEVATION
NOT TO SCALE

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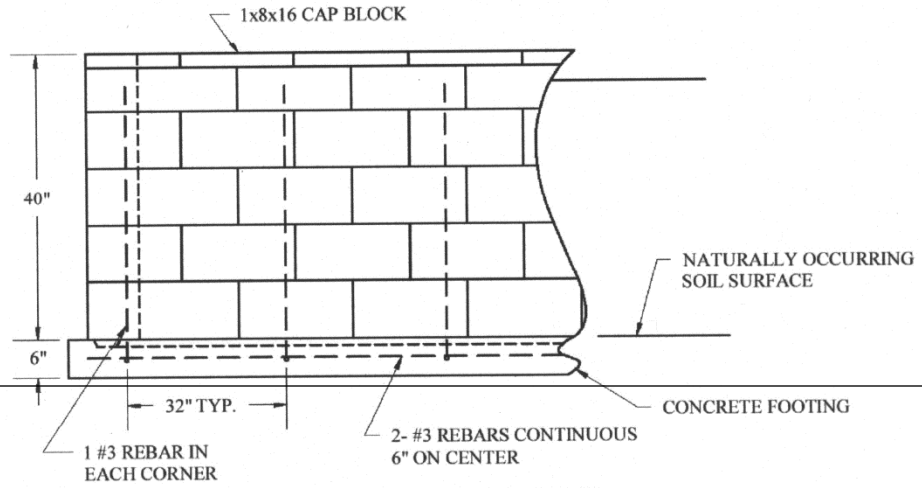
ELEVATED INFILTRATION SYSTEM

PROGRAM 362 / CODE 601

TYPICAL DESIGN ILLUSTRATION

SQUARE CONCRETE & BLOCK FILTER - WALL & FOUNDATION DETAIL



WALL & FOUNDATION DETAIL
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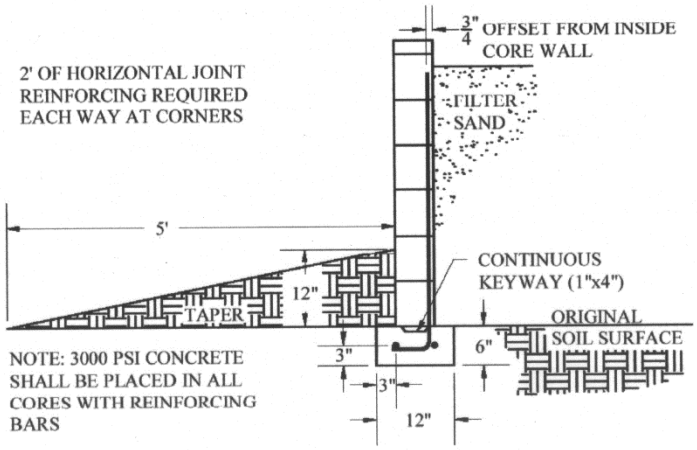

WALL SECTION DETAIL
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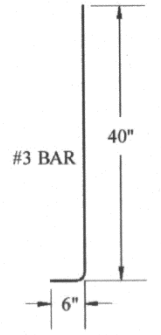

REBAR DETAIL
NOT TO SCALE

NOTE: 14 DAY MINIMUM CURE TIME FOR WALL & FOUNDATION REQUIRED BEFORE INSTALLING FILTER SAND

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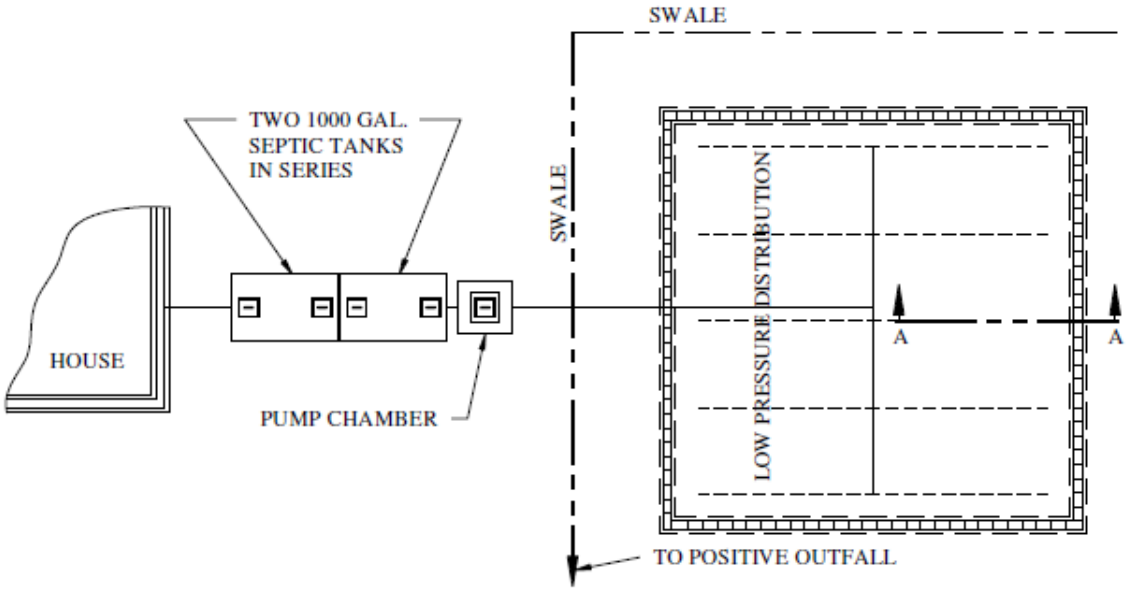
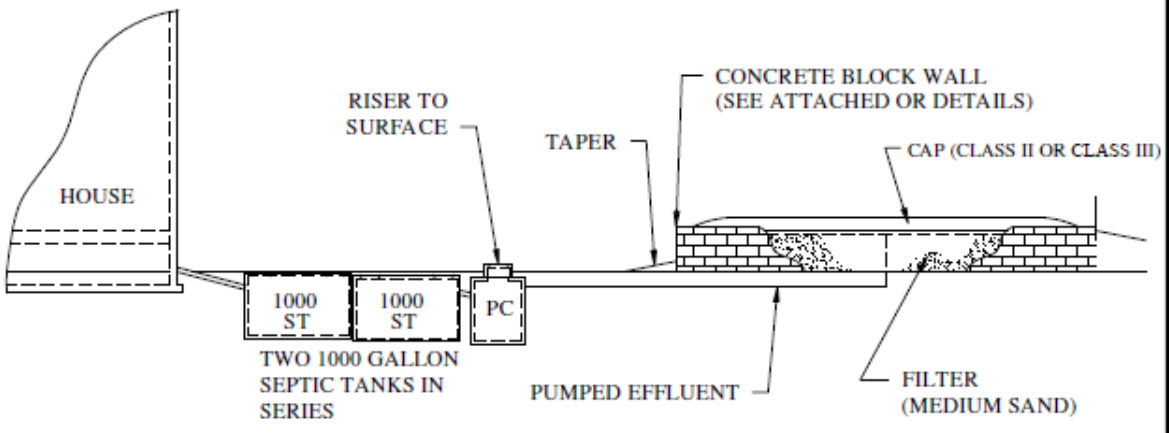
TYPICAL DESIGN ILLUSTRATION - FIGURE A
SQUARE CONCRETE & BLOCK FILTER DETAILS



PLAN VIEW
NOT TO SCALE



ELEVATION
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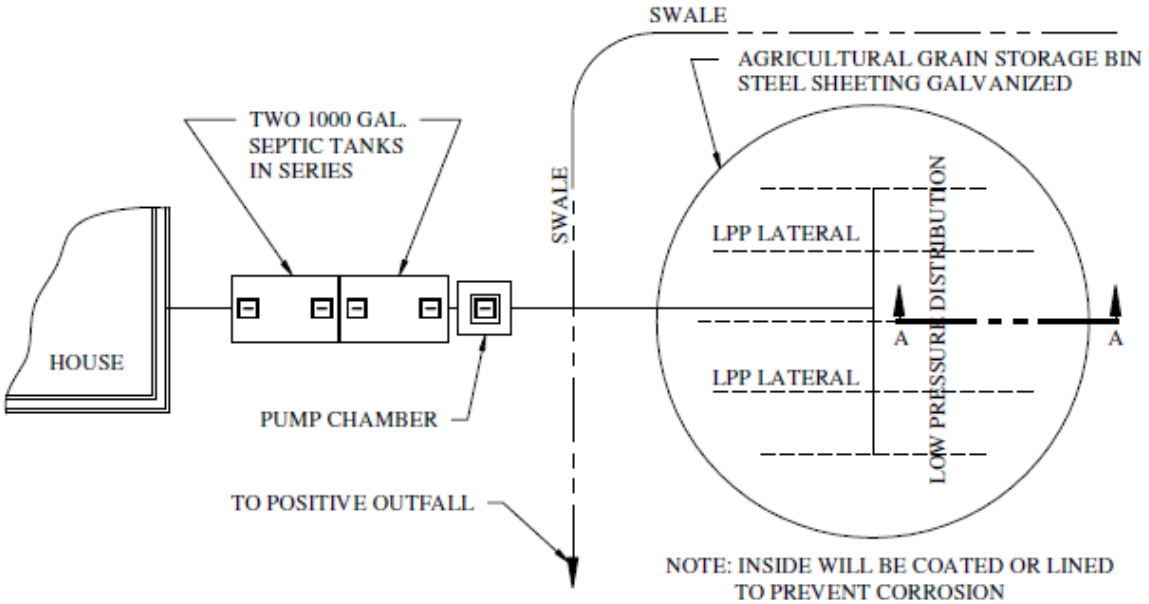
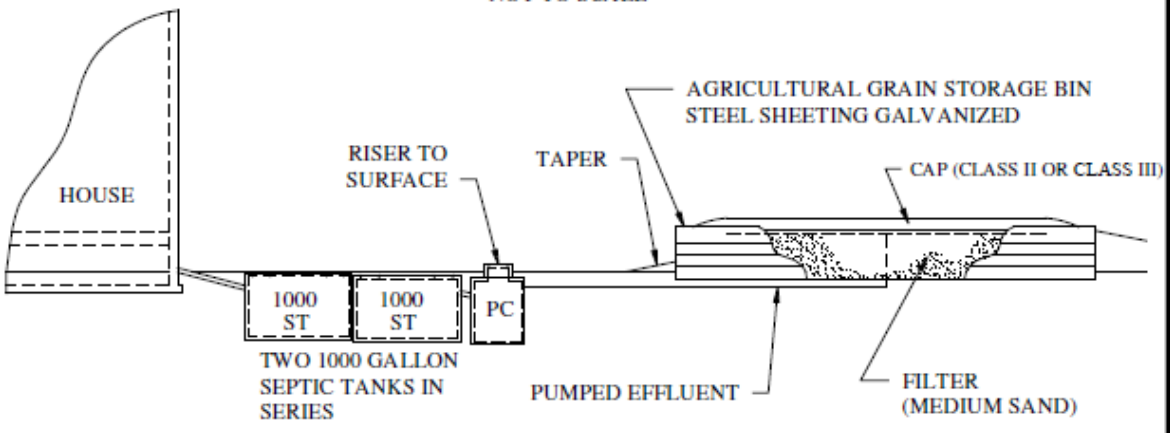
TYPICAL DESIGN ILLUSTRATION - FIGURE A

CIRCULAR STEEL FILTER DETAILS



PLAN VIEW
NOT TO SCALE



ELEVATION
NOT TO SCALE

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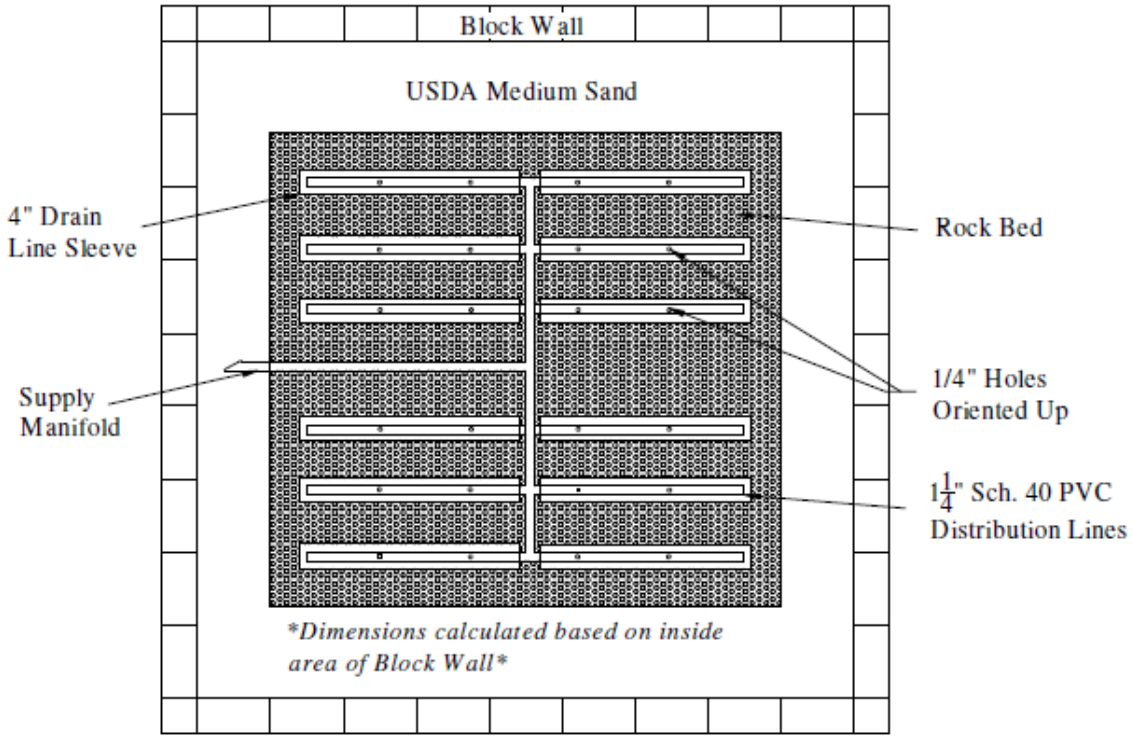
TYPICAL DESIGN ILLUSTRATION - FIGURE B
SQUARE CONCRETE & BLOCK FILTER DETAILS



EACH LATERAL TO BE INSTALLED IN A ROCK BED

ALL LATERAL PRESSURE LINES ARE REQUIRED TO HAVE ELBOWS AT THE ENDS OF EACH LINE AND EXTEND TO FINISHING GRADE WITH SCREW-ON CLEANOUT CAPS

ALL HOLES ARE TO BE EQUALLY SPACED FROM ENDS OF EACH LINE AND BETWEEN EACH HOLE

ELEVATION
NOT TO SCALE

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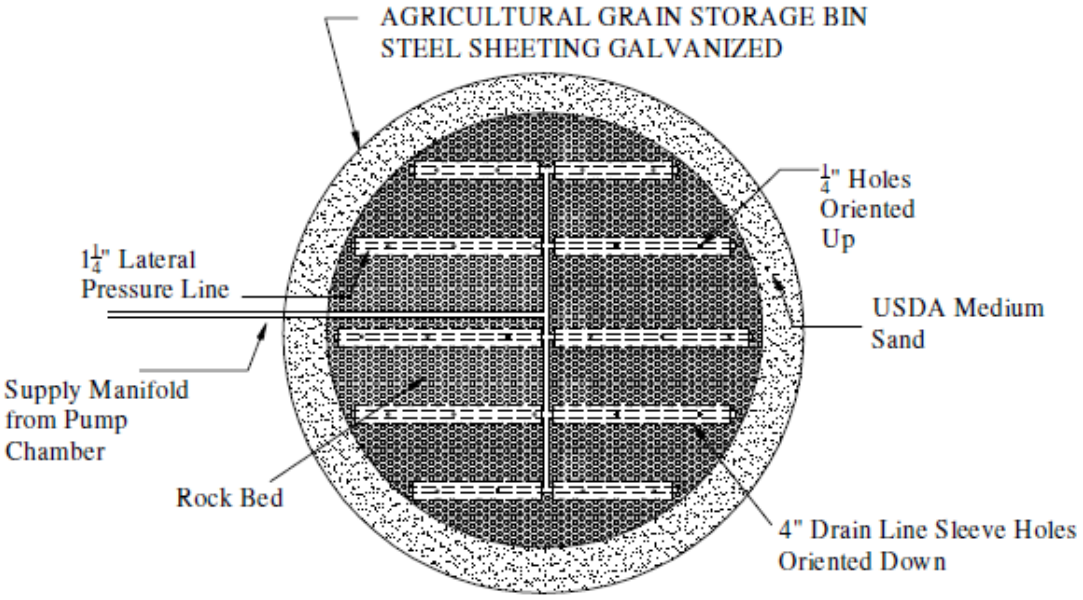
TYPICAL DESIGN ILLUSTRATION - FIGURE B
CIRCULAR STEEL FILTER DETAILS



EACH LATERAL TO BE INSTALLED IN A ROCK BED

ALL LATERAL PRESSURE LINES ARE REQUIRED TO HAVE ELBOWS AT THE ENDS OF EACH LINE AND EXTEND TO FINISHING GRADE WITH SCREW-ON CLEANOUT CAPS

ALL HOLES ARE TO BE EQUALLY SPACED FROM ENDS OF EACH LINE AND BETWEEN EACH HOLE

ELEVATION
NOT TO SCALE

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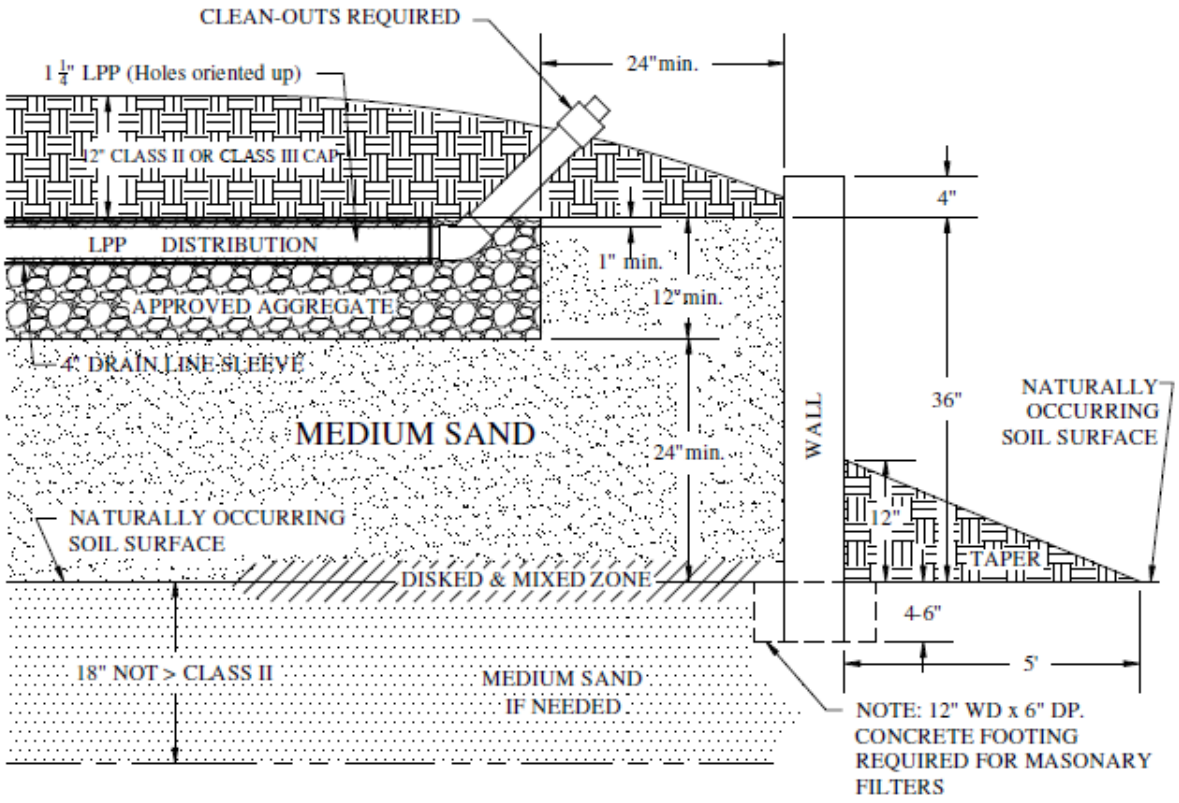
SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
BUREAU OF ENVIRONMENTAL HEALTH SERVICES

ALTERNATIVE STANDARD
ELEVATED INFILTRATION SYSTEM

PROGRAM 362 / CODE 601

TYPICAL DESIGN ILLUSTRATION -FIGURE C



NOT TO SCALE

Rev. 03/09/18

~~415 APPENDIX Q SYSTEM STANDARD 610 SPECIALIZED ONSITE WASTEWATER SYSTEM DESIGNS (LESS THAN 1500 GPD)~~**Appendix Q – System Standard 610 – Specialized Onsite Wastewater System Designs (less than 1500 gpd)**

(1) Site/Permitting Requirements

~~(1)~~ (a) This Standard shall not apply to the following:

~~(a)~~ (i) Projects where two (2) or more pieces of deeded property will share a common system.

~~(b)~~ (ii) Residential or commercial projects where the individual or combined peak sewage flow is estimated to be in excess of fifteen hundred (1500) gpd.

~~(c)~~ (iii) Projects that discharge wastes containing high amounts of fats, grease and oil, including restaurants and other food service facilities, unless the system manufacturer certifies that the proposed system is designed to treat such high strength wastes.

~~(d)~~ (iv) Industrial process wastewater.

~~(2)~~ (b) A site may be considered for a specialized onsite wastewater system design if written documentation provided by a Registered Professional Engineer licensed in ~~the State of~~ South Carolina, including soil studies performed by a ~~Professional Soil Classifier licensed in the State of South Carolina~~licensed person meeting the criteria of Section 102.1(2)(b) or (c), indicates that the proposed system will function satisfactorily and in accordance with all requirements of ~~R.61-56~~this regulation. Such substantiating documentation must include the following:

~~(a)~~ (i) A Soils Report from a ~~Professional Soil Classifier licensed in the State of South Carolina~~licensed person meeting the criteria of Section 102.1(2)(b) or (c) including detailed soil profile descriptions and Soil Series classification(s) utilizing methods and terminology specified in the Field Book for Describing and Sampling Soils; depth to the zone of saturation utilizing methods and terminology outlined in Redoximorphic Features for Identifying Aquic Conditions, and other appropriate principles specified in Soil Taxonomy; the depth to restrictive horizons; and a description of topography and other pertinent land features.

~~(b) Delineation of any affected jurisdictional wetlands, if applicable. Should any part of the proposed onsite wastewater system be located in jurisdictional wetlands, approval from the appropriate permitting agency(s) (i.e., US Army Corps of Engineers, SCDHEC Ocean and Coastal Resource Management) shall accompany the application for a specialized onsite wastewater system design.~~

(ii) For drain field and replacement areas with a less than fifteen (15) inch zone of saturation, no part of a specialized onsite wastewater system may be installed within one hundred twenty-five (125) feet of the critical area line or tidal waters as determined by the Department or within one hundred twenty-five (125) feet of the ordinary high water elevation within the banks of non-tidal, environmentally sensitive waters.

~~(c)~~ (iii) There shall be a replacement area equivalent to at least fifty (50) percent in size of the original system area held in reserve for system repair. This area shall have a suitable configuration~~,~~ and shall meet the minimum soil and site conditions of ~~R.61-56~~this regulation.

~~(d)~~ (iv) A plan that has been sealed, signed and dated by a Registered Professional Engineer licensed in ~~the State of~~ South Carolina certifying that the proposed onsite wastewater system has been designed in

accordance with the requirements of ~~R.61-56~~this regulation and will function satisfactorily. The plan should also show an area equivalent to at least fifty (50) percent in size of the original system held in reserve for system repair.

~~(e)~~ (v) The manufacturer's recommendations for operation and maintenance of the system, and the consulting Registered Professional ~~e~~Engineer's management plan to meet this. For systems that have mechanical components and/or require a higher degree of maintenance to ensure the proper treatment and disposal of Domestic Wastewater, an operation and maintenance (O&M) plan must be developed by the designing Registered Professional Engineer to be given to the party who is ultimately responsible for the operation of the system. O&M plans must be recorded along with the property deed and must run with the land.

~~(3)~~ (c) Any ~~Permit to Construct~~ permit to construct that is issued pursuant to this standard shall be based upon the consulting Registered Professional ~~e~~Engineer's design, certification, and other supporting documentation provided by the ~~Professional Soil Classifier~~licensed person meeting the criteria of Section 102.1(2)(b) or (c).

~~(4)~~ (d) The consulting Registered Professional ~~e~~Engineer shall be responsible for supervising construction of the system and providing the Department with a certified ~~"as-built"~~as-built plan of the actual installation containing all details required by the Department. The certified as-built plan must be submitted to the Department within two (2) business days of completing the system installation. If the construction schedule for a specialized system installation is more than forty-eight (48) hours, the Department must be notified in advance of the beginning of construction. Any Final Approval that is released pursuant to this standard shall be based upon this engineering certification.

~~416 APPENDIX P – Curtain Drain Standard~~**Appendix R – Curtain Drain Standard**

~~416.1 Minimum Construction Requirements~~ (1) Minimum Construction Requirements

~~(1)~~ (a) Only pipe having received written approval from the Department may be utilized in curtain drains. This approval shall be based upon the pipe meeting all applicable ASTM standards.

~~(2)~~ (b) The aggregate used in curtain drains shall be a material approved by the Department. ~~and shall range in size from one-half (½) inch to two and one-half (2 ½) inches. Fines are prohibited.~~

~~(3)~~ (c) The curtain drain trench utilizing tire chips or gravel or a similar type of Department approved product shall be at least six (6) inches wide.

~~(4)~~ (d) The curtain drain shall be placed ten (10) feet upslope and twenty-five (25) feet down-slope of a subsurface wastewater infiltration area or repair area. Where the aggregate portion of the curtain is installed at the same or lower (down–slope) elevation relative to an adjacent subsurface wastewater infiltration area or repair area, the aggregate portion of the curtain must be a minimum of twenty-five (25) feet from the adjacent ~~the~~ subsurface wastewater infiltration area or repair area.

~~(5)~~ (e) The trench bottom shall have a uniform slope to the discharge point. ~~A minimum one (1) percent fall (12 inches per 100 feet) shall be utilized.~~ Trench excavation with a ditch witch is permissible provided the trench bottom has a uniform down-slope gradient.

~~(6)~~ (f) The solid discharge (non-aggregate) line shall be fifteen (15) feet from adjacent subsurface wastewater infiltration area or repair area.

~~(7)~~ (g) The down-slope side of the trench toward the subsurface wastewater infiltration area shall have a minimum six (6) mil poly or an equivalent ~~strong~~strength~~,~~ treated impervious material draped from the trench surface to the trench bottom to prevent groundwater from bridging the curtain drain.

~~(8)~~ (h) Agricultural drainpipe (slitted) with a minimum diameter of four (4) inches shall be placed along the trench bottom in the aggregate portion. Perforated pipe is acceptable, provided the perforations are installed facing either sideways or upward.

~~(9)~~ (i) There shall be at least two (2) inches of aggregate beneath the drainpipe.

~~(10)~~ (j) The aggregate shall be brought to at least six (6) inches from the ground surface.

~~(11)~~ (k) The aggregate shall be covered with a strong, untreated pervious material to prevent infiltration of back fill material.

~~(12)~~ (l) Solid drainpipe with a minimum diameter of four (4) inches shall be placed along the trench bottom from the aggregate to the discharge point.

~~(13)~~ (m) The curtain drain must discharge to the ground surface past the last wastewater infiltration trench line.

~~(14)~~ (n) Rodent barriers on discharge pipe outlet(s) are required.

~~(15)~~ (o) If the curtain drain's trench bottom depth exceeds thirty (30) inches, it shall be inspected prior to the aggregate being installed to ~~i~~ensure proper trench depth and grade. It is acceptable to place the pipe and aggregate in the trench prior to the final inspection when a probe rod inspection port can be used to accurately measure trench bottom depth.

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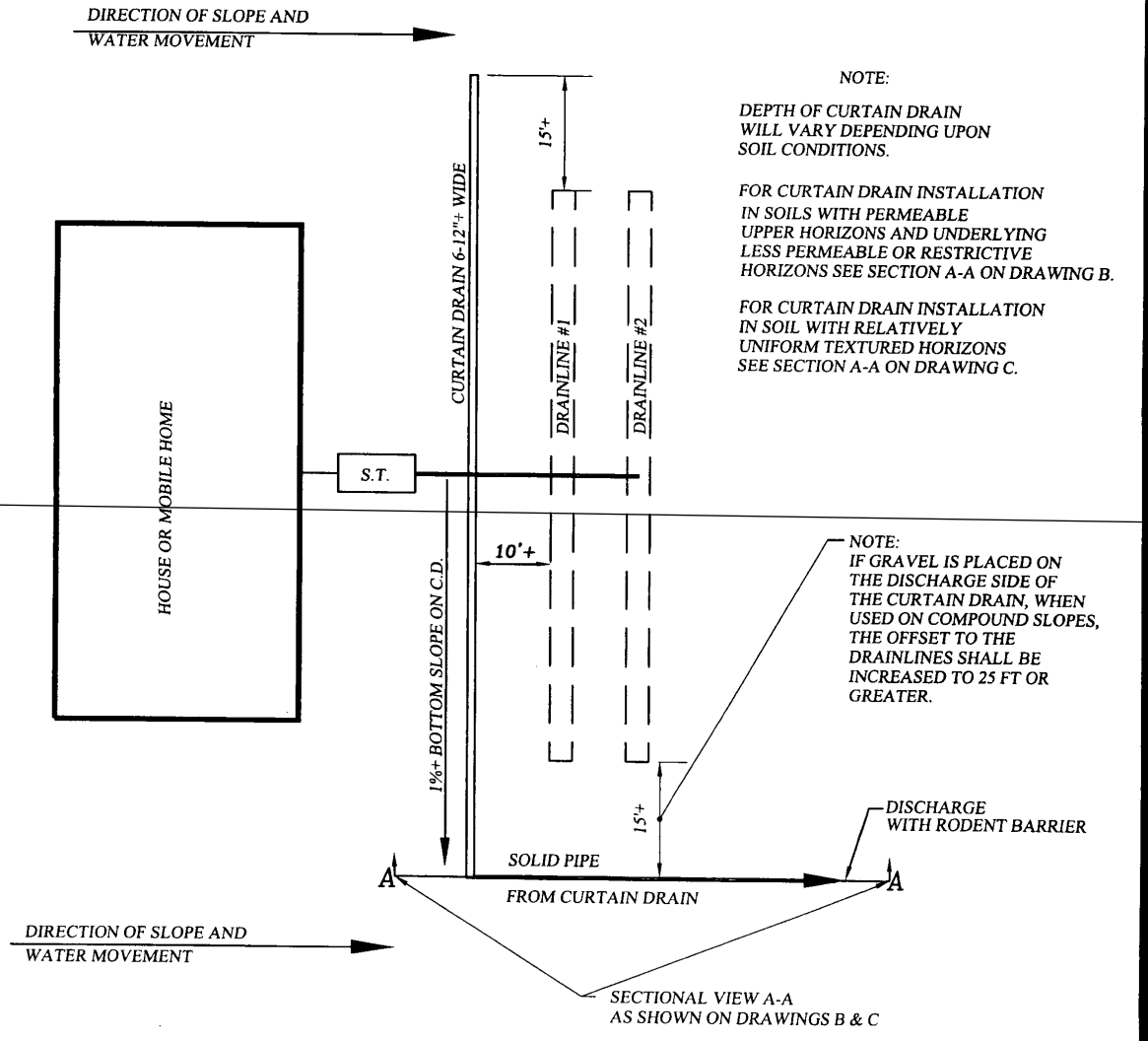
CURTAIN DRAIN STANDARD

TYPICAL DESIGN SKETCH



NOTE:

DEPTH OF CURTAIN DRAIN WILL VARY DEPENDING UPON SOIL CONDITIONS.

FOR CURTAIN DRAIN INSTALLATION IN SOILS WITH PERMEABLE UPPER HORIZONS AND UNDERLYING LESS PERMEABLE OR RESTRICTIVE HORIZONS SEE SECTION A-A ON DRAWING B.

FOR CURTAIN DRAIN INSTALLATION IN SOIL WITH RELATIVELY UNIFORM TEXTURED HORIZONS SEE SECTION A-A ON DRAWING C.

NOTE:
IF GRAVEL IS PLACED ON THE DISCHARGE SIDE OF THE CURTAIN DRAIN, WHEN USED ON COMPOUND SLOPES, THE OFFSET TO THE DRAINLINES SHALL BE INCREASED TO 25 FT OR GREATER.

DRAWING A

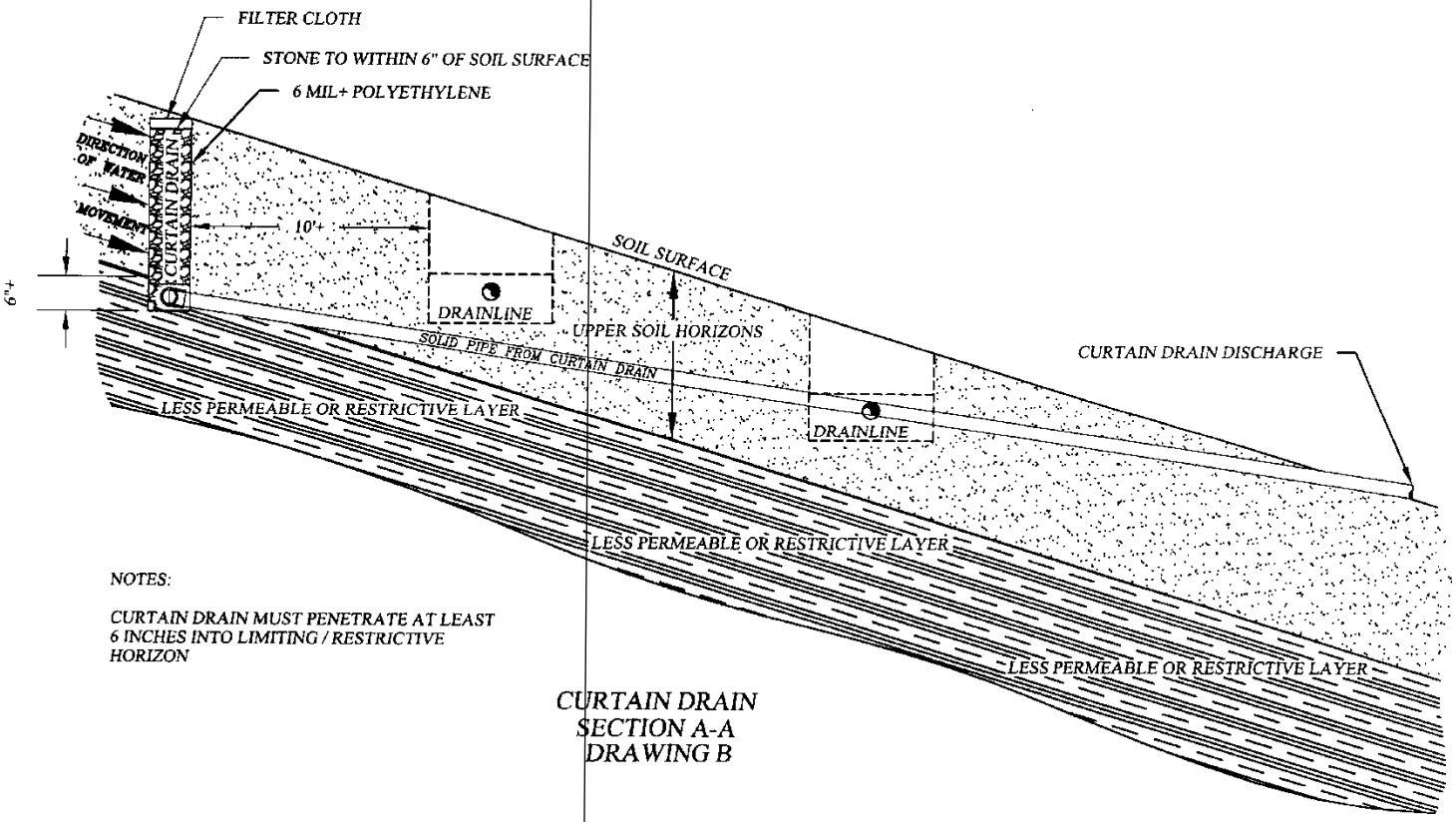
T.L.S.

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
BUREAU OF ENVIRONMENTAL HEALTH

CURTAIN DRAIN STANDARDS

CURTAIN DRAIN INSTALLATION IN SOILS WITH RESTRICTIVE OR LESS PERMEABLE HORIZONS BELOW THE DRAINFIELD

TYPICAL DESIGN SKETCH



NOTES:

CURTAIN DRAIN MUST PENETRATE AT LEAST 6 INCHES INTO LIMITING / RESTRICTIVE HORIZON

CURTAIN DRAIN
SECTION A-A
DRAWING B

DRAWING NOT TO SCALE

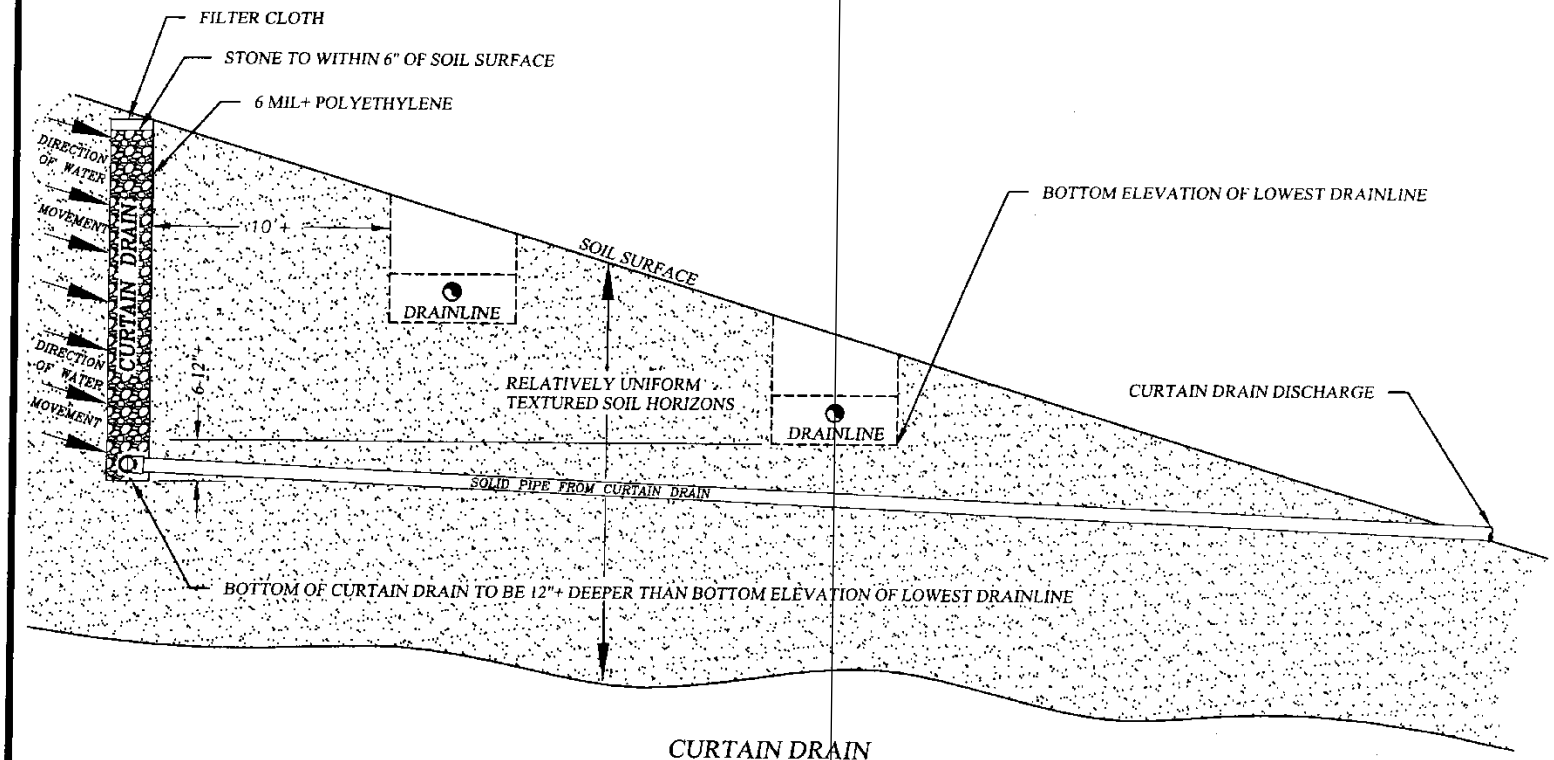
T.L.S.

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
BUREAU OF ENVIRONMENTAL HEALTH

CURTAIN DRAIN STANDARDS

CURTAIN DRAIN INSTALLATION IN SOILS WITH RELATIVELY UNIFORM HORIZONS

TYPICAL DESIGN SKETCH



CURTAIN DRAIN
SECTION A-A
DRAWING C

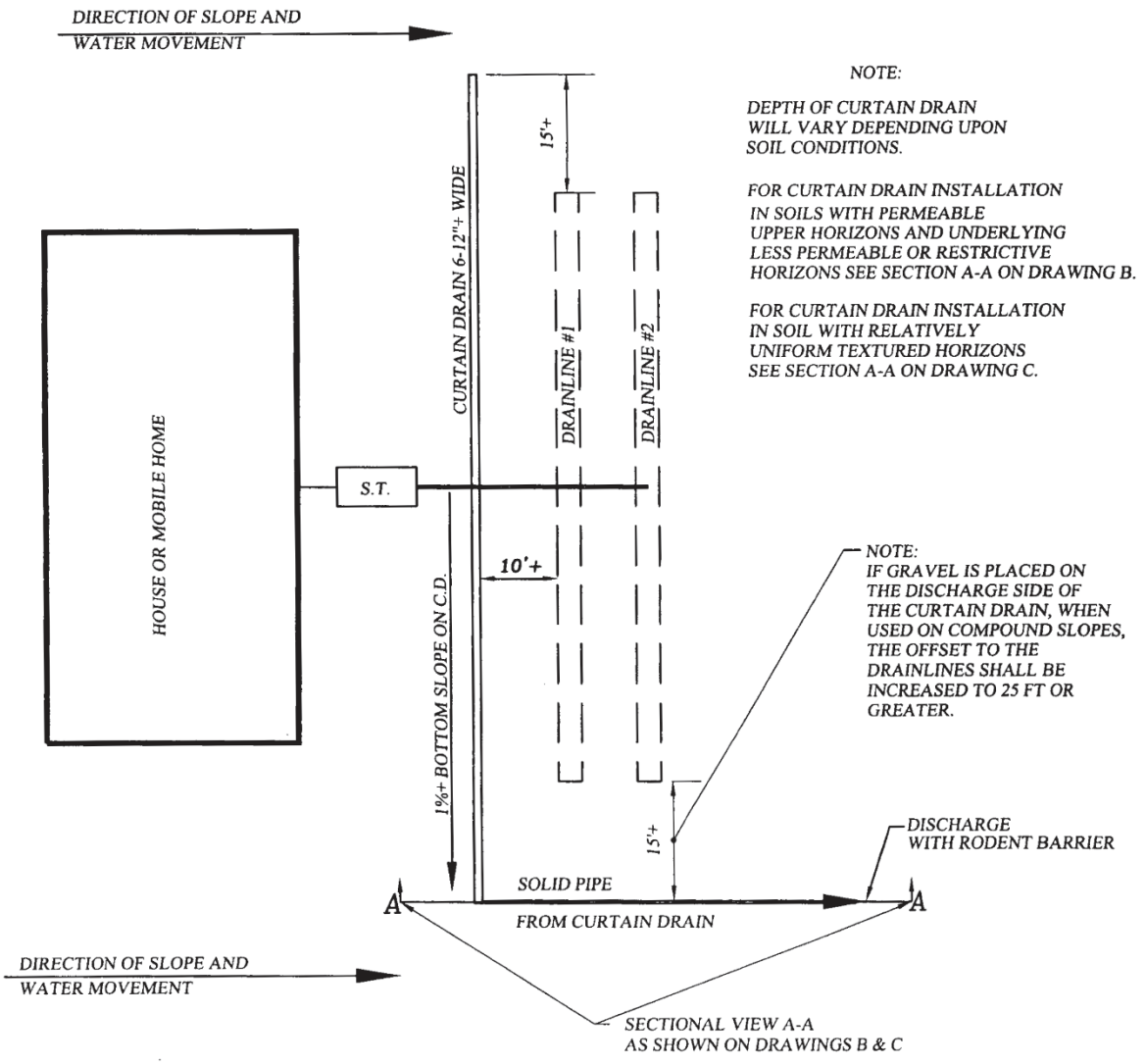
DRAWING NOT TO SCALE

T.L.S.

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
BUREAU OF ENVIRONMENTAL HEALTH SERVICES

CURTAIN DRAIN STANDARD

TYPICAL DESIGN SKETCH



NOTE:

DEPTH OF CURTAIN DRAIN WILL VARY DEPENDING UPON SOIL CONDITIONS.

FOR CURTAIN DRAIN INSTALLATION IN SOILS WITH PERMEABLE UPPER HORIZONS AND UNDERLYING LESS PERMEABLE OR RESTRICTIVE HORIZONS SEE SECTION A-A ON DRAWING B.

FOR CURTAIN DRAIN INSTALLATION IN SOIL WITH RELATIVELY UNIFORM TEXTURED HORIZONS SEE SECTION A-A ON DRAWING C.

NOTE:
IF GRAVEL IS PLACED ON THE DISCHARGE SIDE OF THE CURTAIN DRAIN, WHEN USED ON COMPOUND SLOPES, THE OFFSET TO THE DRAINLINES SHALL BE INCREASED TO 25 FT OR GREATER.

DRAWING A

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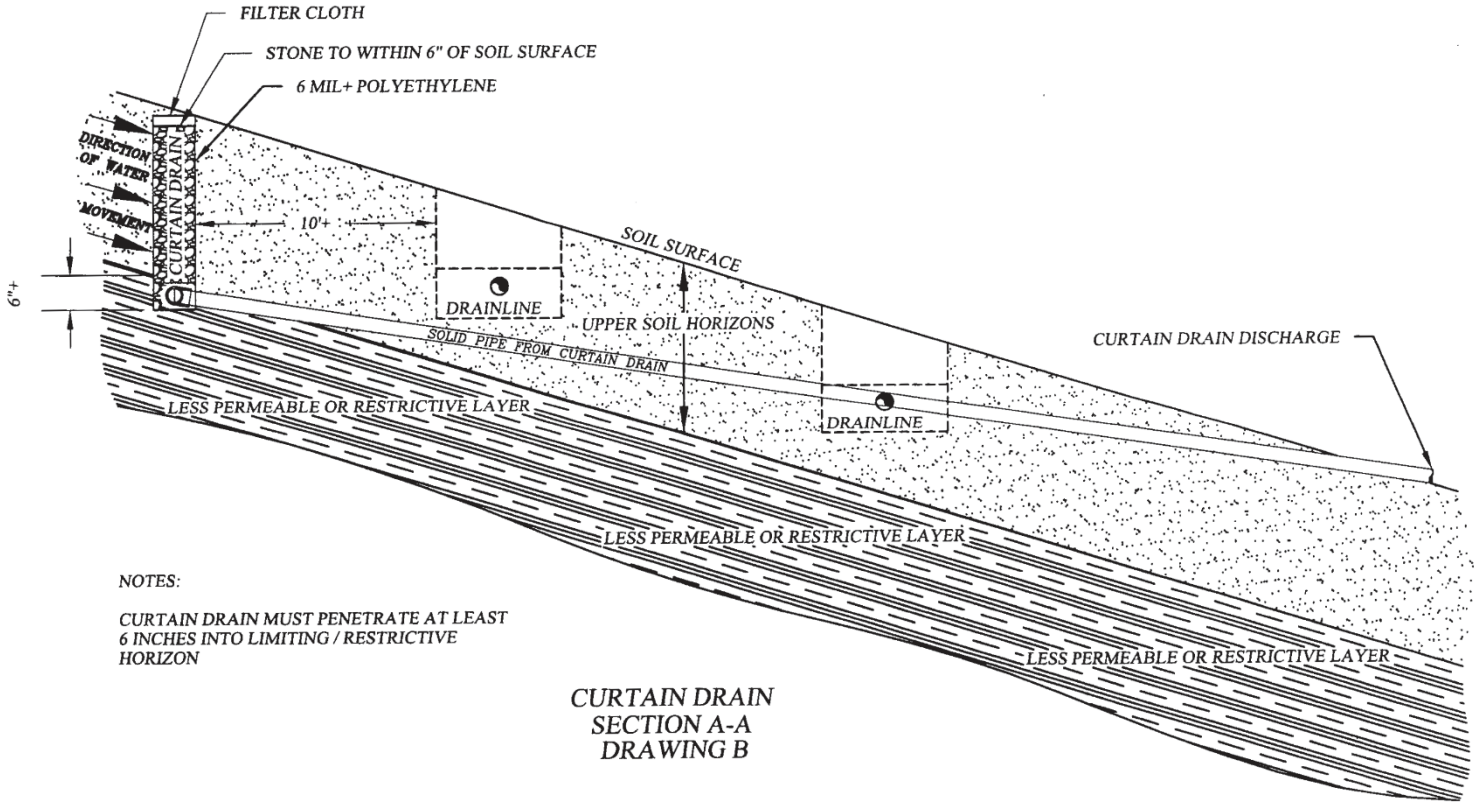
BUREAU OF ENVIRONMENTAL HEALTH SERVICES

CURTAIN DRAIN STANDARDS

CURTAIN DRAIN INSTALLATION IN SOILS WITH RESTRICTIVE OR LESS PERMEABLE HORIZONS BELOW THE DRAINFIELD

TYPICAL DESIGN SKETCH



NOTES:

CURTAIN DRAIN MUST PENETRATE AT LEAST 6 INCHES INTO LIMITING / RESTRICTIVE HORIZON

CURTAIN DRAIN
SECTION A-A
DRAWING B

DRAWING NOT TO SCALE Rev. 03/09/18 T.L.S.

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
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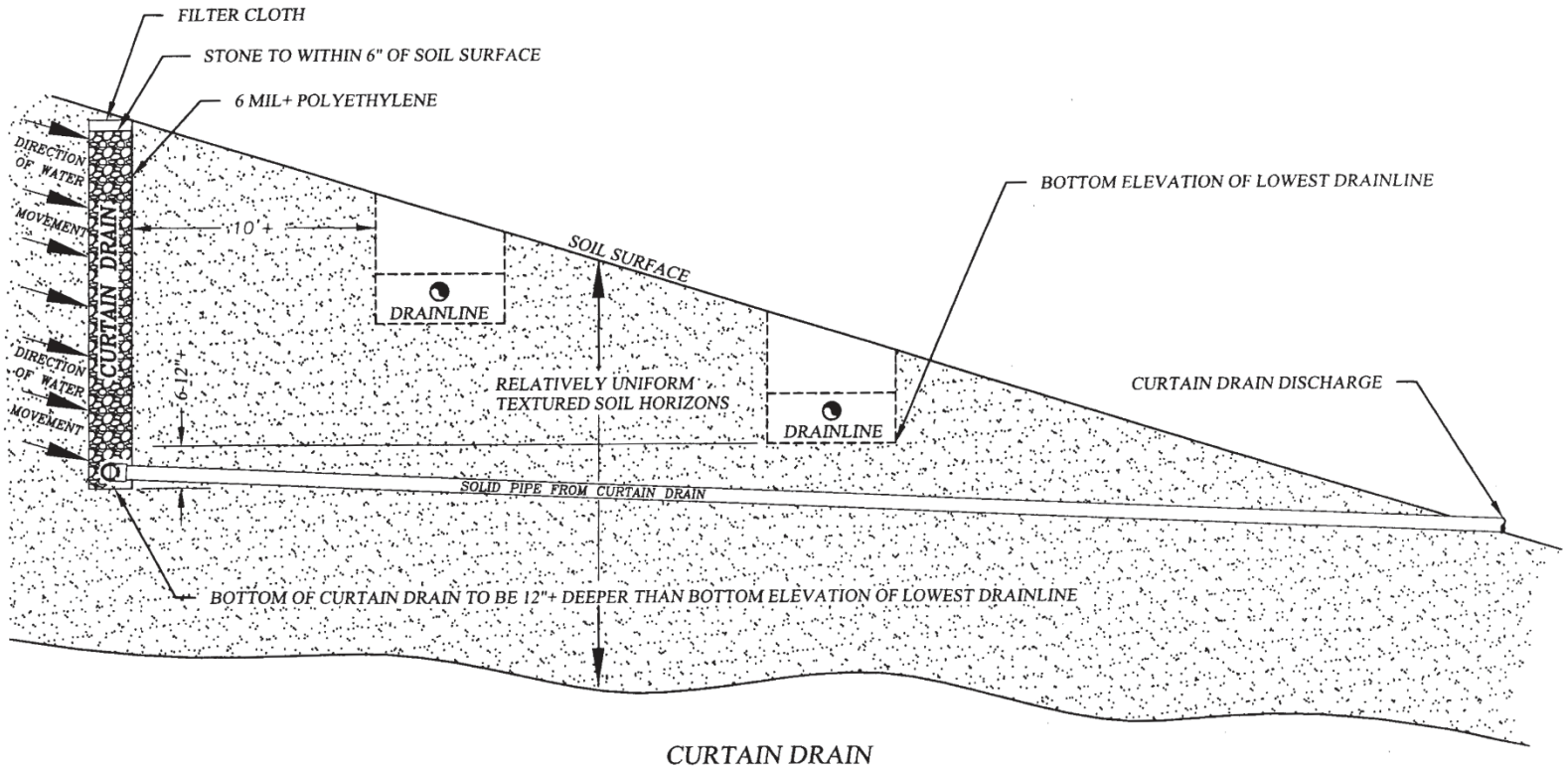
CURTAIN DRAIN STANDARDS

CURTAIN DRAIN INSTALLATION IN SOILS WITH RELATIVELY UNIFORM HORIZONS

TYPICAL DESIGN SKETCH



CURTAIN DRAIN
SECTION A-A
DRAWING C

DRAWING NOT TO SCALE Rev. 03/09/18 T.L.S.

Appendix S – Nonwater-Carried Sewage Treatment Systems

(1) The permitting of nonwater-carried sewage treatment systems, such as a biological, composting, or incinerating toilet, may be considered for toilet wastes when a proposed site is unsuitable for the issuance of an onsite wastewater system permit under the system standards in Appendices A through R. Nonwater-carried sewage treatment systems shall be designed, installed, maintained, and operated without endangering public health, the environment, or creating a nuisance.

(2) With the application for a permit to construct, all applicants seeking to install a nonwater-carried sewage treatment system must submit to the Department plans from a Registered Professional Engineer licensed in South Carolina that describe the design and installation of the proposed nonwater-carried sewage treatment system and demonstrate the following:

(a) The system complies with all local codes and ordinances.

(b) All products and processes meet applicable National Sanitation Foundation (NSF) Standards and American National Standards Institute (ANSI) Standard 41 and bear the seal of approval of the NSF or an equivalent testing and certification program.

(c) Compartment and appurtenances are insect and vector-proof and have continuous exterior ventilation.

(d) There will be no liquid wastewater produced by the system.

(e) Methods for training the owner/operator in the proper use, function, and maintenance of the system including safe handling and disposal methods for any residue generated by the system.

(f) All manufacturer recommendations for installation, operation, and maintenance will be followed.

(3) Applicants seeking to install a nonwater-carried sewage treatment system at a site where water under pressure will be connected to the structure and gray water is generated (from showers, sinks, etc.), but where nonwater-carried sewage treatment systems will be the only means for toilet waste disposal, must:

(a) Submit plans from a Registered Professional Engineer licensed in South Carolina that meet the requirements of Appendix S, paragraphs (2)(a) through (f), for all toilet wastes; and

(b) Apply for and obtain a Department permit to construct and approval to operate an onsite wastewater system for treatment of gray water. This system must meet all permit, licensing, and onsite wastewater system requirements under this regulation, except that the initial system size may be reduced by twenty-five (25) percent.

(4) A licensed installer is not required for the installation of a nonwater-carried sewage treatment system under this standard. However, engineering certifications using the applicable Department form must be submitted to the Department before the Department will issue an approval to operate a system under this standard.

Appendix T – Wastewater Combustion Systems

(1) Wastewater combustion systems may be considered when a proposed site is unsuitable for the issuance of an onsite wastewater system permit under the system standards in Appendices A through R. A

wastewater combustion system shall be designed, installed, maintained, and operated without endangering public health, the environment, or creating a nuisance.

(2) With the application for a permit to construct, all applicants seeking to install a wastewater combustion system must submit to the Department plans from a Registered Professional Engineer licensed in South Carolina that describe the design and installation of the proposed wastewater combustion system and demonstrate the following:

(a) The system complies with all local codes and ordinances.

(b) CSA Group certification of the wastewater combustion system in the United States.

(c) The system must be of adequate size to handle the wastewater volume and peak flow generated by the structure.

(d) Compartment and appurtenances are insect and vector-proof and have continuous exterior ventilation.

(e) All liquid wastewater produced must be sent to the combustion system. Liquid wastewater must not be sent to an onsite wastewater system or held in a storage system to be pumped and hauled.

(f) Methods for training the owner/operator in the proper use, function, and maintenance of the system including safe handling and disposal methods for any residue generated by the system.

(g) All manufacturer recommendations for installation, operation, and maintenance will be followed.

(3) Applicants seeking to install a wastewater combustion system for toilet wastes in conjunction with an onsite wastewater system for treatment of gray water generated by the structure must:

(a) Submit to the Department plans from a Registered Professional Engineer licensed in South Carolina that meet the requirements of Appendix T, paragraphs (2)(a) through (g), for all toilet wastes; and

(b) Apply for and obtain a Department permit to construct and approval to operate an onsite wastewater system for treatment of gray water. This system must meet all permit, licensing, and onsite wastewater system requirements under this regulation, except that the initial system size may be reduced by twenty-five (25) percent.

(4) A licensed installer is not required for the installation of a wastewater combustion system under this standard. However, engineering certifications using the applicable Department form must be submitted to the Department before the Department will issue an approval to operate a system under this standard.

Appendix U – Gray Water Subsurface Reuse Systems

(1) With the application for a permit to construct, all applicants seeking to install a gray water subsurface reuse system must submit to the Department for approval plans from a Registered Professional Engineer licensed in South Carolina that describe the design and installation of the proposed gray water subsurface reuse system and demonstrate the following:

(a) The system complies with all local codes and ordinances.

(b) The system must be of adequate size to handle the wastewater volume and peak flow generated by the structure.

(c) Compartment and appurtenances are insect and vector-proof and have continuous exterior ventilation.

(d) All gray water produced by the structure must be sent to the gray water subsurface reuse system or to a separate onsite wastewater system for treatment and disposal of domestic wastewater. Liquid wastewater must not be held in a storage system to be pumped and hauled.

(e) Methods for training the owner/operator in the proper use, function, and maintenance of the system including safe handling and disposal methods for any residue generated by the system.

(f) All manufacturer recommendations for installation, operation, and maintenance will be followed.

(2) This regulation does not apply to or permit the reuse of gray water for any purpose, or by any means, other than subsurface irrigation. This regulation also does not apply to or permit any reuse or recirculation of gray water within the confines of (i.e., via the plumbing within) a dwelling unit, building, business, or other structure.

(3) A property owner proposing to install a gray water subsurface reuse system for the reuse and disposal of gray water shall ensure that there is also an approved method of treatment and disposal for all other domestic wastewater and sewage generated by the structure. An onsite wastewater system for the treatment and disposal of all other domestic wastewater and sewage generated by the structure shall meet all requirements of this regulation, including standard sizing requirements.

(4) A licensed installer is not required for the installation of a gray water subsurface reuse system under this standard. However, engineering certifications using the applicable Department form must be submitted to the Department before the Department will issue an approval to operate a system under this standard.

~~500 APPENDIX Q – LONG-TERM ACCEPTANCE RATE STANDARD FOR ONSITE WASTEWATER SYSTEMS~~**500. Long-Term Acceptance Rate Standard for Onsite Wastewater Systems.**

USDA-NRCS SOIL TEXTURE	SOIL CHARACTERISTICS WHEN MOIST (FIELD TEST)	LONG-TERM ACCEPTANCE RATE (GPD/SF)	
Sand (S)	~~Sandy~~Sand has a gritty feel, does not stain the fingers, and does not form ribbon or ball when wet or moist.	0.9 – 1.0	Class I
Loamy Sand (LS)	Loamy sand has a gritty feel, stains the fingers, forms a weak ball, and cannot be handled without breaking.		
Sandy Loam (SL)	Sandy loam has a gritty feel and forms a ball that can be picked up with the fingers and handled with care without breaking.	0.7 – 0.8	Class II
Loam (L)	Loam may have a slightly gritty feel but does not show a fingerprint, and forms only short ribbons ~~of~~ from 0.25 – 0.50 inch. Loam will form a ball that can be handled without breaking.		

USDA-NRCS SOIL TEXTURE	SOIL CHARACTERISTICS WHEN MOIST (FIELD TEST)	LONG-TERM ACCEPTANCE RATE (GPD/SF)	
Sandy Clay Loam (SCL)	Sandy clay loam has a gritty feel but contains enough clay to form a firm ball~~,~~ and may ribbon from 0.75 – 1.0 inch.	0.5 – 0.6	Class III
Clay Loam (CL)	Clay loam is sticky when moist, forms a ribbon of 1.0 – 2.0 inches, and produces a slight sheen when rubbed with the thumbnail. Clay loam produces a nondistinct fingerprint.		
Silt Loam (SiL)	Silt loam has a floury feel when moist and will show a fingerprint, but will not ribbon and forms only a weak ball.		
Silt (Si)	Silt has a floury feel when moist and is sticky when wet but will not ribbon and forms a ball that will tolerate some handling.	0.1 – 0.4	Class IV
Silty Clay Loam (SiCL)	Silty clay loam has a slight floury feel, is sticky when moist, and will ribbon from 1.0 – 2.0 inches. Rubbing with thumbnail produces a moderate sheen. Silty clay loam produces a distinct fingerprint.		
Sandy Clay (SC)	Sandy clay is plastic, gritty, and sticky when moist, forms a firm ball, and produces a ribbon in excess of 2.0 inches.		
Clay (C)	Clay is both sticky and plastic when moist, produces a ribbon in excess of 2.0 inches, produces a high sheen when rubbed with the thumbnail, and forms a strong ball resistant to breaking.		
Silty Clay (SiC)	Silty clay has a slight floury feel, is both sticky and plastic when moist, forms a ball, and produces a ribbon in excess of 2.0 inches.		

(1) The long-term acceptance rate for system sizing shall be based upon the most hydraulically limiting naturally occurring soil texture from the ground surface to twelve (12) inches below the bottom of the proposed wastewater infiltration trenches. Alternative and experimental systems installed beneath expansive soils shall be sized at a long-term acceptance rate not to exceed 0.2-0.25 ~~GPD/SF~~gpd/sf as specified in approved standards.

(2) Soil texture shall be estimated by field testing as described above. Laboratory determination of soil texture may be substituted for field testing when conducted in accordance with: (1) Bouyoucos, G.J. 1962. Hydrometer Method Improved for Making Particle Size Analyses of Soils. Agron. J. 53:464-465; (2) ASTM D-422, Procedures for Sieve and Hydrometer Analyses; or (3) the Pipette Method (ASA-CSSA-SSSA), USDA Methods of Soils Analysis, Soil Survey Laboratory Information Manual, and Soil Survey Laboratory Methods Manual.

(3) The total linear feet (~~LF~~lf) for conventional onsite wastewater systems shall be calculated by dividing the peak daily flow (~~GPD~~gpd) by the long-term acceptance rate (~~GPD/SF~~gpd/sf) and dividing the result by the trench width (~~FT~~ft): ~~LF~~lf = ~~GPD~~gpd ÷ ~~GPD/SF~~gpd/sf ÷ ~~FT~~ft. The total linear feet for alternative systems may either be increased or decreased in accordance with factors specified in alternative standards.

~~501 APPENDIX R - PEAK SEWAGE FLOW RATE STANDARD~~**501. Peak Sewage Flow Rate Standard.**

ESTABLISHMENT	UNIT	PEAK FLOW RATE GAL/UNIT/DAY
Airport (Not Including Food Service)	Passenger	3
Assembly Halls	Person	3
Bar (Not Including Food Service)	Customer Seat	5 15
Beauty/Style Shops/Barber Shops	Chair	100
Businesses/Offices/Factories (Add for Showers)	Employee/Shift Transient Employee (4 hrs or Less/Shift) Employee	15 10 10
Camps (No Laundry) -Labor/Summer/Retreat (Separate Food Service) (Separate Bath House) -Day Camps (with meal) (without meal)	 Person Person Person Person Person	 35 10 25 15 10
Campgrounds (No Laundry) -Full Water/Sewer -No Sewer Risers, Bathhouse only (Add for Dump Station)	 Campsite Campsite Campsite	 120 50 40
Car Wash (Non-automatic)	Bay	500
Church (No Daycare) -With Kitchen -Without Kitchen -Family Life Center	 Seat Seat Person	 3 2 5
Day Care	Child	10
Food Service -Full Service Utensils -Paper/Plastic Utensils	 Meal Person Seat	 4 10 40 Reduce by 50 percent
Golf Course Club House (Not Including Foodservice)	Player	10
Kennel	Run	25
Laundromat	Machine	500
~~ESTABLISHMENT~~	~~UNIT~~	~~PEAK FLOW RATE GAL/UNIT/DAY~~
Mortuary (for domestic wastewater only, no infectious waste)	Body	25
Hotel/Motel (Not Including Food Service)	Room	100
Picnic Park	Visitor	10
Public Restroom	User	3

ESTABLISHMENT	UNIT	PEAK FLOW RATE GAL/UNIT/DAY
Residential/Dwelling ~~(i.e., Apartment/Condominium/Individual Dwelling, including Resort Rental and Resort Residence)~~	Bedroom	120
Residential Care	Resident	100
Residential Out-Building (not used as a dwelling; e.g., pool house, private workshop or garage with private-use bathroom with toilet and sink; barn with hand-wash sink)	1 to 3 Users Without washing machine With washing machine/shower	 60 120
School -With Cafeteria, Gym & Showers -With Cafeteria only -Without Cafeteria, Gym or Showers -Boarding School	 Student Student Student Person	 15 10 8 60
Stadium (Not Including Food Service)	Seat/Occupancy	3
Swimming Area Bathhouse	Person	10
Visitor Center	Visitor	5

The peak flow rate (~~GPD~~gpd) for non-residential facilities may either be increased or reduced when comparable peak water consumption data for similar establishments in similar locations vary from the requirement. When considering such data, at least twelve (12) consecutive months must be presented with the maximum month of consumption and the days of operation per month being utilized to arrive at the peak flow rate (~~GPD~~gpd).

~~600 APPENDIX S – ONSITE WASTEWATER PUMP SYSTEM STANDARD~~ **502. Onsite Wastewater Pump System Standard.**

~~600.1 PUMP TANK (GENERAL)~~ 502.1. Pump Tank (General).

(1) The submersible sewage effluent pump(s) must be housed in a properly vented, watertight tank that is readily accessible from the surface.

(2) A watertight access opening with removable lid shall be provided~~,~~ and shall be designed and maintained to prevent surface water inflow. Risers and other pump tank sections, where present, shall be joined using mastic, butyl rubber, or other pliable sealant that is waterproof, corrosion-resistant, and approved for use in septic tanks.

(3) When the pump tank must be located in an area characterized by a shallow zone of ~~seasonal~~ saturation, the Department may require the use of a pre-cast manhole, a fiberglass or polyethylene basin, or any other acceptable method for preventing groundwater intrusion.

(4) When the pump tank must be located in an area that is environmentally sensitive or subject to flooding, applicable portions of ~~R. 61-67~~R.61-67, Standards for Wastewater Facility Construction, shall apply.

(5) The pump tank shall have sufficient capacity to accommodate all level control and alarm switches; to keep the pump(s) totally submersed in liquid at all times~~;~~ and to provide the required dosing volume and minimum pump run time. ~~It is strongly recommended that pump~~ Pump tank ~~capacities~~capacity must be at least 500 gallons ~~be as large as possible (i.e., 500-1000 gal.)~~ in order to provide emergency storage in the event of pump or power failure and to assist in maintaining the minimum pumping rate as listed in Section 502.2.

(6) Pre-engineered, manufactured packaged pump stations can be utilized in lieu of the composite design described herein, provided the pump meets the minimum capacity requirements of the system and no alterations are made to the pump station other than those specifically authorized by the manufacturer.

~~600.2 MINIMUM PUMPING RATES (PEAK INFLOW) AND MINIMUM RUN TIMES~~502.2. Minimum Pumping Rates (Peak Inflow) and Minimum Run Times.

(1) For residential systems, the maximum daily flow entering the pump tank shall be based upon one hundred twenty (120) gpd per bedroom. ~~-~~For commercial and other facilities, this value shall be based upon ~~the Standard for Determining Sewage Flow Rates from Commercial and Recreational Establishments~~ Section 501, Peak Sewage Flow Rate Standard.

(2) The minimum pumping rate (peak inflow) for discharges up to fifteen hundred (1500) gpd shall be determined as follows:

Maximum Estimated Daily Flow (gpd)	Minimum Pumping Rate (peak inflow) (gpm)
480 and less	10
481 - 720	15
721 - 1500	20

(3) The minimum pumping rate (peak inflow) for discharges in excess of fifteen hundred (1500) gpd shall be determined by multiplying the average flow rate (gpm) times a peaking factor of not less than 2.5, where the average flow rate is based upon actual minutes per day of facility operation.

(4) The minimum pump run time for all pump systems shall be determined as follows:

Minimum Pumping Rate (peak inflow) (gpm)	Minimum Pump Run time (min)
10 - 14	3
15 - 24	4
25 and above	5

~~600.3 MINIMUM DOSING VOLUME, SCOURING VELOCITY, AND PUMP CAPACITY~~ 502.3. Minimum Dosing Volume, Scouring Velocity, and Pump Capacity.

(1) The minimum dosing volume (gal) shall be determined by multiplying the minimum pumping rate (gpm) times the minimum pump run time (min).

(2) The selected pump(s) must have the capacity to deliver the minimum pumping rate (gpm) at a scouring velocity of at least one (1) ft/sec (effluent) or two (2) ft/sec (raw) against the total dynamic head of the system. This minimum pump capacity (gpm at total feet of dynamic head) shall be specified on ~~SCDHEC Form 1739~~the permit to construct.

(3) Duplex pumps shall be required when the maximum estimated daily flow is equal to or greater than fifteen hundred (1500) gallons, and each pump shall meet the minimum capacity as stated above.

(4) In those cases where the minimum pump capacity or any other system requirements exceed what can be specified ~~thru~~ through the use of this Standard, the Department shall require the applicant to retain the services of a Registered Professional Engineer licensed in South Carolina.

~~600.4 FORCE MAIN, VALVES, AND FITTINGS~~ 502.4. Force Main, Valves, and Fittings.

(1) The force main shall be Schedule 40 PVC, and the diameter shall be sufficient to provide a velocity of at least one (1) ft/sec (effluent) or two (2) ft/sec (raw) using a C Factor of one hundred fifty (150) (effluent) or one hundred forty (140) (raw) at the minimum pumping rate (peak inflow). The force main shall be installed a minimum of eight (8) inches below the ground surface. Fittings and valves shall be of compatible corrosion resistant material.

(2) A threaded union, flange, or similar disconnect device shall be provided in each pump discharge line. The pump(s) shall be easily removable at ground surface without requiring entrance into the tank. Valves shall also be readily accessible from the ground surface. Duplex pump systems shall be equipped with a separate pit or box for the placement and operation of valves.

(3) A shutoff valve (e.g., gate valve) and a check valve shall be located on the discharge line from each pump. The check valve shall be placed between the pump and the shutoff valve.

(4) A three-sixteenths (3/16) inch anti-siphon hole(s) shall be placed between the pump(s) and the check valve(s) when the discharge elevation of the distribution system is below the inlet to the pump tank.

(5) In cases where the force main must be installed over undulating terrain, automatic air relief valves shall be placed at high points in the line to prevent air locking.

(6) Exposed force mains crossing ditches and bodies of water (e.g., creeks and wetlands) and force mains under driveways and parking areas must be protected by encasing them within a larger diameter pipe that can withstand potential damage (e.g., galvanized pipe, steel pipe, ductile iron). Force mains under driveways and parking areas may also be protected by encasing them within a larger diameter schedule 80 PVC pipe. The protective piping should extend beyond the area of needed protection for at least ten (10) linear feet.

~~(6)~~(7) The force main effluent shall discharge into a separate discharge box or distribution manifold before entering either a septic tank or a soil wastewater infiltration trench. The flow shall be directed to the bottom of the box ~~thru~~through a PVC elbow~~,~~ or into a distribution manifold at an angle of ninety (90) degrees to the septic tank or first wastewater infiltration trench.

~~600.5~~502.5. Pumps, Control Devices, and Electrical Connections.

(1) Pumps shall be listed by Underwriter's Laboratory or an equivalent ~~third party~~third-party testing and listing agency~~,~~ and shall be specifically manufactured for use with domestic wastewater.

(2) Sealed mercury control floats or similar devices designed for detecting liquid levels in septic tank effluent shall be provided to control pump cycles. A separate level sensing device shall be provided to activate an audible and visible high water alarm. Pump-off levels shall be set to keep the pump submerged at all times.

(3) Pump and control circuits shall be provided with manual circuit disconnects within a watertight, corrosion resistant, outside enclosure (NEMA 4X or equivalent) adjacent to the pump tank, securely mounted at least twelve (12) ~~in.~~inches above finished grade, unless installed within a weather-tight building. Alarm circuits shall be supplied ahead of any pump overload or short circuit protective devices. The pump(s) shall be manually operable without requiring special tools or entrance into the tank for testing purposes. Conductors shall be conveyed to the disconnect enclosure through water proof, gas proof, and corrosion resistant conduit(s)~~,~~ with no splices or junction boxes provided inside the tank. Wire grips, duct seal, or other suitable material shall be used to seal around wire and wire conduit openings inside the pump tank and disconnect enclosure.

(4) For systems requiring duplex pumps, each pump shall operate in a lead-lag sequence and be on an alternating cycle. A control panel shall be provided which shall include short circuit protection for each pump and for the control system, independent disconnects, automatic pump sequencer, hands-off-automatic (H-O-A) switches, run lights, and elapsed time counters for each pump.

~~600.6 FINAL INSPECTION AND APPROVAL~~502.6. Final Inspection and Approval.

(1) Before or during final inspection, the property owner or agent shall provide literature, including a pump curve, describing the specific pump installed. The inspector shall evaluate the system in accordance with this Standard, and shall confirm that all items, including the minimum pump capacity specified on ~~SCDHEC Form 1739~~the permit to construct, have been satisfied.

(2) Prior to final approval, the installer or electrician shall provide the Department with written documentation verifying that pump system electrical connections were made in accordance with all applicable codes. The Department may require testing of the pump system, demonstration of watertight integrity, or any other procedure deemed necessary to confirm the acceptability of the installation.

~~600.7~~502.7. Raw Sewage Pump Stations.

(1) In those cases where it is necessary to pump raw sewage from a residence or facility to an onsite wastewater system, the pump station shall meet all applicable portions of this Standard and ~~R. 61-67~~R.61-67, Standards for Wastewater Facility Construction.

(2) Adherence to the pump manufacturer's recommendations shall also be a major consideration with such systems.

~~700. APPENDIX T - MINIMUM DESIGN STANDARDS FOR TANK CONSTRUCTION~~**503. Minimum Design Standards for Tank Construction.**

~~700.1 INTRODUCTION~~503.1. Introduction.

The following standards describing tank designs intended to be utilized for septic tanks, grease traps, or pump chambers for onsite wastewater ~~disposal~~ systems have been adopted in an effort to assure a quality product of sufficient strength and resistance, capable of fulfilling its intended purpose.

~~700.2 DESIGN APPROVAL~~503.2. Design Approval.

(1) No person shall manufacture tanks intended to be utilized for septic tanks, grease traps, or pump chambers for onsite wastewater ~~disposal~~ systems without receiving approval from the Department. All manufactured tanks must receive approval of design and reinforcement methods prior to manufacturing.

(2) Any person desiring to manufacture tanks shall ~~make~~ submit a written application on forms provided by the Department. Such application shall include the name and address, the location of the facility, tank capacity, and design information.

(3) Prior to approval, the Department shall review the tank design, reinforcement, and manufacturing methods to determine compliance.

(4) The Department shall approve plans for manufactured tanks to ~~i~~ensure compliance with the South Carolina Minimum Design Standards for Tank Construction.

(5) The Department shall approve plans for fabricated tanks, other than those for precast reinforced concrete tanks, on an individual basis. Fabricated tanks shall meet the requirements of precast reinforced concrete tanks to provide equivalent effectiveness.

(6) The Department shall issue an approval to the tank manufacturer if the tank design, reinforcement and manufacturing method complies with the South Carolina Minimum Design Standards for Tank Construction. Tank manufacturing approvals are not transferable. When a change of ownership occurs, the new owner shall ~~make~~ submit a written application on forms provided by the Department.

(7) The Department shall revoke approval to manufacture tanks for onsite wastewater ~~disposal~~ systems if the tank manufacturer fails to comply with the South Carolina Minimum Design Standards for Tank Construction.

~~700.3 GENERAL~~503.3. General.

(1) Septic tanks and grease traps shall be manufactured as single compartment or partitioned tanks.

(2) If septic tanks and grease traps are manufactured with a partition so that the tank contains two (2) compartments, the inlet compartment of the tank shall contain two-thirds (2/3) of the overall capacity, and the outlet compartment shall contain one-third (1/3) of the overall capacity. The top of the partition shall terminate two (2) inches below the bottom side of the tank top in order to leave space for air or gas passage between compartments. The top and bottom halves of the partition shall be constructed in such manner as to leave a four (4) inch water passage at the vertical ~~mid-point~~mid-point of the partition wall for the full width of the tank.

(3) The minimum liquid capacity requirements shall be met by the use of a single septic tank or two (2) or more tanks installed in series. Septic tanks joined in series shall be interconnected by an upper effluent pipe(s) with a minimum diameter of four (4) inches and a lower sludge pipe(s) with a minimum diameter of twelve (12) inches. The upper connection(s) shall be installed level from tank to tank, and the lower sludge pipe connection(s) shall be installed level and shall be placed twelve (12) inches above the bottoms of the tanks. The lower sludge pipe connection(s) can be eliminated if the first tank in series contains at least two-thirds (2/3) of the total required liquid capacity. There shall be no more than two (2) inches of fall from the inlet invert of the first tank to the outlet invert of the last tank in series.

(4) It is required that all pump chambers function as a single compartment tank. If a two (2) compartment tank is used, at least two (2) six (6) inch diameter holes or equivalent, must be provided in the partition wall six (6) inches from the tank bottom.

(5) The septic tank and grease trap tank length shall be at least two (2) but not more than three (3) times the width.

(6) The liquid depth shall not be less than four (4) feet.

(7) A minimum of nine (9) inches of freeboard shall be provided in all tanks, unless otherwise approved by the Department.

(8) Useable liquid capacity for septic tanks or grease traps shall not be less than one thousand (1000) gallons.

(9) The pump tank shall have sufficient capacity to accommodate all level control and alarm switches; to keep the pump(s) totally submersed in liquid at all times~~;~~ and to provide the required dosing volume and minimum pump run time. It is strongly recommended that pump tank capacities be as large as possible in order to provide emergency storage in the event of pump or power failure.

(10) There shall be a minimum of two (2) openings in the tank wall~~,~~ located at the inlet and outlet ends or sides of the inlet and outlet ends of the tank. The knockouts for the inlet and outlet openings of pre-cast concrete tanks shall have a concrete thickness of not less than one (1) inch in the tank wall. The openings shall allow for a minimum of four (4) inch pipe or a maximum of six (6) inch pipe. No openings shall be permitted below the tank liquid level.

(11) The inlet and outlet for septic tanks and grease traps shall be a cast-in-place concrete tee, a polyvinyl chloride (PVC) tee, an acrylonitrile butadiene styreneor (ABS), or a polyethylene (PE) tee~~,~~ made of not less than Schedule 40 pipe or equivalent fittings and material. The cast-in-place concrete tees shall have a minimum thickness of not less than two (2) inches. The invert of the outlet shall be at least two (2) inches lower in elevation than the invert of the inlet. The inlet and outlet tees shall extend above liquid ~~depth~~level a minimum of six (6) inches and to ~~approximately~~no less than one (1) inch from the top of the tank to allow venting between tank compartments and multiple tank configurations.

(12) The inlet tee for septic tanks and grease traps shall extend sixteen (16) inches below the liquid level.

(13) The outlet tee for a septic tank shall extend eighteen (18) inches below the liquid level and the outlet tee for a grease trap shall extend between six (6) and twelve (12) inches above the tank bottom.

(14) The inlet, outlet, and wiring conduit openings of all tanks must utilize a resilient, watertight, non-corrosive connective sleeve. The use of grout is prohibited.

(15) Access to each tank or compartment shall be provided by an opening located above the inlet and outlet with an inside dimension of at least eighteen (18) inches square (18 x 18) or in diameter, with removable tank access lids.

(16) Concrete tank access lids shall be equipped with steel lift rings at least three-eighths (3/8) inch diameter~~,~~ or by an alternative method approved by the Department.

(17) Should risers or manholes be utilized to allow access into septic tanks, grease traps, or pump chambers, the risers~~/manholes~~ or manhole covers, as applicable, shall be constructed to prevent the release

of odors, entry of vectors, and water. Grade level riser/manhole covers shall be secured by bolts, ~~or~~ locking mechanisms, fasteners that can only be removed by tools, or have sufficient weight to prevent unauthorized access. The ground shall slope away from any access extended to grade level.

(18) Risers/manholes shall be sealed to the tank by using bituminous mastic, butyl rubber, or other pliable sealant that is waterproof, corrosion-resistant, and approved for use in tank construction. The sealant shall have a minimum size of one (1) inch diameter or equivalent. The joint shall be smooth, intact, and free of all deleterious substances before sealing.

(19) After curing, all multi-piece tanks shall be joined and sealed at the joints by using a bituminous mastic, butyl rubber, or other pliable sealant that is waterproof, corrosion-resistant, and approved for use in tank construction. The sealant shall have a minimum size of one (1) inch diameter or equivalent. The joint shall be smooth, intact, and free of all deleterious substances before sealing. The use of grout is prohibited.

(20) All concrete tanks must pass the ASTM C–1227 Standard for watertight testing. The Department will choose tanks at random for testing. Tanks will be approved for use in South Carolina after the Department ascertains that the standard is met. After joining, tanks manufactured in multiple sections shall be plastered along the section joints with hydraulic cement or other waterproofing sealant. Other methods of waterproofing tanks may be used as specifically approved in the plans and specifications for the tank. Prior to backfilling, the ~~local health department~~Department shall make a finding that multiple section tanks are watertight if a soil wetness condition is present within five feet of the elevation of the top of the tank. Any tank found to be improperly sealed, having cracks or holes, which will allow for water infiltration or discharge of sewage from the tank bottom, walls, or top, will not be approved for use.

(21) ~~Tank~~Concrete tank manufacturers must have equipment and capabilities for portion control to maintain constant mixture formulation ratios and provide for systematic inspection of finished products to ~~insure~~ensure compliance with the minimum tank construction and design standards.

(22) The concrete mix used for concrete tank components must be formulated to yield a minimum twenty-eight (28) day compressive strength of four thousand (4,000) pounds per square inch (psi).

(23) The aggregate size utilized in the concrete mix shall not exceed one-third (1/3) of the wall thickness. Suitable aggregates include sand particle sizes from a fine to one-fourth (1/4) inch gravel or crushed stone. Granite dust or fine screenings from a crusher operation may be used in lieu of sand.

(24) An identifying seal must be cast, molded, or permanently affixed by an approved method from the Department on the outlet tank wall within six (6) inches of the top. The identifying seal shall identify the manufacturer and the liquid capacity of the tank. The concrete tank's cast date shall be located on the identifying seal or imprinted on the top of the tank within six (6) inches from outlet tank wall near the identifying seal. The lettering on the identifying seal or date imprinted on the top of the tank shall be no more than six (6) inches in height.

(25) The tank manufacturer shall guarantee all tanks in writing for two (2) years against failure due to poor workmanship and materials.

(26) Changes in approved tank design, construction, and alternative reinforcing methods will not be allowed without prior approval from the Department.

~~700.4 PRE-CAST CONCRETE NON-FIBER REINFORCED SEPTIC TANKS AND GREASE TRAPS~~
503.4. Pre-Cast Concrete Non-Fiber Reinforced Septic Tanks and Grease Traps.

(1) The tank walls and bottom shall be reinforced with six ~~inch~~ by six ~~inch~~ (6 x 6) inch ten (10) gauge wire mesh.

(2) Tank tops shall be reinforced with six by six ~~inch~~ (6 x 6) inch ten (10) gauge wire mesh, a minimum of five (5) sections of three-eighths (3/8) inch diameter steel reinforcing bars oriented perpendicular to the tank sidewalls beginning at the center spaced twelve (12) inches apart~~,~~ and four (4) sections of three-eighths (3/8) inch diameter steel reinforcing bars placed diagonally from the corners to the center of the tank. The length of the perpendicular reinforcing bars shall be of sufficient length to extend two (2) inches into the sidewall. The length of the four (4) diagonal steel reinforcing bars shall be of sufficient length to extend two (2) inches into the sidewall and six (6) inches beyond the closest perpendicular steel reinforcing bar.

(3) If a septic tank or grease trap is manufactured with a partition, the tank partition (both halves) shall be reinforced with six by six ~~inch~~ (6 x 6) inch ten (10) gauge wire mesh. The reinforcing wire shall be bent to form an angle of ninety (90) degrees on the ends in order to form a leg not less than four (4) inches long. When the wire is placed in the mold, the four-inch legs shall lay parallel with the sidewall wire and adjacent to it.

(4) The tank walls and bottom thickness shall be at least two and one-half (2½) inches, and top thickness shall be at least three (3) inches.

(5) All reinforcing wire and rods must be covered by at least one-half (1/2) inch of concrete.

(6) An acceptable vibration method shall be employed in the construction of the tank to prevent voids in the tank walls, bottom, and top.

~~700.5 PRE-CAST CONCRETE FIBER REINFORCED SEPTIC TANKS AND GREASE TRAPS~~503.5. Pre-Cast Concrete Fiber Reinforced Septic Tanks and Grease Traps.

(1) Tank tops shall be reinforced with a minimum of five (5) sections of three-eighths (3/8) inch diameter steel reinforcing bars oriented perpendicular to the tank sidewalls beginning at the center spaced twelve (12) inches apart, and four (4) sections of three-eighths (3/8) inch diameter steel reinforcing bars placed diagonally from the corners to the center of the tank. The length of the perpendicular reinforcing bars shall be of sufficient length to extend two (2) inches into the sidewall. The length of the four (4) diagonal steel reinforcing bars shall be of sufficient length to extend two (2) inches into the sidewall and six (6) inches beyond the closest perpendicular steel reinforcing bar.

(2) Tank bottoms shall be reinforced with a minimum of seven (7) sections of three-eighths (3/8) inch diameter steel reinforcing bars oriented perpendicular to the tank sidewalls beginning at the center spaced twelve (12) inches apart. The length of the perpendicular reinforcing bars shall be of sufficient length to extend two (2) inches into the sidewall.

(3) If a septic tank or grease trap is manufactured with a partition, the tank partition (both halves) shall be reinforced with six by six ~~inch~~ (6 x 6) inch ten (10) gauge wire mesh. The reinforcing wire shall be bent to form an angle of ninety (90) degrees on the ends in order to form a leg not less than four (4) inches long. When the wire is placed in the mold, the four-inch legs shall lay parallel with the sidewall wire and adjacent to it.

(4) The tank perimeter walls shall be reinforced with three-eighths (3/8) inch diameter steel reinforcing bars located one (1) inch from the tank's top and bottom section seams.

(5) The tank walls and bottom thickness shall be at least two and one-half (2½) inches, and top thickness shall be at least three (3) inches.

(6) All reinforcing wire and rods must be covered by at least one-half (1/2) inch of concrete.

(7) Fiber products used with this reinforcement design must be added during the mixing process in order to achieve even distribution throughout the concrete mixture.

(8) Fiber length must range from at least one (1) to no more than two (2) inches.

(9) The fiber must be specifically manufactured for use as a concrete secondary reinforcement and be a polypropylene fibrillated (two-dimensional fiber mesh network) material.

(10) An acceptable vibration method shall be employed in the construction of the tank to prevent voids in the tank walls, bottom, and top.

~~700.6 CONCRETE BLOCK SEPTIC TANKS AND GREASE TRAPS~~503.6. Concrete Block Septic Tanks and Grease Traps.

(1) The tank walls and partition thickness shall be at least eight (8) inches and the top cover slabs thickness shall be at least four (4) inches.

(2) The tank bottom shall be a single pour concrete slab to a depth of at least four (4) inches within the first block course.

(3) If a septic tank or grease trap is manufactured with a partition, the tank walls and partition shall be constructed of solid sixteen ~~inch~~ by eight ~~inch~~ by eight ~~inch~~ (16 x 8 x 8) inch concrete blocks. The use of hollow blocks is prohibited.

(4) All joints between concrete blocks shall be mortared using masonry cement mortar or equivalent. The joints shall have a nominal thickness of three-eighths (3/8) inch.

(5) The upper partition wall may be supported by the use of two ~~inch~~ by four ~~inch~~ by eight (2 x 4 x 8) inch bricks (or equivalent support material) standing on edge located at the block seams of the upper partition wall.

(6) The top cover slabs shall be constructed such that the individual slabs will not exceed two (2) feet in width and the length will be sufficient to extend to the outside tank width with a minimum slab thickness of four (4) inches.

(7) The individual top cover slabs shall be reinforced with a minimum of two (2) sections of three-eighths (3/8) inch diameter steel reinforcing bars oriented perpendicular to the tank sidewalls spaced twelve (12) inches apart from the center. The length of the perpendicular reinforcing bars shall be of sufficient length to extend the full length of the slab.

(8) The end cover slabs shall be constructed such that the individual slabs will not exceed three (3) feet in width and the length will be sufficient to extend to the outside tank width with a minimum slab thickness of four (4) inches.

(9) The end cover slabs shall be cast to allow access to each tank or compartment by providing an opening located above the inlet and outlet tee with an inside dimension of eighteen (18) inches square (18 x 18 inches) or in diameter with removable tank access lids.

(10) The individual end cover slabs shall be reinforced with two (2) sections of three-eighths (3/8) inch diameter steel reinforcing bars oriented perpendicular to the tank sidewalls spaced twelve (12) inches apart from the center and two (2) sections of three-eighths (3/8) inch diameter steel reinforcing bars oriented perpendicular to the tank sidewalls spaced sixteen (16) inches apart from the center. The length of the perpendicular reinforcing bars shall be of sufficient length to extend the full length of the slab.

(11) The top and end cover slab seams shall be sealed to the tank walls and at all joints by using a bituminous mastic, butyl rubber, or other pliable sealant that is waterproof, corrosion-resistant, and approved for use in septic tanks. The sealant shall have a minimum size of one (1) inch diameter or equivalent. The use of grout is prohibited.

(12) The tank top and end cover slabs shall be equipped with steel lift handles at least one half (1/2) inch diameter, or by an alternative method approved by the Department.

(13) All reinforcing rods must be covered by at least one-half (1/2) inch of concrete.

(14) The interior of the tank (walls and bottom) shall be plastered with a waterproofing cement compound.

(15) An acceptable vibration method shall be employed in the construction of the tank to prevent voids in the tank access lids, tank bottom, and top and end slabs.

~~700.7 PRE-CAST CONCRETE NON-FIBER REINFORCED PUMP CHAMBERS~~503.7. Pre-Cast Concrete Non-Fiber Reinforced Pump Chambers.

(1) The tank walls and bottom shall be reinforced with six ~~inch~~ by six ~~inch~~ (6 x 6) inch ten (10) gauge wire mesh.

(2) Tank tops shall be reinforced with six by six ~~inch~~ (6 x 6) inch ten (10) gauge wire mesh, a minimum of five (5) sections of three-eighths (3/8) inch diameter steel reinforcing bars oriented perpendicular to the tank sidewalls beginning at the center spaced twelve (12) inches apart, and four (4) sections of three-eighths (3/8) inch diameter steel reinforcing bars placed diagonally from the corners to the center of the tank. The length of the perpendicular reinforcing bars shall be of sufficient length to extend two (2) inches into the sidewall. The length of the four (4) diagonal steel reinforcing bars shall be of sufficient length to extend two (2) inches into the sidewall and six (6) inches beyond the closest perpendicular steel reinforcing bar.

(3) The tank walls and bottom thickness shall be at least two and one-half (2½) inches, and top thickness shall be at least three (3) inches.

(4) All reinforcing wire and rods must be covered by at least one-half (1/2) inch of concrete.

(5) An acceptable vibration method shall be employed in the construction of the tank to prevent voids in the tank walls, bottom, and top.

~~700.8 PRE-CAST CONCRETE FIBER REINFORCED PUMP CHAMBERS~~503.8. Pre-Cast Concrete Fiber Reinforced Pump Chambers.

(1) Tank tops shall be reinforced with a minimum of five (5) sections of three-eighths (3/8) inch diameter steel reinforcing bars oriented perpendicular to the tank sidewalls beginning at the center spaced twelve (12) inches apart~~,~~ and four (4) sections of three-eighths (3/8) inch diameter steel reinforcing bars placed diagonally from the corners to the center of the tank. The length of the perpendicular reinforcing bars shall be of sufficient length to extend two (2) inches into the sidewall. The length of the four (4) diagonal steel reinforcing bars shall be of sufficient length to extend two (2) inches into the sidewall and six (6) inches beyond the closest perpendicular steel reinforcing bar.

(2) Tank bottoms shall be reinforced with a minimum of seven (7) sections of three-eighths (3/8) inch diameter steel reinforcing bars oriented perpendicular to the tank sidewalls beginning at the center spaced twelve (12) inches apart. The length of the perpendicular reinforcing bars shall be of sufficient length to extend two (2) inches into the sidewall.

(3) The tank perimeter walls shall be reinforced with three-eighths (3/8) inch diameter steel reinforcing bars located one (1) inch from the tank's top and bottom section seams.

(4) The tank walls and bottom thickness shall be at least two and one-half (2½) inches, and top thickness shall be at least three (3) inches.

(5) All reinforcing wire and rods must be covered by at least one-half (1/2) inch of concrete.

(6) Fiber products used with this reinforcement design must be added during the mixing process in order to achieve even distribution throughout the concrete mixture.

(7) Fiber length must range from at least one (1) to no more than two (2) inches.

(8) The fiber must be specifically manufactured for use as a concrete secondary reinforcement and be a polypropylene fibrillated (two-dimensional fiber mesh network) material.

(9) An acceptable vibration method shall be employed in the construction of the tank to prevent voids in the tank walls, bottom, and top.

~~800 APPENDIX U - FIBERGLASS REINFORCED PLASTIC TANKS STANDARD~~**504. Fiberglass Reinforced Plastic Tanks Standard.**

Standards describing fiberglass reinforced plastic septic tanks have been adopted ~~assure~~to ensure a quality product of sufficient strength and resistance, capable of fulfilling its intended purpose. Many of these standards were derived from NBS Voluntary Product Standard PS 15-69, which covers custom contact-molded reinforced polyester chemical resistant process equipment.

~~800.1 GENERAL REQUIREMNETS~~504.1. General Requirements.

The following general requirements are applicable to fiberglass reinforced plastic septic tanks as defined ~~herein~~within this regulation, and approved design standards and structural properties of the same shall be not less than those stated ~~herein~~.

(1) Material

Resins and sealants used in the tank manufacturing process shall be capable of effectively resisting corrosive influences of liquid components of sewage, gases generated by the digestion of sewage, and soil burial. Materials used shall be formulated to withstand vibration, shock, normal household chemicals, earth,

and hydrostatic pressure both when full and empty. Not less than thirty (30) percent of the total weight of the tank shall be fiberglass reinforcement. For tanks not exceeding a fifteen hundred (1500) ~~gallons~~gallon liquid capacity, the minimum wall thickness shall be three-sixteenths (3/16) inch, provided, however, that isolated small spots may be as thin as eighty (80) percent of the minimum.

(2) Inner Coating

Internal surfaces shall be coated with an appropriate gel coating to provide a smooth, pore-free, watertight surface for fiberglass reinforced plastic parts.

(3) Physical Properties

Tanks shall be so constructed that all parts of the tank shall meet the following requirements:

(a) Ultimate Tensile Strength (Minimum) – Nine thousand (9,000) pounds per square inch (psi) when tested in accordance with ASTM D 638-7la, Standard Method of Test for Tensile Properties of Plastics.

(b) Flexural Strength (Minimum) – Sixteen thousand (16,000) psi when tested in accordance with ASTM D 790-71, Standard Method of Test for Flexural Properties of Plastics.

(c) Flexural Modulus of Elasticity Tangent (Minimum) – Seven hundred thousand (700,000) psi when tested in accordance with ASTM D 790-71, Standard Method of Test for Flexural Properties of Plastics.

(4) Watertight Integrity

Tanks shall be so constructed as to be watertight for the designed life of the tank. Lids or covers shall be sufficiently tight when installed to preclude the entrance of surface or ground water into the tank.

(5) Longevity

Proof from an independent testing laboratory shall be submitted substantiating a minimum life expectancy of twenty years of service for the intended use of the tank and appurtenant components such as necessary sealants, connective fastenings, resins, etc.

(6) Safety

As a safety measure, provisions shall be made in the construction of septic tank lids or covers to preclude unauthorized entry or removal when the use of the tank necessitates positioning of access openings at or above ground level.

(7) Workmanship

Tanks shall be of uniform thickness and free from defects that may affect their serviceability or durability. Completed tanks ~~are to present~~shall have a smooth inside finish free of spills, pits, and honeycombs. Plant quality control shall be sufficient to maintain a high degree of uniformity in tank quality.

~~800.2 SPECIFIC REQUIREMENTS~~504.2. Specific Requirements.

Specific requirements for design and construction shall be not less than those specified herein~~,~~ and shall be in conformity with recognized National Standards for design and construction and in accordance with this regulation.

~~800.3 CAPACITY AND DESIGN LIMITS~~ 504.3. Capacity and Design Limits.

(1) Dimensions

(a) The inside length of a horizontal cylindrical tank shall be at least two (2) but not more than three (3) times the width.

(b) The uniform liquid depth shall not be less than four (4) feet.

(c) At least fifteen (15) percent of the total volume of the tank shall be above the liquid level.

(d) If tanks of other shapes are proposed, specifications must be submitted to the ~~Division of Onsite Wastewater Management~~Department for approval.

(2) Inlet

(a) Provisions shall be made for the building sewer to enter the center of one end of the septic tank two (2) inches above the normal liquid level of the tank.

(b) A tee shall be constructed as an integral part of the tank to receive the building sewer, or as an alternative, an integrally constructed baffle may be used.

(c) If baffles are used, suitable integrally fitted sleeves or collars shall be provided in the inlet openings of the tank to provide surface areas sufficient to ~~i~~ensure capability of watertight bonding between the tank and the inlet sewer.

(d) If the tee or baffle is constructed of plastic material, it shall meet NSF Standard #14 for drain, waste, and vent system application.

(e) If fiberglass reinforced plastic is used, it shall be of the same constituency as material of which the tank is constructed.

(f) The inlet tee ~~of~~ or baffle shall extend sixteen (16) inches below the designed liquid level and be placed and secured in a vertical position so as to be watertight and preclude dislodgement during installation, operation, or maintenance activities.

(3) Outlet

(a) Provisions shall be made for the outlet sewer to receive the discharge from the tank by providing an opening in the center of the end of the tank opposite the inlet, the invert elevation of which shall be at the liquid level of the tank.

(b) A tee shall be constructed as an integral part of the tank to connect to the outlet sewer~~,~~ or, as an alternative, an integrally constructed baffle may be used.

(c) If baffles are used, suitable integrally fitted sleeves or collars shall be provided in the outlet opening of the tank to provide surface areas sufficient to ~~i~~ensure capability of water-tight bonding between the tank and the outlet sewer.

(d) If the tee or baffle is constructed of plastic material, it shall meet NSF Standard #14 for drain, waste, and vent system application.

(e) If fiberglass reinforced plastic is used, it shall be of the same constituency as material of which the tank is constructed.

(f) The outlet tee or baffle shall extend eighteen inches below the design liquid level and be placed and secured in a vertical position so as to be watertight and preclude dislodgement during installation, operation, or maintenance activities.

(g) ~~A one (1) inch opening between the top of the inlet tee and top of the tank shall be provided to permit free passage of gas back to the house vent.~~The inlet and outlet tees shall extend above liquid level a minimum of six (6) inches and to no less than one (1) inch from the top of the tank to allow venting between tank compartments and multiple tank configurations.

(4) Access Openings

Openings in the top of the septic tank shall be provided over the inlet and outlet tees or baffles with sufficient area to enable maintenance service to such tees or baffles.

(5) Identifying Markings

Fiberglass septic tanks shall be provided with a suitable legend, cast or stamped into the wall at the outlet end, and within six inches of the top of the tank, identifying the manufacturer, and indicating the liquid capacity of the tank in gallons.

~~900 APPENDIX V THERMOPLASTIC TANKS STANDARD~~**505. Thermoplastic Tanks Standard.**

(1) The Department shall approve plans for thermoplastic tanks on an individual basis.

(a) Thermoplastic tanks shall be certified by an American National Standards Institute or Standards Council of Canada accredited third-party to comply with the most recent edition of IAPMO/ANSI Z1000 or CSA B66.

(b) The uniform liquid depth shall be at least three (3) feet.

(c) The inside length of the tank shall be at least two (2) times the inside width of the tank.

(2) If thermoplastic tanks having other dimensional characteristics are proposed, specifications must be submitted to the ~~Division of Onsite Wastewater Management~~Department for approval, and the proposed design must be demonstrated to provide equivalent effectiveness for storage and distribution to that of concrete or thermoplastic tanks described in this regulation.

(3) Thermoplastic tank manufacturers must renew their product approvals by submitting new applications and plans to the Department every five (5) years and before changing any previously approved plans.

600. License to Clean Onsite Wastewater Systems, Self-Contained Toilets, and Other Sewage Holding Systems (i.e., Licensing of Pumper/Haulers).

600.1. No person shall be responsible for the cleaning of onsite wastewater systems, self-contained toilets, and other sewage holding systems in South Carolina without first applying for, receiving, and subsequently maintaining a valid license to conduct such activities as herein required by the Department. This includes, but is not limited to, nonwater-carried sewage treatment devices and gray water subsurface reuse system.

600.2. Licenses, Applications, and Fees.

(1) License applications, on forms approved by the Department, shall be submitted to the Department's regional environmental office which covers the county where the applicant's primary place of business is located; persons whose primary place of business is out of state must submit their applications to the Department's regional environmental office where it is reasonably anticipated the bulk of the activities sought to be licensed would occur.

(2) The following shall apply to applications submitted by persons engaged in the business of cleaning onsite wastewater systems, self-contained toilets, and other sewage holding systems:

(a) The applicant shall list on the application form each approved septage and sewage disposal facility they intend to use. Written verification of permission to use each disposal facility shall accompany the application.

(b) The applicant shall list on the application form all locations where pumping and transporting vehicles are parked/stored when not in use.

(c) For each annual renewal of an existing license, the person seeking renewal shall submit changes to any information included on the original license application to the Department through an updated application.

(d) Upon request by the Department, each person seeking a new license or renewal of an existing license shall make available for inspection all vehicles and equipment used in the pumping and transporting of septage and sewage.

(e) Additional inspections of vehicles and equipment may be conducted by the Department to ensure compliance with this regulation.

(f) If a licensee replaces, deletes, or adds to their inventory of vehicles used in pumping and transporting septage or sewage, the licensee shall immediately notify the Department for the purpose of updating their application. A vehicle may not be placed into use without prior inspection and approval from the Department.

(3) Prior to receipt of a license authorizing a person to be responsible for the cleaning of onsite wastewater systems, self-contained toilets, and other sewage holding systems, applicants shall complete an examination demonstrating their knowledge and comprehension of this regulation. Any applicant failing to satisfactorily complete the licensing examination may be eligible to retake the examination after thirty (30) calendar days. Applicants who fail to satisfactorily complete their second examination may then be allowed to retake subsequent examinations after a sixty (60)-day waiting period.

(4) A fee shall be assessed for a new license and for the annual renewal of a license.

(a) No person who seeks to be responsible for the cleaning of onsite wastewater systems, self-contained toilets, and other sewage holding systems shall be issued a new license pursuant to this regulation until a fee of one hundred dollars ($100.00) has been paid to the Department, except that a person applying both for this license (i.e., pumper/hauler license) and an installers license (i.e., license to construct or repair systems) shall pay a fee of only fifty dollars ($50.00) for the license to clean onsite wastewater systems, self-contained toilets, and other sewage holding systems.

(b) Every license issued by the Department under this regulation shall be valid for a period of one (1) year, unless otherwise suspended or revoked.

(c) Each licensee must pay an annual renewal fee of one hundred dollars ($100.00), except that a person applying to renew both this license (i.e., pumper/hauler license) and an installers license (i.e., license to construct or repair systems) shall pay a fee of only fifty dollars ($50.00) for the renewal of the license to clean onsite wastewater systems, self-contained toilets, and other sewage holding systems.

(d) Annual renewal fees shall be due on a date not less than thirty (30) calendar days from the billing date. A penalty charge of thirty dollars ($30.00) shall be assessed for license fees that are past due. A second penalty of thirty dollars ($30.00) shall be assessed for license fees sixty (60) days past due.

(e) Expiration of a license shall occur when the license fee is ninety (90) calendar days past due. No person with an expired license may be engaged in the business of cleaning onsite wastewater systems, self-contained toilets, and other sewage holding systems.

(f) An expired license shall not be renewed. Any person with an expired license may apply for a new license and must meet all applicable requirements for a new license.

(5) Licenses issued in accordance with this regulation shall not be transferable.

600.3. Further Governmental Restriction Not Prohibited.

Nothing within this regulation shall be construed to limit the power of any municipal, county, or governmental entity to enforce other license requirements or additional measures for the restrictions of persons cleaning onsite wastewater systems, self-contained toilets, and other sewage holding systems.

600.4. License Not Required.

Public or private sewer providers using pumping and transporting vehicles for the sole purpose of maintaining their sewer systems shall be exempt from the licensing requirements of Section 600 of this regulation. This exemption does not apply to public or private sewer providers using pumping and transporting vehicles to provide cleaning services to the public.

601. Vehicles, Equipment, and Practices.

601.1. All vehicles and equipment used to remove and transport septage and sewage shall be maintained in a manner that will prevent the occurrence of leaks, spills, and other nuisance conditions. All vehicles shall be properly identified.

(1) Hoses, valves, tanks, and other equipment must be maintained in good repair and working order.

(2) All vehicles used to transport septage and sewage must bear the company name and license number in a prominent place on the sides and rear of each vehicle, using letters and numbers that are at least four (4) inches in height.

601.2. The cleaning of septic tanks and similar units and the pumping and transporting of septage and sewage shall be done in a manner that is safe and does not create a hazard to the public health and the environment. The proper cleaning of any septic tank or similar unit shall include the substantial removal of its contents (solids, semi-solids, and liquids).

601.3. Disposal of septage and sewage shall be allowed only at facilities approved by the Department. A licensee may dispose of septage and sewage only at those approved facilities designated by the licensee's application and any renewals or updates of the application.

(1) Discharge of septage and sewage shall be allowed only at those specific locations designated by the owners/operators of approved disposal facilities.

(2) Discharge of septage and sewage into a public sewage collection system, without the consent and permission of the owner/operator of such system, is prohibited.

(3) The storage of domestic wastewater, sewage, or septage in underground or partially buried tanks/subsurface containment units, is prohibited.

601.4. A licensee shall adequately supervise employees and ensure that onsite wastewater systems, self-contained toilets, and other sewage holding systems are cleaned in accordance with this regulation and other applicable regulations, permits, and standards issued by the Department.

602. Records of Operation.

602.1. Each person licensed to clean onsite wastewater systems, self-contained toilets, and other sewage holding systems is required to maintain accurate records of cleaning and transporting activities.

(1) Records shall be kept current and shall include at least the following information for each cleaning/transporting activity:

(a) Date and time of septage and sewage removal.

(b) Name and address of residence or facility where septage and sewage was removed. Where one or more self-contained toilets are cleaned at one location (e.g., construction site, special event, etc.), one recorded entry per location will be acceptable.

(c) Quantity and type of septage and sewage removed (e.g., grease trap, septic tank, self-contained toilet, etc.). Where one or more self-contained toilets are cleaned at one location, quantity may be expressed by the total number of units cleaned at that location.

(d) Date, time, and location of septage and sewage disposal.

602.2. Records shall be made available for inspection by the Department upon request. All licensees must retain their records for a minimum of two (2) years.

700. License to Construct or Repair Onsite Wastewater Systems (i.e. Licensing of Installers).

700.1. License Requirements and Fees.

(1) No person shall be responsible for the construction or repair of onsite wastewater systems in South Carolina without first applying for, receiving, and subsequently maintaining a valid license to conduct such activities as herein required by the Department, provided that a person may construct or repair an onsite wastewater system for personal use at the person's residence without obtaining a license.

(2) Licenses, Applications, and Fees

(a) License applications, on forms approved by the Department, shall be submitted to the Department's regional environmental office which covers the county where the applicant's primary place of business is located; persons whose primary place of business is out of state must submit their applications to the Department's regional environmental office where it is reasonably anticipated the bulk of the activities sought to be licensed would occur.

(b) Prior to receipt of a license authorizing a person to be responsible for the construction or repair of an onsite wastewater system, the applicant shall complete an examination demonstrating the applicant's knowledge and comprehension of this regulation. Any applicant failing to satisfactorily complete the licensing examination may be eligible to retake the examination after thirty (30) calendar days. Applicants who fail to satisfactorily complete their second examination may then be allowed to retake subsequent examinations after a sixty (60) calendar day waiting period.

(c) Each license requires fees for the initial license issuance and annual renewal. The required fees vary depending on the tier of licensure sought. The required initial license and renewal fees for each tier are as follows:

(i) Tier 1 – One hundred dollar ($100.00) fee

(ii) Tier 2 – One hundred dollar ($100.00) fee

(iii) Tier 3 – Two hundred dollar ($200.00) fee

(d) Every license issued by the Department under this regulation shall be valid for a period of one (1) year, unless otherwise suspended or revoked.

(e) Renewal fees shall be due on a date not less than thirty (30) calendar days from the billing date. A penalty charge of thirty dollars ($30.00) shall be assessed for license fees that are past due. A second penalty of thirty dollars ($30.00) shall be assessed for license fees sixty (60) days past due.

(f) Expiration of a license shall occur when the license fee is ninety (90) calendar days past due. No person with an expired license may be engaged in the business of constructing and repairing onsite wastewater systems, sewage holding systems, or self-contained toilets.

(g) An expired license shall not be renewed. Any person with an expired license may apply for a new license and must meet all applicable requirements for a new license.

(h) Licenses issued in accordance with this regulation shall not be transferable.

(3) Further Governmental Restriction Not Prohibited

Nothing within this regulation shall be construed to limit the power of any municipal, county, or governmental entity to enforce other license requirements or additional measures for the restrictions of persons constructing or repairing onsite wastewater systems.

(4) Eligibility

Only a person who meets the following criteria is eligible to be licensed as an onsite wastewater systems installer:

(a) Applicants to be a Tier 1 or Tier 2 installer must:

(i) Pass an examination administered by the Department with a minimum score of eighty (80) percent ; and

(ii) Submit a properly completed application with supporting documents including proof of continuing education units (CEUs) for any renewal; and

(iii) Pay applicable fees.

(b) Applicants to be a Tier 3 installer must:

(i) Qualify as either:

(A) A licensed onsite wastewater system installer who has been actively installing for three (3) years immediately preceding the date of application with no pending or prior disciplinary or enforcement action involving onsite wastewater system contracting; or

(B) An onsite wastewater system installer licensee from another state with affidavits from the regulatory authority demonstrating five (5) years of experience with no pending or prior disciplinary or enforcement action involving onsite wastewater system contracting; and

(ii) Pass an examination administered by the Department with a minimum score of eighty (80) percent;

(iii) Submit a properly completed application with supporting documents (if required);

(iv) Submit proof of continuing education units (CEUs) for any renewal;

(v) Submit proof of required Bond and insurance coverage; and

(vi) Pay applicable fees.

701. Continuing Education and Training.

701.1. All installers are required to complete the necessary number of continuing education units (CEUs) every two (2) years from the date of licensing to renew the installer license. CEUs must be obtained from the Department-approved list of courses and providers.

701.2. The Department will not renew a license for any installer who has failed to meet the training and education requirements for the previous licensing period.

701.3. If any installer completes more than the required hours in a licensing period, as many as three (3) hours can be rolled over and credited to the requirement for the next licensing period.

701.4. The required CEUs for each Tier for every two (2) year licensing period are as follows:

(1) Tier 1: Eight (8) hours

(2) Tier 2: Twelve (12) hours

(3) Tier 3: Eighteen (18) hours

701.5. Implementation of CEU Requirement.

The requirement for CEUs will enter into effect for any initial or renewal licensing period beginning on or after the date three (3) years following the effective date of this regulation.

702. Practice, Procedure, and Quality Control.

702.1. Practices: All Installers.

(1) A licensee shall adequately supervise employees and ensure that all onsite wastewater systems for which the licensee is responsible are constructed and repaired in accordance with this regulation and other applicable regulations, permits, and standards issued by the Department. Onsite wastewater systems must be installed pursuant to and in compliance with permits to construct issued by the Department.

(2) An installer does not have the authority to make any changes to a construction or repair project that deviate from an issued permit without first obtaining Department approval.

(3) Installers do not have the authority to subcontract unlicensed installers to conduct work under their licenses.

(4) The specific scope of activities authorized under each tier of licensure is set forth in this regulation's definition of "licensed onsite wastewater system installer." A licensed installer is prohibited from performing any construction or repair that is inconsistent with the scope of activities authorized under the licensee's applicable tier.

702.2. Onsite Wastewater System Installer Self-Inspections.

(1) All Tier 3 installers and Tier 1 or Tier 2 installers directed to perform self-inspections under Section 104.3(1)(c) shall provide the Department the opportunity to perform a final inspection and shall arrange with the Department in advance a time for the final inspection of an onsite wastewater system that is being installed. If, after thirty (30) minutes of that arranged time, the Department representative has not arrived for the inspection, the installer shall:

(a) Inspect the system;

(b) Record the findings on a form approved by the Department; and

(c) Cover the system.

(2) It shall be considered a violation of this regulation to conduct a self-inspection of a system or cover a system without first scheduling a final inspection time with the Department and waiting the full thirty (30) minutes of the arranged time for the Department to conduct a final inspection.

(3) The installer shall not cover a system or seek Department final approval for a system that, upon inspection, is determined not to be in compliance with the permit to construct.

(4) Documentation of system installation and self-inspection using the Department-approved format, including the installer's signature and license number, as well as the system measurements and other specified information, shall be submitted to the Department within two (2) business days of the final self-inspection date. A copy of this document(s) must also be furnished to the property owner for whom the system was installed. Failure to submit to the Department the required documentation within the required timeframe shall be considered a violation of this regulation.

(5) An onsite wastewater system shall not be placed into operation unless and until the Department has issued a final approval to operate.

702.3. Quality Control: Installers.

The Department will conduct random final inspections on no less than three (3) percent annually of the total number of systems installed during the preceding fiscal year. The Department will also conduct field reviews of final installation and inspection documentation submitted by the installer and compare them to the actual installations those documents represent.

703. Bonding and Insurance Requirements: Tier 3 Installers.

703.1. Proof of both insurance and bond coverage shall be furnished to the Department prior to licensure as a Tier 3 installer and upon license renewal.

703.2. An onsite wastewater system Tier 3 installer shall be responsible for obtaining and maintaining both insurance and bond coverage for as long as the installer is licensed as a Tier 3 installer.

703.3. Failure to maintain both insurance and bond coverage shall result in the suspension or revocation of the Tier 3 installer license.

704. Transition to Tiered Licensure.

Upon the effective date of the tiered licensure provisions (Section 700) of this regulation, all installers licensed as master contractors under the previous R.61-56.2 shall be considered to hold a Tier 3 license, and all other installers licensed under the previous R.61-56.1 shall be considered to hold a Tier 2 license. The Tier 3 or Tier 2 license shall expire upon the original expiration date of the license held under R.61-56.1 or R.61-56.2, as applicable, unless the license is renewed in accordance with the provisions of Section 700.1 of this regulation.

800. Enforcement.

800.1. Violations of this regulation shall be punishable in accordance with S.C. Code Sections 44-1-150, 44-55-825, 48-1-320, and 48-1-330. The Department may seek enforcement, suspend and revoke permits and licenses, issue civil penalties, and order corrective action in accordance with law. The Department shall have the authority to suspend civil penalties if the violations of this regulation are corrected in a period of time established by the Department.

800.2. Deviation from the installation design and conditions in onsite wastewater permits to construct and approvals to operate may be considered a violation of this regulation.

800.3. Suspension and revocation of permits to construct and approvals to operate an onsite wastewater system, nonwater-carried sewage treatment system, wastewater combustion system, or gray water subsurface reuse system.

(1) The Department may temporarily suspend a permit to construct or approval to operate for a violation of this regulation.

(2) The Department may revoke a permit to construct or approval to operate for a violation of this regulation. The Department will revoke a permit or approval when:

(a) The onsite wastewater system, nonwater-carried sewage treatment system, wastewater combustion system, or gray water subsurface reuse system is malfunctioning and sewage is discharging to the ground or the groundwater, the holder of the permit has received notice that the system is malfunctioning, the Department has given notice that repairs must be made within a reasonable period of time, the holder of the permit has not made the repairs, and the system continues to discharge sewage to the ground or the groundwater; or

(b) The onsite wastewater system, nonwater-carried sewage treatment system, wastewater combustion system, or gray water subsurface reuse system is malfunctioning and sewage is discharging to the ground or the groundwater, the holder of the permit has received notice that the system is malfunctioning, the Department has given notice that a wastewater treatment facility is accessible for connection.

800.4. Enforcement against persons licensed to construct, clean, and/or repair onsite wastewater systems.

(1) A licensee shall be subject to suspension, revocation, and civil penalties as provided in Sections 800.1 and 800.4(2) for the construction, cleaning, or repair of onsite wastewater systems, self-contained toilets, and other sewage holding systems in violation of state laws, regulations, and standards.

In determining whether a license should be suspended or revoked, the Department may consider such factors as the seriousness of a violation and whether a violation is a repeat of previous violations, among any other relevant factors. The interference by a licensee or their employees with a representative of the Department in performing their duties with respect to this regulation shall constitute grounds for revocation of license.

(2) Violation of an onsite wastewater system installation permit or any provisions of this regulation by a licensed onsite wastewater system installer or person licensed to clean onsite wastewater systems must be enforced as follows:

(a) First offense violations may be enforced under S.C. Code Section 44-1-150 or by suspension of the license for a period not to exceed one (1) year.

(b) Second offense violations shall be enforced under S.C. Code Section 44-1-150 or by suspension of the license for a period not to exceed three (3) years.

(c) Third offense violations shall be enforced under S.C. Code Section 44-1-150 or by permanent revocation of the license.

(3) The Department may suspend licenses for failure to pay a civil penalty required pursuant to a Department order.

800.5. Prior to suspending or revoking a permit to construct, approval to operate, or license, the Department shall provide written notification to the person stating the basis for suspension or revocation. A permit to construct, approval to operate, or license may be summarily suspended by the Department without prior warning if the Department determines there is an immediate threat to public health.

801. Severability Clause.

Should any section, paragraph, sentence, clause, or phrase of this regulation be declared unconstitutional or invalid for any reason, the remainder of this regulation shall not be affected thereby.

61-56.1. ~~License to Construct or Clean Onsite Sewage Treatment and Disposal Systems and Self-Contained Toilets.~~

~~SECTION I. PURPOSE~~

~~To regulate persons engaged in the business of constructing, repairing, or cleaning onsite sewage treatment and disposal systems and cleaning self-contained toilets, to protect public health and the environment.~~

~~SECTION II. DEFINITIONS~~

~~A. Cleaning - the removal and transportation of septage from an onsite sewage treatment and disposal system or self-contained toilet to an approved disposal location.~~

~~B. Construct - the installation or repair of an onsite sewage treatment and disposal system.~~

~~C. Department - the South Carolina Department of Health and Environmental Control and its authorized representatives.~~

~~D. License - the official document issued by the Department authorizing a person to be engaged in the business of construction, repair, or cleaning of onsite sewage treatment and disposal systems or the cleaning of self-contained toilets.~~

~~E. Onsite Sewage Treatment and Disposal System - a system, or any part of a system, designed to treat and dispose of, or store sewage. Examples include septic tank systems, sewage holding systems, and similar devices.~~

~~F. Person - any individual, firm, company, corporation, or association.~~

~~G. Revocation - the permanent withdrawal of rights and privileges granted by a license.~~

~~H. Self-Contained Toilet - a single or multiple-unit toilet and holding tank combination.~~

~~I. Septage - the mixture of solids and liquids removed during cleaning of a septic tank, grease trap, or any other part of an onsite sewage treatment and disposal system, holding system, or self-contained toilet which receives domestic sewage; includes the liquid, solid and semi-solid materials which settle to the bottom of transport containers.~~

J. Sewage - any liquid waste containing animal, vegetable, or chemical matter in suspension or solution from water closets, urinals, lavatories, bathtubs, laundry tubs or devices, floor drains, drinking fountains or other water-using fixtures.

K. Suspension - the temporary or indefinite withdrawal or cessation of rights and privileges granted by a license.

SECTION III. LICENSE REQUIRED

A. No person may engage in the business of and be responsible for the construction, repair, or cleaning of onsite sewage treatment and disposal systems or the cleaning of self-contained toilets in South Carolina without first applying for, receiving, and subsequently maintaining a valid license to conduct such activities, as herein required by the Department; provided, that a person may construct or repair an onsite sewage treatment and disposal system for personal use at his residence without obtaining a license.

B. Licenses, Applications, and Fees.

1. License applications, on forms approved by the Department, shall be submitted to the Department in the county where the applicant's primary place of business is located; provided, persons residing out of state must submit their applications to the Department in the South Carolina county where it is reasonably anticipated the bulk of the activities sought to be licensed would occur.

2. The following shall apply to applications submitted by persons engaged in the business of cleaning onsite sewage treatment and disposal systems or self-contained toilets:

a. The applicant shall list on the application form each approved septage disposal facility they intend to use. Written verification of permission to use each disposal facility shall accompany the application.

b. For each renewal of an existing license, the person seeking renewal shall submit to the Department an updated application.

c. Upon request by the Department, each person seeking a new license or renewal of an existing license shall make available for inspection all vehicles and equipment used in the pumping and transporting of septage.

d. Additional inspections of vehicles and equipment may be conducted by the Department to ensure compliance with this regulation.

e. If a licensee replaces, deletes, or adds to his inventory of vehicles used in pumping and transporting septage, the licensee shall immediately notify the Department for the purpose of updating his application.

3. Prior to receipt of a license authorizing a person to engage in the business of and be responsible for the construction or repair of an onsite sewage disposal system, the applicant shall complete an examination, demonstrating his knowledge and comprehension of the onsite sewage treatment and disposal regulation (Regulation 61-56, 1976 Code of Laws of South Carolina, as amended). Any applicant failing to satisfactorily complete the licensing examination may be eligible to retake the examination after 30 days. If the applicant fails to satisfactorily complete his second examination, he may then be allowed to retake subsequent examinations after a 60-day waiting period.

4. Persons engaged only in the business of cleaning onsite sewage treatment and disposal systems, holding systems, or self-contained toilets, shall be exempt from the aforementioned examination, and shall be issued a license upon satisfactory compliance with this regulation.

5. A fee shall be assessed for a new license and for the annual renewal of license.

a. No person engaged in the business of either constructing and repairing or the cleaning of onsite sewage treatment and disposal systems shall be issued a new license pursuant to this regulation until a fee of one hundred ($100) dollars has been paid to the Department; provided, persons engaged in the dual business of constructing/repairing and cleaning systems shall pay a fee of one hundred fifty ($150) dollars. Every license issued by the Department under this regulation shall be valid for a period of one year, unless otherwise suspended or revoked.

b. Each licensee must pay an annual renewal fee of one hundred ($100) dollars, or, for a dual license, one hundred fifty ($150) dollars, to the Department.

c. Annual renewal fees shall be due on a date not less than thirty (30) days from the billing date. A penalty charge of $30.00 shall be assessed for license fees that are past due. A second penalty of $30.00 shall be assessed for license fees sixty (60) days past due.

d. Expiration of a license shall occur when the license fee is ninety (90) days past due. No person with an expired license may be engaged in the business of either constructing and repairing or cleaning onsite sewage treatment and disposal systems, sewage holding systems, or self-contained toilets.

e. an expired license shall not be renewed. Any person with an expired license may apply for a new license and must meet all applicable requirements for a new license.

6. Licenses issued in accordance with this regulation shall not be transferable.

C. Further Governmental Restrictions Not Prohibited.

Nothing within this regulation shall be construed to limit the power of any municipal, county, or governmental entity to enforce other license requirements or additional measures for the restrictions of persons constructing, repairing, or cleaning onsite sewage treatment and disposal systems or cleaning self-contained toilets.

SECTION IV. VEHICLES, EQUIPMENT, AND PRACTICES

A. All vehicles and equipment used to remove and transport septage shall be maintained in a manner that will prevent the occurrence of leaks, spills, and other nuisance conditions. All vehicles shall be properly identified.

1. Hoses, valves, tanks, and other equipment must be maintained in good repair and working order.

2. All vehicles used to transport septage must bear the company name and license number in a prominent place on the sides and rear of each vehicle, using letters and numbers that are at least four (4) inches in height.

B. The cleaning of septic tanks and similar units, and the pumping and transporting of septage shall be done in a manner that is safe and does not create a nuisance or health hazard. The proper cleaning of any septic tank or similar unit shall include the substantial removal of its contents.

C. Disposal of septage shall be allowed only at facilities approved by the Department. A licensee may dispose of septage only at those approved facilities designated by his application and any renewals or updates of his application.

1. Discharge of septage shall be allowed only at those specific locations designated by the owners/operators of approved disposal facilities.

2. Discharge of septage into a public sewage collection system, without the consent and permission of the owner/operator of such system, is prohibited.

D. A licensee shall adequately supervise employees and ensure that all systems for which the licensee is responsible shall be constructed, repaired, and cleaned in accordance with Regulation 61-56 and other applicable regulations, permits, and standards issued by the Department.

SECTION V. RECORDS OF OPERATION

A. Each person licensed to clean onsite sewage treatment and disposal systems and self-contained toilets is required to maintain accurate, written records of cleaning and transporting activities.

1. Records shall be kept current and shall include at least the following information for each cleaning/transporting activity:

a. Date and time of septage removal.

b. Name and address of residence or facility where septage was removed. Where one or more self-contained toilets are cleaned at one location (construction site, special event, etc.), one recorded entry per location will be acceptable.

c. Quantity and type of septage removed (i.e., grease trap, septic tank, self-contained toilet). Where one or more self-contained toilets are cleaned at one location, quantity may be expressed by the total number of units cleaned at that location.

d. Date, time, and location of septage disposal.

B. Records shall be made available for inspection by the Department upon request. Records must be retained for a minimum of two (2) years.

SECTION VI. SUSPENSION/REVOCATION OF LICENSE

A. A licensee shall be subject to suspension and revocation of license and to penalties, as provided in Section VIII for the construction, repair, or cleaning of onsite sewage treatment and disposal systems, or cleaning of self-contained toilets for which he is responsible in violation of State Laws, Regulations, and Standards.

In determining whether a license should be suspended or revoked, the Department may consider such factors as the seriousness of a violation and whether a violation is a repeat of previous violations, among any other relevant factors. The interference by a licensee or his employees with a representative of the Department in performing his duties with respect to this regulation shall constitute grounds for revocation of license. Only the person responsible for supervision and enforcement of this regulation in each county or health district is authorized to initiate action to revoke the license on the grounds of interference.

B. Any person whose license is revoked shall not be eligible to apply for relicensing within one year from the date of revocation. Any person whose license has previously been revoked and who obtains a subsequent license and violates the provisions of this regulation, which results in the revocation of his license for the second time, shall not be granted another license.

C. Prior to such action, the Department shall provide written notification to the licensee, stating the basis for suspension or revocation, and advise the licensee that the license shall be suspended or revoked on the fifteenth (15th) day following receipt of the written notification, unless a Petition for Administrative Review, complying with the requirements of Regulation 61-72, is filed with the Department, within fifteen (15) days of receipt. All hearings shall be conducted in accordance with the Administrative Procedures Act and Regulation 61-72.

D. A license may be summarily suspended by the Department pending a hearing, as herein provided, if the licensee acts in such a manner as to pose an immediate threat to public health. In the case of a summary suspension, the licensee shall be given a hearing as soon as possible after the Department receives a written request for a hearing.

SECTION VII. EXPIRATION OF LICENSE

The expiration of a license due to failure to pay the required annual renewal fee, plus applicable late charges, shall not constitute a contested case and shall not create a right to a hearing pursuant to the South Carolina Administrative Procedures Act.

SECTION VIII. PENALTIES

Violations of this regulation shall be punishable in accordance with Sections 44-1-150, 48-1-320, and 48-1-330, of the 1976 Code of Laws of South Carolina, as amended.

SECTION IX. SEVERABILITY CLAUSE

Should any section, paragraph, sentence, clause or phrase of this regulation be declared unconstitutional or invalid for any reason, the remainder of said regulation shall not be affected thereby. [Repealed].

61-56.2. Licensing Of Onsite Wastewater System Master Contractors.

CONTENTS

100. PURPOSE

The purpose of this regulation is to protect public health and the environment by ensuring the competence of onsite wastewater system master contractors. Proper construction, installation and approval practices for onsite wastewater systems are essential for the safe treatment and disposal of domestic wastewater.

200. DEFINITIONS

ALTERNATIVE SYSTEM – A system incorporating design modifications of the proposed subsurface wastewater infiltration area (drainfield) or absorption trench geometry for the purpose of achieving compliance with required setbacks and offset to the zone of saturation and/or restrictive horizons. No such system shall be utilized unless the Department has established a specific standard.

ALTERNATIVE TILEFIELD PRODUCTS – Products specifically designed to replace or eliminate the aggregate typically utilized in soil absorption trenches. Such products must be approved for use by the Department and must adhere to required equivalency values established herein.

APPLICANT – A property owner, general contractor or agent representing the property owner, or a developer who seeks a permit to construct and operate an onsite wastewater system.

BOND – A sum of money set aside (Surety Bond) to insure completion of work under a contract.

CONVENTIONAL SYSTEM – An onsite wastewater system that utilizes a network of conventional absorption trenches installed in the naturally occurring soil for the treatment and disposal of domestic wastewater.

CONSTRUCT – The installation or repair of an onsite sewage treatment and disposal system.

DEPARTMENT – The South Carolina Department of Health and Environmental Control (DHEC).

DOMESTIC WASTEWATER – The untreated liquid and solid human body waste and the liquids generated by water-using fixtures and appliances, including those associated with food service operations. For the purposes of this regulation, domestic wastewater shall not include industrial process wastewater.

EFFLUENT – The liquid discharged from a septic tank, effluent pump station, or other sewage treatment device.

EXISTING SYSTEM – An onsite wastewater system, which has received final construction approval or has been serving a legally occupied residence or structure.

FAILING ONSITE WASTEWATER SYSTEM – An onsite wastewater system that is discharging effluent in an improper manner or has ceased to function properly.

LICENSE – The official document issued by the Department authorizing a person to provide services for installation, repair, modification or final inspection and approval of onsite wastewater systems that they install.

LICENSED SEPTIC TANK CONTRACTOR – A person authorized under Regulation 61-56.1, License to Construct or Clean Onsite Sewage Treatment and Disposal Systems and SelfContained Toilets, to construct, repair or clean onsite sewage disposal systems or self contained toilets.

ONSITE WASTEWATER SYSTEM – A system, generally consisting of a collection sewer, septic tank(s), and soil absorption trenches (subsurface wastewater infiltration area), designed to treat and dispose of

domestic wastewater through a combination of natural processes that ultimately result in effluent being transmitted through the soil, renovated, and ultimately discharged to groundwater.

ONSITE WASTEWATER SYSTEM MASTER CONTRACTOR – A person authorized under this regulation to construct, repair, modify, inspect and issue final construction approval for onsite wastewater systems that they install.

PERMIT – A written document issued by the Department authorizing the construction and operation of an onsite wastewater system under Regulation 61-56. The construction and operation permit survives the life of the onsite wastewater system that it authorizes.

REPAIR – Any work performed on an existing onsite wastewater system for the purposes of correcting a surface failure or other unauthorized discharge, enhancing system performance, or relocating the entire system or system components, provided there are no changes in use that would impact the existing system.

REVOCATION – The permanent withdrawal of rights and privileges granted by a license.

SEPTIC TANK – A watertight, covered receptacle designed and constructed to receive the discharge of domestic wastewater from a building sewer, separate solids from the liquid, digest organic matter, store digested solids through a period of detention and biological conditioning of liquid waste, and allow the effluent to discharge for final treatment and disposal.

SOIL ABSORPTION TRENCH – A trench installed in the naturally occurring soil that is utilized for the treatment and disposal of domestic wastewater. A conventional trench is characterized by the following: (a) at least twenty-three (23) inches in depth; (b) thirty-six (36) inches in width; (c) filled with aggregate so that at least six (6) inches is beneath the distribution pipe, with at least five (5) inches on both sides of the pipe, and at least three (3) inches covering the pipe; and (d) at least nine (9) inches of backfill. Other trench configurations are specified in Regulation 61-56 Appendices of Standards for Onsite Wastewater Systems.

STANDARD – A group of requirements developed by the Department that specifies the minimum site conditions and design criteria necessary for the approval of a specific type of onsite wastewater system (i.e., alternative system) that differs from a conventional system. A standard may also address minimum design criteria for certain components of onsite wastewater systems as well as methodologies for determining system sizing.

SUBSURFACE WASTEWATER INFILTRATION AREA (DRAINFIELD) – A specific area where a network of soil absorption trenches or other devices of sewage application are installed to provide the final treatment and disposal of effluent.

SURETY AGREEMENT – Through this agreement, the surety agrees to uphold – for the benefit of the obligee – the contractual promises (obligations) made by the principal if the principal fails to uphold its promises to the obligee.

SUSPENSION – The temporary or indefinite withdrawal of rights and privileges granted by a license.

300. ELIGIBILITY

An onsite wastewater systems contractor currently licensed under R. 61.56.1, who meets the following criteria, is eligible to be licensed as an onsite wastewater systems master contractor:

(1) a licensed onsite wastewater systems contractor who has been actively installing for three (3) years immediately preceding the date of application with no disciplinary action pending involving septic tank contracting; or

(2) an onsite wastewater systems contractor licensee from another state with affidavits from the regulatory authority supporting five (5) years of experience with no pending disciplinary action involving septic tank contracting; and

(3) the ability to pass an examination administered by the Department with a minimum score of eighty percent (80 %); and

(4) a properly completed application with supporting documents (if required); and

(5) proof of required bond and insurance coverage; and

(6) payment of applicable fees.

400. CONTINUING EDUCATION AND TRAINING

400.1. The master contractor will be required to complete six (6) contact hours of training and continuing education every year from the date of licensing to renew the master contractor license. The Department will provide a listing of approved training providers and courses to meet this requirement.

400.2. The master contractor who fails to meet the training and continuing education requirements will lose the rights and privileges granted under that license until such time as these requirements have been met.

400.3. If the master contractor fails to meet the training and education requirement within the next licensing period, the license will be considered void.

400.4. If a master contractor completes more than the required six (6) hours in a licensing period, as many as three (3) hours can be rolled over into the requirement for the next licensing period.

500. PRACTICE, PROCEDURE AND QUALITY CONTROL

500.1. Practice

(1) Onsite wastewater systems installed and approved by master contractors must be installed pursuant to, and in compliance with, construction and operation permits issued by the Department.

(2) The master contractor does not have the authority to change an issued permit without first obtaining Department approval.

(3) A master contractor authorized under this regulation will be able to install, inspect and approve any system permitted by the Department under Regulation 61-56 that the master contractor installs himself except those systems designed by a Licensed Professional Engineer.

(4) The master contractor, after giving the Department the opportunity to do a final inspection of the installed system, may record and document the necessary measurements on a form approved by the Department, issue final approval, and cover the installation.

(5) The as-built drawings, along with the master contractor's signature and license number, must be submitted to the Department, with a copy being provided to the property owner for whom the system was installed.

500.2. Procedure

(1) The master contractor shall arrange a time, for the final inspection of an onsite wastewater system that is being installed, with a representative of the Department. If, after thirty (30) minutes of that arranged time, the Department representative has not arrived for the inspection, the master contractor may:

(a) inspect the system;
(b) record the findings on a form approved by the Department;
(c) grant final construction approval to the installation; and
(d) cover the system.

(2) The as-built drawings containing the required measurements and other documentation shall be submitted to the Department no later than the close of business on the next business day. A copy of this document(s) must also be furnished to the property owner for whom the system was installed.

500.3. Quality Control

The Department is required to conduct random final inspections on no less than three percent (3%) annually of the total number of systems installed during the preceding fiscal year. The Department will also conduct field reviews of the as-built drawings submitted by the master contractor compared with the actual installations those drawings represent.

600. BONDING AND INSURANCE REQUIREMENTS

600.1. Proof of both insurance and bond coverage shall be furnished to the Department prior to licensure as a master contractor and upon annual license renewal.

600.2. The onsite wastewater system master contractor shall be responsible for obtaining and maintaining both insurance and bond coverage for as long as the contractor is operating as a master contractor.

600.3. Failure to maintain both insurance and bond coverage shall result in the suspension or revocation of the master contractor license.

700. APPLICATION AND LICENSE FEES

700.1. The application fee for an onsite wastewater systems master contractor license shall be seventy-five dollars ($75.00); this fee must be submitted with the completed application. The application fee is non-refundable.

700.2. Upon successful completion of the application and examination requirements, each licensee shall pay a licensing fee of two hundred dollars ($200.00).

700.3. The annual renewal fee for each license shall be two hundred dollars ($200.00).

700.4. Failure to pay the annual renewal fee shall result in the suspension or revocation of the master contractor license.

~~700.5. Licenses issued in accordance with this regulation shall not be transferable.~~

~~800. ENFORCEMENT~~

~~800.1. Deviation from the installation design and conditions in onsite wastewater permits may be considered a violation of this regulation.~~

~~800.2. Violation of an onsite wastewater system installation permit, or any provisions of this regulation, by a master contractor, must be enforced in accordance as follows:~~

~~(1) First offense violations may be enforced under S.C. Code Section 44-1-150 or by suspension of the installer's license for a period not to exceed one (1) year.~~

~~(2) Second offense violations may be enforced under S.C. Code Section 44-1-150 or by suspension of the installer's license for a period not to exceed three (3) years.~~

~~(3) Third offense violations may be enforced under S.C. Code Section 44-1-150 or by permanent revocation of the installer's license.~~

~~800.3. A Department decision involving the issuance, denial, renewal, modification, suspension, or revocation of a permit or license may be appealed by an affected person with standing pursuant to applicable law, including S.C. Code Title 44, Chapter 1 and Title 1, Chapter 23.~~

~~900. SEVERABILITY CLAUSE~~

~~This regulation is issued under the authority of Sections 441140(11), 44-1-150, 44-55-827, and 48110 et seq. of the 1976 Code of Laws, as amended. It shall be enforced in accordance with interpretations and public health reasons approved by the Department. Should any section, paragraph, sentence, clause or phrase of this regulation be declared unconstitutional or invalid for any reason, the remainder of this regulation shall not be affected thereby.~~ [Repealed].

Fiscal Impact Statement:

There is no anticipated additional cost to the Department or state government due to any requirements of this amendment.

Statement of Need and Reasonableness:

The following presents an analysis of the factors listed in 1976 Code Sections 1-23-115(C)(1)-(3) and (9)-(11):

DESCRIPTION OF REGULATION: 61-55, Septic Tank Site Evaluation Fees; 61-56, Onsite Wastewater Systems; 61-56.1, License To Construct Or Clean Onsite Sewage Treatment And Self-Contained Toilets; and 61-56.2, Licensing Of Onsite Wastewater Systems Master Contractors.

Purpose: The Department is amending R.61-56, Onsite Wastewater Systems, to add new system standards, clarify and amend definitions, and clarify and update selected sections. The amendments modernize the regulation and streamline permitting procedures to address needed updates in administering the Onsite Wastewater program. The Department is also amending provisions of R.61-56.1 and R.61-56.2 and merging R.61-56.1 and R.61-56.2 into R.61-56 to improve efficiency and clarity for regulated entities and the public. This entails repealing R.61-56.1 and R.61-56.2 and simultaneously adding their provisions, as amended, to

R.61-56. The amendments include changes to licensing requirements for pumpers and haulers currently under R.61-56.1. The amendments revise provisions currently contained in R.61-56.2 to implement a tiered licensing program to establish improved competency of onsite wastewater system contractors/installers. This approach includes new requirements for examination and continuing education. In addition, because R.61-56.1 and R.61-56.2 are being combined with R.61-56, previously separate enforcement provisions are also consolidated and updated for clarity and to improve administration of the Onsite Wastewater program. In the interest of efficiency, the Department is also repealing R.61-55 and adding its provisions to R.61-56. The amendments related to R.61-55 include amendments to definitions and other changes as necessary to facilitate merging this regulation into R.61-56. The Department has also made other corrections for clarity and readability, grammar, punctuation, codification, and regulation text improvement.

Legal Authority: 1976 Code Sections 44-1-140(11), 44-1-150, 44-55-825, 44-55-827, and 48-1-10 et seq.

Plan for Implementation: Upon taking legal effect, Department personnel will take appropriate steps to inform the regulated community of the new amendments and repeals and any associated information. The DHEC Regulation Development Update (accessible at http://www.scdhec.gov/Agency/RegulationsAndUpdates/RegulationDevelopmentUpdate/) provides a summary of and link to these amendments and repeals. Additionally, printed copies are available for a fee from the Department's Freedom of Information Office.

DETERMINATION OF NEED AND REASONABLENESS OF THE REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

The amendments and repeals are needed and reasonable, as they provide clarification regarding the requirements and standards contained in R.61-56 and consistency with the latest scientific, industrial, and technological changes in onsite wastewater system design, construction, and installation. Furthermore, the amendments simplify the licensure of those operators that clean or pump sewage treatment and disposal systems and, for organization and clarity, provide a tiered structure for the licensure of operators that construct or install these systems. The amendments also serve to modernize the regulation and streamline permitting procedures to improve overall effectiveness of the Department's administration of the regulation.

DETERMINATION OF COSTS AND BENEFITS:

Internal Costs: Implementation of these amendments will not require additional resources. There is no anticipated additional cost to the Department or state government due to any inherent requirements of these revisions.

External Costs: The revisions do not increase any fees charged by the Department under the current regulations. The revisions expand existing site evaluation options and allow more streamlined permit processing by allowing an applicant to submit a proposed system layout from a licensed Professional Soil Classifier ("PSC") or other licensed person qualified by statute to practice professional soil classifying. Under this regulation, applicants desiring to install systems for a subdivision will be required to submit third-party soils work from a PSC or other licensed person qualified by statute to practice professional soil classifying. That person will then have the option to either submit a proposed system layout under one of the system standards established within R.61-56 or give the soils report to a Registered Professional Engineer to design a specialized septic system through the 610 Standard. Subdivision permit applicants may incur additional costs for the third-party work performed under this process. Outside of the subdivision context, applicants for conventional systems will retain the option to use a qualified third party or allow the Department to conduct a soil evaluation and prepare a system layout. The expanded options and enhanced involvement of third-party contractors serve to streamline and expedite the permit process for the Department and the regulated community.

Benefits: These amendments upgrade overall quality and practicality, improve clarity and consistency, reflect changes in design, construction, and installation of onsite wastewater system nomenclature and technology, separate the licensing of pumper/haulers and installers, provide for tiered licensure, streamline permitting, clarify existing definitions, and add new definitions and standards for site and system requirements.

UNCERTAINTIES OF ESTIMATES:

None.

EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH:

There is no anticipated negative environmental or public health effect resulting from the amendments and repeals of these regulations. Positive benefits include fostering increased installer competency through new continuing education requirements and the tiered system of licensure according to system complexity. The additions also enable the Department to focus efforts on ensuring installations are performed in accordance with the issued permit while allowing additional input in the soil evaluation and system layout stages from professionally certified persons.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED:

The negative effect on the environment and public health if the amendment of this regulation is not implemented would be less efficiency and clarity for industry and reduced effectiveness and efficiency in the Department's oversight of the disposal of septage and sewage.

Statement of Rationale:

Here below is the Statement of Rationale pursuant to S.C. Code Section 1-23-110(A)(3)(h):

The Department is amending R.61-56, Onsite Wastewater Systems, to add new system standards, clarify and amend definitions, and clarify and update selected sections. The amendments modernize the regulation and streamline permitting procedures to address needed updates in administering the Onsite Wastewater program. The Department is also amending provisions of R.61-56.1 and R.61-56.2 and merging R.61-56.1 and R.61-56.2 into R.61-56 to improve efficiency and clarity for regulated entities and the public. This entails repealing R.61-56.1 and R.61-56.2 and simultaneously adding their provisions, as amended, to R.61-56. The amendments include changes to licensing requirements for pumpers and haulers currently under R.61-56.1. The amendments revise provisions currently contained in R.61-56.2 to implement a tiered licensing program to establish improved competency of onsite wastewater system contractors/installers. This approach includes new requirements for examination and continuing education. In addition, because R.61-56.1 and R.61-56.2 are being combined with R.61-56, previously separate enforcement provisions are also consolidated and updated for clarity and to improve administration of the Onsite Wastewater program. In the interest of efficiency, the Department is also repealing R.61-55 and adding its provisions to R.61-56. The amendments related to R.61-55 include amendments to definitions and other changes as necessary to facilitate merging this regulation into R.61-56. The Department has also made other corrections for clarity and readability, grammar, punctuation, codification, and regulation text improvement.

ATTACHMENT B

SUMMARY OF PUBLIC COMMENTS AND DEPARTMENT RESPONSES

Document No. 4979
R.61-56, *Onsite Wastewater Systems*

As of the September 28, 2020, close of the Notice of Proposed Regulation comment period:

Name	Section
Comment #1: James Burton	**104.3(c)**
Comment: As to the comment, I really wish you guys would consider letting us inspect our own systems in tier 1 or 2- Us personally always try and schedule the day after so that we aren't wasting our inspectors time in the event we don't complete the install. I wouldn't be opposed to being bonded in tier two to inspect the system right after install is complete. I can only speak for myself but I have never cut a corner on an install, I respect the environmental impact of a failed system and trust me when I say this— NEVER want to have to return to a used system. Our inspector here in Oconee is great and professional, but she simply can't be everywhere at once and I feel that it would be more streamlined if we could self inspect. **Department Response:** Clarification - Self-inspections by Tier 1 and Tier 2 contractors may be allowed as described within Section 104.3(c) of the revised regulation.	
Name	**Section**
Comment #2: Katie Callahan (Director for Clemson University Center for Watershed Excellence & Erika Hollis (Upstate Forever)	
Comment: We have been working on projects related to failing septic systems through the watershed management and 319(h) programs at DHEC and are concerned with the increasing failures we have heard of and witnessed from this past, very wet year. On this note, I wanted to share some documents with you that you might find helpful in shaping our regulations and this discussion, in hopes that they are a resource to you. Also, since I admittedly have not done all of my homework yet, were any design requirements modified to prepare new septic systems for the climate changes ahead during their lifespan? Ideas from other states include clustering systems on small package plants further inshore away from water sources and flooding in coastal communities (see https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0162104 for research background). Also, any inclusion on advanced systems, like drip or shallow pressurized dispersal systems, where setbacks cannot be achieved near waterways? **Department Response:** Clarification - Certain system standards have been revised within this regulation to provide additional protection to the environment. An example of this is an increased setback to the critical area line, tidal waters or environmentally sensitive waters for Specialized systems in the 610 standard. Within this standard the regulations also require an Operation and Maintenance plan be developed by the designing Registered Professional Engineer, recorded with the property deed, and must run with the land.	

Name	Section
Comment #3: Dennis DeFrancesco (Professional Soil Classifier)	**102.1(5); 104.1(5); 400; Appendix Q(1)(b)(v); 700**

Comment:

Section 102.1(5): *"The Department will not perform a soil evaluation or prepare a system layout for any subdivision or portion of a subdivision. Soil evaluations for any lots that are part of a subdivision must be conducted by a Professional Soil Classifier. Proposed system layouts for any lots that are part of a subdivision must be prepared by a third-party Registered Professional Engineer or Professional Soil Classifier meeting the criteria under Section 102.1(3)(c). The Soils Report and proposed system layout must be submitted with the onsite wastewater system permit application for the purpose of the Department review and issuance of a permit to construct."* I suggest this revision is deleted for the following reasons: 1. Personally, I will not be doing any of these, except for some custom builders. In the past, many of these tract-builder clients have proved troublesome; they ignore recommendations and often violate the permit by grading the site or by other means. I will not take the liability for their actions, nor the aggravation when I'm asked to revise the permit under untenable conditions. 2. There are relatively few licensed soil classifiers actually located in SC presently. Even if we all agreed to accept all requests, I doubt we could keep up with demand as it is today. In theory, other soil classifiers will become licensed in SC for the increased business. If this does happen, it will take several years anyway. 3. I doubt the developers will willingly pay the extra soil classifiers fee. This will certainly cause them to complain.

Department Response: Not Adopted - The Department is currently not able to meet the demand for permit applications and, in most cases, carries a backlog across the state. Given resource and logistical considerations, it is not practicable for Department staff to directly perform soils evaluations for subdivision developments. The Department has determined that the provision referenced by the commenter will allow for more efficient use of Department resources, ease backlogs, and facilitate continued cooperation with licensed Professional Soil Classifiers in the private sector who are qualified to perform this work. Should any tract-builder or other person violate an issued permit, this should be brought to the Department's attention so that the matter can be addressed through corrective action and enforcement against the violator as appropriate. In addition, other Professional Soil Classifiers with whom the Department has engaged in developing these amendments have indicated their ability to take steps to meet any increased demand resulting from this amendment. The Department has also made changes to the regulation to allow soil evaluations to be conducted by a licensed person qualified to practice professional soil classifying under S.C. Code Section 40-65-40(7) (see Department response to Comment #16 below). This may further bolster the private sector's ability to meet any increased demand for subdivision soil evaluations.

Section 104.1 (5): *"Backhoe pits shall be required above the Fall Line that separates the Piedmont area from the Coastal Plain as defined by the South Carolina Geological Survey."* I am much in favor of this proposed revision. Pits give a much more accurate picture of the soil profile. A hand auger is merely a 3-inch peep hole that can often miss important soil qualities. (Is the rock stopping the auger a golf-ball-size rock, a Volkswagen-size rock, or a mountain-size rock? A backhoe pit tells all.) The Mom-and-Pop applicants may complain due to the extra expense of hiring a backhoe, but the significantly better drainfield designs will give everyone better results.

Department Response: Acknowledged - The Department appreciates the commenter's support of the proposed regulatory change.

Section 400: *"(a) The depth to the zone of saturation (ZOS) must be at least twenty-nine (29) inches below the naturally occurring soil surface and at least six (6) inches below the bottom of the proposed wastewater infiltration trenches at the deepest point of effluent application."* I might be missing it, but is there a slope factor listed to adjust for minimum depths? This concern applies to all Standards for maximum and minimum trench depths.

Department Response: Clarification - This concern is addressed in Standards 100, 210, 220, 230, 240, 260, 290, and 420. These standards indicate: *This system must not be used on sloping sites that require serial distribution unless it can be demonstrated that the entire wastewater infiltration trench installation (i.e., side wall to side wall and end to end) can meet the required textural limitations and the required offsets to the zone of saturation and restrictive horizons.*

Appendix Q (1) (b) (v): *"For systems that have mechanical components and/or require a higher degree of maintenance to ensure the proper treatment and disposal of Domestic Wastewater, an operation and maintenance (O&M) plan must be developed by the designing Registered Professional Engineer to be given to the party who is ultimately responsible for the operation of the system. O&M plans must be recorded along with the property deed and must run with the land."* This is a great idea. Future homeowners must be made aware of their specialized septic system's maintenance needs.

Department Response: Acknowledged - The Department appreciates the commenter's support of the proposed regulatory change.

Section 700: 1. First, I suggest that DHEC transfer all septic licensing to Department of Labor, Licensing, and Regulation. (LLR). My question is this: why does DHEC license septic tank installers? I mean, licensing installers itself is obviously needed, but why is DHEC doing it? The Department of Labor, Licensing, and Regulation (LLR) has been doing this exact job since July 1, 1994. I feel that DHEC could save itself a lot of headaches by getting this off their plate, and given to an agency that specializes in licensing. DHEC would also save real money by re-assigning staff from this task to other needs. 2. If DHEC does continue to license septic installers, I highly suggest an Ethics Statement is included and signed by each licensee. This is common language in most professional licenses, and gives more leverage in any license revocation actions.

Department Response: Not Adopted - As to the commenter's first suggestion: S.C. Code Section 44-55-827, Promulgation of Regulations, requires the Department to promulgate regulations for the licensure of an Onsite Wastewater Systems Contractor. The Department is bound to comply with this statutory directive by licensing septic contractors. As to the commenter's second suggestion: the commenter's suggestion for an ethics statement to be included in license applications is outside the scope of revisions to Department regulations. License applicants currently sign a statement indicating their understanding that violation of onsite wastewater regulations may constitute grounds for suspension or revocation of the license. License suspension and revocation actions will be pursued consistent with the enforcement provisions of the regulations.

Additional Suggestions: Although not included in the proposed 61-56 revisions, I propose that DHEC hire selected retired sanitarians as "Soil Evaluators" to continue their work as retirees for $1 per year. This approach would insure compliance with the Soil Classifiers statute and would greatly alleviate the septic permit backlog. I have many additional details to suggest, but below is a brief summary: All of this is done with merely an administrative directive and NO change in regulation or statute. In a nutshell:

- DHEC hand-selects the best retirees to hire for this trial run to minimize all liability. After all, DHEC now has liability for all of its current employees regardless of experience.

- The soil evaluators basically work exactly as they did while active sanitarians: examining soils and designing systems.
- They can be fired for any reason, no questions asked.
- DHEC supplies the contact info for these soil evaluators to permit applicants.
- The program is evaluated after a one year trial period and either adjusted or discontinued.

Department Response: Not Adopted/Clarification - This comment does not propose a change to Department regulations. The regulations as revised contain a variety of changes to help reduce septic permitting backlogs in a manner consistent with applicable law.

Name	Section
Comment #4: Patrick Mulhall (Polylok, Inc. & Zabel Environmental)	**503.3(17) and 504.1(6)**

Comment: I have just briefly reviewed the proposed regulations I apologize about being a little late to the dance. I could not help but notice that the regulations did not address safety screens or a secondary device to prevent people and pets from falling into a tank. I also did not see where the regulations are requiring effluent filters to be installed on the outlet of septic tanks and grease traps.

Department Response: Safety Screens: Clarification - Sections 503.3(17) and 504.1(6) of the revised regulations (former sections 700.3(17) and 800.1(6)) identify requirements to prevent unauthorized tank access. The Department deems these provisions adequate to address the commenter's concerns. The use of safety screens is also allowed under the regulations.

Effluent Filters: Not Adopted - While effluent filters may be used, the Department has not proposed to require effluent filters as part of this regulatory revision. The use of effluent filters has the potential to cause increased occurrence of malfunctions without proper maintenance and upkeep by the property owner. Requiring installation of effluent filters would require additional regulatory oversight not contemplated by this regulatory revision.

Name	Section
Comment #5: David Lentz (Professional Engineer)	**704; 101.1; 101.2(2)(3)(4); 201(6); 503.3(3); 500; 503.3(10); 503.3(11); 503.3(12)(13); 503.3(17); 503.3(20)(21)(24); 505(1)(A)**

Comment:
704: H3646 from the 2015-2016 session makes reference to R.61-56.1 relative to the minimum qualifications for the installation of non-gravel, nonmechanical, soil absorption trench systems, such as chambers and bundled expanded polystyrene synthetic aggregate. In order for the session law and any other documents containing references to R.61-56.1 and R.61-56.2 to remain effective, the rescission of R.61-56.1 and R.61-56.2 should be addressed in R.61-56. Infiltrator requests that DHEC confer with its legal counsel on the language necessary to maintain the licensing requirement for installers using H3646, with one potential option presented below.

Upon the effective date of the tiered licensure provisions (Section 700) of this regulation, all installers licensed as master contractors under the previous R.61-56.2 shall be considered to hold a Tier 3 license, and all other installers licensed under the previous R.61-56.1 shall be considered to hold a Tier 2

license. The Tier 3 or Tier 2 license shall expire upon the original expiration date of the license held under R.61-56.1 or R.61-56.2, as applicable, unless the license is renewed in accordance with the provisions of Section 700.1 of this regulation. Upon the rescission of R.61-56.1 and R.61-56.2, all references to R.61.56.1 and R.61-56.2 in statute, rule, and policy refer to requirements set forth in this regulation.

Department Response: Not Adopted - As noted by the commenter, S.C. Code Section 44-55-1330(A) (enacted through H3646) references the installation of passive soil-based onsite disposal systems by installers licensed under the preexisting R.61-56.1. Through this regulatory revision, the requirements of R.61-56.1 and R.61-56.2 have been merged into the revised R.61-56. While the Department is unable to directly update the reference to R.61-56.1 in statute, the Department will continue to implement Section 44-55-1330(A) by requiring that all onsite wastewater systems (including passive soil-based onsite disposal systems) be installed by contractors licensed under R.61-56. Other requirements of S.C. Code Sections 44-55-1310 through 44-55-1330 also continue to be implemented by the Department and will be directly incorporated into R.61-56 through future regulatory action.

101.1: The definitions section includes "Professional Soil Classifier", but not "Registered Professional Engineer", with both titles occurring extensively throughout the rule. We suggest adding a definition for Registered Professional Engineer for two reasons: 1) for consistency with the manner in which Professional Soil Classifier is defined and referenced; and 2) by defining Registered Professional Engineer once, all subsequent references will not need to be followed by the words "in South Carolina" because that information would be included in the definition.

Department Response: Changes Made - In response to the comment, the Department has added a definition for Registered Professional Engineer and has updated the definition of Professional Soil Classifier to ensure accuracy and consistency in the Department's manner of defining these terms.

101.2(2), (3), and (4): Subsections (2) and (3) make reference to the American Society for Testing and Materials. According to its web site, the organization has transitioned its name to ASTM International (https://www.astm.org/ABOUT/overview.html). Subsection (4) makes reference to the "Canadian Standards Association (CSA)". According to its web site, the organization has transitioned its name to CSA Group (https://www.csagroup.org/).

Department Response: Changes Made - In response to the comment, the Department has revised the names of ASTM International and CSA Group to ensure accuracy and consistency in the Department's manner of referencing these terms.

201.1(6) and 503.3(3): Under these identically worded sections (Is that intentional, or can one section be deleted?), tanks in series must be connected with a minimum 12-inch-diameter pipe positioned 12 inches above the bottom of the tank. Infiltrator has a concern with this requirement for two reasons: 1) tanks in series would work more effectively for primary treatment/solids separation without a tank-to-tank connection designed to move sludge toward the outlet tee; and 2) the connection of thermoplastic tanks with a 12-inch diameter pipe is not possible for thermoplastic tanks, excluding this tank construction material from certain applications.
Infiltrator offers its IM-Series tanks in all 50 states and is not aware of another state that requires a sludge pipe below the liquid level between tanks in series. Tanks in series are typically connected at and above the liquid level, with the first tank serving as the first compartment and subsequent tanks serving as the second compartment of a multi-compartment tank. Excerpts from the Georgia and North Carolina rules are provided below as local examples:

Georgia Manual for On-site Sewage Management Systems: (5) Tanks in Series. The County Board of Health may approve the installation of tanks placed in series as equivalent to a single compartmented septic tank. Tanks in series should be single compartment tanks, with the first tank being at least 1000 gallons and equal to 2/3 of the required liquid capacity. When tanks in series are used, they shall be connected with a sealed sewer line, and all sewage shall initially enter the first tank.

North Carolina 15A NCAC 18A .1952(b)(2)(E): The minimum liquid capacity requirements of Subparagraph (b)(2) of this Rule shall be met by use of a single two-compartment septic tank or by two tanks installed in series, provided the first tank is constructed without a baffle wall and contains at least two-thirds of the total required liquid capacity.
In terms of in-series tanks effectively providing primary treatment by separating liquids from solids, it would seem preferable to eliminate the sludge pipe, isolating the majority of the sludge in the first tank, similar to the first compartment of a 2-compartment tank, leaving the second and subsequent tanks for a more quiescent environment where further liquid-solids separation can occur, ultimately leading to an effluent with reduced total suspended solids concentration. The installation of a sludge pipe for tanks in series is equivalent to purposefully transferring sludge to the second compartment of a 2-compartment tank, seemingly defeating the purpose of isolating the outlet from as much solids volume as possible. Furthermore, by requiring that the first in-series tank provide 2/3 of the working volume, on a proportional basis, this tank would function the same as a single 2-compartment tank having a partition installed to create a first compartment with 2/3 of the working volume.

This highly prescriptive requirement prevents the participation of thermoplastic tanks where a series configuration with a sludge pipe is required. Thermoplastic tanks cannot comply with this requirement for two reasons: 1) the molded pipe inletting and outletting shapes are too narrow to accept a 12-inch pipe; and 2) the surface where the pipe must be installed is corrugated, irregularly shaped, sloped, or curved, preventing the creation of a watertight pipe connection. With flat, orthogonally oriented walls, concrete tanks would be expected to conform with this requirement, although creating a watertight seal around a 12-inch-diameter pipe where the installer creates a knockout using a hammer and chisel and applies a grout seal is concerning. This method of pipe connection below the tank working level will very often result in leaks at the grouted pipe-to-tank connection.

The rules should be revised to promote better liquid-solid separation and allow a fair, level playing field for all tank construction materials, including both concrete and thermoplastic, by eliminating the sludge pipe with the following amendments, which apply the same to both sections of the regulation.

(6) The minimum liquid capacity requirements shall be met by the use of a single septic tank or two (2) or more tanks installed in series. Septic tanks joined in series shall be interconnected by an upper effluent pipe(s) with a minimum diameter of four (4) inches ~~and a lower sludge pipe(s) with a minimum diameter of twelve (12) inches~~. The ~~upper~~ connection(s) shall be installed level from tank to tank~~,~~ ~~and the lower sludge pipe connection(s) shall be installed level and shall be placed twelve (12) inches above the bottoms of the tanks~~. The ~~lower sludge pipe connection(s) can be eliminated if the~~ first tank in series shall contain~~s~~ at least two-thirds (2/3) of the total required liquid capacity. There shall be no more than two (2) inches of fall from the inlet invert of the first tank to the outlet invert of the last tank in series.

Department Response: Not Adopted - The Department notes that the requirements of the referenced provisions of R.61-56 are consistent with those referenced in Georgia and North Carolina, except that Georgia and North Carolina require that the first tank in series contain two-thirds (2/3) of the liquid volume regardless of whether a sludge pipe is used. Allowing for the installation of a sludge pipe without requiring the first tank to contain at least two-thirds (2/3) of the liquid volume decreases financial burden

on homeowners by not requiring them to install septic tanks with a larger volume than system designs specify.

500: South Carolina's minimum required dispersal system size in highly permeable soils, such as sand and loamy sand, is less than that of some other states in the region. The relatively small system size is due to the higher allowable loading rates of 0.9 gpd/sf to 1.0 gpd/sf in sand and loamy sand soil textures. The USEPA1 recommends a more conservative loading rate of 0.8 gpd/sf for both sand and loamy sand soil textures. Table 1 below provides a comparison of effluent loading rates for several Southeastern states.

Table 1 - Comparison of Long-Term Acceptance Rates by Soil Texture

	Long-Term Acceptance Rate, Daily Flow, and Septic Tank Effluent Vertical Separation (LTAR expressed in gpd/sf)				
USDA-NRCS Soil Texture	**South Carolina** *120 gpd/br 6 inch VS*	**Georgia** *150 gpd/br 24-36 inch VS*	**North Carolina** *120 gpd/br 12-18 inch VS*	**Alabama** *150 gpd/br 24-36 inch VS*	**Virginia** *150 gpd/br 18 inch VS*
Sand	0.9 to 1.0	0.91	0.8 to 1.2	0.75	0.91
Loamy sand	0.9 to 1.0	0.79	0.8 to 1.2	0.75	0.76
Sandy loam	0.7 to 0.8	0.71	0.6 to 0.8	0.60	0.69
Loam	0.7 to 0.8	0.60	0.6 to 0.8	0.60	0.58
Sandy clay loam	0.5 to 0.6	0.54	0.3 to 0.6	0.50	0.58
Clay loam	0.5 to 0.6	0.48	0.3 to 0.6	0.50	0.44
Silt loam	0.5 to 0.6	0.45	0.3 to 0.6	0.50	0.36
Silty clay loam	0.1 to 0.4	0.42	0.3 to 0.6	0.45	0.28
Sandy clay	0.1 to 0.4	0.40	0.1 to 0.4	0.37	0.19
Clay	0.1 to 0.4	0.38	0.1 to 0.4	0.29	0.13
Silty clay	0.1 to 0.4	0.37	0.1 to 0.4	0.23	0.11

Sources:
– SC - R.61-56, Onsite Wastewater Systems
– NC - 15A NCAC 18A .1949(a) and Table I
– GA - Manual for On-site Sewage Management Systems, Table DT-2
– AL - Chapter 420-3-1 Onsite Sewage Treatment and Disposal, Appendix A, Tables 1 and 3
– VA - Sewage Handling and Disposal Regulations, Tables 5.1 and 5.4

1 USEPA Onsite Wastewater Treatment Systems Manual, 2002, Table 4-3: Suggested Hydraulic and Organic Loading Rates for Sizing Infiltrative Surfaces.

The significance of the effluent loading rate differences are shown in Table 2. With as little as 6 inches of separation from the bottom of the wastewater infiltration trenches and zone of saturation, South Carolina allows the nation's smallest vertical separation from trench bottom to saturated soil for septic tank effluent. North Carolina's vertical separation is 12 to 18 inches with 18 inches applying to the state's fastest-flowing Group I sand textures. Virginia requires 18 inches of vertical separation for all soil textures. Alabama and Georgia require 24 to 36 inches separation, with 36 inches required for higher-LTAR sand textures.

Table 2 - Comparison of Minimum Trench Basal Area For a 3-Bedroom Home

USDA-NRCS Soil Texture	Trench Basal Area, Daily Flow, and Septic Tank Effluent Vertical Separation (basal area expressed in sf)				
	South Carolina *120 gpd/br 6 inch VS*	**Georgia** *150 gpd/br 24-36 inch VS*	**North Carolina** *120 gpd/br 12-18 inch VS*	**Alabama** *150 gpd/br 24-36 inch VS*	**Virginia** *150 gpd/br 18 inch VS*
Sand	360	495	360	600	495
Loamy sand	400	570	400	600	594
Sandy loam	450	630	450	750	654
Loam	514	750	514	750	780
Sandy clay loam	600	840	600	900	780
Clay loam	655	930	655	900	1,032
Silt loam	720	1,005	720	900	1,236
Silty clay loam	900	1,065	900	990	1,632
Sandy clay	1,200	1,125	1,200	1,230	2,358
Clay	1,800	1,170	1,800	1,530	3,414
Silty clay	3,600	1,230	3,600	1,950	4,104

The combination of trench system designs having a comparatively compressed vertical separation, sand and loamy sand soil textures, and small trench bottom area leads to an increased potential for hydraulic malfunction as compared to situations when the trench bottom area is larger and vertical separation is greater. While changing South Carolina's vertical separation distance to soil saturation is not practical for a variety of reasons, implementing an increased trench bottom area for the more permeable soil textures to increase the design factor of safety against hydraulic malfunction and increase the expected useful system life is implementable.

Currently, the elevated effluent loading rates of 0.9 gpd/sf to 1.0 gpd/sf specified in R.61-56-500 result in a smaller dispersal system, which can cause premature system failure. Such failures require costly and invasive repair or system replacement and produce an unnecessary burden on South Carolinians. To re-align South Carolina's effluent loading rates with other states in the region and EPA guidelines, and to subsequently lessen future burden on South Carolinian homeowners, Infiltrator recommends that effluent loading rates in sand and loamy sand soil textures be decreased. Ideally, the LTAR for both soil textures could be reduced to 0.8 gpd/sf. If this is not feasible, another approach would be to lower loading rates in sand and loamy sand soil textures to 0.9 and 0.8 gpd/sf, respectively.

It should be noted that this type of change is not without precedent, as Alabama lowered its sand loading rate from 1.2 to 0.75 gpd/sf in 2009, and Florida moved from 1.0 to 0.8 gpd/sf in 2009. Attachment 1 includes a presentation from the Florida Department of Health's August 27, 2008 Technical Review and Advisory Panel meeting, where modifications to Florida's long-term accepted rate (LTAR) rules were presented and rationalized. To Infiltrator's knowledge, a follow-up performance study was not implemented after the rule change reducing LTARs for sandy soil textures to measure the effect on system hydraulic performance.

Department Response: Not Adopted - The Department did not propose any changes to the long-term acceptance rate standards for sand or loamy sand as part of this regulatory revision, and the Department declines to make adjustments to these standards at this time. As a general matter, the Department has not observed an increased rate of malfunction or other problematic trend based on application of the existing long-term acceptance rates for sand and loamy sand, and the Department deems the existing rates to represent conservative figures for purposes of ensuring appropriate system sizing. In addition, the

Department utilizes a more conservative approach than some other states for determining zone of saturation (ZOS) (i.e., by requiring a separation above the first occurrence of indicators of the water table, such as gray mottling, rather than identifying a percentage of the overall soil matrix). This results in a greater vertical separation from the water table and, in turn, reduced risk of malfunction. The Department is unable to speak to long-term acceptance rates used by other jurisdictions and the reasons those rates were adopted.

503.3(10): Propose adding the ability to inlet or outlet from a septic tank from the sides or ends, which is customary in most North American regulatory jurisdictions. Being limited to the use of only the ends of a tank is a burden when side ports are available and provide a superior manner of tank installation and configuration flexibility in the field. Also, the type of material used for a "pre-cast" tank should be specified as concrete.

(10) There shall be a minimum of two (2) openings in the tank wall, located at the inlet and outlet ends or sides of the inlet and outlet ends of the tank. The knockouts for the inlet and outlet openings of precast concrete tanks shall have a concrete thickness of not less than one (1) inch in the tank wall. The openings shall allow for a minimum of four (4) inch pipe or a maximum of six (6) inch pipe. No openings shall be permitted below the tank liquid level.

Department Response: Changes Made - With the exception of Section 800, Appendix U, all current Department approvals for septic tanks include options for connections to the side and center of the tank on opposite ends. The Department acknowledges this comment and has revised the text accordingly.

503.3(11): Propose adding an allowable tee manufacturing material the recognizes a very common product offered by Polylok and Tuf-Tite (PL-68 and EF-4 inlet/outlet tees, respectively) and defining a minimum height for the outlet tee and minimum distance from the top of tank to top of tee, ensuring adequate air flow and restriction of floating scum from entering the top of the tee, without being as prescriptive. The current rules establish a single distance from top of tee to tank that is burdensome because other configurations work to also allow ample airflow, but are impermissible as written in R.61-56-503.3(11). Specifying a minimum tee-to-liquid distance is a functionality issue to prevent floating scum from escaping the tank and causing costly drainfield failure to the homeowner due to clogging of the soil pore structure with solids.

(11) The inlet and outlet for septic tanks and grease traps shall be a cast-in-place concrete tee, a polyvinyl chloride (PVC) tee, an acrylonitrile butadiene styreneor (ABS), or a polyethylene (PE) tee, made of not less than Schedule 40 pipe or equivalent fittings and material. The cast-in-place concrete tees shall have a minimum thickness of not less than two (2) inches. The invert of the outlet shall be at least two (2) inches lower in elevation than the invert of the inlet. The inlet and outlet tees shall extend above liquid ~~depth~~ level a minimum of 6 inches and to no less than ~~approximately~~ one (1) inch from the top of the tank to allow venting between tank compartments and multiple tank configurations.

Department Response: Changes Made - The Department acknowledges this comment and has revised the text accordingly.

503.3(12) and (13): Propose providing a range of allowable depths for the inlet and outlet tees, such that commercially available pre-fabricated tee products (e.g., Polylok, Tuf-Tite offerings) can be used in the South Carolina market. Currently, some products, which are in current use across North America, cannot be used because of the prescriptive, inflexible requirements for a 16inch inlet depth or 18-inch outlet depth. Note that this proposed range aligns with the tee requirements in IAPMO/ANSI Z1000-2019, as shown in this excerpt from the IAPMO standard:

4.5 Inlets and Outlets

4.5.2 Design

Inlet and outlet devices shall:

(a) be open-topped;

(b) extend below the liquid surface between 50% and 75% of the liquid depth, measured from the inside floor of the septic tank; and

(c) extend at least 120 mm (5 in) above the liquid surface.

The objective is to place effluent into a downward trajectory at the inlet and discharge from within the clear zone at the outlet. Both objectives are achieved with this proposal.

(12) The inlet tee for septic tanks and grease traps shall extend below the liquid surface between 50% and 75% of the liquid depth, measured from the inside floor of the septic tank ~~sixteen (16) inches below the liquid level~~.

(13) The outlet tee for a septic tank shall extend below the liquid surface between 50% and 75% of the liquid depth, measured from the inside floor of the septic tank ~~eighteen (18) inches below the liquid level~~\ and the outlet tee for a grease trap shall extend between six (6) and twelve (12) inches above the tank bottom.

Department Response: Not Adopted - The Department did not propose any changes to allowable depths for inlet and outlet tees under Sections 503.3(12) and (13) as part of this regulatory revision, and the Department declines to make adjustments to these provisions at this time. Further review would be necessary before adjusting these established specifications for inlet and outlet tees, which are deemed to be protective against malfunctions.

503.3(17): Propose adding provisions for the use of fasteners that can only be removed with tools as a means for securing a tank cover. This is frequently achieved using a square-head nut or similar fastener. Also propose specifying that the cover cannot slide, rotate, or flip open as an added safety measure. There are incidences of people falling into septic tanks and drowning because the cover was not designed to resist flipping when stepped on. These proposed changes mitigate the burden of injury or death to an unsuspecting passerby that could step on an unstable cover.

(17) Should risers or manholes be utilized to allow access into septic tanks, grease traps, or pump chambers, the risers or manhole covers, as applicable, shall be constructed to prevent the release of odors, entry of vectors, and water. Grade level riser/manhole covers shall be secured by bolts~~, or~~ locking mechanisms, or fasteners that can only be removed with tools, or have sufficient weight to prevent unauthorized access. Grade level riser/manhole covers shall not slide, rotate, or flip open. The ground shall slope away from any access extended to grade level.

Department Response: Use of fasteners: Changes Made - The Department acknowledges the comment pertaining to fasteners that can only be removed with tools and has revised the text accordingly.

Additional language regarding covers: Not Adopted - The additional suggested language pertaining to access covers not being capable of sliding, rotating, or flipping open is not deemed necessary, as the current regulatory language is deemed sufficiently protective against unauthorized access.

503.3(20), (21), and (24): Propose clarifying that these sections or passages within the section are applicable to concrete tanks. Fiberglass-reinforced plastic and thermoplastic tank manufactures should not be held to non-germane concrete tank requirements. In (24) below, the identifying seal is most frequently molded into the tank in the form of an embossment.

(20) All concrete tanks must pass the ASTM C–1227 Standard for watertight testing. The Department will choose tanks at random for testing. Tanks will be approved for use in South Carolina after the Department ascertains that the standard is met. After joining, tanks manufactured in multiple sections shall be plastered along the section joints with hydraulic cement or other waterproofing sealant. Other methods of waterproofing tanks may be used as specifically approved in the plans and specifications for the tank. Prior to backfilling, the Department shall make a finding that multiple section tanks are watertight if a soil wetness condition is present within five feet of the elevation of the top of the tank. Any tank found to be improperly sealed, having cracks or holes, which will allow for water infiltration or discharge of sewage from the tank bottom, walls, or top, will not be approved for use.

(21) ~~Tank~~ Concrete tank manufacturers must have equipment and capabilities for portion control to maintain constant mixture formulation ratios and provide for systematic inspection of finished products to ensure compliance with the minimum tank construction and design standards.

(24) An identifying seal must be cast, molded, or permanently affixed by an approved method from the Department on the outlet tank wall within six (6) inches of the top. The identifying seal shall identify the manufacturer and the liquid capacity of the tank. The concrete tank's cast date shall be located on the identifying seal or imprinted on the top of the tank within six (6) inches from outlet tank wall near the identifying seal. The lettering on the identifying seal or date imprinted on the top of the tank shall be no more than six (6) inches in height.

Department Response: Changes Made - The Department acknowledges this comment and has revised the text accordingly.

505(1)(A): Under the current rules, thermoplastic tanks must be certified by an accredited organization. Nationally, many rules provide reference as to where the accreditation must originate, such as the American National Standards Institute or Standards Council of Canada. The suggested amendment incorporates both accreditation organizations to ensure that certifications originate from proven and reliable independent organizations. Note this this is the only accreditation reference in the draft rule, so there are no other sections that would need a similar change.

(a) Thermoplastic tanks shall be certified by an American National Standards Institute or Standards Council of Canada accredited third-party to comply with the most recent edition of IAPMO/ANSI Z1000 or CSA B66.

Department Response: Changes Made - The Department acknowledges this comment and has revised the text accordingly.

Name	Section
Comment #6: Roger Owens (Owens Onsite Services, LLC)	**102.1(5); 104.3(c); 200.6(i); Appendix R(1)(d); 201.2; 702.3**

Comment: 102. Onsite Wastewater System Site Evaluation and Fees.
(5) The Department will not perform a soil evaluation or prepare a system layout for any subdivision or portion of a subdivision. Soil evaluations for any lots that are part of a subdivision must be conducted by a Professional Soil Classifier. Proposed system layouts for any lots that are part of a subdivision must be prepared by a third-party Registered Professional Engineer or Professional Soil Classifier meeting the criteria under Section 102.1(3)(c). The Soils Report and proposed system layout must be submitted with the onsite wastewater system permit application for the purpose of the Department review and issuance of a permit to construct.

Comment: I am concerned that the private sector will not be able to meet the demand that this proposed change will cause. This could result in this process being opened by the General Assembly to unqualified individuals.

Department Response: Clarification - The Department is currently not able to meet the demand for permit applications and in most cases carries a backlog across the state. Given resource and logistical considerations, it is not practicable for Department staff to directly perform soils evaluations for subdivision developments. The Department has determined that the provision referenced by the commenter will allow for more efficient use of Department resources, ease backlogs, and facilitate continued cooperation with licensed Professional Soil Classifiers in the private sector who are qualified to perform this work. In addition, other Professional Soil Classifiers with whom the Department has engaged in developing these amendments have indicated their ability to take steps to meet any increased demand resulting from this amendment. The Department has also made changes to the regulation to allow soil evaluations to be conducted by a licensed person qualified to practice professional soil classifying under S.C. Code Section 40-65-40(7) (see Department response to Comment #16 below). This may further bolster the private sector's ability to meet any increased demand for subdivision soil evaluations.

104.3. Final Inspections and Approval.
(c) Except as provided in Section 104.3(2)(a), the Department may, in its discretion, direct Tier 1 and Tier 2 installers with no pending enforcement actions or prior Department findings of violation under Section 800 of this regulation to self-inspect systems they have installed using a process and form directed by the Department. Tier 1 and Tier 2 installers allowed to conduct self-inspections shall comply with Section 702.2 in its entirety. The Department reserves the right to withdraw any direction to Tier 1 and Tier 2 installers to conduct self-inspections at any time.

Comment: Based on my 28 years of experience with DHEC (1990-2018) the contractors are not qualified to self-inspect. I believe all the installations by Tier 1 and Tier 2 should be inspected by the Department.

Department Response: Not Adopted/Clarification - The Department is mandated by state statute to inspect a minimum of 3% of the previous years number of installations. The contractor self-inspection process allows the Department to ensure that all system installations undergo an inspection prior to receiving final approval while also accounting for Department resource limitations. This further enables the Department to maintain public expectations for permitting turnaround times and reduction of backlogs. Under the regulations, all installers must first provide Department staff the opportunity to inspect prior to performing a self-inspection. In addition, every self-inspection form will be reviewed by the Department prior to Department issuance of final approval to operate. Section 702.3 of the amended regulation further addresses the auditing of final installation and inspection documentation. Various streamlining changes to this regulation (including enhanced involvement by Professional Soil Classifiers and Professional Engineers in subdivision permitting) are likely to afford the Department the opportunity to increase the number of final inspections it performs beyond current levels (and above the 3% threshold).

200.6. Setbacks, and Appendix R – Curtain Drain Standard
Section 200.6
Within twenty-five (25) feet upslope of a basement or within fifteen (15) feet of the sides of a basement. These setbacks do not apply to a septic tank/pump chamber location or where trench installations are downslope of a basement;
Standard Appendix R – Curtain Drain Standard
(d) The curtain drain shall be placed ten (10) feet upslope and twenty-five (25) feet down slope of a subsurface wastewater infiltration area or repair area. Where the aggregate portion of the curtain is installed at the same or lower (down-slope) elevation relative to an adjacent subsurface wastewater infiltration area or repair area, the aggregate portion of the curtain must be a minimum of twenty-five (25) feet from the adjacent subsurface wastewater infiltration area or repair area.

Comment: I believe these two sections are not consistent. I think drainline installed beside a basement at grade with or at a higher elevation than the foundation drain along the basement would require a 25' offset.

Department Response: Changes Made - The Department acknowledges this comment and has revised the text accordingly.

201.2. Grease Traps.
(1) Any new food service facilities permitted under R.61-25, Retail Food Establishments, and served by an onsite wastewater system that is permitted after the effective date of this regulation shall be required to have a properly sized grease trap. This requirement may also apply to new facilities not requiring a food service permit under R.61-25. Exception may be granted in cases where a permitted retail food service establishment performs limited food preparation and/or cooking.

Comment: I think this change will result in more facilities that need grease traps not being required to install them.

Department Response: Clarification - Both the preexisting and revised regulation require all new Department-permitted food service facilities to have a grease trap if they are on a septic system. The revised language falls in line with current procedures by retaining the option for the Department to grant an exception if the operations do not produce an amount of grease considered to be detrimental to the onsite wastewater treatment system. i.e. A limited menu operation may not produce grease as a part of the process.

702.3. Quality Control: Installers.
The Department will conduct random final inspections on no less than three (3) percent annually of the total number of systems installed during the preceding fiscal year. The Department will also conduct field reviews of final installation and inspection documentation submitted by the installer and compare them to the actual installations those documents represent.

Comment: Again, based on my experience of 28 years with the Department I believe all installations by Tier 1 and Tier 2 installers should be inspected. The majority of contractors are not anywhere near ready to self-inspect. I believe more than 3% of Tier 3 installations need to be inspected.

Department Response: Not Adopted/Clarification - The Department is currently not able to meet the demand for permit applications and associated inspections and carries a backlog across the state. The contractor self-inspection process allows the Department to continue to provide oversight while also addressing resource limitations. See also Department response to comment on Section 104.3 above. The three percent inspection criteria is a minimum established by statute. Various streamlining changes

to this regulation (including enhanced involvement by Professional Soil Classifiers and Professional Engineers in subdivision permitting) are likely to afford the Department the opportunity to increase the number of final inspections it performs beyond current levels (and above the 3% threshold).

Name	Section
Comment #7: Bob Eppinett (Lowcountry Soil Consulting)	**102.1(5); 400; 701**

Comment: First, I am very pleased that DHEC has turned the septic system soil evaluations and design for subdivisions over to Soil Classifiers and Engineers. Developers have been subsidized by the taxpayer for years by allowing DHEC staff to spend hours or days doing the field work and paper work on subdivisions when this should have been done by the private sector. This has been a ripoff to the taxpayer.

Department Response: Acknowledged – The Department appreciates the commenter's support of the proposed regulatory change.

Second, I also would like to see this applied to realtors and speculators. They intentionally buy a tract of land and cut it into smaller tracts or lots knowing they can get DHEC to do their leg work for only $150.00 per permit. They also can play the game of doing this piece-meal to get around property being considered a subdivision. I think any tract of land being broken up this way should be considered a subdivision.

Department Response: Clarification - The new regulation defines a subdivision as "all divisions of a tract or parcel of land into two (2) or more lots, building sites, or other divisions, for the purpose, whether immediate or future, of sale or building development, and includes all division of land involving a new street or a change in existing streets, and includes resubdivision. This definition shall apply whether the lots are to be sold, rented, or leased. This definition shall not apply when the division or partition of the land, or the conveyance of property is pursuant to a will, an intestacy statute, or an order by a probate judge". This definition encompasses the dividing of all large tracts of land into smaller tracts.

Third, I think DHEC has one of the best septic system design standards in the south. It is straight forward and easy to understand (in most cases). Please keep any revisions to the standards like this.

Department Response: Acknowledged – The Department appreciates the commenter's support of the proposed regulatory change.

Fourth, I do not necessarily agree with the 6 inch offset to a seasonal water table. I know this will be difficult if not impossible to change in the regulations especially for the Lowcountry. I try on just about all of my site/soil evaluations to increase this as much as possible. For example if there is a 16 inch seasonal water table, I recommend the depth of the trench to be 6 inches from the soil surface, which gives me a 10 inch offset. I would do this up to a 20 inch seasonal water table (trench depth of 6 inches). This gives me a buffer of more that a 6 inch offset. It would require a 9 inch cap on most systems. I don't know if this is allowable, but I would like to continue to do this if possible.

Department Response: Clarification - There is no prohibition against increasing the offset to a water table in a proposed onsite wastewater system layout.

Fifth, DHEC and LLR Professional Soil Classifiers need to find a way for those in the septic system business to acquire CEU's. It is difficult to travel to North Carolina or Georgia for a class or demonstration. I believe soil classifiers, installers, engineers and septic system manufacturers would support an annual meeting. We need someone to initiate this.

Department Response: Clarification - The Department would support additional opportunities for those in the septic industry to acquire CEU's within the state. While outside the scope of the regulatory revisions, the Department is available to assist the private sector in identifying and helping facilitate CEU opportunities. The Department is currently working with Clemson University to develop a training program for in-house staff, and it is possible this may be opened to the public at a later date as further developments occur. The Department is also proposing a three year delayed implementation of CEU requirements in order to assist in developing Department administered opportunities as well as outside resources to decrease the burden as described.

Name	Section
Comment #8: Malcolm Baldwin (Professional Engineer)	**Appendix Q(1)(b)(ii); 200.6; 400; 202**

Comment: Critical line setback increased to 125' in the 610 standard: This increase could make a number of existing lots unbuildable. A 67% increase in the current setback is excessive and would create a hardship.

Where systems installed under the 610 standard have pretreatment measures, a reduction in the setback should be allowed. A secondary settling tank allows for a reduction in separation to the water table, it should also allow for a reduction in vertical setbacks. Package pretreatment systems should also be allowed significant reductions in setbacks.

Setbacks are measured to "any part of the system". With a 1' fill cap, the systems I design often have a 16' taper which currently is looked at as part of the system.

- This area is not part of the application area.
- The topsoil or unsuitable soils are not removed from underneath the tapers
- Highly permeable soils are placed under the application area and stripped topsoil which is less permeable is used to build the tapers. This prevents lateral movement.
- Offsets should be from the application area only.

Tanks are currently required to meet these setbacks. The tanks are not part of the application area and are not applying effluent to the soils. They should have setbacks considerably less than the areas designed to receive effluent.

In my opinion, there is a push for "big pipe" and making it more difficult to install septic systems will put pressure to extend public systems. Properly designed and installed individual septic systems are clean and safe and help dampen the push for development. These increases in setbacks should be considered carefully for the unintended consequences that may arise.

Department Response: Not Adopted - There are several studies that cite failing septic systems as a contributor to high bacterial counts in coastal waters. Due to the varied nature of engineered systems the Department has determined that it is prudent to increase these setbacks.

Comment: Tire chips should not be allowed. I prohibit them in my designs based on the failures I have seen.

Department Response: Not Adopted - Tire chips have been an approved alternative to gravel for quite some time, and the Department has no data that represents increased failure rates in systems that utilize tire chips as opposed to other approved products.

Name	Section
Comment #9: Susan Milliken	**R.61-56**

Comment: I am writing to give public input on the proposed amendments to the regulations re. onsite wastewater systems.
In reviewing the amendments, it appears that the regs will be updated and clarified. This is helpful and necessary. The amended regs include the involvement of more professionals and include more oversight of wastewater systems. On James Island, we know that unregulated septic systems may be polluting our creeks and waterways. Our hope is that more clear, updated regulations will help to solve these issues. Thank you for SC DHEC's work in updating these regulations.

Department Response: Clarification - The comment is in support of the proposed regulatory changes to update and clarify regulatory requirements. DHEC is aware of the bacteria issues in James Island Creek and has been engaged for years with local leaders to address the issues. In January of 2020, DHEC's Total Maximum Daily Load (TMDL) for James Island Creek was approved by EPA. The TMDL identifies point sources that contribute to the bacteria impairment and requires them to address the issue through their permits. For nonpoint source pollution (such as malfunctioning or failing septic tanks), funding may be available for local groups to address problems.

Name	Section
Comment #10: Ross Appel (City of Charleston Councilmember)	**R.61-56**

Comment: Thank you for revising and improving these regulations. We would like to see DHEC take a more active role in making sure that all septic systems are properly maintained. We at the local level lack the resources and legal ability to do this work. My district includes the James Island Creek, which recently received a TMDL designation due to fecal pollution. We believe there to be hundreds of old and poorly maintained septic systems in the watershed.

Department Response: Clarification - DHEC is aware of the bacteria issues in James Island Creek and has been engaged for years with local leaders to address the issues. In January of 2020, DHEC's TMDL for James Island Creek was approved by EPA. The TMDL identifies point sources that contribute to the bacteria impairment and requires them to address the issue through their permits. For nonpoint source pollution (such as malfunctioning or failing septic tanks), funding may be available for local groups to address problems.

The Department is unable to implement continuous oversight over all existing septic systems to ensure their ongoing maintenance. However, the regulations as revised require property owners to properly operate and maintain septic systems in good working order, and the Department will continue to respond to reported system failures or malfunctions by investigating and taking enforcement action as appropriate. In addition, local municipalities retain the option to develop and enforce codes that are more stringent than Regulation 61-56.

Name	Section
Comment #11: Annie Kines	**R.61-56**

Comment: I'm a resident of James Island in Charleston, SC. I’m writing to encourage DHEC to put in place rigorous requirements for inspection and soundness of existing and new septic tanks. Our waterways are our most valued possession in the lowcountry both for recreation and food! Thank you for considering.

Department Response: Clarification - DHEC is aware of the bacteria issues in James Island Creek and has been engaged for years with local leaders to address the issues. In January of 2020, DHEC's TMDL for James Island Creek was approved by EPA. The TMDL identifies point sources that contribute to the bacteria impairment and requires them to address the issue through their permits. For nonpoint source pollution (such as malfunctioning or failing septic tanks), funding may be available for local groups to address problems.

The Department currently is mandated to inspect a percentage of all new installations of septic systems to ensure proper installation and working order. Under the amended regulation, provisions are being made to ensure timely inspection of all new installations by either Department personnel, licensed installers, or Registered Professional Engineers. The Department will continue to respond to reported system failures or malfunctions by investigating and taking enforcement action as appropriate.

Name	Section
Comment #12: Louis Kines	**R.61-56**

Comment: I'm a resident of James Island in Charleston, SC. I'm writing to encourage DHEC to put in place rigorous requirements for inspection and soundness of existing and new septic tanks. Our waterways are important to us! Thank you for considering.

Department Response: Clarification - DHEC is aware of the bacteria issues in James Island Creek and has been engaged for years with local leaders to address the issues. In January of 2020, DHEC's TMDL for James Island Creek was approved by EPA. The TMDL identifies point sources that contribute to the bacteria impairment and requires them to address the issue through their permits. For nonpoint source pollution (such as malfunctioning or failing septic tanks), funding may be available for local groups to address problems.

The Department currently is mandated to inspect a percentage of all new installations of septic systems to ensure proper installation and working order. Under the new regulation's provisions are being made to ensure timely inspection of all new installations by either Department personnel, licensed installers, or Registered Professional Engineers. The Department will continue to respond to reported system failures or malfunctions by investigating and taking enforcement action as appropriate.

Name	Section
Comment # 13: Lauren M. Milton (member, South Carolina Environmental Law Project)	**R.61-56**

Comment: On behalf of the Charleston Waterkeeper and the Coastal Conservation League, we submit these comments in response to the Department of Health and Environmental Control's proposal to rescind R.61-55, R.61-56.1 and R.61-56.2 and incorporate their contents within R.61-56. We approve of the proposed revisions that will streamline the regulatory framework of the licensing system and also appreciate the invitation to provide input on other improvements that should be brought forth during the revision process. Our comments below focus on revisions we consider essential: we request the Department create regular inspection, maintenance, and reporting requirement for septic owners and operators. We also request the Department develop special provisions for (1) settlement/heirs property communities, (2) barrier islands, and (3) watersheds with existing bacteria TMDLs. The impacts to both ground and surface water from septic systems in South Carolina highlight a need for bold and decisive action to better protect public health and the environment.

Department Response: Clarification - The Department appreciates the support for revisions designed to streamline the regulatory framework of the licensing system. The Department's specific responses to comments related to inspection, maintenance, reporting, and requests for additional special provisions

follow under section I through VII of the South Carolina Environmental Law Project's (SCELP's) comments below. The Department also offers the following general response (General Department Response) to SCELP's collective comments:

The Department's commitment to its mission of *protecting and promoting the health of the public and the environment* is reflected in the proposed revisions to the Onsite Wastewater (*i.e.*, septic tanks and systems) Regulations. These most recent proposed revisions are designed to: (a) update and clarify standards and requirements to ensure they reflect the latest dependable technologies and (b) be effectively implemented and enforced.

It is important to note that existing Department regulations have long required homeowners connect to public sewer, if accessible, in lieu of installing a new septic system; septic system permits cannot be issued where public sewer is available.

Additionally, the means and methods of permitting onsite septic systems has evolved over the years to take advantage of the new soil science and system technology information, all intended to be more protective of public health and the environment. For example, one of the most important changes that was made many years ago was to replace the old Percolation test method (aka Perc Test) which evaluated how quickly soil drains with a more scientific approach based on soil classifications and types.

Onsite septic systems that are properly planned, sited, installed, operated, and maintained provide excellent domestic wastewater treatment. Failing or malfunctioning onsite septic systems present obvious signs of septic odor, soil saturation by wastewater and/or pooling of wastewater associated with the drainfield. It is the Department's overall experience that owners are generally responsive to quickly making repairs to a malfunctioning or failing system, because it impacts them personally. However, if repairs are not made in a timely manner, the public observes the discharge and the Department is then notified. Upon being notified of and confirming an ongoing discharge, the Department's current process is to require the property owner to take prompt action to correct the issue, and if that does not occur, the Department proceeds with enforcement action (typically an Administrative Order) requiring immediate correction and the issuance of a suspended civil penalty. If, in these situations, public sewer is accessible, the owner is required to connect to public sewer.

Onsite septic systems can be contributors to ambient surface water impairment (i.e., water quality degradation). Most often, this impairment is in conjunction with bacteriological quality. However, it is critical to note that other anthropogenic activities may also contribute to water quality impairment if not executed and managed properly (e.g., wastewater treatment facility effluents and sanitary sewer overflows, some agricultural activities, natural wildlife and domesticated animal populations, residential and urban areas, etc.). Other than the wastewater treatment facility category, the transport of pollutants from the other sources is principally by stormwater runoff. No measurable data for impairment source allocation have been collected from the variety of nonpoint sources. Consequently, it is not possible to delineate quantified contributions from each of the various nonpoint source types, including septic tanks.

When a surface water system, or a portion of it has been identified and confirmed as impaired, a Total Maximum Daily Load (TMDL) for the pollutant(s) of concern is developed. A TMDL estimates likely potential pollutant contributions from identified point sources and areal-specific nonpoint sources that contribute to the impairment. A TMDL is implemented through permits (i.e., effluent discharge limits) for point sources and through voluntary activities and measures for nonpoint sources. Implementation occurs through a collaborative process to develop local solutions to address the pollution of concern.

In the case of the James Island Creek TMDL, there are four regulated entities (Charleston County, City of Charleston, Town of James Island and SCDOT). These are all municipal separate storm sewer systems (MS4s) within the watershed that are required to develop an iterative approach through a collaborative process that leads to locally driven solutions to address the pollutant load reductions specified in the TMDL. These MS4s are required to develop a stormwater management plan (SWMP) that includes the following: public education, public involvement, illicit discharge detection and elimination, construction site runoff control, post construction runoff control, and pollution prevention/good housekeeping.

To provide further clarity regarding point and nonpoint sources:

The term **"point source"** means any discernible, confined and discrete conveyance, including but not limited to any pipe, ditch, channel, tunnel, conduit, well, discrete fissure, container, rolling stock, concentrated animal feeding operation, or vessel or other floating craft, from which pollutants are or may be discharged. This term does not include agricultural storm water discharges and return flows from irrigated agriculture.

Nonpoint source pollution generally results from land runoff, precipitation, atmospheric deposition, drainage, seepage or hydrologic modification. Nonpoint source (NPS) pollution, unlike pollution from industrial and sewage treatment plants, comes from many diffuse sources. NPS pollution is caused by rainfall or snowmelt moving over and through the ground. As the runoff moves, it picks up and carries away natural and human-made pollutants, finally depositing them into lakes, rivers, wetlands, coastal waters and ground waters.

Nonpoint source pollution can include:

- Excess fertilizers, herbicides and insecticides from agricultural lands and residential areas
- Oil, grease and toxic chemicals from urban runoff and energy production
- Sediment from improperly managed construction sites, crop and forest lands, and eroding streambanks
- Salt from irrigation practices and acid drainage from abandoned mines
- Bacteria and nutrients from livestock, pet wastes and faulty septic systems
- Atmospheric deposition and hydromodification

I. INTRODUCTION AND SUMMARY

South Carolina must incorporate a mechanism by which it becomes mandatory for owners of any kind of sewage disposal system — especially when located adjacent to a waterbody — to be responsible for regularly pumping and maintaining their system and ensuring the system is of adequate size and ability to treat the waste it receives. The EPA and U.S. Bureau of the Census report that in South Carolina over 40 percent of homes depend on septic systems.[1] The condition of our waters indicates that a large number of these systems are failing or improperly maintained. Failing and inadequately maintained septic systems are a cause of groundwater contamination. They pose a significant threat to human and animal health by contaminating water and food sources. This contamination causes infections and diseases ranging from eye and ear infections, acute gastrointestinal illness, to hepatitis. The EPA recommends homeowners have typical septic systems inspected at least every 3 years by a professional and have the tanks pumped as recommended by the inspector, which is generally 3 to 5 years.[2] DHEC recommends a more rigorous inspection for South Carolina, recommending septic systems be inspected every 1 to 2 years by a licensed septic tank contractor and follow his or her advice about how often to clean out the tank.[3] However, this approach is failing and it is imperative that the state make these

inspection and pumping regimens mandatory and take additional steps to protect our wildlife and communities from waters contaminated with sewage.

Department Response: Clarification - As noted by the commenter, the Department continues to recommend that homeowners have their septic systems inspected by a licensed contractor every one to two years and follow his or her advice about how often to clean the tank; alternative septic systems with mechanical parts such as a pump should be inspected at least once a year or more frequently as recommended by the manufacturer. However, this remains a recommendation, as it is not practicable for the Department to implement routine oversight and enforcement with respect to such a requirement, and individual circumstances vary from owner to owner and site to site. The regulations as revised require property owners to properly operate and maintain septic systems in good working order, and the Department will continue to respond to reported system failures or malfunctions by investigating and taking enforcement action as appropriate so as to ensure that necessary repairs are made.

II. SEPTIC TANKS IN SOUTH CAROLINA

The EPA reports that malfunctioning septic systems are currently the second greatest threat to groundwater quality in the United States.[4] Most septic system failures are related to inappropriate design and/or poor maintenance. Some soil-based systems with a leach or drain field have been installed at sites with inadequate or inappropriate soils, excessive slopes, or high groundwater tables. These conditions can cause hydraulic failures and water resource contamination. Failure to perform routine maintenance, such as pumping the septic tank, can cause solids to build up and restrict flow into the tank or to migrate into the drain field and clog the system.

The exact number of failing septic systems in South Carolina is unknown because, after installation, South Carolina law does not require property owners to have existing systems inspected. Estimates from federal sources provide some insight. In 2019, the U.S. Bureau of the Census reported 2,351,286 housing units in South Carolina and the EPA reports that over 40 percent of those homes depend on septic systems.[5] From these numbers, we can estimate South Carolina has approximately 940,514.4 septic systems.[6] The EPA also estimates a 10 to 20 percent failure rate, leading South Carolina waters to contend with approximately 94,051-188,102 malfunctioning septic systems.[7] Because septic systems are out of sight, many homeowners don't realize there may be a problem until their system is already failing. One 2009 study exploring the circumstances that lead homeowners to ignore their systems found the following:[8]

> [H]ouseholds do not maintain their septic systems because it is not in their rational self-interest to do so. Educating households is an insufficient response. Similarly, it is not in the rational self-interest of local governments to establish effective regulations. State-established regulations, combined with incentives and sanctions to ensure implementation by local governments, appear to offer more environmentally and fiscally sustainable solutions to the problem.

Id. South Carolina examples prove the veracity of this statement. In 2013, Greenville County Soil and Water Conservation District offered to help pay 60 percent of the costs to fix septic systems for 60 people, however, there was so little interest and so much resistance that only two septic systems received repair in the first year.[9] State-level implementation is the best, and most effective, way to ensure that (1) the estimated average 141,076 failing septic systems in South Carolina are repaired, replaced or connected to local sewer; and, (2) the remaining systems stay in good repair.

Department Response: Clarification - The Department is unable to speak to estimates regarding the total number of septic systems in South Carolina or their failure rate. Because failing or malfunctioning

septic systems have the obvious signs of septic odor, soil saturation, and pooling water over the drainfield, owners are generally responsive to quickly making repairs. When repairs are not made in a timely fashion, the public reports these concerns to the Department and the Department responds by investigating and taking enforcement action as appropriate to ensure that the necessary repairs are made (or if sewer is available, to require connection to public sewer).

III. SOUTH CAROLINA'S WATERS

Across the nation, the system that Congress created to protect the nation's waters under the Clean Water Act of 1972 today often fails to prevent pollution. South Carolina only contains 38 waterbodies with no impairments.[10] The 303(d) list is the list of impaired waterbodies that do not meet water quality standards. The 1,041 sites on the draft 2018 §303(d) list[11] represent 1,242 total impairments since some sites are impaired for more than one parameter. The list makes clear that bacteria is - by far - the greatest threat to our waterbodies:

Table 1. Impairments by Category and Waterbody Type on the Draft 2018§303(d) List

Category	Total Impairments	Lakes	Streams	Estuaries	Shellfish Waters	Beaches
Bacteria	362	5	167	60	116	14
Nutrients, pH, DO	197	197				
Fish Tissue Hg and PCBs	190	190				
Macroinvertebrates	173		173			
Dissolved Oxygen	142		108	34		
Turbidity	92	13	16	63		
Metals	36	4	23	9		
pH	45		40	5		
Ammonia Toxicity	5	1	3	1		

Once a site is included on the 303(d) list of impaired waters, a TMDL, or Total Maximum Daily Load, must be developed. A TMDL is a requirement found in Section 303(d) of the Clean Water Act and is the amount of a single pollutant (such as bacteria, nutrients, metals) that can enter a waterbody on daily basis and still meet water quality standards set forth by the State. There are currently 117 approved TMDLs for waterbodies in South Carolina[12] and eight more underway.[13]

In these waterbodies, DHEC's website states that over 400 sites or stations are covered under a TMDL developed in South Carolina and approved by USEPA Region 4 and approximately 350 of these approved TMDLs are for fecal coliform bacteria.[14] A large percentage of these impaired waterbodies list malfunctioning or failing septic systems as a primary contributing factor of the impairments, which can lead to death. For example, the TMDL document for Sandy Run and Dean Swamp[15] says:

> Some Shiga toxin producing strains of E. coli, such as 0157:H7 can cause ***gastrointestinal illnesses, kidney failure and death***. E. coli bacteria in surface waters are indicators of recent human or animal waste contamination and may originate from failing septic systems…***Failed or non-conforming septic systems, however, can be a major contributor of E. coli and other FC bacteria to the Dean Swamp watershed***. Wastes from failing septic systems enter surface waters either as direct overland flow or via groundwater. Although loading to streams from

> failing septic systems is likely to be a continual source, wet weather events can increase the rate of transport of pollutants from failing septic systems because of the wash-off effect from runoff and the increased rate of groundwater recharge. Based on the 2010 U.S. census, there are an estimated 359 households with 832 people in subwatershed 115. Within subwatershed 030 there are 1500 household with 3345 people. ***Because none of these households are serviced by a public sewer system, there are as many septic systems as there are households. Some number of these are likely to be failing and contributing to bacteria in the stream***.

Id. When a septic system is flawed or failing, elevated nitrogen and phosphorus levels can be released into local water bodies or ground water. This rapid growth, known as eutrophication, can cause algae blooms that reduce water quality, kill aquatic animals and plants, and form toxins in the water. In 2009, the American Rivers conservation group added the Saluda River to a list of imminently threatened rivers in the United States and stated:

> Excess levels of sewage waste threaten the drinking water of more than 500,000 South Carolina residents, conservationists say. Sewage in the river increases phosphorus and algae levels, depletes oxygen, and kills fish and other aquatic life. American Rivers is asking the South Carolina Department of Health and Environmental Control to improve sewage-treatment standards and ensure the river reduces its phosphorus levels by 25 to 50 percent.[16]

In the Upstate, the Saluda River is tainted with human waste from failed septic tanks in the rapidly growing area.[17] The watershed-based plan for the Craven, Grove, Big and Hurricane Creeks of the Saluda River[18] notes an estimated 10,821 septic systems and states: "[d]amaged or improperly maintained septic systems are a significant nonpoint source of bacteria to surface and groundwater resources." Pee Dee River Basin also has a history of high coliform pollution that was specifically noted to be from septic systems.[19]

Department Response: Clarification - The Department acknowledges and appreciates information provided by the commenter regarding South Carolina's waterbodies and potential impacts from failing septic systems. As stated previously, numerous anthropogenic activities can contribute to water quality impairment if not executed and managed properly, and no measurable data for impairment source allocation have been collected from the variety of nonpoint sources. Therefore, it is not possible to delineate quantified contributions from each of the various nonpoint source types, including septic tanks. Please see the above General Department Response for further detail and the Department's responses to other portions of SCELP's comments for responses to specific questions and suggestions proposed by the commenter.

IV. SOUTH CAROLINA'S COAST

Though fecal contamination in waterways is a grave concern for the entire state of South Carolina, it is of particular concern in coastal counties. If not sited, built, and maintained properly, septic systems near the coast can leach wastewater into recreational waters, contaminating beaches. Natural Resources Defense Council's 2014 State of the Beaches Report cited leaky septic systems as a leading cause of beach water contamination.[20] South Carolina's coastal areas are experiencing increased and constant development pressure, particularly outside of sewered areas.[21]

In these areas, conventional septic tank systems were often chosen for household wastewater disposal because of the low initial cost to the developer as well as the ease with which installation permits were obtained from local officials.[22] This permitting ease highlights one shortcoming: the DHEC process exempts septic tanks from its usual Coastal Zone Consistency review. Practically any other activity requiring a state or federal permit in the eight-county coastal zone must also go through a separate

review for consistency with our state's Coastal Zone Management Program. Counties are in a standoff and beach communities have commented that the only way the residents would commit to sewer tie-ins is if the state ordered it.[23] This is not a new problem, however. As stated in one journal article:[24]

> In 2004 coastal states ordered 19,950 days of closures and pollution advisories affecting 1,234 ocean and freshwater beaches, or about one third of all the beaches regularly monitored by health officials. The total number of beach days covered by the regulatory actions was 9 percent higher than the total for 2003 (which, in turn, was 50 percent higher than the 2002 total, although that jump was partly caused by changes in federal monitoring rules). The reason for 85 percent of the closures and advisories was the detection of excessive counts of fecal bacteria in the beach waters.

Id. The density of septic tanks along the coast also has been shown to have a direct impact on the nearby waterbodies because where excessive crowding occurs, individual septic plumes will intermingle to pollute large areas of groundwater. One study that focused on six tidal watersheds in coastal North Carolina found significant positive correlations between fecal and total coliform levels and increased densities of septic tank drain fields in the watersheds.[25] The study also rediscovered that watersheds where septic-system density exceeded 0.62 drain fields per ha (0.25 drain fields per acre), had closed shellfish beds due to high fecal bacteria counts; and, in watersheds where drain field densities were less than 0.37 per ha (0.15 per acre), water quality was acceptable and shellfish beds were open. *Id*. The USEPA has designated areas with greater than 0.15 septic tanks per ha (0.06 septic tanks per acre) as potentially problematic. *Id*. In Horry County, one study indicated beachfront high fecal levels were due to contamination from septic systems in the community.[26] Fortunately, those homes were ultimately tied-in to a local sewer system, but many more on our coasts are not.

Today, the effluent from septic tanks flows into fissured limestone or sandy soils that allow fecal microbes to seep into the groundwater of many coastal towns. *Id*. Our waters are suffering; the water in James Island Creek and Ellis Creek failed state water standards for recreation nearly two-thirds of the time and the TMDL lists malfunctioning and failing septic systems as a continual cause of the water's bacterial contamination, outlining 792 septic systems installed before 1969.[27] Sixty years exceeds even the most gracious septic system lifespan estimate.[28] The James Island Creek TMDL document could not be clearer on what action is needed: "encouraging homeowners to have their septic systems inspected and pumped on regular basis is another potential intervention for reducing bacterial runoff/contamination from these systems."[29]

Improperly maintained and failing septic tanks were also listed as a contributing factor to pollution in Shem Creek and Dorchester Creek's TMDLs.[30] Malfunctioning or improperly installed septic systems or Individual Sewage Treatment and Disposal Systems (ISTDs) were similarly identified as a source of fecal coliform contamination to the Litchfield-Pawley's Estuary where the percentage of failing septic systems was determined to be 20%.[31] Obviously, "encouragement" has not worked and is not going to move the needle. The state must step up and implement mandatory requirements.

Department Response: Clarification - The Department acknowledges and appreciates information provided by the commenter regarding fecal contamination in coastal counties. As stated above, the regulations as revised require property owners to properly operate and maintain septic systems in good working order, and the Department will continue to respond to reported system failures or malfunctions by investigating and taking enforcement action as appropriate so as to ensure that necessary repairs are made (or, if sewer is available, to require connection to public sewer). As stated previously, the means and methods of permitting a septic system have changed drastically since many coastal systems were installed. The Department has long since replaced the old Percolation test method for soils with a more scientific approach based in principles of soil science and hydrology. These are much more efficient

methods and have proven to be much more reliable and environmentally protective. Please see the above General Department Response for further detail, including discussion of the James Island Creek TMDL. See also the Department's responses to other portions of SCELP's comments for responses to other specific questions and suggestions proposed by the commenter.

V. WHAT'S THE COST?

Human health is also at risk from failing septic systems which are known to cause contamination of drinking water, beaches, shellfish beds, and surface water resources. Failed systems have been associated with many serious problems. According to DHEC and the EPA, outbreaks of diseases, such as skin infections or ear, nose and throat infections, hepatitis A, meningitis or encephalitis may result from unmitigated wastewater pathogens [32] Untreated effluent can accelerate the eutrophication process of nearby waterbodies, lowering oxygen levels and suffocating aquatic life. Hormones and pharmaceutical compounds have been located in the groundwater near septic systems in New England.[33] In Alabama, failing septic systems are blamed for an outbreak of roundworms, tropical parasites and the resurgence of hookworms, which were previously believed to be eradicated from the United States.[34] In 1980, 49 cases of hepatitis A occurred as the result of septic tank failure that contaminated a well and in 1992, a failed septic system was the cause of 46 cases of hepatitis A in Racine, Missouri.[35]

Leaking septic systems also impact the availability and safe consumption of shellfish. In 1995, the National Oceanic and Atmospheric Administration (NOAA) reported that the discharge of partially treated sewage from malfunctioning septic systems was identified as a principal or contributing factor in 32 percent of all harvest-limited growing areas.[36] The primary criterion limiting shellfish harvest areas is the coliform bacteria contamination, which is generally associated with the presence of human fecal material.[37] However, before the contamination is detected by authorities, human noroviruses – which spread when a person ingests fecal matter from another person – are the most common cause of epidemic gastroenteritis following consumption of contaminated bivalve shellfish.[38] DHEC must lead the way in protecting the health and safety of South Carolinians.

Moreover, we cannot afford impaired waters; in South Carolina, tourism is a $22.6 billion industry.[39] Our waters and seafood bring tourists from all over the world. Maintaining clean water for a sustainable commercial fishing industry is essential to preserving the unique character of South Carolina's internationally-loved local seafood-base cuisine, which primarily consists of shrimp, shellfish, crabs, and offshore finfish.[40] More than 6% of the state's surface offers water-based recreational opportunities. [41] *Id*. Our fishing,[42] hunting, and wildlife viewing brings a total annual economic contribution of $2.74 billion and 31,958 jobs. *Id*. If the changes discussed herein are implemented, we can preserve our water assets bring us revenue in perpetuity. Failing to do so will have a devastating effect on our economy.

Department Response: Clarification - The Department acknowledges and appreciates information provided by the commenter regarding health risks associated with failed septic systems. Additional description of the public health risks associated with fecal contamination is set forth in Section 100 of the Department's onsite wastewater regulations. The Department remains committed to its mission of protecting and promoting the health of the public and the environment, and this mission is reflected throughout the Department's revisions, which are designed to update and clarify standards and requirements to ensure they reflect the latest technology and can be effectively implemented and enforced. Moreover, septic systems that are properly planned, sited, installed, operated, and maintained can provide excellent wastewater treatment. Please see the above General Department Response and the Department's responses to other portions of SCELP's comments for responses to specific questions and suggestions proposed by the commenter.

VI. STATE GOVERNANCE IS REQUIRED

South Carolina currently has no laws requiring property owners to inspect or repair their septic systems or have their systems inspected when selling their homes. Some counties have passed stricter rules while others haven't, leaving a confusing mix of regulations for developers and home buyers. As discussed above, the failure rate and consequences from failed septic systems is a crisis and we must now require septic tank inspections *at least* when a property changes hands, and optimally, more frequently.

Septic systems also must be subject to CZC review and account for both erosion and accretion, i.e., renourishment. Presently, the expertise and knowledge of DHEC's coastal division is completely excluded when reviewing suitability for septic systems in coastal areas subject to a variety of natural and man-made actions. Ideally, we recommend requiring homes to tie-in if sewer is available and creating more programs to help homeowners be partners for clean water. First and foremost, however, South Carolina must initiate a record-keeping program to inventory of all existing systems. As that system is implemented, there are numerous ways states can – and have – launched successful inspection programs.

Department Response: Clarification - As discussed above in the Department's response to Section I of SCELP's comments, the Department continues to recommend regular inspections of septic systems by a licensed contractor. However, state law does not require a specific rate of inspection, or that systems be inspected upon sale of a person's home. As stated above, it is not possible for the Department to implement routine oversight and enforcement with respect to such a requirement, and individual circumstances vary from owner to owner and site to site. The regulations as revised require property owners to properly operate and maintain septic systems in good working order, and the Department will continue to respond to reported system failures or malfunctions by investigating and taking enforcement action as appropriate so as to ensure that necessary repairs are made. In addition, Department regulations have long required that homeowners connect to municipal sewer if it is accessible in lieu of installing a new septic system or in the event of existing septic system failure. Septic system permits cannot be issued where sewer is available.

The commenter asserts that septic systems should be subject to Coastal Zone Consistency (CZC) review. The S.C. Coastal Zone Management Program document sets forth a set list of state permit types subject to CZC review. This list of state permits excludes from review septic permits for systems handling 1,500 gallons per day or less. Implementation and enforcement of CZMP requirements is carried out by the S.C. Office of Ocean and Coastal Resource Management (OCRM) and falls outside the scope of the Department's authority in revising R.61-56.

An inventory of all existing septic systems is a matter outside the scope of these revisions to Department regulations, and resource and other constraints preclude Department implementation of such a project at this time. Local municipalities retain the option to institute requirements that are more stringent than R.61-56 but cannot be less stringent.

A. Compliance Inspections

To determine whether the system is functioning properly to protect public health and groundwater, some states have periodic inspections to certify that the septic systems are still functional and in good repair. In January 2015, the Ohio Department of Health adopted new rules regarding septic systems in Ohio, which are codified at Ohio Administrative Code 3701-29.43 Ohio Administrative Code 3701-29 mandates every private septic system has an operation permit and be monitored on a regular basis to

ensure the systems are working correctly and not polluting the environment. These new rules mandate that all health districts in the state develop and implement a local Operation & Maintenance (O&M) program to ensure all systems in their jurisdiction are monitored for regular maintenance and proper function. The program requires that every owner of a property with a septic tank obtain, and continually renew, an operation permit and regularly submit proof that their system is receiving the minimum required maintenance as directed by that permit. Compliance with permit conditions will be tracked on an ongoing basis, allowing counties to identify and address neglected and/or failing systems.

In 2000, Wisconsin changed the state's plumbing code, which counties are required to administer.[44] The changes, codified at SPS 383 require all septic systems – also known as Private Onsite Wastewater Treatment Systems (POWTS) – regardless of age, to be inspected by a qualified inspector at least once every three years.[45] If the accumulated solids in the tank occupies more than one-third of the tank volume, the tank must be pumped. If a system is failing, it must be replaced. While WI Admin. Code SPS 383.52[46] places the onus of maintenance on owners, it has made compliance simple by teaming up with numerous agencies and organizations. The county is required to compile a database of all septic systems located within the county limits and send notices to those owners due for inspection and pumping to make sure that it is completed and reported to the once every three years. Wisconsin has also joined with numerous state and federal partners to ease the financial burden on homeowners.[47]

Department Response: Not Adopted/Clarification - Please see the Department's response to Sections I and VI of SCELP's comments regarding Department recommendations for ongoing maintenance, limitations on Department oversight and enforcement capacity, and R.61-56's requirement that property owners properly operate and maintain septic systems in working order. The Department is unable to speak to requirements adopted in other jurisdictions or the particular circumstances surrounding their promulgation, implementation, and enforcement. The Department will continue to respond to reported system failures or malfunctions by investigating and taking enforcement action as appropriate so as to ensure that necessary repairs are made or connection to sewer is accomplished. Local municipalities retain the option to institute requirements that are more stringent than R.61-56 but cannot be less stringent.

B. Sales Inspections

An additional path to inspection is found in numerous states' codification of Time of Sale/Transfer (TOST) or Point of Sale/Transfer (POST) septic ordinances. South Carolina currently does not require homeowners to have their septic systems inspected at the time their home is sold, though the state tried to pass such a regulation in 2008. These TOST/POST ordinances require local inspection of well and septic systems prior to the sale of a property. In Massachusetts, these requirements are known as "Title V tests". Title V refers to the state law passed in 1995 which requires all homeowners to have their septic system inspected by their local Board of Health prior to selling the home *or* when there is a change in use or an expansion of the facility.[48] These inspections aim to be as unobtrusive as possible while protecting public health.[49]

Similar to Massachusetts, Iowa's time of transfer septic system inspection law (SF261) took effect July 1, 2009. The law requires that every home/building served by a septic system have that septic system inspected prior to the sale or deed transfer of the home. We propose that the language from Iowa's Time of Transfer Provision[50] §455B.172(11) be added to the language of R. 61.56.

Department Response: Not Adopted - As stated above, South Carolina law does not require a specific rate of inspection, or that systems be inspected upon sale of a person's home. At this point in time, there is no clear statutory basis for the Department to regulate and enforce mandatory inspections upon sale of property, as real estate transactions are outside of the Department's purview. Local

municipalities retain the option to institute requirements that are more stringent than R.61-56 but cannot be less stringent.

C. Additional Provisions

Due to the comprehensive natures of Wisconsin's *routine* maintenance tracking program, and Iowa's time of transfer laws, those states' laws should serve as South Carolina's model on language and implementation for routine and time of sale inspections; however, the following examples from other states have provisions for tie-ins, heirs property and coastal areas that South Carolina should also include in our septic law revisions.

a. Sewer Tie-In Provisions

Georgia's On-Site Sewage Management Systems regulations allow it to force homeowners to tie-in if sewer is available. *See* Ga. Comp. R. & Regs., r. 511-3-1-.03(1)(a)[51] ("Connection shall be made to a public or community sewage treatment system if such system is available within two hundred feet (200') of the property line, or available in a public right-of-way abutting the property."). Counties have the power to enforce stricter standards, leading some to mandate that tie-ins to the system must be done within ninety (90) days after service is available.[52]

Department Response: Clarification - Currently, the Department requires that homeowners connect to municipal sewer if it is accessible in lieu of installing a new septic system or in the event of existing septic system failure. Septic system permits cannot be issued where sewer is available. Please see Section 300 of both the existing and revised R.61-56 for further information.

b. Heirs Property Provisions

Another provision that should be included is a special exception or funding source for repair or replacement for those living on heirs' property, defined at SC Code § 15-61-320(5). Heirs property generally describes land held in common by the descendants of someone who has died without a probated will. In some states, planners and advocates have found it difficult to provide grants and loans to heirs property owners seeking to upgrade failing septic systems because they cannot prove that they are the rightful owner of the property, an essential requirement for most government grant and loan programs.[53] Provisions must be made to ensure those unable to take advantage of traditional grants and loans do not remain exposed to significant public health threats, or are stymied in their efforts to improve water quality.

Department Response: Not Adopted - The Department lacks statutory authority to create or update third-party grant and loan requirements. Funding sources and their eligibility criteria are a matter outside the Department's purview. Where known to the Department, Department personnel are happy to help homeowners identify funding resources that may be of assistance to them.

c. Coastal Protection Provisions

Our Coastal and Tidelands Act provides plainly that DHEC shall: "Develop a system whereby the department shall have the authority to review all state and federal permit applications in the coastal zone, and to certify that these do not contravene the management plan." S.C Code § 49-39-80 (emphasis added). DHEC plainly, then, has been delegated the authority to conduct coastal zone consistency review for beachfront septic permits, and must certify them as consistent or inconsistent with the management plan. However, the Coastal Zone Management Program document (p. V-5) purports to exempt septic permits, that document, cannot supersede the plain language of its S.C Code

§ 49-39-80.54 We urge the Agency to revisit the question of CZC review for septic permits, especially on the oceanfront, and to reconsider the legal and technical basis on which it defers to the Program document over the Act. The Program document reflects an antiquated view of wastewater management on the beachfront, and the Agency should exercise its full authority to correct that shortcoming.[55]

Rhode Island's Coastal Resources Management Council (CRMC) is guided by a document not unlike our own state's Coastal Zone Management Program, which is known as the Coastal Resources Management Program.[56] The key difference, however, is that the installation, repair, modification or replacement of any septic system within CRMC's jurisdiction must also be reviewed and a permit issued by CRMC to ensure that the new OWTS will conform with all applicable coastal program provisions. *See* CRMP Section 300.6. In addition, the Rhode Island Cesspool Act of 2007 (RIGL § 23-19.15), as amended in 2015, mandates that all septic tanks, also known as "cesspools", within the state must, over time, be removed from service. The structure served by the cesspool must either be upgraded to a new zero discharge system or connected to a sewer line if one is available.[57]

Rhode Island also has another key difference from South Carolina's coastal policy: it requires that care be taken when installing or repairing any septic system directly along the coastal shoreline to ensure that ongoing coastal erosion will not damage the system or leave it vulnerable to coastal erosion in the near future.[58] Rhode Island Department of Environmental Management (DEM) and the CRMC established guidelines known as the OWTS Repair Guidance in Critical Erosion Areas and also stringently follow their *Rules Establishing Minimum Standards Relating to Location, Design, Construction, and Maintenance of Onsite Wastewater Treatment Systems*, which provide the agencies with discretion in approving applications for repair (Rule 17.7.2) on lots with limiting conditions.[59] The location of the actively eroding edge of the coastal feature must be shown on the site plans and confirmed by CRMC staff. *Id*.

Rhode Island's requirements accounting for erosion and future inundation provide a stark contrast to South Carolina's laws. DHEC also has authority under the septic regulations to give oceanfront septic systems a level of review matching their potential environmental impacts. A primary obstacle – and difference from Rhode Island's laws – is the manner in which the Agency applies its septic setback requirements. DHEC's septic regulations require a minimum 75-foot setback between septic systems and mean high water. R.61-56.200.6. A fundamental weakness in such requirement, though, is that the Agency only requires that such setback be satisfied at a single snapshot in time, through a survey produced by the septic applicant, in order to receive a septic permit. DHEC's septic permitting currently does not consider that a property has been eroded into the ocean in the recent past, or that it is likely to be eroded away in the near future, or even that it would be ocean if not for a recent artificial renourishment. This is more important than ever and the Conservation Law Foundation[60] recently explored how climate change's rising sea levels, increased precipitation, and warmer temperatures will impact septic systems.[61]

Other states utilize a combination of approaches to protect waters. Across the country, landlocked states even have more protection for their lake shores than we do for our coasts. Minnesota, for example, requires that septic systems be inspected and compliant before a title transfer can occur in designated shoreland areas.[62] The inspection must assess the sewage tank for leaks below the designed operating depth, measure accumulations of scum and sludge depths and seeing if the riser connections, joints and sewage tank tops leak.[63] If the system passes inspection, the septic system receives a certificate of compliance (COC) which is valid for three years and five years for a newly constructed septic system.[64] Maine requires home buyers to complete septic system inspections before the purchase of lakefront and riverfront homes and camps. The new law, LD 216, took effect in January of 2020 and extended the existing laws that required home buyers of coastal shoreland properties to complete septic system inspections prior completing the purchase.[65] In May 2004, Maryland Governor, Robert L.

Ehrlich, Jr., signed the Bay Restoration Fund into Law.[66] The Bay Restoration Fund law created a dedicated fund, financed by wastewater treatment plant users, to upgrade Maryland's wastewater treatment plants with enhanced nutrient removal technology so they are capable of achieving wastewater effluent quality of 3 mg/l total nitrogen and 0.3 mg/l total phosphorus. Sixty percent of the funds, not targeted for wastewater treatment plant upgrades, will be used for septic system upgrades. Bay Restoration Funds have been provided for upgrades of existing systems to best available technology (BAT) for nitrogen removal or for the marginal cost of using BAT instead of conventional technology. Under this program, priority is be given to failing septic systems within the Critical Area.[67] Maryland legislation also requires that new or replacement septic systems within 1000 feet of the bay and its tributaries must have nitrogen-removal capacity. Md. Code Ann., Envir. § 9-1108 (2009).

The simplest path to resolution of these problems plaguing oceanfront septic permitting is for the Agency to prioritize the safety of our coasts. Like Rhode Island, we must begin encouraging the removal of septic systems from our coasts. Until these systems can be removed from service, we must implement routine inspections to ensure the systems are in safe working condition. Septic tanks cannot be exempt from CZC review and laws should encourage coordination between the Agency's coastal section and the septic permitting staff so DHEC can reevaluate the manner in which it interprets and applies the septic setback. DHEC must recognize that a 75-foot setback is one of the "*Minimum* Site Conditions" and that the establishment of a *minimum* number confers discretion to extend the setback based on site conditions and history. The septic regulations are written to prohibit systems *within* 75 feet of the critical line, but nothing in the regulatory language suggests that 75 feet is the limit to what DHEC *can* require. DHEC should exercise its authority to be more protective of septic systems adjacent to our coastal waters, including imposing a minimum of a 150-foot setback or availing itself of the existing language allowing it to require more than the minimum buffer, especially for our eroding oceanfront beaches. More fundamentally, recognition of the designated septic setback as a minimum creates the perfect vehicle for coordination between septic staff and OCRM and the perfect opportunity to activate the Agency's understanding of factors like coastal erosion, sand migration, and renourishment durability. These factors must be contemplated and relied upon to extend the setback for oceanfront septic when warranted.

Department Response: Not Adopted/Clarification - These revisions to R.61-56 are promulgated, implemented, and enforced by the Department's Bureau of Environmental Health Services. As stated above, CZC review pursuant to the Coastal and Tidelands Act and CZMP document is separately carried out by OCRM and is a matter outside the scope of this regulatory revision. State Supreme Court precedent further provides that the current CZMP document is valid and enforceable as written.

The revisions to R.61-56 require a 125' critical line setback for all new Specialized 610 systems (in contrast to the 75' setback applicable under the preexisting regulations). This change is intended to promote additional protection of coastal waters, particularly given the varied nature of engineered systems. The Department is also able to approve of site plans including setbacks greater than the minimum setbacks, though the Department lacks clear legal basis for requiring a homeowner to agree to a greater setback and must fairly and consistently administer regulatory requirements.

As stated previously, the Department is unable to speak to requirements adopted in other jurisdictions or the particular circumstances surrounding their promulgation, implementation, and enforcement. Local municipalities retain the option to institute requirements that are more stringent than R.61-56 but cannot be less stringent.

VII. CONCLUSION

South Carolina Department of Health and Environmental Control's stated mission is "to improve the quality of life for all South Carolinians by protecting and promoting the health of the public and the environment." We cannot pass a regulatory overhaul of septic tanks without making any substantial progress on the above-described issues. Our failing septic systems are a public health crisis and we must now require septic tank inspections at least when a property changes hands, and optimally, more frequently. We recommend South Carolina model other states' laws to provide a mechanism for compliance. Ohio Administrative Code 3701's provisions for routine inspections of existing septic systems should be incorporated into 61.56 and Iowa's Time of Transfer Provision at §455B.172(11) for mandatory inspections upon land transfer would address ongoing maintenance and upgrade of systems. South Carolina must emulate Rhode Island's Cesspool Act of 2007 (RIGL § 23-19.15) to phase out septic systems on our coasts but first we must ensure septic systems are subject to CZC review and take erosion into account for setback calculations. Ideally, we must also pass legislation requiring homes to tie-in if sewer is available and create more programs to help homeowners be partners in our mission for clean water.

In closing, we'd like to draw your attention to the enclosed petition signatures in support of the enclosed comments and reserve our right to supplement these comments. We also wish to note that the recommendations contained in this letter were informed by numerous scientific articles, studies, and reports along with federal, state, and local laws, regulations and policies. In the course of preparing these comments, we reviewed volumes of material, the incorporation of which directly into these comments would be unnecessary. We hope that these references will be useful to you as you move forward with revisions to R. 61.56, and we welcome the opportunity to work with the agency in advancing any of the recommendations contained in this letter.

We thank you for your consideration and would be happy to meet with you by phone or in person to discuss our concerns and answer any questions.

Department Response: Clarification – The Department remains committed to its mission of protecting and promoting the health of the public and the environment, and this mission is reflected throughout the proposed revisions to the Onsite Wastewater regulations. Please see the above General Department Response for additional detail and information in response to the commenter's concerns. See also Department responses to SCELP comments under I. through VII. above, which are incorporated by reference hereby. The Department also appreciates all scientific and other information provided in the comments.

FOOTNOTES

[1] https://www.epa.gov/septic/septic-systems-overview
[2] https://www3.epa.gov/npdes/pubs/homeowner_guide_long.pdf
[3] https://scdhec.gov/environment/your-home/septic-tanks/septic-tank-inspections
[4] https://www.epa.gov/sites/production/files/2015-06/documents/scb_decent_ar_2013_final-508compliant.pdf; *see also* https://www.miamicountyin.gov/DocumentCenter/View/901/Chapter-1----Introduction-PDF
[5] https://www.census.gov/quickfacts/SC; *see also* https://www.epa.gov/septic/septic-systems-overview
[6] *See also* https://www.postandcourier.com/news/failing-septic-systems-foul-sc-homes-and-waterways-but-solutions-are-costly/article_5565349a-7016-11e9-b3da-bbff3f84db65.html ("Regular water testing has shown that many septic systems aren't working correctly. The test results make sense because state and federal environmental regulators estimate that 10 to 20 percent of septic systems aren't working safely and there are more than a million in South Carolina alone.")

[7] https://www.epa.gov/nutrientpollution/sources-and-solutions-wastewater
[8] Mohamed, R. 2009. Why Households in the United States do not Maintain Their Septic Systems and Why State-Led Regulations are Necessary: Explanations from Public Goods Theory. International Journal of Sustainable Development. 4(2):41-55. (available at http://www.doh.wa.gov/Portals/1/Documents/4450/WW-SM-008.pdf)
[9] https://www.greenvilleonline.com/story/opinion/editorials/2013/12/26/rules-needed-for-septic-systems-/4191263/
[10] https://scdhec.gov/waterbodies-no-advisories
[11] https://scdhec.gov/sites/default/files/media/document/PN_IR_Part_I_2018.pdf
[12] https://scdhec.gov/environment/your-water-coast/approved-tmdls
[13] See https://scdhec.gov/environment/your-water-coast/tmdls-under-development (listing 8 waterbodies, seven of which are under concern for fecal coliform and/or E. coli: Chauga River, Black Creek and Cattail Branch, Caper's Creek/Shellfish Management Area 15, Central Midlands/3 Rivers, Cow Castle Creek; Lower Four Holes Swamp and Tributaries, Lower Catawba Basin (Cedar Creek, Fishing Creek, Great Falls, Lake Wateree) , McAlpine Creek and Sugar Creek, Reedy River).
[14] https://scdhec.gov/bow/south-carolina-303d-list-impaired-waters-tmdls#6
[15] https://apps.dhec.sc.gov/Environment/PublicNotices/SearchAndDisplay/PDF/9137
[16]https://www.cnn.com/2009/TECH/science/04/07/rivers.endangered.list/index.html#:~:text=Excess%20levels%20of%20sewage%20waste,fish%20and%20other%20aquatic%20life.
[17] https://scdhec.gov/sites/default/files/docs/HomeAndEnvironment/Docs/tmdl_usaluda_fc.pdf
[18]https://scdhec.gov/sites/default/files/media/document/Craven_Grove_Big_Hurricane%20Crks%20of%20Upr%20Saluda%20WBP_2013.pdf
[19] https://scdhec.gov/sites/default/files/docs/HomeAndEnvironment/Docs/tmdl_pd_fc.pdf
[20] https://www.nrdc.org/sites/default/files/ttw2014_Sources_of_Beach_Pollution.pdf
[21] https://decentralizedwater.waterrf.org/documents/05-dec-3sg/05-dec-3sgc%20state%20reports%20summary.pdf
[22] Duda. A.M, K.D. Cromartie. 1982. Coastal Pollution from Septic Tank Drainfields. J. Environ. Eng. Div. Amer. Soc. Civil Eng. 108:1265-1279.
[23] https://www.postandcourier.com/news/bubbling-beaches-south-carolina-oceanfront-septics-cause-stink/article_a0e42590-8447-11e8-a4d3-8f2a09b57064.html
[24] Mallin, M.A., 2006. Wading in waste. Sci. Am. 294, 52–59.
[25] Duda. A.M, K.D. Cromartie. 1982. Coastal Pollution from Septic Tank Drainfields. J. Environ. Eng. Div. Amer. Soc. Civil Eng. 108:1265-1279.
[26] See https://www.horrycounty.org/Portals/0/Docs/stormwater/Studies/Briarcliffe%20Acres%20Bacteria%20Study%202011%20Web.pdf
[27] https://scdhec.gov/sites/default/files/media/document/Post_NODD_JIC_Entero_TMDLs_final.pdf
[28] https://www.epa.gov/sites/production/files/2017-08/documents/170803-homebuyerssepticguide_508c.pdf
[29] https://scdhec.gov/sites/default/files/media/document/Post_NODD_JIC_Entero_TMDLs_final.pdf
[30] https://scdhec.gov/sites/default/files/media/document/Post_NODD_SHCRK_Entero_TMDLs_Final.pdf; *see also* https://scdhec.gov/sites/default/files/docs/HomeAndEnvironment/Docs/tmdl_sawmill.pdf
[31] https://scdhec.gov/sites/default/files/docs/HomeAndEnvironment/Docs/tmdl_litchfld_pawleys_fc.pdf
[32] https://scdhec.gov/environment/your-water-coast/stay-well-water; *see also* https://www.epa.gov/sites/production/files/2015-10/documents/csossortc2004_full.pdf
[33] https://www.sciencedirect.com/science/article/abs/pii/S0048969714017690
[34] https://www.nrdc.org/stories/its-2018-alabamans-shouldnt-have-worry-about-hookworms; *see also* https://www.foxnews.com/health/dirty-water-leads-to-return-of-parasite
[35] https://archive.epa.gov/water/archive/web/html/phs.html

[36] National Oceanic and Atmospheric Administration (NOAA). 1995. National Shellfish Register. National Oceanic and Atmospheric Administration, Washington, DC; *see also* https://www.epa.gov/sites/production/files/2015-09/documents/urban_ch06.pdf
[37] https://spo.nmfs.noaa.gov/sites/default/files/pdf-content/MFR/mfr584/mfr5841.pdf
[38] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4054135/
[39] https://www.postandcourier.com/business/economic-impact-of-tourism-in-sc-grew-again-reaching-22-6-billion-last-year/article_32269c48-2e31-11e9-816d-771fa7777b39.html
[40] https://www.dnr.sc.gov/economic/EconomicContributionsSC.pdf
[41] https://www.dnr.sc.gov/economic/EconomicContributionsSC.pdf
[42] This number excludes saltwater fishing; including it would increase the number by $329 million.
[43] http://codes.ohio.gov/oac/3701-29
[44] https://docs.legis.wisconsin.gov/statutes/statutes/145/20
[45] https://docs.legis.wisconsin.gov/code/admin_code/sps/safety_and_buildings_and_environment/380_387/383/v/52
[46] https://docs.legis.wisconsin.gov/code/admin_code/sps/safety_and_buildings_and_environment/380_387/383/v/52?view=section
[47] *See* https://dnr.wisconsin.gov/aid/Sources.html; *see also* https://dsps.wi.gov/Pages/Programs/WisconsinFund/Default.aspx
[48] https://malegislature.gov/laws/generallaws/parti/titleii/chapter21a/section13
[49] 310 Mass. Reg. 15.302
[50] https://www.legis.iowa.gov/docs/code/455B.172.pdf
[51] http://rules.sos.state.ga.us/GAC/511-3-1-.03
[52] *See, e.g.*, http://www.cityofgrovetown.com/DocumentCenter/View/398/CITY-ORDINANCE-234?bidId=
[53] *See* Failing Septic Systems and Heirs' Property: Financial Lending Challenges And Possible Solutions [available at https://www.srs.fs.usda.gov/pubs/gtr/gtr_srs225.pdf]; *see also* Brian R. Giaquinto & Stephanie Showalter Otts, Failing Septic Systems and Heirs' Property: Financial Lending Challenges and Possible Solutions (2012), National Sea Grant Law Center, University of Mississippi School of Law, available at nsglc.olemiss.edu/Advisory/Heir-Property-Final[updated].pdf.; James Deaton, Land "in Heirs": Building A Hypothesis Concerning Tenancy in Common and the Persistence of Poverty in Central Appalachia, 11 Journal of Appalachian Studies, 83, 86 (2005).
[54]https://scdhec.gov/sites/default/files/docs/HomeAndEnvironment/Docs/SC_Coastal_%20Program%20(Pt.%202%20-%20Ch.%20V).pdf
[55] Further, as it relates specifically to beachfront septic systems, the Agency has authority and is bound to consider whether a proposed septic system requires alteration of "beaches" critical area, even if the septic system is placed landward of the jurisdictional lines for "beach/dune." Pursuant to the Act, DHEC has critical area permitting authority over "beaches," which are "those lands subject to periodic inundation by tidal and wave action so that no non-littoral vegetation is established," regardless of the presence of jurisdictional lines. S.C Code § 49-39-10(H). Given the need for additional regulatory oversight for malfunctioning beachfront septic systems, we urge the Agency to begin considering and evaluating whether its authority over "beaches" is implicated by proposed septic systems. We submit that a critical area permit is required on such basis, even with the enormous artificial avulsion preceding its proposal.
[56] http://www.crmc.ri.gov/regulations/RICRMP.pdf
[57] http://webserver.rilin.state.ri.us/Statutes/TITLE23/23-19.15/23-19.15-5.HTM; *see also* http://www.beachsamp.org/relatedprojects/coastalpropertyguide/septic-systems/
[58] http://www.crmc.ri.gov/owt.html
[59] http://www.dem.ri.gov/programs/benviron/water/permits/isds/pdfs/coastrpr.pdf; *see also* http://www.dem.ri.gov/pubs/regs/regs/water/owts12.pdf

[60] https://www.clf.org/blog/climate-change-risks-septic-systems/
[61] https://www.clf.org/publication/avoiding-septic-shock/
[62] https://www.pca.state.mn.us/sites/default/files/wq-wwists4-39.pdf
[63] *See* https://www.revisor.mn.gov/statutes/cite/115.55; *see also* https://www.revisor.mn.gov/statutes/cite/115.03
[64] https://www.revisor.mn.gov/rules/7081/
[65] http://www.mainelegislature.org/legis/bills/getPDF.asp?paper=HP0179&item=1&snum=129
[66] https://mde.maryland.gov/programs/Water/BayRestorationFund/Pages/index.aspx
[67] http://mlis.state.md.us/2004rs/billfile/sb0320.htm

A Petition

We the undersigned do petition the South Carolina Department of Health and Environmental Control to improve septic tank regulations and better protect human health and the health of our waterways.

Charleston Waterkeeper's testing data shows that high levels of bacteria often make many popular local waterways like Shem Creek and James Island Creek unsafe for swimming.
DHEC estimates there are more than 800 septic tanks around James Island Creek alone. According to EPA, as many as 20% of septic tanks are likely malfunctioning and leaking poorly treated waste and bacteria pollution into nearby creeks and waterways.

Accordingly, DHEC must:
• Create regular inspection, maintenance, and reporting requirements for septic tank operators to make sure tanks are working properly and not polluting nearby waterways
• Focus resources in: watersheds with documented bacteria problems, settlement/heirs property communities, and on barrier islands with erosion issues to protect the health of those most exposed to bacteria pollution.

Stand up for clean water today by adding your name below! We will submit this petition to DHEC and with your support, we can make sure they do a better job of protecting your health and health of your favorite waterway from bacteria pollution.
*This is a joint effort with the South Carolina Environmental Law Project and South Carolina Coastal Conservation League.

Department Response: Clarification - See the above General Department Response and the Department responses to SCELP comments under I. through VII. above, which are incorporated by reference hereby. A list of signatories to the petition submitted by SCELP appears in Attachment B.1.

Name	Section
Comment #14: Matt Napier	**200.6**

Comment: Please start considering the beach erosion history on or near a parcel as part of any septic system permitting process near the beach. I.e. if a lot was so eroded that it did not qualify for a septic permit immediately prior to a beach renourishment and did not meet the septic system setbacks, a septic permit should not be granted for the lot, period, regardless of a temporary sand avulsion that temporarily makes it look like a septic permit meets the 75' setback, knowing the beach will start eroding again immediately.

Also, please start requiring all old septic permits to meet a 75' setback, rather than the decades old permits only needing a 50' setback. See the attached OSWW Permit to Construct PDF. These old

permits should be required to meet a 75' setback, just like all other new septic permits. Either that, or these decades old permits should be immediately cancelled permanently.

Department: Not Adopted/Clarification - The Department must make permit decisions based on site conditions at the time of the Department's review of all application materials and must also ensure fair and consistent implementation of regulatory requirements. Once a permit to construct is issued, it will not remain valid if the permitted system has not yet been installed and, due to beach erosion or other factors, the conditions of the original permit cannot be met. In such cases, the permit to construct may be revoked and an approval to operate will not be issued.

In prior revisions to R.61-56 (in 2008), the Department established a five-year expiration date for all permits issued from that point forward. Some older permits issued by the Department do not have an expiration date, and the Department is unable to retroactively assign one.

Name	Section
Comment #15: Jackie Napier	**200.6**

Comment: Please consider all beach erosion history on or near a parcel as part of any septic system permitting process near the beach. If a lot was eroded and didn't qualify for a septic permit immediately prior to a sand renourishment, didn't meet the septic system setbacks, a septic permit should not be granted for the lot, period, regardless of a temporary sand avulsion that temporarily makes it look like a septic permit meets the 75' setback, knowing the beach will start eroding again immediately. Please require old septic permits to meet a 75' setback, rather than the decades old permits only needing a 50' setback.

Department Response: Not Adopted/Clarification - Please see the above response to Matt Napier's comment, which is incorporated by reference hereby.

Name	Section
Comment #16: W. Thomas (Tommy) Lavender, Jr (Nexsen Pruet, LLC)	**102.1**

Comment: I am wondering why a licensed soil classifier is required [to perform soil evaluations] in it appears that a licensed geologist is not acceptable. This [soils report] form implies that only a PSC can sign. There appear to be fewer than 50, if not closer to 40, of these on their roster.

Department: Changes Made - The Department cannot speak directly to whether geologists or other professionals are authorized to practice soil classification, as this is a matter within the purview of the relevant licensing boards within the S.C. Department of Labor, Licensing and Regulation (LLR). However, in response to the comment, the Department has revised Section 102.1(2) to permit soil evaluations to be conducted by either a certified Department staff member, licensed Professional Soil Classifier, or another licensed person qualified to practice professional soil classifying under S.C. Code Section 40-65-40(7). As stated in Section 102.1(2) as amended, a licensed person seeking to conduct a soil evaluation under R.61-56 must provide to the Department verification of qualification from the relevant licensing authority.

ATTACHMENT B.1

SUPPLEMENTAL DOCUMENTATION FOR PUBLIC COMMENT #13

Number	Date Submitted	Name	City	Zip
1	2020-09-24	Wunderley, Andrew	Charleston	29412
2	2020-09-25	Kasha, Michael	Anderson	29624
3	2020-09-25	Richardson, Sharon	Charleston	29403
4	2020-09-25	Park, Scot	Charleston	29407
5	2020-09-25	Aren, Dale	Charleston	29407
6	2020-09-25	Fraser, Mary Edna	Charleston	29412
7	2020-09-25	Milliken, Garrett	Charleston	29412
8	2020-09-25	Smith, William	Charleston	29412
9	2020-09-25	Williams, Brink	Charleston	29412
10	2020-09-25	Nunn, John	Charleston	29412
11	2020-09-25	Mytty, Marlo	Charleston	29412
12	2020-09-25	Smith, Tripp	Charleston	29412
13	2020-09-25	Lee, Gary	Charleston	29412
14	2020-09-25	Freeman, Brittany	Charleston	29412
15	2020-09-25	Stroble, Josh	Charleston	29412
16	2020-09-25	Taylor, Jc	Charleston	29412
17	2020-09-25	Newton, Nancy	Charleston	29412
18	2020-09-25	Taylor, Kimberly	Charleston	29412
19	2020-09-25	Barattini, Kate	Charleston	29412
20	2020-09-25	Sancho, Gorka	Charleston	29412
21	2020-09-25	Amis, Nancy	Charleston	29412
22	2020-09-25	Cole, Carl	Charleston	29412
23	2020-09-25	Tyrrell, Jennifer	Charleston	29412
24	2020-09-25	Toussaint, Patty	Charleston	29412
25	2020-09-25	Wilson, Sara	Charleston	29414
26	2020-09-25	Shervinski, Joshua	Charleston	29414
27	2020-09-25	Daughtry, Gracie	Charleston	29492
28	2020-09-25	Hare, Robert	Edisto Island	29438

29	2020-09-25	Napier, Matthew	Folly Beach	29439
30	2020-09-25	Zabel, Bridget	Fort Mill	29708
31	2020-09-25	Landrum, Tracy	Fort Mill	29715
32	2020-09-25	Chow, Lorraine	Georgetown	29440
33	2020-09-25	MacDonald, Cara	Greenville	29611
34	2020-09-25	Vanderwerker, Greg	Johns Island	29455
35	2020-09-25	Foley, Adam	Ladson	29456
36	2020-09-25	Crislip, Johnny	Mount Pleasant	29464
37	2020-09-25	Jones, Myra	Mount Pleasant	29464
38	2020-09-25	Thornley, Katie	Mount Pleasant	29464
39	2020-09-25	Stoney, Martha	Mount Pleasant	29464
40	2020-09-25	LeClercq, Anne	Mount Pleasant	29464
41	2020-09-25	Schwartz, Ann	Mount Pleasant	29464
42	2020-09-25	Jenkins, Amy	Mount Pleasant	29464
43	2020-09-25	Cantey, Paulette	Mount Pleasant	29464
44	2020-09-25	Rowland, Meghan	Mount Pleasant	29464
45	2020-09-25	Valponi, Lelia	Mount Pleasant	29464
46	2020-09-25	Krieck, George	Mount Pleasant	29464
47	2020-09-25	Abro, Michael	Mount Pleasant	29464
48	2020-09-25	Scarafile, Julie	Mount Pleasant	29464
49	2020-09-25	Arnett, Linda	Mount Pleasant	29464
50	2020-09-25	Moore, Holly	Mount Pleasant	29464
51	2020-09-25	Crolley, Chris	Mount Pleasant	29464
52	2020-09-25	Bonn-Miller, Monika	Mount Pleasant	29464
53	2020-09-25	Franko, Cecilia	Mount Pleasant	29464
54	2020-09-25	Stewart, Mark	Mount Pleasant	29464
55	2020-09-25	Miller, D	Mount Pleasant	29464
56	2020-09-25	Skoglund, Felicia	Mount Pleasant	29464
57	2020-09-25	Riggs, Becky	Mount Pleasant	29464
58	2020-09-25	Hawes, Sally	Mount Pleasant	29464
59	2020-09-25	Beall, Kim	Mount Pleasant	29464

60	2020-09-25	Wilson, Stan	Mount Pleasant	29464
61	2020-09-25	LaMaster, Katherine	Mount Pleasant	29464
62	2020-09-25	Percival, Kim	Mount Pleasant	29464
63	2020-09-25	Coleman-Socia, Elizabeth	Mount Pleasant	29464
64	2020-09-25	Benton, Alicia	Mount Pleasant	29466
65	2020-09-25	Lang, Pearon Lang	Mount Pleasant	29464
66	2020-09-25	Lang, Pearon Lang	Mount Pleasant	29464
67	2020-09-25	Stone, Barbara	Mount Pleasant	29464
68	2020-09-25	Lemmons, Jo	Mount Pleasant	29464
69	2020-09-25	Martin, Elizabeth	Mount Pleasant	29464
70	2020-09-25	Joseph, Molly	Mount Pleasant	29464
71	2020-09-25	Henney, Ashlee	Mount Pleasant	29464
72	2020-09-25	Stelling, Grace	Mount Pleasant	29464
73	2020-09-25	Herbig, Julie	Mount Pleasant	29464
74	2020-09-25	Caldwell, Tracy	Myrtle Beach	29588
75	2020-09-25	Caldwell, Quentin	Myrtle Beach	29588
76	2020-09-25	Armstrong, Amy	Pawleys Island	29585
77	2020-09-25	Daughtry, Sheila	Piedmont	29673
78	2020-09-25	Daughtry, Jed	Piedmont	29673
79	2020-09-25	Gantt, Bessie	Sullivans Island	29482
80	2020-09-26	Wilson, Nancy	Charleston	29403
81	2020-09-26	Liebmann, Morgan	Charleston	29403
82	2020-09-26	Wigley, James	Charleston	29403
83	2020-09-26	Gates, Oliver	Charleston	29403
84	2020-09-26	Nguyen, Diemchi	Charleston	29403
85	2020-09-26	Plumer, Scott	Charleston	29403
86	2020-09-26	Brundrett, Katherine	Charleston	29406
87	2020-09-26	Crawford, Rick	Charleston	29407
88	2020-09-26	Muhl, Melissa	Charleston	29407
89	2020-09-26	Johnson, Addison	Charleston	29407
90	2020-09-26	Frear, Gary	Charleston	29412

91	2020-09-26	Avnayim, Alicia	Charleston	29412
92	2020-09-26	Tyler, Dede	Charleston	29412
93	2020-09-26	Fashjian, Meghan	Charleston	29412
94	2020-09-26	Hare, Nicholas	Charleston	29412
95	2020-09-26	Janiak, Rachel	Charleston	29412
96	2020-09-26	Gustafson, Ann	Charleston	29412
97	2020-09-26	Wilson, Amanda	Charleston	29412
98	2020-09-26	Peterson, Jennifer	Charleston	29412
99	2020-09-26	Kowalchick, Kathy	Charleston	29412
100	2020-09-26	Hicks, Natalie	Charleston	29414
101	2020-09-26	Phillips, Vickie	Charleston	29414
102	2020-09-26	Nemeth, Elizabeth	Charleston	29414
103	2020-09-26	Volborth, Veronica	Charleston	29492
104	2020-09-26	Crall, Kate Hewett	Charleston	29492
105	2020-09-26	Keough, Andrew	Columbia	29210
106	2020-09-26	Helmer, Lee	Erie	80516
107	2020-09-26	Morris, Justin	Folly Beach	29439
108	2020-09-26	Garbarini, Alison	Johns Island	29455
109	2020-09-26	Humphrey, Bernadette	Mc Clellanville	29458
110	2020-09-26	Devenny, Jan	Mount Pleasant	29464
111	2020-09-26	Cooper, Lisa	Mount Pleasant	29464
112	2020-09-26	Stone, Stephen Preston	Mount Pleasant	29464
113	2020-09-26	Davis, Ashley	Mount Pleasant	29464
114	2020-09-26	Collins, Timothy H	Mount Pleasant	29464
115	2020-09-26	Fowler, Sydney	Mount Pleasant	29464
116	2020-09-26	Von, Judith	Mount Pleasant	29464
117	2020-09-26	Meyers, Jeff	Mount Pleasant	29464
118	2020-09-26	Jordan, Elizabeth	Mount Pleasant	29464
119	2020-09-26	Seigel, Diane	Mount Pleasant	29464
120	2020-09-26	Sabbagh, Mike	Mount Pleasant	29464
121	2020-09-26	Oliphant, Drane	Mount Pleasant	29464

122	2020-09-26	Calla, Jim	Mount Pleasant	29464
123	2020-09-26	Merritt, Faye	Mount Pleasant	29464
124	2020-09-26	Donoso, Alberto	Mount Pleasant	29464
125	2020-09-26	Herbig, Jimmy	Mount Pleasant	29464
126	2020-09-26	Klomparens, Whitney	Mount Pleasant	29464
127	2020-09-26	Pavao, Adam	Mount Pleasant	29464
128	2020-09-26	Van Tiem, Lynn	Mount Pleasant	29464
129	2020-09-26	Line, Jackie	Mount Pleasant	29464
130	2020-09-26	Vantiem, Thomas	Mount Pleasant	29464
131	2020-09-26	Martin, John	Mount Pleasant	29464
132	2020-09-26	Nettles, Rosanne	Mount Pleasant	29464
133	2020-09-26	Gorham, Jason	Mount Pleasant	29466
134	2020-09-26	Barker, Bonnie	Mount Pleasant	29466
135	2020-09-26	Johnson, Nikki	Mount Pleasant	29466
136	2020-09-26	Zeaser-Sydow, Kristin	Mount Pleasant	29466
137	2020-09-26	Houston, Chris	Mount Pleasant	29466
138	2020-09-26	White, Katharine	Mount Pleasant	29464
139	2020-09-26	Klomparens, Rob	Mount Pleasant	29464
140	2020-09-26	Crawford, Carol	Mount Pleasant	29464
141	2020-09-26	Nettles, Gene	Mount Pleasant	29464
142	2020-09-26	Nichols, Jill	North Charleston	29405
143	2020-09-26	Durand, Ezekiel	North Charleston	29420
144	2020-09-26	Arturo, Marly	Summerville	29485
145	2020-09-26	Brack, Emi	Summerville	29486
146	2020-09-27	Dorman, Jacqui	Charleston	29401
147	2020-09-27	Latimer, Jen	Charleston	29407
148	2020-09-27	Gantt, Jacqueline	Charleston	29412
149	2020-09-27	Milliken, Susan	Charleston	29412
150	2020-09-27	Absher, Leah	Charleston	29412
151	2020-09-27	Rose, Nick	Charleston	29412
152	2020-09-27	Jackson, Larry	Charleston	29492

153	2020-09-27	Graham, Brittnany	Lexington	40511
154	2020-09-27	Hodgkiss, Ashley	Mount Pleasant	29464
155	2020-09-27	Quick, David	Mount Pleasant	29464
156	2020-09-27	Stein, Thomas	Mount Pleasant	29464
157	2020-09-27	Leite, Renata	Mount Pleasant	29464
158	2020-09-27	Crislip, Carol	Mount Pleasant	29464
159	2020-09-27	Fernanndes, Jyotika	Mount Pleasant	29464
160	2020-09-27	Guimaraes, Rossana	Mount Pleasant	29464
161	2020-09-27	McInerney, Caroline	Mount Pleasant	29464
162	2020-09-27	Powers, Catherine	Mount Pleasant	29464
163	2020-09-27	Da Costa, Nanci	Mount Pleasant	29466
164	2020-09-28	Morrison, Susan	Charleston	29412
165	2020-09-28	Thomas, Chadd	Charleston	29412
166	2020-09-28	Darr, Stacie	Charleston	29412
167	2020-09-28	Kines, Louis	Charleston	29412
168	2020-09-28	Chapman, Katherine	Charleston	29412
169	2020-09-28	Perry, Kimberly	Charleston	29412
170	2020-09-28	Shaw, Anna	Mount Pleasant	29464
171	2020-09-28	Pease, Jay	Mount Pleasant	29464
172	2020-09-28	Northcutt, Charlie	Mount Pleasant	29464

ATTACHMENT B.2

COMMENTS RECEIVED OUTSIDE OF PUBLIC COMMENT PERIOD

Late Comment #1: Paula Stubblefield

From: Paula Stubblefield [redacted]
Sent: Monday, September 28, 2020 5:04 PM
To: Vaughan, David R. <vaughadr@dhec.sc.gov>
Subject: Onsite Wastewater Updates

*** Caution. This is an EXTERNAL email. DO NOT open attachments or click links from unknown senders or unexpected email. ***

Hey David,

Please start using the erosional history of a parcel as part of the septic permitting process. It has been an issue on Folly Beach where a lot can't get a permit. Then, the day after a sand renourishment, a developer gets a survey to show false high ground that will not stay. Please stop allowing people to use a false renourishment as means to obtain a septic permit.

Also, please make sure all septic permits (old and new) are required to have at least a 75' setback from any water.

Thanks,

Paula Stubblefield
[redacted]

Late Comment #2: Caleb Rodgers

From: Caleb Rodgers [redacted]
Sent: Monday, September 28, 2020 10:17 PM
To: Vaughan, David R. <vaughadr@dhec.sc.gov>
Subject: SCDHEC Septic Regulation Change Comment

*** Caution. This is an EXTERNAL email. DO NOT open attachments or click links from unknown senders or unexpected email. ***
Good Evening Mr. Vaughan,

I am reaching out in regards to the below proposed regulation revision that I was made aware of today. I am a civil engineer who's primary practice is onsite wastewater in South Carolina and have many clients in the coastal areas.

"For lots with an adjacent Critical Line, the setback increases from 75 ft. to 125 ft, if the ZOS < 15 in. They are basically aligning our "Cut & Fill" Engineered (610) Ultra-Shallow designs with the SCDHEC 362/260 & 362/240 Standards setbacks (that have only primary effluent treatment)."

I attended the webinar presentation of the proposed regulation changes, and do not recall a proposed coastal setback change being presented so I am concerned this may be slipping past many landowners and professionals in the field.

It would be very valuable to provide the opportunity for the South Carolina network of Onsite Wastewater Professionals the opportunity to weigh in on this change and compare to other coastal states. I agree sensitive areas should be protected, however, I don't believe a wholesale setback increase this significant is the only way. Establishing pretreatment effluent standards (similar to neighboring NC) for sensitive areas would be a great start.

In closing, I once listened to a great Economics lecturer that shared the story of a regulation change that was meant to protect the "preferred" tree that a highly endangered bird nests in. When word of this proposed change got out to landowners who knew they had this tree on their property, they immediately had the tree cut down prior to the legislation change that would have rendered their property useless. I worry that this significant change in setback requirement, versus evaluating a technical approach to solve coastal concerns, would only drive coastal landowners to push to develop and permit their properties even quicker than these areas are already being pressured.

Thank you for your time and I am happy to discuss further.

Regards,

Caleb

Onsite Septic Engineering

Caleb P. Rodgers, PE, MBA
President & Principal Engineer
[redacted]
www.onsitesepticengineering.com

Late Comment #3: Chris Fincham

[redacted]

Late Comment #4: John Thorp

From: John Thorp [redacted]
Sent: Tuesday, September 29, 2020 6:16 PM
To: Vaughan, David R. <vaughadr@dhec.sc.gov>
Subject: Comments on Reg. 61-56

*** Caution. This is an EXTERNAL email. DO NOT open attachments or click links from unknown senders or unexpected email. ***

Dear Mr. Vaughan,

Thank you very much for your time spent with me yesterday on our telephone call.

Please accept and consider my comments on the proposed changes to Reg. 61-56, specifically regarding Alternative Standard 362/610.

I realize that your Agency's current setback from the approved SCDHEC/OCRM Critical Line is 125 ft. for Non- Engineered, Alternative System types 362/240 and 362/260 Typically, these State issued Permits to Construct a Septic System contain a primary and possibly a secondary, anaerobic, pumped (to the drain field) tank system.

It is my professional opinion that the current, proposed regulatory change for Specialized (Engineered) septic systems, that increases the septic setback away from the approved SCDHEC/OCRM Critical Line from 75 ft. to 125 ft. is "***Arbitrary and Capricous***".

I am not aware of any published scientific research or published S.C.D.H.E.C. septic system performance Reports that support this + 67% horizontal distance increase, especially given the availability of multiple modern, effective "Effluent Pre-Treatment" septic design options that greatly reduce the concentration of undesirable aqueous, soluble soil / groundwater pollutants that are dispersed into a suitably created drainfield area. Many of these similar systems are approved by our adjacent states:
http://reports.oah.state.nc.us/ncac/title%2015a%20-%20environmental%20quality/chapter%2018%20-%20environmental%20health/subchapter%20a/15a%20ncac%2018a%20.1948.pdf

Permitting & Regulatory simplicity has its expedient merits from SCDHEC's administrative standpoint, but given the abundance and high property value of many of S.C. coastal private residential land ownerships, I respectfully urge you and SCDHEC and the subsequent legislative committee(s) to amend the Alternative Standard 362/610 to allow for site specific, science- based, hydrological, professional studies that may quantify the appropriate, horizontal separation of dispersal of highly treated septic effluent from the SCDHEC/OCRM Critical Line.

I recognize that a permitted 362/610 system that merits a lesser C.L. setback distance must present a verifiable effluent treatment performance record.

[redacted]

Late Comment #5: Carol A. Jackson

From: Jackson, Carol [redacted]
Sent: Monday, September 28, 2020 6:14 PM
To: Vaughan, David R. <vaughadr@dhec.sc.gov>
Cc: Ross Appel [redacted]
Subject: DHEC Notice for Comment concerning Septics Regulations

*** Caution. This is an EXTERNAL email. DO NOT open attachments or click links from unknown senders or unexpected email. ***

Dear Mr. Vaughan,

I want to associate myself with the public comment concerning this regulatory topic sent in today by CM Ross Appel. I am CM Appel's City of Charleston Council colleague, representing District 12 on James Island. My neighborhood borders the eastern portion of Ellis Creek, incorporated into the large James Island Creek watershed. We know many of the original properties subdivided in older areas, first developed in the 1950's, are not being maintained nor inspected, especially as they are on the Creek and Marsh shorelines. We will appreciate the stiffening of DHEC inspection and monitoring regulations, as well as assistance with the ongoing challenge of citizen education and engagement, so that owners and renters become stakeholders in the resulting quality of our creeks, marshes and waterways.

Thank you. Sincerely, Carol A. Jackson [redacted]

Carol A Jackson
Council District 12
[redacted]

Late Comment #6: Lauren Milton

A Petition

We the undersigned do petition the South Carolina Department of Health and Environmental Control to improve septic tank regulations and better protect human health and the health of our waterways.

Charleston Waterkeeper's testing data shows that high levels of bacteria often make many popular local waterways like Shem Creek and James Island Creek unsafe for swimming. DHEC estimates there are more than 800 septic tanks around James Island Creek alone. According to EPA, as many as 20% of septic tanks are likely malfunctioning and leaking poorly treated waste and bacteria pollution into nearby creeks and waterways.

Accordingly, DHEC must:

• Create regular inspection, maintenance, and reporting requirements for septic tank operators to make sure tanks are working properly and not polluting nearby waterways

• Focus resources in: watersheds with documented bacteria problems, settlement/heirs property communities, and on barrier islands with erosion issues to protect the health of those most exposed to bacteria pollution.

Stand up for clean water today by adding your name below! We will submit this petition to DHEC and with your support, we can make sure they do a better job of protecting your health and health of your favorite waterway from bacteria pollution.

*This is a joint effort with the South Carolina Environmental Law Project and South Carolina Coastal Conservation League

Number	Date Submitted	Name	City	Zip
1	2020-09-24	Wunderley, Andrew	Charleston	29412
2	2020-09-25	Kasha, Michael	Anderson	29624
3	2020-09-25	Daughtry, Gracie	Charleston	29492
4	2020-09-25	Fraser, Mary Edna	Charleston	29412
5	2020-09-25	Richardson, Sharon	Charleston	29403
6	2020-09-25	Milliken, Garrett	Charleston	29412
7	2020-09-25	Smith, William	Charleston	29412
8	2020-09-25	Williams, Brink	Charleston	29412
9	2020-09-25	Nunn, John	Charleston	29412
10	2020-09-25	Mytty, Marlo	Charleston	29412
11	2020-09-25	Smith, Tripp	Charleston	29412
12	2020-09-25	Lee, Gary	Charleston	29412
13	2020-09-25	Freeman, Brittany	Charleston	29412
14	2020-09-25	Stroble, Josh	Charleston	29412

15	2020-09-25	Taylor, Jc	Charleston	29412
16	2020-09-25	Newton, Nancy	Charleston	29412
17	2020-09-25	Taylor, Kimberly	Charleston	29412
18	2020-09-25	Barattini, Kate	Charleston	29412
19	2020-09-25	Sancho, Gorka	Charleston	29412
20	2020-09-25	Wilson, Sara	Charleston	29414
21	2020-09-25	Shervinski, Joshua	Charleston	29414
22	2020-09-25	Amis, Nancy	Charleston	29412
23	2020-09-25	Park, Scot	Charleston	29407
24	2020-09-25	Cole, Carl	Charleston	29412
25	2020-09-25	Tyrrell, Jennifer	Charleston	29412
26	2020-09-25	Toussaint, Patty	Charleston	29412
27	2020-09-25	Aren, Dale	Charleston	29407
28	2020-09-25	Hare, Robert	Edisto Island	29438
29	2020-09-25	Napier, Matthew	Folly Beach	29439
30	2020-09-25	Zabel, Bridget	Fort Mill	29708
31	2020-09-25	Landrum, Tracy	Fort Mill	29715
32	2020-09-25	Landrum, Tracy	Fort Mill	29715
33	2020-09-25	Chow, Lorraine	Georgetown	29440
34	2020-09-25	MacDonald, Cara	Greenville	29611
35	2020-09-25	Vanderwerker, Greg	Johns Island	29455
36	2020-09-25	Foley, Adam	Ladson	29456
37	2020-09-25	Benton, Alicia	Mount Pleasant	29466
38	2020-09-25	Crislip, Johnny	Mount Pleasant	29464
39	2020-09-25	Jones, Myra	Mount Pleasant	29464
40	2020-09-25	Thornley, Katie	Mount Pleasant	29464
41	2020-09-25	Stoney, Martha	Mount Pleasant	29464
42	2020-09-25	LeClercq, Anne	Mount Pleasant	29464
43	2020-09-25	Schwartz, Ann	Mount Pleasant	29464
44	2020-09-25	Jenkins, Amy	Mount Pleasant	29464
45	2020-09-25	Cantey, Paulette	Mount Pleasant	29464

46	2020-09-25	Rowland, Meghan	Mount Pleasant	29464
47	2020-09-25	Valponi, Lelia	Mount Pleasant	29464
48	2020-09-25	Krieck, George	Mount Pleasant	29464
49	2020-09-25	Abro, Michael	Mount Pleasant	29464
50	2020-09-25	Scarafile, Julie	Mount Pleasant	29464
51	2020-09-25	Arnett, Linda	Mount Pleasant	29464
52	2020-09-25	Moore, Holly	Mount Pleasant	29464
53	2020-09-25	Crolley, Chris	Mount Pleasant	29464
54	2020-09-25	Bonn-Miller, Monika	Mount Pleasant	29464
55	2020-09-25	Franko, Cecilia	Mount Pleasant	29464
56	2020-09-25	Stewart, Mark	Mount Pleasant	29464
57	2020-09-25	Miller, D	Mount Pleasant	29464
58	2020-09-25	Skoglund, Felicia	Mount Pleasant	29464
59	2020-09-25	Riggs, Becky	Mount Pleasant	29464
60	2020-09-25	Hawes, Sally	Mount Pleasant	29464
61	2020-09-25	Beall, Kim	Mount Pleasant	29464
62	2020-09-25	Wilson, Stan	Mount Pleasant	29464
63	2020-09-25	LaMaster, Katherine	Mount Pleasant	29464
64	2020-09-25	Percival, Kim	Mount Pleasant	29464
65	2020-09-25	Coleman-Socia, Elizabeth	Mount Pleasant	29464
66	2020-09-25	Lang, Pearon Lang	Mount Pleasant	29464
67	2020-09-25	Lang, Pearon Lang	Mount Pleasant	29464
68	2020-09-25	Stone, Barbara	Mount Pleasant	29464
69	2020-09-25	Lemmons, Jo	Mount Pleasant	29464
70	2020-09-25	Martin, Elizabeth	Mount Pleasant	29464
71	2020-09-25	Joseph, Molly	Mount Pleasant	29464
72	2020-09-25	Henney, Ashlee	Mount Pleasant	29464
73	2020-09-25	Stelling, Grace	Mount Pleasant	29464
74	2020-09-25	Herbig, Julie	Mount Pleasant	29464
75	2020-09-25	Caldwell, Tracy	Myrtle Beach	29588
76	2020-09-25	Caldwell, Quentin	Myrtle Beach	29588

77	2020-09-25	Armstrong, Amy	Pawleys Island	29585
78	2020-09-25	Daughtry, Sheila	Piedmont	29673
79	2020-09-25	Daughtry, Jed	Piedmont	29673
80	2020-09-25	Gantt, Bessie	Sullivans Island	29482
81	2020-09-26	Wilson, Nancy	Charleston	29403
82	2020-09-26	Frear, Gary	Charleston	29412
83	2020-09-26	Avnayim, Alicia	Charleston	29412
84	2020-09-26	Tyler, Dede	Charleston	29412
85	2020-09-26	Hicks, Natalie	Charleston	29414
86	2020-09-26	Crawford, Rick	Charleston	29407
87	2020-09-26	Fashjian, Meghan	Charleston	29412
88	2020-09-26	Hare, Nicholas	Charleston	29412
89	2020-09-26	Phillips, Vickie	Charleston	29414
90	2020-09-26	Volborth, Veronica	Charleston	29492
91	2020-09-26	Liebmann, Morgan	Charleston	29403
92	2020-09-26	Muhl, Melissa	Charleston	29407
93	2020-09-26	Johnson, Addison	Charleston	29407
94	2020-09-26	Wigley, James	Charleston	29403
95	2020-09-26	Gates, Oliver	Charleston	29403
96	2020-09-26	Janiak, Rachel	Charleston	29412
97	2020-09-26	Nguyen, Diemchi	Charleston	29403
98	2020-09-26	Gustafson, Ann	Charleston	29412
99	2020-09-26	Plumer, Scott	Charleston	29403
100	2020-09-26	Crall, Kate Hewett	Charleston	29492
101	2020-09-26	Nemeth, Elizabeth	Charleston	29414
102	2020-09-26	Wilson, Amanda	Charleston	29412
103	2020-09-26	Peterson, Jennifer	Charleston	29412
104	2020-09-26	Brundrett, Katherine	Charleston	29406
105	2020-09-26	Kowalchick, Kathy	Charleston	29412
106	2020-09-26	Keough, Andrew	Columbia	29210
107	2020-09-26	Helmer, Lee	Erie	80516

108	2020-09-26	Morris, Justin	Folly Beach	29439
109	2020-09-26	Garbarini, Alison	Johns Island	29455
110	2020-09-26	Humphrey, Bernadette	Mc Clellanville	29458
111	2020-09-26	Devenny, Jan	Mount Pleasant	29464
112	2020-09-26	Cooper, Lisa	Mount Pleasant	29464
113	2020-09-26	Stone, Stephen Preston	Mount Pleasant	29464
114	2020-09-26	Davis, Ashley	Mount Pleasant	29464
115	2020-09-26	Collins, Timothy H	Mount Pleasant	29464
116	2020-09-26	Fowler, Sydney	Mount Pleasant	29464
117	2020-09-26	Von, Judith	Mount Pleasant	29464
118	2020-09-26	Meyers, Jeff	Mount Pleasant	29464
119	2020-09-26	Jordan, Elizabeth	Mount Pleasant	29464
120	2020-09-26	Seigel, Diane	Mount Pleasant	29464
121	2020-09-26	Sabbagh, Mike	Mount Pleasant	29464
122	2020-09-26	Oliphant, Drane	Mount Pleasant	29464
123	2020-09-26	Gorham, Jason	Mount Pleasant	29466
124	2020-09-26	Calla, Jim	Mount Pleasant	29464
125	2020-09-26	Merritt, Faye	Mount Pleasant	29464
126	2020-09-26	Donoso, Alberto	Mount Pleasant	29464
127	2020-09-26	Herbig, Jimmy	Mount Pleasant	29464
128	2020-09-26	Barker, Bonnie	Mount Pleasant	29466
129	2020-09-26	Klomparens, Whitney	Mount Pleasant	29464
130	2020-09-26	Pavao, Adam	Mount Pleasant	29464
131	2020-09-26	Van Tiem, Lynn	Mount Pleasant	29464
132	2020-09-26	Line, Jackie	Mount Pleasant	29464
133	2020-09-26	Vantiem, Thomas	Mount Pleasant	29464
134	2020-09-26	Johnson, Nikki	Mount Pleasant	29466
135	2020-09-26	Zeaser-Sydow, Kristin	Mount Pleasant	29466
136	2020-09-26	Martin, John	Mount Pleasant	29464
137	2020-09-26	Nettles, Rosanne	Mount Pleasant	29464
138	2020-09-26	Houston, Chris	Mount Pleasant	29466

139	2020-09-26	White, Katharine	Mount Pleasant	29464
140	2020-09-26	Klomparens, Rob	Mount Pleasant	29464
141	2020-09-26	Crawford, Carol	Mount Pleasant	29464
142	2020-09-26	Nettles, Gene	Mount Pleasant	29464
143	2020-09-26	Durand, Ezekiel	North Charleston	29420
144	2020-09-26	Nichols, Jill	North Charleston	29405
145	2020-09-26	Brack, Emi	Summerville	29486
146	2020-09-26	Arturo, Marly	Summerville	29485
147	2020-09-27	Gantt, Jacqueline	Charleston	29412
148	2020-09-27	Latimer, Jen	Charleston	29407
149	2020-09-27	Jackson, Larry	Charleston	29492
150	2020-09-27	Milliken, Susan	Charleston	29412
151	2020-09-27	Absher, Leah	Charleston	29412
152	2020-09-27	Rose, Nick	Charleston	29412
153	2020-09-27	Dorman, Jacqui	Charleston	29401
154	2020-09-27	Graham, Brittnany	Lexington	40511
155	2020-09-27	Hodgkiss, Ashley	Mount Pleasant	29464
156	2020-09-27	Quick, David	Mount Pleasant	29464
157	2020-09-27	Stein, Thomas	Mount Pleasant	29464
158	2020-09-27	Leite, Renata	Mount Pleasant	29464
159	2020-09-27	Crislip, Carol	Mount Pleasant	29464
160	2020-09-27	Fernanndes, Jyotika	Mount Pleasant	29464
161	2020-09-27	Guimaraes, Rossana	Mount Pleasant	29464
162	2020-09-27	Da Costa, Nanci	Mount Pleasant	29466
163	2020-09-27	McInerney, Caroline	Mount Pleasant	29464
164	2020-09-27	Powers, Catherine	Mount Pleasant	29464
165	2020-09-28	Guy, Susan	Beaufort	29902
166	2020-09-28	Morrison, Susan	Charleston	29412
167	2020-09-28	Thomas, Chadd	Charleston	29412
168	2020-09-28	Darr, Stacie	Charleston	29412
169	2020-09-28	Kines, Louis	Charleston	29412

170	2020-09-28	Chapman, Katherine	Charleston	29412
171	2020-09-28	Perry, Kimberly	Charleston	29412
172	2020-09-28	Wells, Cindy	Charleston	29412
173	2020-09-28	Woodruff, Margaret	Charleston	29412
174	2020-09-28	Gay, Alexis	Charleston	29403
175	2020-09-28	Riley, Morgan	Charleston	29414
176	2020-09-28	Knox, Tanner	Charleston	29412
177	2020-09-28	Hackathorn, Kaitlyn	Charleston	29407
178	2020-09-28	Culligan, Thomas	Charleston	29412
179	2020-09-28	Levier, Jeanne	Charleston	29412
180	2020-09-28	Crompton, Craig	Charleston	29412
181	2020-09-28	Bueno, Olivia	Charleston	29412
182	2020-09-28	Kepski, Julien	Charleston	29412
183	2020-09-28	Hicks, Helen	Charleston	29412
184	2020-09-28	Baker, Lisa	Charleston	29412
185	2020-09-28	Aldrich, Jane	Charleston	29414
186	2020-09-28	Hodges, Will	Charleston	29412
187	2020-09-28	Kelly, Erin	Charleston	29492
188	2020-09-28	McSwain, Rebecca	Charleston	29412
189	2020-09-28	Kotnik, Frances	Charleston	29412
190	2020-09-28	Schaay, Justin	Charleston	29422
191	2020-09-28	Jackson, Jodi	Charleston	29412
192	2020-09-28	Hansen, Joy	Charleston	29414
193	2020-09-28	Henty, Franny	Charleston	29412
194	2020-09-28	Wright MD, Rhonda D.	Charleston	29414
195	2020-09-28	Parkman, Joanna	Durham	27705
196	2020-09-28	Girault, John	Edisto Island	29438
197	2020-09-28	Stubblefield, Paula	Folly Beach	29439
198	2020-09-28	Doherty, Katherine	Greenville	29615
199	2020-09-28	Holscher, Carolyn	Isle Of Palms	29451
200	2020-09-28	Wildermann, Margaret	Johns Island	29455

201	2020-09-28	Napier, Jackie	Johns Island	29455
202	2020-09-28	Stathis, Gaye	Kiawah Island	29455
203	2020-09-28	Shaw, Anna	Mount Pleasant	29464
204	2020-09-28	Pease, Jay	Mount Pleasant	29464
205	2020-09-28	Northcutt, Charlie	Mount Pleasant	29464
206	2020-09-28	Gray, Sunny	Mount Pleasant	29464
207	2020-09-28	Schwartz, Andy	Mount Pleasant	29464
208	2020-09-28	Bagwell, Jimmy	Mount Pleasant	29464
209	2020-09-28	Collins, Sandra	Mount Pleasant	29464
210	2020-09-28	Wever, Robert	Mount Pleasant	29464
211	2020-09-28	McArdle, Kati	Mount Pleasant	29464
212	2020-09-28	Savage, Henry	Mount Pleasant	29464
213	2020-09-28	Campaigne, Alys	Mount Pleasant	29464
214	2020-09-28	Lewis, Kate	Mount Pleasant	29464
215	2020-09-28	Miller, James	Mount Pleasant	29464
216	2020-09-28	Smith, Cherie	Mount Pleasant	29464
217	2020-09-28	Milton, Lauren	Mount Pleasant	29464
218	2020-09-28	Bagwell, Penny	Mount Pleasant	29464
219	2020-09-28	Creech, Maribeth	Mount Pleasant	29464
220	2020-09-28	Hammes, Michel	North Charleston	29405
221	2020-09-28	Barrett, Madeline	Summerville	29485
222	2020-09-29	Barresi, April	Asbury Park	07712
223	2020-09-29	Zamler, Assaf	Charleston	29412
224	2020-09-29	Janse, Sheena	Charleston	29412
225	2020-09-29	Buckhout, Dane	Charleston	29401
226	2020-09-29	Derrick, Sydney	Charleston	29412
227	2020-09-29	Fraser, Rebecca	Charleston	29412
228	2020-09-29	Wheeler, Ian	Charleston	29412
229	2020-09-29	Tippens, Adrian	Charleston	29412
230	2020-09-29	All, James	Charleston	29412
231	2020-09-29	LoVullo, Lisa	Charleston	29412

232	2020-09-29	Strickland, Andrea	Charleston	29412
233	2020-09-29	Jackson, Bailey	Charleston	29403
234	2020-09-29	Denny Price, Shannon	Folly Beach	29439
235	2020-09-29	Chase, Megan	Greenville	29601
236	2020-09-29	Bohinc, Tyler	Ladson	29456
237	2020-09-29	Bohinc, Ashley	Ladson	29456
238	2020-09-29	Shaffer, Christine	Mount Pleasant	29464
239	2020-09-29	Palmer, Pip	Mount Pleasant	29464
240	2020-09-29	Zweigoron, Rachael	Mount Pleasant	29464
241	2020-09-29	Ravalico, Filippo	Mount Pleasant	29464
242	2020-09-29	Hill, Janene	Mount Pleasant	29464
243	2020-09-29	Creech, Maribeth	Mount Pleasant	29464
244	2020-09-29	Carlson, Christian	North Charleston	29405
245	2020-09-29	Miranda, Jennifer	Summerville	29485
246	2020-09-29	Thepaut, Benjamin	Summerville	29485
247	2020-09-30	Tamblyn, Amy	Charleston	29412
248	2020-09-30	Golden, K. Alane	Folly Beach	29439
249	2020-09-30	Frenzel, Michael	Mount Pleasant	29464
250	2020-09-30	Frenzel, George	Mount Pleasant	29464
251	2020-09-30	Harrison, Sharon	Mount Pleasant	29464
252	2020-09-30	Wilson, Anna	Mount Pleasant	29464
253	2020-09-30	Rodar, Jodi	Pelham	01002
254	2020-09-30	Bellamy, B	Sullivans Island	29482
255	2020-09-30	Tuten, Sally	Walterboro	29488
256	2020-10-01	Zabel, Maureen	Fort Mill	29708
257	2020-10-01	Gaffney, Lincoln	Isle Of Palms	29451
258	2020-10-01	Campbell, Becky	Mount Pleasant	29464
259	2020-10-01	Martin, Coleen	Mount Pleasant	29464
260	2020-10-01	Campbell, Richard	Mount Pleasant	29464
261	2020-10-01	Frenzel, Caroline	Mount Pleasant	29464
262	2020-10-02	Rogers, Helen	Charleston	29412

Date: November 12, 2020

To: S.C. Board of Health and Environmental Control

From: Bureau of Land and Waste Management

Re: Public Hearing for Notice of Final Regulation Amending R.61-79, *Hazardous Waste Management Regulations*, Document No. 4976

I. Introduction

The Bureau of Land and Waste Management ("Bureau") proposes the attached Notice of Final Regulation amending R.61-79, *Hazardous Waste Management Regulations*, for publication in the November 27, 2020, *South Carolina State Register* ("*State Register*"). Legal authority resides in the South Carolina Hazardous Waste Management Act, S.C. Code Ann. §§ 44-56-10 *et seq*., which authorizes the Department of Health and Environmental Control ("Department") to promulgate hazardous waste management regulations, procedures, or standards as may be necessary to protect human health and the environment. The Administrative Procedures Act, S.C. Code Ann. §1-23-120(H)(1), exempts these amendments from General Assembly review, as the Department promulgates these amendments for compliance with federal law. These amendments will take legal effect as of the November 27, 2020, after publication in the *State Register*.

II. Facts

1. Pursuant to the South Carolina Hazardous Waste Management Act, S.C. Code Ann. §§ 44-56-10 *et seq*., the Department is authorized to promulgate hazardous waste management regulations, procedures, or standards as may be necessary to protect human and environmental health.

2. The Bureau proposes amending R.61-79, *Hazardous Waste Management Regulations*, to adopt the Environmental Protection Agency ("EPA") final rule "Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine," published on February 22, 2019, at 84 FR 5816-5950. This rule creates new standards for the management of hazardous waste pharmaceuticals by healthcare facilities and reverse distributors in lieu of the existing generator regulations and reduces regulatory burdens for over-the-counter Food and Drug Administration-approved nicotine replacement therapies. Adoption of this rule is required to comply with federal law and will bring R.61-79 into conformity with the federal regulations.

3. The Bureau had a Notice of Drafting published in the April 24, 2020, *State Register*. The Bureau received no comments during the public comment period.

4. The Bureau published a summary of the proposed amendments on the Department's Regulation Development Update website. The Bureau provided notice to stakeholders via an email list on April 24, 2020. The Bureau maintains a website (https://www.scdhec.gov/about-dhec/laws-regulationsregulatory-updates/hazardous-waste-management-regulations-update-status) which provides more detail on the proposed amendments.

5. Appropriate Department staff conducted an internal review of the proposed rule on June 3, 2020.

6. The Department had a Notice of Proposed Regulation published in the August 28, 2020, *State Register*. The Department received no public comments by the September 28, 2020, close of the public comment period.

III. Request for Approval

The Bureau respectfully requests the Board to find need and reasonableness of the attached proposed amendments of R.61-79, *Hazardous Waste Management Regulations*, for legal effect as of the November 27, 2020, publication in the *State Register*.

Henry Porter
Bureau Chief

Myra C. Reece
Director

Attachments:
A. Notice of Final Regulation

ATTACHMENT A

STATE REGISTER NOTICE OF FINAL REGULATION
FOR R.61-79, HAZARDOUS WASTE MANAGEMENT REGULATIONS

November 12, 2020

Document No. 4976
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Sections 44-56-10 et seq.

61-79. Hazardous Waste Management Regulations.

Synopsis:

The Department of Health and Environmental Control ("Department") amends R.61-79, Hazardous Waste Management Regulations, to adopt the Environmental Protection Agency ("EPA") final rule "Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine," published on February 22, 2019, at 84 FR 5816-5950. The rule creates new standards for the management of hazardous waste pharmaceuticals by healthcare facilities and reverse distributors in lieu of the existing generator regulations and reduces regulatory burdens for over-the-counter Food and Drug Administration ("FDA")-approved nicotine replacement therapies.

The Department had a Notice of Drafting published in the April 24, 2020, *South Carolina State Register*.

Instructions:

Amend R.61-79 pursuant to each individual instruction provided with the text of the amendments below.

Text:

~~Indicates Matter Stricken~~
Indicates New Matter

61-79. Hazardous Waste Management Regulations.

Statutory Authority: 1976 Code Ann. Section 44-56-30

Revise 261.4(a)(1)(ii) to read:

(ii) Any mixture of domestic sewage and other wastes that passes through a sewer system to a publicly owned treatment works for treatment, except as prohibited by Section 266.505 and Clean Water Act requirements at R.61-9.403.5(b)(1). "Domestic sewage" means untreated sanitary wastes that pass through a sewer system.

Add 261.7(c) to read:

(c) Containers of hazardous waste pharmaceuticals are subject to section 266.507 for determining when they are considered empty, in lieu of this section, except as provided by sections 266.507(c) and (d).

Revise 261.33(c) and comment to read:

(c) Any residue remaining in a container or in an inner liner removed from a container that has held any commercial chemical product or manufacturing chemical intermediate having the generic name listed in paragraphs (e) or (f) of this section, unless the container is empty as defined in Section 261.7(b) or 266.507 of this chapter.

[Comment: Unless the residue is being beneficially used or reused, or legitimately recycled or reclaimed; or being accumulated, stored, transported or treated prior to such use, re-use, recycling or reclamation, the Department considers the residue to be intended for discard, and thus, a hazardous waste. An example of a legitimate re-use of the residue would be where the residue remains in the container and the container is used to hold the same commercial chemical product or manufacturing chemical intermediate it previously held. An example of the discard of the residue would be where the drum is sent to a drum reconditioner who reconditions the drum but discards the residue.]

Revise the entries in 261.33(e) Table to read:

Section 261.33(e) Lists of Acute Hazardous Wastes ~~(amended 11/90; 12/92; 5/96)~~		
Hazardous waste No.	Chemical abstracts No.	Substance
P023	107-20-0	Acetaldehyde, chloro-
P002	591-08-2	Acetamide, N-(aminothioxomethyl)-
P057	640-19-7	Acetamide, 2-fluoro-
P058	62-74-8	Acetic acid, fluoro-, sodium salt
P002	591-08-2	1-Acetyl-2-thiourea
P003	107-02-8	Acrolein
P070	116-06-3	Aldicarb
P203	1646-88-4	Aldicarb sulfone
P004	309-00-2	Aldrin
P005	107-18-6	Allyl alcohol
P006	20859-73-8	Aluminum phosphide (R,T)
P007	2763-96-4	5-(Aminomethyl)-3-isoxazolol
P008	504-24-5	4-Aminopyridine
P009	131-74-8	Ammonium picrate (R)
P119	7803-55-6	Ammonium vanadate
P099	506-61-6	Argentate(1-), bis(cyano-C)-, potassium
P010	7778-39-4	Arsenic acid H3 AsO4
P012	1327-53-3	Arsenic oxide As2 O3
P011	1303-28-2	Arsenic oxide As2 O5
P011	1303-28-2	Arsenic pentoxide
P012	1327-53-3	Arsenic trioxide
P038	692-42-2	Arsine, diethyl-
P036	696-28-6	Arsonous dichloride, phenyl-
P054	151-56-4	Aziridine

Section 261.33(e) Lists of Acute Hazardous Wastes ~~(amended 11/90; 12/92; 5/96)~~		
Hazardous waste No.	Chemical abstracts No.	Substance
P067	75-55-8	Aziridine, 2-methyl-
P013	542-62-1	Barium cyanide
P024	106-47-8	Benzenamine, 4-chloro-
P077	100-01-6	Benzenamine, 4-nitro-
P028	100-44-7	Benzene, (chloromethyl)-
P042	51-43-4	1,2-Benzenediol, 4-[1-hydroxy-2-(methylamino)ethyl]-, (R)-
P046	122-09-8	Benzeneethanamine, alpha,alpha-dimethyl-
P014	108-98-5	Benzenethiol
P127	1563-66-2	7-Benzofuranol, 2,3-dihydro-2,2-dimethyl-, methylcarbamate
P188	57-64-7	Benzoic acid, 2-hydroxy-, compd. with (3aS-cis)-1,2,3,3a,8,8a-hexahydro-1,3a,8-trimethylpyrrolo[2,3-b]indol-5-yl methylcarbamate ester (1:1)
P001	[1] 81-81-2	2H-1-Benzopyran-2-one, 4-hydroxy-3-(3-oxo-1-phenylbutyl)-, & salts, when present at concentrations greater than 0.3%
P028	100-44-7	Benzyl chloride
P015	7440-41-7	Beryllium powder
P017	598-31-2	Bromoacetone
P018	357-57-3	Brucine
P045	39196-18-4	2-Butanone, 3,3-dimethyl-1-(methylthio)-, O-[(methylamino)carbonyl] oxime
P021	592-01-8	Calcium cyanide
P021	592-01-8	Calcium cyanide Ca(CN)2
P189	55285-14-8	Carbamic acid, [(dibutylamino)- thio]methyl-, 2,3-dihydro-2,2-dimethyl- 7-benzofuranyl ester.
P191	644-64-4	Carbamic acid, dimethyl-, 1-[(dimethyl-amino) carbonyl]- 5-methyl-1H- pyrazol-3-yl ester
P192	119-38-0	Carbamic acid, dimethyl-, 3-methyl-1- (1-methylethyl)-1H- pyrazol-5-yl ester.
P190	1129-41-5	Carbamic acid, methyl-, 3-methylphenyl ester
P127	1563-66-2	Carbofuran
P022	75-15-0	Carbon disulfide
P095	75-44-5	Carbonic dichloride
P189	55285-14-8	Carbosulfan
P023	107-20-0	Chloroacetaldehyde
P024	106-47-8	p-Chloroaniline
P026	5344-82-1	1-(o-Chlorophenyl)thiourea
P027	542-76-7	3-Chloropropionitrile
P029	544-92-3	Copper cyanide
P029	544-92-3	Copper cyanide Cu(CN)
P202	64-00-6	m-Cumenyl methylcarbamate.
P030		Cyanides (soluble cyanide salts), not otherwise specified

Section 261.33(e) Lists of Acute Hazardous Wastes ~~(amended 11/90; 12/92; 5/96)~~		
Hazardous waste No.	Chemical abstracts No.	Substance
P031	460-19-5	Cyanogen
P033	506-77-4	Cyanogen chloride
P033	506-77-4	Cyanogen chloride (CN)Cl
P034	131-89-5	2-Cyclohexyl-4,6-dinitrophenol
P016	542-88-1	Dichloromethyl ether
P036	696-28-6	Dichlorophenylarsine
P037	60-57-1	Dieldrin
P038	692-42-2	Diethylarsine
P041	311-45-5	Diethyl-p-nitrophenyl phosphate
P040	297-97-2	O,O-Diethyl O-pyrazinyl phosphorothioate
P043	55-91-4	Diisopropylfluorophosphate (DFP)
P004	309-00-2	1,4,5,8-Dimethanonaphthalene, 1,2,3,4,10,10-hexa- chloro-1,4,4a,5,8,8a,-hexahydro-, (1alpha,4alpha,4abeta,5alpha,8alpha,8abeta)-
P060	465-73-6	1,4,5,8-Dimethanonaphthalene, 1,2,3,4,10,10-hexa- chloro-1,4,4a,5,8,8a-hexahydro-, (1alpha,4alpha,4abeta,5beta,8beta,8abeta)-
P037	60-57-1	2,7:3,6-Dimethanonaphth[2,3-b]oxirene, 3,4,5,6,9,9-hexachloro-1a,2,2a,3,6,6a,7,7a-octahydro-, (1aalpha,2beta,2aalpha,3beta,6beta,6aalpha,7beta, 7aalpha)-
P051	[1] 72-20-8	2,7:3,6-Dimethanonaphth [2,3-b]oxirene, 3,4,5,6,9,9-hexachloro-1a,2,2a,3,6,6a,7,7a-octahydro-, (1aalpha,2beta,2abeta,3alpha,6alpha,6abeta,7beta, 7aalpha)-, & metabolites
P044	60-51-5	Dimethoate
P046	122-09-8	alpha,alpha-Dimethylphenethylamine
P191	644-64-4	Dimetilan
P047	[1] 534-52-1	4,6-Dinitro-o-cresol, & salts
P048	51-28-5	2,4-Dinitrophenol
P020	88-85-7	Dinoseb
P085	152-16-9	Diphosphoramide, octamethyl-
P111	107-49-3	Diphosphoric acid, tetraethyl ester
P039	298-04-4	Disulfoton
P049	541-53-7	Dithiobiuret
P185	26419-73-8	1,3-Dithiolane-2-carboxaldehyde, 2,4-dimethyl-, O- [(methylamino)- carbonyl]oxime.
P050	115-29-7	Endosulfan
P088	145-73-3	Endothall
P051	72-20-8	Endrin
P051	72-20-8	Endrin, & metabolites
P042	51-43-4	Epinephrine

Section 261.33(e) Lists of Acute Hazardous Wastes ~~(amended 11/90; 12/92; 5/96)~~		
Hazardous waste No.	Chemical abstracts No.	Substance
P031	460-19-5	Ethanedinitrile
P194	23135-22-0	Ethanimidothioic acid, 2-(dimethylamino)-N-[[(methylamino) carbonyl]oxy]-2-oxo-, methyl ester.
P066	16752-77-5	Ethanimidothioic acid, N-[[(methylamino)carbonyl]oxy]-, methyl ester
P101	107-12-0	Ethyl cyanide
P054	151-56-4	Ethyleneimine
P097	52-85-7	Famphur
P056	7782-41-4	Fluorine
P057	640-19-7	Fluoroacetamide
P058	62-74-8	Fluoroacetic acid, sodium salt
P198	23422-53-9	Formetanate hydrochloride
P197	17702-57-7	Formparanate.
P065	628-86-4	Fulminic acid, mercury(2) salt (R,T)
P059	76-44-8	Heptachlor
P062	757-58-4	Hexaethyl tetraphosphate
P116	79-19-6	Hydrazinecarbothioamide
P068	60-34-4	Hydrazine, methyl-
P063	74-90-8	Hydrocyanic acid
P063	74-90-8	Hydrogen cyanide
P096	7803-51-2	Hydrogen phosphide
P060	465-73-6	Isodrin
P192	119-38-0	Isolan
P202	64-00-6	3-Isopropylphenyl N-methylcarbamate.
P007	2763-96-4	3(2H)-Isoxazolone, 5-(aminomethyl)-
P196	15339-36-3	Manganese, bis(dimethylcarbamodithioato-S,S′)-,
P196	15339-36-3	Manganese dimethyldithiocarbamate
P092	62-38-4	Mercury, (acetato-O)phenyl-
P065	628-86-4	Mercury fulminate (R,T)
P082	62-75-9	Methanamine, N-methyl-N-nitroso-
P064	624-83-9	Methane, isocyanato-
P016	542-88-1	Methane, oxybis[chloro-
P112	509-14-8	Methane, tetranitro- (R)
P118	75-70-7	Methanethiol, trichloro-
P198	23422-53-9	Methanimidamide, N,N-dimethyl-N′-[3-[[(methylamino)-carbonyl]oxy]phenyl]-, monohydrochloride
P197	17702-57-7	Methanimidamide, N,N-dimethyl-N′-[2-methyl-4-[[(methylamino)carbonyl]oxy]phenyl]-

Section 261.33(e) Lists of Acute Hazardous Wastes ~~(amended 11/90; 12/92; 5/96)~~		
Hazardous waste No.	Chemical abstracts No.	Substance
P050	115-29-7	6,9-Methano-2,4,3-benzodioxathiepin, 6,7,8,9,10,10-hexachloro-1,5,5a,6,9,9a-hexahydro-, 3-oxide
P059	76-44-8	4,7-Methano-1H-indene, 1,4,5,6,7,8,8-heptachloro-3a,4,7,7a-tetrahydro-
P199	2032-65-7	Methiocarb
P066	16752-77-5	Methomyl
P068	60-34-4	Methyl hydrazine
P064	624-83-9	Methyl isocyanate
P069	75-86-5	2-Methyllactonitrile
P071	298-00-0	Methyl parathion
P190	1129-41-5	Metolcarb.
P128	315-8-4	Mexacarbate
P072	86-88-4	alpha-Naphthylthiourea
P073	13463-39-3	Nickel carbonyl
P073	13463-39-3	Nickel carbonyl Ni(CO)4, (T-4)-
P074	557-19-7	Nickel cyanide
P074	557-19-7	Nickel cyanide Ni(CN)2
P075	[1] 54-11-5	Nicotine & salts (this listing does not include patches, gums, and lozenges that are FDA-approved over-the-counter nicotine replacement therapies)
P076	10102-43-9	Nitric oxide
P077	100-01-6	p-Nitroaniline
P078	10102-44-0	Nitrogen dioxide
P076	10102-43-9	Nitrogen oxide NO
P078	10102-44-0	Nitrogen oxide NO2
P081	55-63-0	Nitroglycerine (R)
P082	62-75-9	N-Nitrosodimethylamine
P084	4549-40-0	N-Nitrosomethylvinylamine
P085	152-16-9	Octamethylpyrophosphoramide
P087	20816-12-0	Osmium oxide OsO4, (T-4)-
P087	20816-12-0	Osmium tetroxide
P088	145-73-3	7-Oxabicyclo[2.2.1]heptane-2,3-dicarboxylic acid
P194	23135-22-0	Oxamyl
P089	56-38-2	Parathion
P034	131-89-5	Phenol, 2-cyclohexyl-4,6-dinitro-
P048	51-28-5	Phenol, 2,4-dinitro-
P047	[1] 534-52-1	Phenol, 2-methyl-4,6-dinitro-, & salts
P020	88-85-7	Phenol, 2-(1-methylpropyl)-4,6-dinitro-
P009	131-74-8	Phenol, 2,4,6-trinitro-, ammonium salt (R)
P128	315-18-4	Phenol, 4-(dimethylamino)-3,5-dimethyl-, methylcarbamate (ester)

Section 261.33(e) Lists of Acute Hazardous Wastes ~~(amended 11/90; 12/92; 5/96)~~		
Hazardous waste No.	Chemical abstracts No.	Substance
P199	2032-65-7	Phenol, (3,5-dimethyl-4-(methylthio)-, methylcarbamate
P202	64-00-6	Phenol, 3-(1-methylethyl)-, methyl carbamate.
P201	2631-37-0	Phenol, 3-methyl-5-(1-methylethyl)-, methyl carbamate
P092	62-38-4	Phenylmercury acetate
P093	103-85-5	Phenylthiourea
P094	298-02-2	Phorate
P095	75-44-5	Phosgene
P096	7803-51-2	Phosphine
P041	311-45-5	Phosphoric acid, diethyl 4-nitrophenyl ester
P039	298-04-4	Phosphorodithioic acid, O,O-diethyl S-[2-(ethylthio)ethyl] ester
P094	298-02-2	Phosphorodithioic acid, O,O-diethyl S-[(ethylthio)methyl] ester
P044	60-51-5	Phosphorodithioic acid, O,O-dimethyl S-[2-(methylamino)-2-oxoethyl] ester
P043	55-91-4	Phosphorofluoridic acid, bis(1-methylethyl) ester
P089	56-38-2	Phosphorothioic acid, O,O-diethyl O-(4-nitrophenyl) ester
P040	297-97-2	Phosphorothioic acid, O,O-diethyl O-pyrazinyl ester
P097	52-85-7	Phosphorothioic acid, O-[4-[(dimethylamino)sulfonyl]phenyl] O,O-dimethyl ester
P071	298-00-0	Phosphorothioic acid, O,O,-dimethyl O-(4-nitrophenyl) ester
P204	57-47-6	Physostigmine
P188	57-64-7	Physostigmine salicylate
P110	78-00-2	Plumbane, tetraethyl-
P098	151-50-8	Potassium cyanide
P098	151-50-8	Potassium cyanide K(CN)
P099	506-61-6	Potassium silver cyanide
P201	2631-37-0	Promecarb
P070	116-06-3	Propanal, 2-methyl-2-(methylthio)-, O-[(methylamino)carbonyl]oxime
P203	1646-88-4	Propanal, 2-methyl-2-(methyl-sulfonyl)-, O-[(methylamino)carbonyl] oxime
P101	107-12-0	Propanenitrile
P027	542-76-7	Propanenitrile, 3-chloro-
P069	75-86-5	Propanenitrile, 2-hydroxy-2-methyl-
P081	55-63-0	1,2,3-Propanetriol, trinitrate (R)
P017	598-31-2	2-Propanone, 1-bromo-
P102	107-19-7	Propargyl alcohol
P003	107-02-8	2-Propenal
P005	107-18-6	2-Propen-1-ol
P067	75-55-8	1,2-Propylenimine

Section 261.33(e) Lists of Acute Hazardous Wastes ~~(amended 11/90; 12/92; 5/96)~~		
Hazardous waste No.	Chemical abstracts No.	Substance
P102	107-19-7	2-Propyn-1-ol
P008	504-24-5	4-Pyridinamine
P075	[1] 54-11-5	Pyridine, 3-(1-methyl-2- pyrrolidinyl),- (S)-, & salts (this listing does not include patches, gums, and lozenges that are FDA-approved over-the-counter nicotine replacement therapies)
P204	57-47-6	Pyrrolo[2,3-b]indol-5-ol, 1,2,3,3a,8,8a-hexahydro-1,3a,8-trimethyl-, methylcarbamate (ester), (3aS-cis)-
P114	12039-52-0	Selenious acid, dithallium(1) salt
P103	630-10-4	Selenourea
P104	506-64-9	Silver cyanide
P104	506-64-9	Silver cyanide Ag(CN)
P105	26628-22-8	Sodium azide
P106	143-33-9	Sodium cyanide
P106	143-33-9	Sodium cyanide Na(CN)
P108	[1] 57-24-9	Strychnidin-10-one, & salts
P018	357-57-3	Strychnidin-10-one, 2,3-dimethoxy-
P108	[1] 57-24-9	Strychnine, & salts
P115	7446-18-6	Sulfuric acid, dithallium(1) salt
P109	3689-24-5	Tetraethyldithiopyrophosphate
P110	78-00-2	Tetraethyl lead
P111	107-49-3	Tetraethyl pyrophosphate
P112	509-14-8	Tetranitromethane (R)
P062	757-58-4	Tetraphosphoric acid, hexaethyl ester
P113	1314-32-5	Thallic oxide
P113	1314-32-5	Thallium oxide Tl2 O3
P114	12039-52-0	Thallium(I) selenite
P115	7446-18-6	Thallium(I) sulfate
P109	3689-24-5	Thiodiphosphoric acid, tetraethyl ester
P045	39196-18-4	Thiofanox
P049	541-53-7	Thioimidodicarbonic diamide [(H2 N)C(S)]2 NH
P014	108-98-5	Thiophenol
P116	79-19-6	Thiosemicarbazide
P026	5344-82-1	Thiourea, (2-chlorophenyl)-
P072	86-88-4	Thiourea, 1-naphthalenyl-
P093	103-85-5	Thiourea, phenyl-
P185	26419-73-8	Tirpate
P123	8001-35-2	Toxaphene
P118	75-70-7	Trichloromethanethiol
P119	7803-55-6	Vanadic acid, ammonium salt

Section 261.33(e) Lists of Acute Hazardous Wastes ~~(amended 11/90; 12/92; 5/96)~~		
Hazardous waste No.	Chemical abstracts No.	Substance
P120	1314-62-1	Vanadium oxide V2 O5
P120	1314-62-1	Vanadium pentoxide
P084	4549-40-0	Vinylamine, N-methyl-N-nitroso-
P001	[1] 81-81-2	Warfarin, & salts, when present at concentrations greater than 0.3%
P205	137-30-4	Zinc, bis(dimethylcarbamodithioato-S,S′)-,
P121	557-21-1	Zinc cyanide
P121	557-21-1	Zinc cyanide Zn(CN)2
P122	1314-84-7	Zinc phosphide Zn3 P2, when present at concentrations greater than 10% (R,T)
P205	137-30-4	Ziram
P001	[1] 81-81-2	2H-1-Benzopyran-2-one, 4-hydroxy-3-(3-oxo-1-phenylbutyl)-, & salts, when present at concentrations greater than 0.3%
P001	[1] 81-81-2	Warfarin, & salts, when present at concentrations greater than 0.3%
P002	591-08-2	Acetamide, -(aminothioxomethyl)-
P002	591-08-2	1-Acetyl-2-thiourea
P003	107-02-8	Acrolein
P003	107-02-8	2-Propenal
P004	309-00-2	Aldrin
P004	309-00-2	1,4,5,8-Dimethanonaphthalene, 1,2,3,4,10,10-hexa-chloro-1,4,4a,5,8,8a,-hexahydro-, (1alpha,4alpha,4abeta,5alpha,8alpha,8abeta)-
P005	107-18-6	Allyl alcohol
P005	107-18-6	2-Propen-1-ol
P006	20859-73-8	Aluminum phosphide (R,T)
P007	2763-96-4	5-(Aminomethyl)-3-isoxazolol
P007	2763-96-4	3(2H)-Isoxazolone, 5-(aminomethyl)-
P008	504-24-5	4-Aminopyridine
P008	504-24-5	4-Pyridinamine
P009	131-74-8	Ammonium picrate (R)
P009	131-74-8	Phenol, 2,4,6-trinitro-, ammonium salt (R)
P010	7778-39-4	Arsenic acid H3 AsO4
P011	1303-28-2	Arsenic oxide As2 O5
P011	1303-28-2	Arsenic pentoxide
P012	1327-53-3	Arsenic oxide As2 O3
P012	1327-53-3	Arsenic trioxide
P013	542-62-1	Barium cyanide
P014	108-98-5	Benzenethiol
P014	108-98-5	Thiophenol
P015	7440-41-7	Beryllium powder

Section 261.33(e) Lists of Acute Hazardous Wastes ~~(amended 11/90; 12/92; 5/96)~~		
Hazardous waste No.	Chemical abstracts No.	Substance
P016	542-88-1	Dichloromethyl ether
P016	542-88-1	Methane, oxybis[chloro-
P017	598-31-2	Bromoacetone
P017	598-31-2	2-Propanone, 1-bromo-
P018	357-57-3	Brucine
P018	357-57-3	Strychnidin-10-one, 2,3-dimethoxy-
P020	88-85-7	Dinoseb
P020	88-85-7	Phenol, 2-(1-methylpropyl)-4,6-dinitro-
P021	592-01-8	Calcium cyanide
P021	592-01-8	Calcium cyanide Ca(CN)2
P022	75-15-0	Carbon disulfide
P023	107-20-0	Acetaldehyde, chloro-
P023	107-20-0	Chloroacetaldehyde
P024	106-47-8	Benzenamine, 4-chloro-
P024	106-47-8	p-Chloroaniline
P026	5344-82-1	1-(o-Chlorophenyl)thiourea
P026	5344-82-1	Thiourea, (2-chlorophenyl)-
P027	542-76-7	3-Chloropropionitrile
P027	542-76-7	Propanenitrile, 3-chloro-
P028	100-44-7	Benzene, (chloromethyl)-
P028	100-44-7	Benzyl chloride
P029	544-92-3	Copper cyanide
P029	544-92-3	Copper cyanide Cu(CN)
P030		Cyanides (soluble cyanide salts), not otherwise specified
P031	460-19-5	Cyanogen
P031	460-19-5	Ethanedinitrile
P033	506-77-4	Cyanogen chloride
P033	506-77-4	Cyanogen chloride (CN)Cl
P034	131-89-5	2-Cyclohexyl-4,6-dinitrophenol
P034	131-89-5	Phenol, 2-cyclohexyl-4,6-dinitro-
P036	696-28-6	Arsonous dichloride, phenyl-
P036	696-28-6	Dichlorophenylarsine
P037	60-57-1	Dieldrin
P037	60-57-1	2,7:3,6-Dimethanonaphth[2,3-b]oxirene, 3,4,5,6,9,9-hexachloro-1a,2,2a,3,6,6a,7,7a-octahydro-, (1aalpha,2beta,2aalpha,3beta,6beta,6aalpha,7beta, 7aalpha)-
P038	692-42-2	Arsine, diethyl-
P038	692-42-2	Diethylarsine
P039	298-04-4	Disulfoton

Section 261.33(e) Lists of Acute Hazardous Wastes ~~(amended 11/90; 12/92; 5/96)~~		
Hazardous waste No.	Chemical abstracts No.	Substance
P039	298-04-4	Phosphorodithioic acid, O,O-diethyl S-[2-(ethylthio)ethyl] ester
P040	297-97-2	O,O-Diethyl O-pyrazinyl phosphorothioate
P040	297-97-2	Phosphorothioic acid, O,O-diethyl O-pyrazinyl ester
P041	311-45-5	Diethyl-p-nitrophenyl phosphate
P041	311-45-5	Phosphoric acid, diethyl 4-nitrophenyl ester
P042	51-43-4	1,2-Benzenediol, 4-[1-hydroxy-2-(methylamino)ethyl]-, (R)-
P042	51-43-4	Epinephrine
P043	55-91-4	Diisopropylfluorophosphate (DFP)
P043	55-91-4	Phosphorofluoridic acid, bis(1-methylethyl) ester
P044	60-51-5	Dimethoate
P044	60-51-5	Phosphorodithioic acid, O,O-dimethyl S-[2-(methyl amino)-2-oxoethyl] ester
P045	39196-18-4	2-Butanone, 3,3-dimethyl-1-(methylthio)-, O-[(methylamino)carbonyl] oxime
P045	39196-18-4	Thiofanox
P046	122-09-8	Benzeneethanamine, alpha,alpha-dimethyl-
P046	122-09-8	alpha,alpha-Dimethylphenethylamine
P047	[1] 534-52-1	4,6-Dinitro-o-cresol, & salts
P047	[1] 534-52-1	Phenol, 2-methyl-4,6-dinitro-, & salts
P048	51-28-5	2,4-Dinitrophenol
P048	51-28-5	Phenol, 2,4-dinitro-
P049	541-53-7	Dithiobiuret
P049	541-53-7	Thioimidodicarbonic diamide [(H2 N)C(S)]2 NH
P050	115-29-7	Endosulfan
P050	115-29-7	6,9-Methano-2,4,3-benzodioxathiepin, 6,7,8,9,10,10-hexachloro-1,5,5a,6,9,9a-hexahydro-, 3-oxide
P051	[1] 72-20-8	2,7:3,6-Dimethanonaphth [2,3-b]oxirene, 3,4,5,6,9,9-hexachloro-1a,2,2a,3,6,6a,7,7a-octahydro-, (1aalpha,2beta,2abeta,3alpha,6alpha,6abeta,7beta, 7aalpha)-, & metabolites
P051	72-20-8	Endrin
P051	72-20-8	Endrin, & metabolites
P054	151-56-4	Aziridine
P054	151-56-4	Ethyleneimine
P056	7782-41-4	Fluorine
P057	640-19-7	Acetamide, 2-fluoro-
P057	640-19-7	Fluoroacetamide
P058	62-74-8	Acetic acid, fluoro-, sodium salt
P058	62-74-8	Fluoroacetic acid, sodium salt
P059	76-44-8	Heptachlor
P059	76-44-8	4,7-Methano-1H-indene, 1,4,5,6,7,8,8-heptachloro-3a,4,7,7a-tetrahydro-

Section 261.33(e) Lists of Acute Hazardous Wastes ~~(amended 11/90; 12/92; 5/96)~~		
Hazardous waste No.	Chemical abstracts No.	Substance
P060	465-73-6	1,4,5,8-Dimethanonaphthalene, 1,2,3,4,10,10-hexa-chloro-1,4,4a,5,8,8a-hexahydro-, (1alpha,4alpha,4abeta,5beta,8beta,8abeta)-
P060	465-73-6	Isodrin
P062	757-58-4	Hexaethyl tetraphosphate
P062	757-58-4	Tetraphosphoric acid, hexaethyl ester
P063	74-90-8	Hydrocyanic acid
P063	74-90-8	Hydrogen cyanide
P064	624-83-9	Methane, isocyanato-
P064	624-83-9	Methyl isocyanate
P065	628-86-4	Fulminic acid, mercury(2) salt (R,T)
P065	628-86-4	Mercury fulminate (R,T)
P066	16752-77-5	Ethanimidothioic acid, N-[[(methylamino)carbonyl]oxy]-, methyl ester
P066	16752-77-5	Methomyl
P067	75-55-8	Aziridine, 2-methyl-
P067	75-55-8	1,2-Propylenimine
P068	60-34-4	Hydrazine, methyl-
P068	60-34-4	Methyl hydrazine
P069	75-86-5	2-Methyllactonitrile
P069	75-86-5	Propanenitrile, 2-hydroxy-2-methyl-
P070	116-06-3	Aldicarb
P070	116-06-3	Propanal, 2-methyl-2-(methylthio)-, O-[(methylamino)carbonyl]oxime
P071	298-00-0	Methyl parathion
P071	298-00-0	Phosphorothioic acid, O,O,-dimethyl O-(4-nitrophenyl) ester
P072	86-88-4	alpha-Naphthylthiourea
P072	86-88-4	Thiourea, 1-naphthalenyl-
P073	13463-39-3	Nickel carbonyl
P073	13463-39-3	Nickel carbonyl Ni(CO)4, (T-4)-
P074	557-19-7	Nickel cyanide
P074	557-19-7	Nickel cyanide Ni(CN)2
P075	[1] 54-11-5	Nicotine~~,~~ & salts (this listing does not include patches, gums, and lozenges that are FDA-approved over-the-counter nicotine replacement therapies)
P075	[1] 54-11-5	Pyridine, 3-(1-methyl-2-pyrrolidinyl),- (S)-, & salts (this listing does not include patches, gums, and lozenges that are FDA-approved over-the-counter nicotine replacement therapies)
P076	10102-43-9	Nitric oxide
P076	10102-43-9	Nitrogen oxide NO
P077	100-01-6	Benzenamine, 4-nitro-
P077	100-01-6	p-Nitroaniline
P078	10102-44-0	Nitrogen dioxide

Section 261.33(e) Lists of Acute Hazardous Wastes ~~(amended 11/90; 12/92; 5/96)~~		
Hazardous waste No.	Chemical abstracts No.	Substance
P078	10102-44-0	Nitrogen oxide NO2
P081	55-63-0	Nitroglycerine (R)
P081	55-63-0	1,2,3-Propanetriol, trinitrate (R)
P082	62-75-9	Methanamine, -methyl-N-nitroso-
P082	62-75-9	N-Nitrosodimethylamine
P084	4549-40-0	N-Nitrosomethylvinylamine
P084	4549-40-0	Vinylamine, -methyl-N-nitroso-
P085	152-16-9	Diphosphoramide, octamethyl-
P085	152-16-9	Octamethylpyrophosphoramide
P087	20816-12-0	Osmium oxide OsO4, (T-4)-
P087	20816-12-0	Osmium tetroxide
P088	145-73-3	Endothall
P088	145-73-3	7-Oxabicyclo[2.2.1]heptane-2,3-dicarboxylic acid
P089	56-38-2	Parathion
P089	56-38-2	Phosphorothioic acid, O,O-diethyl O-(4-nitrophenyl) ester
P092	62-38-4	Mercury, (acetato-O)phenyl-
P092	62-38-4	Phenylmercury acetate
P093	103-85-5	Phenylthiourea
P093	103-85-5	Thiourea, phenyl-
P094	298-02-2	Phorate
P094	298-02-2	Phosphorodithioic acid, O,O-diethyl S-[(ethylthio)methyl] ester
P095	75-44-5	Carbonic dichloride
P095	75-44-5	Phosgene
P096	7803-51-2	Hydrogen phosphide
P096	7803-51-2	Phosphine
P097	52-85-7	Famphur
P097	52-85-7	Phosphorothioic acid, O-[4-[(dimethylamino)sulfonyl]phenyl] O,O-dimethyl ester
P098	151-50-8	Potassium cyanide
P098	151-50-8	Potassium cyanide K(CN)
P099	506-61-6	Argentate(1-), bis(cyano-C)-, potassium
P099	506-61-6	Potassium silver cyanide
P101	107-12-0	Ethyl cyanide
P101	107-12-0	Propanenitrile
P102	107-19-7	Propargyl alcohol
P102	107-19-7	2-Propyn-1-ol
P103	630-10-4	Selenourea
P104	506-64-9	Silver cyanide
P104	506-64-9	Silver cyanide Ag(CN)

Section 261.33(e) Lists of Acute Hazardous Wastes ~~(amended 11/90; 12/92; 5/96)~~		
Hazardous waste No.	Chemical abstracts No.	Substance
P105	26628-22-8	Sodium azide
P106	143-33-9	Sodium cyanide
P106	143-33-9	Sodium cyanide Na(CN)
P108	[1] 157-24-9	Strychnidin-10-one, & salts
P108	[1] 157-24-9	Strychnine, & salts
P109	3689-24-5	Tetraethyldithiopyrophosphate
P109	3689-24-5	Thiodiphosphoric acid, tetraethyl ester
P110	78-00-2	Plumbane, tetraethyl-
P110	78-00-2	Tetraethyl lead
P111	107-49-3	Diphosphoric acid, tetraethyl ester
P111	107-49-3	Tetraethyl pyrophosphate
P112	509-14-8	Methane, tetranitro-(R)
P112	509-14-8	Tetranitromethane (R)
P113	1314-32-5	Thallic oxide
P113	1314-32-5	Thallium oxide Tl2 O3
P114	12039-52-0	Selenious acid, dithallium(1) salt
P114	12039-52-0	Tetraethyldithiopyrophosphate
P115	7446-18-6	Thiodiphosphoric acid, tetraethyl ester
P115	7446-18-6	Plumbane, tetraethyl-
P116	79-19-6	Tetraethyl lead
P116	79-19-6	Thiosemicarbazide
P118	75-70-7	Methanethiol, trichloro-
P118	75-70-7	Trichloromethanethiol
P119	7803-55-6	Ammonium vanadate
P119	7803-55-6	Vanadic acid, ammonium salt
P120	1314-62-1	Vanadium oxide V2O5
P120	1314-62-1	Vanadium pentoxide
P121	557-21-1	Zinc cyanide
P121	557-21-1	Zinc cyanide Zn(CN)2
P122	1314-84-7	Zinc phosphide Zn3 P2, when present at concentrations greater than 10% (R,T)
P123	8001-35-2	Toxaphene
P127	1563-66-2	7-Benzofuranol, 2,3-dihydro-2,2-dimethyl-, methylcarbamate
P127	1563-66-2	Carbofuran
P128	315-8-4	Mexacarbate
P128	315-18-4	Phenol, 4-(dimethylamino)-3,5-dimethyl-, methylcarbamate (ester)
P185	26419-73-8	1,3-Dithiolane-2-carboxaldehyde, 2,4-dimethyl-, O-[(methylamino)-carbonyl]oxime
P185	26419-73-8	Tirpate

Section 261.33(e) Lists of Acute Hazardous Wastes ~~(amended 11/90; 12/92; 5/96)~~		
Hazardous waste No.	Chemical abstracts No.	Substance
P188	57-64-7	Benzoic acid, 2-hydroxy-, compd. with (3aS-cis)-1,2,3,3a,8,8a-hexahydro-1,3a,8-trimethylpyrrolo[2,3-b]indol-5-yl methylcarbamate ester (1:1)
P188	57-64-7	Physostigmine salicylate
P189	55285-14-8	Carbamic acid, [(dibutylamino)-thio]methyl-, 2,3-dihydro-2,2-dimethyl-7-benzofuranyl ester
P189	55285-14-8	Carbosulfan
P190	1129-41-5	Carbamic acid, methyl-, 3-methylphenyl ester
P190	1129-41-5	Metolcarb
P191	644-64-4	Carbamic acid, dimethyl-, 1-[(dimethyl-amino)carbonyl]-5-methyl-1H-pyrazol-3-yl ester
P191	644-64-4	Dimetilan
P192	119-38-0	Carbamic acid, dimethyl-, 3-methyl-1-(1-methylethyl)-1H-pyrazol-5-yl ester
P192	119-38-0	Isolan
P194	23135-22-0	Ethanimidthioic acid, 2-(dimethylamino)-N-[[(methylamino) carbonyl]oxy]-2-oxo-, methyl ester
P194	23135-22-0	Oxamyl
P196	15339-36-3	Manganese, bis(dimethylcarbamodithioato-S,S′)-,
P196	15339-36-3	Manganese dimethyldithiocarbamate
P197	17702-57-7	Formparanate
P197	17702-57-7	Methanimidamide, N,N-dimethyl-N′-[2-methyl-4-[[(methylamino)carbonyl]oxy]phenyl]-
P198	23422-53-9	Formetanate hydrochloride
P198	23422-53-9	Methanimidamide, N,N-dimethyl-N′-[3-[[(methylamino)-carbonyl]oxy]phenyl]-monohydrochloride
P199	2032-65-7	Methiocarb
P199	2032-65-7	Phenol, (3,5-dimethyl-4-(methylthio)-, methylcarbamate
P201	2631-37-0	Phenol, 3-methyl-5-(1-methylethyl)-, methyl carbamate
P201	2631-37-0	Promecarb
P202	64-00-6	m-Cumenyl methylcarbamate
P202	64-00-6	3-Isopropylphenyl N-methylcarbamate
P202	64-00-6	Phenol, 3-(1-methylethyl)-, methyl carbamate
P203	1646-88-4	Aldicarb sulfone
P203	1646-88-4	Propanal, 2-methyl-2-(methyl-sulfonyl)-, O-[(methylamino)carbonyl] oxime
P204	57-47-6	Physostigmine
P204	57-47-6	Pyrrolo[2,3-b]indol-5-ol, 1,2,3,3a,8,8a-hexahydro-1,3a,8-trimethyl-, methylcarbamate (ester), (3aS-cis)-
P205	137-30-4	Zinc, bis(dimethylcarbamodithioato-S,S′)-,
P205	137-30-4	Ziram

Add 262.10(m) to read:

(m) All reverse distributors (as defined in Section 266.500) are subject to part 266, subpart P for the management of hazardous waste pharmaceuticals in lieu of this part.

Add 262.10(n) to read:

(n) Each healthcare facility (as defined in Section 266.500) must determine whether it is subject to part 266, subpart P for the management of hazardous waste pharmaceuticals, based on the total hazardous waste it generates per calendar month (including both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste). A healthcare facility that generates more than 100 kg (220 pounds) of hazardous waste per calendar month, or more than 1 kg (2.2 pounds) of acute hazardous waste per calendar month, or more than 100 kg (220 pounds) per calendar month of any residue or contaminated soil, water, or other debris, resulting from the cleanup of a spill, into or on any land or water, of any acute hazardous wastes listed in Section 261.31 or Section 261.33(e), is subject to part 266, subpart P for the management of hazardous waste pharmaceuticals in lieu of this part. A healthcare facility that is a very small quantity generator when counting all of its hazardous waste, including both its hazardous waste pharmaceuticals and its non-pharmaceutical hazardous waste, remains subject to Section 262.14 and is not subject to part 266, subpart P, except for Sections 266.505 and 266.507 and the optional provisions of Section 266.504.

Add 262.13 (c)(9) to read:

(9) Is a hazardous waste pharmaceutical, as defined in Section 266.500, that is subject to or managed in accordance with part 266, subpart P or is a hazardous waste pharmaceutical that is also a Drug Enforcement Administration controlled substance and is conditionally exempt under Section 266.506.

Add 262.14(a)(5)(ix) to read:

(ix) A reverse distributor (as defined in Section 266.500), if the hazardous waste pharmaceutical is a potentially creditable hazardous waste pharmaceutical generated by a healthcare facility (as defined in Section 266.500).

Add 262.14(a)(5)(x) to read:

(x) A healthcare facility (as defined in Section 266.500) that meets the conditions in Sections 266.502(l) and 266.503(b), as applicable, to accept non-creditable hazardous waste pharmaceuticals and potentially creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator.

Add and reserve 264.1(g)(12) to read:

(12) [Reserved]

Add 264.1(g)(13) to read:

(13) Reverse distributors accumulating potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals, as defined in Section 266.500. Reverse distributors are subject to regulation under part 266, subpart P in lieu of this part for the accumulation of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

Add and reserve 265.1(c)(15) to read:

(15) [Reserved]

Add 265.1(c)(16) to read:

(16) Reverse distributors accumulating potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals, as defined in Section 266.500. Reverse distributors are subject to regulation under part 266, subpart P in lieu of this part for the accumulation of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

Revise the 266.Table of Contents to read:

SUBPART O: [RESERVED]

SUBPART P: HAZARDOUS WASTE PHARMACEUTICALS

Add 266.500 to read:

266.500. Definitions for this subpart.

The following definitions apply to this subpart:

"Evaluated hazardous waste pharmaceutical" means a prescription hazardous waste pharmaceutical that has been evaluated by a reverse distributor in accordance with Section 266.510(a)(3) and will not be sent to another reverse distributor for further evaluation or verification of manufacture credit.

"Hazardous waste pharmaceutical" means a pharmaceutical that is a solid waste, as defined in Section 261.2, and exhibits one or more characteristics identified in part 261 subpart C or is listed in part 261, subpart D. A pharmaceutical is not a solid waste, as defined in Section 261.2, and therefore not a hazardous waste pharmaceutical, if it is legitimately used/reused (e.g., lawfully donated for its intended purpose) or reclaimed. An over-the-counter pharmaceutical, dietary supplement, or homeopathic drug is not a solid waste, as defined in Section 261.2, and therefore not a hazardous waste pharmaceutical, if it has a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for its intended purpose) or reclaimed.

"Healthcare facility" means any person that is lawfully authorized to –

(1) provide preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling, service, assessment or procedure with respect to the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body; or

(2) distribute, sell, or dispense pharmaceuticals, including over-the-counter pharmaceuticals, dietary supplements, homeopathic drugs, or prescription pharmaceuticals. This definition includes, but is not limited to, wholesale distributors, third-party logistics providers that serve as forward distributors, military medical logistics facilities, hospitals, psychiatric hospitals, ambulatory surgical centers, health clinics, physicians' offices, optical and dental providers, chiropractors, long-term care facilities, ambulance services, pharmacies, long-term care pharmacies, mail-order pharmacies, retailers of pharmaceuticals, veterinary clinics, and veterinary hospitals. This definition does not include pharmaceutical manufacturers, reverse distributors, or reverse logistics centers.

"Household waste pharmaceutical" means a pharmaceutical that is a solid waste, as defined in Section 261.2, but is excluded from being a hazardous waste under Section 261.4(b)(1).

"Long-term care facility" means a licensed entity that provides assistance with activities of daily living, including managing and administering pharmaceuticals to one or more individuals at the facility. This definition includes, but is not limited to, hospice facilities, nursing facilities, skilled nursing facilities, and the nursing and skilled nursing care portions of continuing care retirement communities. Not included within the scope of this definition are group homes, independent living communities, assisted living facilities, and the independent and assisted living portions of continuing care retirement communities.

"Non-creditable hazardous waste pharmaceutical" means a prescription hazardous waste pharmaceutical that does not have a reasonable expectation to be eligible for manufacturer credit or a nonprescription hazardous waste pharmaceutical that does not have a reasonable expectation to be legitimately used/reused or reclaimed. This includes but is not limited to, investigational drugs, free samples of pharmaceuticals received by healthcare facilities, residues of pharmaceuticals remaining in empty containers, contaminated personal protective equipment, floor sweepings, and clean-up material from the spills of pharmaceuticals.

"Non-hazardous waste pharmaceutical" means a pharmaceutical that is a solid waste, as defined in Section 261.2, and is not listed in part 261, subpart D, and does not exhibit a characteristic identified in part 261, subpart C.

"Non-pharmaceutical hazardous waste" means a solid waste, as defined in Section 261.2, that is listed in part 261, subpart D, or exhibits one or more characteristics identified in part 261, subpart C, but is not a pharmaceutical, as defined in this Section.

"Pharmaceutical" means any drug or dietary supplement for use by humans or other animals; any electronic nicotine delivery system (e.g., electronic cigarette or vaping pen); or any liquid nicotine (e-liquid) packaged for retail sale for use in electronic nicotine delivery systems (e.g., pre-filled cartridges or vials). This definition includes, but is not limited to, dietary supplements, as defined by the Federal Food, Drug and Cosmetic Act; prescription drugs, as defined by 21 CFR 203.3(y); over-the-counter drugs; homeopathic drugs; compounded drugs; investigational new drugs; pharmaceuticals remaining in non-empty containers; personal protective equipment contaminated with pharmaceuticals; and clean-up material from spills of pharmaceuticals. This definition does not include dental amalgam or sharps.

"Potentially creditable hazardous waste pharmaceutical" means a prescription hazardous waste pharmaceutical that has a reasonable expectation to receive manufacturer credit and is-

(1) in original manufacturer packaging (except pharmaceuticals that were subject to a recall);

(2) undispensed; and

(3) unexpired or less than one year past expiration date.

The term does not include evaluated hazardous waste pharmaceuticals or nonprescription pharmaceuticals including, but not limited to, over-the-counter drugs, homeopathic drugs, and dietary supplements.

"Reverse distributor" means any person that receives and accumulates prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit. Any person, including forward distributors, third-party logistics providers, and pharmaceutical manufacturers, that processes prescription pharmaceuticals for the facilitation or verification of manufacturer credit is considered a reverse distributor.

Add 266.501 to read:

266.501. Applicability.

(a) A healthcare facility that is a very small quantity generator when counting all of its hazardous waste, including both its hazardous waste pharmaceuticals and its non-pharmaceutical hazardous waste, remains subject to Section 262.14 and is not subject to this subpart, except for Sections 266.505 and 266.507 and the optional provisions of Section 266.504.

(b) A healthcare facility that is a very small quantity generator when counting all of its hazardous waste, including both its hazardous waste pharmaceuticals and its non-pharmaceutical hazardous waste, has the option of complying with Section 266.501(d) for the management of its hazardous waste pharmaceuticals as an alternative to complying with Section 262.14 and the optional provisions of Section 266.504.

(c) A healthcare facility or reverse distributor remains subject to all applicable hazardous waste regulations with respect to the management of its non-pharmaceutical hazardous waste.

(d) With the exception of healthcare facilities identified in subsection (a), a healthcare facility is subject to the following in lieu of parts 262–265:

(1) Sections 266.502 and 266.505 through 266.508 of this subpart with respect to the management of:

(i) Non-creditable hazardous waste pharmaceuticals, and

(ii) Potentially creditable hazardous waste pharmaceuticals if they are not destined for a reverse distributor.

(2) Sections 262.502(a), 266.503, 266.505 through 266.507, and 266.509 of this subpart with respect to the management of potentially creditable hazardous waste pharmaceuticals that are prescription pharmaceuticals and are destined for a reverse distributor.

(e) A reverse distributor is subject to Sections 266.505 through 266.510 of this subpart in lieu of parts 262 through 265 with respect to the management of hazardous waste pharmaceuticals.

(f) Hazardous waste pharmaceuticals generated or managed by entities other than healthcare facilities and reverse distributors (e.g., pharmaceutical manufacturers and reverse logistics centers) are not subject to this subpart. Other generators are subject to 40 CFR part 262 for the generation and accumulation of hazardous wastes, including hazardous waste pharmaceuticals.

(g) The following are not subject to parts 260 through 273, except as specified:

(1) Pharmaceuticals that are not solid waste, as defined by Section 261.2, because they are legitimately used/re-used (e.g., lawfully donated for their intended purpose) or reclaimed.

(2) Over-the-counter pharmaceuticals, dietary supplements, or homeopathic drugs that are not solid wastes, as defined by Section 261.2, because they have a reasonable expectation of being legitimately used/re-used (e.g., lawfully redistributed for their intended purpose) or reclaimed.

(3) Pharmaceuticals being managed in accordance with a recall strategy that has been approved by the Food and Drug Administration in accordance with 21 CFR part 7, subpart C. This subpart does apply to the management of the recalled hazardous waste pharmaceuticals after the Food and Drug Administration approves the destruction of the recalled items.

(4) Pharmaceuticals being managed in accordance with a recall corrective action plan that has been accepted by the Consumer Product Safety Commission in accordance with 16 CFR part 1115. This subpart does apply to the management of the recalled hazardous waste pharmaceuticals after the Consumer Product Safety Commission approves the destruction of the recalled items.

(5) Pharmaceuticals stored according to a preservation order, or during an investigation or judicial proceeding until after the preservation order, investigation, or judicial proceeding has concluded and/or a decision is made to discard the pharmaceuticals.

(6) Investigational new drugs for which an investigational new drug application is in effect in accordance with the Food and Drug Administration's regulations in 21 CFR part 312. This subpart does apply to the management of the investigational new drug after the decision is made to discard the investigational new drug or the Food and Drug Administration approves the destruction of the investigational new drug, if the investigational new drug is a hazardous waste.

(7) Household waste pharmaceuticals, including those that have been collected by an authorized collector (as defined by the Drug Enforcement Administration), provided the authorized collector complies with the conditional exemption in Sections 266.506(a)(2) and 266.506(b).

Add 266.502 to read:

266.502. Standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals.

(a) Notification and withdrawal from this subpart for healthcare facilities managing hazardous waste pharmaceuticals—

(1) Notification. A healthcare facility must notify the Department, using the Site Identification Form (EPA Form 8700-12), that it is a healthcare facility operating under this subpart. A healthcare facility is not required to fill out Box 10.B. (Waste Codes for Federally Regulated Hazardous Waste) of the Site

Identification Form with respect to its hazardous waste pharmaceuticals. A healthcare facility must submit a separate notification (Site Identification Form) for each site or EPA identification number.

(i) A healthcare facility that already has an EPA identification number must notify the Department using the Site Identification Form (EPA Form 8700-12) that it is a healthcare facility. A large quantity generator must notify the Department in its next quarterly report per Section 262.41. A small quantity generator must notify the Department in its annual declaration per Section 262.44.

(ii) A healthcare facility that does not have an EPA identification number must obtain one by notifying the Department using the Site Identification Form (EPA Form 8700-12) that it is a healthcare facility within thirty (30) calendar days of the effective date of this subpart or within thirty (30) calendar days of becoming subject to this subpart.

(iii) A healthcare facility must keep a copy of its notification on file for as long as the healthcare facility is subject to this subpart.

(2) Withdrawal. A healthcare facility that operated under this subpart but is no longer subject to this subpart, because it is a very small quantity generator under Section 262.14, and elects to withdraw from this subpart, must notify the Department using the Site Identification Form (EPA Form 8700-12) that it is no longer operating under this subpart. A healthcare facility is not required to fill out Box 10.B. (Waste Codes for Federally Regulated Hazardous Waste) of the Site Identification Form with respect to its hazardous waste pharmaceuticals. A healthcare facility must submit a separate notification (Site Identification Form) for each EPA identification number.

(i) A healthcare facility must submit the Site Identification Form notifying that it is withdrawing from this subpart before it begins operating under the conditional exemption of Section 262.14.

(ii) A healthcare facility must keep a copy of its withdrawal on file for three years from the date of signature on the notification of its withdrawal.

(b) Training of personnel managing non-creditable hazardous waste pharmaceuticals at healthcare facilities. A healthcare facility must ensure that all personnel that manage non-creditable hazardous waste pharmaceuticals are thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies.

(c) Hazardous waste determination for non-creditable pharmaceuticals. A healthcare facility that generates a solid waste that is a non-creditable pharmaceutical must determine whether that pharmaceutical is a hazardous waste pharmaceutical (i.e., it exhibits a characteristic identified in part 261, subpart C or is listed in part 261, subpart D) in order to determine whether the waste is subject to this subpart. A healthcare facility may choose to manage its non-hazardous waste pharmaceuticals as non-creditable hazardous waste pharmaceuticals under this subpart.

(d) Standards for containers used to accumulate non-creditable hazardous waste pharmaceuticals at healthcare facilities.

(1) A healthcare facility must place non-creditable hazardous waste pharmaceuticals in a container that is structurally sound, compatible with its contents, and that lacks evidence of leakage, spillage, or damage that could cause leakage under reasonably foreseeable conditions.

(2) A healthcare facility that manages ignitable or reactive non-creditable hazardous waste pharmaceuticals, or that mixes or commingles incompatible non-creditable hazardous waste pharmaceuticals must manage the container so that it does not have the potential to:

(i) Generate extreme heat or pressure, fire or explosion, or violent reaction;

(ii) Produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health;

(iii) Produce uncontrolled flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions;

(iv) Damage the structural integrity of the container of non-creditable hazardous waste pharmaceuticals; or

(v) Through other like means threaten human health or the environment.

(3) A healthcare facility must keep containers of non-creditable hazardous waste pharmaceuticals closed and secured in a manner that prevents unauthorized access to its contents.

(4) A healthcare facility may accumulate non-creditable hazardous waste pharmaceuticals and non-hazardous non-creditable waste pharmaceuticals in the same container, except that non-creditable hazardous waste pharmaceuticals prohibited from being combusted because of the dilution prohibition of Section 268.3(c) must be accumulated in separate containers and labeled with all applicable hazardous waste numbers (i.e., hazardous waste codes).

(e) Labeling containers used to accumulate non-creditable hazardous waste pharmaceuticals at healthcare facilities. A healthcare facility must label or clearly mark each container of non-creditable hazardous waste pharmaceuticals with the phrase "Hazardous Waste Pharmaceuticals."

(f) Maximum accumulation time for non-creditable hazardous waste pharmaceuticals at healthcare facilities.

(1) A healthcare facility may accumulate non-creditable hazardous waste pharmaceuticals on-site for one (1) year or less without a permit or having interim status.

(2) A healthcare facility that accumulates non-creditable hazardous waste pharmaceuticals on-site must demonstrate the length of time that the non-creditable hazardous waste pharmaceuticals have been accumulating, starting from the date it first becomes a waste. A healthcare facility may make this demonstration by any of the following methods:

(i) Marking or labeling the container of non-creditable hazardous waste pharmaceuticals with the date that the non-creditable hazardous waste pharmaceuticals became a waste;

(ii) Maintaining an inventory system that identifies the date the non-creditable hazardous waste pharmaceuticals being accumulated first became a waste; or

(iii) Placing the non-creditable hazardous waste pharmaceuticals in a specific area and identifying the earliest date that any of the non-creditable hazardous waste pharmaceuticals in the area became a waste.

(g) Land disposal restrictions for non-creditable hazardous waste pharmaceuticals. The non-creditable hazardous waste pharmaceuticals generated by a healthcare facility are subject to the land disposal restrictions of part 268. A healthcare facility that generates non-creditable hazardous waste pharmaceuticals must comply with the land disposal restrictions in accordance with Section 268.7(a) requirements, except that it is not required to identify the hazardous waste numbers (i.e., hazardous waste codes) on the land disposal restrictions notification.

(h) Procedures for healthcare facilities for managing rejected shipments of non-creditable hazardous waste pharmaceuticals. A healthcare facility that sends a shipment of non-creditable hazardous waste pharmaceuticals to a designated facility with the understanding that the designated facility can accept and manage the waste, and later receives that shipment back as a rejected load in accordance with the manifest discrepancy provisions of Section 264.72 or Section 265.72 of this chapter may accumulate the returned non-creditable hazardous waste pharmaceuticals on-site for up to an additional ninety (90) calendar days provided the rejected or returned shipment is managed in accordance with paragraphs (d) and (e) of this section. Upon receipt of the returned shipment, the healthcare facility must:

(1) Sign either:

(i) Item 18c of the original manifest, if the original manifest was used for the returned shipment; or

(ii) Item 20 of the new manifest, if a new manifest was used for the returned shipment;

(2) Provide the transporter a copy of the manifest;

(3) Within thirty (30) calendar days of receipt of the rejected shipment, send a copy of the manifest to the designated facility that returned the shipment to the healthcare facility; and

(4) Within ninety (90) calendar days of receipt of the rejected shipment, transport or offer for transport the returned shipment in accordance with the shipping standards of Section 266.508(a).

(i) Reporting by healthcare facilities for non-creditable hazardous waste pharmaceuticals.

(1) Reporting by healthcare facilities. Healthcare facilities are not subject to reporting requirements under Section 262.41 or Section 262.44 with respect to non-creditable hazardous waste pharmaceuticals managed under this subpart.

(2) Exception reporting by healthcare facilities for a missing copy of the manifest.

(i) For shipments from a healthcare facility to a designated facility:

(A) If a healthcare facility does not receive a copy of the manifest with the signature of the owner or operator of the designated facility within sixty (60) days of the date the non-creditable hazardous waste pharmaceuticals were accepted by the initial transporter, the healthcare facility must submit:

(*1*) A legible copy of the original manifest, indicating that the healthcare facility has not received confirmation of delivery, to the Department for the Region in which the healthcare facility is located, and

(*2*) A handwritten or typed note on the manifest itself, or on an attached sheet of paper, stating that the return copy was not received and explaining the efforts taken to locate the non-creditable hazardous waste pharmaceuticals and the results of those efforts.

(B) [Reserved]

(ii) For shipments rejected by the designated facility and shipped to an alternate facility.

(A) If a healthcare facility does not receive a copy of the manifest for a rejected shipment of the non-creditable hazardous waste pharmaceuticals that is forwarded by the designated facility to an alternate facility (using appropriate manifest procedures), with the signature of the owner or operator of the alternate facility, within sixty (60) days of the date the non-creditable hazardous waste was accepted by the initial transporter forwarding the shipment of non-creditable hazardous waste pharmaceuticals from the designated facility to the alternate facility, the healthcare facility must submit:

(*1*) A legible copy of the original manifest, indicating that the healthcare facility has not received confirmation of delivery, to the Department for the state in which the healthcare facility is located; and

(*2*) A handwritten or typed note on the manifest itself, or on an attached sheet of paper, stating that the return copy was not received and explaining the efforts taken to locate the non-creditable hazardous waste pharmaceuticals and the results of those efforts.

(B) [Reserved]

(3) Additional reports. The Department may require healthcare facilities to furnish additional reports concerning the quantities and disposition of non-creditable hazardous waste pharmaceuticals.

(j) Recordkeeping by healthcare facilities for non-creditable hazardous waste pharmaceuticals.

(1) A healthcare facility must keep a copy of each manifest signed in accordance with Section 262.23(a) for three (3) years or until it receives a signed copy from the designated facility that received the non-creditable hazardous waste pharmaceuticals. This signed copy must be retained as a record for at least three (3) years from the date the waste was accepted by the initial transporter.

(2) A healthcare facility must keep a copy of each exception report for a period of at least three (3) years from the date of the report.

(3) A healthcare facility must keep records of any test results, waste analyses, or other determinations made to support its hazardous waste determination(s) consistent with Section 262.11(f), for at least three (3) years from the date the waste was last sent to on-site or off-site treatment, storage, or disposal. A healthcare facility that manages all of its non-creditable non-hazardous waste pharmaceuticals as non-creditable hazardous waste pharmaceuticals is not required to keep documentation of hazardous waste determinations.

(4) The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the Department.

(5) All records must be readily available upon request by an inspector.

(k) Response to spills of non-creditable hazardous waste pharmaceuticals at healthcare facilities. A healthcare facility must immediately contain all spills of non-creditable hazardous waste pharmaceuticals and manage the spill clean-up materials as non-creditable hazardous waste pharmaceuticals in accordance with the requirements of this subpart.

(l) Accepting non-creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator. A healthcare facility may accept non-creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator under Section 262.14, without a permit or without having interim status, provided the receiving healthcare facility:

(1) Is under the control of the same person (as defined in Section 260.10) as the very small quantity generator healthcare facility that is sending the non-creditable hazardous waste pharmaceuticals off-site ("control," for the purposes of this section, means the power to direct the policies of the healthcare facility, whether by the ownership of stock, voting rights, or otherwise, except that contractors who operate healthcare facilities on behalf of a different person as defined in Section 260.10 of this chapter shall not be deemed to "control" such healthcare facilities) or has a contractual or other documented business relationship whereby the receiving healthcare facility supplies pharmaceuticals to the very small quantity generator healthcare facility;

(2) Is operating under this subpart for the management of its non-creditable hazardous waste pharmaceuticals;

(3) Manages the non-creditable hazardous waste pharmaceuticals that it receives from off site in compliance with this subpart; and

(4) Keeps records of the non-creditable hazardous waste pharmaceuticals shipments it receives from off site for three years from the date that the shipment is received.

Add 266.503 to read:

266.503. Standards for healthcare facilities managing potentially creditable hazardous waste pharmaceuticals.

(a) Hazardous waste determination for potentially creditable pharmaceuticals. A healthcare facility that generates a solid waste that is a potentially creditable pharmaceutical must determine whether the potentially creditable pharmaceutical is a potentially creditable hazardous waste pharmaceutical (i.e., it is listed in part 261, subpart D or exhibits a characteristic identified in part 261, subpart C). A healthcare facility may choose to manage its potentially creditable non-hazardous waste pharmaceuticals as potentially creditable hazardous waste pharmaceuticals under this subpart.

(b) Accepting potentially creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator. A healthcare facility may accept potentially creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator under Section 262.14, without a permit or without having interim status, provided the receiving healthcare facility:

(1) Is under the control of the same person, as defined in Section 260.10, as the very small quantity generator healthcare facility that is sending the potentially creditable hazardous waste pharmaceuticals off site, or has a contractual or other documented business relationship whereby the receiving healthcare facility supplies pharmaceuticals to the very small quantity generator healthcare facility;

(2) Is operating under this subpart for the management of its potentially creditable hazardous waste pharmaceuticals;

(3) Manages the potentially creditable hazardous waste pharmaceuticals that it receives from off site in compliance with this subpart; and

(4) Keeps records of the potentially creditable hazardous waste pharmaceuticals shipments it receives from off site for three (3) years from the date that the shipment is received.

(c) Prohibition. Healthcare facilities are prohibited from sending hazardous wastes other than potentially creditable hazardous waste pharmaceuticals to a reverse distributor.

(d) Reporting by healthcare facilities. Healthcare facilities are not subject to reporting requirements under Section 262.41 or Section 262.44 with respect to potentially creditable hazardous waste pharmaceuticals managed under this subpart.

(e) Recordkeeping by healthcare facilities.

(1) A healthcare facility that initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor must keep the following records (paper or electronic) for each shipment of potentially creditable hazardous waste pharmaceuticals for three (3) years from the date of shipment:

(i) The confirmation of delivery; and

(ii) The shipping papers prepared in accordance with 49 CFR part 172, subpart C, if applicable.

(2) The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the Department.

(3) All records must be readily available upon request by an inspector.

(f) Response to spills of potentially creditable hazardous waste pharmaceuticals at healthcare facilities. A healthcare facility must immediately contain all spills of potentially creditable hazardous waste pharmaceuticals and manage the spill clean-up materials as non-creditable hazardous waste pharmaceuticals in accordance with this subpart.

Add 266.504 to read:

266.504. Healthcare facilities that are very small quantity generators for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste.

(a) Potentially creditable hazardous waste pharmaceuticals. A healthcare facility that is a very small quantity generator for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may send its potentially creditable hazardous waste pharmaceuticals to a reverse distributor.

(b) Off-site collection of hazardous waste pharmaceuticals generated by a healthcare facility that is a very small quantity generator. A healthcare facility that is a very small quantity generator for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may send its hazardous waste pharmaceuticals off-site to another healthcare facility, provided:

(1) The receiving healthcare facility meets the conditions in Section 266.502(l) of this subpart and Section 266.503(b), as applicable; or

(2) The very small quantity generator healthcare facility meets the conditions in section 262.14(a)(5)(viii) and the receiving large quantity generator meets the conditions in Section 262.17(f).

(c) Long-term care facilities that are very small quantity generators. A long-term care facility that is a very small quantity generator for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may dispose of its hazardous waste pharmaceuticals (excluding contaminated personal protective equipment or clean-up materials) in an on-site collection receptacle of an authorized collector (as defined by the Drug Enforcement Administration) that is registered with the Drug Enforcement Administration provided the contents are collected, stored, transported, destroyed, and disposed of in compliance with all applicable Drug Enforcement Administration regulations for controlled substances.

(d) Long-term care facilities with twenty (20) beds or fewer. A long-term care facility with twenty (20) beds or fewer is presumed to be a very small quantity generator subject to Section 262.14 for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste and not subject to this subpart, except for Sections 266.505 and 266.507 and the other optional provisions of this section. The Department has the responsibility to demonstrate that a long-term care facility with twenty (20) beds or fewer generates quantities of hazardous waste that are in excess of the very small quantity generator limits as defined in Section 260.10. A long-term care facility with more than twenty (20) beds that operates as a very small quantity generator under Section 262.14 must demonstrate that it generates quantities of hazardous waste that are within the very small quantity generator limits as defined by Section 260.10.

Add 266.505 to read:

266.505. Prohibition of sewering hazardous waste pharmaceuticals.

All healthcare facilities—including very small quantity generators operating under section 262.14 in lieu of this subpart—and reverse distributors are prohibited from discharging hazardous waste pharmaceuticals to a sewer system that passes through to a publicly owned treatment works. Healthcare facilities and reverse distributors remain subject to the prohibitions in R.61-9.403.5(b)(1).

Add 266.506 to read:

266.506. Conditional exemptions for hazardous waste pharmaceuticals that are also controlled substances and household waste pharmaceuticals collected in a take-back event or program.

(a) Conditional exemptions. Provided the conditions of paragraph (b) of this section are met, the following are exempt from parts 262 through 273:

(1) Hazardous waste pharmaceuticals that are also listed on a schedule of controlled substances by the Drug Enforcement Administration in 21 CFR part 1308, and

(2) Household waste pharmaceuticals that are collected in a take-back event or program, including those that are collected by an authorized collector (as defined by the Drug Enforcement Administration) registered with the Drug Enforcement Administration that commingles the household waste pharmaceuticals with controlled substances from an ultimate user (as defined by the Drug Enforcement Administration).

(b) Conditions for exemption. The hazardous waste pharmaceuticals must be:

(1) Managed in compliance with the sewer prohibition of Section 266.505;

(2) Collected, stored, transported, and disposed of in compliance with all applicable Drug Enforcement Administration regulations for controlled substances; and

(3) Destroyed by a method that the Drug Enforcement Administration has publicly deemed in writing to meet their non-retrievable standard of destruction or combusted at one of the following:

(i) A permitted large municipal waste combustor, subject to 40 CFR part 62, subpart FFF or applicable state plan for existing large municipal waste combustors, or 40 CFR part 60, subpart Eb for new large municipal waste combustors; or

(ii) A permitted small municipal waste combustor, subject to 40 CFR part 62, subpart JJJ or applicable state plan for existing small municipal waste combustors, or 40 CFR part 60, subpart AAAA for new small municipal waste combustors; or

(iii) A permitted hospital, medical and infectious waste incinerator, subject to 40 CFR part 62, subpart HHH or applicable state plan for existing hospital, medical and infectious waste incinerators, or 40 CFR part 60, subpart Ec for new hospital, medical and infectious waste incinerators.

(iv) A permitted commercial and industrial solid waste incinerator, subject to 40 CFR part 62, subpart III or applicable state plan for existing commercial and industrial solid waste incinerators, or 40 CFR part 60, subpart CCCC for new commercial and industrial solid waste incinerators.

(v) A permitted hazardous waste combustor subject to 40 CFR part 63, subpart EEE.

Add 266.507 to read:

266.507. Residues of hazardous waste pharmaceuticals in empty containers.

(a) Stock, dispensing, and unit-dose containers. A stock bottle, dispensing bottle, vial, or ampule (not to exceed 1 liter or 10,000 pills); or a unit-dose container (e.g., a unit-dose packet, cup, wrapper, blister pack, or delivery device) is considered empty and the residues are not regulated as hazardous waste provided the pharmaceuticals have been removed from the stock bottle, dispensing bottle, vial, ampule, or the unit-dose container using the practices commonly employed to remove materials from that type of container.

(b) Syringes. A syringe is considered empty and the residues are not regulated as hazardous waste under this subpart provided the contents have been removed by fully depressing the plunger of the syringe. If a syringe is not empty, the syringe must be placed with its remaining hazardous waste pharmaceuticals into a container that is managed and disposed of as a non-creditable hazardous waste pharmaceutical under this subpart and any applicable federal, state, and local requirements for sharps containers and medical waste.

(c) Intravenous (IV) bags. An intravenous (IV) bag is considered empty and the residues are not regulated as hazardous waste provided the pharmaceuticals in the intravenous (IV) bag have been fully administered to a patient. If an intravenous (IV) bag is not empty, the intravenous (IV) bag must be placed with its remaining hazardous waste pharmaceuticals into a container that is managed and disposed of as a non-creditable hazardous waste pharmaceutical under this subpart, unless the intravenous (IV) bag held non-acute hazardous waste pharmaceuticals and is empty as defined in Section 261.7(b)(1).

(d) Other containers, including delivery devices. Hazardous waste pharmaceuticals remaining in all other types of unused, partially administered, or fully administered containers must be managed as non-creditable hazardous waste pharmaceuticals under this subpart, unless the container held non-acute hazardous waste pharmaceuticals and is empty as defined in Section 261.7(b)(1) or (2). This includes, but is not limited to, residues in inhalers, aerosol cans, nebulizers, tubes of ointments, gels, or creams.

Add 266.508 to read:

266.508. Shipping non-creditable hazardous waste pharmaceuticals from a healthcare facility or evaluated hazardous waste pharmaceuticals from a reverse distributor.

(a) Shipping non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals. A healthcare facility must ship non-creditable hazardous waste pharmaceuticals and a reverse distributor must ship evaluated hazardous waste pharmaceuticals off-site to a designated facility (such as a permitted or interim status treatment, storage, or disposal facility) in compliance with:

(1) The following pre-transport requirements, before transporting or offering for transport off-site:

(i) Packaging. Package the waste in accordance with the applicable U.S. Department of Transportation regulations on hazardous materials under 49 CFR parts 173, 178, and 180.

(ii) Labeling. Label each package in accordance with the applicable U.S. Department of Transportation regulations on hazardous materials under 49 CFR part 172, subpart E.

(iii) Marking.

(A) Mark each package of hazardous waste pharmaceuticals in accordance with the applicable U.S. Department of Transportation regulations on hazardous materials under 49 CFR part 172, subpart D;

(B) Mark each container of 119 gallons or less used in such transportation with the following words and information in accordance with the requirements of 49 CFR 172.304:

"HAZARDOUS WASTE—Federal Law Prohibits Improper Disposal. If found, contact the nearest police or public safety authority or the U.S. Environmental Protection Agency.

Healthcare Facility's or Reverse distributor's Name and Address _____.

Healthcare Facility's or Reverse distributor's EPA Identification Number_____.

Manifest Tracking Number _____."

(C) Lab packs that will be incinerated in compliance with Section 268.42(c) are not required to be marked with EPA Hazardous Waste Number(s), except D004, D005, D006, D007, D008, D010, and D011, where applicable. A nationally recognized electronic system, such as bar coding or radio frequency identification, may be used to identify the EPA Hazardous Waste Number(s).

(iv) Placarding. Placard or offer the initial transporter the appropriate placards according to U.S. Department of Transportation regulations for hazardous materials under 49 CFR part 172, subpart F.

(2) The manifest requirements of part 262, subpart B, except that:

(i) A healthcare facility shipping non-creditable hazardous waste pharmaceuticals is not required to list all applicable hazardous waste numbers (i.e., hazardous waste codes) in Item 13 of EPA Form 8700-22.

(ii) A healthcare facility shipping non-creditable hazardous waste pharmaceuticals must write the word "PHARMS" in Item 13 of EPA Form 8700-22.

(b) Exporting non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals. A healthcare facility or reverse distributor that exports non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals is subject to part 262, subpart H.

(c) Importing non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals. Any person that imports non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals is subject to part 262, subpart H. A healthcare facility or reverse distributor may not accept imported non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals unless they have a permit or interim status that allows them to accept hazardous waste from off site.

Add 266.509 to read:

266.509. Shipping potentially creditable hazardous waste pharmaceuticals from a healthcare facility or a reverse distributor to a reverse distributor.

(a) Shipping potentially creditable hazardous waste pharmaceuticals. A healthcare facility or a reverse distributor who transports or offers for transport potentially creditable hazardous waste pharmaceuticals off-site to a reverse distributor must comply with all applicable U.S. Department of Transportation regulations in 49 CFR part 171 through 180 for any potentially creditable hazardous waste pharmaceutical that meets the definition of hazardous material in 49 CFR 171.8. For purposes of the U.S. Department of Transportation regulations, a material is considered a hazardous waste if it is subject to the Hazardous Waste Manifest Requirements of the U.S. Environmental Protection Agency specified in 40 CFR part 262. Because a potentially creditable hazardous waste pharmaceutical does not require a manifest, it is not considered hazardous waste under the U.S. Department of Transportation regulations.

(b) Delivery confirmation. Upon receipt of each shipment of potentially creditable hazardous waste pharmaceuticals, the receiving reverse distributor must provide confirmation (paper or electronic) to the healthcare facility or reverse distributor that initiated the shipment that the shipment of potentially creditable hazardous waste pharmaceuticals has arrived at its destination and is under the custody and control of the reverse distributor.

(c) Procedures for when delivery confirmation is not received within thirty-five (35) calendar days. If a healthcare facility or reverse distributor initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor and does not receive delivery confirmation within thirty-five (35) calendar days from the date that the shipment of potentially creditable hazardous waste pharmaceuticals was sent, the healthcare facility or reverse distributor that initiated the shipment must contact the carrier and the intended recipient (i.e., the reverse distributor) promptly to report that the delivery confirmation was not received and to determine the status of the potentially creditable hazardous waste pharmaceuticals.

(d) Exporting potentially creditable hazardous waste pharmaceuticals. A healthcare facility or reverse distributor that sends potentially creditable hazardous waste pharmaceuticals to a foreign destination must

comply with the applicable sections of part 262, subpart H, except the manifesting requirement of Section 262.83(c), in addition to paragraphs (a) through (c) of this section.

(e) Importing potentially creditable hazardous waste pharmaceuticals. Any person that imports potentially creditable hazardous waste pharmaceuticals into the United States is subject to paragraphs (a) through (c) of this section in lieu of part 262, subpart H. Immediately after the potentially creditable hazardous waste pharmaceuticals enter the United States, they are subject to all applicable requirements of this subpart.

Add 266.510 to read:

266.510. Standards for the management of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals at reverse distributors.

A reverse distributor may accept potentially creditable hazardous waste pharmaceuticals from off site and accumulate potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals on-site without a hazardous waste permit or without having interim status, provided that it complies with the following conditions:

(a) Standards for reverse distributors managing potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals—

(1) Notification. A reverse distributor must notify the Department, using the Site Identification Form (EPA Form 8700-12), that it is a reverse distributor operating under this subpart.

(i) A reverse distributor that already has an EPA identification number must notify the Department, using the Site Identification Form (EPA Form 8700-12), that it is a reverse distributor, as defined in section 266.500, within 60 days of the effective date of this subpart, or within 60 days of becoming subject to this subpart.

(ii) A reverse distributor that does not have an EPA identification number must obtain one by notifying the Department, using the Site Identification Form (EPA Form 8700-12), that it is a reverse distributor, as defined in Section 266.500, within sixty (60) calendar days of the effective date of this subpart, or within sixty (60) calendar days of becoming subject to this subpart.

(2) Inventory by the reverse distributor. A reverse distributor must maintain a current inventory of all the potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that are accumulated on-site.

(i) A reverse distributor must inventory each potentially creditable hazardous waste pharmaceutical within thirty (30) calendar days of each waste arriving at the reverse distributor.

(ii) The inventory must include the identity (e.g., name or national drug code) and quantity of each potentially creditable hazardous waste pharmaceutical and evaluated hazardous waste pharmaceutical.

(iii) If the reverse distributor already meets the inventory requirements of this paragraph because of other regulatory requirements, such as State Board of Pharmacy regulations, the facility is not required to provide a separate inventory pursuant to this section.

(3) Evaluation by a reverse distributor that is not a manufacturer. A reverse distributor that is not a pharmaceutical manufacturer must evaluate a potentially creditable hazardous waste pharmaceutical within

thirty (30) calendar days of the waste arriving at the reverse distributor to establish whether it is destined for another reverse distributor for further evaluation or verification of manufacturer credit or for a permitted or interim status treatment, storage, or disposal facility.

(i) A potentially creditable hazardous waste pharmaceutical that is destined for another reverse distributor is still considered a "potentially creditable hazardous waste pharmaceutical" and must be managed in accordance with paragraph (b) of this section.

(ii) A potentially creditable hazardous waste pharmaceutical that is destined for a permitted or interim status treatment, storage, or disposal facility is considered an "evaluated hazardous waste pharmaceutical" and must be managed in accordance with paragraph (c) of this section.

(4) Evaluation by a reverse distributor that is a manufacturer. A reverse distributor that is a pharmaceutical manufacturer must evaluate a potentially creditable hazardous waste pharmaceutical to verify manufacturer credit within thirty (30) calendar days of the waste arriving at the facility and following the evaluation must manage the evaluated hazardous waste pharmaceuticals in accordance with paragraph (c) of this section.

(5) Maximum accumulation time for hazardous waste pharmaceuticals at a reverse distributor.

(i) A reverse distributor may accumulate potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals on-site for one hundred eighty (180) calendar days or less. The one hundred eighty (180) days start after the potentially creditable hazardous waste pharmaceutical has been evaluated and applies to all hazardous waste pharmaceuticals accumulated on-site, regardless of whether they are destined for another reverse distributor (i.e., potentially creditable hazardous waste pharmaceuticals) or a permitted or interim status treatment, storage, or disposal facility (i.e., evaluated hazardous waste pharmaceuticals).

(ii) Aging pharmaceuticals. Unexpired pharmaceuticals that are otherwise creditable but are awaiting their expiration date (i.e., aging in a holding morgue) can be accumulated for up to 180 days after the expiration date, provided that the unexpired pharmaceuticals are managed in accordance with paragraph (a) of this section and the container labeling and management standards in Section 266.510(c)(4)(i)-(vi).

(6) Security at the reverse distributor facility. A reverse distributor must prevent unknowing entry and minimize the possibility for the unauthorized entry into the portion of the facility where potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals are kept.

(i) Examples of methods that may be used to prevent unknowing entry and minimize the possibility for unauthorized entry include, but are not limited to:

(A) A 24-hour continuous monitoring surveillance system;

(B) An artificial barrier such as a fence; or

(C) A means to control entry, such as keycard access.

(ii) If the reverse distributor already meets the security requirements of this paragraph because of other regulatory requirements, such as Drug Enforcement Administration or State Board of Pharmacy regulations, the facility is not required to provide separate security measures pursuant to this section.

(7) Contingency plan and emergency procedures at a reverse distributor. A reverse distributor that accepts potentially creditable hazardous waste pharmaceuticals from off-site must prepare a contingency plan and comply with the other requirements of part 262, subpart M.

(8) Closure of a reverse distributor. When closing an area where a reverse distributor accumulates potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals, the reverse distributor must comply with Section 262.17(a)(8)(ii) and (iii).

(9) Reporting by a reverse distributor.

(i) Unauthorized waste report. A reverse distributor must submit an unauthorized waste report if the reverse distributor receives waste from off site that it is not authorized to receive (e.g., non-pharmaceutical hazardous waste, regulated medical waste). The reverse distributor must prepare and submit an unauthorized waste report to the Department within forty-five (45) calendar days after the unauthorized waste arrives at the reverse distributor and must send a copy of the unauthorized waste report to the healthcare facility (or other entity) that sent the unauthorized waste. The reverse distributor must manage the unauthorized waste in accordance with all applicable regulations. The unauthorized waste report must be signed by the owner or operator of the reverse distributor, or its authorized representative, and contain the following information:

(A) The EPA identification number, name and address of the reverse distributor;

(B) The date the reverse distributor received the unauthorized waste;

(C) The EPA identification number, name, and address of the healthcare facility that shipped the unauthorized waste, if available;

(D) A description and the quantity of each unauthorized waste the reverse distributor received;

(E) The method of treatment, storage, or disposal for each unauthorized waste; and

(F) A brief explanation of why the waste was unauthorized, if known.

(ii) Additional reports. The Department may require reverse distributors to furnish additional reports concerning the quantities and disposition of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

(10) Recordkeeping by reverse distributors. A reverse distributor must keep the following records (paper or electronic) readily available upon request by an inspector. The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the Department.

(i) A copy of its notification on file for as long as the facility is subject to this subpart;

(ii) A copy of the delivery confirmation and the shipping papers for each shipment of potentially creditable hazardous waste pharmaceuticals that it receives, and a copy of each unauthorized waste report, for at least three (3) years from the date the shipment arrives at the reverse distributor;

(iii) A copy of its current inventory for as long as the facility is subject to this subpart.

(b) Additional standards for reverse distributors managing potentially creditable hazardous waste pharmaceuticals destined for another reverse distributor. A reverse distributor that does not have a permit or interim status must comply with the following conditions, in addition to the requirements in paragraph (a) of this section, for the management of potentially creditable hazardous waste pharmaceuticals that are destined for another reverse distributor for further evaluation or verification of manufacturer credit:

(1) A reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from a healthcare facility must send those potentially creditable hazardous waste pharmaceuticals to another reverse distributor within one hundred eighty (180) calendar days after the potentially creditable hazardous waste pharmaceuticals have been evaluated or follow paragraph (c) of this section for evaluated hazardous waste pharmaceuticals.

(2) A reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from another reverse distributor must send those potentially creditable hazardous waste pharmaceuticals to a reverse distributor that is a pharmaceutical manufacturer within one hundred eighty (180) calendar days after the potentially creditable hazardous waste pharmaceuticals have been evaluated or follow paragraph (c) of this section for evaluated hazardous waste pharmaceuticals.

(3) A reverse distributor must ship potentially creditable hazardous waste pharmaceuticals destined for another reverse distributor in accordance with Section 266.509.

(4) Recordkeeping by reverse distributors. A reverse distributor must keep the following records (paper or electronic) readily available upon request by an inspector for each shipment of potentially creditable hazardous waste pharmaceuticals that it initiates to another reverse distributor, for at least three (3) years from the date of shipment. The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the Department.

(i) The confirmation of delivery; and

(ii) The DOT shipping papers prepared in accordance with 49 CFR part 172, subpart C, if applicable.

(c) Additional standards for reverse distributors managing evaluated hazardous waste pharmaceuticals. A reverse distributor that does not have a permit or interim status must comply with the following conditions, in addition to the requirements of paragraph (a) of this section, for the management of evaluated hazardous waste pharmaceuticals:

(1) Accumulation area at the reverse distributor. A reverse distributor must designate an on-site accumulation area where it will accumulate evaluated hazardous waste pharmaceuticals.

(2) Inspections of on-site accumulation area. A reverse distributor must inspect its on-site accumulation area at least once every seven (7) calendar days, looking at containers for leaks and for deterioration caused by corrosion or other factors, as well as for signs of diversion.

(3) Personnel training at a reverse distributor. Personnel at a reverse distributor that handle evaluated hazardous waste pharmaceuticals are subject to the training requirements of Section 262.17(a)(7).

(4) Labeling and management of containers at on-site accumulation areas. A reverse distributor accumulating evaluated hazardous waste pharmaceuticals in containers in an on-site accumulation area must:

(i) Label the containers with the words, “hazardous waste pharmaceuticals”;

(ii) Ensure the containers are in good condition and managed to prevent leaks;

(iii) Use containers that are made of or lined with materials that will not react with, and are otherwise compatible with, the evaluated hazardous waste pharmaceuticals, so that the ability of the container to contain the waste is not impaired;

(iv) Keep containers closed, if holding liquid or gel evaluated hazardous waste pharmaceuticals. If the liquid or gel evaluated hazardous waste pharmaceuticals are in their original, intact, sealed packaging; or repackaged, intact, sealed packaging, they are considered to meet the closed container standard;

(v) Manage any container of ignitable or reactive evaluated hazardous waste pharmaceuticals, or any container of commingled incompatible evaluated hazardous waste pharmaceuticals so that the container does not have the potential to:

(A) Generate extreme heat or pressure, fire or explosion, or violent reaction;

(B) Produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health;

(C) Produce uncontrolled flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions;

(D) Damage the structural integrity of the container of hazardous waste pharmaceuticals; or

(E) Through other like means threaten human health or the environment; and

(vi) Accumulate evaluated hazardous waste pharmaceuticals that are prohibited from being combusted because of the dilution prohibition of Section 268.3(c) (e.g., arsenic trioxide (P012)) in separate containers from other evaluated hazardous waste pharmaceuticals at the reverse distributor.

(5) Hazardous waste numbers. Prior to shipping evaluated hazardous waste pharmaceuticals off site, all containers must be marked with the applicable hazardous waste numbers (i.e., hazardous waste codes). A nationally recognized electronic system, such as bar coding or radio frequency identification, may be used to identify the EPA Hazardous Waste Number(s).

(6) Shipments. A reverse distributor must ship evaluated hazardous waste pharmaceuticals that are destined for a permitted or interim status treatment, storage, or disposal facility in accordance with the applicable shipping standards in Section 266.508(a) or (b).

(7) Procedures for a reverse distributor for managing rejected shipments. A reverse distributor that sends a shipment of evaluated hazardous waste pharmaceuticals to a designated facility with the understanding that the designated facility can accept and manage the waste, and later receives that shipment back as a rejected load in accordance with the manifest discrepancy provisions of Section 264.72 or Section 265.72 of this chapter, may accumulate the returned evaluated hazardous waste pharmaceuticals on-site for up to an additional ninety (90) calendar days in the on-site accumulation area provided the rejected or returned shipment is managed in accordance with Sections 266.510(a) and (c). Upon receipt of the returned shipment, the reverse distributor must:

(i) Sign either:

(A) Item 18c of the original manifest, if the original manifest was used for the returned shipment; or

(B) Item 20 of the new manifest, if a new manifest was used for the returned shipment;

(ii) Provide the transporter a copy of the manifest;

(iii) Within thirty (30) calendar days of receipt of the rejected shipment of the evaluated hazardous waste pharmaceuticals, send a copy of the manifest to the designated facility that returned the shipment to the reverse distributor; and

(iv) Within ninety (90) calendar days of receipt of the rejected shipment, transport, or offer for transport the returned shipment of evaluated hazardous waste pharmaceuticals in accordance with the applicable shipping standards of Section 266.508(a) or (b).

(8) Land disposal restrictions. Evaluated hazardous waste pharmaceuticals are subject to the land disposal restrictions of part 268. A reverse distributor that accepts potentially creditable hazardous waste pharmaceuticals from off-site must comply with the land disposal restrictions in accordance with Section 268.7(a) requirements.

(9) Reporting by a reverse distributor for evaluated hazardous waste pharmaceuticals.

(i) Reporting by a reverse distributor. A reverse distributor that ships more than 1,000 kg per month of evaluated hazardous waste pharmaceuticals off-site must report to the Department in its quarterly report per Section 262.41. A reverse distributor that ships less than 1,000 kg per month of evaluated hazardous waste pharmaceuticals off-site must report to the Department in its annual declaration per Section 262.44.

(ii) Exception reporting by a reverse distributor for a missing copy of the manifest.

(A) For shipments from a reverse distributor to a designated facility.

(*1*) If a reverse distributor does not receive a copy of the manifest with the signature of the owner or operator of the designated facility within thirty-five (35) calendar days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter, the reverse distributor must contact the transporter or the owner or operator of the designated facility to determine the status of the evaluated hazardous waste pharmaceuticals.

(*2*) A reverse distributor must submit an exception report to the Department for the state in which the reverse distributor is located if it has not received a copy of the manifest with the signature of the owner or operator of the designated facility within forty-five (45) calendar days of the date the evaluated hazardous waste pharmaceutical was accepted by the initial transporter. The exception report must include:

(*i*) A legible copy of the manifest for which the reverse distributor does not have confirmation of delivery; and

(*ii*) A cover letter signed by the reverse distributor, or its authorized representative, explaining the efforts taken to locate the evaluated hazardous waste pharmaceuticals and the results of those efforts.

(B) For shipments rejected by the designated facility and shipped to an alternate facility.

(*1*) A reverse distributor that does not receive a copy of the manifest with the signature of the owner or operator of the alternate facility within thirty-five (35) calendar days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter must contact the transporter or the owner or operator of the alternate facility to determine the status of the hazardous waste. The thirty-five (35)-day time frame begins the date the evaluated hazardous waste pharmaceuticals are accepted by the transporter forwarding the hazardous waste shipment from the designated facility to the alternate facility.

(*2*) A reverse distributor must submit an exception report to the Department for the state in which the reverse distributor is located if it has not received a copy of the manifest with the signature of the owner or operator of the alternate facility within forty-five (45) calendar days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter. The forty-five (45)-day timeframe begins the date the evaluated hazardous waste pharmaceuticals are accepted by the transporter forwarding the hazardous waste pharmaceutical shipment from the designated facility to the alternate facility. The exception report must include:

(*i*) A legible copy of the manifest for which the generator does not have confirmation of delivery; and

(*ii*) A cover letter signed by the reverse distributor, or its authorized representative, explaining the efforts taken to locate the evaluated hazardous waste pharmaceuticals and the results of those efforts.

(10) Recordkeeping by a reverse distributor for evaluated hazardous waste pharmaceuticals.

(i) A reverse distributor must keep a log (written or electronic) of the inspections of the on-site accumulation area, required by paragraph (c)(2) of this section. This log must be retained as a record for at least three (3) years from the date of the inspection.

(ii) A reverse distributor must keep a copy of each manifest signed in accordance with Section 262.23(a) for three (3) years or until it receives a signed copy from the designated facility that received the evaluated hazardous waste pharmaceutical. This signed copy must be retained as a record for at least three (3) years from the date the evaluated hazardous waste pharmaceutical was accepted by the initial transporter.

(iii) A reverse distributor must keep a copy of each quarterly report or annual declaration for at least three (3) years from the due date of the report or declaration.

(iv) A reverse distributor must keep a copy of each exception report for at least three years from the submission of the report.

(v) A reverse distributor must keep records to document personnel training, in accordance with Section 262.17(a)(7)(iv).

(vi) All records must be readily available upon request by an inspector. The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the Department.

(d) When a reverse distributor must have a permit. A reverse distributor is an operator of a hazardous waste treatment, storage, or disposal facility and is subject to the requirements of parts 264, 265, and the permit requirements of part 270, if the reverse distributor:

(1) Does not meet the conditions of this section;

(2) Accepts manifested hazardous waste from off site; or

(3) Treats or disposes of hazardous waste pharmaceuticals on-site.

Revise 268.7 title and item (a) to read:

268.7. Testing, tracking, and recordkeeping requirements for generators, reverse distributors, treaters, and disposal facilities.

(a) Requirements for generators and reverse distributors:

Add 268.50(a)(4) and (5) to read:

(4) A healthcare facility accumulates such wastes in containers on-site solely for the purpose of the accumulation of such quantities of hazardous waste pharmaceuticals as necessary to facilitate proper recovery, treatment, or disposal and the healthcare facility complies with the applicable requirements in Sections 266.502 and 266.503 of this chapter.

(5) A reverse distributor accumulates such wastes in containers on-site solely for the purpose of the accumulation of such quantities of hazardous waste pharmaceuticals as necessary to facilitate proper recovery, treatment, or disposal and the reverse distributor complies with Section 266.510 of this chapter.

Revise 270.1(c)(2)(x) to read:

(x) ~~Any transporter who moves hazardous waste only on the site of a hazardous waste generator or a permitted hazardous waste treatment, storage or disposal facility.~~Reverse distributors accumulating potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals, as defined in Section 266.500. Reverse distributors are subject to regulation under part 266, subpart P for the accumulation of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

Add 270.1(c)(2)(xi) to read:

(xi) Any transporter who moves hazardous waste only on the site of a hazardous waste generator or a permitted hazardous waste treatment, storage or disposal facility.

Revise 273.80(a) to read:

(a) Except as provided in paragraph (d) of this section, ~~A~~any person seeking to add a hazardous waste or a category of hazardous waste to this part may petition for a regulatory amendment under this subpart and 260.20 and 260.23.

Add 273.80(d) to read:

(d) Hazardous waste pharmaceuticals are regulated by part 266, subpart P and may not be added as a category of hazardous waste for management under this part.

Statement of Need and Reasonableness:

The following presents an analysis of the factors listed in 1976 Code Sections 1-23-115(C)(1)-(3) and (9)-(11):

DESCRIPTION OF REGULATION: 61-79, Hazardous Waste Management Regulations.

Purpose: The purpose of these amendments is to maintain state consistency with the following EPA regulation published in the Federal Register: "Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine" rule, published on February 22, 2019, at 84 FR 5816-5950.

Legal Authority: 1976 Code Sections 44-56-10 et seq.

Plan for Implementation: The Department's Regulation Development Update (accessible at http://www.scdhec.gov/Agency/RegulationsAndUpdates/RegulationDevelopmentUpdate/) provides a summary of and link to this amendment. Additionally, printed copies are available for a fee from the Department's Freedom of Information Office. Upon taking legal effect, Department personnel will take appropriate steps to inform the regulated community of the amendment and any associated information.

DETERMINATION OF NEED AND REASONABLENESS OF THE REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

The Department adopts the "Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine" rule, published on February 22, 2019, at 84 FR 5816-5950. This rule creates new standards for the management of hazardous waste pharmaceuticals by healthcare facilities and reverse distributors in lieu of the existing generator regulations and reduces regulatory burdens for over-the-counter FDA-approved nicotine replacement therapies. Adoption of this rule is required to comply with federal law and brings R.61-79 into conformity with the federal regulations.

DETERMINATION OF COSTS AND BENEFITS:

The EPA estimates that the annualized cost to industry to comply with the requirements will be off-set by the cost-savings resulting from streamlined management standards for healthcare facilities and regulatory relief with regards to FDA-approved over-the-counter nicotine replacement therapy products (Federal Register, Vol. 84, No. 36, page 5818). The provisions of the final rule are expected to improve regulatory clarity and reduce regulatory burden. Additionally, to the extent that the rule reduces concentrations of hazardous waste pharmaceuticals in surface and drinking waters, this rule may result in improved ecosystems and human health outcomes.

UNCERTAINTIES OF ESTIMATES:

There are no uncertainties of estimates relative to the costs to the state or its political subdivisions.

EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH:

The revisions to R.61-79 provide continued protection of the environment and human health in accordance with updates to federal law.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED:

If the Department does not adopt these amendments, the EPA's delegation of authority to the state to implement environmental protection programs would be compromised. As a delegated state program, the EPA requires South Carolina's regulations be at least as stringent as the federal regulations. Adoption of these revisions ensure equivalency with federal requirements.

Date: November 12, 2020

To: S.C. Board of Health and Environmental Control

From: Bureau of Land and Waste Management

Re: Public Hearing for Notice of Final Regulation Amending R.61-79, *Hazardous Waste Management Regulations*, Document No. 4975

I. Introduction

The Bureau of Land and Waste Management ("Bureau") proposes the attached Notice of Final Regulation amending R.61-79, *Hazardous Waste Management Regulations*. Legal authority resides in the South Carolina Hazardous Waste Management Act, S.C. Code Ann. § 44-56-10 *et seq*., which authorizes the Department of Health and Environmental Control ("Department") to promulgate hazardous waste management regulations, procedures, or standards as may be necessary to protect human health and the environment. The Administrative Procedures Act, S.C. Code Ann. § 1-23-120(A), requires General Assembly review of these proposed amendments.

II. Facts

1. Pursuant to the South Carolina Hazardous Waste Management Act, S.C. Code Ann. §§ 44-56-10 *et seq*., the Department is authorized to promulgate hazardous waste management regulations, procedures, or standards as may be necessary to protect human and environmental health.

2. The Bureau proposes amending R.61-79, *Hazardous Waste Management Regulations*, to adopt Environmental Protection Agency ("EPA") interim final rule "Safe Management of Recalled Airbags," published on November 30, 2018, at 83 FR 61552-61563. This rule provides a conditional exemption from the Resource Conservation and Recovery Act ("RCRA") hazardous waste requirements for entities, including but not limited to, automobile dealerships, automotive salvage and scrap yards, independent repair facilities, and collision centers that collect airbag modules and inflators ("airbag waste") from automobiles as long as certain conditions are met. This rule enables expedited removal of defective airbag inflators.

3. The Bureau also proposes amending R.61-79, *Hazardous Waste Management Regulations*, to adopt EPA final rule "Universal Waste Regulations: Addition of Aerosol Cans," published on December 9, 2019, at 84 FR 67202-67220. This rule adds hazardous waste aerosol cans to the universal waste program under the federal RCRA regulations. Adopting the rule will reduce regulatory burdens on retail stores and other establishments that generate, manage, and dispose of aerosol cans by providing a clear, protective system for handling waste aerosol cans. This will promote the collection and recycling of aerosol cans and encourage the development of municipal and commercial programs to reduce the amount of aerosol can waste going to municipal solid waste landfills or combustors.

4. The Bureau had a Notice of Drafting published in the April 24, 2020, *State Register*. The Bureau received no comments during the public comment period.

5. The Bureau published a summary of the proposed amendments on the Department's Regulation Development Update website. The Bureau provided notice to stakeholders via an email list on April 24, 2020. The Bureau maintains a website (https://www.scdhec.gov/about-dhec/laws-regulations-regulatory-updates/hazardous-waste-management-regulations-update-status) which provides more detail on the amendments.

6. Appropriate Department staff conducted an internal review of the proposed amendments on June 3, 2020.

7. The Department had a Notice of Proposed Regulation published in the August 28, 2020, *State Register*. The Department received public comments from one (1) person by the September 28, 2020, close of the public comment period.

III. Request for Approval

The Bureau respectfully requests the Board to find need and reasonableness of the attached proposed amendments of R.61-79, *Hazardous Waste Management Regulations*, for submission to the General Assembly.

Henry Porter
Bureau Chief

Myra C. Reece
Director

Attachments:
A. Notice of Final Regulation
B. Summary of Public Comments and Department Responses

ATTACHMENT A

STATE REGISTER NOTICE OF FINAL REGULATION
FOR R.61-79, *Hazardous Waste Management Regulations*

November 12, 2020

Document No. 4975
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Sections 44-56-10 et seq.

61-79. Hazardous Waste Management Regulations.

Synopsis:

The Department of Health and Environmental Control ("Department") amends R.61-79 to adopt two Environmental Protection Agency ("EPA") rules published in the Federal Register. The EPA has given authorized states, including South Carolina, the discretion to adopt these rules as they will make existing standards less stringent and provide more flexibility to the regulated community. The "Safe Management of Recalled Airbags" interim final rule, published on November 30, 2018, at 83 FR 61552-61563 creates a conditional exemption from Resource Conservation and Recovery Act ("RCRA") requirements for certain entities that collect airbag waste from automobiles. The "Universal Waste Regulations: Addition of Aerosol Cans" final rule published on December 9, 2019, at 84 FR 67202-67220 reduces regulatory burdens on businesses that generate, manage, and dispose of aerosol cans. The Department also revises the R.61-79 to make corrections for clarity and readability, grammar, punctuation, codification, and other such regulatory text improvements.

The Department had a Notice of Drafting published in the April 24, 2020, *South Carolina State Register*.

Instructions:

Amend R.61-79 pursuant to each individual instruction provided with the text of the amendments below.

Text:

~~Indicates Matter Stricken~~
Indicates New Matter

61-79. Hazardous Waste Management Regulations.

Statutory Authority: 1976 Code Ann. Section 44-56-30

Add the following definitions in alphabetical order to 260.10 to read:

"Aerosol can" means a non-refillable receptacle containing a gas compressed, liquefied, or dissolved under pressure, the sole purpose of which is to expel a liquid, paste, or powder and fitted with a self-closing release device allowing the contents to be ejected by the gas.

"Airbag waste" means any hazardous waste airbag modules or hazardous waste airbag inflators.

"Airbag waste collection facility" means any facility that receives airbag waste from airbag handlers subject to regulation under 261.4(j) of this chapter, and accumulates the waste for more than ten (10) days.

"Airbag waste handler" means any person, by site, who generates airbag waste that is subject to regulation under this chapter.

Revise 260.10 to read:

"Universal Waste" means any of the following hazardous wastes that are managed under the universal waste requirements of 273: ~~(5/96)~~

(1) Batteries as described in 273.2;

(2) Pesticides as described in 273.3;

(3) Mercury-containing equipment as described in 273.4; ~~and~~

(4) Lamps as described in 273.5 of this chapter~~.~~; and

(5) Aerosol cans as described in 273.6 of this chapter.

Revise 260.10 "Universal waste handler" (2)(i) to read:

(i) A person who treats (except under the provisions of ~~R.61-79.~~273.13 (a) or (c), or 273.33 (a) or (c)), disposes of, or recycles (except under the provisions of 273.13(e) or 273.33(e)) universal waste; or

Add Subparts I through CC to R.61-79.261. Table of Contents to read:

SUBPART I: Use and Management of Containers

261.170. Applicability.
261.171. Condition of containers.
261.172. Compatibility of hazardous secondary materials with containers.
261.173. Management of containers.
261.175. Containment.
261.176. Special requirements for ignitable or reactive hazardous secondary material.
261.177. Special requirements for incompatible materials.
261.179. Air emission standards.

SUBPART J: Tank Systems

261.190. Applicability.
261.191. Assessment of existing tank system's integrity.
261.192. [Reserved]
261.193. Containment and detection of releases.
261.194. General operating requirements.
261.195. [Reserved]
261.196. Response to leaks or spills and disposition of leaking or unfit-for-use tank systems.
261.197. Termination of remanufacturing exclusion.
261.198. Special requirements for ignitable or reactive materials.
261.199. Special requirements for incompatible materials.

261.200. Air emission standards.

SUBPART L: [Reserved]

SUBPART M: Emergency Preparedness and Response for Management of Excluded Hazardous Secondary Materials

261.400. Applicability.
261.410. Preparedness and prevention.
261.411. Emergency procedures for facilities generating or accumulating 6000 kilograms or less of hazardous secondary material.
261.420. Contingency planning and emergency procedures for facilities generating or accumulating more than 6000 kilograms of hazardous secondary material.

SUBPART N-Z: [Reserved]

SUBPART AA: Air Emission Standards for Process Vents

261.1030. Applicability.
261.1031. Definitions.
261.1032. Standards: Process vents.
261.1033. Standards: Closed-vent systems and control devices.
261.1034. Test methods and procedures.
261.1035. Recordkeeping requirements.
261.1036. [Reserved]
261.1037. [Reserved]
261.1038. [Reserved]
261.1039. [Reserved]
261.1040. [Reserved]
261.1041. [Reserved]
261.1042. [Reserved]
261.1043. [Reserved]
261.1044. [Reserved]
261.1045. [Reserved]
261.1046. [Reserved]
261.1047. [Reserved]
261.1048. [Reserved]
261.1049. [Reserved]

SUBPART BB: Air Emission Standards for Equipment Leaks

261.1050. Applicability.
261.1051. Definitions.
261.1052. Standards: Pumps in light liquid service.
261.1053. Standards: Compressors.
261.1054. Standards: Pressure relief devices in gas/vapor service.
261.1055. Standards: Sampling connection systems.
261.1056. Standards: Open-ended valves or lines.
261.1057. Standards: Valves in gas/vapor service or in light liquid service.
261.1058. Standards: Pumps and valves in heavy liquid service, pressure relief devices in light liquid or heavy liquid service, and flanges and other connectors.

261.1059. Standards: Delay of repair.
261.1060. Standards: Closed-vent systems and control devices.
261.1061. Alternative standards for valves in gas/vapor service or in light liquid service: percentage of valves allowed to leak.
261.1062. Alternative standards for valves in gas/vapor service or in light liquid service: skip period leak detection and repair.
261.1063. Test methods and procedures.
261.1064. Recordkeeping requirements.
261.1065. [Reserved]
261.1066. [Reserved]
261.1067. [Reserved]
261.1068. [Reserved]
261.1069. [Reserved]
261.1070. [Reserved]
261.1071. [Reserved]
261.1072. [Reserved]
261.1073. [Reserved]
261.1074. [Reserved]
261.1075. [Reserved]
261.1076. [Reserved]
261.1077. [Reserved]
261.1078. [Reserved]
261.1079. [Reserved]

SUBPART CC: Air Emission Standards for Tanks and Containers

261.1080. Applicability.
261.1081. Definitions.
261.1082. Standards: General.
261.1083. Material determination procedures.
261.1084. Standards: Tanks.
261.1085. [Reserved]
261.1086. Standards: Containers.
261.1087. Standards: Closed-vent systems and control devices.
261.1088. Inspection and monitoring requirements.
261.1089. Recordkeeping requirements.
261.1090. [Reserved]

Add and reserve 261.4(h) and (i) to read:

(h) [Reserved]

(i) [Reserved]

Add 261.4(j) to read:

(j) (1) Airbag waste at the airbag waste handler or during transport to an airbag waste collection facility or designated facility is not subject to regulation under parts 124, 262 through parts 268, or 270 of this chapter, and is not subject to the notification requirements of section 3010 of RCRA provided that:

(i) The airbag waste is accumulated in a quantity of no more than 250 airbag modules or airbag inflators, for no longer than 180 days;

(ii) The airbag waste is packaged in a container designed to address the risk posed by the airbag waste and labeled "Airbag Waste – Do Not Reuse";

(iii) The airbag waste is sent directly to either:

(A) An airbag waste collection facility in the United States under the control of a vehicle manufacturer or their authorized representative, or under the control of an authorized party administering a remedy program in response to a recall under the National Highway Traffic Safety Administration, or

(B) A designated facility as defined in 260.10;

(iv) The transport of the airbag waste complies with all applicable U.S. Department of Transportation (DOT) regulations in 49 CFR part 171 through 180 during transit;

(v) The airbag waste handler maintains at the handler facility for no less than three (3) years records of all off-site shipments of airbag waste and all confirmations of receipt from the receiving facility. For each shipment, these records must, at a minimum, contain the name of the transporter and date of the shipment; name and address of receiving facility; and the type and quantity of airbag waste (i.e., airbag modules or airbag inflators) in the shipment. Confirmations of receipt must include the name and address of the receiving facility; the type and quantity of the airbag waste (i.e., airbag modules and airbag inflators) received; and the date which it was received. Shipping records and confirmations of receipt must be made available for inspection and may be satisfied by routine business records (e.g., electronic or paper financial records, bills of lading, copies of DOT shipping papers, or electronic confirmations of receipt).

(2) Once the airbag waste arrives at an airbag waste collection facility or designated facility, it becomes subject to all applicable hazardous waste regulations, and the facility receiving airbag waste is considered the hazardous waste generator for the purposes of the hazardous waste regulations and must comply with the requirements of part 262.

(3) Reuse in vehicles of defective airbag modules or defective airbag inflators subject to a recall under the National Highway Traffic Safety Administration is considered sham recycling and prohibited under 261.2(g).

Revise 261.6(d) to read:

(d) Owners or operators of facilities subject to RCRA permitting requirements with hazardous waste management units that recycle hazardous wastes are subject to the requirements of subparts AA and BB of parts 264 or 265 of this chapter.

Revise 261.9 to read:

The wastes listed in this section are exempt from regulation under parts 262 through 270 except as specified in part 273 and, therefore, are not fully regulated as hazardous waste. The wastes listed in this section are subject to regulation under 273: ~~(5/96)~~

(a) Batteries as described in 273.2;

(b) Pesticides as described in 273.3;

(c) Mercury-containing equipment as described in 273.4; ~~and~~

(d) Lamps as described in 273.5~~.~~; and

(e) Aerosol cans as described in 273.6 of this chapter.

Revise 261.31(b)(4)(i) to read:

(i). Motor vehicle manufacturing is defined to include the manufacture of automobiles and light trucks/utility vehicles (including light duty vans, pick-up trucks, minivans, and sport utility vehicles). Facilities must be engaged in manufacturing complete vehicles (body and chassis or unibody) or chassis only.

Revise 261.31(b)(4)(ii) to read:

(ii) Generators must maintain in their on-site records documentation and information sufficient to prove that the wastewater treatment sludges to be exempted from the F019 listing meet the conditions of the listing. These records must include: the volume of waste generated and disposed of off site; documentation showing when the waste volumes were generated and sent off site; the name and address of the receiving facility; and documentation confirming receipt of the waste by the receiving facility. Generators must maintain these documents on-site for no less than three (3) years. The retention period for the documentation is automatically extended during the course of any enforcement action or as requested by the Department ~~or the state regulatory authority~~.

Add 262.13(f)(1)(iii) to read:

(iii) If a very small quantity generator's wastes are mixed with used oil, the mixture is subject to R. 61-107.279. Any material produced from such a mixture by processing, blending, or other treatment is also regulated under R.61-107.279.

Add 262.14(a)(5)(ix) through (xi) to read:

(ix) [Reserved]

(x) [Reserved]

(xi) For airbag waste, an airbag waste collection facility or a designated facility subject to the requirements of 261.4(j) of this chapter.

Revise 262.21(a)(1) to read:

(1) A registrant may not print, or have printed, the manifest for use of distribution unless it has received approval from the EPA Director of ~~Office of Solid Waste~~ the Office of Resource Conservation and Recovery to do so under paragraphs (c) and (e) of this section.

Revise 262.21(b) to read:

(b) A registrant must submit an initial application to the EPA Director of the Office of ~~Solid Waste~~Resource Conservation and Recovery that contains the following information:

Revise 264.1(g)(11) to read:

(11) Universal waste handlers and universal waste transporters (as defined in R.61-79.260.10) handling the wastes listed below. These handlers are subject to regulation under R.61-79.273, when handling the below listed universal wastes. ~~(added 5/96)~~

(i) Batteries as described in ~~R.61-79.~~273.2;

(ii) Pesticides as described in ~~R.61-79.~~273.3; ~~and~~

(iii) Mercury-containing equipment as described in 273.4; ~~and~~

(iv) Lamps as described in 273.5~~.~~; and

(v) Aerosol cans as described in 273.6 of this chapter.

Revise 264.119(b)(1)(ii) to read:

(ii) Its use is restricted under R.61-79.264 ~~and R.61-79.265 S~~subpart G; and

Revise 264.151(a)(2) to read:

(2) Certification of acknowledgment which must accompany the trust agreement for a trust fund as specified in 264.143(a) and 264.145(a) or 265.143(a) and 265.145(a). This document must be worded as noted in 264.151 Appendix A(2) except that instructions in brackets are to be replaced with the relevant information and the brackets deleted. ~~(amended 11/90)~~

Revise 265.1(c)(14) to read:

(14) Universal waste handlers and universal waste transporters (as defined in R.61-79.260.10) handling the wastes listed below. These handlers are subject to regulation under R.61-79.273, when handling the below listed universal wastes. ~~(added 5/96)~~

(i) Batteries as described in ~~R.61-79.~~273.2;

(ii) Pesticides as described in 273.3~~,~~;

(iii) Mercury-containing equipment as described in 273.4; ~~and~~

(iv) Lamps as described in 273.5~~.~~; and

(v) Aerosol cans as described in 273.6 of this chapter.

Revise 265.195(a) to read:

(a) The owner or operator must inspect, where present, at least once each operating day, data gathered from monitoring and leak detection equipment (e.g., pressure or temperature gauges, monitoring wells) to ensure that the tank system is being operated according to its design.

~~(1) Overfill/spill control equipment (e.g., waste feed cutoff systems, bypass systems, and drainage systems) to ensure that it is in good working order;~~

~~(2) The above ground portions of the tank system, if any, to detect corrosion or releases of waste;~~

~~(3) Data gathered from monitoring equipment and leak-detection equipment (e.g., pressure and temperature gauges, monitoring wells) to ensure that the tank system is being operated according to its design; and~~

~~(4) The construction materials and the area immediately surrounding the externally accessible portion of the tank system including secondary containment structures (e.g., dikes) to detect erosion or signs of releases of hazardous waste (e.g., wet spots, dead vegetation);~~

Note: Section 265.15(c) requires the owner or operator to remedy any deterioration or malfunction he finds. Section 265.196 requires the owner or operator to notify the Department ~~and Regional Administrator~~ within 24 hours of confirming a release. Also, 40 CFR part 302 may require the owner or operator to notify the National Response Center of a release. ~~(revised 12/92) paragraphs (a) and (b) of this section.~~

Revise 268.1(f) to read:

(f) Universal waste handlers and universal waste transporters (as defined in 260.10) are exempt from 268.7 and 268.50 for the hazardous wastes listed below. These handlers are subject to regulation under part 273. ~~(5/96)~~

(1) Batteries as described in 273.2;

(2) Pesticides as described in 273.3;

(3) Mercury-containing equipment as described in 273.4; ~~and~~

(4) Lamps as described in 273.5~~.~~; and

(5) Aerosol cans as described in 273.6 of this chapter.

Revise 270.1(c)(2)(viii) to read:

(viii) Universal waste handlers and universal waste transporters (as defined in R.61-79.260.10) managing the wastes listed below. These handlers are subject to regulation under R.61-79.273. ~~(revised 5/96)~~

(A) Batteries as described in ~~R.61-79.~~273.2;

(B) Pesticides as described in 273.3;

(C) Mercury-containing equipment as described in 273.4; ~~and~~

(D) Lamps as described in 273.5~~.~~; and

(E) Aerosol cans as described in 273.6 of this chapter.

Revise 270.19(e) to read:

(e) When an owner or operator of a hazardous waste incineration unit becomes subject to RCRA permit requirements after October 12, 2005, or when an owner or operator of an existing hazardous waste incineration unit demonstrates compliance with the air emission standards and limitations in part 63, Subpart EEE, (i.e., by conducting a comprehensive performance test and submitting a Notification of Compliance) under 63.1207(j) and 63.1210(~~b~~d) documenting compliance with all applicable requirements of Part 63, subpart EEE, the requirements do not apply, except those provisions the Department determines are necessary to ensure compliance with 264.345(a) and 264.345(c) if you elect to comply with 270.235(a)(1)(i) to minimize emissions of toxic compounds from startup, shutdown, and malfunction events. Nevertheless, the Department may apply the provisions, on a case-by-case basis, for purposes of information collection in accordance with 270.10(k), 270.10(l), 270.32(b)(2), and 270.32(b)(3).

Revise R.61-79.273. Table of Contents to read:

273.6. Applicability—Aerosol Cans.

Revise 273.1(a) to read:

(a) This part establishes requirements for managing the following:

(1) Batteries as described in 273.2;

(2) Pesticides as described in ~~R.61-79.~~273.3;

(3) Mercury-containing equipment as described in 273.4; ~~and~~

(4) Lamps as described in 273.5~~.~~; and

(5) Aerosol cans as described in 273.6 of this chapter.

Revise 273.3(b)(2) to read:

(2) Pesticides not meeting the conditions set forth in paragraph (a) of this section. These pesticides must be managed in compliance with the hazardous waste regulations in parts 260 through 272, except that aerosol cans as defined in 273.9 that contain pesticides may be managed as aerosol can universal waste under 273.13(e) or 273.33(e);

Add 273.6 to read:

273.6 Applicability—Aerosol Cans.

(a) Aerosol cans covered under this part. The requirements of this part apply to persons managing aerosol cans, as described in 273.9, except those listed in paragraph (b) of this section.

(b) Aerosol cans not covered under this part. The requirements of this part do not apply to persons managing the following types of aerosol cans:

(1) Aerosol cans that are not yet waste under part 261 of this chapter. Paragraph (c) of this section describes when an aerosol can becomes a waste;

(2) Aerosol cans that are not hazardous waste. An aerosol can is a hazardous waste if the aerosol can exhibits one or more of the characteristics identified in part 261 subpart C of this chapter or the aerosol can contains a substance that is listed in part 261 subpart D of this chapter; and

(3) Aerosol cans that meet the standard for empty containers under 261.7 of this chapter.

(c) Generation of waste aerosol cans.

(1) A used aerosol can becomes a waste on the date it is discarded.

(2) An unused aerosol can becomes a waste on the date the handler decides to discard it.

Add the following definition in alphabetical order to 273.9 to read:

Aerosol can means a non-refillable receptacle containing a gas compressed, liquefied, or dissolved under pressure, the sole purpose of which is to expel a liquid, paste, or powder and fitted with a self-closing release device allowing the contents to be ejected by the gas.

Revise 273.9 "Large quantity handler of universal waste" to read:

Large Quantity Handler of Universal Waste means a universal waste handler (as defined in this section) who accumulates 5,000 kilograms or more total of universal waste (batteries, pesticides, mercury-containing equipment, ~~or~~ lamps, or aerosol cans, calculated collectively) at any time. This designation as a large quantity handler of universal waste is retained through the end of the calendar year in which the 5,000-kilogram limit is met or exceeded.

Revise 273.9 "Pesticide" to read:

Pesticide means any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, or intended for use as a plant regulator, defoliant, or desiccant, other than any article that:

(~~a~~1) is a new animal drug under FFDCA section 201(w)~~,~~; or

(~~b~~2) is an animal drug that has been determined by regulation of the Secretary of Health and Human Services not to be a new animal drug~~,~~; or

(~~c~~3) is an animal feed under FFDCA section 201(x) that bears or contains any substances described by paragraph (~~a~~1) or (~~b~~2) of this definition ~~section~~.

Revise 273.9 "Small quantity handler of universal waste" to read:

Small Quantity Handler of Universal Waste means a universal waste handler (as defined in this section) who does not accumulate 5,000 kilograms or more of universal waste (batteries, pesticides, mercury-containing equipment, ~~or~~ lamps, or aerosol cans, calculated collectively) at any time.

Revise 273.9 "Universal waste" to read:

Universal Waste means any of the following hazardous wastes that are subject to the universal waste requirements of part 273:

(1) Batteries as described in 273.2;

(2) Pesticides as described in 273.3;

(3) Mercury-containing equipment as described in 273.4; ~~and~~

(4) Lamps as described in 273.5~~.~~; and

(5) Aerosol cans as described in 273.6 of this chapter.

Revise 273.9 "Universal waste handler" to read:

Universal Waste Handler:

(~~a~~1) Means:

(~~1~~i) A generator (as defined in this section) of universal waste; or

(~~2~~ii) The owner or operator of a facility, including all contiguous property, that receives universal waste from other universal waste handlers, accumulates universal waste, and sends universal waste to another universal waste handler, to a destination facility, or to a foreign destination.

(~~b~~2) Does not mean:

(~~1~~i) A person who treats (except under the provisions of 273.13(a) or (c), or 273.33(a) or (c)), disposes of, or recycles (except under the provisions of 273.13(e) or 273.33(e)) universal waste; or

(~~2~~ii) A person engaged in the off-site transportation of universal waste by air, rail, highway, or water, including a universal waste transfer facility.

Revise 273.13(c)(2)(iii) and (iv) to read:

(iii) Ensures that a mercury clean-up system is readily available to immediately transfer any mercury resulting from spills or leaks from broken ampules from that containment device to a container that ~~meets the requirements of 262.34~~ is subject to all applicable requirements of parts 260 through 272;

(iv) Immediately transfers any mercury resulting from spills or leaks from broken ampules from the containment device to a container that ~~meets the requirements of 262.34~~ is subject to all applicable requirements of parts 260 through 272;

Add 273.13(e) to read:

(e) Aerosol cans. A small quantity handler of universal waste must manage universal waste aerosol cans in a way that prevents releases of any universal waste or component of a universal waste to the environment, as follows:

(1) Universal waste aerosol cans must be accumulated in a container that is structurally sound, compatible with the contents of the aerosol cans, lacks evidence of leakage, spillage, or damage that could cause leakage under reasonably foreseeable conditions, and is protected from sources of heat.

(2) Universal waste aerosol cans that show evidence of leakage must be packaged in a separate closed container or overpacked with absorbents, or immediately punctured and drained in accordance with the requirements of paragraph (e)(4) of this section.

(3) A small quantity handler of universal waste may conduct the following activities as long as each individual aerosol can is not breached and remains intact:

(i) Sorting aerosol cans by type;

(ii) Mixing intact cans in one container;

(iii) Removing actuators to reduce the risk of accidental release; and

(4) A small quantity handler of universal waste who punctures and drains their aerosol cans must recycle the empty punctured aerosol cans and meet the following requirements while puncturing and draining universal waste aerosol cans:

(i) Conduct puncturing and draining activities using a device specifically designed to safely puncture aerosol cans and effectively contain the residual contents and any emissions thereof.

(ii) Establish and follow a written procedure detailing how to safely puncture and drain the universal waste aerosol can (including proper assembly, operation and maintenance of the unit, segregation of incompatible wastes, and proper waste management practices to prevent fires or releases); maintain a copy of the manufacturer's specification and instruction on site; and ensure employees operating the device are trained in the proper procedures.

(iii) Ensure that puncturing of the can is done in a manner designed to prevent fires and to prevent the release of any component of universal waste to the environment. This manner includes, but is not limited to, locating the equipment on a solid, flat surface in a well-ventilated area.

(iv) Immediately transfer the contents from the waste aerosol can or puncturing device, if applicable, to a container or tank that meets the applicable requirements of 262.14, 262.15, 262.16, or 262.17.

(v) Conduct a hazardous waste determination on the contents of the emptied aerosol can per 262.11. Any hazardous waste generated as a result of puncturing and draining the aerosol can is subject to all applicable requirements of parts 260 through 272. The handler is considered the generator of the hazardous waste and is subject to part 262.

(vi) If the contents are determined to be nonhazardous, the handler may manage the waste in any way that is in compliance with applicable federal, state, or local solid waste regulations.

(vii) A written procedure must be in place in the event of a spill or leak and a spill clean-up kit must be provided. All spills or leaks of the contents of the aerosol cans must be cleaned up promptly.

Add 273.14(f) to read:

(f) Universal waste aerosol cans (i.e., each aerosol can), or a container in which the aerosol cans are contained, must be labeled or marked clearly with any of the following phrases: "Universal Waste—Aerosol Can(s)," "Waste Aerosol Can(s)," or "Used Aerosol Can(s)."

Revise 273.32(b)(4) to read:

(4) A list of all the types of universal waste managed by the handler (e.g., batteries, pesticides, mercury-containing equipment, ~~and~~ lamps, and aerosol cans); and

Revise 273.33(c)(2)(iii) and (iv) to read:

(iii) Ensures that a mercury clean-up system is readily available to immediately transfer any mercury resulting from spills or leaks of broken ampules from that containment device to a container that ~~meets the requirements of 262.34~~ is subject to all applicable requirements of parts 260 through 272;

(iv) Immediately transfers any mercury resulting from spills or leaks from broken ampules from the containment device to a container that ~~meets the requirements of 262.34~~ is subject to all applicable requirements of parts 260 through 272;

Add 273.33(e) to read:

(e) Aerosol cans. A large quantity handler of universal waste must manage universal waste aerosol cans in a way that prevents releases of any universal waste or component of a universal waste to the environment, as follows:

(1) Universal waste aerosol cans must be accumulated in a container that is structurally sound, compatible with the contents of the aerosol cans, lacks evidence of leakage, spillage, or damage that could cause leakage under reasonably foreseeable conditions, and is protected from sources of heat.

(2) Universal waste aerosol cans that show evidence of leakage must be packaged in a separate closed container or overpacked with absorbents, or immediately punctured and drained in accordance with the requirements of paragraph (e)(4) of this section.

(3) A large quantity handler of universal waste may conduct the following activities as long as each individual aerosol can is not breached and remains intact:

(i) Sorting aerosol cans by type;

(ii) Mixing intact cans in one container;

(iii) Removing actuators to reduce the risk of accidental release; and

(4) A large quantity handler of universal waste who punctures and drains their aerosol cans must recycle the empty punctured aerosol cans and meet the following requirements while puncturing and draining universal waste aerosol cans:

(i) Conduct puncturing and draining activities using a device specifically designed to safely puncture aerosol cans and effectively contain the residual contents and any emissions thereof.

(ii) Establish and follow a written procedure detailing how to safely puncture and drain the universal waste aerosol can (including proper assembly, operation and maintenance of the unit, segregation of incompatible wastes, and proper waste management practices to prevent fires or releases); maintain a copy of the manufacturer's specification and instruction on site; and ensure employees operating the device are trained in the proper procedures.

(iii) Ensure that puncturing of the can is done in a manner designed to prevent fires and to prevent the release of any component of universal waste to the environment. This includes, but is not limited to, locating the equipment on a solid, flat surface in a well-ventilated area.

(iv) Immediately transfer the contents from the waste aerosol can or puncturing device, if applicable, to a container or tank that meets the applicable requirements of 262.14, 262.15, 262.16, or 262.17.

(v) Conduct a hazardous waste determination on the contents of the emptied aerosol can per 262.11. Any hazardous waste generated as a result of puncturing and draining the aerosol can is subject to all applicable requirements of parts 260 through 272. The handler is considered the generator of the hazardous waste and is subject to part 262.

(vi) If the contents are determined to be nonhazardous, the handler may manage the waste in any way that is in compliance with applicable federal, state, or local solid waste regulations.

(vii) A written procedure must be in place in the event of a spill or leak and a spill clean-up kit must be provided. All spills or leaks of the contents of the aerosol cans must be cleaned up promptly.

Add 273.34(f) to read:

(f) Universal waste aerosol cans (i.e., each aerosol can), or a container in which the aerosol cans are contained, must be labeled or marked clearly with any of the following phrases: "Universal Waste—Aerosol Can(s)," "Waste Aerosol Can(s)," or "Used Aerosol Can(s)."

Fiscal Impact Statement:

The amendments have no substantial fiscal or economic impact on the state or its political subdivisions. Implementation of this regulation will not require additional resources beyond those allowed. There is no anticipated additional cost by the Department or state government due to any requirements of this regulation.

Statement of Need and Reasonableness:

The following presents an analysis of the factors listed in 1976 Code Sections 1-23-115(C)(1)-(3) and (9)-(11):

DESCRIPTION OF REGULATION: 61-79, Hazardous Waste Management Regulations.

Purpose: The purpose of these amendments is to realize the benefits of and maintain state consistency with the following EPA regulations published in the Federal Register: "Universal Waste Regulations: Addition of Aerosol Cans," published on December 9, 2019, at 84 FR 67202-67220, and "Safe Management of Recalled Airbags," published on November 30, 2018, at 83 FR 61552-61563.

Legal Authority: 1976 Code Sections 44-56-10 et seq.

Plan for Implementation: The Department's Regulation Development Update (accessible at http://www.scdhec.gov/Agency/RegulationsAndUpdates/RegulationDevelopmentUpdate/) provides a summary of and link to this amendment. Additionally, printed copies are available for a fee from the Department's Freedom of Information Office. Upon taking legal effect, Department personnel will take appropriate steps to inform the regulated community of the amendments and any associated information.

DETERMINATION OF NEED AND REASONABLENESS OF THE REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

The Department amends R.61-79, Hazardous Waste Management Regulations, to adopt EPA interim final rule "Safe Management of Recalled Airbags," published on November 30, 2018, at 83 FR 61552-61563. This rule provides a conditional exemption from the RCRA hazardous waste requirements for entities, including but not limited to, automobile dealerships, automotive salvage and scrap yards, independent repair facilities, and collision centers that collect airbag modules and inflators ("airbag waste") from automobiles as long as certain conditions are met. This rule enables expedited removal of defective airbag inflators.

The Department further amends R.61-79 to adopt the EPA final rule "Universal Waste Regulations: Addition of Aerosol Cans," published on December 9, 2019, at 84 FR 67202-67220. This rule adds hazardous waste aerosol cans to the universal waste program under the federal RCRA regulations. Adopting the rule reduces regulatory burdens on retail stores and other establishments that generate, manage, and dispose of aerosol cans by providing a clear, protective system for handling waste aerosol cans. This will promote the collection and recycling of aerosol cans and encourage the development of municipal and commercial programs to reduce the amount of aerosol can waste going to municipal solid waste landfills or combustors.

DETERMINATION OF COSTS AND BENEFITS:

There is no anticipated increased cost to the state or its political subdivisions resulting from this revision. The EPA estimates that the "Safe Management of Recalled Airbags" interim final rule will result in industry savings between $1.7 million and $13 million (Federal Register, Vol 83, No. 231, page 61561). Similarly, the EPA estimates annual industry cost savings for the "Universal Waste Regulations: Addition of Aerosol Cans" final rule to be between $5.3 million and $47.8 million (Federal Register Vol. 84, No. 236, page 67203).

UNCERTAINTIES OF ESTIMATES:

There are no uncertainties of estimates regarding costs to the state or its political subdivisions.

EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH:

The revisions to R.61-79 will provide continued protection of the environment and public health, as indicated above.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED:

If the regulation is not implemented, there will be detrimental effects on the environment and public health because South Carolina would not be implementing or realizing the benefits of the EPA's "Universal Waste Regulations: Addition of Aerosol Cans" final rule and the "Safe Management of Recalled Airbags" interim final rule described above.

Statement of Rationale:

Below is the Statement of Rationale pursuant to S.C. Code Section 1-23-110(h):

The Department amends R.61-79 to adopt two EPA rules published in the Federal Register. The EPA has given authorized states, including South Carolina, the discretion to adopt these rules as they make existing standards less stringent and provide more flexibility to the regulated community. The "Safe Management of Recalled Airbags" interim final rule, published on November 30, 2018, at 83 FR 61552-61563 creates a conditional exemption from RCRA requirements for certain entities that collect airbag waste from automobiles. The "Universal Waste Regulations: Addition of Aerosol Cans" final rule published on December 9, 2019, at 84 FR 67202-67220 reduces regulatory burdens on businesses that generate, manage, and dispose of aerosol cans.

ATTACHMENT B

SUMMARY OF PUBLIC COMMENTS AND DEPARTMENT RESPONSES

Document No. 4975
R.61-79, *Hazardous Waste Management Regulations*

As of the September 28, 2020, close of the Notice of Proposed Regulation comment period:

Name	Section	Department Response
Household & Commercial Products Association (HCPA)	**None Cited**	The Department agrees with the below comments from the HCPA, this new rule, modeled from the EPA will reduce regulatory burdens on retail stores and other establishments that generate, manage, and dispose of aerosol cans by providing a clear, protective system for handling waste aerosol cans. This will promote the collection and recycling of aerosol cans and encourage the development of municipal and commercial programs to reduce the amount of aerosol can waste going to municipal solid waste landfills or combustors.
Comment: The Household & Commercial Products Association (HCPA) appreciates the opportunity to offer comments to the South Carolina Department of Health and Environmental Control (SCDHEC) on their proposed amendment to R.61-79, which would include aerosol cans in South Carolina's Universal Waste program. HCPA supports SCDHEC's proposed amendment as it is based on EPA's Increasing Recycling: Adding Aerosol Cans to the Universal Waste Regulations rule.		

Date: November 12, 2020

To: S.C. Board of Health and Environmental Control

From: Bureau of Facilities Oversight

Re: Public Hearing for Notice of Final Regulation Amending R.61-75, *Standards for Licensing Day Care Facilities for Adults*, Document No. 4977

I. Introduction

The Bureau of Facilities Oversight ("Bureau") proposes the attached Notice of Final Regulation amending R.61-75, *Standards for Licensing Day Care Facilities for Adults*. Legal authority resides in S.C. Code Section 44-7-260, which requires the Department of Health and Environmental Control ("Department") to establish and enforce basic standards for the licensure, maintenance, and operation of health facilities and services in order to ensure the safe and adequate treatment of persons served in this state. The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments.

II. Facts

1. The Bureau proposes amending R.61-75 to update provisions in accordance with current practices and standards. Proposed amendments incorporate and revise provisions relating to statutory mandates, update definitions to conform to terminology widely used and understood within the provider community, and revise requirements for incident reporting, staffing and training, medication management, patient care and services, infection control, meal service, emergency procedures, design and construction, fire and life safety, and licensure. The proposed amendments also update the structure of the regulation throughout for consistency with other Department regulations.

2. The Department had a Notice of Drafting published in the February 28, 2020, *State Register*.

3. The Bureau held a stakeholder meeting on March 12, 2020. The Bureau considered stakeholder feedback in formulating the proposed amendments herein.

4. Appropriate Department staff conducted an internal review of the proposed amendments on June 29, 2020.

5. The Department had a Notice of Proposed Regulation published in the August 28, 2020, *State Register*. The Department received public comments from three (3) people by the September 28, 2020, close of the public comment period. Attachment B presents a summary of these public comments received and Department responses.

6. The Bureau held another stakeholder meeting on September 16, 2020. The Bureau considered stakeholder feedback in formulating the proposed amendments herein.

7. After consideration of all timely received comments, staff has made substantive changes to the regulatory text of the Notice of Proposed Regulation approved by the Board in the August 13, 2020, Board meeting and published in the August 28, 2020, *State Register*. Descriptions of the changes appear in Attachment B, Summary of Public Comments and Department Responses.

III. Request for Approval

The Bureau of Facilities Oversight respectfully requests the Board to find need and reasonableness of the attached proposed amendment of R.61-75, *Standards for Licensing Day Care Facilities for Adults*, for submission to the General Assembly.

Angie Smith
Interim Director
Facilities Oversight

Gwendolyn C. Thompson
Deputy Director
Healthcare Quality

Attachments:
A. Notice of Final Regulation
B. Summary of Public Comments and Department Responses

ATTACHMENT A

STATE REGISTER NOTICE OF FINAL REGULATION
FOR R.61-75, *Standards for Licensing Day Care Facilities for Adults*

November 12, 2020

Document No. 4977
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Sections 44-7-260 et seq.

61-75. Standards for Licensing Day Care Facilities for Adults.

Synopsis:

The Department of Health and Environmental Control ("Department" or "DHEC") amends R.61-75 to update provisions in accordance with current practices and standards. Amendments incorporate and revise provisions relating to statutory mandates, update definitions to conform to terminology widely used and understood within the provider community, and revise requirements for incident reporting, staffing and training, medication management, patient care and services, infection control, meal service, emergency procedures, design and construction, fire and life safety, and licensure. The amendments also update the structure of the regulation throughout for consistency with other DHEC Healthcare Quality regulations.

The Department further revises R.61-75 for clarity and readability, grammar, references, codification, and overall improvement to the text of the regulation. R.61-75 was last amended in 2015.

The Department had a Notice of Drafting published in the February 28, 2020, *South Carolina State Register*.

Instructions:

Replace R.61-75, *Standards for Licensing Day Care Facilities for Adults*, in its entirety with this amendment.

Text:

~~Indicates Matter Stricken~~
Indicates New Matter

61-75. Standards for Licensing Day Care Facilities for Adults.

Statutory Authority: 1976 Code Section 44-7-260

TABLE OF CONTENTS

~~**SECTION 100. DEFINITIONS AND GENERAL REQUIREMENTS.**~~
SECTION 100 – DEFINITIONS AND LICENSURE

101. Definitions.

A. Abuse. Physical ~~a~~Abuse or ~~p~~Psychological ~~a~~Abuse.

1. Physical Abuse. The act of intentionally inflicting or allowing to be inflicted physical injury on a ~~p~~Participant by an act or failure to act. Physical ~~a~~Abuse includes, but is not limited to, slapping, hitting, kicking, biting, choking, pinching, burning, actual or attempted sexual battery, use of ~~m~~Medication outside

the standards of reasonable medical practice for the purpose of controlling behavior, and unreasonable confinement. Physical ~~a~~Abuse also includes the use of a restrictive or physically intrusive procedure to control behavior for the purpose of punishment except that a therapeutic procedure prescribed by a licensed physician or other ~~a~~Authorized ~~h~~Healthcare ~~p~~Provider or that is part of a written plan of care by a physician or other ~~a~~Authorized ~~h~~Healthcare ~~p~~Provider is not considered ~~p~~Physical ~~a~~Abuse. Physical ~~a~~Abuse does not include altercations or acts of assault between ~~p~~Participants.

2. Psychological Abuse. The deliberate use of any oral, written, or gestured language or depiction that includes disparaging or derogatory terms to a ~~p~~Participant or within the ~~p~~Participant's hearing distance, regardless of the ~~p~~Participant's age, ability to comprehend, or disability, including threats or harassment or other forms of intimidating behavior causing fear, humiliation, degradation, agitation, confusion, or other forms of serious emotional distress.

B. Administrator. The individual responsible for the day-to-day management of the Day Care Facility for Adults.

C. Adult. A person eighteen (18) years of age or older.

~~C~~D. Adult Day Care Services. Activities and therapies offered in a Day Care Facility for Adults through an ~~individualized plan of care~~Individual Plan of Care which sets forth measurable goals or behaviorally stated objectives, with such services being designed to activate, motivate, and retrain impaired or other categories of ~~a~~Adults to enable them to sustain or regain functional independence and promote community integration.

E. Annual. A time period that requires an activity to be performed at least every twelve (12) months.

~~D~~F. Authorized Healthcare Provider. An individual authorized by law and currently licensed in South Carolina as a physician, advanced practice registered nurse, or physician assistant to provide specific treatments, care, or services to ~~p~~Participants~~, e.g., advanced practice registered nurse, physician assistant~~.

G. Blood Assay for *Mycobacterium tuberculosis*. A general term to refer to in vitro diagnostic tests that assess for the presence of tuberculosis infection with *Mycobacterium tuberculosis*. This term includes, but is not limited to, interferon gamma release assays.

H. Consultation. A meeting with a licensed Facility and individuals authorized by the Department to provide information to Facilities in order to enable Facilities to better comply with the regulation.

I. Controlled Substance. A Medication or other substance included in Schedule I, II, III, IV, and V of the Federal Controlled Substances Act or the South Carolina Controlled Substances Act.

~~E~~ J. Day Care Facility for Adults (Facility). A facility~~,~~ for ~~a~~Adults ~~18 years of age or older~~, which offers in a group setting a program of individual and group activities and therapies. The program is directed toward providing community-based day care services for those ~~a~~Adults in need of a supportive setting, thereby preventing unnecessary institutionalization. The program shall provide a minimum of four (4) and a maximum of fourteen (14) hours of operation a day.

~~F~~K. Department. The South Carolina Department of Health and Environmental Control.

~~G. Dietitian. A person who is registered by or meets the requirements of the American Dietetic Association and has at least one (1) year of experience in clinical nutrition.~~

~~H~~L. Direct Care Staff. Those ~~i~~individuals who are employees (full- and part-time) of the Facility providing ~~responsible for the provision of~~direct care and ~~supervision~~services to the Participants, and those individuals contracted to provide care and services ~~of the~~to ~~p~~Participants.

M. Discharge. The point at which treatment, care, and services in a Facility are terminated and the Facility no longer maintains active responsibility for the care of the Participant.

N. Elopement. An instance when a Participant who is physically, mentally, or chemically impaired wanders, walks, runs away, escapes, or otherwise leaves the Facility unsupervised or unnoticed.

~~I~~O. Exploitation.

1. Causing or requiring a ~~p~~Participant to engage in activity or labor that is improper, unlawful, or against the reasonable and rational wishes of the ~~p~~Participant;

2. An improper, unlawful, or unauthorized use of the funds, assets, property, power of attorney, guardianship, or conservatorship of a ~~p~~Participant by an individual for the profit or advantage of that individual or another individual; or

3. Causing a ~~p~~Participant to purchase goods or services for the profit or advantage of the seller or another individual through undue influence, harassment, duress, force, coercion, or swindling by overreaching, cheating, or defrauding the ~~p~~Participant through cunning arts or devices that delude the ~~p~~Participant and cause him or her to lose money or other property.

4. Exploitation does not include requiring a ~~p~~Participant to participate in an activity or labor that is a part of a written plan of care or prescribed or authorized by the ~~p~~Participant's attending physician.

P. Health Assessment. An evaluation of the health status of a Staff member and/or Volunteer by a physician, other Authorized Healthcare Provider, or a registered nurse. A registered nurse may complete the Health Assessment pursuant to standing orders approved by a physician as evidenced by the physician's signature. The standing orders shall be reviewed Annually by the physician, with a copy of the review maintained at the Facility.

Q. Incident. An unusual, unexpected adverse event in the Facility or on Facility grounds, including any accidents, that could potentially cause harm, injury, or death to Participants or Staff members.

R. Individual Plan of Care (IPC). A documented regimen of appropriate care and services or written action plan prepared by the Facility for each Participant based on the Participant's needs and preferences and which is to be implemented for the benefit of the Participant.

S. Inspection. A visit by the Department for the purpose of determining compliance with this regulation.

T. Investigation. A visit by Department representatives to a licensed Facility or unlicensed entity for the purpose of determining the validity of allegations received by the Department relating to statutory and regulatory compliance.

U. License. The authorization to operate a Facility as defined in this regulation and as evidenced by a current certificate issued by the Department to a Facility.

~~J~~V. Licensee. ~~The person on whom rests the ultimate responsibility and authority for the conduct of the Day Care Facility for Adults.~~ The individual, organization, or public entity that has received a License to

provide care and services at the Facility and with whom rests the ultimate responsibility for compliance with the current regulation.

~~K. Licensing Agency. The Department of Health and Environmental Control.~~

~~L~~W. Neglect. The failure or omission of a ~~d~~Direct ~~c~~Care ~~s~~Staff member or direct care ~~v~~Volunteer to provide the care, goods, or services necessary to maintain the health or safety of a ~~p~~Participant including, but not limited to, food, clothing, medicine, shelter, supervision, and medical services. Failure to provide adequate supervision resulting in harm to ~~p~~Participants, including altercations or acts of assault between ~~p~~Participants, may constitute ~~n~~Neglect. Neglect may be repeated conduct or a single ~~i~~Incident that has produced or could result in physical or psychological harm or substantial risk of death. Noncompliance with regulatory standards alone does not constitute ~~n~~Neglect.

~~M~~X. Participant. An ~~a~~Adult~~, 18 years and above,~~ who is receiving service in a Day Care Facility for Adults.

~~N. Person. An individual, trust or estate, partnership, corporation including an association, joint stock company, state, political subdivision, or instrumentality including a municipal corporation of a state, or any legal entity recognized by the State.~~

Y. Physical Examination. An examination of a Participant by a physician or other Authorized Healthcare Provider which addresses those issues identified in Section 1100 of this regulation.

Z. Prescription Medication. A drug that is required by any applicable federal or state law to be dispensed pursuant only to a Prescription Medication order or is restricted to use by Physicians or other Authorized Healthcare Providers only.

AA. Responsible Party. A Participant's legal guardian, committee, next of kin, or other person acting as agent of the Participant who does not have a legally appointed guardian.

BB. Revocation of License. An action by the Department to cancel or annul a Facility License by recalling, withdrawing, or rescinding its authority to operate.

~~O~~CC. Sponsor~~:~~. ~~A family member, guardian, agency, or other person who acts on behalf of the participant.~~ A person, company, institution, group, or organization that assumes responsibility, advocates, and/or pays for care and services for the Participant.

DD. Staff. Those individuals who are employees (full- and part-time) of the Facility, to include those individuals contracted to provide care and services for the Participants.

EE. Suspension of License. An action by the Department requiring a Facility to cease operations for a period of time or to require a Facility to cease admitting Participants, until such time as the Department rescinds that restriction.

FF. Variance. A variance is an alternative method that ensures the equivalent level of compliance with the standards in this regulation.

GG. Volunteer. An individual who performs tasks that are associated with the operation of the Facility without pay and at the direction of the Administrator or his or her designee.

102. Licensure ~~Requirements~~. (II)

A. License. No person, private or public organization, political subdivision, or governmental agency shall establish, operate, maintain, ~~or~~ represent, advertise, or market itself ~~(advertise/market)~~ as a Day Care Facility for Adults ~~with~~in South Carolina without ~~possessing~~ first obtaining and possessing a ~~valid l~~License ~~issued annually by~~from the Department. The Facility shall not enroll Participants prior to the effective date of the License. When it has been determined by the Department that treatment, care, or services are being provided at a location, and the owner has not been issued a License from the Department to provide such treatment, care, and services, the owner shall cease operation immediately and ensure the safety, health, and well-being of the Participants. Current or previous violations of South Carolina Code of Laws or Department regulations may jeopardize the issuance of a License for the Facility or the licensing of any other Facility, or addition to an existing Facility that is owned and/or operated by the Licensee. The Facility shall provide only the treatment, care, and services it is licensed to provide pursuant to the definition in Section 101.J. (I)

B. Compliance. An applicant ~~license~~ shall not ~~be issued to a~~receive an initial License for a proposed ~~f~~Facility ~~that has not been previously and continuously licensed under Department regulations until~~unless the ~~licensee~~applicant ~~has demonstrated~~ demonstrates to the Department that the proposed ~~f~~Facility is in substantial compliance with ~~the~~Department licensing standards. In the event a Licensee who already has a Facility or activity licensed by the Department makes application for another Facility or an increase in licensed Participants, the currently licensed Facility or activity shall be in substantial compliance with the applicable licensing standards prior to receiving a License for the proposed Facility or an amended License to the existing Facility. ~~A~~The Facility shall maintain a paper or electronic copy of the licensing standards ~~shall be maintained~~ at the ~~f~~Facility ~~and~~ accessible to all ~~s~~Staff members~~/v~~ and Volunteers. Facilities shall comply with applicable local, state, and federal laws, codes, and regulations. ~~A new facility, or one that has not been continuously licensed under these or prior standards, shall not provide care to participants until it has been issued an initial license.~~

~~C. Issuance of License. A license is issued pursuant to the provisions of 1976 Code Section 44-7-260(A), as amended, and the regulations promulgated thereunder, and shall be posted in a conspicuous place in a public area within the facility. The issuance of a license does not guarantee adequacy of individual care, treatment, personal safety, fire safety or the well-being of any occupant of a facility. A license is not assignable or transferable and is subject to revocation by the Department for failure to comply with the laws and regulations of the State of South Carolina.~~

~~D. Effective Date and Term of License. A license shall be effective for a twelve (12) month period following the date of issue and shall expire one (1) year following such date.~~

~~E. Separate Licenses. Separate licenses are required for facilities not maintained on the same premises. A single license or separate licenses may be issued for facilities maintained in separate buildings on the same premises.~~

C. Licensed Services. Facilities authorized to provide services to a set number of Participants, as identified on the face of the License, shall not exceed the number of Participants identified on the face of the License. Facilities shall obtain authorization from the Department prior to establishing new care or services or occupying additional or renovated space. (I)

D. Issuance and Terms of License.

1. The Facility shall post the License in a conspicuous place in a public area within the Facility.

2. The issuance of a License does not guarantee adequacy of individual care, services, personal safety, fire safety, or the well-being of any Participant or occupant of a Facility.

3. A License is not assignable or transferable and is subject to revocation at any time by the Department for the Licensee's failure to comply with the laws and regulations of this state.

4. A License shall be effective for a specified Facility at a specific location for a specified period following the date of issue as determined by the Department. A License shall remain in effect until the Department notifies the Licensee of a change in that status.

5. Facilities owned by the same entity but which are not located on the same adjoining or contiguous property shall be separately licensed. Roads or local streets, except limited access, shall not be considered as dividing otherwise adjoining or contiguous property. For Facilities owned by the same entity, separate Licenses are not required for separate buildings on the same or adjoining grounds where a single level or type of care is provided.

6. Multiple types of Facilities on the same premises shall be licensed separately even though owned by the same entity.

~~F~~E. Facility Name. No proposed ~~f~~Facility shall be named nor shall any existing ~~f~~Facility have its name changed to the same or similar name as any other ~~f~~Facility licensed in South Carolina. ~~The Department shall determine if names are similar.~~ If the ~~f~~Facility is part of a "chain operation" it shall then have the geographic area in which it is located as part of its name.

~~G~~F. Application. Applicants for a ~~l~~License shall submit to the Department a completed and accurate application on a form prescribed and furnished by the Department prior to initial licensing and periodically thereafter at intervals determined by the Department. The application shall be signed by the owner(s) if an individual or partnership; by two (2) officers if a corporation; or by the head of the governmental department having jurisdiction if a governmental unit. Corporations or limited partnerships, limited liability companies, or any other organized business entity shall be registered with the South Carolina Secretary of State's Office if required to do so by state law.

G. Required Documentation. The application for initial licensure shall include:

1. The full name and address of the proposed Facility and the owner, and the names of the persons in control of the Facility. The Department may require additional information, including affirmative evidence of the applicant's ability to comply with this regulation;

2. The applicant's oath assuring that the contents of the application are accurate and true, and that the applicant will comply with this regulation;

3. Proof of ownership of real property in which the Facility is located, or lease agreement allowing the Licensee to occupy the real property in which the Facility is located;

4. Verification of Administrator's qualifications; and

5. Number of Participants.

H. Licensing Fees. Each applicant shall pay a License fee prior to the issuance of a License. The ~~annual license~~ fee for the initial License shall be three dollars ($3.00) for each ~~licensed p~~Participant. The fee for an increase in the number of Participants for which the Facility is licensed shall be three dollars ($3.00) for

each Participant. The License renewal fee shall be three dollars ($3.00) per Participant, based upon average Participant census number . The License renewal fees shall also include any outstanding Inspection fees. ~~Such~~All fees are non-refundable, shall be made payable by check or credit card to the Department ~~of Health and Environmental Control~~ or a secured portal or specific website, and ~~are not refundable~~shall be submitted with the application.

I. Licensing Late Fee. Failure to submit a renewal application ~~or~~and fee ~~thirty (30) days or more after~~to the Department by the ~~l~~License expiration date ~~may~~shall result in a late fee of seventy-five dollars ($75.00) or twenty-five percent (25%) of the ~~licensing~~License fee amount, whichever is greater, in addition to the ~~licensing~~License fee. ~~Continual f~~Failure to submit ~~completed and accurate renewal applications and/or~~the License fee and License late fee~~s by the time period specified by the Department may result in an enforcement action~~to the Department within thirty (30) calendar days of the License expiration date shall render the Facility unlicensed.

J. License Renewal. For a License to be renewed, the applicant shall file an application with the Department, shall pay the License renewal fee, and shall not have pending enforcement actions by the Department. If the License renewal is delayed due to enforcement actions, the License renewal shall be issued only when the matter has been resolved satisfactorily by the Department, or when the adjudicatory process is completed, whichever is applicable.

~~J~~K. ~~Change of License~~Amended License.

~~1. A~~The ~~f~~Facility shall request issuance of an amended ~~l~~License by application to the Department prior to any of the following circumstances:

~~a~~1. Change of ~~ownership by purchase or lease~~Facility location from one geographic site to another;

~~b~~2. Change of ~~f~~Facility's name or address; or

~~c~~3. Change in licensed number of ~~p~~Participants.

~~2. Changes in facility name or address (as notified by the post office) shall be accomplished by application or by letter from the licensee.~~

~~K. Day Care Facilities for Adults shall not serve participants whose needs exceed resources outlined in these regulations. (II)~~

~~L. Number of Participants. No facility shall at any given time care for more participants than approved and so stated on the face of the license. (II)~~

~~M. Rights of Participants. A Statement of Rights of Adult Day Care Participants is in Section 901 of this regulation and shall be posted in a conspicuous place in the facility.~~

~~N. Exceptions to Licensing Standards. The Department may make exceptions to these standards where the Department determines the health, safety, and well-being of participants are not compromised, and provided the standard is not specifically required by statute.~~

L. Change of Licensee. The Facility shall request issuance of a new License by application to the Department prior to any of the following circumstances:

1. A change in the controlling interest even if, in the case of a corporation or partnership, the legal entity retains its identity and name; or

2. A change of the legal entity, for example, sole proprietorship to or from a corporation, partnership to or from a corporation, even if the controlling interest does not change.

M. Variance. The Facility may request a variance to this regulation in a format as determined by the Department. Variances shall be considered on a case-by-case basis by the Department. The Department may revoke issued variances as it determines appropriate.

~~103. Facility Closure~~

~~A. Prior to the permanent closure of a facility, the licensee shall notify the Department in writing of the intent to close and the effective closure date. Within ten (10) days of the closure, the facility shall notify the Department of the provisions for the maintenance of the records. On the date of closure, the license shall be returned to the Department.~~

~~B. In instances where a facility temporarily closes, the licensee shall notify the Department in writing within fifteen (15) days prior to temporary closure. At a minimum this notification shall include, but not be limited to: the reason for the temporary closure, the manner in which the records are being stored, and the anticipated date for reopening. The Department shall consider, upon appropriate review, the necessity of inspecting and determining the applicability of current construction standards of the facility prior to its reopening. If the facility is closed for a period longer than one (1) year, and there is a desire to re-open, the facility shall re-apply to the Department for licensure and shall be subject to all licensing requirements at the time of that application, including construction-related requirements for a new facility.~~

~~104. Zero Census~~

~~In instances when there have been no participants in a facility for any reason for a period of ninety (90) days or more, the facility shall notify the Department in writing that there have been no admissions, no later than the 100th day following the date of departure of the last active participant. At the time of that notification, the Department shall consider, upon appropriate review of the situation, the necessity of inspecting the facility prior to any new and/or re-admissions to the facility. The facility shall still submit an application and pay the licensing fee to keep the license active, even though the facility is at zero census or temporarily closed. If the facility has no participants for a period longer than one (1) year, and there is a desire to admit a participant, the facility shall re-apply to the Department for licensure and shall be subject to all licensing requirements at the time of that application, including construction-related requirements for a new facility.~~

~~SECTION 200. ENFORCING REGULATIONS~~
SECTION 200 – ENFORCEMENT OF REGULATIONS

201. General.

The Department shall utilize ~~inspections~~Inspections, ~~investigations~~Investigations, ~~consultations~~Consultations, and other pertinent documentation regarding a proposed or licensed ~~facility~~Facility in order to enforce this regulation.

202. Inspections~~/~~ and Investigations.

A. The Facility shall be inspected~~Inspections~~ by the Department ~~shall be conducted~~ prior to initial licensing, ~~of a facility~~ and the Facility shall be inspected subsequently ~~inspections conducted~~ as deemed appropriate by the Department. (I)

B. ~~All f~~Facilities are subject to ~~i~~Inspection~~/~~ and ~~i~~Investigation at any time without prior notice by individuals authorized by South Carolina Code of Laws. When ~~s~~Staff ~~members/volunteers/participant~~members, Volunteers, and Participants are absent, the ~~f~~Facility shall ~~provide~~post information at the entrance of the Facility to those seeking legitimate access to the ~~f~~Facility, including visitors, as to the expected return of ~~s~~Staff ~~members/volunteers/participants~~members, Volunteers, and Participants. The Facility shall ensure the posted information includes contact information and the expected time of return of the Staff members and Participants. The Facility shall ensure the contact information includes the name of a designated contact and his or her telephone number. The Facility shall ensure the telephone number for the designated contact is not the Facility telephone number. (I)

C. Individuals authorized by South Carolina law shall be granted access to all properties and areas, objects, documents, and records at the time of the Inspections and Investigations and in a timely manner, and have the authority to require the ~~f~~Facility to make photocopies of those documents required in the course of ~~i~~Inspections ~~or~~and ~~i~~Investigations. Photocopies shall be used only for purposes of enforcement of regulations and confidentiality shall be maintained except to verify the identity of individuals in enforcement action proceedings. The ~~P~~physical area of Department ~~i~~Inspections and Investigations shall be determined by the ~~extent to which there is potential impact/affect upon~~ Department based on the potential impact or effect on ~~p~~Participants ~~as determined by the inspector~~. (I)

D. When there is noncompliance with the licensing standards, the ~~f~~Facility shall submit an acceptable written plan of correction ~~to~~in a format determined by the Department. ~~that the~~ Facility shall return the plan of correction ~~shall be signed by the administrator and returned~~ by the date specified on the report of ~~i~~Inspection~~/~~ or ~~i~~Investigation. The Facility shall describe the following in the~~written~~ plan of correction ~~shall describe~~: (II)

1. The actions taken to correct each cited deficiency;

2. The actions taken to prevent recurrences (actual and similar); and

3. The actual or expected completion dates of those actions.

E. Inspection Fees. The Facility shall pay the Inspection fee for initial, relocation, and routine Inspections of two hundred twenty-five dollars ($225.00), plus ten dollars ($10.00) per Participant. The Facility shall pay the Inspection fee for a Participant increase and/or service modification of one hundred twenty-five dollars ($125.00), plus ten dollars ($10.00) per Participant. The Facility shall pay the Inspection fee for follow-up Inspections of one hundred twenty-five dollars ($125.00), plus ten dollars ($10.00) per Participant.

F. The Facility shall pay the following Inspection fees during the construction phase of the project. The plan Inspection fee is based on the total estimated cost of the project whether new construction, an addition, or a renovation. The fees are detailed in the table below.

Construction Inspection Fees	
Plan Inspection	
Total Project Cost	**Fee**
< $10,001	$750

$10,001 - $100,000	$1,500
$100,001 - $500,000	$2,000
> $500,000	$2,500 plus $100 for each additional $100,000 in project cost
Site Inspection	
50% Inspection	$500
80% Inspection	$500
100% Inspection	$500

203. Consultations.

Consultations ~~shall~~may be provided by the Department as requested by the ~~f~~Facility or as deemed appropriate by the Department.

~~**SECTION 300. ENFORCEMENT ACTIONS**~~

SECTION 300 – ENFORCEMENT ACTIONS

301. ~~Enforcement Actions~~General.

When the Department determines that a ~~f~~Facility is in violation of any statutory provision, rule, or regulation relating to the operation or maintenance of such ~~f~~Facility, the Department, upon proper notice to the ~~l~~Licensee, may ~~impose a monetary penalty,~~ deny, suspend, or revoke ~~l~~Licenses and/or assess a monetary penalty.

302. Violation Classifications.

Violations of standards in this regulation are classified as follows:

A. Class I violations are those ~~which the Department determines to~~that present an imminent danger to the health ~~and welfare~~, safety, or well-being of the ~~p~~Participants of the ~~f~~Facility or a substantial probability that death or serious physical harm could result therefrom. A physical condition, one or more practices, means, methods or operations in use in a ~~f~~Facility may constitute such a violation. The condition or practice constituting a Class I violation shall be abated or eliminated immediately unless a fixed period of time, as stipulated by the Department, is required for correction. Each day such violation shall exist after expiration of said time established by the Department shall be considered a subsequent violation.

B. Class II violations are those, other than Class I violations, ~~which the Department determines to have a direct or immediate relationship to the health, safety or security of the facility's~~that have a negative impact on the health, safety, or well-being of ~~p~~Participants in the Facility. The citation of a Class II violation shall specify the time within which the violation is required to be corrected. Each day such violation ~~shall~~ exists after expiration of ~~said~~this time shall be considered a subsequent violation.

C. Class III violations are those which are not classified ~~as serious~~as Class I or II in ~~these~~this regulation~~s~~ or those ~~which~~that are against the best practices ~~as interpreted by the Department~~. The citation of a Class III violation shall specify the time within which the violation is required to be corrected. Each day such violation ~~shall~~ exists after expiration of ~~said~~this time shall be considered a subsequent violation.

D. ~~Class I and II violations are indicated by notation after each applicable section, i.e.,~~ The notations (I) or (II), placed within sections of this regulation, indicate those standards are Class I or II violations if they

are not met, respectively. ~~Violations of sections which are not annotated in that manner denote~~Failure to meet standards not so annotated are Class III violations.

~~E. The Department shall exercise discretion in arriving at its decision to penalize a facility. The Department will consider the following factors: specific conditions and their impact or potential impact on health, safety or welfare; efforts by the facility to correct; overall conditions; history of compliance; any other pertinent conditions.~~

~~F~~E. When imposing a monetary penalty, the Department may invoke ~~1976~~South Carolina Code Section 44-7-320(C) to determine the dollar amount or may utilize the following schedule:

~~MONETARY PENALTY RANGES~~			
~~Frequency of Violation of standard within a 24-month period~~	~~Class I~~	~~Class II~~	~~Class III~~
~~1st~~	~~$200-1000~~	~~$100-500~~	~~$0~~
~~2nd~~	~~500-2000~~	~~200-1000~~	~~100-500~~
~~3rd~~	~~1000-5000~~	~~500-2000~~	~~200-1000~~
~~4th~~	~~5000~~	~~1000-5000~~	~~500-2000~~
~~5th~~	~~5000~~	~~5000~~	~~1000-5000~~
~~6th~~	~~5000~~	~~5000~~	~~5000~~

FREQUENCY	CLASS I	CLASS II	CLASS III
1st	$500-1,500	$300-800	$100-300
2nd	1,000-3,000	500-1,500	300-800
3rd	2,000-5,000	1,000-3,000	500-1,500
4th	5,000	2,000-5,000	1,000-3,000
5th	5,000	5,000	2,000-5,000
6th	5,000	5,000	5,000

~~SECTION 400. POLICIES AND PROCEDURES~~
SECTION 400 – POLICIES AND PROCEDURES (II)

~~401. Policies and Procedures~~

A. The Facility shall maintain and adhere to ~~W~~written policies and procedures addressing ~~each section of~~the manner in which the requirements of this regulation ~~regarding participant care, rights, and the operation of the facility shall be developed and implemented, and revised as required in order to accurately reflect actual facility operations~~shall be met. ~~The facility shall establish a time period for review of all policies and procedures and such reviews shall be documented. The facility shall make its policies and procedures available to staff at all times and available to participants and their families and/or caregivers for inspection upon request.~~ The Facility shall be in full compliance with the policies and procedures.

B. ~~They~~The Facility shall ensure the written policies and procedures ~~shall~~ include ~~but not be limited to~~ the following:

~~1. Purpose of the facility, to include scope and quality of services;~~

~~2. Criteria for enrollment;~~

~~3. Organizational structure defining lines of authority;~~

~~4. Fees charged;~~

~~5. Ensuring the compliance with all relevant Federal, State, and local laws which govern operations of the facility; and~~

~~6. Rights and responsibilities of participants.~~

1. Staffing and training;

2. Reporting Incidents, closure, and zero census;

3. Participant records;

4. Participant care and services;

5. Participant rights and assurances;

6. Medication management;

7. Admissions and Discharge;

8. Fire prevention;

9. Housekeeping;

10. Infection control including prevention, identification, reporting, investigation, and control of infections and communicable diseases among Participants, Staff, Volunteers, visitors, and any individual providing care and services; and

11. Facilities providing an Alzheimer's special care program shall include in its policies and procedures the form of care or treatment provided that distinguishes it as being especially applicable to or suitable for persons with Alzheimer's disease pursuant to the South Carolina Alzheimer's Special Care Disclosure Act.

C. The Facility shall establish a time period for review, not to exceed two (2) years, of all policies and procedures, and such reviews shall be documented and signed by the Administrator. The Facility shall ensure all policies and procedures are accessible to Staff, printed or electronically, at all times.

~~402. Administrator~~

~~A. The governing authority or owner shall select a full-time Administrator to manage the facility. The governing authority shall report within seventy-two (72) hours to the Department in writing any change in the position of the Administrator. The governing authority, owner, or Administrator shall appoint in writing an individual to act in the absence of the Administrator.~~

~~B. An Administrator shall have a bachelor's degree, or at least two (2) years of college or technical school with at least an additional four (4) years of experience in the field of nursing, social service, sociology, psychology or in an area closely related to health and social development for the aging. (II)~~

~~403. Administrative Records~~

The facility shall have on file at the facility the following documents and references:

A. A record of annual inspection by the fire safety authority having jurisdiction, to verify that all applicable fire safety requirements have been met; (I)

B. A record of programs and activities;

C. A complete record of daily attendance of participants and staff for the previous six (6) months;

D. The daily menu served for the previous six (6) months with substitute food items noted;

E. Current regulations;

F. Reports of inspections, reviews, and corrective actions taken related to licensure for the previous three (3) years;

G. Annual elevator safety inspections, if applicable; and (II)

H. Annual heating, ventilation, and air conditioning inspection report.

404. Personnel

A. Direct care staff members and volunteers shall undergo a criminal background check prior to being employed or contracting with a Day Care Facility for Adults pursuant to S.C. Code Section 44-7-2910.

B. Each facility shall have a staff capable of providing program services and supervision to the participants. The minimum staff/participant ratio shall be one (1) direct care staff member to eight (8) participants. Volunteers and interns may count as staff. (II)

C. There shall be accurate and current information maintained regarding all staff members/volunteers of the facility, to include at least address, telephone number, and personal/work/training background.

D. All staff members/direct care volunteers who have contact with participants shall have a health assessment within twelve (12) months prior to initial participant contact. The health assessment shall include tuberculin skin testing as described in Sections 807 and 808.

E. All new staff members/direct care volunteers shall have documented orientation to the organization and environment of the facility, specific duties and responsibilities of staff members/direct care volunteers, and participants' needs within twenty-four (24) hours of their first day on the job in the facility.

F. In-service training programs shall be planned and provided for all employees to ensure and maintain their understanding of their duties and responsibilities. Records shall be maintained to reflect program content and individuals attending. Documentation of all in-service training shall be signed and dated by both the individual providing the training and the individual receiving the training. A signature for the individual providing the training may be omitted for computer-based training. The following training shall be provided prior to participant contact at a minimum:

1. Fire Safety Measures;

2. Infection Control;

3. Participant Rights; and

4. Confidentiality of participant information and records and the protecting of participants' rights, including prevention of abuse, neglect, and exploitation;

G. A personnel record folder shall be maintained for each employee and for each direct care and food service volunteer. The folder shall contain a current job description that reflects the employee's responsibilities and work assignments, and documentation indicating that job orientation, in-service education, annual performance evaluations (except for volunteers), pre-employment physical and TB skin tests were performed.

H. At least one (1) staff member who is certified with American Red Cross first-aid training and CPR (or American Heart Association CPR) and capable of recognizing symptoms of distress shall be present when participants are in the facility. If the staff member is a licensed nurse, first-aid training will not be required. (I)

SECTION 500. CARE OF PARTICIPANTS

501. Activities and Programs

A. Activities and therapies shall be offered through individualized plans of care which set forth measurable goals or behaviorally stated objectives. These shall be designed to activate, motivate, and/or assist participants to enable them to sustain or regain functional independence. Group and individual type services shall be provided.

B. A planned, well-balanced program of activities and services shall be provided at each facility.

C. Each facility shall provide supervision and personal care training in order to assist the participant in developing self-help skills.

D. Each facility shall make available social, group, individual, educational, recreational, and other activities such as:

1. Opportunities for arts and crafts;

2. Daily exercise by the participant;

3. Development of hobbies;

4. Assistance with community and personal referral activities;

5. Reading of magazines and books, television viewing, and listening to the radio;

6. Excursions or outings to points of interest; or

7. Planned indoor and outdoor recreation.

E. A schedule of the program(s) shall be posted at all times.

F. Rest periods shall be provided when needed or as prescribed by a physician.

G. The emergency/sick bed ratio shall be one (1) bed per twenty (20) licensed participants or fraction thereof. The emergency/sick beds that are required shall be set up and ready for use. Roll-away beds are not permitted. The facility shall include private room(s), cubicle curtains, portable partitions, or other means to insure privacy of participants when utilizing the bed(s). (II)

H. A facility shall provide at least one chair with arms per participant, including one recliner or comfortable lounge chair per four participants, for resting or other leisure activities. (II)

I. A facility shall provide sufficient table space for dining and crafts.

502. Medical Needs

A. A physical examination is required within sixty (60) days prior to the enrollment of any participant. The physician's report shall include recommendations regarding limitations of activities, special diet, medications (name, type, dosage and whether the individual is capable of self-administering), and other considerations to determine whether appropriate services are available. The facility shall provide dietary and other health needs. The physical and mental condition of a participant must not confine him/her to a bed. (II)

B. In the event of a transfer of a participant from one licensed facility to another licensed facility, a new, pre-enrollment physical examination is not required if the new facility obtains a copy of the latest physical examination of the transferred participant, provided the latest physical exam occurred within the prior two (2) years.

C. Subsequent physical examinations or periodic health screening to determine a participant's ability to continue in the program is required at least every two (2) years.

D. The facility shall properly store and safeguard medications to prevent access by unauthorized persons. Storage areas shall be locked, and of sufficient size for clean and orderly storage. Narcotics shall be secured by double-lock. Medications requiring refrigeration shall be kept in a secured refrigerator used exclusively for medications, or in a secured manner in which medications are separated from other items kept in a refrigerator (e.g., Lock Box). All refrigerators storing medications shall have accurate thermometers (within plus or minus two (2) degrees).

E. A standard first-aid kit or equivalent first-aid supplies shall be on hand and readily accessible to include, but not limited to, the following:

1. Adhesive compresses;

2. Bandage compresses;

3. Plain gauze pads;

4. Antiseptic cleanser;

5. Absorbent gauze;

6. Triangular bandage;

7. Tourniquet; and

~~8. Scissors and tweezers.~~

~~503. Participant Records~~

~~A. A file shall be maintained for each participant. Each file shall contain, but not be limited to, the following information: (II)~~

~~1. A personal data sheet to include: full name, address, phone number, social security number, photo, race, religious preference, next of kin or sponsor, marital status, name of spouse, and any other appropriate information;~~

~~2. Pre-enrollment physician's examination (within sixty (60) days prior to enrollment) and subsequent health screenings;~~

~~3. A listing (to include telephone numbers) of the participant's personal physician(s) and next of kin, legal guardian or sponsor to be contacted in case of emergency or illness;~~

~~4. A complete record setting forth an individual plan of care and activities; this care plan shall be completed within thirty (30) days of enrollment and shall include, but not be limited to:~~

~~a. Initial assessment by facility staff of the participant's physical condition, capabilities, and needs;~~

~~b. Objectives;~~

~~c. Notes of observation at least quarterly (An observation note is an entry made by a direct care staff member in reference to the progress of a participant relative to the achievement of goals as indicated in the care plan. Any appropriate routine entry made on a more frequent basis will satisfy this requirement.); and~~

~~d. Review and/or revision as changes in participant needs occur but not less than semi-annually;~~

~~5. Signed agreement between the facility and participant or sponsor stating the amount of fees for listed services;~~

~~6. A record of incidents, accidents, emergencies and illnesses which occur while the participant is receiving day care services.~~

~~7. Written acknowledgement of the Statement of Rights of Adult Day Care Participants (see Section 901) signed by the participant or responsible party/sponsor.~~

SECTION 500 – STAFF AND TRAINING

501. General. (II)

A. Before being employed or contracted as a Staff member or Volunteer, all Direct Caregiver Staff shall undergo a criminal background check pursuant to South Carolina Code Section 44-7-2910. Staff members and Volunteers shall not have a prior conviction or have pled no contest (nolo contendere) to unlawful conduct toward a child, as defined by South Carolina Code Section 63-45-70; Abuse, Neglect, or Exploitation of a vulnerable Adult, as defined by South Carolina Code Sections 43-35-10, et seq.; or any similar criminal offense. The Facility shall maintain documentation of all criminal background checks and make them available to the Department upon request. (I)

B. The Facility shall maintain a personnel file for each Staff member and Volunteer. The Facility shall ensure the personnel file for each Staff member and Volunteer contains:

1. Accurate and current information to include at least address, phone number, date of hire, first day on the job, date of initial Participant contact, and personal, work, and training background; and

2. A current job description that reflects responsibilities and work assignments, job orientation, in-service education, and Health Assessment including tuberculin skin testing as described in Section 1702.

502. Administrator. (II)

A. The Facility shall maintain a full-time Administrator to manage the Facility.

B. The Administrator shall have a bachelor's degree or at least two (2) years of college or technical school with at least an additional four (4) years of experience in the field of nursing, social service, sociology, psychology, or in an area closely related to health and social development for the aging.

C. The Facility shall designate in writing a Staff member to act in the absence of the Administrator.

D. The Facility shall notify the Department in writing within seventy-two (72) hours of any change in Administrator status and shall provide the Department the name of the newly appointed Administrator, the effective date of the appointment, and documentation of the newly appointed Administrator's qualifications pursuant to Section 502.B.

503. Staffing. (I)

A. The Facility shall have Staff capable of providing program services and supervision to the Participants. The Facility shall maintain a Staff-to-Participant ratio of at least one (1) Direct Care Staff member or Volunteer to eight (8) Participants.

B. The Facility shall maintain documentation to ensure the Facility meets Section 503.A.

504. Orientation. (I)

The Facility shall develop and execute a written orientation program to familiarize all new Staff members and Volunteers with the Facility, its policies and procedures, the Staff members' job responsibilities, and needs of the Participants. The Facility shall maintain documentation of orientation that includes orientation source and duration and shall be signed and dated by the orientation trainer and trainee. The Facility shall ensure all orientation is completed within twenty-four (24) hours of the first day on the job in the Facility.

505. Training. (I)

The Facility shall require all Staff members and Volunteers to complete the necessary training to perform their duties and responsibilities. The Facility shall ensure documentation of all training is signed and dated by both the individual providing the training and the individual receiving the training. A signature for the individual providing the training may be omitted for computer-based training. The following training shall be provided to all Staff and Volunteers prior to Participant contact and at a frequency determined by the Facility, but at least Annually unless otherwise specified by certificate, e.g., cardiopulmonary resuscitation (CPR):

A. Fire Safety Measures;

B. Infection Control;

C. Participant Rights including prevention of Abuse, Neglect, and Exploitation;

D. Confidentiality of Participant information and records;

E. Depending on the type of Participants, care of persons specific to the physical and/or mental condition being cared for in the Facility including dementia, cognitive disability, mental illness, or aggressive, violent, and/or inappropriate behavioral symptoms, and etc., to include communication techniques (cueing and mirroring), understanding and coping with behaviors, safety, activities, etc.; and

F. At least one (1) Staff member who has certification of first-aid training, cardiopulmonary resuscitation (CPR) certification, and is capable of recognizing symptoms of distress shall be present when Participants are in the Facility. If the Staff member is a licensed nurse, first-aid training shall not be required. (I)

506. Health Assessment. (I)

A. All Staff members and Volunteers who have contact with Participants shall have a Health Assessment within twelve (12) months prior to initial Participant contact. The Health Assessment shall include tuberculin skin testing as described in Section 1702.

B. For Staff members working at multiple Facilities operated by the same Licensee, copies of the documented Health Assessment shall be accessible at each Facility.

~~**SECTION 600. FOOD SERVICE (II)**~~

~~601. General~~

~~A. All facilities that prepare food on-site shall be approved by the Department and regulated, inspected, and permitted pursuant to R.61-25.~~

~~B. When meals are catered to a facility, such meals shall be obtained from a food service establishment graded by the Department, pursuant to R.61-25, and there shall be a written executed contract with the food service establishment.~~

~~C. The transportation of all food from a permitted food service establishment to another location for service shall meet the requirements of R.61-25 for storage, display, and general protection against contamination.~~

~~D. The use of home canned foods is not allowed.~~

~~E. All cleaning supplies, detergents and other potentially poisonous items shall be stored away from food items.~~

~~F. At least one (1) handwash sink equipped with hot and cold, sanitary soap dispenser, and towel dispenser or electric hand dryer shall be present in the food preparation areas.~~

~~G. If a dishwashing machine is used, it shall meet the standards for sanitization required by the Department. Domestic (home-type) dishwashing machines shall be equipped with a self-contained water heating element or otherwise be provided an inlet water temperature of 160 degrees Fahrenheit.~~

~~602. Meals and Special Diets~~

~~A. A facility shall provide at least one (1) meal for participants who receive adult day care services for four (4) hours or more per day, unless otherwise directed by a physician in writing. A facility shall provide at least two (2) meals for each participant receiving care for ten (10) or more hours per day unless otherwise directed by a physician.~~

~~B. All facilities shall provide dietary services to meet the daily dietary needs of participants in accordance with written dietary policies and procedures. Each meal shall provide at least one-third of the U.S.D.A. recommended dietary requirement and other standards established by the Department. Facilities shall post weekly menus where they may be observed by participants. Snacks are permitted but not in lieu of full meals.~~

~~C. Facilities with participants in need of special or therapeutic diets shall employ or contract with (either directly or through a caterer) a dietitian or qualified food service supervisor to provide appropriate consultations for such diets. A qualified food service supervisor is a person who:~~

~~1. Is a graduate of a dietetic technician or dietetic assistant training program, (correspondence or classroom), approved by the American Dietetic Association; or~~

~~2. Is a graduate of a State-approved course that provided ninety (90) or more hours of classroom instruction in food service supervision, and has experience as a supervisor in a health care institution with consultation from a dietitian; or~~

~~3. Has training and experience in food service supervision and management in a military service equivalent in content to the programs in paragraphs (1) or (2) above.~~

~~D. Special diets shall be prescribed, dated and signed by the physician.~~

SECTION 600 – REPORTING

601. Incidents. (II)

A. The Facility shall document every Incident and include an Incident review, Investigation, and evaluation as well as corrective action taken, if any. The Facility shall retain all documented Incidents reported pursuant to this section for six (6) years after the Participant involved is last Discharged. The Facility shall keep the documents onsite and readily available at the Facility for the first year following Participant Discharge.

B. The Facility shall report the following types of Incidents to the Department, Responsible Party, Sponsor, and/or emergency contact for each affected Participant within twenty-four (24) hours of the Incident. The Facility shall notify the Department via the Department's electronic reporting system or as otherwise determined by the Department. Incidents requiring reporting include:

1. Confirmed or suspected crimes against Participants;

2. Confirmed or suspected Abuse, Neglect, or Exploitation;

3. Hospitalization or death resulting from an Incident;

4. Elopement;

5. Medication errors;

6. Burns, hematoma, or laceration requiring medical attention;

7. Bone or joint fracture;

8. Other injuries requiring medical attention or hospitalization;

9. Attempted suicide; and

10. Fire.

C. The Facility shall submit a separate written investigation report within five (5) calendar days of every Incident required to be reported to the Department pursuant to Section 601.B via the Department's electronic reporting system or as otherwise determined by the Department. Reports submitted to the Department shall contain only: Facility name, License number, type of Incident, the date the Incident occurred, number of Participants directly injured or affected, Participant medical record identification number, Participant age and sex, number of Staff directly injured or affected, number of visitors directly injured or affected, witness(es') name(s), identified cause of Incident, internal investigation results if cause unknown, a brief description of the Incident including location where occurred, and treatment of injuries.

602. Closure and Zero Census.

A. The Facility shall notify the Department and Participants, or Participants' representatives when appropriate, in writing prior to permanent closure of the Facility and shall provide the effective closure date. The Facility shall return its License to the Department on the date of closure.

B. The Facility shall notify the Department in writing within fifteen (15) calendar days prior to a temporary closure, or within forty-eight (48) hours if the temporary closure is due to an emergency. The notification shall include the reason for the temporary closure, records maintenance plan, anticipated reopening date, and documentation of Participant notification. Facilities that are temporarily closed longer than one (1) year shall reapply for licensure with the Department and shall be subject to all applicable licensing and construction requirements for new Facilities.

C. The Facility shall notify the Department in writing if there have been no Participants in the Facility for any reason for ninety (90) calendar days or more no later than one hundred (100) calendar days after the last Participant is Discharged. Facilities that are zero census longer than one (1) year shall reapply for licensure with the Department and shall be subject to all applicable licensing and construction requirements for new Facilities.

D. Prior to closing the Facility for any reason, the Licensee shall arrange for preservation of records to ensure compliance with this regulation. The Facility shall notify the Department in writing within ten (10) calendar days of closure of the provisions for records maintenance describing the arrangements and the location of the records.

603. Reportable Diseases and Infections. (I)

The Facility shall immediately report animal bites, diseases, and infections in accordance with Regulation 61-20, Communicable Diseases, to the Department's local health department and Bureau of Facilities Oversight. The Facility shall maintain documentation of reported animal bites, diseases, and infections in the Participant records.

~~SECTION 700. FUNCTIONAL SAFETY~~

~~701. Maintenance~~

~~A facility's structure, its component parts, and all equipment such as elevators, furnaces and emergency lights, shall be kept in good repair and operating condition. Areas used by participants shall be maintained in good repair and kept free of hazards, to include obstructions which may block exits in case of emergency. (II)~~

~~702. Emergency/Disaster Preparedness~~

~~A. The facility shall have a written emergency plan and have a floor diagram posted for evacuation of participants, staff, and visitors in case of fire or other emergency. (I)~~

~~B. At least one (1) fire drill shall be held every three (3) months to familiarize all employees with fire safety procedures. Records of the drills and attendees shall be maintained. Upon identification of procedural problems with regard to the drills, records shall show what corrective action has been taken. (I)~~

~~C. The facility shall post emergency call data in a conspicuous place and shall include at least the telephone numbers of fire and police departments, ambulance service, and the poison control center. Other emergency call information shall be available, to include the names, addresses, and telephone numbers of staff members/volunteers to be notified in case of emergency.~~

~~703. Accidents/Incidents (II)~~

~~A. The facility shall report each accident and/or incident resulting in unexpected death or serious injury to the next-of-kin or responsible party for each affected individual at the earliest practicable hour, not exceeding twenty-four (24) hours. The facility shall notify the Department immediately, not to exceed twenty-four (24) hours, via telephone, email or facsimile. The facility shall submit a report of the licensee's investigation of the accident and/or incident to the Department within five (5) days. Accidents and/or incidents requiring reporting include, but are not limited to,:~~

~~1. Abuse, Neglect or Exploitation (Confirmed);~~

~~2. Abuse, Neglect or Exploitation (Suspected);~~

~~3. Adverse or severe medication reaction;~~

~~4. Criminal event against participant;~~

~~5. Death;~~

~~6. Elopement;~~

~~7. Fire;~~

~~8. Fracture of bone or joint;~~

~~9. Hospitalization as a result of accident/incident;~~

~~10. Medication Error resulting in hospitalization or death;~~

~~11. Burns, hematoma, laceration requiring medical attention; and~~

~~12. Attempted Suicide.~~

~~B. Reports submitted to the Department shall contain only: facility name, license number, type of accident/incident, date accident/incident occurred, number of participants directly injured or affected, participant record number or last four (4) digits of Social Security Number, participant age and sex, number of staff directly injured or affected, number of visitors directly injured or affected, witness(es) name(s), identified cause of accident/incident, internal investigation results if cause unknown, a brief description of the accident/incident including location where occurred, and treatment of injuries. The report retained by the facility, in addition to the minimum reported to the Department, shall contain: names of participant(s), staff, and/or visitor(s), the injuries and treatment associated with each Participant, staff, and/or visitor. Records of all accidents and incidents shall be retained by the facility for six (6) years after the participant stops receiving services.~~

SECTION 700 – PARTICIPANT RECORDS

701. Content. (II)

A. The Facility shall maintain an organized record for each Participant. The Facility shall ensure all entries in the Participant record are permanently written, typed, or electronic media, authenticated by the author, and dated. The Facility shall have policies and procedures to prohibit access to Participant records that are generated by electronic or optical means.

B. The Facility shall maintain current Participant records for each Participant that contain:

1. A personal data sheet to include: full name, address, phone number, photo, race, religious preference, marital status, name of spouse, Responsible Party, Sponsor, emergency contact, and Participant's personal physician(s);

2. An enrollment Physical Examination and subsequent Physical Examinations;

3. Progress Notes. The Facility shall document, at least quarterly, progress notes by Direct Care Staff for each Participant. The Facility shall ensure that all progress notes include the progress of each Participant relative to the achievement of goals as indicated in the Individual Plan of Care;

4. A signed written agreement between the Participant and/or the Participant's Sponsor or Responsible Party and the Facility. The Facility shall revise the agreement upon any changes and document the signatures of the Participant, Sponsor, or Responsible Party. The Facility shall ensure the written agreement includes at least the following:

a. An explanation of the specific care, services, and activities provided by the Facility; and

b. Disclosure of fees for all care, services, and activities provided;

5. A record of Incidents, emergencies, and illnesses that occur while the Participant is receiving Adult Day Care Services; and

6. A written acknowledgement of the Statement of Rights of Adult Day Care Participants signed by the Participant, or Responsible Party or Sponsor.

702. Enrollment Assessment. (II)

The Facility shall ensure a Staff member conducts and documents a written initial enrollment assessment of the Participant to include the Participant's physical condition, capabilities, preferences, and needs. The Facility shall ensure the Staff member conducts the initial enrollment assessment within a time period determined by the Facility that is evidenced and documented by the signature and date of the Staff member.

703. Individual Plan of Care. (II)

A. The Facility shall complete the Individual Plan of Care for each Participant within thirty (30) calendar days of the Participant's enrollment and shall review and/or revise as changes in Participant's needs occur but not less than semi-annually with the Participant, Administrator or designee, and/or the Sponsor or Responsible Party as evidenced by their signatures and date. The Facility shall provide the Responsible Party and or Sponsor a copy of the Individual Plan of Care upon request.

B. The Facility shall ensure the Individual Plan of Care:

1. Describes the needs of the Participant including the activities of daily living for which the Participant requires assistance, i.e., what assistance, how much, who will provide the assistance, how often, and when;

2. Delineates the responsibilities of the Facility in meeting the needs of the Participant including provisions to monitor the care and the effectiveness of the Facility in meeting those needs; and

3. Includes specific goal-related objectives based on the needs and preferences of the Participant as identified during the assessment, activities, access to the community, other special needs, and the methods for achieving objectives and meeting needs in measurable terms with expected achievement dates.

704. Record Maintenance.

A. The Licensee shall provide accommodations, space, supplies, and equipment for the protection, storage, and maintenance of Participant records in an organized manner.

B. The Participant record is confidential and shall be made available only to individuals authorized by the Facility and in accordance with local, state, and federal laws, codes, and regulations. (II)

C. Records generated by organizations or individuals contracted by the Facility for care or services shall be maintained by the Facility that has enrolled the Participants.

D. Upon Discharge of a Participant, the record shall be completed within thirty (30) calendar days, and filed in an inactive or closed file maintained by the Licensee.

E. Participants records shall be maintained for at least six (6) years following the Discharge of the Participant. Unless otherwise indicated, other regulation-required documents shall be retained at least twelve (12) months or since the last Department general Inspection, whichever is the longer period.

F. Current Participant records are the property of the Facility, shall be maintained at the Facility, and shall not be removed from the Facility without court order.

~~SECTION 800. INFECTION CONTROL AND SANITATION~~

~~801. General~~

~~The facility shall provide adequate space, equipment, and staff in the facility to assure protection of all participants and staff against cross-infection. (II)~~

~~802. Linen and Laundry (II)~~

~~A. An adequate supply of clean linen or disposable materials shall be maintained for the sick bed(s). Each bed shall be made up with at least one (1) clean linen change (bottom and top sheets and pillowcase) and a bedspread or coverlet.~~

~~B. Facilities shall provide clean mattress covers, in addition to linen.~~

~~C. Liquid or powder soap dispensers and sanitary paper towels shall be available at each handwash lavatory. Alcohol-based waterless hand sanitizers shall not be used in lieu of liquid or powder soap.~~

~~803. Housekeeping (II)~~

~~A. A facility shall be kept clean and free from odors. Accumulated waste material must be removed daily or more often if necessary. There must be frequent cleaning of floors, walls, ceilings, woodwork, and windows. The premises must be kept free from rodent and insect infestation. Pesticide spraying shall be conducted when participants are not present. Bath and toilet facilities must be maintained in a clean and sanitary condition at all times.~~

~~B. Cleaning materials and supplies shall be stored in a safe manner. All harmful agents shall be locked in a closet or cabinet used for this purpose only.~~

~~C. Dry sweeping and dusting of walls and floors are prohibited while participants are in the area being cleaned.~~

~~D. Floors shall have a smooth, washable surface and shall be kept clean, in good repair, and free from hazards. If carpeting is used, it shall be cleaned regularly and maintained in good repair.~~

~~804. Sanitation (II)~~

~~A. All garbage and waste shall be collected, stored and disposed of in a manner designed to prevent the transmission of disease. Containers shall be washed and sanitized before being returned to work areas. Disposable type containers shall not be reused.~~

~~B. Containers for garbage and refuse shall be covered and stored outside in durable, rust resistant, non-absorbent, watertight, rodent-proof, easily cleanable containers placed on an approved platform to prevent overturning by animals, the entrance of flies, or the creation of a nuisance. All solid waste shall be disposed of at sufficient frequencies in a manner so as not to create a rodent, insect or other vermin problem.~~

~~C. Containers for garbage shall be cleaned as necessary.~~

D. All sewage and liquid waste shall be disposed of in a manner not to create a public health hazard and by a sanitary method approved by the Department.

805. Outside Areas (II)

All outside areas, grounds and/or adjacent buildings shall be kept free of rubbish, grass, and weeds that may serve as a fire hazard or as a haven for roaches, rodents and other pests. Measures for the control of insects, rodents, and other vermin shall be applied to prevent harborage, breeding, and infestation of the premises. All stairs, walkways, ramps and porches shall be maintained free from accumulations of water, ice, snow and other impediments.

806. Pets

A. If the facility chooses to permit pets, healthy animals that are free of fleas, ticks, and intestinal parasites and have been screened by a veterinarian prior to participant contact, have received required inoculations, if applicable, and that present no apparent threat to the health, safety, and well-being of the participants, may be permitted in the facility, provided they are sufficiently fed and cared for and that both the pets and their housing are kept clean.

B. Pets shall not be allowed near participants who have allergic sensitivities to pets, or for other reasons such as participants who do not wish to have pets near them.

C. Pets shall not be allowed in the kitchen area. Pets shall be permitted in participant dining areas only during times when food is not being served. If the dining area is adjacent to a food preparation or storage area, those areas shall be effectively separated by walls and closed doors while pets are present.

807. Tuberculosis Risk Assessment (I)

A. All facilities shall conduct an annual tuberculosis risk assessment in accordance with CDC guidelines to determine the appropriateness and frequency of tuberculosis screening and other tuberculosis related measures to be taken.

B. The risk classification, *i.e.*, low risk, medium risk, shall be used as part of the risk assessment to determine the need for an ongoing TB screening program for staff and participants and the frequency of screening. A risk classification shall be determined for the entire facility. In certain settings, *e.g.*, healthcare organizations that encompass multiple sites or types of services, specific areas defined by geography, functional units, participant population, job type, or location within the setting may have separate risk classifications.

808. Staff Tuberculosis Screening (I)

A. Tuberculosis Status. Prior to date of hire or initial participant contact, the tuberculosis status of direct care staff shall be determined in the following manner in accordance with the applicable risk classification:

B. Low Risk:

1. Baseline two-step Tuberculin Skin Test (TST) or a single Blood Assay for *Mycobacterium tuberculosis* (BAMT): All staff (within three (3) months prior to contact with participants) unless there is a documented TST or a BAMT result during the previous twelve (12) months. If a newly employed staff has

had a documented negative TST or a BAMT result within the previous twelve (12) months, a single TST (or the single BAMT) can be administered to serve as the baseline.

2. Periodic TST or BAMT is not required.

3. Post-exposure TST or a BAMT for staff upon unprotected exposure to *M. tuberculosis*: Perform a contact investigation when unprotected exposure is identified.

4. Administer one (1) TST or a BAMT as soon as possible to all staff who have had unprotected exposure to an infectious TB case/suspect. If the TST or the BAMT result is negative, administer another TST or a BAMT eight to ten (8-10) weeks after that exposure to *M. tuberculosis* ended.

C. Medium Risk:

1. Baseline two-step TST or a single BAMT: All staff (within three (3) months prior to contact with participants) unless there is a documented TST or a BAMT result during the previous twelve (12) months. If a newly employed staff has had a documented negative TST or a BAMT result within the previous twelve (12) months, a single TST (or the single BAMT) can be administered to serve as the baseline.

2. Periodic testing (with TST or BAMT): Annually, of all staff who have risk of TB exposure and who have previous documented negative results. Instead of participating in periodic testing, staff with documented TB infection (positive TST or BAMT) shall receive a symptom screen annually. This screen shall be accomplished by educating the staff about symptoms of TB disease (including the staff and/or direct care volunteers responses), documenting the questioning of the staff about the presence of symptoms of TB disease, and instructing the staff to report any such symptoms immediately to the administrator or director of nursing. Treatment for latent TB infection (LTBI) shall be considered in accordance with CDC and Department guidelines and, if recommended, treatment completion shall be encouraged.

3. Post-exposure TST or a BAMT for staff upon unprotected exposure to *M. tuberculosis*: Perform a contact investigation when unprotected exposure is identified. Administer one (1) TST or a BAMT as soon as possible to all staff who have had unprotected exposure to an infectious TB case/suspect. If the TST or the BAMT result is negative, administer another TST or a BAMT eight to ten (8-10) weeks after that exposure to *M. tuberculosis* ended.

D. Baseline Positive or Newly Positive Test Result:

1. Staff with a baseline positive or newly positive test result for *M. tuberculosis* infection (*i.e.*, TST or BAMT) or documentation of treatment for latent TB infection (LTBI) or TB disease or signs or symptoms of tuberculosis, *e.g.*, cough, weight loss, night sweats, fever, shall have a chest radiograph performed immediately to exclude TB disease (or evaluate an interpretable copy taken within the previous three (3) months). These staff members will be evaluated for the need for treatment of TB disease or latent TB infection (LTBI) and will be encouraged to follow the recommendations made by a physician with TB expertise (*i.e.*, the Department's TB Control program).

2. Staff who are known or suspected to have TB disease shall be excluded from work, required to undergo evaluation by a physician or legally authorized healthcare provider, and permitted to return to work only with approval by the Department TB Control program. Repeat chest radiographs are not required unless symptoms or signs of TB disease develop or unless recommended by a physician or legally authorized healthcare provider.

SECTION 800 – ENROLLMENT AND RETENTION. (I)

A. The Facility shall only enroll Adult Participants.

B. The Facility shall not enroll or retain a Participant who is bed-confined.

C. The Facility shall not retain Participants beyond thirty (30) calendar days if the Facility is incapable of providing the necessary care and/or services needed by the Participant, the Participant has a medical condition or behavior which is unsafe for continued retention in the Facility, or the decision to Discharge the Participant is in accordance with the Facility's policy and procedures.

~~**SECTION 900. STATEMENT OF RIGHTS OF ADULT DAY CARE PARTICIPANTS**~~

~~901. Statement of Rights of Adult Day Care Participants~~

~~A. Each participant must be accorded the following rights: (II)~~

~~1. The right to be treated as an adult, with consideration, respect, and dignity, including privacy in treatment and in care for personal needs.~~

~~2. The right to participate in a program of services and activities designed to encourage independence, learning, growth, and awareness of constructive ways to develop one's interests and talents.~~

~~3. The right to self-determination within the day care setting, including the opportunity to:~~

~~a. Participate in developing one's plan for services and any changes therein.~~

~~b. Decide whether or not to participate in any given activity.~~

~~c. Be involved to the extent possible in program planning and operation.~~

~~d. Refuse treatment, if applicable, and be informed of the consequences of such refusal.~~

~~e. End participation in the adult day care center at any time.~~

~~4. The right to be cared about in an atmosphere of sincere interest and concern in which needed support and services are provided.~~

~~5. The right to a safe, secure and clean environment.~~

~~6. The right to confidentiality and the requirement for written consent for release of information to persons not authorized under law to receive it.~~

~~7. The right to voice grievances without discrimination or reprisal with respect to care or treatment, if applicable, that is (or is not) provided.~~

~~8. The right to be fully informed, as evidenced by the participant's written acknowledgment of these rights, of all rules and regulations regarding participant conduct and responsibilities.~~

~~9. The right to be free from harm, including isolation, excessive medication, if applicable, abuse, or neglect.~~

~~10. The right to be fully informed, at the time of acceptance into the program, of services and activities available and related charges.~~

~~11. The right to communicate with others and be understood by them to the extent of the participant's capability.~~

~~B. The Statement of Rights of Adult Day Care Participants shall provide a grievance and complaint procedure to be exercised on behalf of the participants to enforce the Statement of Rights of Adult Day Care Participants that includes the Department's email address and telephone number.~~

~~C. The Statement of Rights of Adult Day Care Participants shall be posted in a conspicuous place in the facility.~~

SECTION 900 – PARTICIPANT CARE AND SERVICES

901. Activities and Programs.

A. The Facility shall offer a regular and ongoing program of varied, meaningful activities designed to suit the interests and physical and cognitive capabilities of the Participants who choose to participate in activities. The Facility shall provide activities that offer intellectual and physical stimulation; promote or enhance physical, mental, and/or emotional health; are age-appropriate; and are based on input from the Participants and/or Responsible Party, as well as information obtained in the initial enrollment assessment. These activities shall include appropriate group activities and also activities for individuals with particular interests and needs.

B. The Facility shall provide supervision and personal care training in order to assist the Participant in developing self-help skills.

C. The Facility shall make social, group, individual, educational, recreational, and other activities available.

D. The Facility shall post the current month's schedule in order for Participants to be made aware of activities offered. This schedule shall include activities, dates, times, and locations. Participants may choose activities and schedules consistent with their interests and physical, mental, and psychosocial well-being. If a Participant is unable to choose for himself or herself, Staff members and Volunteers shall encourage participation and assist when necessary.

902. Daily Census. (II)

The Facility shall maintain an accurate daily census of Participants. The Facility shall maintain records of daily attendance for at least twelve (12) months and make the records available to the Department.

~~SECTION 1000. DESIGN AND CONSTRUCTION~~

~~1001. General (II)~~

~~A. A facility shall be planned, designed, and equipped to provide and promote the health, safety, and well-being of each participant.~~

~~B. Rooms shall be provided to accommodate a variety of programs and participants served. At a minimum, the facility shall provide one (1) group activity room and a room for resting purposes to~~

accommodate the appropriate licensed participants. The facility shall provide adequate storage space for supplies and personal belongings.

C. A minimum of fifty (50) square feet of usable activity space, exclusive of hallways, storage space, kitchen, toilet and resting area(s), office and other similar space, shall be provided for each participant. However, when the adult day care program is combined with a similar program, a minimum of twenty-five (25) feet of usable activity space in one (1) group activity room is permissible, provided that this area is for the exclusive use of the adult day care participants and other recreational and craft areas are available.

D. Only first floor occupancy shall be permitted except where elevators are provided or if only non-participant areas are located on the above floor(s), e.g., storage areas, staff offices, lounges, etc.

E. Every facility shall be accessible to participants with disabilities to include all participant areas and restrooms.

F. The entrance to the building shall be at grade level, be sheltered from the weather and accommodate wheelchairs.

G. There shall be at least two (2) exits remote from each other to exit the building or space.

1002. Applicable Code (II)

A. New facility design and construction shall comply with codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal. No facility shall be licensed unless the Department has received in writing that responsible local officials (zoning and building) have approved the facility for code compliance.

B. Unless specifically required otherwise by the Department, existing facilities shall remain in compliance with the construction codes and construction regulations applicable at the time its license was issued.

C. Any facility that closes, has its license revoked, or surrenders its license and applies for re-licensure at the same site, shall be considered a new building and shall meet the codes, regulations, and requirements for the building and its essential equipment and systems in effect at the time of application for re-licensing.

1003. Submission of Plans and Specifications

A. Plans and specifications shall be prepared by an architect and/or engineer registered in South Carolina. Unless directed otherwise by the Department, submit plans at the schematic, design development, and final stages. All plans shall be drawn to scale with the title, stage of submission and date shown thereon. Any construction changes from the approved documents shall be approved by the Department. Construction work shall not commence until a plan approval has been received from the Department. During construction the owner shall employ a registered architect and/or engineer for observation. Upon approval of the Department, construction administration may be performed by an entity other than the architect. The Department shall conduct periodic inspections throughout each project.

B. Plans and specifications shall be submitted to the Department for new construction and for any projects that has an effect on:

1. The function of a space;

~~2. The accessibility to or of an area;~~

~~3. The structural integrity of the facility;~~

~~4. The active and/or passive fire safety systems (including kitchen equipment such as exhaust hoods or equipment required to be under an exhaust hood);~~

~~5. Doors;~~

~~6. Walls;~~

~~7. Ceiling system assemblies;~~

~~8. Exit corridors;~~

~~9. Life safety systems; or~~

~~10. Increases the occupant load or licensed capacity of the facility.~~

~~C. All subsequent addenda, change orders, field orders, and documents altering the Department review must be submitted. Any substantial deviation from the accepted documents shall require written notification, review and re-approval from the Department.~~

~~D. Cosmetic changes utilizing paint, wall covering, floor covering, etc., that are required to have a flame spread rating or other safety criteria shall be documented with copies of the documentation and certifications kept on file at the facility and made available to the Department.~~

~~E. Any construction work which violates codes or standards shall be brought into compliance.~~

~~1004. Construction Inspections~~

~~All projects shall obtain all required permits from the locality having jurisdiction. Construction without proper permitting shall not be inspected by Department.~~

SECTION 1000 – PARTICIPANT RIGHTS

1001. Statement of Rights of Adult Day Care Participants. (II)

A. Each Participant must be accorded the following rights:

1. The right to be treated as an Adult, with consideration, respect, and dignity, including privacy in treatment and in care for personal needs;

2. The right to participate in a program of services and activities designed to encourage independence, learning, growth, and awareness of constructive ways to develop one's interests and talents;

3. The right to self-determination within the day care setting, including the opportunity to:

a. Participate in developing one's plan for services and any changes therein;

b. Decide whether or not to participate in any given activity;

c. Be involved to the extent possible in program planning and operation;

d. Refuse treatment, if applicable, and be informed of the consequences of such refusal; and

e. End participation in the Facility any time;

4. The right to be cared about in an atmosphere of sincere interest and concern in which needed support and services are provided;

5. The right to a safe, secure, and clean environment;

6. The right to confidentiality and the requirement for written consent for release of information to persons not authorized under law to receive it;

7. The right to voice grievances without discrimination or reprisal with respect to care or treatment, if applicable, that is or is not provided;

8. The right to be fully informed, as evidenced by the Participant's written acknowledgment of these rights, of all rules and regulations regarding Participant conduct and responsibilities;

9. The right to be free from harm, Exploitation, Abuse, or Neglect; (I)

10. The right to be fully informed, at the time of enrollment, of services and activities available and related charges; and

11. The right to communicate with others and be understood by them to the extent of the Participant's capability.

B. The Facility shall provide grievance and complaint procedures for Participants, Sponsors, and Responsible Parties on the Statement of Rights of Adult Day Care Participants to be exercised on behalf of the Participants to enforce the Statement of Rights of Adult Day Care Participants that includes the Department's email address and telephone number.

C. The Facility shall post the Statement of Rights of Adult Day Care Participants in a conspicuous place in the Facility.

1002. Discharge. (II)

The Facility shall notify the Participant, Responsible Party, and/or Sponsor in writing immediately upon the determination to Discharge the Participant. The Facility shall ensure the Discharge notice includes the reason for Discharge, the proposed date of Discharge, and contact information for how to access community services, if applicable. The Facility shall maintain a copy of the Discharge notice in the Participant's medical record.

~~**SECTION 1100. FIRE PROTECTION EQUIPMENT AND SYSTEMS**~~

~~1101. Alarms~~

~~A. facility shall include a partial, manual, automatic, supervised fire alarm system. The system shall be arranged to transmit an alarm automatically to a third party by an approved method. The alarm system shall~~

~~notify by audible and visual alarm all areas and floors of the building. The alarm system shall shut down central recirculating systems and outside air units that serve the area(s) of alarm origination as a minimum.~~

~~B. All fire, smoke, heat, sprinkler flow, or manual fire alarming devices or systems must be connected to the main fire alarm system and trigger the system when they are activated.~~

~~C. A facility shall include a sprinkler system.~~

~~1102. Gases (I)~~

~~Safety precautions shall be taken against fire and other hazards when oxygen is dispensed, administered, or stored. "No Smoking" signs shall be posted conspicuously inside the facility and on oxygen cylinders. All cylinders shall be properly stored and secured in place.~~

SECTION 1100 – PARTICIPANT PHYSICAL EXAMINATION. (I)

A. The Facility shall ensure a physician or other Authorized Healthcare Provider conducts a Physical Examination of the Participant within sixty (60) calendar days prior to enrollment. The Facility shall ensure the Physical Examination includes recommendations regarding limitations of activities, special diet, medications (name, type, dosage, and whether the individual is capable of self-administering), and other considerations to determine whether appropriate services are available. The Facility shall ensure the Participant receives Physical Examinations at least every two (2) years upon enrollment.

B. When a Participant is transferred from one Facility to another Facility, the transferring Facility shall forward a transfer summary to the receiving Facility at the time of transfer or immediately after the transfer. The transferring Facility shall include the following in the transfer summary at a minimum:

1. Copies of the most recent Physical Examination, the two-step tuberculosis test or Blood Assay for Mycobacterium tuberculosis, and the Individual Plan of Care.

2. The date sent to the receiving Facility and the signature of the transferring Facility Staff member.

~~SECTION 1200. PREVENTIVE MAINTENANCE EQUIPMENT AND UTILITIES~~

~~1201. General~~

~~The facility shall keep the structure, its component parts, facilities and all equipment in good repair and operating condition and documented. Facilities shall comply with provisions of the code officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal.~~

~~1202. Signal System~~

~~A. All facilities shall have a signal system consisting of a call button for each bed, bath, and toilet. A light shall be at or over each participant room door visible from the corridor. There shall be an audio-visual master station in a location continuously monitored by staff.~~

~~B. Facilities shall have a signal system consisting of an audio-visual device that cannot be interrupted located in all utility rooms, medicine preparation rooms, lounges, storage rooms and areas where staff congregate.~~

C. Activation of signal system shall be by pull cord or electronic device. Pull cord shall hang to a maximum of four (4) inches above finished floor.

1203. Restrooms (II)

A. There shall be an appropriate number of restrooms in the facility to accommodate participants, staff, and visitors.

B. Restrooms shall be accessible during all operating hours of the facility.

C. All restrooms shall be equipped with at least one (1) toilet fixture, toilet paper installed in a holder, a handsink supplied with hot and cold running water, liquid or granulated soap, single-use disposable paper towels or electric air dryer, and a covered waste receptacle.

D. All toilet fixtures used by participants shall have approved grab bars securely fastened in a usable fashion.

E. Privacy shall be provided at toilet fixtures and urinals.

F. Bathrooms shall accommodate persons with disabilities as required by codes, whether or not any of the staff or participants are classified as disabled.

G. All restroom floors shall be entirely covered with an approved nonabsorbent covering. Walls shall be nonabsorbent, washable surfaces to the highest level of splash.

H. One toilet shall be provided for each fifteen (15) participants. Where separate staff and/or public toilets are not provided, employees and volunteers shall be included in the ratio.

1204. Janitor's Closets

A. The facility shall include at least one (1) lockable janitor's closet.

B. Each janitor's closet shall contain a floor receptor or service sink and storage space for housekeeping equipment and supplies, *e.g.*, mops.

1205. Storage Areas

A. Facilities shall have adequate general storage areas for equipment, supplies and wheelchairs.

B. Storage buildings on the premises shall meet the requirements of the codes regarding distance from the licensed building. Storage in buildings other than on the facility premises shall be secure and accessible. An appropriate controlled environment shall be provided if necessary for storage of items requiring such an environment.

C. Chemicals indicated as harmful on the product label, cleaning materials, and supplies shall be safely stored in cabinets or well-lighted closets/rooms.

1206. Elevators (II)

Elevators shall be inspected and tested upon installation, prior to first use, and annually thereafter by a certified elevator inspector.

~~1207. Telephone Service~~

~~At least one (1) land-line telephone shall be available on each floor of the facility for use by participants and/or visitors for their private, discretionary use.~~

~~1208. Location~~

~~A. Transportation. The facility shall be served by roads that are passable at all times and are adequate for the volume of expected traffic.~~

~~B. Parking. The facility shall have a parking area to reasonably satisfy the needs of participants, staff members, and visitors.~~

~~C. Access to firefighting equipment. Facilities shall maintain adequate access to and around the building(s) for firefighting equipment. (I)~~

~~1209. Furnishings/Equipment (I)~~

~~A. The facility shall maintain the physical plant free of fire hazards and impediments to fire prevention.~~

~~B. No portable electric or unvented fuel heaters shall be permitted in the facility.~~

~~C. Wastebaskets, furniture, window dressings, portable partitions, cubicle curtains, mattresses, and pillows shall be noncombustible, inherently flame-resistant, or treated or maintained flame-resistant in accordance with the applicable codes.~~

~~D. Wall finishes shall be washable, and, in the immediate area of plumbing fixtures, shall be smooth and moisture resistant.~~

~~E. Wall bases in areas which are frequently subject to wet cleaning methods shall be tightly sealed and constructed without voids that can harbor insects.~~

~~F. Floor and wall penetrations by pipes, ducts, and conduits shall be tightly sealed to minimize entry of rodents and insects. Joints of structural elements shall be similarly sealed.~~

~~G. Interior finish materials shall comply with the flame spread requirements.~~

~~H. Floors shall not have cracks or be of uneven elevation and shall be of non-skid surfaces to prevent falls.~~

~~1210. Water Requirements~~

~~A. The facility shall establish written policies and procedures to prevent waterborne microbial contamination within the water distribution system.~~

~~B. The facility shall ensure the practice of hand hygiene to prevent the hand transfer of pathogens, and the use of barrier precautions (*e.g.*, gloves) in accordance with established guidelines.~~

~~C. The facility shall eliminate contaminated water or fluid from environmental reservoirs (*e.g.*, in equipment or solutions) wherever possible.~~

D. The facility shall not place decorative fountains and fish tanks in participant areas. If decorative fountains are used in separate public areas, the facility shall ensure they are disinfected in accordance with manufacturer's instructions and safely maintained.

E. The facility plumbing fixtures that require hot water and are accessible to participants shall be supplied with water which is thermostatically controlled to a temperature of at least 100 degrees F. (37.8 degrees C) and not exceeding 125 degrees F. (51.7 degrees C.) at the fixture.

F. The facility shall have a written plan to respond to disruptions in water supply. The plan must include a contingency plan to estimate water demands for the entire facility in advance of significant water disruptions (i.e., those expected to result in extensive and heavy microbial or chemical contamination of the potable water), sewage intrusion, or flooding.

G. When a significant water disruption or an emergency occurs, the facility shall:

1. Adhere to any advisory to boil water issued by the municipal water utility;

2. Alert participants, families, employees, volunteers, students and visitors not to consume water from drinking fountains, ice, or drinks made from municipal tap water while the advisory is in effect, unless the water has been disinfected;

3. After the advisory is lifted, run faucets and drinking fountains at full flow for greater than five (5) minutes or use high-temperature water flushing or chlorination;

4. All ice and drinks that may have been contaminated must be disposed and storage containers cleaned; and

5. Decontaminate the hot water system as necessary after a disruption in service or a cross-connection with sewer lines has occurred.

H. The facility shall follow appropriate recommendations to prevent cross connection and other sources of contamination of ice for human consumption.

I. The facility shall maintain and implement policies and procedures addressing the management of failure of waste water systems.

J. Participant and staff handwashing lavatories and showers, if any, shall include hot and cold water at all times.

K. If a non-community water supply is used, approval from the Department shall be obtained to insure safe location, construction, proper maintenance and operation of the system.

L. The use of "common drinking cups" is prohibited. Disposable cups, if used, shall be stored properly to prevent contamination.

M. If a swimming pool is part of the facility, it shall be designed, constructed, and maintained pursuant to the Department's regulations governing swimming pools, Regulation 61-51.

1211. Panelboards (II)

~~The directory shall be labeled to conform to the actual room designations. Clear access shall be maintained to the panel.~~

~~1212. Lighting~~

~~A. Spaces occupied by persons, machinery, equipment within buildings, approaches to buildings, and parking lots shall be lighted. (II)~~

~~B. The facility shall have adequate artificial light to include sufficient illumination for reading, observation, and activities.~~

~~1213. Heating, Ventilation, and Air Conditioning (HVAC) (II)~~

~~A. The HVAC system shall be inspected at least once a year by a certified/licensed technician.~~

~~B. No HVAC supply or return grill shall be installed within three (3) feet of a smoke detector. (I)~~

~~C. Intake air ducts shall be filtered and maintained to prevent the entrance of dust, dirt, and other contaminating materials.~~

~~D. Each bath/restroom shall have either operable windows or approved mechanical ventilation.~~

SECTION 1200 – MEDICATION MANAGEMENT. (I)

A. The Facility shall store and safeguard medications in a locked medicine preparation room, cabinet or cart. The Facility shall monitor and attend to medications at all times to prevent access by unauthorized individuals. The Facility shall not store expired or discontinued medications with current medications. The Facility shall ensure storage areas are not located near sources of heat, humidity, or other hazards that may negatively impact medication effectiveness or shelf life.

B. The Facility shall store medications requiring refrigeration or freezing in a locked refrigerator or freezer as appropriate at the temperature range established by the manufacturer used exclusively for that purpose. The Facility shall not store food and drinks in the same refrigerator or freezer in which medications and biologicals are stored. The Facility shall provide each refrigerator and freezer with a thermometer accurate to plus or minus two (2) degrees Fahrenheit.

C. The Facility shall ensure that Prescription Medication is administered to the Participant in accordance with state practice acts by a licensed nurse or an Authorized Healthcare Provider. The Facility shall ensure that doses of Prescription Medication are administered to the Participant by the same licensed nurse or Authorized Healthcare Provider who prepared them for administration. (I)

D. The Facility shall maintain a standard first-aid kit, or equivalent first-aid supplies on hand, that is readily accessible to include, but not limited to, the following:

1. Absorbent compress dressings;

2. Adhesive bandages, assorted sizes;

3. Adhesive cloth tape;

4. Antibiotic ointment;

5. Antiseptic wipes;

6. Non-latex gloves;

7. Hydrocortisone ointment;

8. Gauze roll bandage; and

9. Sterile gauze pads.

~~**SECTION 1300. SEVERABILITY**~~

~~1301. General~~

~~In the event that any portion of these regulations is construed by a court of competent jurisdiction to be invalid, or otherwise unenforceable, such determination shall in no manner affect the remaining portions of these regulations, and they shall remain in effect as if such invalid portions were not originally a part of these regulations.~~

SECTION 1300 – MEAL SERVICE

1301. General. (II)

A. Facilities that prepare food on-site shall be approved by the Department, and regulated, inspected, and permitted pursuant to Regulation 61-25, Retail Food Establishments.

B. The Facility shall ensure that meals that are catered to the Facility are obtained from a food service establishment graded by the Department pursuant to R.61-25, and the Facility shall have a written executed contract with the food service establishment.

C. The Facility shall ensure food served to the Participants meets the requirements of R.61-25 for temperature, storage, display, and general protection against contamination. The Facility shall not permit the use of home canned foods.

D. The Facility shall maintain at least one (1) hand sink equipped with hot and cold water, liquid soap, and an individualized method of drying hands. The Facility shall ensure handwashing sinks are equipped to provide water at a temperature of at least one hundred (100) degrees Fahrenheit through a mixing valve or combination faucet.

1302. Meals and Special Diets.

A. The Facility shall provide at least one (1) meal for each Participant receiving Adult Day Care Services for four (4) hours or more per day unless otherwise directed by a physician or other Authorized Healthcare Provider in writing. The Facility shall provide at least two (2) meals for each Participant receiving Adult Day Care Services for ten (10) or more hours per day unless otherwise directed by a physician in writing.

B. The Facility shall provide dietary services to meet the daily dietary needs of Participants in accordance with written dietary policies and procedures. The Facility may permit snacks but not in lieu of full meals.

C. The Facility shall establish specific times for serving meals to Participants.

D. The Facility shall maintain suitable food and snacks and offer to Participants between meals at no additional cost to the Participants. (II)

E. The Facility shall wash and sanitize all food contact and non-food contact surfaces, equipment, and utensils in accordance with the standards required by R.61-25.

1303. Menus.

The Facility shall ensure one (1) week of menus, including routine and special diets and any substitutions or changes made, is readily available and posted in one (1) or more conspicuous places in a public area.

1304. Ice and Drinking Water. (II)

A. The Facility shall ensure ice is available and precautions are be taken to prevent contamination. The Facility shall store ice scoops in a sanitary manner outside of ice containers. The Facility shall ensure ice delivered to Participant areas in bulk shall be in nonporous, covered containers cleaned after each use.

B. The Facility shall ensure potable drinking water shall be available and accessible to Participants at all times.

C. The Facility shall not permit the use of common drinking cups. The Facility shall ensure unused disposable cups are stored to prevent contamination.

~~**SECTION 1400. GENERAL**~~

~~1401. General~~

~~Conditions that have not been addressed in these regulations shall be managed in accordance with the best practices as interpreted by the Department.~~

SECTION 1400 – EMERGENCY PROCEDURES AND DISASTER PREPAREDNESS

1401. Disaster Preparedness. (II)

The Facility shall develop and maintain a written plan for actions to be taken in the event of a disaster or an emergency evacuation. The Facility shall implement the plan when necessary and at the time of need. The Facility shall make the plan available upon request by Participants, Participants' Sponsors and Responsible Parties, and the Department.

1402. Continuity of Essential Services. (II)

The Facility shall maintain and implement a plan that ensures the continuation of essential Participant services for such reasons as power outage and/or water shortage or in the event of the absence from work of any portion of the work force resulting from inclement weather or other causes.

SECTION 1500 – FIRE PREVENTION

1501. Arrangements for Fire Department Response and Protection. (I)

A. The Facility shall develop, in coordination with its supporting fire department and/or disaster preparedness agency, suitable written plans for actions to be taken in the event of fire such as fire plan and evacuation plan.

B. Facilities located outside of a service area or range of a public fire department shall arrange for the nearest fire department to respond in case of fire by written agreement with that fire department. The Facility shall keep a copy of the current agreement on file in the Facility and shall provide a copy of the current agreement and updated agreements to the Department.

1502. Tests and Inspections. (I)

The Facility shall maintain and test all fire protection and suppression systems in accordance with the provisions of the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal applicable to the Facility.

1503. Fire Response Training. (I)

The Facility shall ensure Staff complete Annual fire response training in accordance with specific duties and responsibilities outlined in their job descriptions. The Facility shall document and maintain the training in the Staff record at the Facility.

A. The Facility shall ensure the Staff fire response training addresses, at a minimum, the following:

1. Reporting a fire;

2. Use of the fire alarm system, if applicable;

3. Location and use of fire-fighting equipment;

4. Methods of fire containment; and

5. Specific responsibilities, tasks, or duties of each individual.

B. The Facility shall maintain a written plan for fire and other emergency evacuations of Participants, Staff members, Volunteers, and visitors that includes evacuation routes and procedures, and shall post the plan in a conspicuous public area in the Facility.

C. The Facility shall train the Participants capable of self-evacuation on actions to take in the event of a fire, including if the primary escape route is blocked.

1504. Fire Drills. (I)

A. The Facility shall complete at least one (1) fire drill every month to familiarize all Staff, Volunteers, and Participants with fire safety procedures. The Facility shall maintain records of the fire drills, including date, time, description, and evaluation of the drill, and the names of Staff members, Volunteers, and Participants directly involved in responding to the drill. If fire drill requirements are mandated by statute or regulation, then the mandated statute or regulation requirements supersede the requirements of this regulation, and the Facility shall comply with the provisions of the statute or regulation.

B. The Facility shall design and conduct the fire drills to reflect the contents of the fire response training described in Section 1503.

C. The Facility shall encourage all Participants to participate in fire drills and utilize counseling, incentive programs, and specific Staff-to-Participant assignments, if appropriate.

1505. Fire Extinguishers, Standpipes, and Automatic Sprinklers. (I)

The Facility shall provide fire-fighting equipment such as fire extinguishers, standpipes, and automatic sprinklers as required by the provisions of the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal applicable to the Facility. The Facility shall ensure extinguishers are sized, located, installed, and maintained in accordance with National Fire Protection Association No. 10. The Facility shall install suitable fire extinguishers in all hazardous areas. The Facility shall comply with all state and local fire and safety provisions. (I)

SECTION 1600 – MAINTENANCE

1601. General Maintenance.

The Facility shall keep all equipment and building components including, but not limited to, carpet and flooring, doors, windows, lighting fixtures, and plumbing fixtures in good repair and operating condition. The Facility shall document preventive maintenance. (II)

1602. Preventive Maintenance of Emergency Equipment and Supplies (I).

A. The Facility shall develop and implement a written preventive maintenance program for all fire alarm, electrical, mechanical, plumbing, fire protection systems and for all equipment and supplies including, but not limited to, all Participant monitoring equipment, isolated electrical systems, conductive flooring, Participant grounding systems, and medical gas systems. The Facility shall check and test the equipment at intervals ensuring proper operation and state of good repair. After repairs and alterations to any equipment or system, the Facility shall thoroughly test the equipment or system for proper operation before returning it to service. The Facility shall maintain records for each piece of emergency equipment to indicate its history of testing and maintenance.

B. The Facility shall comply with the provisions of the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal applicable to the Facility. (I)

SECTION 1700 – INFECTION CONTROL AND ENVIRONMENT

1701. Staff Practices. (I)

A. The Facility shall maintain and implement Staff practices that promote conditions that prevent the spread of infectious, contagious, or communicable diseases, including but not limited to standard precautions, transmission-based precautions, contact precautions, airborne precautions, and isolation techniques. The Facility shall ensure proper disposal of toxic and hazardous substances. The Facility shall ensure the preventive measures and practices are in compliance with applicable guidelines of the Bloodborne Pathogens Standard of the Occupational Safety and Health Act of 1970; the Centers for Disease Control and Prevention; R.61-105, Infectious Waste Management; and other applicable federal, state, and local laws and regulations.

B. The Facility shall ensure the practice of hand hygiene to prevent the hand transfer of pathogens, and the use of barrier precautions such as gloves in accordance with established guidelines.

1702. Tuberculosis Risk Assessment and Screening (I).

A. Tuberculosis Testing. The Facility shall utilize either Tuberculin Skin Test or Blood Assay for Mycobacterium Tuberculosis for detecting Myobacterium tuberculosis infection.

B. The Facility shall conduct an Annual tuberculosis risk assessment in accordance with the Centers for Disease Control and Prevention guidelines to guide the Facility's infection control policies and procedures related to the appropriateness and frequency of tuberculosis screening and other tuberculosis related measures to be taken.

C. Baseline Status.

1. The Facility shall determine the baseline status of all Staff according to current Centers for Disease Control and Prevention and Department tuberculosis guidelines.

2. Tuberculosis Screening. All Staff within three (3) months prior to Participant contact shall have a baseline two-step Tuberculin Skin Test or a single Blood Assay for Mycobacterium Tuberculosis. If a new Staff member or Volunteer has had a documented negative Tuberculin Skin Test or a Blood Assay for Mycobacterium tuberculosis result within the previous twelve (12) months, a single Tuberculin Skin Test or the single Blood Assay for Mycobacterium tuberculosis may be administered and read to serve as the baseline prior to Participant contact.

D. Post Exposure. After known exposure to a person with potentially infectious tuberculosis disease without the use of adequate personal protection, the Facility shall ensure the tuberculosis status of all Staff is determined in a manner prescribed in the current Centers for Disease Control and Prevention and Department tuberculosis guidelines.

E. Annual Tuberculosis Training. The Facility shall ensure all Staff receive Annual training regarding tuberculosis to include risk factors and signs and symptoms of tuberculosis disease. The Facility shall ensure the Annual tuberculosis training is documented in a Staff record and maintained at the Facility.

F. Serial Screening. The Facility shall follow the current Centers for Disease Control and Prevention and Department tuberculosis guidelines related to serial screening.

1703. Linen and Laundry. (II)

The Facility shall maintain an adequate supply of clean linen or disposable materials for each sick bed. The Facility shall ensure each sick bed has a clean moisture-proof mattress cover and at least one (1) clean linen change including bottom and top sheets, pillowcase, and a bedspread or coverlet.

1704. Housekeeping. (II)

The Facility and its grounds shall be clean, and free of vermin and offensive odors.

A. The Facility shall ensure that interior housekeeping, at a minimum, includes:

1. Cleaning each specific area of the Facility;

2. Cleaning and disinfection, as needed, of equipment used and/or maintained in each area appropriate to the area and the equipment's purpose or use;

3. Chemicals indicated as harmful on the product label, cleaning materials, and supplies shall be in locked storage areas and inaccessible to Participants; and

4. During use of chemicals indicated as harmful on the product label, cleaning materials, and supplies shall be in direct possession of the Staff member and monitored at all times.

B. The Facility shall ensure that exterior housekeeping, at a minimum, includes:

1. Cleaning of all exterior areas, such as, porches and ramps, and removal of safety impediments such as snow and ice;

2. Keeping Facility grounds free of weeds, rubbish, overgrown landscaping, and other potential breeding sources for vermin; and

3. Safe storage of chemicals indicated as harmful on the product label, equipment and supplies inaccessible to Participants.

1705. Sanitation. (II)

A. The Facility shall ensure garbage and waste collection, storage, and disposal prevent the transmission of disease. The Facility shall wash and sanitize garbage and waste containers prior to returning them to work areas. The Facility shall not reuse disposable garbage or waste containers.

B. The Facility shall ensure garbage and waste are covered and stored outside in durable, rust-resistant, non-absorbent, watertight, rodent-proof, easily cleanable containers placed on an approved platform to prevent overturning by animals, the entrance of flies, or the creation of a nuisance. The Facility shall dispose of all solid waste at sufficient frequencies in a manner so as not to create a rodent, insect, or other vermin problem.

C. The Facility shall dispose of all sewage and liquid waste in a manner so as not to create a public health hazard and by a sanitary method.

1706. Outside Areas. (II)

The Facility shall keep all outside areas, grounds, and/or adjacent buildings free of rubbish, grass, and weeds that may serve as a fire hazard or as a haven for insects, rodents, and other vermin. The Facility shall apply measures that prevent and control insect, rodent, and other vermin harborage, breeding, and infestation on the premises. The Facility shall maintain all stairs, walkways, ramps, and porches, and keep them free from accumulations of water, ice, snow, and any other impediments.

1707. Pets.

A. The Facility may permit pets that are healthy, free of fleas, ticks, and intestinal parasites, up-to-date on vaccinations, and pre-screened by a veterinarian prior to Participant contact, and present no apparent threat to the health, safety, and well-being of the Participants provided the pets are sufficiently fed and cared for and that both the pets and their housing are kept clean.

B. The Facility shall ensure pets remain separate from Participants with allergic sensitivities to pets and Participants wanting to avoid pets for any other reason.

C. The Facility shall not allow pets in the kitchen area. The Facility may permit pets in the Participant dining areas only when food is not being served to Participants. The Facility shall ensure dining areas adjacent to a food preparation or storage area are separated by walls and closed doors while pets are present.

SECTION 1800 – [RESERVED]

SECTION 1900 – DESIGN AND CONSTRUCTION

1901. General. (II)

A. The Facility shall be planned, designed, and equipped to provide and promote the health, safety, and well-being of each Participant.

B. The Facility shall provide rooms to accommodate a variety of programs and Participants served. At a minimum, the Facility shall provide one (1) group activity room and one (1) resting room to accommodate the Participants. The Facility shall ensure the resting room bed ratio is one (1) bed per thirty (30) licensed Participants or fraction thereof. The Facility shall have resting room beds set up and ready to use. The Facility shall not utilize roll-away beds as resting room beds. The Facility shall include private room, cubicle curtains, portable partitions, or other means to ensure privacy of Participants when utilizing the resting room bed. The Facility shall provide adequate storage space for supplies and personal belongings.(II)

C. The Facility shall provide a minimum of fifty (50) net square feet of usable activity space, exclusive of hallway, passageway, corridor, storage space, kitchen, toilet, resting area, office, and other similar space for each Participant. When the Facility shares space with another entity, and individuals not affiliated with the Facility have access to the building during operating hours, the Facility is allowed a minimum of twenty-five (25) net square feet of usable activity and/or dining space, provided the space has a permanent one (1) hour rated barrier, pursuant to South Carolina Building Codes, exclusive for use of the Participants. The Facility shall maintain all minimum requirements of the existing use of the building.

D. The Facility shall have only level of exit discharge floor occupancy except where elevators are provided, or if only non-Participant areas are located on the above floor(s), e.g., storage areas, Staff offices, lounges.

E. The Facility shall be accessible to Participants with disabilities to include all Participant areas and bathrooms.

F. The Facility shall ensure the entrance to the building is at the level of the exit discharge. The Facility shall have a canopy for weather protection inclusive of the vehicle drop-off location to the entrance door.

G. The Facility shall have at least two (2) exits remote from each other to exit the building or space.

1902. Applicable Code. (II)

A. The new Facility design and construction shall comply with codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal.

B. The existing Facility shall remain in compliance with the construction codes and construction regulations applicable at the time its License was initially issued, unless specifically required otherwise by the Department.

C. A Facility that closes, has its License revoked, or surrenders its License and then applies for re-licensure at the same site shall be considered a new building and shall meet the codes, regulations, and

requirements for the building and its essential equipment and systems in effect at the time of application for licensing.

1903. Submission of Plans and Specifications.

A. The Facility shall have all plans and specifications prepared by an architect and/or engineer registered in South Carolina. The Facility shall submit plans at the schematic, design development, and final stages, unless directed otherwise by the Department. The Facility plans shall be drawn to scale with the title, stage of submission, and date shown thereon. The Facility shall submit to the Department, for approval, all construction changes to the Department-approved plans. The Facility shall not commence construction work prior to receiving plan approval from the Department. The owner shall employ a registered architect and/or engineer during construction for observation. Upon approval of the Department, construction administration may be performed by an entity other than the architect. The Department shall conduct periodic Inspections throughout each project phase.

B. The Facility shall submit plans and specifications to the Department for new construction and for any projects that have an effect on:

1. The function of a space;

2. The accessibility to or of an area;

3. The structural integrity of the Facility;

4. The active and/or passive fire safety systems (including kitchen equipment such as exhaust hoods or equipment required to be under an exhaust hood);

5. Doors;

6. Walls;

7. Ceiling system assemblies;

8. Exit corridors;

9. Life safety systems; or

10. Increases the occupant load or licensed capacity of the Facility.

C. The Facility shall submit all subsequent addenda, change orders, field orders, and documents altering the Department-approved review to the Department. The Facility shall be subject to the written notification requirement, review, and re-approval from the Department for any substantial deviation from the Department-approved documents.

D. The Facility shall maintain copies of documentation and certifications related to cosmetic changes utilizing paint, wall covering, floor covering, etc. that are required to have a flame-spread rating or other safety criteria shall be documented with copies of the documentation and certifications kept on file at the Facility and made available to the Department.

1904. Construction Inspections.

The Facility shall bring into compliance construction work that violates codes or standards. The Facility shall obtain all required permits from the locality having jurisdiction for all projects. The Facility conducting construction without proper permits shall not be inspected by the Department. (I)

SECTION 2000 - FIRE PROTECTION, EQUIPMENT, AND LIFE SAFETY

2001. Alarms.

A. The Facility shall have an alarm system that includes smoke detection in all main areas and pull stations throughout the building, all supervised by the fire alarm system. The Facility shall ensure the alarm system is arranged to transmit an alarm automatically to a third party by an approved method. The Facility shall ensure the alarm system notifies by audible and visual alarm all areas and floors of the building. The Facility shall ensure the alarm system shuts down central recirculating systems and outside air units that serve the area(s) of alarm origination as a minimum.

B. The Facility shall connect all fire, smoke, heat, sprinkler flow, duct detector, and pull stations to the main fire alarm system and ensure they trigger the system when activated.

C. The Facility shall not have a single or multi-station detector or a private system.

2002. Gases. (I)

The Facility shall take safety precautions against fire and other hazards when oxygen is dispensed, administered, or stored. The Facility shall post "No Smoking" signs conspicuously inside the Facility and on oxygen cylinders. The Facility shall properly store all cylinders and secure them in place.

SECTION 2100 - [RESERVED]

SECTION 2200 - [RESERVED]

SECTION 2300 - WATER SUPPLY

A. The Facility shall ensure all hot water plumbing fixtures accessible to Participants are supplied with water that is thermostatically controlled to a temperature of at least one hundred (100) degrees Fahrenheit and not exceeding one hundred twenty-five (125) degrees Fahrenheit at the fixture.

B. The Facility shall have a written plan to respond to disruptions in water supply that includes a contingency plan to estimate water demands for the entire Facility in advance of significant water disruptions, sewage intrusion, or flooding.

C. The Facility shall prevent cross connection and other sources of contamination of ice for human consumption.

D. The Facility shall equip all hand washing lavatories utilized by Participants and Staff with hot and cold water at all times.

E. The Facility shall obtain approval from the Department prior to using a non-community water supply to ensure safe location, construction, proper maintenance, and operation of the system.

SECTION 2400 - ELECTRICAL

2401. General. (I)

The Facility shall have emergency electric services that provide the following:

A. Exit lights, if required by code;

B. Exit access corridor lighting;

C. Illumination of means of egress; and

D. Fire detection and alarm systems, if required by code.

2402. Lighting and Electrical Services. (I)

A. The Facility shall maintain all electrical and other equipment free of defects that could be a potential hazard to Participants or Staff. The Facility shall provide safe lighting for individual activities as required by applicable codes.

B. The Facility shall maintain all electrical installations and equipment in a safe, operable condition in accordance with the applicable codes.

C. The Facility shall maintain documentation of Annual electrical system inspections by a certified or licensed technician.

2403. Ground Fault Protection. (I)

A. The Facility shall have ground fault circuit-interrupter protection for all outside receptacles and bathrooms.

B. The Facility shall provide ground fault circuit-interrupter protection for any receptacles within six (6) feet of a sink or any other wet location. If the sink is an integral part of the metal splashboard grounded by the sink, the entire metal area is considered part of the wet location.

2404. Exit Signs. (I)

A. The Facility shall have exits and ways to access in compliance with current code requirements and which are identified by electrically illuminated exit signs.

B. The Facility shall ensure changes in egress direction are marked with exit signs with directional arrows.

C. The Facility shall have exit signs in corridors that indicate two (2) directions of exit.

2405. Emergency Electric Service. (I)

The Facility shall have the following emergency electric services:

A. Exit lights, if required per code;

B. Exit access corridor lighting;

C. Illumination of means of egress; and

D. Fire detection and alarm system, if required per code.

2406. Electrical Panelboards. (II)

The Facility shall ensure the electrical panel directory is labeled to conform to actual room designations. The Facility shall maintain clear access to the panel.

SECTION 2500 - HEATING, VENTILATION, AND AIR CONDITIONING

A. The Facility shall maintain documentation of Annual heating, ventilation, and air conditioning system inspections by a certified or licensed technician. (I)

B. The Facility shall maintain a temperature of between seventy-two (72) and seventy-eight (78) degrees Fahrenheit in Participant areas. (II)

C. The Facility shall not install a heating, ventilation, and air conditioning supply or return grille within three (3) feet of a smoke detector. (I)

D. The Facility shall not install heating, ventilation, and air conditioning grilles in floors. (II)

E. The Facility shall filter and maintain intake air ducts that prevent the entrance of dust, dirt, and other contaminating materials. The Facility shall ensure the system does not discharge in such a manner that would be an irritant to the Participants, Staff, or Volunteers. (II)

F. The Facility shall have either operable windows or approved mechanical ventilation in the bathrooms. (II)

SECTION 2600 - PHYSICAL PLANT

2601. Signal System.

A. The Facility shall have a signal system consisting of a call button for each bed, bath, and toilet. The Facility shall have a light at or over each resting room visible from the corridor. The Facility shall have an audio-visual master station in a location continuously monitored by Staff or a radio frequency wireless system per the most current version of UL 1069 standards for Emergency Call Systems.

B. The Facility shall have a signal system consisting of an audio-visual device that cannot be interrupted located in all utility rooms, medicine storage rooms, lounges, storage rooms, and areas where Staff congregate.

C. The Facility shall ensure the signal system activates by pull cord or electronic device. The Facility shall ensure the pull cord hangs to a maximum of four (4) inches above the finished floor.

2602. Bathrooms. (II)

A. The Facility shall make bathrooms accessible for use during all operating hours of the Facility.

B. The Facility shall equip bathrooms with at least one (1) toilet fixture, toilet paper installed in a holder, a hand sink supplied with hot and cold running water, liquid or granulated soap, single-use disposable paper towels or electric air dryer, and a waste receptacle.

C. The Facility shall install and maintain approved, securely fastened grab bars at each toilet fixture used by Participants.

D. The Facility shall ensure privacy for Participants at toilet fixtures and urinals.

E. The Facility shall equip each hand sink with liquid soap and an individualized method of drying hands. Alcohol-based waterless hand sanitizers shall not be used in lieu of liquid soap.

F. The Facility shall ensure the bathrooms accommodate persons with disabilities as required by codes, whether or not any of the Staff or Participants are classified as disabled.

G. The Facility shall have in each of the bathrooms floors that are entirely covered with an approved nonabsorbent covering, nonabsorbent walls, and washable surfaces to the highest level of splash.

2603. Janitor's Closets.

A. The Facility shall have at least one (1) lockable janitor's closet.

B. The Facility shall ensure the janitor's closet contains a floor receptor or service sink and storage space for housekeeping equipment and supplies.

2604. Storage Areas.

A. The Facility shall have general storage space for equipment, supplies, and wheelchairs.

B. The Facility shall ensure storage buildings on the premises meet the requirements of the codes regarding distance from the licensed building. The Facility shall ensure that storage in buildings other than on the Facility premises are secured and accessible. The Facility shall provide a controlled environment for storage of items requiring such an environment.

C. The Facility shall safely store chemicals indicated as harmful on the product label, cleaning materials, and supplies in cabinets or well-lighted closets and rooms, inaccessible to Participants.

2605. Elevators. (II)

The Facility shall have elevators inspected and tested upon installation, prior to first use, and Annually thereafter by a certified elevator inspector. The Facility shall maintain documentation of all elevator inspections.

2606. Telephone Service.

The Facility shall have at least one (1) land-line telephone available on each floor of the Facility for use by Participants and/or visitors for their private, discretionary use.

2607. Location.

A. Transportation. The Facility shall be served by roads that are passable at all times and are adequate for the volume of expected traffic.

B. Parking. The Facility shall have a parking area to meet the needs of Participants, Staff members, and visitors.

C. Access to firefighting equipment. The Facility shall maintain adequate access to and around the building(s) for firefighting equipment. (I)

2608. Furnishings/Equipment. (I)

A. The Facility shall maintain the physical plant free of fire hazards and impediments to fire prevention.

B. The Facility shall not use or permit the use of portable electric or unvented fuel heaters in the Facility.

C. The Facility shall ensure that wastebaskets, furniture, window dressings, portable partitions, cubicle curtains, mattresses, and pillows shall be noncombustible, inherently flame-resistant, or treated or maintained flame-resistant in accordance with the applicable codes.

D. The Facility shall have wall finishes that are washable, and, in the immediate area of plumbing fixtures, are smooth and moisture resistant.

E. The Facility shall have wall bases, in areas which are frequently subject to wet cleaning methods, tightly sealed and constructed without voids that can harbor insects, rodents, and other vermin.

F. The Facility shall have floor and wall penetrations by pipes, ducts, and conduits tightly sealed to minimize entry of rodents and insects. The Facility shall ensure joints of structural elements are similarly sealed.

G. The Facility shall have interior finish materials in compliance with all code requirements for flame spread.

H. The Facility shall have floors with no cracks or are uneven in elevation and which are of non-skid surfaces to prevent falls.

2609. Lighting.

A. The Facility shall maintain lighting in spaces occupied by persons, machinery, equipment within buildings, approaches to buildings, and parking lots. (II)

B. The Facility shall have artificial light to include sufficient illumination for reading, observation, and activities per code requirements.

SECTION 2700 - SEVERABILITY

In the event that any portion of these regulations is construed by a court of competent jurisdiction to be invalid, or otherwise unenforceable, such determination shall in no manner affect the remaining portions of these regulations, and they shall remain in effect as if such invalid portions were not originally a part of these regulations.

SECTION 2800 - GENERAL

Conditions that have not been addressed in these regulations shall be managed in accordance with the best practices as interpreted by the Department.

Fiscal Impact Statement:

Implementation of this regulation will not require additional resources. There is no anticipated additional cost by the Department or state government due to any requirements of this regulation.

Statement of Need and Reasonableness:

The following presents an analysis of the factors listed in 1976 Code Sections 1-23-115(C)(1)-(3) and (9)-(11):

DESCRIPTION OF REGULATION: 61-75, Standards for Licensing Day Care Facilities for Adults.

Purpose: The Department amends R.61-75 to update provisions in accordance with current practices and standards. The Department further revises R.61-75 for clarity and readability, grammar, references, codification, and overall improvement to the text of the regulation.

Legal Authority: 1976 Code Sections 44-7-260 et seq.

Plan for Implementation: The DHEC Regulation Development Update (accessible at http://www.scdhec.gov/Agency/RegulationsAndUpdates/RegulationDevelopmentUpdate/) will provide a summary of and link to a copy of the amendments. Additionally, printed copies are available for a fee from the Department's Freedom of Information Office. Upon taking legal effect, Department personnel will take appropriate steps to inform the regulated community of the amended regulation and any associated information.

DETERMINATION OF NEED AND REASONABLENESS OF THE REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

The amendments are necessary to update provisions in accordance with current practices and standards. The amendments include updated language for facilities applying for licensure and incorporate provisions delineating new requirements in training staff members, as well as new nursing and medical staff requirements. The amendments revise and incorporate requirements regarding maintenance of policies and procedures, Department inspections and investigations, maintenance of accurate and current contact and training information for staff members, and other requirements for licensure. The amendments also update the structure of the regulation throughout for consistency with other Department regulations.

DETERMINATION OF COSTS AND BENEFITS:

Implementation of these amendments will not require additional resources. There is no anticipated additional cost to the Department or state government due to any requirements of these amendments. There are no anticipated additional costs to the regulated community.

UNCERTAINTIES OF ESTIMATES:

None.

EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH:

The amendments to R.61-75 seek to support the Department's goals relating to the protection of public health through implementing updated requirements for day care facilities for adults. There are no anticipated effects on the environment.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED:

There is no anticipated detrimental effect on the environment. If the amendments are not implemented, the regulation will be maintained in its current form without realizing the benefits of the amendments herein.

Statement of Rationale:

Here below is the Statement of Rationale pursuant to S.C. Code Section 1-23-110(h):

The Department of Health and Environmental Control amends R.61-75 to update provisions in accordance with current practices and standards. The amendments include updated language for facilities applying for licensure and incorporate provisions delineating new requirements for training staff members and new nursing and medical staff requirements. The amendments revise and incorporate requirements regarding maintenance of policies and procedures, Department inspections and investigations, maintenance of accurate and current contact and training information for staff members, and other requirements for licensure.

ATTACHMENT B

SUMMARY OF PUBLIC COMMENTS AND DEPARTMENT RESPONSES

Document No. 4977
R.61-75, *Standards for Licensing Day Care Facilities for Adults*

As of the September 28, 2020, close of the Notice of Proposed Regulation comment period:

Name	Section(s)	Department Response
1. Sara DeVeaux President, Mother Deveaux Adult Day Care		**Acknowledged.**
Comment: "I am in agreement with regulation that has been provided."		
Name	**Section(s)**	**Department Response**
2. Rebekah D. Spannagel Attorney, South Carolina Protection and Advocacy for People with Disabilities, Inc.	800. 1002.	**Adopted** 800.C. and 1002 were amended to reflect the recommendations.
Comment: "In our prior comments, P&A recommended deleting a phrase regarding the needs of participants and the resources of a facility due to its lack of clarity. We thank DHEC for integrating this comment and clarifying its meaning. However, in reference to the latest draft of Section 800 and Section 1002, we would like to make a few additional comments. In both sections, P&A suggests that DHEC require facilities to adhere to more specific notification requirements when discharging a participant, such as requiring a notice to contain the reason for discharge and the proposed date of discharge. Section 800 should also include a requirement of written notice immediately upon determination. In all instances of discharge, but particularly as it relates to Section 800, P&A suggests that DHEC adds additional parameters regarding a facility's responsibilities when discharging a participant. In these situations, a participant, his family, and/or his case manager often may need more than fourteen days to secure placement in a more appropriate program; a premature discharge could result in a sudden lapse of services for these individuals. P&A suggests that DHEC considers requiring a facility to delay discharge until the participant, his family, and/or his case manager identify more appropriate programs or services. Additionally, a facility should play a role in aiding a participant during this process, such as providing information to other potential facilities and/or service providers about the participant's current needs. Thank you for your work to ensure DHEC's regulations best protect the right of individuals with disabilities receiving services in day care facilities for adults."		
Name	**Section**	**Department Response**
3. Ralph Shenefelt Senior Vice President, Regulatory & Quality Assurance Health & Safety Institute	505.	**Clarification** The section was amended to remove "American Red Cross" to provide clarity. The requirement is a CPR certification that is not specific to a particular company or entity.
Comment:		

"Requested Amendment
505. Training. (I) F. At least one (1) Staff member who has certification of in American Red Cross or American Safety and Health Institute first - aid training, and cardiopulmonary resuscitation (CPR) certification, and is capable of recognizing symptoms of distress shall be present when Participants are in the Facility. If the Staff member is a licensed nurse, first - aid training shall not be required. (I)"

Date: November 12, 2020

To: South Carolina Board of Health and Environmental Control

From: Bureau of Facilities Oversight

Re: Public Hearing for Notice of Final Regulation Amending R.61-24, *Licensed Midwives*, Document No. 4974

I. Introduction

The Bureau of Facilities Oversight ("Bureau") proposes the attached Notice of Final Regulation amending R.61-24, *Licensed Midwives*. Legal authority resides in South Carolina Code Sections 44-1-140 et seq., which requires the Department of Health and Environmental Control ("Department") to establish and enforce basic standards for the licensure of midwives and midwifery services to ensure the safe and adequate treatment of persons served in this state. The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments.

II. Facts

1. The Department proposes amending R.61-24 to update provisions in accordance with current practices and standards. Proposed amendments incorporate and revise provisions relating to statutory mandates, update definitions to conform to the terminology widely used and understood within the provider community, and revise requirements for scope of practice, incident reporting, continuing education training requirements, prescription medication administration, client and neonate care and services, infection control, monetary penalties, and other requirements for licensure.

2. The Department had a Notice of Drafting published in the February 28, 2020, *State Register*.

3. The Bureau held a stakeholder meeting on March 17, 2020. The Bureau considered stakeholder feedback in formulating the proposed amendments herein.

4. Appropriate Department staff conducted an internal review of the proposed amendments on July 10, 2020.

5. The Midwifery Advisory Council reviewed the proposed amendments, and on July 21, 2020, the Department received the Council's comments. Attachment C presents a summary of the comments received and Department responses.

6. The Department had a Notice of Proposed Regulation published in the August 28, 2020, *State Register*. The Department received public comments from 107 people by the September 28, 2020, close of the public comment period. Attachment B presents a summary of these public comments received and Department responses.

7. The Bureau held another stakeholder meeting on September 14, 2020. The Bureau considered stakeholder feedback in formulating the proposed amendments herein.

8. After consideration of all timely received comments, staff has made substantive changes to the regulatory text of the Notice of Proposed Regulation approved by the Board in the August 13, 2020, Board meeting and published in the August 28, 2020, *State Register*. Descriptions of the changes appear in Attachment B, Summary of Public Comments and Department Responses.

III. Request for Approval

The Bureau of Facilities Oversight respectfully requests the Board to find need and reasonableness of the attached proposed amendments of R.61-24, *Licensed Midwives*, for submission to the General Assembly.

Angie Smith
Interim Director
Facilities Oversight

Gwendolyn C. Thompson
Deputy Director
Healthcare Quality

Attachments:
A. Notice of Final Regulation
B. Summary of Public Comments and Department Responses
C. Summary of Advisory Council Comments and Department Responses

ATTACHMENT A

STATE REGISTER NOTICE OF FINAL REGULATION
FOR R.61-24, *Licensed Midwives*

November 12, 2020

Document No. 4974
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Sections 44-1-140 et seq.

61-24. Licensed Midwives.

Synopsis:

The Department of Health and Environmental Control ("Department") amends R.61-24 to update provisions in accordance with current practices and standards. Amendments incorporate and revise provisions relating to statutory mandates, update definitions to conform to the terminology widely used and understood within the provider community, and revise requirements for scope of practice, incident reporting, continuing education training requirements, prescription medication administration, client and neonate care and services, infection control, monetary penalties, and other requirements for licensure. The amendments also update the structure of the regulation throughout for consistency with other DHEC Healthcare Quality regulations. The Department further revises R.61-24 for clarity and readability, grammar, references, codification, and overall improvement to the text of the regulation. R.61-24 was last amended in 2013.

The Department had a Notice of Drafting published in the February 28, 2020, *South Carolina State Register*.

Instructions:

Replace R.61-24, *Licensed Midwives,* in its entirety with this amendment.

Text:

~~Indicates Matter Stricken~~
Indicates New Matter

61-24. Licensed Midwives.

Statutory Authority: S.C. Code Sections 44-1-140~~, 40-33-30, 44-37-40, 44-37-50, and 44-89-10~~ et seq.~~, S.C. Code of Laws, 1976, as amended.~~

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SECTION 2800 – GENERAL

~~A. Purpose and Scope; Definitions.~~

~~1. Purpose and Scope. The purpose of this regulation is to provide requirements for licensure, education, minimum standards of care and practice to individuals who desire to practice midwifery in the State of South Carolina.~~

SECTION 100 – DEFINITIONS AND LICENSURE

~~2.~~**101**. ~~Definitions~~**Definitions**. ~~For the purposes of these regulations the following definitions apply:~~

A. Administering Medication. The acts of preparing and giving of a single dose of a medication to the body of a Client or Neonate by injection, ingestion, or any other means in accordance with the orders of a Physician or other Authorized Healthcare Provider.

~~a~~B. Apprentice Midwife. A person authorized by the Department to engage in a course of study to include clinical experience under the ~~s~~Supervision of a Midwife licensed in South Carolina, ~~p~~Physician, ~~c~~Certified ~~n~~Nurse-~~m~~Midwife, or ~~c~~Certified ~~p~~Professional ~~m~~Midwife~~, or midwife licensed in the State of South Carolina~~ who will prepare that person to become a licensed ~~m~~Midwife.

~~b~~C. Apprentice Midwife ~~License~~Permit. ~~A license issued by the Department to authorize a person desiring to become a midwife to obtain clinical experience under supervision of a physician, certified nurse-midwife, certified professional midwife, or midwife licensed in the State of South Carolina. This license is not transferable.~~A permit issued by the Department to authorize an Apprentice Midwife to provide Midwifery Services while he or she obtains the required clinical experience under Supervision of a Midwifery Preceptor.

D. Authorized Healthcare Provider. An individual authorized by law and currently licensed in South Carolina as a Physician, advanced practice registered nurse, or physician assistant to provide specific treatments, care, and services to Clients.

E. Birthing Center. A facility or other place where human births are planned to occur. This does not include the usual residence of the mother or any facility which is licensed as a hospital or the private practice of a Physician who attends the birth.

F. Blood Assay for Mycobacterium Tuberculosis. A general term to refer to in vitro diagnostic tests that assess for the presence of tuberculosis infection with Mycobacterium tuberculosis. This term includes, but is not limited to, interferon gamma release assays.

~~c~~G. Certified Nurse-Midwife. A registered nurse licensed to practice in this state that has been certified by the American College of Nurse-Midwives and officially recognized by the ~~State~~South Carolina Board of Nursing ~~for South Carolina~~.

H. Certified Professional Midwife. A professional midwifery practitioner who has met the accreditation standards for certification set by the North American Registry of Midwives.

I. Client. An individual who is receiving services from a Midwife or an Apprentice Midwife.

~~d. Community Health Center. A not-for-profit organization which receives federal funding to operate a local health center.~~

J. Compliance Meeting. A meeting with a Licensee and individuals authorized by the Department to provide information in order to enable the Licensee to better comply with this regulation.

~~e~~K. Contact Hour. A unit of measurement to describe fifty to sixty (50-60) minutes of an approved, organized learning experience or two (2) hours of planned and supervised clinical practice ~~which~~that is designed to meet professional educational objectives.

~~f~~L. Continuing Education. Participation in an accredited organized learning experience ~~under responsible sponsorship or supervised clinical practice, capable direction and qualified instruction and~~ approved by the Department ~~for the purpose of meeting requirements for renewal of licensure under these regulations~~.

~~g. Certified Professional Midwife (CPM). A professional midwifery practitioner who has met the standards for certification set by the North American Registry of Midwives (NARM).~~

~~h~~M. Department. The ~~S.C.~~South Carolina Department of Health and Environmental Control.

N. Discharge. The point at which care and services by a Midwife are terminated and the Midwife no longer maintains active responsibility for the care and services of the Client.

~~i. Health Care Provider. A physician or nurse practitioner.~~

O. Fetal Presentation. The part of the fetus's body that leads the way out through the birth canal called the presenting part.

P. Home Birth. A birth planned to occur or occurring at the usual residence of the Client.

Q. Incident. An unusual, unexpected adverse event, including any accidents, that could potentially cause harm, injury, or death to Clients or Neonates.

R. Inspection. An in-person meeting or a request for and review of materials by Department representatives for the purpose of determining compliance with this regulation.

S. Investigation. An in-person meeting or review of materials by Department representatives for the purpose of determining the validity of allegations received by the Department relating to regulatory compliance.

~~j~~T. License. ~~A document issued by the Department which authorizes an individual to practice midwifery within the scope of these regulations. The license is not transferable.~~The authorization to practice as a Midwife as defined in this regulation and as evidenced by a certificate issued by the Department to a Midwife.

~~k~~U. Licensee. ~~A licensed midwife or a licensed apprentice midwife.~~The individual licensed pursuant to this regulation to provide midwifery care and services.

V. Low Risk Pregnancy. A normal, uncomplicated prenatal course as determined by adequate prenatal care and prospects for a normal, uncomplicated birth as defined by reasonable and generally accepted criteria of maternal and fetal health.

W. Medical Consultation. A procedure whereby a Midwife makes contact with a Physician or other Authorized Healthcare Provider for recommendations as to care and treatment of the Client based on the Midwife's observations and assessment.

X. Medication. A substance that has therapeutic effects, including, but not limited to, Prescription Medications, over-the counter, and nonprescription Medications, herbal products, vitamins, and nutritional supplements.

~~l~~Y. Midwife. A person licensed by the ~~State of South Carolina~~Department who provides ~~midwifery services~~Midwifery Services as defined ~~below~~in this regulation.

~~m~~Z. Midwifery ~~Instructor~~Preceptor. A ~~physician, certified nurse-midwife or licensed midwife~~ Physician, Certified Nurse-Midwife, or Midwife, licensed in ~~the State of~~ South Carolina, who has a supervisory relationship with an ~~a~~Apprentice ~~m~~Midwife.

~~n~~AA. Midwifery Services. Those services provided by a person who is not a medical or nursing professional licensed by an agency of the State of South Carolina, for the purpose of giving primary assistance in the birth process either free, for trade, or for money, provided, however, that this shall not preclude any medical or nursing professional from being licensed in accordance with this regulation. This definition shall not be interpreted to include emergency services provided by lay persons or emergency care providers under emergency conditions.

BB. Neonate. An infant younger than four (4) weeks old.

~~o~~CC. North American Registry of Midwives ~~(NARM)~~. National organization ~~which~~that provides and maintains an evaluative process for multiple routes of midwifery education and training, and develops and administers a standardized examination system for ~~CPM~~Certified Professional Midwife credentialing.

~~p~~DD. Nurse Practitioner. A registered nurse licensed to practice in this state and registered with the ~~S.C.~~South Carolina ~~State~~ Board of Nursing. A ~~c~~Certified ~~n~~Nurse-midwife is accepted by the Board of Nursing as meeting these requirements.

EE. Physical Examination. An examination of a Client by a Physician or other Authorized Healthcare Provider that addresses those issues identified in Section 1100 of this regulation.

~~q~~FF. Physician. A ~~person~~doctor of medicine or doctor of osteopathic medicine ~~who is~~ licensed ~~to practice medicine in~~ by the ~~State of~~ South Carolina Board of Medical Examiners.

GG. Prescription Medication. A drug that is required by any applicable federal or state law to be dispensed pursuant only to a Prescription Medication order or is restricted to use by Physicians or other Authorized Healthcare Providers only.

HH. Quarterly. A time period that requires an activity to be performed every three (3) months.

II. Referral. The Midwife's directing or sending a Client to obtain additional care provided by a Physician or other Authorized Healthcare Provider.

JJ. Revocation of License. An action by the Department to cancel or annul a License by recalling, withdrawing, or rescinding the authority to operate or provide care.

rKK. Supervision. Coordination of learning experiences, direction, and continued evaluation of the practice of an apprentice midwife.Being physically present within immediate distance and available to respond to the needs of the Apprentice Midwife and/or Clients, and ensuring that the Apprentice Midwife is providing appropriate care to the Client.

LL. Suspension of License. An action by the Department requiring a Licensee or Permit holder to cease operations for a period of time or to require a Licensee or Permit holder to cease admitting Clients, until such time as the Department rescinds that restriction.

MM. Transfer of Care. The point at which the Midwife discontinues care and relinquishes further care to an Authorized Healthcare Provider or emergency medical services personnel.

NN. Tuberculin Skin Test. A small dose (one-tenth (0.1) milliliter) of purified protein derivative tuberculin is injected just beneath the surface of the skin by the intradermal Mantoux method, and the area is examined for induration of hard, dense, raised area at the site of the Tuberculin Skin Test administration forty-eight to seventy-two (48 to 72) hours after the injection though positive reactions can still be measurable up to a week after administering the Tuberculin Skin Test. The size of the indurated area is measured with a millimeter ruler and the reading is recorded in millimeters, including zero (0) millimeters to represent no induration. Redness and/or erythema is insignificant and is not measured or recorded.

OO. Variance. An alternative method that ensures the equivalent level of compliance with the standards in this regulation.

B. Interpretations.

1. License. It shall be unlawful to conduct midwifery services within South Carolina without possessing a valid license issued by the Department.

2. Issuance of License.

a. A license is issued pursuant to the provisions of Section 44-7-260(A) of the South Carolina Code of Laws of 1976, as amended, and the standards promulgated thereunder. The issuance of a license does not guarantee adequacy of individual care, treatment, personal safety, or the well-being of any patient.

b. A license is not assignable or transferable and is subject to revocation by the Department for failure to comply with the laws and regulations of the State of South Carolina.

c. The license must be posted in a conspicuous place visible to patients.

3. Effective Date and Term of License. A license for a midwife shall be effective for a 24-month period following the date of issue. An apprentice midwife license shall be effective for a one year period following the date of issue.

4. Fees. The license fee for each midwife license is one hundred fifty dollars ($150) per 24-month licensing period. The annual license fee for an apprentice midwife shall be fifty dollars ($50). The license fees shall be payable to the Department and shall be used exclusively in support of activities pursuant to this regulation. Fees are not refundable.

5. Initial License. A person who has not been continuously licensed under these or prior standards shall not provide care to patients until issued an initial license.

6. Inspections. The Department is authorized to inspect records of mothers and newborns delivered by midwives at any time.

7. Noncompliance. When noncompliance with the licensing standards exists, the licensee shall be notified by the Department of the violations and required to provide information as to how and when such an item will be corrected.

8. Exceptions to Licensing Standards. The Department may make exceptions to these standards where it is determined that the health and welfare of the community require the services of the licensee and that the exception, as granted, will have no significant impact on the safety, security or welfare of the licensee's patients.

9. Change of License. A licensee shall request to the Department by letter issuance of an amended license prior to a change in the licensee's name or address.

10. Revocation of License. The Department may refuse to issue, suspend for a definite period, or revoke a license for any of the following causes:

a. Dereliction of any duty imposed by law;

b. Incompetence as determined by the Department;

c. Conviction of a felony;

d. Practicing under a false name or alias;

e. Violation of any of the provisions of this regulation;

f. Obtaining any fee by fraud or misrepresentation;

g. Knowingly employing, supervising, or permitting (directly or indirectly) any person or persons not licensed as apprentice or midwife to perform any work covered by these regulations;

h. Using, causing, or promoting the use of any advertising matter, promotional literature, testimonial, or any other representation however disseminated or published, which is misleading or untruthful;

i. Representing that the service or advice of a person licensed to practice medicine or nursing will be used or made available when that is not true, or using the words, "doctor" or "nurse," or similar words, abbreviations or symbols implying involvement by the medical or nursing professions when such is not the case;

j. Permitting another to use the license; and

k. Revocation of certification by NARM or other Department approved organization(s).

11. Hearings and Appeals.

a. A Department decision involving the issuance, denial, or revocation of a license may be appealed by an affected person with standing pursuant to applicable law, including S.C. Code Title 44, Chapter 1; and Title 1, Chapter 23.

b. Any person to whom an order is issued may appeal it pursuant to applicable law, including S.C. Code Title 44, Chapter 1; and Title 1, Chapter 23.

C. Requirements for Licensure. No person may provide midwifery services or represent that s/he is a midwife without first possessing a license issued by the Department in accordance with the provisions of these regulations. Licensure as a midwife shall be by certification by NARM or other Department approved organization(s). Midwives requesting initial licensure will receive a license, provided they have evidence of certification by NARM or other Department approved organization(s) and have also met other requirements as established by the Department.

EXCEPTION: Individuals licensed by the Department prior to the publication date of this regulation will not be required to obtain certification by NARM or other Department approved organization(s). However, if a midwife is delinquent in submitting her/his license renewal application and the delinquency period exceeds 30 days the midwife must obtain certification by NARM or other similar Department approved organization(s) and also meet the requirements outlined in this section.

1. Midwife Apprentice License. Upon application, an apprentice license may be issued. An apprentice license authorizes the person to obtain the required clinical experience under supervision of a physician, certified nurse-midwife, certified professional midwife, or licensed midwife. Applications for renewal of apprentice licenses must be submitted at least 90 days prior to the expiration of the initial license. A licensed apprentice midwife may apply for renewal of an apprentice license three times before obtaining certification by NARM or other Department approved organization(s). Under extenuating circumstances, one additional renewal may be granted at the discretion of the Department on a case-by-case basis. The applicant for an apprentice midwife license must:

a. Provide written verification of apprentice/supervisor relationship from the person(s) supervising the applicant and their verified relationship(s) when the apprentice license is renewed;

b. Be enrolled in an approved course of education, or have submitted evidence of a planned course of education, subject to the approval of the Department;

c. Show evidence that s/he has had negative testing for tuberculosis or is noninfectious for the same;

d. Be able to read and write English.

2. Initial Midwife License. A licensed midwife may provide care only as allowed by these regulations. In order to apply to become a licensed midwife, a person must submit:

a. Application for a midwife license;

b. Evidence of completion of certification by NARM or other Department approved organization(s);

c. Evidence of completion of an educational program to be evaluated by NARM or other Department approved organization;

d. Evidence of completed apprenticeship and a recommendation by the supervising person (clinical experience shall be supervised by a licensed midwife, a certified nurse-midwife, a certified professional midwife, or a physician active in perinatal care) to be submitted to the certifying agency;

e. Evidence of valid Healthcare Provider cardiopulmonary resuscitation (CPR) certificate by the American Red Cross or American Heart Association and Neonatal Resuscitation Program (NRP) certificate in accordance with current NARM or other Department approved organization standards;

f. Evidence that the person has had negative testing for tuberculosis or is noninfectious for the same.

3. Examination.

a. Upon approval of the above documentation by the Department the applicant may sit for the examination, and upon successfully passing the examination, may be licensed as a midwife.

b. Applicants for licensure as a midwife who lack apprenticeship in South Carolina but who have equivalent experience from another jurisdiction may apply for a midwife license and sit for the qualifying examination after submitting evidence of experience and of all other requirements to the Department. Action will be taken on each request on an individual basis.

4. Limitations. A licensed midwife may sponsor a maximum of three apprentice midwives simultaneously.

5. Renewal of Midwife License. Licenses must be renewed every 24 months. An applicant for renewal of a midwife license must submit at least 60 days prior to the expiration of his/her license:

a. A midwife license renewal application;

b. Evidence of completion of certification by NARM or other Department approved organization(s);

c. Evidence of completion of 30 contact hours of continuing education during the licensing period;

d. Evidence of certification from the American Red Cross or American Heart Association in cardiopulmonary resuscitation of adult and newborn within the previous year;

e. Evidence of participation in an annual peer review;

f. Evidence of an annual negative skin test for tuberculosis or is noninfectious for the same.

g. EXCEPTION: Individuals licensed by the Department prior to the publication date of this regulation and not certified by NARM or other Department approved organization(s) must submit the following to the Department:

(1) Evidence of completion of 30 contact hours of continuing education during the licensing period;

(2) Evidence of valid Healthcare Provider cardiopulmonary resuscitation (CPR) certificate by the American Red Cross or American Heart Association and Neonatal Resuscitation Program (NRP) certificate in accordance with current NARM or other Department approved organization standards;

(3) Evidence of participation in an annual peer review.

6. Tuberculin Skin Test Requirements. Within three months prior to initial application and annually thereafter, midwives and apprentices shall have a tuberculin skin test, unless a previously positive reaction can be documented. The intradermal (Mantoux) method, using five tuberculin units of stabilized purified protein derivative (PPD) is to be used. Persons with tuberculin test reactions of 10mm or more of induration

~~should be referred to a physician for appropriate evaluation. The two-step procedure (one Mantoux test followed one week later by another) is required for initial testing in order to establish a reliable baseline.~~

~~a. Persons with reactions of 10mm and over to the initial application tuberculin test, those who have previously documented positive reactions, those with new positive reactions to the skin tests, and those with symptoms suggestive of TB (e.g., cough, weight loss, night sweats, fever, etc.), shall be given a chest X-ray to determine whether TB is present. If TB is diagnosed, the person shall be referred to a physician for appropriate treatment and contacts examined.~~

~~b. There is no need to conduct an initial or routine chest X-ray on persons with negative tuberculin tests who are asymptomatic.~~

~~c. Persons with negative tuberculin skin tests shall have an annual tuberculin skin test.~~

~~d. No person who has a positive reaction to the skin test shall have patient contact until certified non-contagious by a physician.~~

~~e. New applicants who have a history of TB shall be required to have certification by a physician that they are non-contagious prior to patient contact.~~

~~f. Applicants who are known or suspected to have TB shall be required to be evaluated by a physician and will not be allowed to have patient contact until they have been certified non-contagious by the physician.~~

~~g. Preventive treatment of personnel with new positive reactions is essential, and shall be considered for all infected applicants who have patient contact, unless specifically contraindicated. Persons who complete treatment may be exempt from further routine chest X-rays unless they have symptoms of TB. Routine annual chest X-rays of persons with positive reactions do little to prevent TB and therefore are not a substitute for preventive treatment.~~

~~h. Post exposure skin tests should be provided for tuberculin negative persons within 12 weeks after termination of contact for any suspected exposure to a documented case of TB.~~

~~7. Delinquency Period. Delinquency in renewal of licensure of 30 days after the license expiration date shall result in a delinquency fee of $25 in addition to the licensure fees noted in Section B.4. If after that period of time application has not been received, the applicant will be required to retake the midwife examination, to include payment of the examination fee.~~

~~D. Scope of Practice. The licensed midwife may provide care to low-risk women and neonates determined by medical evaluation to be prospectively normal for pregnancy and childbirth (see Sections J., K. and L.), and may deliver only women who have completed between 37 to 42 weeks of gestation, except under emergency circumstances. Care includes:~~

~~1. Prenatal supervision and counseling;~~

~~2. Preparation for childbirth;~~

~~3. Supervision and care during labor and delivery and care of the mother and newborn in the immediate postpartum, so long as progress meets criteria generally accepted as normal.~~

E. Educational Requirements. The Department shall set minimum educational standards and requirements. The Department may suggest or require specific topics for continuing education based on any problem areas indicated by midwives' quarterly reports, consumer feedback, or on advances in available knowledge. The Department shall keep all applicants for licensure or renewal fully informed of requirements for attaining, demonstrating and upgrading knowledge and skills.

F. Prenatal Care.

1. Required Visits. The midwife shall, upon acceptance of a woman for care, require her to have two visits with a physician, community health center or health department. One of these visits must be in the final six weeks of pregnancy. The midwife shall make entries in the patient's record of the physician, health center, or health department visits.

2. Scheduled Visits. During pregnancy, the patient shall be seen by the midwife or other appropriate health care provider according to the following schedule: at least once every four weeks until 32 weeks gestation, once every two weeks from 32 until 36 weeks, and weekly after 36 weeks.

3. Home Visit. At least one prenatal visit shall be made to each woman's home during the last six weeks of pregnancy.

4. Nature of Care. Each prenatal visit shall include the following care:

a. Assessment of general health and obstetric status;

b. Nutritional counseling;

c. Blood pressure;

d. Gross urinalysis: dip stick for sugar and protein;

e. Weight;

f. Gestational age assessment;

g. Fundal height;

h. Palpation of abdomen, Leopold's maneuvers;

i. Auscultation of FHT after 20 weeks;

j. Assessment of psychological status;

k. Education as to cause, treatment, and prognosis of any symptoms, problems, or concerns;

l. Information regarding childbirth classes and other community resources; and

m. Hematocrit and/or hemoglobin shall be assessed at approximately three and eight months gestation.

5. Informed Consent. The midwife shall assure that all women under his/her care understand that s/he is a midwife licensed by this Department to perform midwifery services by virtue of approved education, clinical experience, and examination, but is not a nurse or physician, and are advised of the risks,

~~responsibilities and alternatives for care. In consultation with the expectant parents, s/he shall, prior to the expected date of confinement, plan a strategy for backup medical care for mother and infant, and for transportation to medical facilities in case of emergency, and shall coordinate such arrangements with the backup health care providers. The midwife shall obtain a signed informed consent form to keep in his/her permanent records.~~

~~6. Parent Education. The midwife shall assure that natural childbirth and breastfeeding education in some form is available to all of his/her patients, and that they are aware of their rights and responsibilities as consumers of maternity care.~~

~~G. Intrapartum Care.~~

~~1. Intrapartum Midwife Duties. During labor, the midwife's duties are to support the natural process and the mother's own efforts, in an attitude of appropriate observation and patience, as well as alertness to the parameters of normality. These duties include, but are not limited to:~~

~~a. Ascertaining that labor is in progress;~~

~~b. Assessing and monitoring maternal and fetal well-being;~~

~~c. Monitoring the progress of labor;~~

~~d. Assisting with labor coaching;~~

~~e. Monitoring the emotional atmosphere;~~

~~f. Delivering the baby and placenta; and~~

~~g. Managing any problems in accordance with the guidelines cited elsewhere in these regulations and in accord with sound obstetric and neonatal practice.~~

~~2. Examination in Labor. The midwife will not perform any vaginal examinations on a woman with ruptured membranes and no labor, other than an initial sterile examination to be certain there is no prolapsed cord. Once active labor is assuredly in progress, exams may be made as necessary.~~

~~3. Sanitation. The midwife will conduct all applicable clinical procedures and maintain all equipment used in practice in an aseptic manner.~~

~~4. Operative Procedures. The midwife will not perform routinely any operative procedure other than artificial rupture of membranes at the introitus and/or clamping and cutting the umbilical cord.~~

~~5. Medications. Drugs or medications shall be administered only after consultation with and prescription by, a physician. The midwife shall not administer any drugs or medications except:~~

~~a. For control of postpartum hemorrhage;~~

~~b. When administering medication in accordance with regulations governing the prevention of infant blindness;~~

~~c. When administering RhoGam in accordance with accepted standards of professional practice.~~

H. Postpartum Care.

1. Immediate Care. The midwife must remain with the mother and infant for a minimum of two hours after the birth or until s/he is certain that both are in stabilized condition, whichever is longer. S/he shall leave clear instructions for self-care until his/her next visit. Immediate postpartum duties include:

a. Monitoring the physical status of mother and infant, and offering any necessary routine comfort measures;

b. Facilitation of maternal-infant bonding and family adjustment; and

c. Inspection of the placenta and membranes.

2. Subsequent Checkups. Within 24 to 36 hours after delivery, the midwife shall visit the mother and neonate; however, if the midwife is present for the first 20 to 24 hours after delivery, the visit at 24 to 36 hours is not considered mandatory.

3. RhoGam Requirements. Women needing RhoGam should be evaluated and treated by the midwife or a health care provider within 72 hours of delivery.

I. Care of the Newborn.

1. Immediate Care. Immediate care includes assuring that the airways are clear, Apgar scoring, maintenance of warmth, clamping and cutting of umbilical cord, eye care, establishment of feeding and physical assessment.

2. Eye Care. The midwife shall instill into each of the eyes of the newborn, within one hour of birth, a prophylactic agent such as silver nitrate or a suitable substitute.

3. Metabolic Screening. All requirements for metabolic screening shall be made clear to parents. The midwife shall notify the county health department in the county where the infant resides within three days of delivery in order for a specimen to be obtained.

4. Subsequent Care. In the days and weeks following birth, care includes monitoring jaundice, counseling for feeding, continued facilitation of the attachment and parenting process, cord care, etc.

5. Infant Care. In consultation with parents, the midwife shall encourage that the infant be seen by a health care provider within two weeks of birth.

6. Provision of Information. The midwife shall assure that the parents are fully informed as to available community resources for emergency medical care for infants, well-baby care, or other needed services.

J. Referral to Physician.

1. Recognition of Problems. The midwife must be able at all times to recognize the warning signs of abnormal or potentially abnormal conditions necessitating referral to a physician. It shall be the midwife's duty to consult with a physician whenever there are significant deviations from the normal. The midwife's training and practice must reflect a particular emphasis on thorough risk assessment.

2. Continuity of Care. When referring a patient to a physician, the midwife shall remain in consultation with the physician until the resolution of the situation. It is appropriate for the midwife to maintain care of

her patient to the greatest degree possible, in accordance with the patient's wishes, remaining present through delivery if possible.

K. Maternal Conditions Requiring Physician Referral or Consultation. At any time in the maternity cycle, the midwife shall obtain medical consultation, or refer for medical care, any woman who:

1. Has a history of serious problems not discovered at the initial visit with a health care provider;

2. Develops a blood pressure of 141/89 or more, or a persistent increase of 30 systolic or 15 diastolic over her usual blood pressure;

3. Develops marked edema of face and hands;

4. Develops severe persistent headaches, epigastric pain, or visual disturbances;

5. Develops proteinuria or glycosuria;

6. Has convulsions of any kind;

7. Does not gain at least 14 pounds by 30 weeks gestation or at least four pounds per month in the last trimester, or gains more than six pounds in any two-week period;

8. Has vaginal bleeding before the onset of labor;

9. Has symptoms of kidney or urinary tract infection;

10. Has symptoms of vaginitis;

11. Has symptoms of gonorrhea, syphilis or genital herpes;

12. Smokes more than 10 cigarettes per day and does not decrease usage;

13. Appears to abuse alcohol or drugs;

14. Does not improve nutrition within satisfactory limits;

15. Is anemic (Hematocrit under 32; Hemoglobin under 11.5);

16. Develops symptoms of diabetes;

17. Has excessive vomiting;

18. Has "morning sickness" (nausea) continuing past 24 weeks gestation;

19. Develops symptoms of pulmonary disease;

20. Has polyhydramnios or oligohydramnios;

21. Is Rh negative for periodic blood testing;

22. Has severe varicosities of the vulva or extremities;

~~23. Has inappropriate gestational size;~~

~~24. Has suspected multiple gestation;~~

~~25. Has suspected malpresentation;~~

~~26. Has marked decrease in or cessation of fetal movements;~~

~~27. Has rupture of membranes or other signs of labor before completion of 37 weeks gestation;~~

~~28. Is past 42 weeks gestation by estimated date of confinement and/or examination;~~

~~29. Has a fever of 100.4 for 24 hours;~~

~~30. Demonstrates serious psychiatric illness or severe psychological problems;~~

~~31. Demonstrates unresolved fearfulness regarding home birth or midwife care, or otherwise desires consultation or transfer;~~

~~32. Develops respiratory distress in labor;~~

~~33. Has ruptured membranes without onset of labor within 12 hours;~~

~~34. Has meconium-stained amniotic fluid;~~

~~35. Has more than capillary bleeding in labor prior to delivery;~~

~~36. Has persistent or recurrent fetal heart tones significantly above or below the baseline, or late or irregular decelerations which do not disappear permanently with change in maternal position, or abnormally slow return to baseline after contractions;~~

~~37. Has excessive fetal movements during labor;~~

~~38. Develops ketonuria or other signs of exhaustion;~~

~~39. Develops pathological retraction ring;~~

~~40. Does not progress in dilation, effacement or station in any two-hour period in active labor;~~

~~41. Does not show continued progress to delivery after two hours in second stage (primigravida); one hour for multigravida;~~

~~42. Has a partially separated placenta or atonic uterus;~~

~~43. Has bleeding of over three cups before or after delivery of placenta;~~

~~44. Has firm uterus with no bleeding but retained placenta more than one hour;~~

~~45. Has significant change in blood pressure, pulse over 100, or is pale, cyanotic, weak or dizzy;~~

~~46. Retains placental or membrane fragments;~~

~~47. Has laceration requiring repair;~~

~~48. Has a greater than normal lochial flow;~~

~~49. Does not void urine within six hours of birth;~~

~~50. Develops a fever greater than 100.4 on any two of the first ten days postpartum excluding the first day;~~

~~51. Develops a foul-smelling or otherwise abnormal lochial flow;~~

~~52. Develops a breast infection;~~

~~53. Has signs of serious postpartum depression; and~~

~~54. Develops any other condition about which the midwife feels concern, at the midwife's discretion.~~

~~L. Neonatal Conditions Requiring Physician Referral. The midwife shall obtain medical consultation from a physician for, or shall refer for medical care, any infant who:~~

~~1. Has an Apgar score of less than seven at five minutes;~~

~~2. Has any obvious anomaly or suspected disorder, abnormal facies, etc.;~~

~~3. Develops grunting respirations, chest retractions, or cyanosis;~~

~~4. Has cardiac irregularities;~~

~~5. Has a pale, cyanotic or gray color;~~

~~6. Develops jaundice in the first 36 hours;~~

~~7. Develops an unusual degree of jaundice at any time;~~

~~8. Has an abnormal cry;~~

~~9. Has skin lesions suggesting pathology;~~

~~10. Has eye discharge suggesting pathology;~~

~~11. Has excessive moulding of head, large cephalhematoma, excessive bruising, apparent fractures, dislocations, or other injuries;~~

~~12. Weighs less than five and one-half pounds;~~

~~13. Weighs more than nine pounds, if maternal diabetes or infant birth trauma is suspected;~~

~~14. Shows signs of hypoglycemia, hypocalcemia, or other metabolic disorders;~~

15. Shows signs of postmaturity;

16. Has meconium staining;

17. Has edema;

18. Does not urinate or pass meconium in first 12 hours after birth;

19. Is lethargic, weak or flaccid or does not feed well;

20. Has rectal temperature below 97 degrees F. or above 100.6 degrees F.;

21. Has full, bulging or abnormally sunken fontanel; and

22. Appears abnormal in any other respect.

M. Emergency Measures. The midwife must be able to carry out emergency measures in the absence of medical help. S/he must be trained to deal effectively with those life-threatening complications most likely to arise in the course of childbirth.

1. Examples of Emergency Situations. These are:

a. Respiratory or circulatory failure in mother or infant;

b. Postpartum hemorrhage;

c. Cord prolapse;

d. Tight nuchal cord;

e. Multiple births and malpresentations;

f. Shoulder dystocia;

g. Gross prematurity or intra-uterine growth retardation; and

h. Serious congenital anomalies.

2. Examples of Emergency Measures. These are:

a. Episiotomy; and

b. Intramuscular administration of Pitocin for the control of postpartum hemorrhage.

N. Prohibitions in the Practice of Midwifery.

1. Medications. The midwife shall not administer any drugs or injections of any kind, except as indicated in Sections G.5 and M.2.b.

2. Surgical Procedures. The midwife shall not perform any operative procedures or surgical repairs other than artificial rupture of membranes at the introitus, and clamping and cutting of the umbilical cord or as noted above in an emergency.

3. Artificial Means. The midwife shall not use any artificial, forcible or mechanical means to assist the delivery.

4. Induced Abortion. The midwife shall not perform nor participate in induced abortions.

O. Record Keeping and Report Requirements.

1. Record Keeping. The midwife shall maintain records of each mother and neonate which shall contain information as described below. All notes shall be legibly written or typed, dated and signed.

a. The mother's record shall include as a minimum:

(1) Face Sheet: Name, address (including county), telephone number, age, race, date of birth, occupation, marital status, religion, social security number, name of baby's father, midwife in attendance, apprentice midwife (if present), address and telephone number of person(s) to be contacted in the event of emergency, and name and address of physician to be contacted in the event of emergency;

(2) History of hereditary conditions in mother's and/or father's family;

(3) First day of the last menstrual period and estimated day of confinement;

(4) Blood group and Rh type;

(5) Serological test for syphilis (including dates performed);

(6) Number, duration and outcome of previous pregnancies, with dates;

(7) Drugs taken during pregnancy, labor and delivery;

(8) Duration of ruptured membranes and labor, including length of second stage;

(9) Complications of labor, e.g., hemorrhage or evidence of fetal distress;

(10) Description of placenta at delivery, including number of umbilical vessels; and

(11) Estimated amount and description of amniotic fluid.

b. The neonate's record shall include at a minimum:

(1) Name, sex, race, date of birth, place of birth, parents' names, address and telephone number, midwife in attendance, and apprentice midwife (if present).

(2) Results of measurements of fetal maturity and well-being;

(3) Apgar scores at one and five minutes of age;

(4) Description of resuscitations, if required;

(5) Detailed description of abnormalities and problems occurring from birth until transfer to a referral facility;

(6) Care of the umbilical cord;

(7) Eye care; and

(8) Counseling to the mother regarding feeding, community resources for emergency medical care, well-baby care, or other needed services, and metabolic screening.

c. Records shall be maintained for no less than 25 years. All records are subject to review by the Department.

2. Registration of Birth. The midwife shall assure that the registration of the baby's birth with the County Health Department is made within five days of birth.

3. Reporting Requirements.

a. Quarterly Reports. Each midwife shall file quarterly reports with the Department on forms provided by the Department. This report includes an Individual Data Sheet which shall be completed for each mother delivered by the midwife. This form includes such information as delivery date, parity, antepartum, labor, newborn, and postpartum statistics, as well as conditions which required consultation by a health care provider. A Summary Sheet is also submitted as a part of the quarterly report. This sheet contains a summary of the mothers cared for during the quarter, e.g., number of undelivered women registered for care with the midwife at the beginning and end of the quarter, women transferred out during antepartum, and women delivered during the quarter.

b. Special Reports. When any of the emergency measures listed in Section M. are utilized, a special report must be filed with the quarterly report to the Department, describing in detail the emergency situation, the measure(s) taken, and the outcome.

c. Consumer Reports. The midwife shall ask all mothers to complete a Consumer Feedback Form after the delivery experience and mail to the Department. These forms, which are provided to the midwives by the Department, request the mother to furnish information regarding certain statistics about the baby, e.g., name, sex, weight, date and place of delivery, and other information such as types of care the midwife provided and whether or not the mother was satisfied with that care.

d. Reporting Mortalities. The midwife shall report any maternal or infant death on a Report of Fetal Death Form (DHEC 665) to the Department, Attn: Vital Records and Public Health Statistics, within 48 hours. This report requires information concerning the death, to include sex, weight, date and place of delivery, pregnancy history, obstetric procedures, complications of labor and/or delivery, method of delivery, congenital anomalies of the fetus, and cause of death.

P. Department Responsibilities.

1. Midwifery Advisory Council.

a. The Commissioner of DHEC shall appoint a Midwifery Advisory Council which shall meet at least annually for the purpose of reviewing and advising the Department regarding matters pertaining to the training, practices, and regulation of midwives in South Carolina. The Council shall consist of three licensed

~~midwives, one consumer of midwife care, two certified nurse-midwives, one physician active in perinatal care, and one member-at-large. Each member shall be appointed for a three-year term of office.~~

~~b. The Council shall establish a committee for peer review to consult with midwives in questions of ethics, competency and performance, and to serve as an appeal committee when disciplinary action has been taken. The committee may recommend denying, suspending, or revoking a license, or may recommend specific educational objectives, apprenticeship or other improvement measures as necessary.~~

~~2. Monitoring Outcomes.~~

~~a. As part of the monitoring process, the Department shall evaluate consumer feedback forms issued through midwives to all consumers of midwifery care. The Department shall also issue to, collect, and evaluate quarterly forms from midwives regarding their practices.~~

~~b. The Department shall ensure that high quality services are provided by midwives and apprentice midwives in this State through compliance with the standards in these regulations.~~

~~Q. General. Conditions arising which have not been addressed in these regulations shall be managed in accordance with the best practices as determined by the Department.~~

102. Licensure. (II)

A. License. No person shall provide Midwifery Services or represent, advertise, or market that he or she is a Midwife without first obtaining and possessing a License from the Department. When it has been determined by the Department that Midwifery Services are being provided and the individual has not been issued a License from the Department, the individual shall cease provision of services immediately and ensure the health, safety, and well-being of the Clients. Current and/or previous violation of the South Carolina Code or Department regulations may jeopardize the issuance of a License as a Midwife. (I)

B. Compliance. An initial License shall not be issued to a Midwife until the Licensee has demonstrated to the Department that he or she is in substantial compliance with the licensing standards.

C. Issuance and Terms of License.

1. A License is issued pursuant to the provisions of South Carolina Code Section 44-1-140 and this regulation. The issuance of a License does not guarantee adequacy of individual care, treatment, personal safety, or the well-being of any Client.

2. A License is not assignable or transferable and is subject to Revocation by the Department for failure to comply with applicable state laws and regulations.

3. A License for a Midwife shall be effective for a thirty-six (36) month period following the date of issue.

D. Application. Applicants for a License shall submit to the Department a completed application on a form prescribed, prepared, and furnished by the Department prior to initial licensing. Applicants for a License shall file an application with the Department that includes an oath assuring that the contents of the application are accurate and true and in compliance with this regulation.

E. Required Documentation. The applicant shall include:

1. Evidence of current Certified Professional Midwife certification by the North American Registry of Midwives or other Department-approved organization(s);

2. Evidence of completion of an educational program evaluated by the North American Registry of Midwives or other Department-approved organization(s);

3. Evidence of completed apprenticeship in accordance with Section 103 and a written recommendation by the supervising Preceptor;

4. Evidence of a valid cardiopulmonary resuscitation certificate by the American Red Cross or American Heart Association and Neonatal Resuscitation Program certificate, or other American Academy of Pediatric neonatal resuscitation certification; and

5. Evidence of tuberculosis testing pursuant to Section 1702.

F. Licensing Fees. Each applicant shall pay a License fee prior to the issuance of a License. All fees are non-refundable, shall be made payable by check or money order to the Department or by credit card on a secured portal or website as determined by the Department, and shall be submitted with the application. The initial and renewal License fee for Midwife Licenses shall be two hundred twenty-five dollars ($225.00) every thirty-six (36) months.

G. Licensing Late Fee. Failure to submit a renewal application and fee to the Department by the License expiration date shall result in a late fee of twenty-five dollars ($25.00) in addition to the licensing fee. Failure to submit the licensing fee and licensing late fee to the Department within thirty (30) calendar days of the License expiration date shall render the Midwife unlicensed.

H. License Renewal. The Midwife shall renew his or her License every thirty-six (36) months prior to the expiration of the license by submitting a complete and accurate application on a form prescribed and furnished by the Department, shall pay the License fee, and shall not have pending enforcement actions by the Department. If the License renewal is delayed due to enforcement actions, the renewal License shall be issued only when the matter has been resolved by the Department or when the adjudicatory process is completed, whichever is applicable. The Midwife shall submit the following along with the renewal application:

1. Evidence of current Certified Professional Midwife certification by the North American Registry of Midwives or other Department-approved organization(s);

2. Evidence of completion of forty-five (45) Contact Hours of Continuing Education during the licensing period; and

3. Evidence of a valid cardiopulmonary resuscitation certificate by the American Red Cross or American Heart Association and Neonatal Resuscitation Program certificate or other American Academy of Pediatric neonatal resuscitation certification.

I. Amended License. The Midwife shall request issuance of an amended License by application to the Department upon a change in the Midwife's name and/or address.

103. Apprentice Midwife Permit. (II)

A. Permit Application. Applicants for an Apprentice Midwife Permit shall submit to the Department a completed application on a form prescribed, prepared, and furnished by the Department prior to issuance

of a Permit. Applicants for an Apprentice Midwife Permit shall file an application with the Department that includes an oath assuring that the contents of the application are accurate and true and in compliance with this regulation. An initial Apprentice Midwife Permit shall not be issued until the Apprentice Midwife has demonstrated to the Department that he or she is in substantial compliance with the licensing standards.

B. Required Documentation. The application for an initial or a renewal of an Apprentice Midwife Permit shall include:

1. Written verification of Apprentice and Preceptor relationship from the person(s) supervising the applicant and their verified relationship(s) when the Permit is renewed;

2. Documentation of enrollment in an approved course of education or evidence of a planned course of education, subject to the approval of the Department;

3. Documentation of tuberculosis screening pursuant to Section 1702;

4. Documentation to verify applicant is twenty-one (21) years of age or older; and

5. Verification of the applicant's ability to read and write in English.

C. Issuance and Terms of Permit.

1. An Apprentice Midwife Permit shall be effective for twelve (12) months following the date of issuance.

2. The Apprentice Midwife Permit is not assignable or transferable and is subject to Revocation by the Department for failure to comply with applicable state laws and regulations.

D. Permit Renewal. Applications for renewal of the Apprentice Midwife Permit must be submitted at least ninety (90) calendar days prior to the expiration of the prior Permit. An Apprentice Midwife Permit holder may apply for renewal of their Apprentice Midwife Permit a maximum of three (3) times before obtaining certification by the North American Registry of Midwives or other Department-approved organization(s). Under extenuating circumstances, one (1) additional renewal may be granted at the discretion of the Department on a case-by-case basis. (II)

E. Permit Fees. The initial and renewal Apprentice Midwife Permit fee shall be fifty ($50.00) dollars. Permit fees shall be made payable by check or money order to the Department or by credit card on a secured portal or website as determined by the Department and are not refundable. (II)

104. Variance.

The Midwife and Apprentice Midwife may request a variance to this regulation in a format as determined by the Department. Variances shall be considered on a case-by-case basis by the Department. The Department may revoke issued variances as determined to be appropriate by the Department.

SECTION 200 – ENFORCEMENT OF REGULATIONS

201. General.

The Department shall utilize Inspections, Investigations, Compliance Meetings, and other pertinent documentation regarding an Apprentice Midwife Permit holder applicant, Licensed Midwife applicant, Apprentice Midwife Permit holder, and Licensed Midwife in order to enforce this regulation.

202. Inspections and Investigations.

A. Records of Clients and Neonates delivered by Midwives are subject to Inspections and Investigations as deemed appropriate by the Department. (I)

B. The Midwife shall provide the Department all requested records and documentation in the manner and within the timeframe specified by the Department. (I)

C. When there is noncompliance with the licensing standards, the Midwife shall submit an acceptable plan of correction in a format determined by the Department. The plan of correction shall be signed by the Midwife and returned by the date specified by the Department. The plan of correction shall describe: (II)

1. The actions taken to correct each cited deficiency;

2. The actions taken to prevent recurrences (actual and similar); and

3. The actual or expected completion dates of those actions.

203. Compliance Meetings.

Compliance Meetings may be provided by the Department as requested by the Licensee or as deemed appropriate by the Department.

SECTION 300 – ENFORCEMENT ACTIONS

301. General.

When the Department determines that a Midwife is in violation of any statutory provision or regulation, the Department, upon proper notice to the Midwife, may deny, suspend, or revoke a License and/or assess a monetary penalty.

302. Violation Classifications.

Violation of standards in this regulation are classified as follows:

A. Class I violations are those that present an imminent danger to the health, safety, or well-being of the persons serviced by the Licensee or a substantial probability that death or serious physical harm could result therefrom. A physical condition or one or more practices, means, methods or operations in use by the Licensee may constitute such a violation. The Midwife shall immediately abate or eliminate the condition or practice constituting a Class I violation unless a fixed period of time, as stipulated by the Department, is required for correction. Each day such violation exists after expiration of the time established by the Department shall be considered a subsequent violation.

B. Class II violations are those, other than Class I violations that have a negative impact on the health, safety, or well-being of persons serviced by the Licensee. The citation of a Class II violation shall specify the time within which the violation is required to be corrected. Each day such violation exists after expiration of this time shall be considered a subsequent violation.

C. Class III violations are those that are not classified as Class I or II in this regulation. The citation of a Class III violation shall specify the time within which the violation is required to be corrected. Each day such violation exists after expiration of this time shall be considered a subsequent violation.

D. The notations "(I)" or "(II)," placed within sections of this regulation, indicate those standards are Class I or II violations if they are not met, respectively. Failure to meet standards not so annotated are Class III violations.

E. When imposing a monetary penalty, the Department may invoke South Carolina Code Section 44-1-150 to determine the dollar amount or may utilize the following schedule:

FREQUENCY	CLASS I	CLASS II	CLASS III
1st	$200-1,000	$100-500	$0
2nd	500-2,000	200-1,000	100-500
3rd	1,000-5,000	500-2,000	200-2,000
4th	5,000	1,000-5,000	500-2,000
5th	5,000	5,000	1,000-5,000
6th	5,000	5,000	5,000

SECTION 400 – SCOPE OF PRACTICE (I)

A. The Midwife shall only provide care within his or her scope of practice to Clients with Low Risk Pregnancy and Neonates as documented in the Physical Examination pursuant to Section 1100. Midwives to whom the South Carolina Board of Nursing has issued a license as a registered nurse or licensed practical nurse shall practice within the scope of his or her nursing license.

B. Midwifery care and services include the following:

1. Prenatal supervision and counseling;

2. Preparation for childbirth; and

3. Supervision and care during labor and delivery including care and services in the immediate postpartum, so long as progress meets criteria generally accepted as normal.

C. The Midwife and Apprentice Midwife may perform any of the following after submitting signed and dated documentation to the Department of the Midwifery Bridge Certificate, Midwifery Education Accreditation Council, American College of Nurse-Midwives, or other Department-approved training course completion on the topic:

1. Administering intravenous fluids;

2. Suturing of first-degree and second-degree tears; and

3. Administering intra-muscular and subcutaneous injections.

D. The Midwife shall not perform any of the following:

1. Assistance in delivery using vacuum extraction, forceps, or other mechanical equipment;

2. Provision of care for a Client with a previous cesarean section;

3. Induction of abortions or participation in inducing abortions;

4. Procedures other than artificial rupture of membranes at the introitus and/or clamping and cutting the umbilical cord;

5. Episiotomy; and

6. Circumcision.

SECTION 500 – CONTINUING EDUCATION (II)

A. The Midwife shall complete forty-five (45) Continuing Education Contact Hours per licensure period to improve the Midwife's ability to provide services within the Midwife's scope of practice. The Midwife shall ensure all Continuing Education training is documented with the signatures and the dates of the instructors and the Midwife. A signature for the instructor may be omitted for computer-based training. All Continuing Education courses shall be accredited by one of the following:

1. Any organizations approved by the South Carolina Board of Nursing for nursing professionals Continuing Education hours;

2. American College of Obstetrics and Gynecologists;

3. American College of Nurse Midwives;

4. Midwifery Education Accreditation Council;

5. North American Registry of Midwives Bridge Certification Program;

6. International Confederation of Midwives;

7. Accreditation Commission for Midwifery Education; or

8. Another organization approved by the Department.

B. The Midwife shall complete additional Continuing Education on specific topics as required by the Department.

SECTION 600 – REPORTING

601. Incidents.

The Midwife shall report the following Incidents to the Department at the earliest practicable hour, not exceeding forty-eight (48) hours of the Incident, via the Department's electronic reporting system or as otherwise determined by the Department:

A. Emergent events that require Transfer of Care during intrapartum, postpartum, and newborn periods;

B. Death of the Neonate or Client while under the care of the Midwife; and

C. Prescription Medication errors with adverse effects.

602. Quarterly Report Forms.

The Midwife shall submit complete Quarterly report forms to the Department in a manner and format as determined by the Department.

603. Reporting Mortalities.

The Midwife shall report all maternal and infant deaths to the Department's Office of Vital Statistics within forty-eight (48) hours of the fatality.

604. Registration of Birth.

The Midwife shall ensure that each birth is registered with the Department's Regional Vital Records Office within five (5) days of the birth.

SECTION 700 – CLIENT AND NEONATE RECORDS

A. The Midwife shall maintain an organized record for each Client and Neonate. The Midwife shall ensure all entries are permanently written, typed, or entered and stored in electronic media, authenticated by the author, and dated. If the Midwife permits any portion of a Client's record to be generated by electronic or optical means, the Midwife shall maintain policies and procedures to prohibit the use or authentication by unauthorized users.

B. The Midwife shall maintain current records: (II)

1. Client's records which shall include:

a. Client's Face Sheet: Name, address (including county), telephone number, age, date of birth, Midwife in attendance, Apprentice Midwife (if present), address and telephone number of person(s) to be contacted in the event of emergency, and name and address of the Client's Physician;

b. History of hereditary conditions;

c. First day of the last menstrual period and due date;

d. Blood group and Rhesus type;

e. Serological test for syphilis;

f. Gestational diabetes screening;

g. Number, dates, duration, and outcome(s) of previous pregnancies;

h. Medications prescribed and taken during pregnancy, labor, and delivery;

i. Duration of ruptured membranes and labor, including length of second stage;

j. Complications of labor, including hemorrhage or evidence of fetal distress;

k. Description of placenta at delivery, including number of umbilical vessels;

l. Estimated amount (small, moderate, or large) and description of amniotic fluid;

m. Documentation of scheduled prenatal visits;

n. Documentation of Physician or other Authorized Healthcare Provider examinations, visits, Referrals, and Medical Consultations;

o. Documentation of Discharge or Transfer of Care to include the date, time, and reasoning for the Discharge or Transfer of Care;

p. Client counseling regarding breastfeeding, community resources for emergency medical care, well-baby care, or other needed services, metabolic screening, newborn hearing screening, congenital heart disease; and

q. Any other documentation required to be in the Client's record by this regulation.

2. Neonate's records which shall include:

a. Name, gender, date of birth, place of birth, Client's name, address, and telephone number, Midwife in attendance, and Apprentice Midwife (if present);

b. Results of measurements of fetal maturity and well-being;

c. Apgar scores at one (1) and five (5) minutes of age;

d. Description of resuscitation, if required;

e. Care of the umbilical cord;

f. Eye care; and

g. Any other documentation required to be included in the Neonate's record by this regulation.

C. The Midwife shall maintain all records for no less than twenty-five (25) years. The Midwife shall provide a complete copy of a current or former Client's record to the Client or Neonate delivered by the Midwife or the Client's or child's legal representative within thirty (30) calendar days of written request.

SECTION 800 – [RESERVED]

SECTION 900 – CLIENT CARE AND SERVICES (I)

901. Prenatal Care.

A. Scheduled Prenatal Visits. The Midwife shall conduct prenatal visits with the Client at least one (1) time every four (4) weeks until thirty-two (32) weeks gestation, at least one (1) time every two (2) weeks from thirty-two (32) to thirty-six (36) weeks, and at least one (1) time per week after thirty-six (36) weeks, and document each visit in the Client's record.

B. The Midwife shall document every visit in the Client's record and include the following care:

1. Assessment of general health and obstetric status;

2. Nutritional counseling;

3. Blood pressure monitoring;

4. Urine dipstick for sugar and protein as needed or if symptomatic;

5. Weight;

6. Fundal height;

7. Palpation of abdomen, Leopold's maneuvers;

8. Auscultation of fetal heart tones after twenty (20) weeks; and

9. Education as to cause, treatment, and prognosis of any symptoms, problems, or concerns.

C. Home Visit. The Midwife shall conduct at least one (1) of the prenatal visits to the Client's home during the last six (6) weeks of pregnancy if the Client is preparing for a Home Birth. The Midwife may omit the visit to the Client's home during the last six (6) weeks of pregnancy if the Client is preparing for a birth in a Birthing Center licensed by the Department. The Midwife shall maintain documentation in the Client's record indicating the Client's decision to have a Home Birth or to give birth in a licensed Birthing Center and make the documentation in the Client's record available for review by the Department.

D. Prenatal Testing.

1. The Midwife shall ensure and document in the Client's record that the following prenatal tests and screenings are completed by the Client between eight (8) weeks, zero (0) days and sixteen (16) weeks, zero (0) days gestation, or upon initiation of Midwifery Services:

a. Antibody screen;

b. ABO blood typing;

c. Rhesus factor;

d. Complete blood count with differential for hemoglobin and hematocrit and mean corpuscular volume;

e. Hepatitis B surface antigen;

f. Syphilis screening;

g. Platelet count;

h. Human immunodeficiency virus test, optional;

i. Sexually transmitted infections;

j. Gestational diabetes screening; and

k. Rubella test.

2. The Midwife shall ensure and document in the Client's record that the Client completes the complete blood count with differential for hemoglobin and hematocrit and mean corpuscular volume prenatal test and screening between twenty-four (24) weeks, zero (0) days and twenty-eight (28) weeks, zero (0) days of gestation.

3. The Midwife shall ensure and document in the Client's record that the following prenatal tests and screening are completed by the Client between thirty-five (35) weeks, zero (0) days and thirty-seven (37) weeks, zero (0) days of gestation:

a. Screening for Group B Streptococcus. The Midwife shall inform the Client of the effects of Group B Streptococcus; and

b. Sexually transmitted infections for Clients with risk factors.

E. The Midwife shall discuss the following with the Client and document the discussion in the Client's record:

1. Nutritional counseling;

2. Education on cause, treatment, and prognosis of any symptoms, problems, or concerns;

3. Childbirth classes and other community resources; and

4. Available community resources for emergency medical care for infants, well-baby care, or other needed services.

F. The Midwife shall provide written instructions to the Client during antepartum for postpartum care, self-care, and newborn care, and document the date provided to the Client in the Client's record.

902. Intrapartum Care.

The Midwife shall provide and document in the Client's record the provision of the following care during the intrapartum period:

A. Assessment, evaluation, and documentation of the status of labor and the Client and fetal conditions throughout the labor and birth process, including Client's vital signs and fetal heart tones;

B. Examination in Labor. The Midwife shall not perform any vaginal examinations on the Client with ruptured membranes and no labor, other than an initial sterile examination to be certain there is no prolapsed umbilical cord. The Midwife shall conduct exams as needed once active labor is in progress;

C. Assisting with labor coaching;

D. Delivering the baby; and

E. Complete delivery of the placenta.

903. Postpartum Care.

A. Immediate Postpartum Care. Immediately following the birth, the Midwife shall remain with the Client and Neonate for a minimum of two (2) hours after the birth or until the Midwife confirms Client and Neonate stability prior to leaving the place of birth. The Midwife shall provide and document in the Client's record the provision of the following care during the immediate postpartum period:

1. Monitoring the physical status of Client and Neonate, including monitoring and recording vital signs within the first two (2) hours and upon Discharge. Assessment, evaluation, and documentation of the physical status of Client and Neonate, and offering any necessary routine comfort measures;

2. Facilitation of maternal-infant bonding and family adjustment;

3. Assistance with breastfeeding and facilitation of bonding based on Client's preferences;

4. Examination of the placenta, umbilical cord, and membranes;

5. Evaluation of the perineum and repairing any first-degree or second-degree tears pursuant to Section 400.C;

6. Monitoring bleeding and condition of the fundus and treatment for hemorrhage pursuant to Section 1200;

7. Obtain a cord blood sample for Rhesus factor testing if Client is Rhesus negative; and

8. Administer Rho(D) immune globulin pursuant to Section 1200.

B. The Midwife shall visit the Client and Neonate twenty-four (24) to thirty-six (36) hours after delivery and document the visit in the Client's record and the Neonate's record.

904. Newborn Care.

A. Immediate Newborn Care. The Midwife shall provide and document in the Neonate's record the provision of the following care to the immediate newborn:

1. Assurance that the airways are clear;

2. Assessment of the Neonate's condition at one (1) minute and five (5) minutes after birth according to Apgar scoring;

3. Provision of warmth and stimulation if necessary;

4. Obtain a cord blood sample for Rhesus factor testing if Client is Rhesus negative; and

5. Administration of vitamin K to the Neonate with documented informed consent from the Client.

B. Newborn Screening. The Midwife, as the person in attendance, shall collect a specimen from every child born pursuant to South Carolina Code Section 44-37-30 and Regulation 61-80, Neonatal Screening for Inborn Metabolic Errors, and in accordance with the official Department instructions and for submission

of the specimen to the Department's Bureau of Laboratories on the day of collection. The Midwife shall notify the Department's Bureau of Maternal and Child Health as specified in the official Department instructions if the specimen is not collected within three (3) calendar days of delivery by the Midwife. If the parents object to the screening based on religious convictions, the Midwife shall ensure the parents complete the procedure specified in the official Department instructions.

SECTION 1000 – INFORMED CONSENT (II)

The Midwife shall ensure an informed consent is documented in writing, signed, and dated by the Midwife and the Client, and shall include the following:

A. Explanation of the specific care and services provided by the Midwife, that the Midwife is not a licensed nurse, Physician, or other Authorized Healthcare Provider, and the risks, responsibilities, and alternatives for care;

B. Explanation of the Midwife's scope of care and conditions requiring Medical Consultation, Discharge, and Transfer of Care;

C. Disclosure of fees for all care and services provided;

D. Explanation of the benefits and risks of having an anatomic ultrasound; and

E. Information for filing a complaint with the Department, including the address and telephone number of the Department and the electronic means and web address for filing a complaint.

SECTION 1100 – PHYSICAL EXAMINATIONS (I)

A. Initial Physical Examination:

1. The Midwife shall require the Client to undergo an initial Physical Examination completed by a Physician or other Authorized Healthcare Provider between ten (10) weeks and twenty (20) weeks of gestation. The Midwife may accept Clients after twenty (20) weeks of gestation provided the Client has undergone a Physical Examination that meets the requirements in Section 1100.A.2.

2. The Midwife shall ensure the initial Physical Examination of the Client is documented in the Client's record and includes:

a. A written and signed statement by the Physician or other Authorized Healthcare Provider that he or she has determined to the best of his or her ability that the pregnancy is a Low Risk Pregnancy as defined by this regulation; and

b. Identification of special conditions and/or care required.

B. Second Physical Examination:

1. The Midwife shall require the Client to undergo a second Physical Examination completed by a Physician or other Authorized Healthcare Provider after thirty-four (34) weeks of gestation.

2. The Midwife shall ensure the second Physical Examination of the Client is documented in the Client's record and includes:

a. A written and signed statement from the Physician or other Authorized Healthcare Provider that the pregnancy remains a Low Risk Pregnancy and the fetus is in the vertex position; and

b. Orders for Medications needed for intrapartum and postpartum.

SECTION 1200 – PRESCRIPTION MEDICATION ADMINISTRATION (I)

A. The Midwife shall administer only the Prescription Medications in Section 1200.B and in accordance with the orders and directions of a Physician or other Authorized Healthcare Provider. The Midwife shall only administer Prescription Medications to the Client and/or Neonate for whom the prescription is ordered. The Midwife shall maintain documentation in the Client record of all Medications administered and shall include the time of administration, the quantity and/or dosage, and any adverse effects.

B. The Midwife shall only administer Medications as prescribed by the Physician or other Authorized Healthcare Provider. The Midwife shall only administer the following Prescription Medications:

1. Oxygen;

2. Eye prophylactic, within one (1) hour of birth, unless written refusal is obtained from the Client. Documentation of the administration or Client's refusal shall be made in the Client's record;

3. Vitamin K to the Neonate unless written refusal is obtained from the Client. Documentation of the administration or Client's refusal shall be made in the Client's record;

4. Oxytocin;

5. Topical Lidocaine;

6. Lactated Ringers or Normal Saline; and

7. Rho(D) immune globulin to the Client within seventy-two (72) hours of delivery.

SECTION 1300 – MEDICAL CONSULTATION AND REFERRAL (I)

A. The Midwife shall obtain all Medical Consultations from a Physician or other Authorized Healthcare Provider, licensed in South Carolina or contiguous state, and maintain documentation of the Medical Consultation in the Client's record, including the reason for the Medical Consultation, the date and time of the Medical Consultation, the name of the Physician or other Authorized Healthcare Provider, the recommendations of the Physician or other Authorized Healthcare Provider, and the Client's decision, as authenticated by the Client's signature. The Midwife shall file documentation of each Medical Consultation in the Client's record within 72 hours of the consultation.

B. The Midwife shall obtain a Medical Consultation for Clients or Neonates presenting any of the following conditions:

1. Antepartum to include:

a. Pregnancy-induced hypertension, as evidenced by a blood pressure greater than or equal to one hundred forty over ninety millimeters of mercury (140/90 mm Hg) on two (2) occasions greater than six (6) hours apart;

b. Persistent severe headaches, epigastric pain, or visual disturbances;

c. Persistent symptoms of urinary tract infection;

d. Significant vaginal bleeding;

e. Abnormal decrease in or cessation of fetal movement with non-reassuring fetal heart tones;

f. Symptoms of anemia that are resistant to treatment;

g. Fever with temperature of one hundred two degrees Fahrenheit (102°F) or greater for more than twenty-four (24) hours;

h. Non-vertex presentation after thirty-eight (38) weeks gestation;

i. Symptoms of hyperemesis or significant dehydration;

j. Isoimmunization, Rhesus factor negative sensitization, or any other positive antibody titer that may have detrimental effect on Client or Neonate;

k. Elevated blood glucose levels;

l. Positive human immunodeficiency virus antibody test;

m. Suspected primary genital herpes infection;

n. Symptoms of malnutrition, anorexia, protracted weight loss, or failure to gain weight without adequate nutrition;

o. Suspected deep vein thrombosis;

p. Signs of labor prior to thirty-seven (37) weeks gestation;

q. Multiple gestation;

r. Abnormal fetal heart tones;

s. Abnormal non-stress test or abnormal biophysical profile;

t. Confirmed polyhydramnios or oligohydramnios;

u. Gestation beyond forty-two (42) weeks and zero (0) days; and

v. Abnormal fetal size for gestation.

2. Intrapartum to include:

a. Prolonged premature rupture of membranes greater than twenty-four (24) hours;

b. Non-vertex presentation;

c. Signs of fetal distress;

d. Abnormal heart tones with non-reassuring fetal heart tones;

e. Meconium staining;

f. Persistent blood pressure greater than one hundred forty over ninety millimeters of mercury (140/90 mm Hg);

g. Significant proteinuria or ketonuria;

h. No progress for greater than five (5) hours during active first stage of labor following six (6) centimeters dilatation;

i. More than two (2) hours without descent during second stage of labor;

j. Abnormal bleeding; and

k. Suspected prolapsed umbilical cord.

3. Postpartum to include:

a. Retained placenta or fragments greater than one (1) hour;

b. Hemorrhage greater than one thousand milliliters (1000 ml), and bleeding is uncontrolled;

c. Signs of uterine infection, including foul-smelling lochia and uterine tenderness; and

d. Fever with a temperature greater than one hundred one point five degrees Fahrenheit (101.5°F).

4. Neonatal to include:

a. Apgar score of less than seven (7) at five (5) minutes without improvement;

b. Obvious anomaly, suspected disorder, or abnormal facies;

c. Grunting respirations, chest retractions, or cyanosis;

d. Cardiac irregularities;

e. Pale, cyanotic, or gray in color;

f. Abnormal cry;

g. Excessive head molding, large cephalohematoma, excessive bruising, apparent fractures, dislocations, or other injuries;

h. Weight of less than five and one half (5.5) pounds or more than ten (10) pounds;

i. Signs of hypoglycemia, hypocalcemia, or other metabolic disorder;

j. Meconium staining;

k. No urination or no passage of meconium in the first twenty-four (24) hours following birth;

l. Signs of edema;

m. Signs of lethargy, weakness, flaccidity, or not feeding well;

n. Rectal temperature below ninety-seven degrees Fahrenheit (97°F) or above one hundred point six degrees Fahrenheit (100.6°F);

o. Full, bulging, or abnormally sunken fontanel; and

p. Signs of any other abnormality.

SECTION 1400 – DISCHARGE

The Midwife shall immediately Discharge a Client during antepartum when care required for the Client is outside the Midwife's scope of practice pursuant to Section 400, the Client refuses the initial or second Physical Examination, or the Client refuses a Referral as recommended by a Physician or other Authorized Healthcare Provider during a Medical Consultation.

SECTION 1500 – TRANSFER OF CARE (I)

A. The Midwife shall immediately initiate a Transfer of Care during intrapartum and postpartum by dialing 911 when the care required is outside the Midwife's scope of practice pursuant to Section 400, as recommended by a Physician or other Authorized Healthcare Provider during a Medical Consultation, or for any event during labor that compromises the health of the Client or Neonate and/or normally requires emergency intervention.

B. Upon arrival of the emergency medical services personnel, Physician, or other Authorized Healthcare Provider, the Midwife shall transfer the care of the Client to the emergency medical services personnel, Physician, or other Authorized Healthcare Provider. The Midwife shall provide information as requested by the emergency medical services personnel, Physician, or other Authorized Healthcare Provider.

SECTION 1600 – MAINTENANCE OF EQUIPMENT

The Midwife shall maintain all equipment used in the provision of care clean, disinfected, and in good repair and operating condition. All equipment used by the Midwife in the provision of care is subject to Inspection as deemed appropriate by the Department.

SECTION 1700 – INFECTION CONTROL

1701. Infection Control Practices.

The Midwife shall maintain policies and procedures to address preventing the spread of infectious, contagious, and communicable diseases.

1702. Tuberculosis Screening. (I)

A. Tuberculosis Testing. Midwives and Apprentice Midwives shall utilize either the Tuberculin Skin Test or the Blood Assay for Mycobacterium Tuberculosis for detecting Mycobacterium tuberculosis infection. Authorized Healthcare Providers may perform the Tuberculin Skin Test and symptom screening.

B. Baseline Status.

1. The baseline status of Midwives and Apprentice Midwives shall be determined according to the Centers for Disease Control and Prevention and the Department's most current tuberculosis guidelines.

2. Tuberculosis Screening. Midwives and Apprentice Midwives within three (3) months prior to submission of the initial application to the Department shall have a baseline two-step Tuberculin Skin Test or a single Blood Assay for Mycobacterium Tuberculosis. If the Midwife or Apprentice Midwife applicant has had documented negative Tuberculin Skin Test or a Blood Assay for Mycobacterium Tuberculosis result within the previous twelve (12) months, a single Tuberculin Skin Test or the single Blood Assay for Mycobacterium Tuberculosis may be administered and read to serve as the baseline prior to submission of the initial application by the Midwife or Midwife Apprentice.

3. If the result is positive and/or if the Midwife or Apprentice Midwife is symptomatic for tuberculosis, the Midwife or Apprentice Midwife shall have a chest X-ray and a written assessment by a Physician or other Authorized Healthcare Provider that there is no active tuberculosis. Midwives and Apprentice Midwives who are symptomatic shall not have contact with Clients while awaiting chest X-ray results. The Midwife or Apprentice Midwife shall ensure that their chest X-ray results indicating tuberculosis disease are reported to the Department's local health department.

4. Midwives and Apprentice Midwives with negative chest X-ray results may have Client contact while reporting to the Department's local health department for latent tuberculosis infection treatment. Midwives and Apprentice Midwives who does not complete treatment for latent tuberculosis infection shall be monitored with a documented annual symptom evaluation in addition to completing the annual training pursuant to Section 1702.D.

C. Post Exposure. After known exposure to a person with potentially infectious tuberculosis disease without use of adequate personal protective equipment, the tuberculosis status of all Midwives and Apprentice Midwives shall be determined in a manner prescribed in the Centers for Disease Control and Prevention and the Department's most current tuberculosis guidelines.

D. Annual Tuberculosis Training. Midwives and Apprentice Midwives shall receive annual training regarding tuberculosis to include risk factors and signs and symptoms of tuberculosis disease. The Midwife and Apprentice Midwife shall maintain documentation of the annual tuberculosis training.

E. Serial Screening. Midwives and Apprentice Midwives shall follow the Centers for Disease Control and Prevention and the Department's most current tuberculosis guidelines related to serial screening.

SECTION 1800 – MIDWIFERY ADVISORY COUNCIL

The Department shall appoint a Midwifery Advisory Council to advise the Department regarding licensing and Inspection of Midwives. The Council shall meet at least annually. The Council shall consist of three (3) licensed Midwives, one (1) consumer of Midwife care, two (2) Certified Nurse-Midwives, one (1) Physician active in perinatal care, and one (1) member-at-large. Each member shall be appointed for a three (3) year term of office.

SECTION 1900 – [RESERVED]

SECTION 2000 – [RESERVED]

SECTION 2100 – [RESERVED]

SECTION 2200 – [RESERVED]

SECTION 2300 – [RESERVED]

SECTION 2400 – [RESERVED]

SECTION 2500 – [RESERVED]

SECTION 2600 – [RESERVED]

SECTION 2700 – SEVERABILITY

In the event that any portion of this regulation is construed by a court of competent jurisdiction to be invalid, or otherwise unenforceable, such determination shall in no manner affect the remaining portions of this regulation, and they shall remain in effect as if such invalid portions were not originally a part of this regulation.

SECTION 2800 – GENERAL

Conditions that have not been addressed in this regulation shall be managed in accordance with the best practices as interpreted by the Department.

Fiscal Impact Statement:

Implementation of this regulation will not require additional resources. There is no anticipated additional cost by the Department or state government due to any requirements of this regulation.

Statement of Need and Reasonableness:

The following presents an analysis of the factors listed in 1976 Code Sections 1-23-115(C)(1)-(3) and (9)-(11):

DESCRIPTION OF REGULATION: 61-24, Licensed Midwives.

Purpose: The Department amends R.61-24 to update provisions in accordance with current practices and standards. The Department further revises for clarity and readability, grammar, references, codification, and overall improvement to the text of the regulation.

Legal Authority: 1976 Code Sections 44-1-140 et seq.

Plan for Implementation: The DHEC Regulation Development Update (accessible at http://www.scdhec.gov/Agency/RegulationsAndUpdates/RegulationDevelopmentUpdate/) provides a summary of and link to the amendment. Additionally, printed copies are available for a fee from the Department's Freedom of Information Office. Upon taking legal effect, Department personnel will take appropriate steps to inform the regulated community of the amended regulation and any associated information.

DETERMINATION OF NEED AND REASONABLENESS OF THE REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

The amendments are necessary to update provisions in accordance with current practices and standards. The amendments include updated language for midwives applying for licensure and incorporate requirements for scope of care, continuing education training, as well as client care and services and prescription medication administration requirements. The amendments revise and incorporate requirements regarding Department inspections and investigations, maintenance of accurate client records, and other requirements for licensure.

DETERMINATION OF COSTS AND BENEFITS:

Implementation of these amendments will not require additional resources. There is no anticipated additional cost to the Department or state government due to any inherent requirements of these amendments. There are no anticipated additional costs to the regulated community.

UNCERTAINTIES OF ESTIMATES:

None.

EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH:

The amendments to R.61-24 seek to support the Department's goals relating to the protection of public health through implementing updated requirements for the licensure of midwives. There are no anticipated effects on the environment.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED:

There is no anticipated detrimental effect on the environment. If the revision is not implemented, the regulation will be maintained in its current form without realizing the benefits of the amendments herein.

Statement of Rationale:

Here below is the Statement of Rationale pursuant to S.C. Code Section 1-23-110(h):

The Department of Health and Environmental Control amends R.61-24 to update provisions in accordance with current practices and standards. The amendments include updated language for midwives applying for licensure and incorporate provisions delineating new requirements in scope of practice, continuing education training, as well as new prescription medication administration and infection control requirements. The amendments revise and incorporate requirements for client and neonate care and services, Department inspections and investigations, maintenance of accurate and current client records, and other requirements for licensure.

ATTACHMENT B

SUMMARY OF PUBLIC COMMENTS AND DEPARTMENT RESPONSES

Document No. 4974
R.61-24, *Licensed Midwives*

As of the September 28, 2020, close of the Notice of Proposed Regulation comment period:

NAME	SECTION	DEPARTMENT RESPONSE
1.Emma Bobbitt	400, 1200	Not Adopted. Not Adopted. Misoprostol is not approved by the U.S. Food and Drug Administration for postpartum hemorrhaging. Any such use is considered an off-label use. This medication is also used in combination with another drug to end a pregnancy. The medication may also be used for induction of cervical softening and dilation in labor. The main problems cited for the medication are hyperstimulation, uterine rupture, and placental abruption. Oxytocin alone is the recommended uterotonic drug for the treatment of postpartum hemorrhage. Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives.
Revising midwife regulations during a pandemic, where more people are choosing out of hospital birth options for the safety of their newborns and their families, is quite despicable. South Carolina midwives are busier than ever. Editing regulations to prohibit midwives having access to a life-saving medication (misoprostol) is foolish. Think of the potential lives that this medication can save when access is granted. Those who live in rural areas that opt for out of hospital birth will be put in danger. Vaginal birth after cesarean (VBAC) is an option that women deserve to have. Many medical providers in hospital settings do not allow VBACs. Are we restricting medical freedoms now? Is that the kind of state that South Carolina wants to be? What is the benefit in that? The main risk associated with VBAC is uterine rupture. The risk of a uterine rupture is less than 1% in women attempting a VBAC. The risks associated with a repeat cesarean are much greater in number and magnitude. Licensed midwives are trained to identify the signs of a uterine rupture and are able to make life-saving decisions. South Carolina women deserve to make their own medical decisions, rather than having the state make those decisions for them through restrictions.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
2.Ida Darragh Executie Director	400, 1100	Partially Adopted. Not Adopted. VBACs are not low-risk deliveries and therefore

North American Registry of Midwives		are outside the scope of practice for licensed midwives. Not Adopted. S.C. 44-89-60(4) requires that a physician make a written determination that the planned birth is low risk. Adopted. Section 400. (regarding intravenous fluids). Adopted. Section 400. (regarding suturing).
The North American Registry of Midwives supports the regulatory changes to midwifery licensure in South Carolina. In addition to supporting the proposed regulations, NARM states that it is within the scope of practice of Certified Professional Midwives to attend VBACs, administer a specific formulary of medications, start IVs and suture tears or episiotomies. It is also very uncommon to require midwifery clients to be seen by another health care provider during the pregnancy; there are a few states that do that but none can provide evidence of the benefits.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
3.Tiffany Thompson	400, 1100, 1200	Not Adopted. Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives. Not Adopted. Misoprostol is not approved by the U.S. Food and Drug Administration for postpartum hemorrhaging. Any such use is considered an off-label use. This medication is also used in combination with another drug to end a pregnancy. The medication may also be used for induction of cervical softening and dilation in labor. The main problems cited for the medication are hyperstimulation, uterine rupture, and placental abruption. Oxytocin alone is the recommended uterotonic drug for the treatment of postpartum hemorrhage. Not Adopted. S.C. 44-89-60(4) requires that a physician make a written determination that the planned birth is low risk.
I am writing in regards to regulation 61-24. Please consider either postponing until this can be held in a public forum or amending 61-24 to better support midwives and their families. Mothers should have the right to choose what they feel is best for their bodies and their babies. Mothers should have a right to choose a VBAC with the care provider of their choice in the setting of their choice. Midwives should have easy access to multiple life-saving medications. In my opinion, mothers should not be required to see a physician at all. This should be her choice. I am responsible for the health of my body and my child's body. Thank you for your consideration.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
4.Kathryn Imgruh Prisma Health	400, 1100, 1200, 1300	Partially Adopted. Adopted. 400.D.2. (regarding vaginal birth after cesarean). Adopted. 1200 (regarding methergine) Not Adopted. Due to South Carolina's geography and rural communities it would be beneficial to the safety of home birth clients to allow a licensed midwife to provide intravenous fluids to stabilize a laboring or recently delivered person while awaiting EMS for transport. Partially Adopted. Section 1500. (regarding transfers to include an admitting Obstetrician). This regulation does not prohibit clients from preregistering and notifying the admitting physician of an emergent transfer. Partially Adopted. Section 1300. (regarding gestational

		diabetes). There is a requirement for Medical Consultation to determine level of risk to the Client.

As an OBGYN physician, taking care of women daily in the midlands for the past 7 years, I write to strongly discuss the proposed changes to midwife scope of practice.

The field of OBGYN in 2020 is complex, nuanced and can rapidly go from low risk to high risk during delivery. We have a high maternal mortality rate without clear indications as to cause. There are challenges with rising rates of obesity and glucose intolerance/diabetes, maternal illnesses affecting pregnancies and an increase in age of pregnant women; all of these are risk factors for poor outcomes. This is true in the best facilities, with the highest trained staff. Thus the scope of practice for licensed midwives CANNOT, in my expert opinion, be broadened to include care of high risk women with prior c sections or diabetes/glucose intolerance, administration of medications such as oxytocin, methergine, lidocaine, epinephrine, penicillin and other antibiotics, IV placement and fluid management. These high risk patients and interventions belong in the hands of highly trained medical professionals held to a high national standard, in a facility that can quickly handle the emergencies that sometimes arise from these situations. Time is blood for mom and brain for baby.
I fully support the recommendations for the requirements for standard neonatal screenings. No newborn should be without due to maternal choices in care. I strongly support that the midwife have an established collaborative relationship with a physician licensed to practice medicine in SC with admitting privileges to a hospital that offers OB services, and that transfer for higher level of care be more than a simple 911 call. The women of South Carolina deserve to have measures in place, such as preregistration at the hospital and a direct phone call with the admitting physician who will assume care, to ensure the best survival and outcomes for herself and her baby when a higher level of care is needed. Again, time is blood for mom and brain for baby.

Home delivery can be beautiful; home delivery can also be likened to playing with a loaded gun. We all hope the gun won't go off, but if it does we OBGYNs know the results can be catastrophic. We must protect the mothers and babies of our state, ensuring licensed midwives have the appropriate education and training (from an accredited program), supervision/collaboration/access to higher level of care, and scope of practice limited to low risk patients with minimal interventions. ONLY THEN can women feel safe making the choice for home delivery.

NAME	SECTION	DEPARTMENT RESPONSE
5. Rachel Hall, M.D.	1200	Not Adopted. Misoprostol is not approved by the U.S. Food and Drug Administration for postpartum hemorrhaging. Any such use is considered an off-label use. This medication is also used in combination with another drug to end a pregnancy. The medication may also be used for induction of cervical softening and dilation in labor. The main problems cited for the medication are hyperstimulation, uterine rupture, and placental abruption. Oxytocin alone is the recommended uterotonic drug for the treatment of postpartum hemorrhage.

My comment is in reference to the limitations on midwives to administer misoprostol in the event of post-partum hemorrhage (PPH). If a prescribing clinician has used their medical knowledge, expertise and wisdom, practicing their art of medicine, and has written a medication during their consult with a midwife's client, and that consult is a relationship between the clinician and the midwife, the midwife should be able to administer the medications. In fact it seems like you are placing regulations on the knowledge, expertise, wisdom, and practice of the prescribing clinician not the midwife.

To deny midwives the ability to administer misoprostol because it is not FDA approved, when it is widely used around the world because it is known to stop bleeding and prevent maternal morbidity and mortality, is unethical. It is setting midwives up for a bad outcome, which should be placed on these regulations and not their skills and abilities.

Misoprostol will never be FDA approved. Why? Because it would be unethical to knowingly deprive women of a drug that is known to work simply so a large, double blind, randomized, placebo controlled study can be done to attain FDA approval.

The limitation to misoprostol is making women choosing home birth less safe, when the purpose of these regulations is to protect the citizens of South Carolina. In the event of a PPH, any delivering provider needs access to more than one response measure. Some women are not candidates for methergine,, so without misoprostol the only response measure is pitocin. If pitocin doesn't work, that woman is in an emergent situation with no other measures to try and keep that situation as urgent, so transfer is not happening while active, massive hemorrhage is occurring.

Please remember, these regulations will not stop women in SC from choosing home birth. Some will still choose it, even if they know they have been made less safe by the limitations put on their midwife. A bad outcome in a PPH situation would not be the fault of the midwife bound by this regulation. It would be the state's. We also must remember that we are in a pandemic and people are not wanting to go to the hospital, especially when they are well, let alone when they are in a mild immune compromised state (pregnancy) and are delivering an immuno-incompetent infant into the pandemic world. We are in a unique time, one that is not going to "disappear" anytime soon, so the possibility of increasing numbers of home and birth center births must be considered during this time of revision.

Please keep in mind these regulations purpose. To protect women of SC. Depriving them of a world wide accepted and used drug, because of how well it works, even though it isn't approved by our country's drug administration, is not serving the women of SC.

NAME	SECTION	DEPARTMENT RESPONSE
6.Chloe Clauser	400, 1200, 1300, 1500	Partially Adopted. Clarification: This comment partially does not pertain to amending R.61-24 but to the internal processes of the Department. Partially Adopted. Section 1300. (regarding medical consultations and referrals). Any condition that requires consultation is considered to move the client beyond a low-risk pregnancy determination. The client has the right to consent to care that may possibly return her to a low-risk determination or to refuse the care. Not Adopted. When events during intrapartum and/or postpartum move the pregnancy, birth, and/or condition of the client or neonate beyond the scope of midwifery care, the client and/or neonate are no longer considered low-risk and a transfer of care is required. Clients have the right to refuse care, treatment or services according to the laws of South Carolina. Clarification regarding Perinatal Levels of Care: This comment does not pertain to R.61-24. Perinatal levels of care

		are regulated within R.61-16. Not Adopted. Misoprostol is not approved by the U.S. Food and Drug Administration for postpartum hemorrhaging. Any such use is considered an off-label use. This medication is also used in combination with another drug to end a pregnancy. The medication may also be used for induction of cervical softening and dilation in labor. The main problems cited for the medication are hyperstimulation, uterine rupture, and placental abruption. Oxytocin alone is the recommended uterotonic drug for the treatment of postpartum hemorrhage. Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives.
1) DHEC again did not accept the advice of the Midwifery Advisory Council (MAC). Additionally, the regulation would reduce the authority of MAC to almost nothing. It is clear from the continued errors in LM proposed regs by DHEC that they desperately need a MAC and they need to adhere to MAC recommendations. 2) The requirements for consultation with a physician in the new regs are extreme and would reduce access to community birth and inhibit the profession of Licensed Midwifery. 3) Requiring a midwife to call 911 as a means of transfer of care if a mother chooses to decline the recommendations of a physician or midwife is not only an infringement upon patient rights, but is a deliberate disparity mandated by a government agency. Licensed Midwives should be listed as a maternity provider within the Perinatal Levels of Care and the families using a midwife should be given the same access to the emergency system as every other maternity provider in SC. 4) Misoprostol needs to be incorporated as an emergency measure. It is a safe and effective medication for postpartum hemorrhage. 5) VBAC should not be banned. A 2006 memo is outdated and not incorporated into the 2013 LM regulation. There have been no major issues with VBAC attendance and certain mothers should be considered low risk, especially since LMs are already required to get a second opinion from a physician.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
7. Laura Smith	400, 1200, 1300, 1500	Partially Adopted. Clarification: This comment partially does not pertain to amending R.61-24 but to the internal processes of the Department. Partially Adopted. Section 1300. (regarding medical consultations and referrals). Any condition that requires consultation is considered to move the client beyond a low-risk pregnancy determination. The client has the right to consent to care that may possibly return her to a low-risk determination or to refuse the care. Not Adopted. When events during intrapartum and/or postpartum move the pregnancy, birth, and/or condition of the client or neonate beyond the scope of midwifery care, the client and/or neonate are no longer considered low-risk and a transfer of care is required. Clients have the right to refuse care, treatment or services according to the laws of South Carolina. Clarification regarding Perinatal Levels of Care: This comment does not pertain to R.61-24. Perinatal levels of care

		are regulated within R.61-16. Not Adopted. Misoprostol is not approved by the U.S. Food and Drug Administration for postpartum hemorrhaging. Any such use is considered an off-label use. This medication is also used in combination with another drug to end a pregnancy. The medication may also be used for induction of cervical softening and dilation in labor. The main problems cited for the medication are hyperstimulation, uterine rupture, and placental abruption. Oxytocin alone is the recommended uterotonic drug for the treatment of postpartum hemorrhage. Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives.
I have had three homebirths with a SC midwife. All three were excellent experiences. I continue to be grateful each day for having that opportunity. My children are very healthy, to a degree, in thanks to having them at home and under the care of a midwife during my prenatal time. My midwife was knowledgeable, responsible and professional. More than once her knowledge was more than my OBGYNs. We as consumers and citizens deserve the excellent care of SC midwives. Please give them the high respect and autonomy they well deserve. Here is where I hope DHEC will reconsider their points: 1) DHEC again did not accept the advice of the Midwifery Advisory Council (MAC). Additionally, the regulation would reduce the authority of MAC to almost nothing. It is clear from the continued errors in LM proposed regs by DHEC that they desperately need a MAC and they need to adhere to MAC recommendations. 2) The requirements for consultation with a physician in the new regs are extreme and would reduce access to community birth and inhibit the profession of Licensed Midwifery. 3) Requiring a midwife to call 911 as a means of transfer of care if a mother chooses to decline the recommendations of a physician or midwife is not only an infringement upon patient rights, but is a deliberate disparity mandated by a government agency. Licensed Midwives should be listed as a maternity provider within the Perinatal Levels of Care and the families using a midwife should be given the same access to the emergency system as every other maternity provider in SC (physicians, smaller hospitals, college and prisons infirmaries have access to this Perinatal Level of Care transfer system). 4) Misoprostol needs to be incorporated as an emergency measure. It is a safe and effective medication for postpartum hemorrhage. 5) VBAC should not be banned. A 2006 memo is outdated and not incorporated into the 2013 LM regulation. There have been no major issues with VBAC attendance and certain mothers should be considered low risk, especially since LMs are already required to get a second opinion from a physician. This physician opinion is more appropriate than the Nursing Opinion stated by DHEC as a rationale for banning VBAC attendance by a LM.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
8.Kennedy Adriane	n/a	Acknowledged.
I do not want midwives & those seeking midwifery care to lose their autonomy. They play a crucial role in the care of women, during pregnancy and after.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
9. Melissa Walker-Dushak	n/a	Acknowledged.
Birth options need to be protected. Home births have been proven to be a safe, affordable option for families, especially families who want to avoid hospital settings during this pandemic.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**

10.Andrea Simcik	n/a	Acknowledged.
PLEASE keep midwifery an option.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
11.Arcelia Cote	400	Not Adopted. Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives.
Section 400: VBAC should not be banned. A 2006 memo is outdated and was not incorporated into the 2013 LM regulation. There have been no major issues with VBAC attendance and certain mothers should be considered low risk, especially since LMs are already required to get a second opinion from a physician in accordance with the current regulations. This physician opinion is more appropriate than the Nursing Opinion #68 stated by DHEC as a rationale for banning VBAC attendance by a LM. Vaginal Birth After Cesarean, with a previous low transverse incision, should be considered low risk with assessment from the Licensed Midwife and after consultation with a physician. 400. D.2. Add: "classical" before cesarean.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
12.Heidi Johnson	400, 1200, 1300, 1500	Not Adopted. Clarification: This comment partially does not pertain to amending R.61-24 but to the internal processes of the Department.. Not Adopted. When events during intrapartum and/or postpartum move the pregnancy, birth, and/or condition of the client or neonate beyond the scope of midwifery care, the client and/or neonate are no longer considered low-risk and a transfer of care is required. Clients have the right to refuse care, treatment or services according to the laws of South Carolina. Clarification regarding Perinatal Levels of Care: This comment does not pertain to R.61-24. Perinatal levels of care are regulated within R.61-16. Not Adopted. Misoprostol is not approved by the U.S. Food and Drug Administration for postpartum hemorrhaging. Any such use is considered an off-label use. This medication is also used in combination with another drug to end a pregnancy. The medication may also be used for induction of cervical softening and dilation in labor. The main problems cited for the medication are hyperstimulation, uterine rupture, and placental abruption. Oxytocin alone is the recommended uterotonic drug for the treatment of postpartum hemorrhage. Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives.
1) DHEC again did not accept the advice of the Midwifery Advisory Council (MAC). Additionally, the regulation would reduce the authority of MAC to almost nothing. It is clear from the continued errors in LM proposed regs by DHEC that they desperately need a MAC and they need to adhere to MAC recommendations. 2) The requirements for consultation with a physician in the new regs are extreme and would reduce access to community birth and inhibit the profession of Licensed Midwifery. 3) Requiring a midwife to call 911 as a means of transfer of care if a mother chooses to decline the		

recommendations of a physician or midwife is not only an infringement upon patient rights, but is a deliberate disparity mandated by a government agency. Licensed Midwives should be listed as a maternity provider within the Perinatal Levels of Care and the families using a midwife should be given the same access to the emergency system as every other maternity provider in SC (physicians, smaller hospitals, college and prisons infirmaries have access to this Perinatal Level of Care transfer system).
4) Misoprostol needs to be incorporated as an emergency measure. It is a safe and effective medication for postpartum hemorrhage.
5) VBAC should not be banned. A 2006 memo is outdated and not incorporated into the 2013 LM regulation. There have been no major issues with VBAC attendance and certain mothers should be considered low risk, especially since LMs are already required to get a second opinion from a physician. This physician opinion is more appropriate than the Nursing Opinion stated by DHEC as a rationale for banning VBAC attendance by a LM.

NAME	SECTION	DEPARTMENT RESPONSE
13.Sarah Cain	1300, 1500, 1800	Not Adopted. Not Adopted. (regarding the midwife advisory council) S.C. 44-1-60 lays out the process for appeals related to Department decisions . Per SC Code 44-1-140 the Department may promulgate and enforce rules and regulations for public health. The South Carolina Department of Health and Environmental Control ("DHEC" or "Department") develops regulations in accordance with the South Carolina Administrative Procedures Act ("APA"), S.C. Code Section 1-23-10 et seq. Regulation Development actions include promulgating new regulations, amending existing regulations, and repealing existing regulations. Not Adopted. Requiring a Physical Examination rather than a Medical Consultation is consistent with other regulations. Not Adopted. When events during intrapartum and/or postpartum move the pregnancy, birth, and/or condition of the client or neonate beyond the scope of midwifery care, the client and/or neonate are no longer considered low-risk and a transfer of care is required. Clients have the right to refuse care, treatment or services according to the laws of South Carolina. Clarification regarding Perinatal Levels of Care: This comment does not pertain to R.61-24. Perinatal levels of care are regulated within R.61-16.

Hello,

I have many concerns regarding many of the changes being recommended on the proposed changes for regulations for licensed midwives. Below are a list of the sections of the changes I am not in favor of and the recommendations I personally have for each.

Reference Section 1800. There should be no change to the current definition of Midwifery Advisory Council.

The title of the Section 1100 MUST be changed from Physical Examination to Client Medical Consultation with no written, signed documentation required by regulation- documentation in the chart is sufficient.

In Section 1300, the requirement for Client's signature for a midwife consulting with a medical provider must be removed. There is no need for more regulation or overseeing in the midwifery field. They are plenty qualified to do what they do and do need a medical provider overseeing them.

Requiring a midwife to call 911 as a means of transfer of care if a mother chooses to decline the recommendations of a physician or midwife is not only an infringement upon patient rights, but is a deliberate disparity mandated by a government agency.
Licensed Midwives should be listed as a maternity provider within the Perinatal Levels of Care and the families using a midwife should be given the same access to the emergency system as every other maternity provider in SC (physicians, smaller hospitals, college and prisons infirmaries have access to this Perinatal Level of Care transfer system). Reference Section 1500
Remove "by dialing 911."

Section 1300: Misoprostol needs to be incorporated as an emergency measure. It is a safe, very inexpensive and effective medication for postpartum hemorrhage, though Licensed Midwives received a memo a few years back stating that they cannot administer this life-saving medication that is on every obstetric crash cart in the world. If an Authorized Medical Provider has written a prescription for use of this medication in the case of postpartum hemorrhage, the midwife must be able to use this without fear of working outside of her regulations. Including this non-evidence based memo in the proposed regulations essentially states that the Department is fine with mothers bleeding out in their homes. This is a dangerous and very troublesome addition to the proposal.
US Department of Health and Human Services/ National Institutes of Health on a study regarding the use of misoprostol: "Off-label use of approved medications is supported by the FDA as long as it is based on sound medical evidence. Researchers and providers must continue to work to further refine the indications for misoprostol in many areas. However, several indications are already supported by high-quality evidence. Given its low cost and ease of use, misoprostol has the potential to improve women's health worldwide."

Section 400: VBAC should not be banned. A 2006 memo is outdated and was not incorporated into the 2013 LM regulation. There have been no major issues with VBAC attendance and certain mothers should be considered low risk, especially since LMs are already required to get a second opinion from a physician in accordance with the current regulations. This physician opinion is more appropriate than the Nursing Opinion #68 stated by DHEC as a rationale for banning VBAC attendance by a LM.
Vaginal Birth After Cesarean, with a previous low transverse incision, should be considered low risk with assessment from the Licensed Midwife and after consultation with a physician.
400. D.2. Add: "classical" before cesarean.

Thank you for considering my concerns to these regulations.

Dr. Sarah Cain

NAME	SECTION	DEPARTMENT RESPONSE
14.Hannah Staley Smith	400, 1100	Not Adopted. Not Adopted. S.C. 44-89-60(4) requires that a physician make a written determination that the planned birth is low risk. Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives.
Here's a sample-		

Letter suggestion #3- Please personalize where ever possible:

South Carolina midwives, health department, and legislators worked together in the 1970's to develop a set of midwifery regulations that were the basis of excellent homebirth regulations in states across the nation. SC was cutting edge!

These regulations evolved over subsequent decades in mostly positive ways, but in the past 15 years, the health department has turned away from the wisdom of the midwives to rely on advice from professionals who have never even attended an out-of-hospital birth of any kind, or even worked in close conjunction with families who prefer to deliver their babies at home or birth center.

Physicians must NOT have veto power over homebirths. While their input is often important and helpful, they cannot be given the final word on where a woman gives birth.

Further more, VBAC moms deserve the same informed choice as any other moms. The majority of states where midwifery is legal clearly recognize this- why don't we?

I know that I don't know enough to give advice on every line of the 2020 proposed midwifery regulations- but I know that the current Licensed Midwives do, and the fact that they are being ignored on crucial aspects of these regulations is disturbing on many levels.

The proposed regulations as they now stand are insufficient and should be rewritten prior to submission for legislative review.

NAME	SECTION	DEPARTMENT RESPONSE
15.Jennifer Kitchton, CPM, LM	400, 1200, 1500, 1800	Not Adopted. Not Adopted. Misoprostol is not approved by the U.S. Food and Drug Administration for postpartum hemorrhaging. Any such use is considered an off-label use. This medication is also used in combination with another drug to end a pregnancy. The medication may also be used for induction of cervical softening and dilation in labor. The main problems cited for the medication are hyperstimulation, uterine rupture, and placental abruption. Oxytocin alone is the recommended uterotonic drug for the treatment of postpartum hemorrhage. Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives. Not Adopted. When events during intrapartum and/or postpartum move the pregnancy, birth, and/or condition of the client or neonate beyond the scope of midwifery care, the client and/or neonate are no longer considered low-risk and a transfer of care is required. Clients have the right to refuse care, treatment or services according to the laws of South Carolina. Not Adopted. (regarding the midwife advisory council) S.C. 44-1-60 lays out the process for appeals related to Department decisions . Per SC Code 44-1-140 the Department may promulgate and enforce rules and regulations for public health. The South Carolina Department of Health and Environmental Control ("DHEC" or "Department") develops regulations in

		accordance with the South Carolina Administrative Procedures Act ("APA"), S.C. Code Section 1-23-10 et seq. Regulation Development actions include promulgating new regulations, amending existing regulations, and repealing existing regulations.
Although I am happy with many of the regulation changes and updates I am seeing, I am still concerned about a few things. 1. I think that misoprostal needs to be added as an emergency measure for hemorrhage. It is inexpensive for mothers, easy to administer without requiring a needle, and a safe and effective medicine for postpartum hemorrhage. 2. I strongly believe that VBAC's should be allowed, especially if the mother is deemed low-risk by an overseeing physician. 3. Requiring us to call 911 as a means of transfer of care if the mother chooses to decline the recommendations of a physician or midwife is an infringement to their rights. They should also be given the option of transfering via their own car or vehicle if they choose and if the reason for transport is for maternal exhaustion or some other non-emergency situation. 4. The Midwifery Advisory Council (MAC) should be a part of the proposed regulations and recommendations.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
16.Lerren Lazo	n/a	Acknowledged. Clarification regarding Perinatal Levels of Care: This comment does not pertain to R.61-24. Perinatal levels of care are regulated within R.61-16.
Thank you for considering these comments. It is my understanding that DHEC is attempting to add new regulations and restrictions to the profession of Midwifery. I do not agree with these new rules and believe they infringe upon maternal rights to have proper access to the medical care that pregnant mothers desire. I ask that DHEC refrain from adding and amending these regulations.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
17.Leandra Cail Licensed Midwife Apprentice	1800	Not Adopted. S.C. 44-1-60 lays out the process for appeals related to Department decisions . Per SC Code 44-1-140 the Department may promulgate and enforce rules and regulations for public health. The South Carolina Department of Health and Environmental Control ("DHEC" or "Department") develops regulations in accordance with the South Carolina Administrative Procedures Act ("APA"), S.C. Code Section 1-23-10 et seq. Regulation Development actions include promulgating new regulations, amending existing regulations, and repealing existing regulations.
In section 1800 there should be no change to the current definition of Midwife Advisory Council.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
18.Joseph Cail Consumer	1800	Not Adopted. S.C. 44-1-60 lays out the process for appeals related to Department decisions . Per SC Code 44-1-140 the Department may promulgate and enforce rules and regulations for public health. The South Carolina Department of Health and Environmental Control ("DHEC" or "Department") develops

		regulations in accordance with the South Carolina Administrative Procedures Act ("APA"), S.C. Code Section 1-23-10 et seq. Regulation Development actions include promulgating new regulations, amending existing regulations, and repealing existing regulations.
In section 1800 there should be no change to the current definition of Midwife Advisory Council.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
19.Leandra Cail Licensed Midwife Apprentice	1100, 1300	Not Adopted. Not Adopted. Requiring a Physical Examination rather than a Medical Consultation is consistent with other regulations. Not Adopted. (regarding the Physician's signature). S.C. Code 44-89-60(4) requires a physician to make a written determination that the planned birth is low risk. The requirement for signatures for verification are consistent with other Department regulations.
In Section 1100, please change the title from Physical Examination to Client Medical Consultation. This visit should not require written and signed documentation by the physician to qualify as one of the required visits - simply documenting in the chart should be sufficient.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
20. Joseph Cail Consumer	1100, 1300	Not Adopted. Not Adopted. Requiring a Physical Examination rather than a Medical Consultation is consistent with other regulations. Not Adopted. (regarding the Physician's signature). S.C. Code 44-89-60(4) requires a physician to make a written determination that the planned birth is low risk. The requirement for signatures for verification are consistent with other Department regulations.
In Section 1100, please change the title from Physical Examination to Client Medical Consultation. This visit should not require written and signed documentation by the physician to qualify as one of the required visits - simply documenting in the chart should be sufficient.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
21.Leandra Cail Licensed Midwife Apprentice	1100	Not Adopted. S.C. Code 44-89-60(4) requires a physician to make a written determination that the planned birth is low risk. The requirement for signatures for verification are consistent with other Department regulations.
In Section 1300, the requirement for Client's signature for a midwife consulting with a medical provider must be removed.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
22.Joseph Cail Consumer	1100	Not Adopted. S.C. Code 44-89-60(4) requires a physician to make a written determination that the planned birth is low risk. The requirement for signatures for verification are consistent with other Department regulations.

In Section 1300, the requirement for Client's signature for a midwife consulting with a medical provider must be removed.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
23.Leandra Cail Licensed Midwife Apprentice	n/a	Acknowledged. Clarification regarding Perinatal Levels of Care: This comment does not pertain to R.61-24. Perinatal levels of care are regulated within R.61-16.
In Section 1500, Licensed Midwives should be listed as a maternity provider within the Perinatal Levels of Care. The families using a midwife should be given the same access to the emergency system as every other maternity provider in SC. Denying this emergency access is a huge oversight of DHEC and could result in potentially life-threatening situations for SC mothers and babies. ALL mothers need to have this access.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
24.Leandra Cail Licensed Midwife Apprentice	1500	Not Adopted. When events during intrapartum and/or postpartum move the pregnancy, birth, and/or condition of the client or neonate beyond the scope of midwifery care, the client and/or neonate are no longer considered low-risk and a transfer of care is required. Clients have the right to refuse care, treatment or services according to the laws of South Carolina.
In Section 1500, please remove the phrase "by dialing 911"		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
25.Joseph CailConsumer	n/a	Acknowledged.Clarification regarding Perinatal Levels of Care: This comment does not pertain to R.61-24. Perinatal levels of care are regulated within R.61-16.
In Section 1500 - licensed midwives should be listed as a maternity provider within the Perinatal Levels of Care and the families using a midwife should be given the same access to the emergency system as every other maternity provider in SC. Remove "by dialing 911"		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
26.Leandra Cail Licensed Midwife Apprentice	1200	Not Adopted. Misoprostol is not approved by the U.S. Food and Drug Administration for postpartum hemorrhaging. Any such use is considered an off-label use. This medication is also used in combination with another drug to end a pregnancy. The medication may also be used for induction of cervical softening and dilation in labor. The main problems cited for the medication are hyperstimulation, uterine rupture, and placental abruption. Oxytocin alone is the recommended uterotonic drug for the treatment of postpartum hemorrhage.
Section 1300 - Misoprostol needs to be included as a medication that midwives can give in emergency situations. While its use is off-label, the US Department of Health and Human Services/ National Institutes of Health said the following regarding the off-label use of misoprostol: "Off-label use of approved medications is supported by the FDA as long as it is based on sound medical evidence...		

several indications are already supported by high-quality evidence. Given its low cost and ease of use, misoprostol has the potential to improve women's health worldwide." If DHEC does not allow licensed midwives to administer this potentially life-saving drug, they are acting irresponsibly. Think of the lives and health of all SC mothers.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
27.Joseph Cail Consumer	1200	Not Adopted. Misoprostol is not approved by the U.S. Food and Drug Administration for postpartum hemorrhaging. Any such use is considered an off-label use. This medication is also used in combination with another drug to end a pregnancy. The medication may also be used for induction of cervical softening and dilation in labor. The main problems cited for the medication are hyperstimulation, uterine rupture, and placental abruption. Oxytocin alone is the recommended uterotonic drug for the treatment of postpartum hemorrhage.
Section 1300 - misoprostol needs to be incorporated as an emergency measure		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
28.Leandra Cail Licensed Midwife Apprentice	400	Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives.
Section 400 - VBAC should not be banned. Banning all VBACs from Licensed Midwives is an infringement on mothers' rights to make an informed decision regarding their health care. Vaginal Birth After Cesarean, with a previous low transverse incision, should be considered low risk with assessment from the Licensed Midwife and after consultation with a physician.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
29.Leandra Cail Licensed Midwife Apprentice	400	Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives.
Section 400. D.2. Add: "classical" before cesarean.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
30.Joseph Cail Consumer	400	Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives.
Section 400 - Vaginal Birth After Cesarean, with a previous low transverse incision, should be considered low risk with assessment from the Licensed Midwife and after consultation with a physician. 400. D.2. Add: "classical" before cesarean.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
31.Vanessa Cangialosi, CPM, LM, LMT	1300, 1500	Partially Adopted. Partially Adopted. Various Sections. PALM's comments were

		reviewed throughout the revision process and partially adopted. Clarification: A hospital is not allowed to turn away a patient at the ER. Partially Adopted. Section 1300. (regarding medical consultations and referrals). Any condition that requires consultation is considered to move the client beyond a low-risk pregnancy determination. The client has the right to consent to care that may possibly return her to a low-risk determination or to refuse the care.
As a practicing midwife, I have some serious concerns about the regulation revisions as written. Concerning specific sections of the revisions, please kindly reference all of the Palmetto Association of Licensed Midwives (PALM) position statements. This comment deals more with the general concept of the right of a woman to choose where and with whom she chooses to birth her baby. In the area that I practice, many of my clients have been denied care due to their choice to work with a SC Licensed Midwife/Certified Professional Midwife. They have to seek their two required visits with consulting care providers up to 2 hours away. When, on very limited occasions, I have had to transfer a client to care in the hospital setting, I have been threatened by medical providers. I have been told that I am not allowed to transfer a client to a specific hospital. This kind of statement to me is in direct violation of federal EMTALA laws. I also had a medical provider threaten to have me "shut down" for an appropriate transfer but this provider just does not believe that there are or should be home births happening in her community. These providers have made it clear that they do not believe in shared decision making with a pregnant client. This is why the language of the revisions is so crucial. The practice of midwifery needs to be safe, but it also needs to be protected from those who are threatened by something they personally would not choose to do. I have a very good reputation with my clients and the care providers I consult with for being a safe and compassionate care provider. I am serving a community that has been refused the kind of quality care they deserve. In my area, many families have chosen to birth unassisted due to the limited choices available. These limitations have been due to resistance to change practice guidelines to come in line with evidence based practices. Birthing people are very aware of valid, evidence based practices and when they are denied those choices that can make their pregnancy and birth healthier and more in line with their wishes, they look elsewhere. The bottom line is, the regulation revisions still contain areas that are NOT based on evidence of what is safest practice nor will they allow me to practice within my full scope. The recommendations of the Midwife Advisory Council (MAC) have NOT been taken into consideration to the proper degree. The pleas of the midwives and consumers in the state to make these revisions AFTER a global pandemic have fallen on deaf ears. This is a time when our services are more crucial than ever. This is not the time to push a revision through just because it is time for it to happen. This should only move forward if it will improve things for the community we serve. The revisions as written have great potential to hamper any progress intended. Please do not continue to ignore our concerns. Lives depend on it.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
32.Bossert Madison	n/a	Acknowledged.
I have had three home births and four hospital births prior to choosing home. I can say with full confidence that I received better care in home before and after delivery.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
33.Stephanie Odell	1100	Not Adopted. S.C. 44-89-60(4) requires that a physician make a written determination that the planned birth is low risk.

As a mother and grandmother I have had the beautiful experience of being part of my daughters home birth with a midwife who had the opportunity to grow a relationship with my daughter and who family. After reading the public forms of the DHEC I feel their thoughts and concerns are more turning back time where the mothers to be have decisions being made for them instead of supporting and giving them knowledge and power. In reference directly to forcing a mother to drive up to two hours away for a visit with someone who doesn't know her and or won't have the time to get to know give support a mother needs to encourage her birthing power.

Women have been taught to not listen to our bodies but to follow a doctors order during a time where our bodies know best and forcing mothers to seek medical care and not empower them is wrong. When a relationship between a mother and midwife is developed the birth is filled with power and if the midwife feels there is a need for a doctor to be involved the mother as no fear of being not heard because of the trust and bond she has built. However; making them see a doctor is ridiculous you are removing their ability to choose, to be free thinking, and removing their power. All over insurance coverage.

The new recommendations should be tabled for the time being and you should be listening to you community on what would better it. With the fear that is comes pandemic don't you think that staying home and having midwives come to a mother to be is safer then forcing them to travel to a doctors office? I feel it is important to listen to the midwives, mothers, and family members who truly have a voice. No person should be denied the medical choices. Take the time to look at the facts based on safest practices and allow midwives to give the proper care, build trust, and allow them the practice with using the full scope in their education. I know for a fact if my daughter had to be forced through a practice of doctors her care would not have been so complete during this time.

NAME	SECTION	DEPARTMENT RESPONSE
34.Tiffany Cartino	1100	Partially Adopted. Clarification: This comment partially does not pertain to amending R.61-24 but to the internal processes of the Department. Partially Adopted. Various Sections. PALM's comments were reviewed throughout the revision process and partially adopted. Not Adopted. S.C. 44-89-60(4) requires that a physician make a written determination that the planned birth is low risk.

Concerning specific sections of the revisions, please kindly reference all of the Palmetto Association of Licensed Midwives (PALM) position statements. This comment deals more with the general concept of the right of a woman to choose where and with whom she chooses to birth her baby. They have to seek their two required visits with consulting care providers up to 2 hours away. These providers have made it clear that they do not believe in shared decision making with a pregnant client. This is why the language of the revisions is so crucial. The practice of midwifery needs to be safe. In my area, many families have chosen to birth unassisted due to the limited choices available. These limitations have been due to resistance to change practice guidelines to come in line with evidence based practices. Birthing people are very aware of valid, evidence based practices and when they are denied those choices that can make their pregnancy and birth healthier and more in line with their wishes, they look elsewhere.

The bottom line is, the regulation revisions still contain areas that are NOT based on evidence of what is safest practice nor will they allow me to practice within my full scope. The recommendations of the Midwife Advisory Council (MAC) have NOT been taken into consideration to the proper degree. The pleas of the midwives and consumers in the state to make these revisions AFTER a global pandemic have fallen on deaf ears. This is a time when our services are more crucial than ever. This is not the time

to push a revision through just because it is time for it to happen. This should only move forward if it will improve things for the community we serve. The revisions as written have great potential to hamper any progress intended. Please do not continue to ignore our concerns. Lives depend on it.

Instead we need to expand our midwives in our area to serve more of the State. Not create further restrictions on these safe practices. Please seek data in states where birthing centers and home births are higher. It is riskier and inhumane to have medical facilities decline services where it is needed in such rare birthing cases.

NAME	SECTION	DEPARTMENT RESPONSE
35.Jessica Harden	400, 1200, 1300, 1500, 1800	Not Adopted. Not Adopted. (regarding the midwife advisory council) S.C. 44-1-60 lays out the process for appeals related to Department decisions . Per SC Code 44-1-140 the Department may promulgate and enforce rules and regulations for public health. The South Carolina Department of Health and Environmental Control ("DHEC" or "Department") develops regulations in accordance with the South Carolina Administrative Procedures Act ("APA"), S.C. Code Section 1-23-10 et seq. Regulation Development actions include promulgating new regulations, amending existing regulations, and repealing existing regulations. Not Adopted. Requiring a Physical Examination rather than a Medical Consultation is consistent with other regulations. Not Adopted. When events during intrapartum and/or postpartum move the pregnancy, birth, and/or condition of the client or neonate beyond the scope of midwifery care, the client and/or neonate are no longer considered low-risk and a transfer of care is required. Clients have the right to refuse care, treatment or services according to the laws of South Carolina. Not Adopted. Misoprostol is not approved by the U.S. Food and Drug Administration for postpartum hemorrhaging. Any such use is considered an off-label use. This medication is also used in combination with another drug to end a pregnancy. The medication may also be used for induction of cervical softening and dilation in labor. The main problems cited for the medication are hyperstimulation, uterine rupture, and placental abruption. Oxytocin alone is the recommended uterotonic drug for the treatment of postpartum hemorrhage. Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives.

As a healthcare professional and a recent mom that had a homebirth, I am writing to speak against some of the recent proposed changes.

1. Section 1800. There should be no change to the current definition of Midwifery Advisory Council.
2. The requirements for consultation with a physician in the new regulations are extreme and would reduce access to community birth and inhibit the profession of Licensed Midwifery. The title of the Section 1100 MUST be changed from Physical Examination to Client Medical Consultation with no written, signed documentation required by regulation- documentation in the chart is sufficient. In

Section 1300, the requirement for Client's signature for a midwife consulting with a medical provider must be removed. Midwives are more than clinically competent to serve pregnant women and take appropriate notes for their examinations. Midwives have the appropriate training to refer out to an OB if examination reveal any red flag or complications.
3. Requiring a midwife to call 911 as a means of transfer of care if a mother chooses to decline the recommendations of a physician or midwife is not only an infringement upon patient rights, but is a deliberate disparity mandated by a government agency. Licensed Midwives should be listed as a maternity provider within the Perinatal Levels of Care and the families using a midwife should be given the same access to the emergency system as every other maternity provider in SC (physicians, smaller hospitals, college and prisons infirmaries have access to this Perinatal Level of Care transfer system). Reference Section 1500. I suggest removing "by dialing 911."
4. Section 1300: Misoprostol needs to be incorporated as an emergency measure. It is a safe, very inexpensive and effective medication for postpartum hemorrhage, though Licensed Midwives received a memo a few years back stating that they cannot administer this life-saving medication that is on every obstetric crash cart in the world. If an Authorized Medical Provider has written a prescription for use of this medication in the case of postpartum hemorrhage, the midwife must be able to use this without fear of working outside of her regulations. Including this non-evidence based memo in the proposed regulations essentially states that the Department is fine with mothers bleeding out in their homes. This is a dangerous and very troublesome addition to the proposal.

US Department of Health and Human Services/ National Institutes of Health on a study regarding the use of misoprostol: "Off-label use of approved medications is supported by the FDA as long as it is based on sound medical evidence. Researchers and providers must continue to work to further refine the indications for misoprostol in many areas. However, several indications are already supported by high-quality evidence. Given its low cost and ease of use, misoprostol has the potential to improve women's health worldwide." Please incorporate Misoprostol into the emergency measures, and retract the memo.

5.Section 400: VBAC should not be banned. A 2006 memo is outdated and was not incorporated into the 2013 LM regulation. There have been no major issues with VBAC attendance and certain mothers should be considered low risk, especially since LMs are already required to get a second opinion from a physician in accordance with the current regulations. This physician opinion is more appropriate than the Nursing Opinion #68 stated by DHEC as a rationale for banning VBAC attendance by a LM.

Vaginal Birth After Cesarean, with a previous low transverse incision, should be considered low risk with assessment from the Licensed Midwife and after consultation with a physician.
400. D.2. Add: "classical" before cesarean.

As a health professional I have cared for HUNDREDS of pregnant women, and have many with testimonials of VBAC births. Midwives are again clinically qualified to observe and monitor births in these situations,

NAME	SECTION	DEPARTMENT RESPONSE
36.Carol Sibiski	n/a	Acknowledged.

My daughter and son-in-law sought the care of a mid-wife when the COVID19 pandemic restrictions at hospitals began. The home birth was a wonderful experience and we felt completely at ease and confident in her care. The birth of my first grandchild in the hospital was in no way comparable to the beautiful birth that they experienced at home. I hope that DHEC will allow midwives to continue the same care that they now provide for their patients.

NAME	SECTION	DEPARTMENT RESPONSE

37.Janelle Sealy	1800	Not Adopted. S.C. 44-1-60 lays out the process for appeals related to Department decisions . Per SC Code 44-1-140 the Department may promulgate and enforce rules and regulations for public health. The South Carolina Department of Health and Environmental Control ("DHEC" or "Department") develops regulations in accordance with the South Carolina Administrative Procedures Act ("APA"), S.C. Code Section 1-23-10 et seq. Regulation Development actions include promulgating new regulations, amending existing regulations, and repealing existing regulations.
NPR_61-24 Section 1800 concerns me, as there should be no change to the current definition of the Midwifery Advisory Council. Based on the continued errors in the LM proposed regs by DHEC, it is clear you need to keep a MAC, and follow their professional, educated recommendations.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
38.Janelle Sealy	1100, 1300	Not Adopted. Clarification: The proposed regulation does not require clients to meet regularly with a Physician Not Adopted. Requiring a Physical Examination rather than a Medical Consultation is consistent with other regulations. Not Adopted. The requirement for client signature is consistent with other Department regulations.
NPR Regulation 61-24 Section 1100 is extreme and ridiculous. By requiring expected mothers to meet regularly with a physician is unnecessary, superfluous, and demeans the Midwifery profession. This will also reduce access to community birth and inhibit the profession of Licensed Midwifery as a whole. * The title of the Section 1100 MUST be changed from Physical Examination to Client Medical Consultation with no written, signed documentation required by regulation.... the documentation in the chart is sufficient. AND *In Section 1300, the requirement for Client's signature for a midwife consulting with a medical provider must be removed.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
39.Janelle Sealy	1500	Not Adopted. When events during intrapartum and/or postpartum move the pregnancy, birth, and/or condition of the client or neonate beyond the scope of midwifery care, the client and/or neonate are no longer considered low-risk and a transfer of care is required. Clients have the right to refuse care, treatment or services according to the laws of South Carolina.
NPR 61-24 Section 1500 needs to remove "by dialing 911". Licensed midwifes should be listed as a maternity provider within the Perinatal Levels of Care and the families using a midwife should be given the same access to the emergency system as every other maternity provider in SC. By requiring a midwife to call 911 as a means of transfer of care if a mother chooses to decline the recommendations of		

a physician or midwife is not only an infringement upon patient rights, but is a deliberate disparity mandated by a government agency.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
40.Janelle Sealy	1200	Not Adopted. Misoprostol is not approved by the U.S. Food and Drug Administration for postpartum hemorrhaging. Any such use is considered an off-label use. This medication is also used in combination with another drug to end a pregnancy. The medication may also be used for induction of cervical softening and dilation in labor. The main problems cited for the medication are hyperstimulation, uterine rupture, and placental abruption. Oxytocin alone is the recommended uterotonic drug for the treatment of postpartum hemorrhage.
NPR 61-24 Section 1300 needs to allow for Licensed Midwifes to continue with permission to use Misoprostol as an emergency measure. This medicine is on EVERY OBSTETRIC CRASH CART IN THE WORLD!!! It is safe, inexpensive and effective, and is easy to administer and can SAVE LIVES in the case of a postpartum hemorrhage. If an Authorized Medical Provider has written a prescription for use of this medication in the case of postpartum hemorrhage, the midwife must be able to use this without fear of working outside of her regulations. WHY ARE YOU OK WITH LETTING MOTHERS POTENTIALLY BLEED OUT IN THEIR HOMES?!?!?!?!?		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
41.Janelle Sealy	400	Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives.
NPR 61-24 Section 400 is ridiculous; VBAC should not be banned. Vaginal Birth After Cesarean, with a previous low transverse incision, should be considered low risk with assessment from the Licensed Midwife and after consultation with a physician. There have been no major issues with VBAC attendance and certain mothers should be considered low risk, especially since LMs are already required to get a second opinion from a physician in accordance with the current regulations. *In Section 400 D.2 you need to add "Classical" before Cesarean.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
42.Carly West Midwife client-mother	n/a	Acknowledged.
I oppose the regulations that are in progress of being placed in midwifery. I recently had a homebirth during the worst of covid in the Myrtle Beach area and I wouldn't change that decision. I kept my healthy family home without going to the hospital with people facing those who were sick in a pandemic. My first birth in the hospital was rather traumatic along with the actions that were taken that could of been prevented. This time when I chose homebirth I was confident and had complete faith my midwife was doing whatever she could to give me a safe and successful delivery. I trusted that she knew exactly what circumstances to take in any situation even if something took a turn and we needed more medical assistance (which we did not because it was such a smooth process!). The prenatal, delivery and postpartum care was remarkable. Although, I understand this situation may not be fit for all, I believe this should remain an option for all women until deemed unfit for health concerns. Homebirth should not be considered unnatural or problematic but much more a normal choice of healthcare. This is why I oppose these new regulations because it is only creating another stipulation to make things harder for		

midwives to provide adequate care for their clients. Please consider and understand from a mother who has delivered safe at home.

NAME	SECTION	DEPARTMENT RESPONSE
43.Mitchell West	n/a	Acknowledged.

My wife and I had a hospital birth for our first daughter and seemed to be going the same route with our second. When covid-19 struck our area, we made a decision to switch over to the care of the midwife who birthed our daughter this past July and it was the best decision we have made for our children. Without a doubt will be returning to our midwife for more pregnancies if we chose to have more children. Not only was she educated, informative, and professional. But friendly, kind, compassionate, honest, and true to what we wanted to do. The regulations that are trying to be enforced upon these angels of life are unfair and honestly not ethical. I without a doubt oppose these regulations and hope that DHEC can grow and mature to seeing pregnancy is not a disease or disability. It is a normal and nature process of life, and we as a community need to start accepting it as such.

NAME	SECTION	DEPARTMENT RESPONSE
44.Caitlin Owens	n/a	Clarification. A hospital is not allowed to turn away a patient at the ER.

As a first time mother who gave birth at home with a licensed Midwife, I feel that the regulation revisions were not created with the best interest of pregnant families. I'm writing this from my own experience and keeping other families like my own in mind.

In the beginning of my pregnancy I was a patient at two different OBGYN offices. I felt like neither took my concerns or wishes seriously. Just think, this is a first time mother bringing HER new baby into the world. Shouldn't her concerns be noted, listened to and taken into consideration? I was worried for what the birth was going to be like for myself and my baby. Every visit I became more and more nervous about giving birth with a provider who made it clear that they had other plans as to what was going to happen during the birth of my baby.

Fast forward to my third trimester, while COVID 19 had just been deemed a pandemic, I decided that through my own research a licensed Midwife may listen to the concerns that the Doctors had ignored through all visits. Also one that practices evidence based birth practices, which I so longed to have for my own birth.

I met with my local licensed midwife and she listened to my wishes, concerns and treated me with the respect I had been longing for. She also advised me on different scenarios whether they be good or bad. The compassion I was given by the licensed midwife was above and beyond what I had received before from Doctors. I knew immediately that I wanted her to deliver my baby and if our family expands, then without a doubt I would have a Midwife every time.

Thankfully, I gave birth with no scares or emergencies. If I had an emergency, we were prepared to drive to my nearest hospital. What would have happened to me or my baby if we were denied care? This is very scary. Is this morally acceptable by hospitals and Doctors?
I ask that you reconsider the the revisions and to listen to the Midwife Advisory Council. It would be unimaginable to be turned away from a hospital in a deadly situation.

NAME	SECTION	DEPARTMENT RESPONSE
45.Jennifer Helms	n/a	Acknowledged.

Changes to regulations on Licensed Midwives should not be made during a pandemic.

NAME	SECTION	DEPARTMENT RESPONSE
46.Jennifer Helms	n/a	Acknowledged.
These regulations fail to give adequate consideration for the recommendations of the midwifery advisory Council. In so doing, a growing population of healthy individuals are being compromised in their freedoms in pregnancy and birth. Taking away freedom can only increase the risks in out of hospital births and in transfers when they become necessary. It is better to fully equip trained professionals for success in all circumstances.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
47.Anthony DeAngelo Doctor of Chriopractic	n/a	Acknowledged.
We chose to have our child at home under the supervision of licensed midwife. She was amazing and so was our experience. 5 hours from start to finish, well below the lengthy average of medically invasive births. I plead with you to allow us as parents to chose the way we bring our children into the world. These policies are becoming to intrusive to the rights of parents choosing the way they want to experience the birth of their children. It's our experience, not anyone else's. DHEC should not be steering parents to have births the way they think we should. Please consider this voice as one for all the parents who have had the joy of experiencing birth like it's supposed to be, in the comfort of our own homes on our terms. Thank you.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
48.Cathy DeAngelo	n/a	Acknowledged
I want to keep my midwife! I have already had one homebirth that went amazing and would like to have more. Please listen to the Midwife Advisory Councils recommendations! Lives depend on you to listen to them! This is VERY important. Thank you!		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
49.Olga Meachum	1100, 1300, 1500, 1800	Not Adopted. Not Adopted. (regarding the midwife advisory council) S.C. 44-1-60 lays out the process for appeals related to Department decisions . Per SC Code 44-1-140 the Department may promulgate and enforce rules and regulations for public health. The South Carolina Department of Health and Environmental Control ("DHEC" or "Department") develops regulations in accordance with the South Carolina Administrative Procedures Act ("APA"), S.C. Code Section 1-23-10 et seq. Regulation Development actions include promulgating new regulations, amending existing regulations, and repealing existing regulations. Not Adopted. Requiring a Physical Examination rather than a Medical Consultation is consistent with other regulations. Not Adopted. Any condition that requires consultation may move the client beyond a low-risk pregnancy, and a consultation is required to be obtained from an physician or other authorized healthcare provider in order to possibly return the client to a low-risk pregnancy determination. Not Adopted. The requirement for client signature is consistent with other Department regulations. Not Adopted. When events during intrapartum and/or postpartum move the pregnancy, birth, and/or condition of the

		client or neonate beyond the scope of midwifery care, the client and/or neonate are no longer considered low-risk and a transfer of care is required. Clients have the right to refuse care, treatment or services according to the laws of South Carolina. Clarification regarding Perinatal Levels of Care: This comment does not pertain to R.61-24. Perinatal levels of care are regulated within R.61-16. Not Adopted. Misoprostol is not approved by the U.S. Food and Drug Administration for postpartum hemorrhaging. Any such use is considered an off-label use. This medication is also used in combination with another drug to end a pregnancy. The medication may also be used for induction of cervical softening and dilation in labor. The main problems cited for the medication are hyperstimulation, uterine rupture, and placental abruption. Oxytocin alone is the recommended uterotonic drug for the treatment of postpartum hemorrhage. Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives.

1) DHEC, again, did not accept the advice of the Midwifery Advisory Council (MAC) regarding several important updates to the regulations. Additionally, the regulation would reduce the authority of MAC to almost nothing. It is clear from the continued errors in the LM proposed regs by DHEC that they desperately need a MAC and they need to adhere to MAC recommendations.
Reference Section 1800. There should be no change to the current definition of Midwifery Advisory Council.

2) The requirements for consultation with a physician in the new regs are extreme and would reduce access to community birth and inhibit the profession of Licensed Midwifery.
The title of the Section 1100 MUST be changed from Physical Examination to Client Medical Consultation with no written, signed documentation required by regulation- documentation in the chart is sufficient.
In Section 1300, the requirement for Client's signature for a midwife consulting with a medical provider must be removed.
These sections are shouting Physician oversight of another profession- louder than the current regulations do. That is demeaning and potentially restricting the trade of Midwifery. According to the Executive Director of North American Registry of Midwives (NARM), Ida Darragh, in regards to this proposed section "...it is inappropriate to require every midwife client to see another provider." There is NO evidence that this makes for more desirable outcomes.

3) Requiring a midwife to call 911 as a means of transfer of care if a mother chooses to decline the recommendations of a physician or midwife is not only an infringement upon patient rights, but is a deliberate disparity mandated by a government agency.
Licensed Midwives should be listed as a maternity provider within the Perinatal Levels of Care and the families using a midwife should be given the same access to the emergency system as every other maternity provider in SC (physicians, smaller hospitals, college and prisons infirmaries have access to this Perinatal Level of Care transfer system). Reference Section 1500
Remove "by dialing 911."

4) Section 1300: Misoprostol needs to be incorporated as an emergency measure. It is a safe, very inexpensive and effective medication for postpartum hemorrhage, though Licensed Midwives received a memo a few years back stating that they cannot administer this life-saving medication that is on every

obstetric crash cart in the world. If an Authorized Medical Provider has written a prescription for use of this medication in the case of postpartum hemorrhage, the midwife must be able to use this without fear of working outside of her regulations. Including this non-evidence based memo in the proposed regulations essentially states that the Department is fine with mothers bleeding out in their homes. This is a dangerous and very troublesome addition to the proposal.
US Department of Health and Human Services/ National Institutes of Health on a study regarding the use of misoprostol: "Off-label use of approved medications is supported by the FDA as long as it is based on sound medical evidence. Researchers and providers must continue to work to further refine the indications for misoprostol in many areas. However, several indications are already supported by high-quality evidence. Given its low cost and ease of use, misoprostol has the potential to improve women's health worldwide."

5) Section 400: VBAC should not be banned. A 2006 memo is outdated and was not incorporated into the 2013 LM regulation. There have been no major issues with VBAC attendance and certain mothers should be considered low risk, especially since LMs are already required to get a second opinion from a physician in accordance with the current regulations. This physician opinion is more appropriate than the Nursing Opinion #68 stated by DHEC as a rationale for banning VBAC attendance by a LM.

NAME	SECTION	DEPARTMENT RESPONSE
50.Olga Meachum	400	Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives.

Vaginal Birth After Cesarean, with a previous low transverse incision, should be considered low risk with assessment from the Licensed Midwife and after consultation with a physician.
400. D.2. Add: "classical" before cesarean.

NAME	SECTION	DEPARTMENT RESPONSE
51.Mathea Arruda	n/a	Acknowledged.

I love the midwife option, my midwife Vanessa Ramey has been very instrumental in providing natural and safe advice and care throughout my pregnancy. I have received excellent care my entire pregnancy and highly recommend her and in general the midwife option. The body is an amazing machine and under proper natural care our bodies respond better and I believe it to be the better option of care during pregnancy.

NAME	SECTION	DEPARTMENT RESPONSE
52.Daniel Meachum	1100, 1300, 1500, 1800	Partially Adopted. Not Adopted. (regarding the midwife advisory council) S.C. 44-1-60 lays out the process for appeals related to Department decisions . Per SC Code 44-1-140 the Department may promulgate and enforce rules and regulations for public health. The South Carolina Department of Health and Environmental Control ("DHEC" or "Department") develops regulations in accordance with the South Carolina Administrative Procedures Act ("APA"), S.C. Code Section 1-23-10 et seq. Regulation Development actions include promulgating new regulations, amending existing regulations, and repealing existing regulations. Partially Adopted. Section 1300. (regarding medical consultations and referrals). Any condition that requires consultation is considered to move the client beyond a low-

		risk pregnancy determination. The client has the right to consent to care that may possibly return her to a low-risk determination or to refuse the care. Not Adopted. Requiring a Physical Examination rather than a Medical Consultation is consistent with other regulations. Not Adopted. When events during intrapartum and/or postpartum move the pregnancy, birth, and/or condition of the client or neonate beyond the scope of midwifery care, the client and/or neonate are no longer considered low-risk and a transfer of care is required. Clients have the right to refuse care, treatment or services according to the laws of South Carolina.

Major areas of concern:
1) DHEC, again, did not accept the advice of the Midwifery Advisory Council (MAC) regarding several important updates to the regulations. Additionally, the regulation would reduce the authority of MAC to almost nothing. It is clear from the continued errors in the LM proposed regs by DHEC that they desperately need a MAC and they need to adhere to MAC recommendations.
Reference Section 1800. There should be no change to the current definition of Midwifery Advisory Council.

2) The requirements for consultation with a physician in the new regs are extreme and would reduce access to community birth and inhibit the profession of Licensed Midwifery.
The title of the Section 1100 MUST be changed from Physical Examination to Client Medical Consultation with no written, signed documentation required by regulation- documentation in the chart is sufficient.
In Section 1300, the requirement for Client's signature for a midwife consulting with a medical provider must be removed.
These sections are shouting Physician oversight of another profession- louder than the current regulations do. That is demeaning and potentially restricting the trade of Midwifery. According to the Executive Director of North American Registry of Midwives (NARM), Ida Darragh, in regards to this proposed section "...it is inappropriate to require every midwife client to see another provider." There is NO evidence that this makes for more desirable outcomes.

3) Requiring a midwife to call 911 as a means of transfer of care if a mother chooses to decline the recommendations of a physician or midwife is not only an infringement upon patient rights, but is a deliberate disparity mandated by a government agency.
Licensed Midwives should be listed as a maternity provider within the Perinatal Levels of Care and the families using a midwife should be given the same access to the emergency system as every other maternity provider in SC (physicians, smaller hospitals, college and prisons infirmaries have access to this Perinatal Level of Care transfer system). Reference Section 1500
Remove "by dialing 911."

NAME	SECTION	DEPARTMENT RESPONSE
53.Daniel Meachum	400, 1200	Not Adopted. Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives. Not Adopted. Misoprostol is not approved by the U.S. Food and Drug Administration for postpartum hemorrhaging. Any such use is considered an off-label use. This medication is also used in combination with another drug to end a pregnancy.

		The medication may also be used for induction of cervical softening and dilation in labor. The main problems cited for the medication are hyperstimulation, uterine rupture, and placental abruption. Oxytocin alone is the recommended uterotonic drug for the treatment of postpartum hemorrhage.

4) Section 1300: Misoprostol needs to be incorporated as an emergency measure. It is a safe, very inexpensive and effective medication for postpartum hemorrhage, though Licensed Midwives received a memo a few years back stating that they cannot administer this life-saving medication that is on every obstetric crash cart in the world. If an Authorized Medical Provider has written a prescription for use of this medication in the case of postpartum hemorrhage, the midwife must be able to use this without fear of working outside of her regulations. Including this non-evidence based memo in the proposed regulations essentially states that the Department is fine with mothers bleeding out in their homes. This is a dangerous and very troublesome addition to the proposal.
US Department of Health and Human Services/ National Institutes of Health on a study regarding the use of misoprostol: "Off-label use of approved medications is supported by the FDA as long as it is based on sound medical evidence. Researchers and providers must continue to work to further refine the indications for misoprostol in many areas. However, several indications are already supported by high-quality evidence. Given its low cost and ease of use, misoprostol has the potential to improve women's health worldwide."

5) Section 400: VBAC should not be banned. A 2006 memo is outdated and was not incorporated into the 2013 LM regulation. There have been no major issues with VBAC attendance and certain mothers should be considered low risk, especially since LMs are already required to get a second opinion from a physician in accordance with the current regulations. This physician opinion is more appropriate than the Nursing Opinion #68 stated by DHEC as a rationale for banning VBAC attendance by a LM. Vaginal Birth After Cesarean, with a previous low transverse incision, should be considered low risk with assessment from the Licensed Midwife and after consultation with a physician.
400. D.2. Add: "classical" before cesarean.

NAME	SECTION	DEPARTMENT RESPONSE
54.Cassidy Staley	n/a	Acknowledged

Vanessa Ramey became my midwife when I was pregnant with my first child. I felt very cared for and well taken care of throughout my entire pregnancy. She was always there when I had any questions or concerns. When it came time to have my baby, everything was set up so comfortably and I was able to have a successful birth in our home under her care. I never felt uncomfortable with the care her and her assistant provided and was very confident they had to knowledge and tools on hand to deliver my baby properly! The postpartum care I recurved was also a 10/10. If I ever have another child I would love to have the same experience I did with Vanessa I'm doing a home birth!

NAME	SECTION	DEPARTMENT RESPONSE
55.Renee Saverance, DC	1100, 1200, 1300	Not Adopted. Not Adopted. (regarding the midwife advisory council) S.C. 44-1-60 lays out the process for appeals related to Department decisions . Per SC Code 44-1-140 the Department may promulgate and enforce rules and regulations for public health. The South Carolina Department of Health and Environmental Control ("DHEC" or "Department") develops regulations in accordance with the South Carolina Administrative Procedures Act ("APA"), S.C. Code Section 1-23-10 et seq. Regulation Development actions include promulgating new regulations,

		amending existing regulations, and repealing existing regulations. Not Adopted. Requiring a Physical Examination rather than a Medical Consultation is consistent with other regulations. signature Not Adopted. The requirement for client signature is consistent with other Department regulations. Clarification regarding Perinatal Levels of Care: This comment does not pertain to R.61-24. Perinatal levels of care are regulated within R.61-16. Not Adopted. Misoprostol is not approved by the U.S. Food and Drug Administration for postpartum hemorrhaging. Any such use is considered an off-label use. This medication is also used in combination with another drug to end a pregnancy. The medication may also be used for induction of cervical softening and dilation in labor. The main problems cited for the medication are hyperstimulation, uterine rupture, and placental abruption. Oxytocin alone is the recommended uterotonic drug for the treatment of postpartum hemorrhage.
Reference Section 1800. There should be no change to the current definition of Midwifery Advisory Council. title of the Section 1100 MUST be changed from Physical Examination to Client Medical Consultation with no written, signed documentation required by regulation Section 1300, the requirement for Client's signature for a midwife consulting with a medical provider must be removed. Licensed Midwives should be listed as a maternity provider within the Perinatal Levels of Care and the families using a midwife should be given the same access to the emergency system as every other maternity provider in SC (physicians, smaller hospitals, college and prisons infirmaries have access to this Perinatal Level of Care transfer system). Reference Section 1500 Section 1300: Misoprostol needs to be incorporated as an emergency measure.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
56.Dana Patterson	400, 1200, 1500	Partially Adopted. Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives. Not Adopted. Misoprostol is not approved by the U.S. Food and Drug Administration for postpartum hemorrhaging. Any such use is considered an off-label use. This medication is also used in combination with another drug to end a pregnancy. The medication may also be used for induction of cervical softening and dilation in labor. The main problems cited for the medication are hyperstimulation, uterine rupture, and placental abruption. Oxytocin alone is the recommended uterotonic drug for the treatment of postpartum hemorrhage. Partially Adopted. Section 1500. (regarding smooth transfers). The Department considers the regulation to adhere to best

		practice for transferring clients during emergent outcomes. Nothing prohibits the client and/or midwife from providing extra measures to ensure a smooth transfer.

I would like to encourage SCDHEC to revise three of their current regulations relating to Licensed Midwives in SC.

First, it would be beneficial for families to have the option of having a VBAC attended by a Licensed Midwife. The current cesarean rate in SC is 33.5 (with an 85% repeat cesarean rate). The WHO suggests that the cesarean rate should be 10-15% with a VBAC rate of at least 80%. VBAC is normally a safer option than a repeat cesarean, especially when a qualified Care Provider, such as a Licensed Midwife, is in attendance.

As a mother, my first VBAC was after 3 cesareans (VBA3C) and it was an unplanned home birth. It was a great experience, but I would have never planned an unassisted home birth, however, I know many mothers who have done so because they felt they had no other option. My 2VBA3C was a beautiful home birth attended by my husband, a midwife, and a doctor. It was important to me to birth legally, so having a doctor in attendance was a requirement, even though the midwife was really all I needed. I realize that this is an option that most women in SC don't have, so prohibiting midwives from attending a VBAC as the Primary Care Provider limits the options of families and can force some families to choose an option such as an unassisted birth, which isn't a safe option. With my 3VBA3C, after nearing the 42 week mark of pregnancy, I agreed with my doctor and midwife that a hospital induction would be best. I am thankful that I had options and that my wishes were respected.

Second, midwives need access to mistoprostol to treat postpartum hemorrhage. This medication is routinely used by hospitals for this very use and to prohibit midwives from using this life saving drug is unfair to families and potentially puts many mothers at risk. While the use of mistoprostol for induction can be dangerous, it is widely used in a safe manner to stop a postpartum hemorrhage. It really doesn't make sense to put mothers at risk by not allowing their midwife to use mistoprostol.

Lastly, midwives should be able to easily transfer a mother to the hospital when needed. Homebirth is a safe option in the vast majority of births, but sometimes unforeseen circumstances can arise. When this happens, it is much better for the family to have a smooth transfer to the hospital. The Licensed Midwives that I know in SC take the health of their patients seriously, and would not hesitate to initiate a transfer if needed, but that process should be able to be initiated by the midwife and streamlined to benefit the birthing family.

We owe it to our future to give the mothers of today more options for their VBAC, a safe protocol in the case of a postpartum hemorrhage, and a smooth hospital transfer if needed by their midwife.

Thank you for reviewing my comments. Please feel free to reach out if I can offer any clarification to my statements.

NAME	**SECTION**	**DEPARTMENT RESPONSE**
57.Sandy Glenn, LM, CPM	400, 1200	Not Adopted. Not Adopted. Misoprostol is not approved by the U.S. Food and Drug Administration for postpartum hemorrhaging. Any such use is considered an off-label use. This medication is also used in combination with another drug to end a pregnancy. The medication may also be used for induction of cervical softening and dilation in labor. The main problems cited for

		the medication are hyperstimulation, uterine rupture, and placental abruption. Oxytocin alone is the recommended uterotonic drug for the treatment of postpartum hemorrhage. Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives. Clarification regarding Perinatal Levels of Care: This comment does not pertain to R.61-24. Perinatal levels of care are regulated within R.61-16.
The major concerns with the proposed draft are the omission of a life-saving and safe medication used for postpartum hemorrhage and the restrictions forbidding midwives from attending certain low-risk VBAC (Vaginal Birth After Cesarean) births despite approval from their physician or approved medical provider. Additionally, despite three years of requests from the Midwifery Advisory Council (MAC) and other midwife organizations, The Department has failed to correct an error in hospital regulations 61-16 that neglects to recognize midwives and birth centers as maternity providers. This oversight does not provide equal access to families using midwives if an emergency occurs or they are in need of expanded services. Not only have midwives been working toward a legislative remedy for equal access with bills H.4966 and S.1137; but the ultimate goal should be to have a Board of Midwifery that can safely regulate the profession under South Carolina LLR. As midwife organizations work towards those oals, introducing another regulation change by DHEC is unproductive. While Licensed Midwives are currently struggling to keep up with the demands of increased clients and policy changes during the pandemic and SC State of Emergency, it is inappropriate to revise their regulations. Proposed changes during this time prejudices their ability to properly address the issues. VAGINAL BIRTH AFTER CESAREAN: In 2006, DHEC wrote a memo forbidding midwives from attending VBAC mothers. The memo contradicted the advice of the MAC and was a matter of much debate. When regulations were revised in 2013, legislators on the House 3M Committee voted against incorporating VBAC into the regulation updates. Prohibiting VBAC also contradicts another DHEC regulation 61-102 which clearly identifies VBAC as being low-risk for some women. Misoprostol/Cytotec is an effective and safe medication that saves lives if an unexpected post-delivery hemorrhage occurs. Licensed Midwives and obstetricians have used it for many years with minimal side effects. Many physicians do not feel comfortable approving a mother for a community birth (home or birth center) without making sure that the prescription is available. In 2017 DHEC wrote a position statement on misoprostol. FOIA requests revealed that DHEC did not consult their own Midwifery Advisory Council (MAC) or the full OB Task Force before creating the statement. Neither did they respond to professional midwife organizations requesting a definitive explanation of their rule and their intentions regarding enforcement. Because some other medications are specifically named in the regulation, we anticipate that the omission of misoprostol will continue to be an area of conflict in the future. Furthermore, it is inappropriate for any medication to be listed by name. As technology and supply sources change frequently, approved medications should be listed by their purpose instead of by their current name.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
58.Addie Jane Lynn Johns Island S.C. resident	400, 600	Not Adopted. Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives. Not Adopted. In South Carolina the insertion of a catheter requires a physician's order, and is only within the scope of practice for a licensed registered nurse or an authorized healthcare provider as defined in the regulation.

		Not Adopted. Records of minors should be retained until after the expiration of the period of election following achievement of majority as prescribed by statute.

Please help
Here is my comments below:

Please listen to the S.C. Certified Professional Midwives

This affects all moms, and future moms- including our daughters.

Stop the ban on home VBACs, and keep all life-saving practices available to out-of-hospital care providers..... VBAC (Vaginal Birth After Cesarean Section) absolutely should not be forbidden. The decision about where to VBAC should be between a mother and her care providers, and include full informed consent.

The other major concern is the ongoing disregard of the state midwives and the Midwifery Advisory Council's advice concerning the updating of these regulations. DHEC needs to listen to and trust SC LMs- they are the specialists in out-of-hospital birth!

There are many less major concerns including required testing for GBS, ambiguous guidelines surrounding late-to-care clients that could keep people from being able to access midwifery care, the 25 year records storage requirement, banning LM use of in/out catheters, and the fact that the public meetings for these regulations are not truly public, due to COVID.

Thanks for listening.

My best,
Addie Jane Lynn
Johns Island S.C. resident

NAME	SECTION	DEPARTMENT RESPONSE
59.Alicia Scott	400, 900, 1100	Partially Adopted. Not Adopted. Misoprostol is not approved by the U.S. Food and Drug Administration for postpartum hemorrhaging. Any such use is considered an off-label use. This medication is also used in combination with another drug to end a pregnancy. The medication may also be used for induction of cervical softening and dilation in labor. The main problems cited for the medication are hyperstimulation, uterine rupture, and placental abruption. Oxytocin alone is the recommended uterotonic drug for the treatment of postpartum hemorrhage. Not Adopted. In South Carolina the insertion of a catheter requires a physician’s order, and is only within the scope of practice for a licensed registered nurse or an authorized healthcare provider as defined in the regulation. Adopted. Sections 900 and 1200. This regulation does not prohibit televisits according to South Carolina statute. Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives.

DHEC,

While I appreciate Health Licensing taking the time and effort to update Regulation 61-24 in such a way that would allow SC Licensed Midwives to offer more that is in their scope of practice, such as suturing and IVs and neonatal Vitamin K, I am very concerned that DHEC has left that important job of properly modernizing our LM's regulations only half completed. There are some glaring omissions in full access to tools such Misoprostol, in/out catheters, and clarification concerning televisits that need to be remedied.

Furthermore, denying the choice of midwifery care to mothers wishing to have a vaginal birth after a previous cesarean section outside of the hospital setting is unacceptable. OOH VBACs are legally and safely practiced in many states and countries, and DHEC has no right to attempt to deny that choice to SC mothers and families. It is a decision that needs to be made by a mother, her family, and her care providers- not dictated by the state.

This directly affects my family, and if the choice to have a vaginal birth after a previous cesarean section is denied in SC, and if the glaring omissions in this regulation are not fixed, I plan on border jumping to either North Carolina or Georgia to have my baby. You are only making things worse in SC by denying parental choices and not fixing the things that need to be fixed.

You need to listen to and trust SC LMs, as they are the ones actually doing this job. Please stop disregarding the state midwives and the Midwifery Advisory Council's advice concerning the updating of these regulations. If you choose to go further with this, I will be attending any and all upcoming protests concerning this issue.

Thank you,

Alicia Scott

NAME	**SECTION**	**DEPARTMENT RESPONSE**
60.Savannah Messer	400	Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives.
See Attachment B.1		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
61.Angela Springer, LM, CPM	400	Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives.
See Attachment B.2		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
62.International Cesarian Awareness Network of the Central Savannah River Area	400	Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives.
See Attachment B.3		

NAME	SECTION	DEPARTMENT RESPONSE
63.Sandy Glenn, LM, CPM	300	Adopted. Section 300.

I hope this is an error. Does The Department intend to fine midwives over a million dollars? Please correct.

E. When imposing a monetary penalty, the Department may invoke South Carolina Code Section
44-1-140 to determine the dollar amount or may utilize the following schedule:
FREQUENCY CLASS I CLASS II CLASS III
1st $2001,000 $100500 $0
2nd 5002,000 2001,000 100500
3rd 1,0005,000 5002,000 2002,000
4th 5,000 1,0005,000 5002,000
5th 5,000 5,000 1,0005,000
6th 5,000 5,000 5,000

NAME	SECTION	DEPARTMENT RESPONSE
64.Sandy Glenn, LM, CPM	300	Adopted Section 300.

In compliance with 44-1-150 civil penalty not exceed one thousand dollars a day for each violation.

NAME	SECTION	DEPARTMENT RESPONSE
65.Sandy Glenn, LM, CPM	n/a	Clarification. The address, room, and admittance procedures for the public hearing are stated in the NPR. In-person public hearings are still being held; the additional option of calling in is provided for those who don't wish to attend in person, thus accommodating both preferences.

SECTION 1-23-110 Procedures for publication of notice of proposed promulgation of regulations; public participation; contest of regulation for procedural defects.

(A) Before the promulgation, amendment, or repeal of a regulation, an agency shall:

(3) give notice of a public hearing ...The notice must include: (b) the date, time, and place of the public hearing which must not be held sooner than thirty days from the date the notice is published in the State Register;

The Department has failed to adequately comply with public notice statues regarding revision of Licensed Midwife Regulation 61-24. The statute requires that the meetings have a "PLACE." Requirement for a place is clear that the meetings should be in person so that everyone would be able to attend.

A State of Emergency does not exempt DHEC from this requirement because the regulation revisions are a long-term alteration of the guidelines. These regulations revisions are not emergent in nature and should be postponed until public notice compliance can be fulfilled. Additionally, the midwives are overwhelmed by client caseloads because so many pregnant mothers do not wish to deliver in a hospital

for fear of the virus.

Not only are these publicly noticed meetings non-compliant; they are overly burdensome to the profession and impede in the safe care of women and babies.

Sandy Glenn, LM CPM MBC
Carolina Birth Center, LLC
864-329-0010

NAME	SECTION	DEPARTMENT RESPONSE
66.Sandy Glenn, LM, CPM	1800	Not Adopted. S.C. 44-1-60 lays out the process for appeals related to Department decisions . Per SC Code 44-1-140 the Department may promulgate and enforce rules and regulations for public health. The South Carolina Department of Health and Environmental Control ("DHEC" or "Department") develops regulations in accordance with the South Carolina Administrative Procedures Act ("APA"), S.C. Code Section 1-23-10 et seq. Regulation Development actions include promulgating new regulations, amending existing regulations, and repealing existing regulations.

The full authority of the Midwifery Advisory Council needs to be kept in the regulations. The council are considered the experts in the field and they should be be consulted for regulations, sanctions and appeals.
SECTION 44-1-60 Appeals from department does not restrict The Department from maintaining The MAC as previously regulated. The use of MAC prior to any appeal process better serves the community and the profession.

New Recommendation – MIDWIFERY ADVISORY COUNCIL The Department shall appoint a Midwifery Advisory Council to advise the Department regarding licensing and Inspection of Midwives.

CURRENT REGULATION:

a. The Commissioner of DHEC shall appoint a Midwifery Advisory Council which shall meet at least annually for the purpose of reviewing and advising the Department regarding matters pertaining to the training, practices, and regulation of midwives in South Carolina. The Council shall consist of three licensed midwives, one consumer of midwife care, two certified nurse-midwives, one physician active in perinatal care, and one member-at-large. Each member shall be appointed for a three-year term of office

b. The Council shall establish a committee for peer review to consult with midwives in questions of ethics, competency and performance, and to serve as an appeal committee when disciplinary action has been taken. The committee may recommend denying, suspending, or revoking a license, or may recommend specific educational objectives, apprenticeship or other improvement measures as necessary.

NAME	SECTION	DEPARTMENT RESPONSE
67.Ida Darragh Executie Director North American Registry of Midwives	400, 1100, 1200	Not Adopted. Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives.

		Not Adopted. S.C. 44-89-60(4) requires that a physician make a written determination that the planned birth is low risk. Not Adopted. (regarding the Physician's signature). S.C. Code 44-89-60(4) requires a physician to make a written determination that the planned birth is low risk. The requirement for signatures for verification are consistent with other Department regulations. Not Adopted. Misoprostol is not approved by the U.S. Food and Drug Administration for postpartum hemorrhaging. Any such use is considered an off-label use. This medication is also used in combination with another drug to end a pregnancy. The medication may also be used for induction of cervical softening and dilation in labor. The main problems cited for the medication are hyperstimulation, uterine rupture, and placental abruption. Oxytocin alone is the recommended uterotonic drug for the treatment of postpartum hemorrhage.

Thank you. I sent a brief comment through the online portal for comments earlier today, and have additional comments based on the hearing that was held this afternoon:

The North American Registry of Midwives supports the regulatory changes to midwifery licensure in South Carolina. In addition to supporting the proposed regulations, NARM states that it is within the scope of practice of Certified Professional Midwives to attend VBACs, administer a specific formulary of medications, start IVs and suture tears or episiotomies. It is also very uncommon to require midwifery clients to be seen by another health care provider during the pregnancy; there are a few states that do that but none can provide evidence of the benefits.

Additional comments by Ida Darragh, Executive Director of the North American Registry of Midwives, based on information from the hearing on 9/14/20:

The new regs require not only two physical assessments by a physician or Health Care Provider, but also require that the physician or HCP provide a written and signed statement assuring that the pregnancy is low risk. First of all, it is inappropriate to require every midwife client to see another provider. It will be impossible to get a written and signed statement verifying low risk status. An alternative that has worked in some states is to have the client obtain a copy of the physician assessment and bring it to the midwife. This is a copy of the client's chart from the physician, but is not a separate signed statement.

In regards to the prohibition against Misoprostol by LMs, the rationale is that the use for postpartum hemorrhage is off-label and cannot be allowed by DHEC. While it is true that most licensure regs in other states often just list "antihemorrhagics" in their formulary, there are eight states that specifically list Misoprostol in their regulations as permitted for use for postpartum hemorrhage: Colorado, Delaware, Kentucky, Maryland, New Mexico, Rhode Island, South Dakota, and Wyoming.

Ida Darragh
Executive Director, North American Registry of Midwives
testing@narm.org ; 501-296-9769 or 8880842-4784 #3

NAME	SECTION	DEPARTMENT RESPONSE
68.Joseph Samaha	400, 1100, 1300	Partially Adopted. Not Adopted. S.C. 44-89-60(4) requires that a physician make a written determination that the planned birth is low risk.

		Partially Adopted. Section 1300. (regarding medical consultations and referrals). Any condition that requires consultation is considered to move the client beyond a low-risk pregnancy determination. The client has the right to consent to care that may possibly return her to a low-risk determination or to refuse the care. Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives.

> DHEC-

> My name is Joseph Samaha and I am the father of a four year old and 2 year old twins. My wife had a successful home birth with our first born, and then an emergency c-section with the twins. In both cases I was pleased with the team we worked with. Having those options available and being able to have the freedom to choose was really important to us. I completely trusted our midwife and never felt as though she would not point us to the hospital if we were in danger. I think is is very important for midwifes to have the tools they need, and the authority to help moms that want to home birth, especially for moms wanting to do a VBAC. Moms having wanting a VBAC are not all at risk, and they should have the option to deliver where and when they want to.

> Thank you for your efforts to protect the health of women and children- however, many sections of the newest set of proposed midwifery regulations appear to move beyond protection into control of women and families' medical freedoms, without nearly enough practical or scientific justification.
>
> Informed consent and refusal are important in any health care setting- but the new proposed regulations include sections that seem to push beyond what are reasonable informed consent requirements. Furthermore, the new proposals do not appear to have taken the advice of the midwives- who are the experts in OOH (out of hospital) births and OOH clients- enough into account.
>
> The practice of OOH midwifery cannot be inextricably tied to physicians (or the CNMs who work under them) granting a woman permission to birth at home, as is essentially outlined in Section 1100.2.A in the new proposed regulations. First- it is a conflict of interest. Second- physician concerns about liability will make this kind of written, signed "permission" very difficult to obtain.
>
> Along the same lines, the requirements outlined Section 1300, in particular Section 1300 A, are overly onerous, and would be impossible in real life. This level of physician oversight described in those passages hinders the midwife from actually serving and helping mothers and babies. Midwives count on consultations and referrals to doctors, CNMs and hospitals, and most midwives have an ongoing relationship with at least one doctor or CNM, but the micromanagement described in Section 1300 would scare off any practitioner. The OOH-friendly providers cannot be available 24/7 and it is just too easy for a practitioner not familiar with OOH birth to insist on inappropriate and unnecessary transfers of care.
>
> This brings us to VBACs. With a proper informed consent contract- which DHEC could do an excellent job of writing, if they wished- a woman with a previous cesarean should be able to make her own choice- in conjunction with her family and care providers- about where she wants to give birth. This choice cannot and should not be dictated by the state.

> Sincerely,

> Joseph Samaha

NAME	SECTION	DEPARTMENT RESPONSE
69.Katie Samaha	n/a	Clarification. This comment partially does not pertain to amending R.61-24 but to the internal processes of the Department.

To whom it may concern,

I plan to digitally "attend" today's stakeholder meeting. However I am very bothered by the fact this meeting is not being held in person. It would be far better to wait until such time that the meeting could be held in person, as a stakeholder I would appreciate the opportunity to physically attend.

Denying the choice of midwifery care to mothers wishing to have a vaginal birth after a previous cesarean section outside of the hospital setting is unacceptable. OOH VBACs are legally and safely practiced in many states and countries, and DHEC has no right to attempt to deny that choice to SC mothers and families. It is a decision that needs to be made by a mother, her family, and her care providers- not dictated by the state.

In 2016, my first child was born by planned homebirth, attended by my licensed midwife and signed off on by my OB. In 2018, my second and third children (twins) were born by emergency c-section at 26 weeks. I am beyond grateful for the c-section that saved their lives! However it should not impact my ability to choose a homebirth again in the future, with guidance from my licensed midwife and OB.

Thank you for your consideration,

Katie Samaha

NAME	SECTION	DEPARTMENT RESPONSE
70.Katie Samaha	400, 1100, 1300	Partially Adopted. Not Adopted. S.C. 44-89-60(4) requires that a physician make a written determination that the planned birth is low risk. Not Adopted. (regarding the Physician's signature). S.C. Code 44-89-60(4) requires a physician to make a written determination that the planned birth is low risk. The requirement for signatures for verification are consistent with other Department regulations. Partially Adopted. Section 1300. (regarding medical consultations and referrals). Any condition that requires consultation is considered to move the client beyond a low-risk pregnancy determination. The client has the right to consent to care that may possibly return her to a low-risk determination or to refuse the care. Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives.

DHEC-

Thank you for your efforts to protect the health of women and children- however, many sections of the newest set of proposed midwifery regulations appear to move beyond protection into control of women and families' medical freedoms, without nearly enough practical or scientific justification.

Informed consent and refusal are important in any health care setting- but the new proposed regulations

include sections that seem to push beyond what are reasonable informed consent requirements. Furthermore, the new proposals do not appear to have taken the advice of the midwives- who are the experts in OOH (out of hospital) births and OOH clients- enough into account.

The practice of OOH midwifery cannot be inextricably tied to physicians (or the CNMs who work under them) granting a woman permission to birth at home, as is essentially outlined in Section 1100.2.A in the new proposed regulations. First- it is a conflict of interest. Second- physician concerns about liability will make this kind of written, signed "permission" very difficult to obtain.

Along the same lines, the requirements outlined Section 1300, in particular Section 1300 A, are overly onerous, and would be impossible in real life. This level of physician oversight described in those passages hinders the midwife from actually serving and helping mothers and babies. Midwives count on consultations and referrals to doctors, CNMs and hospitals, and most midwives have an ongoing relationship with at least one doctor or CNM, but the micromanagement described in Section 1300 would scare off any practitioner. The OOH-friendly providers cannot be available 24/7 and it is just too easy for a practitioner not familiar with OOH birth to insist on inappropriate and unnecessary transfers of care.

This brings us to VBACs. With a proper informed consent contract- which DHEC could do an excellent job of writing, if they wished- a woman with a previous cesarean should be able to make her own choice- in conjunction with her family and care providers- about where she wants to give birth. This choice cannot and should not be dictated by the state.

In 2016, I birthed my first child at home, under the care of a licensed midwife whom I trust. In 2018, I birthed micropreemie twins at 26 weeks via emergency c-section. This procedure was necessary, life-saving, and I am grateful for it. Still, I have the right to make my own informed decisions about any future births I may have. I was not involved in the Dec 2015 protest at Bull St, as I had not yet had children. However, if and when another protest is planned based on these current recommendations, I and my family will be there to support midwives and out-of-hospital birth.

Please support the licensed midwives and the families they serve. Give them regulations that actually help and not hinder their work.

Thank you,

Katie Samaha

NAME	SECTION	DEPARTMENT RESPONSE
71.LaTrice S. Ryant	400, 900, 1100	Partially Adopted. Adopted. Section 400. (regarding suturing). Adopted. Section 400. (regarding intravenous fluids). Partially Adopted. Section 1300. (regarding medical consultations and referrals). Any condition that requires consultation is considered to move the client beyond a low-risk pregnancy determination. The client has the right to consent to care that may possibly return her to a low-risk determination or to refuse the care. Adopted. Sections 900 and 1200. This regulation does not prohibit televisits according to South Carolina statute.

To whom it may concern,

I am a mother who homebirths.

I trust my midwife's judgement to provide the care that myself and my baby needs during my pregnancy, during my labor and delivery and afterward.

South Carolina Licensed Midwives need to be able to practice to a level that matches national standards for CPMs.

My care should be decided based on informed consent and refusal and discussions between myself and my Midwife, and my other healthcare professionals, without over-supervision of my Midwife.

My Midwife should be allowed to suture, potentially saving me an unnecessary trip to the hospital.

My Midwife should be allowed to start an IV in an emergency.

Myself and my Midwife and her consulting practitioner should have the ability to utilize tele-visits that are being perfected during the current pandemic.

Please listen to our state midwives concerning the updates that need to be made to Regulation 61-24. I do not understand all the nuances of midwifery practice, and neither can you. But there are many wise midwives in South Carolina who do. Refer to their judgment, please.
Thank you for your time.

Sincerely,

LaTrice S. Ryant

"Finally, all of you should be of one mind. Sympathize with each other. Love each other as brothers and sisters. Be tenderhearted, and keep a humble attitude." ~1 Peter 3:8

NAME	SECTION	DEPARTMENT RESPONSE
72.Heather King	400	Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives.

Please see attached letter regarding the proposed amendments to R.61-24.

Thank you for your time.

Respectfully,
Heather King

September 15, 2020

To Whom it May Concern:

My name is Heather King and I am writing regarding the proposed amendments to R.61-24 pertaining to Licensed Midwives.

In July of 2005 I had a c-section in Minnesota. I was a young single mom and felt pressured into a c-section, as many mothers do. Although I did have a midwife provider at the time, she was not available and there was an MD who took over my care. There were no pregnancy complications, they were concerned that my baby was small, not emptying her bladder and possible fluid around her heart. They told me I could be induced but there was a high likelihood of an emergency c-section under general anesthesia or I could opt for the c-section first. As a 21-year-old with no one to discuss options with, I agreed to a c-section out of fear, which ended up being a traumatic experience that caused me to start going into shock. Today, I am married and just found out I'm pregnant. I'm much more knowledgeable and understand the risks of VBAC (Vaginal Birth After Cesarean) and want to be as natural in this birth as possible. I prefer the much more supportive, holistic, natural guidance of a midwife, and the more positive, less medical environment of a birth center or my own home. Yet my options in South Carolina are limited because our state does not allow midwives to attend VBAC births in a birth center or at home, regardless of circumstances.

Statistically, a repeat cesarean is more dangerous than a VBAC. Many doctors and hospitals encourage repeat cesareans anyway, under circumstances that are not always entirely necessary. A successful VBAC is associated with far fewer complications than a repeat c-section. I understand there are risks with a VBAC, which are only slightly higher than a traditional vaginal birth. The main risk of VBAC is uterine rupture, yet this happens in less than 1% of VBACs and this risk is lowered after 18 months post c-section. More than 70% of VBACs are successful, which is only slightly less than a first vaginal birth (74%). Women with no prior c-sections face risks in delivering vaginally as well yet are allowed to birth where and how they prefer. Every woman should be able to consider all risks and benefits, along with their choice of provider, and determine what's best for her and her baby. In my case, I believe what is best for me and my baby is a delivery in a birth center under the care of a midwife. Without this option, I feel my only choices are to deliver in a hospital, thus increasing my chances for a repeat c-section, or deliver unassisted at home. I do not want to go against medical advice in terms of care that I receive or where I have my baby. However, I am also well aware of many unnecessary and even interfering procedures that take place in the hospital environment that deny those of us seeking VBAC to have a healthy, natural birth.

I assure you, if there is a valid reason for a repeat c-section and this is fully necessary, all well-trained midwives would transfer to a physician and hospital. Given my health, pregnancy history, past c-section causes, and the wisdom I have gained over these last

15 years, I do believe that it should be an option for me and other healthy VBAC patients to seek care at a birth center or home, with a qualified midwife attending the birth.

Thank you for your consideration regarding these amendments. I appreciate your time. and attention.

Respectfully,

Heather J. King

NAME	SECTION	DEPARTMENT RESPONSE
73.Ralph Shenefelt Senior Vice President Health and Safety Institute	102	Partially Adopted. The section was amended to remove "American Red Cross" to provide clarity The requirement is a CPR certification that is not specific to a particular company or entity.
see attached B.4		

NAME	SECTION	DEPARTMENT RESPONSE
74.Amber P. Walczuk, RN	1100, 1300	Partially Adopted. Not Adopted. S.C. 44-89-60(4) requires that a physician make a written determination that the planned birth is low risk. Partially Adopted. Section 1300. (regarding medical consultations and referrals). Any condition that requires consultation is considered to move the client beyond a low-risk pregnancy determination. The client has the right to consent to care that may possibly return her to a low-risk determination or to refuse the care.
Area of Concern:Hello, I am writing today because I was unable to attend the midwifery online meeting yesterday to discuss physician oversight. I am a registered nurse with over 10 years of experience in hospital, outpatient and home settings. I personally chose to have a home birth earlier this year because I felt that our home would be a much safer and more relaxing atmosphere to give birth in than a cold hospital room and I was correct. I also felt that my midwife would be better suited, equipped, and more knowledgeable about natural birth than any doctor I could've ever chosen. I say this because the majority of doctors DO NOT UNDERSTAND OR SUPPORT NATURAL BIRTH AT HOME. I wrote it in capital letters so I get the point across that doctors are not trained or believe in any form of natural medicine and at home labor falls under this. If they are against it (which most are), why on earth are they going to be allowed to oversee it and consult on it?!? If I went and polled 100 OBGYNs, I have no doubt that most of them would be in favor of a standard hospital birth which means that consulting with a midwife on any normal or standard issue that may arise would result in a "come to the hospital" recommendation. Mind you, the consulting physician may have absolutely no experience with a midwife, no experience with a mother who has already had 2 other home births, and no experience with natural labor if the patient's regular doctor is unavailable to consult. And yet, that person could be the one calling the shots. That is completely outrageous. This is such an EGREGIOUS medical overreach and does not take into account the personal wishes or rights of the patient, whatsoever. Unfortunately, my labor was prolonged and I ended up having to give birth in the hospital so I was fortunate to experience both sides of laboring with a midwife and laboring surrounded by nurses and doctors. While in the hospital, my entire birth plan was destroyed and it resulted in an unnecessary 10 day stay with my newborn to receive unnecessary antibiotics for a condition that she did not have. Had my midwife been able to have the necessary tools to help my labor progress at home, I would've been able to give birth at home and avoid the disaster that happened once 15 doctors got involved. I have you and your many ridiculous regulations to thank for that DHEC. Personally, I think it is HEINOUS crime that the state of South Carolina and DHEC allows a woman to kill an unborn child as late as 22 weeks at an abortion clinic but if she wants to safely have her baby at home, the regulations are a mountain of red tape that one dare not overstep. By YOUR OWN regulations, it's totally fine to murder a baby in utero if it fits your 3 little subjective categories but it's not safe to have your baby at home without a doctor being along for the ride every step of the way. Can you not see how messed up that is? The fact that women and babies are injured and die every single freaking day in the hospital by mismanagement, medical errors, and doctors and nurses who don't know what they are doing is completely overlooked as midwives are placed under a giant microscope and surrounded by an ever increasing mountain of regulations. This new amendment to increase physician oversight needs to not pass PERIOD. You will not keep us from having safe labors at home and you damn sure aren't going to ensure that a doctor who doesn't share my beliefs will be calling the shots with my next pregnancy. If this passes, we will protest and fight you every step of the way. Let us have our natural births at home, without the physicians that WE DIDN'T WANT TO BEGIN WITH, being involved along the way. Our midwives are smart, capable, and far more experienced than any doctor could be with home births and natural labor situations.		

NAME	SECTION	DEPARTMENT RESPONSE
75.Sandy Glenn, LM, CPM	1500	Not Adopted. Not Adopted. When events during intrapartum and/or postpartum move the pregnancy, birth, and/or condition of the client or neonate beyond the scope of midwifery care, the client and/or neonate are no longer considered low-risk and a transfer of care is required. Clients have the right to refuse care, treatment or services according to the laws of South Carolina. Clarification regarding Perinatal Levels of Care: This comment does not pertain to R.61-24. Perinatal levels of care are regulated within R.61-16.
see attachment B.5		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
76.Jami Morris, LM, CPM, MBC	300, 1000, 1100, 1200, 1500, 1700, 1800	Not Adopted. Not Adopted. Each client has the right to be informed of available midwifery services and of related charges. This is consistent with other Departmental regulations. Not Adopted. S.C. 44-89-60(4) requires that a physician make a written determination that the planned birth is low risk. Partially Adopted. Section 1200. (regarding Medications). A client has the right to self-administer any medications that her physician has prescribed. It is not within the scope of direct entry midwives to administer all medications available. Not Adopted. When events during intrapartum and/or postpartum move the pregnancy, birth, and/or condition of the client or neonate beyond the scope of midwifery care, the client and/or neonate are no longer considered low-risk and a transfer of care is required. Clients have the right to refuse care, treatment or services according to the laws of South Carolina. Not Adopted. The tuberculosis requirements are based on the Department's South Carolina's Tuberculosis Control Program and CDC guidelines. Not Adopted. (regarding the midwife advisory council) S.C. 44-1-60 lays out the process for appeals related to Department decisions . Per SC Code 44-1-140 the Department may promulgate and enforce rules and regulations for public health. The South Carolina Department of Health and Environmental Control (“DHEC” or “Department”) develops regulations in accordance with the South Carolina Administrative Procedures Act (“APA”), S.C. Code Section 1-23-10 et seq. Regulation Development actions include promulgating new regulations, amending existing regulations, and repealing existing regulations. Clarification: Regulation was changed to reflect S.C. Section 44-1-140.

see Attachment B.6

NAME	SECTION	DEPARTMENT RESPONSE
77.Sandy Glenn, LM, CPM	400	Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives.

During the virtual stakeholder meeting on 9/14/20 regarding Licensed Midwife Regulation Proposed Revisions; many comments were related to VBAC. It was said by DHEC staff that attending VBACs by a Licensed Midwife was a violation of the current regulation and a memo was referenced.

There was an outdated memo from 2006 on the DHEC website as recently as 2019. In 2013 legislators from House 3M committee voted against adding this memo into the LM regulations. According to the DHEC website; "Some Provider-Wide Exceptions [memos] pre-date the publishing dates of specific Regulation established by the State Register and may no longer be in effect. In these instances, if there is a conflict between a PWE that pre-dates the publishing date of the regulation, the standard in the regulation shall supercede the PWE."
https://scdhec.gov/health-regulation/healthcare-facility-licensing/provider-wide-exceptions-0
Provider-Wide Exceptions | SCDHEC
In the interest of establishing reasonable standards that can be met by providers and yet do not compromise the health and well-being of the patients, residents, and participants cared for in South Carolina licensed facilities, it has been determined that alternative standards will be considered as acceptable.
scdhec.gov

DHEC's statement that VBACs are not permissible within the current regulation was incorrect. There are clearly no restrictions for women who have been deemed low-risk by her midwife and a consulting physician.

Since legislators already voted against adding a VBAC restriction to the LM regulations and there have been no problems with community VBAC care since that time, then there is no rationale for prohibiting the care of these women.

It was noted that DHEC is choosing to site a LLR nursing board opinion as their rationale for prohibiting LM attended VBAC; however, that opinion is outdated and contradicts other more relevant opinions including the American College of Nurse Midwives, American College of Obstetrics and Gynecology and National Association of Registered Midwives.

The Department should consider the most relevant material related to the profession in question instead of referencing a uniquely different profession. There is no rationale for removing a low-risk VBAC mother's right to be attended by a Licensed Midwife.

NAME	SECTION	DEPARTMENT RESPONSE
78.Sandy Glenn, LM, CPM	n/a	Clarification. This comment does not pertain to R.61-24. Perinatal levels of care are regulated within R.61-16.

See attachment B.7

NAME	SECTION	DEPARTMENT RESPONSE

79.South Carolina Affiliate of the American College of Nurse Midwives	101	Partially Adopted 101G - Adopted. Not Adopted. This regulation includes the requirement for each licensed midwife to pass the examination by the North American Registry of Midwives to be credentialed as a Certified Professional Midwife ("CPM"). The NARM CPM credential is a competency-based certification accredited by the National Commission on Certifying Agencies and is evaluated yearly for adherence to the national standards.
see attachment B.8		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
80.SC Section of the American College of Obstetricians and Gynecology	Various Sections	Partially Adopted 101.H : Adopted 101.L: Adopted 101.CC: Not Adopted The definition is taken from NARM.org 101.EE: Partially Adopted The Department cannot regulate the actions of a Physician 101.FF: Not Adopted 101.00: Clarification A variance is a request to fulfill the regulation in a different means that is equal to the requirements in the regulation; it is not the means by which to get around regulation 102.E.2: Not Adopted. This regulation includes the requirement for each licensed midwife to pass the examination by the North American Registry of Midwives to be credentialed as a Certified Professional Midwife ("CPM"). The NARM CPM credential is a competency-based certification accredited by the National Commission on Certifying Agencies and is evaluated yearly for adherence to the national standards. 102.H.2 and 500: Not Adopted. Accepted course sources are listed in Section 500, all of which are either accredited or meet national standards. Section 200 : Clarification regarding Perinatal Levels of Care: This comment does not pertain to R.61-24. Perinatal levels of care are regulated within R.61-16. Adopted. Section 602. Midwives are required to submit quarterly reports which include outcomes. Adverse Incident Reporting - Adopted Section 600 Not Adopted. This is outside the scope of this regulation. Section 300: Clarification Complaints may be submitted by any and every member of the public Please contact the the Bureau of Facilities Oversight to submit a complaint Section 400: Change to Scope of Practice Partially Adopted 400.C Regarding obtaining nursing credentials: Adopted 400.A

		601.B Not Adopted. This is not information that the Department captures. 901: Adopted 903: Adopted. (regarding suturing). 904: Partially Adopted 1100: The Department cannot regulate how a Physician determines that a pregnancy is low-risk Not Adopted. Based on research of other state regulations the physician shall examine the client at least one (1) time during the client's first trimester and one (1) time during the client's third trimester. Partially Adopted. Section 1500. (regarding transfers to include an admitting Obstetrician). This regulation does not prohibit clients from preregistering and notifying the admitting physician of an emergent transfer. 1200: Adopted 1300: Partially Adopted 1500: Not Adopted. When events during intrapartum and/or postpartum move the pregnancy, birth, and/or condition of the client or neonate beyond the scope of midwifery care, the client and/or neonate are no longer considered low-risk and a transfer of care is required. Clients have the right to refuse care, treatment or services according to the laws of South Carolina. 1500: Clarification regarding Non-Emergent transfers: The Department made a distinction between a midwife not being able to continue care during antepartum and intrapartum/postpartum in the regulation for clarity between the two situations and the regulated requirements for each. Not being able to continue care during intrapartum/postpartum should always be considered emergent as the immediate care needed is beyond the scope of the midwife and is no longer considered low-risk. This is referred to as a "transfer of care". If the required care goes beyond the scope of the midwife during antepartum, it is not emergent and is referred to as "discharge". 1800: Addition of a second physician member: Not Adopted
See attachment B.9		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
81.Amanda Walton	400, 1200, 1300, 1500	Not Adopted. Not Adopted. Any condition that requires consultation may move the client beyond a low-risk pregnancy, and a consultation is required to be obtained from an physician or other authorized healthcare provider in order to possibly return the client to a low-risk pregnancy determination. informed consent Not Adopted. When events during intrapartum and/or postpartum move the pregnancy, birth, and/or condition of the client or neonate beyond the scope of midwifery care, the

		client and/or neonate are no longer considered low-risk and a transfer of care is required. Clients have the right to refuse care, treatment or services according to the laws of South Carolina. Clarification regarding Perinatal Levels of Care: This comment does not pertain to R.61-24. Perinatal levels of care are regulated within R.61-16. Not Adopted. Misoprostol is not approved by the U.S. Food and Drug Administration for postpartum hemorrhaging. Any such use is considered an off-label use. This medication is also used in combination with another drug to end a pregnancy. The medication may also be used for induction of cervical softening and dilation in labor. The main problems cited for the medication are hyperstimulation, uterine rupture, and placental abruption. Oxytocin alone is the recommended uterotonic drug for the treatment of postpartum hemorrhage. Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives.

To the Health Regulations Committee,

I am a woman who prefers homebirth to hospital birth and has a deep appreciation for the Midwifery standard of care.

I trust my midwife's judgement concerning my health and the health of my child in prenatal, labor, birth, and postpartum care.

South Carolina Licensed Midwives need to be able to practice to a level that matches national standards for CPMs.

My care should be decided based on informed consent and refusal and discussions between myself and my Midwife, and my other healthcare professionals, without over-supervision of my Midwife.

Please listen to our state midwives concerning the updates that need to be made to Regulation 61-24. I do not understand all the nuances of midwifery practice, and neither can you. But there are many wise midwives in South Carolina who do. Refer to their judgement, please.

It is discouraging and alarming that DHEC has not accepted the advice of the Midwifery Advisory Council and is including in the regulation language that would reduce the authority of Midwifer Advisory Council to almost nothing. It is clear that DHEC needs a MAC and needs to adhere to MAC recommendations.

The requirements for consultation with a physician in the new regulations are extreme and would reduce access to community birth and inhibit the profession of Licensed Midwifery. I believe they are unnecessarily restrictive.l

Requiring a midwife to call 911 as a means of transfer of care if a mother chooses to decline the recommendations of a physician or midwife is not only an infringement upon patient rights, but is a deliberate disparity mandated by a government agency. Licensed Midwives should be listed as a maternity provider within the Perinatal Levels of Care and the families using a midwife should be given the same access to the emergency system as every other maternity provider in SC.

Misoprostol needs to be incorporated as an emergency measure. It is a safe and effective medication for postpartum hemorrhage.

VBAC should not be banned. A 2006 memo is outdated and not incorporated into the 2013 LM regulation. There have been no major issues with VBAC attendance and certain mothers should be considered low risk, especially since Licensed Midwives are already required to get a second opinion from a physician. This physician opinion is more appropriate than the Nursing Opinion stated by DHEC as a rationale for banning VBAC attendance by a Licensed Midwife.

Please listen to our midwives, and to the Midwifery Advisory Council. We, as clients and mothers, trust them with ourselves and our children, and they have earned that trust with skill, wisdom, and quality care. Their training is extensive, their experience vast, and their passion for quality birth care unmatched.
Thank you for your time.
Amanda Walton

NAME	SECTION	DEPARTMENT RESPONSE
82.Hannah Trotter	n/a	Acknowledged. Clarification: This comment partially does not pertain to amending R.61-24 but to the internal processes of the Department.

Women should be able to safely birth in the hospital or AT HOME if they choose. Dhec should heed what the Midwife Advisory Council has to say since they are the experts in home birth. Placing more restrictions on licensed midwives will not help but hinder home births. I had a home birth and it was the most amazing experience of my life. To deprive a woman of safely having that experience would be shameful.

Respectfully,
Hannah Trotter

NAME	SECTION	DEPARTMENT RESPONSE
83.Lisa Aman	n/a	Not Adopted. Clarification: This comment partially does not pertain to amending R.61-24 but to the internal processes of the Department. Not Adopted. When events during intrapartum and/or postpartum move the pregnancy, birth, and/or condition of the client or neonate beyond the scope of midwifery care, the client and/or neonate are no longer considered low-risk and a transfer of care is required. Clients have the right to refuse care, treatment or services according to the laws of South Carolina. Partially Adopted. Section 1300. (regarding medical consultations and referrals). Any condition that requires consultation is considered to move the client beyond a low-risk pregnancy determination. The client has the right to consent to care that may possibly return her to a low-risk determination or to refuse the care. Not Adopted. Misoprostol is not approved by the U.S. Food

		and Drug Administration for postpartum hemorrhaging. Any such use is considered an off-label use. This medication is also used in combination with another drug to end a pregnancy. The medication may also be used for induction of cervical softening and dilation in labor. The main problems cited for the medication are hyperstimulation, uterine rupture, and placental abruption. Oxytocin alone is the recommended uterotonic drug for the treatment of postpartum hemorrhage.
As a LM for over 35 yrs here in SC I am quite concerned about these possible new regs. They seem to be a possible demise for our long standing profession in our state that has a good track record in serving moms and babies in a safe and personal way. Areas of concern.. * DHEC should be using MAC as intended, not just telling them how it is to be. *Requirements for consultation with MD as proposed and calling 911 for a client against her will just wont work in our profession, and will cause many to go unassisted (Like VBACs are doing vs hiring professional midwives for guidance in safety issues.) The way we work with Drs now has worked just fine for me anyways. * Misoprostol is known and used all over the world as a low cost way to save lives for PPH. Why in the world should that be banned when all other practitioners use to save lives? Please dont let us be shot down or drove out of practice by new regs that just wont work Thank you, Lisa AmanLM Lic # 1		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
84.Mary Peterson Cook	400, 1200, 1300, 1500	Partially Adopted. Partially Adopted. Section 1300. (regarding medical consultations and referrals). Any condition that requires consultation is considered to move the client beyond a low-risk pregnancy determination. The client has the right to consent to care that may possibly return her to a low-risk determination or to refuse the care. Not Adopted. When events during intrapartum and/or postpartum move the pregnancy, birth, and/or condition of the client or neonate beyond the scope of midwifery care, the client and/or neonate are no longer considered low-risk and a transfer of care is required. Clients have the right to refuse care, treatment or services according to the laws of South Carolina. Not Adopted. Misoprostol is not approved by the U.S. Food and Drug Administration for postpartum hemorrhaging. Any such use is considered an off-label use. This medication is also used in combination with another drug to end a pregnancy. The medication may also be used for induction of cervical softening and dilation in labor. The main problems cited for the medication are hyperstimulation, uterine rupture, and placental abruption. Oxytocin alone is the recommended uterotonic drug for the treatment of postpartum hemorrhage.

		Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives.

I'm writing about the issues DHEC seems to be having with the Midwifery advisory council. In addition to the below issues I want to explain what these changes mean over time.

You see I gave birth in Hong Kong. While it's a safe health care system, and you can't beat the cost, it wasn't the type of birth I wanted. You see homebirths are legal but they make it so difficult (like you are) as so no licensed midwives will do them. And they believe in midwifes in hk! They just have political concerns that make all the extra work.

So let's be better. Let's give mothers a chance at the birth they want. Especially in these Covid times. Listen to the women who's life is birth.

Major areas of concern:
1) DHEC again did not accept the advice of the Midwifery Advisory Council (MAC). Additionally, the regulation would reduce the authority of MAC to almost nothing. It is clear from the continued errors in LM proposed regs by DHEC that they desperately need a MAC and they need to adhere to MAC recommendations.
2) The requirements for consultation with a physician in the new regs are extreme and would reduce access to community birth and inhibit the profession of Licensed Midwifery.
3) Requiring a midwife to call 911 as a means of transfer of care if a mother chooses to decline the recommendations of a physician or midwife is not only an infringement upon patient rights, but is a deliberate disparity mandated by a government agency. Licensed Midwives should be listed as a maternity provider within the Perinatal Levels of Care and the families using a midwife should be given the same access to the emergency system as every other maternity provider in SC (physicians, smaller hospitals, college and prisons infirmaries have access to this Perinatal Level of Care transfer system).
4) Misoprostol needs to be incorporated as an emergency measure. It is a safe and effective medication for postpartum hemorrhage.
5) VBAC should not be banned. A 2006 memo is outdated and not incorporated into the 2013 LM regulation. There have been no major issues with VBAC attendance and certain mothers should be considered low risk, especially since LMs are already required to get a second opinion from a physician. This physician opinion is more appropriate than the Nursing Opinion stated by DHEC as a rationale for banning VBAC attendance by a LM.

NAME	**SECTION**	**DEPARTMENT RESPONSE**
85.Megan Sullivan	n/a	Acknowledged.

This proposed regulation contradicts the midwifery model of care as a community-based care model. This proposed regulation also demotes midwives as trained medical professionals while also depriving birthing persons half of their rights as patients.

Please reconsider and consult the Midwifery Advice Counsel.

Thank you

NAME	**SECTION**	**DEPARTMENT RESPONSE**
86.Molly Marone	n/a	Acknowledged.

I am Molly Jinnette I am a concerned citizen!
I am concerned that you DEHEC are taking away freedom of self, freedom of choice, freedom of birth!

Here are my concerns:
1 How could you not accept the advice of the Midwifery Advisory Council (MAC). They have proven

facts you are choosing to ignore!

2) The requirements for consultation with a physician in the new regulatuons are extreme to the point of infringing on free will!

3) Requiring a midwife to call 911 as a means of transfer of care if a mother chooses to decline the recommendations of a physician or midwife is not only an infringement upon patient rights, but is a deliberate disparity mandated by a government agency. Licensed Midwives should be listed as a maternity provider within the Perinatal Levels of Care and the families using a midwife should be given the same access to the emergency system as every other maternity provider in SC (physicians, smaller hospitals, college and prisons infirmaries have access to this Perinatal Level of Care transfer system).

4) Misoprostol needs to be incorporated as an emergency measure. It is a safe and effective medication for postpartum hemorrhage.

5) VBAC should not be banned. A 2006 memo is outdated and not incorporated into the 2013 LM regulation. There have been no major issues with VBAC attendance and certain mothers should be considered low risk, especially since LMs are already required to get a second opinion from a physician. This physician opinion is more appropriate than the Nursing Opinion stated by DHEC as a rationale for banning VBAC attendance by a LM.

You can not take away the rights of women and what they choose for their bodies and their babies bodies.

It is obvious you are committed to a globalist agenda!
We the people will not stand for this !
You do not get to dictate or damage how conciousness is incarnated.

Hear the voice of the people now !

NAME	SECTION	DEPARTMENT RESPONSE
87.Sandy Glenn, LM, CPM	1800	Not Adopted. Not Adopted. (regarding the midwife advisory council) S.C. 44-1-60 lays out the process for appeals related to Department decisions . Per SC Code 44-1-140 the Department may promulgate and enforce rules and regulations for public health. The South Carolina Department of Health and Environmental Control ("DHEC" or "Department") develops regulations in accordance with the South Carolina Administrative Procedures Act ("APA"), S.C. Code Section 1-23-10 et seq. Regulation Development actions include promulgating new regulations, amending existing regulations, and repealing existing regulations. Clarification: This comment partially does not pertain to amending R.61-24 but to the internal processes of the Department.
DHEC created a regulation in consultation from an unnamed committee. These actions contradict the mandates in the current LM regulation. The Midwifery Advisory Council (MAC) requested many times to be involved in the writing the reg draft. MAC also requested that DHEC tell them the names and credentials of those being utilized to advice The Department		

regarding regulation revisions. MAC was denied both of these requests. Those actions show a lack of transparency and failure to follow their own regulations by The Department.

MAC should have been the committee used to create the regulations and any other committee should have been consulted as stakeholders AFTER the drafted regulation was completed by MAC. Instead DHEC did the opposite.

After the draft was presented to MAC, MAC presented a detailed list of corrections that needed to be added to the proposal but DHEC failed to accept many major recommendations from the committee.

Additionally, not only did DHEC not accept the advice of MAC but the proposed regulation would reduce the authority of MAC to almost nothing. It is clear from the continued errors and safety issued proposed by DHEC that they desperately need a MAC and they need to adhere to MAC recommendations for all changes to professional guidelines.

CURRENT REG 61-24
P. Department Responsibilities.
1. Midwifery Advisory Council.
a. The Commissioner of DHEC shall appoint a Midwifery Advisory Council which shall meet at least annually for the purpose of reviewing and advising the Department regarding matters pertaining to the training, practices, and regulation of midwives in South Carolina. The Council
shall consist of three licensed midwives, one consumer of midwife care, two certified nurse-midwives, one physician active in perinatal care, and one member-at-large. Each member shall be appointed for a three-year term of office.
b. The Council shall establish a committee for peer review to consult with midwives in questions of ethics, competency and performance, and to serve as an appeal committee when disciplinary action has been taken. The committee may recommend denying, suspending, or revoking a license, or may recommend specific educational objectives, apprenticeship or other improvement measures as necessary.

PROPOSED CHANGE:
SECTION 1800 – MIDWIFERY ADVISORY COUNCIL
The Department shall appoint a Midwifery Advisory Council to advise the Department regarding licensing and Inspection of Midwives. The Council shall meet at least annually. The Council shall consist of three (3) licensed Midwives, one (1) consumer of midwife care, two (2) Certified Nurse Midwives, one (1) Physician active in perinatal care, and one (1) member at large. Each member shall be appointed for a three (3) year term of office.

NAME	SECTION	DEPARTMENT RESPONSE
88.Sandy Glenn, LM, CPM	1100, 1200, 1300	Partially Adopted. Not Adopted. S.C. 44-89-60(4) requires that a physician make a written determination that the planned birth is low risk. Not Adopted. (regarding the Physician's signature). S.C. Code 44-89-60(4) requires a physician to make a written determination that the planned birth is low risk. The requirement for signatures for verification are consistent with other Department regulations. Not Adopted. Abnormal presentations are associated with a much higher risk of obstruction and other birth complications than the vertex presentation. For this reason, all women who

		develop abnormal presentation should ideally have skilled care by health professionals in a facility where there is a comprehensive emergency obstetric service. Partially Adopted. Section 1200. (regarding Medications). A client has the right to self-administer any medications that her physician has prescribed. It is not within the scope of direct entry midwives to administer all medications available.
see attachment B.10		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
89.Stephanie Detweiler	400, 1200, 1300, 1500	Not Adopted. Clarification: This comment partially does not pertain to amending R.61-24 but to the internal processes of the Department. Not Adopted. Any condition that requires consultation may move the client beyond a low-risk pregnancy, and a consultation is required to be obtained from an physician or other authorized healthcare provider in order to possibly return the client to a low-risk pregnancy determination. Not Adopted. When events during intrapartum and/or postpartum move the pregnancy, birth, and/or condition of the client or neonate beyond the scope of midwifery care, the client and/or neonate are no longer considered low-risk and a transfer of care is required. Clients have the right to refuse care, treatment or services according to the laws of South Carolina. Not Adopted. Misoprostol is not approved by the U.S. Food and Drug Administration for postpartum hemorrhaging. Any such use is considered an off-label use. This medication is also used in combination with another drug to end a pregnancy. The medication may also be used for induction of cervical softening and dilation in labor. The main problems cited for the medication are hyperstimulation, uterine rupture, and placental abruption. Oxytocin alone is the recommended uterotonic drug for the treatment of postpartum hemorrhage. Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives.
Major areas of concern: 1) DHEC again did not accept the advice of the Midwifery Advisory Council. Additionally, the regulation would reduce the authority of MAC to almost nothing. It is clear from the continued eros in LM proposed regs by DHEC that they desperately need a MAC and they need to adhere to MAC recommendations. 2) The requirements for consultations with a physician in the new regs are extreme and would reduce the access to community birth and inhibit the profession of Licensed Midwifery. 3) Requiring a midwife to call 911 as a means of transfer of care if a mother chooses to decline the recommendations of a physician or midwife is not only am infringement upon patient rights but is a deliberate disparity mandated by the government agency. Licensed Midwives should be listed as a maternity provider within the Perinatal Levels of Care and the families using a midwife should be given the same access to the emergency system as every other maternity provider in SC. (physicians, smaller		

hospitals, colleges and prisons, infirmaries, have access to this Perinatal Level of Care transfer system.)
4) Misoprostol needs to be incorporated as an emergency measure. It is a safe and effective medication for postpartum hemorrhage.
5) VBACs should not be banned. A 2006 memo is outdated and not incorporated into the 2013 LM regulation. there have been no major issues with VBAC attendance and certain mothers should be considered low risk, especially since LMs are already required to get a second opinion from a physician. This physician opinion is more appropriate than the Nursing Opinion stated by DHEC as a rationale for banning VBAC attendance by LM.

I am a home birth Mama of 2, and will continue to do so, no matter how hard you make it. Barring any emergency, I will never birth in a hospital.

have a good day.

NAME	SECTION	DEPARTMENT RESPONSE
90.Allen Gamble, DO	101	Not Adopted. The term "Authorized Healthcare Provider" is used consistently in other Department regulations and defined for clarity across the healthcare community. The definition is based on SC Code of Laws 40-43-30 to clarify that only healthcare providers authorized by law may diagnose and prescribe drugs and devices.

RE: Reg 61-24 Licensed Midwives

101: Definitions.
B.
D.
If defining Licensed Midwives as healthcare providers, and physicians and their extenders as medical providers, clarifies midwives place among the healthcare and medical providers in South Carolina as inclusive, part of the same team of providers that serve the needs of the people of South Carolina, then this should be clarified.

Physicians, and other medical providers and healthcare providers should be defined in such a way as to recognize each other's role and work together to respectfully cooperate with each other to provide the most safe and effective services to the people of South Carolina.

Thank you for your attention to this suggestion.

Allen E Gamble, DO.

NAME	SECTION	DEPARTMENT RESPONSE
91.Allen Gamble, DO	1200	Partially Adopted. Section 1200. (regarding Medications). A client has the right to self-administer any medications that her physician has prescribed. It is not within the scope of direct entry midwives to administer all medications available.

RE: Reg 61-24 Licensed Midwives

1200 Prescription Medication Administration.

B. Strike “The midwife shall only administer … “

If a medical provider prescribes medications for a midwife client, such as anti-hemorrhagic medications to be available for possible postpartum hemorrhage, it makes sense that the midwife should not only be permitted to, but to be expected to, administer said medication.

Medications allowed should include any medication commonly used by any licensed provider for the purpose of the medication. This should include any/all medications commonly used as standard of care, even if they are used off-label, as may be the case for misoprostol when used for postpartum hemorrhage. Misoprostol may not have ever been DEA approved for this purpose, but it has become a standard of care medication for postpartum hemorrhage. It is well known that, due to the expense of doing so, many manufacturers never seek FDA approval for common, safe, and effective, off label uses of some of their medications.

If a list of medications is made, it should be modified with a statement such as “may include, but not be limited to” - in order to accommodate new medications that may become available for the indication at hand.

If the safety and well-being of the public is the goal, and midwives are licensed by the state of South Carolina to deliver babies outside the hospital, they should be given all the tools they need to provide safe and effective care.

Thank you for your consideration of this suggestion.

Allen E Gamble, DO

NAME	SECTION	DEPARTMENT RESPONSE
92.Allen Gamble, DO	1500	Not Adopted. S.C. Code of Laws 44-61-70(B)(1) does not permit an EMS provider to allow uncertified personnel to perform patient care.

RE: Reg 61-24 Licensed Midwives

1500 Transfer of Care.

A. Strike “by dialing 911”

B. Strike “Upon arrival of EMS … the midwife shall transfer care … to the EMS … “

The most timely and safest transport of a laboring mother with a problem is directly from the field to Labor and Delivery at the hospital.

When a specialist consultation in needed, the standard way this is done is directly from one provider to the other.

As a Family Physician, when I need a consult with a specialist, if it is urgent, I contact the specialist directly, present the case and the reason for the requested consultant; then the specialist either accepts the consult, or suggests a better alternative. Relevant records are sent, in advance or with the patient.

Similarly, in the case of midwives who need an OB consult during delivery, Labor and Delivery should be contacted first and directly, and the midwife should present to case directly to the OB physician on call, explaining the course of the labor so far, and the reason the decision was made to send the laboring mother to the hospital for evaluation and further management. This way, the L & D department and the OB physician are alerted about exactly what to expect so that appropriate management can be implemented ASAP.

If EMS transport is used, this should be done directly under the supervision of the OB, same as a cardiac patient may be transported with paramedics in contact with the ER physician or cardiologist during the transport, and the ER is ready to receive the cardiac patient.

Since EMS personnel are not trained in OB, the safest management would be for the midwife to be on the ambulance to interpret and help carry out the instructions from OB, and to be there for the delivery, should it occur during transport. The midwife should accompany the client to L & D, and update OB on what has transpired since the initial contact between midwife and OB, and should stay with the client for moral support during the unanticipated change, which may be emotionally traumatic for the client/patient.

It would be unsafe, even medically negligent, to transfer an urgent medical problem from the more trained provider (midwife) to a less trained provider (EMS provider) during the urgent problem, and to not have the appropriate hospital department (L & D) alerted as to the exact nature of the problem (best explained by the midwife to the OB who is going to take over management), before the arrival of the patient.

Thank you for your consideration of this suggestion.

Allen E Gamble, D.O.

NAME	SECTION	DEPARTMENT RESPONSE
93.Kathleen Aita Houpt	400, 1100, 1300	Partially Adopted. Not Adopted. S.C. 44-89-60(4) requires that a physician make a written determination that the planned birth is low risk. Not Adopted. (regarding the Physician's signature). S.C. Code 44-89-60(4) requires a physician to make a written determination that the planned birth is low risk. The requirement for signatures for verification are consistent with other Department regulations. Partially Adopted. Section 1300. (regarding medical consultations and referrals). Any condition that requires consultation is considered to move the client beyond a low-risk pregnancy determination. The client has the right to consent to care that may possibly return her to a low-risk determination or to refuse the care. Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives.

DHEC-

Thank you for your efforts to protect the health of women and children- however, many sections of the newest set of proposed midwifery regulations appear to move beyond protection into control of women

and families' medical freedoms, without nearly enough practical or scientific justification.

Informed consent and refusal are important in any health care setting- but the new proposed regulations include sections that seem to push beyond what are reasonable informed consent requirements. Furthermore, the new proposals do not appear to have taken the advice of the midwives- who are the experts in OOH (out of hospital) births and OOH clients- enough into account.

The practice of OOH midwifery cannot be inextricably tied to physicians (or the CNMs who work under them) granting a woman permission to birth at home, as is essentially outlined in Section 1100.2.A in the new proposed regulations. First- it is a conflict of interest. Second- physician concerns about liability will make this kind of written, signed "permission" very difficult to obtain.

Along the same lines, the requirements outlined Section 1300, in particular Section 1300 A, are overly onerous, and would be impossible in real life. This level of physician oversight described in those passages hinders the midwife from actually serving and helping mothers and babies. Midwives count on consultations and referrals to doctors, CNMs and hospitals, and most midwives have an ongoing relationship with at least one doctor or CNM, but the micromanagement described in Section 1300 would scare off any practitioner. The OOH-friendly providers cannot be available 24/7 and it is just too easy for a practitioner not familiar with OOH birth to insist on inappropriate and unnecessary transfers of care.

This brings us to VBACs. With a proper informed consent contract- which DHEC could do an excellent job of writing, if they wished- a woman with a previous cesarean should be able to make her own choice- in conjunction with her family and care providers- about where she wants to give birth. This choice cannot and should not be dictated by the state.

On a more personal note, I myself am a doctor of chiropractic here in the state of SC. Many of my patients choose to birth with homebirth midwives or at birthing centers. I myself have 4 children who were all born at home and all 4 births were attended by a homebirth midwife here in SC. Often times people say "you are so brave to give birth at home!" I quickly correct them and let them know that there is nothing brave about choosing to birth at home. I chose to birth at home because that is where I felt most comfortable and every woman should birth where they feel the most comfort, with the birth provider they feel most comfortable with.

Also, I was at the protest in December 2015 with my 4 children and I am fully prepared to protest again if necessary.

Please support the licensed midwives and the families they serve. Give them regulations that actually help and not hinder their work.

Thank you.
Dr. Kathleen Aita Houpt

NAME	SECTION	DEPARTMENT RESPONSE
94.Julia Babici	400, 1200	Not Adopted. Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives. Not Adopted. Misoprostol is not approved by the U.S. Food and Drug Administration for postpartum hemorrhaging. Any such use is considered an off-label use.

		This medication is also used in combination with another drug to end a pregnancy. The medication may also be used for induction of cervical softening and dilation in labor. The main problems cited for the medication are hyperstimulation, uterine rupture, and placental abruption. Oxytocin alone is the recommended uterotonic drug for the treatment of postpartum hemorrhage.

Good afternoon,

Your Notice of Proposed Regulation 61-24 Licensed Midwives is an infrigement on patient's rights. Pregnant mothers have the right to decide for themselves if they wish to have Pitocin post partum or not. The medical provider aka Midwife present during birth needs to have full rights. Why should a decision be made by a physician who is not even in a room? I am a mother who has had a VBAC with no medication, and no Pitocin after delivery. Mom and baby both healthy. You are tramping on the patient's rights, and you are spitting on Midwives education and experience.

Misoprostol must be included as emergency measure. Do your due dilligence and your research on this. DHEC MUST ADHERE TO Midwifery Advisory Council, it exists with that purpose.
I oppose 61-24.

Thank you

Julia Babici

NAME	SECTION	DEPARTMENT RESPONSE
95.Shelley Chapman, MD Maternal Fetal Medicine	101, 400, 900, 1200, 1300, 1500	Partially Adopted. Adopted. Section 400. (regarding episiotomies). Not Adopted. Perineal trauma occurs in eighty-five percent (85%) of women after having a vaginal birth, it is estimated sixty to seventy percent (60-70 %) of these lacerations will require suturing. This practice is within the national standards of midwifery care and per regulation requires training specific to this practice. Not Adopted. Due to South Carolina's geography and rural communities it would be beneficial to the safety of home birth clients to allow a licensed midwife to provide intravenous fluids to stabilize a laboring or recently delivered person while awaiting EMS for transport. Adopted. 1200.B. (regarding antibiotics). Not Adopted. Oxytocin is the recommended first line uterotonic drug for the prevention of postpartum hemorrhage for all births based on the World Health Organization guidelines. Adopted. 1200.B (regarding Methergine). Partially Adopted. Section 1200. The Department has determined that this is within the national scope of midwifery care to administer topical lidocaine. Adopted. 1200.B. (regarding Epinephrine). Adopted. Section 1200.B (regarding penicillin). Partially Adopted. Section 1300. (regarding gestational

		diabetes). There is a requirement for Medical Consultation to determine level of risk to the Client. GBS Screening - Acknowledged Physician Collaboration - Partially Adopted 101FF Not Adopted. When events during intrapartum and/or postpartum move the pregnancy, birth, and/or condition of the client or neonate beyond the scope of midwifery care, the client and/or neonate are no longer considered low-risk and a transfer of care is required. Clients have the right to refuse care, treatment or services according to the laws of South Carolina. Partially Adopted. Section 1500. (regarding transfers to include an admitting Obstetrician). Partially Adopted. This regulation does not prohibit clients from preregistering and notifying the admitting physician of an emergent transfer.

To whom it may concern:

In reviewing the Regulation proposals 61-24 for licensed midwives (LM), I am quite concerned about the reproductive safety of women in South Carolina. As a high risk obstetric provider in the Upstate for over 20 years, I am well aware of the unexpected intrapartum complications that can occur in an outpatient/home birth/birthing center setting. The following list represents my gravest concerns about the proposals :

1. I oppose the increase in the scope of practice to allow episiotomy and suturing of first and second degree lacerations

2. I oppose the increase in the scope of practice to allow starting an IV and administering IV fluids and medications including antibiotics

3. I oppose the increase in the scope of practice to allow administration of oxytocin, methergine, lidocaine, epinephrine, penicillin and other antibiotics.

4. I strongly support the changes prohibiting LM to provide care for women with a previous cesarean section

5. I strongly support the changes requiring LM to screen all women for Group B Streptococcus

6. I recommend adding specificity to the requirement that any suspicion of gestational diabetes or any degree of glucose intolerance in pregnancy is no longer considered a low-risk pregnancy and requires transfer out of the practice.

7. I recommend additional changes to the requirements addressing physician collaboration. The regulations should specify that the individual performing the physical exam must be licensed to practice medicine or nursing in the State of South Carolina. It should also specify that this individual has current obstetric admitting privileges, or is part of a practice or call pool with partners who have current obstetric admitting privileges at a hospital in South Carolina.

8. I recommend changes in the section on transfer of care. “Dialing 911” is not an appropriate transfer plan when women require a higher level of care. Consideration should be given to requiring all women to pre-register with a physician practice and a hospital which provides OB services in the event that there is an urgent or emergent issue that arises during the course of an attempted home birth.

9. I oppose licensing any midwife who has not completed an accredited educational program.

Please consider the safety of women as you review these proposals.

Respectfully submitted.
Shelley Chapman, MD

Maternal Fetal Medicine

NAME	SECTION	DEPARTMENT RESPONSE
96.Vanessa Smith	n/a	Acknowledged.

To whom it may concern,

As a mama getting ready to have a home birth in the next couple weeks, I'm very concerned with the new midwife regulations.
I've received outstanding care with my midwife and the OB team that I see for the required visits. Coming from another state with less regulations than what SC has (this is my third birth & first in SC), I was so pleased with the balance of needing the two required visits and the freedom of the choice to home birth. I trust my midwife and her judgement. She's been incredible and very professional throughout this journey with me.

In this time of covid concern where women are turning to home birth as an option for staying out of the hospital, where potential exposure is a possibility, taking away freedoms puts more women in position to just birth unassisted, which is much more dangerous for mama and baby.

Please leave our freedoms and don't pass this bill.

Thank you,
Vanessa

NAME	SECTION	DEPARTMENT RESPONSE
97.Anna Dixon	400	Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives.

To Whom It May Concern:

My name is Anna Dixon. I lived in Pennsylvania before moving to South Carolina in 2019. In PA I had an unnecessary c-section due to medical neglect for my own health by my OB-GYN. I did NOT have a c-section because my body couldn't labor or birth a baby. I had NO Trial Of Labor for my first baby. The c-section was due to my own health emergency that was neglected by the doctor until it was too late and c-section became necessary. If I would have been in the care of midwives, I do not believe I would have needed a c-section because they would never have neglected the fact that I had a GI illness and needed medicine to keep from getting dehydrated. The doctor neglected me until I was in distress instead of acting proactively.

I decided to start researching the risks of repeat c-section vs. VBAC for my future births. I decided it was safer to have a VBAC and to work with a midwife.

I subsequently had two low-risk, midwife-attended VBACs in 2014 and 2015. One was in a hospital attended by midwives only and one was a HBAC attended by a midwife. Both were low-risk, peaceful

and successful. There were no complications at all. They were the BEST and most transcendent experiences of my life.

A woman has a right to CHOOSE how she wants to birth and with whom she wants to contract for her birth. We own our bodies. We have a right to choose our preferred healthcare provider and assess the risks of any choice. Hospital births are far more risky and dangerous than homebirths due to vast amounts of interventions with various dangers and side-effects. VBAC and HBAC are low-risk when the mother is low-risk and has an experienced midwife. The chance of uterine rupture is less risky than the car drive to the hospital.

A LM ought to be able to attend a homebirth VBAC if it is the choice of the mother and if the LM agrees to work with her. Keeping mothers from working with the LM of their choice hurts the mother because it prevents her from having the care she needs and desires. Having a baby at home is safest for low-risk mothers. VBACs are safer than repeat c-sections for low-risk mothers.

No law from DHEC should remove freedom of choice for a mother in how she wants to birth and with whom she wants to contract for professional healthcare and midwifery services.

I will be having my 3rd VBAC and second HBAC in November and I will continue to desire to work with an LM for all future children that I have.

Thank you,
Anna Dixon

NAME	SECTION	DEPARTMENT RESPONSE
98.Ashley Coponen	n/a	Acknowledged.

Hello. I am a mother of 9 beautiful babies , and I believe every women/mother should have freedom of birth choices when it comes to decideling how and what work best for their delivery/labor !!!!

NAME	SECTION	DEPARTMENT RESPONSE
99.Christina Szrama	400, 1100, 1300	Not Adopted.Clarification: Low-risk pregnancy and births are within the scope of direct entry midwives and are not overseen by Physicians. Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives.

I have multiple concerns about the proposed regulation changes, starting with WHO is writing these and what knowledge of out-of-hospital birth do they have? What qualifications do they have to make these regulations from an informed place? Why is DHEC not listening the the Midwife Advisory Council, and is instead **reducing** their authority? Seems you are only providing lip service to giving women the options they want but actually trying to force all women into a one-size-fits-all system when it comes to their prenatal, birth & postpartum care.

Two big concerns: first- physicians should NOT get veto power over midwives. Midwives are qualified professionals who are more familiar with the patient, the situation and with physiological birth in general. Physicians have their roles but uncomplicated natural birth doesn't need to be one.

Second- VBAC moms need options. Let women, their midwives and their consulting physicians make a decision about whether a mother is a good candidate for homebirth, we do not need a blanket HBAC ban.

As the COVID situation has shown, our medical model has many flaws and weaknesses— birth is one

aspect of medical care that can certainly be removed from under the hospital's umbrella in many cases. Many moms don't want to expose themselves or their newborns to all kinds of diseases— ie birth in a hospital. Let's allow PARENTS to make these decisions, not a random board who is not even listening to the midwives appointed to supposedly advise them. Thank you for your attention to this matter, Christina Szrama		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
100.Cyndia Rosenblatt Consumer	101, 301, 400, 700, 901, 1100, 1200, 1300, 1400, 1500, 1800	Partially Adopted. 101D: Not Adopted. The term "Authorized Healthcare Provider" is used consistently in other Department regulations and defined for clarity across the healthcare community. The definition is based on SC Code of Laws 40-43-30 to clarify that only healthcare providers authorized by law may diagnose and prescribe drugs and devices. 101E: Not Adopted. The definition for a birthing center is in S.C. Code 44-89-30. 101G: Not Adopted. This is not necessary for this regulation 101J: Clarification regarding Compliance Meetings: This comment partially does not pertain to amending R.61-24 but to the internal processes of the Department. 101P: This definition is consistent with SC 44-89-30. 101W Not Adopted This is consistent with other regulations. 101DD: Not Adopted. This is not necessary for this regulation. 101EE Definition is consistent with other regulations. 101FF: Not Adopted This is consistent with other regulations. 101GG: Not Adopted This is consistent with other regulations. 101II: Not Adopted This is consistent with other regulations. 101MM: Acknowledged. 202b: Not Adopted. This is not consistent with other departmental regulations. They are subject to inspection and investigation at any time without prior notification. 301: Not Adopted. (regarding the midwife advisory council) S.C. 44-1-60 lays out the process for appeals related to Department decisions . Per SC Code 44-1-140 the Department may promulgate and enforce rules and regulations for public health. The South Carolina Department of Health and Environmental Control ("DHEC" or "Department") develops regulations in accordance with the South Carolina Administrative Procedures Act ("APA"), S.C. Code Section 1-23-10 et seq. Regulation Development actions include promulgating new regulations, amending existing regulations, and repealing existing regulations. 400: Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives. 700: Not Adopted This is consistent with other regulations

		901A: Partially Adopted The Client is not a Client until acceptance; therefore, acceptance is an understood criterion 901B: This is not consistent with the definition of home birth 901C: Adopted. Sections 900 and 1200. This regulation does not prohibit televisits according to South Carolina statute nor does it prohibit it from being recorded in the Client's record. 901D Partially Adopted The regulation allows Clients to be accepted after the timeframe specified for the physical examination provided that the client has the physical examination prior to be accepted physician. 1100: Partially Adopted. Section 1300. (regarding medical consultations and referrals). Any condition that requires consultation is considered to move the client beyond a low-risk pregnancy determination. The client has the right to consent to care that may possibly return her to a low-risk determination or to refuse the care. 1200: Not Adopted. Misoprostol is not approved by the U.S. Food and Drug Administration for postpartum hemorrhaging. Any such use is considered an off-label use. This medication is also used in combination with another drug to end a pregnancy. The medication may also be used for induction of cervical softening and dilation in labor. The main problems cited for the medication are hyperstimulation, uterine rupture, and placental abruption. Oxytocin alone is the recommended uterotonic drug for the treatment of postpartum hemorrhage. 1300: This is consistent with other regulations. 1400: Partially Adopted. Section 1300. (regarding medical consultations and referrals). Any condition that requires consultation is considered to move the client beyond a low-risk pregnancy determination. The client has the right to consent to care that may possibly return her to a low-risk determination or to refuse the care. 1500: Not Adopted. When events during intrapartum and/or postpartum move the pregnancy, birth, and/or condition of the client or neonate beyond the scope of midwifery care, the client and/or neonate are no longer considered low-risk and a transfer of care is required. Clients have the right to refuse care, treatment or services according to the laws of South Carolina. 1800: Not Adopted. (regarding the midwife advisory council) S.C. 44-1-60 lays out the process for appeals related to Department decisions . Per SC Code 44-1-140 the Department may promulgate and enforce rules and regulations for public health. The South Carolina Department of Health and Environmental Control ("DHEC" or "Department") develops regulations in accordance with the South Carolina Administrative Procedures Act ("APA"), S.C. Code Section 1-23-10 et seq. Regulation Development actions include promulgating new regulations, amending existing regulations, and repealing existing regulations.

see attachment B.11

NAME	SECTION	DEPARTMENT RESPONSE
101.Danielle Popham	400	Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives.

To whom it may concern,

I ask that Vaginal Birth After Cesarean (VBAC) not be banned for homebirth with a midwife in the state of South Carolina.

Vbac has lower risks than repeat cesarean and most hospitals in my area have high cesarean rates. The risk of uterine rupture for VBAC is less than 2% which means you have a 98+% chance at achieving VBAC.

A lot of VBAC moms would love the opportunity to birth at home in their own comfortable environment and we want the chance to have a midwife for care.

Hospitals are generally not okay with family centered birth. You are only allowed 2 people in the room during delivery at my local hospital and this makes me disappointed as I'd like the chance to have my husband, mom and a doula. If I were free to birth at home with a midwife, I could have all three and my daughter.

Please do not ban VBAC from midwifery practice and allow homebirth to become normal!

Thank you,

VBAC Mama, Danielle Popham

NAME	SECTION	DEPARTMENT RESPONSE
102.Denese Norris	400, 1100, 1200	Not Adopted. Not Adopted. S.C. 44-89-60(4) requires that a physician make a written determination that the planned birth is low risk. Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives. Not Adopted. Misoprostol is not approved by the U.S. Food and Drug Administration for postpartum hemorrhaging. Any such use is considered an off-label use. This medication is also used in combination with another drug to end a pregnancy. The medication may also be used for induction of cervical softening and dilation in labor. The main problems cited for the medication are hyperstimulation, uterine rupture, and placental abruption. Oxytocin alone is the recommended uterotonic drug for the treatment of postpartum hemorrhage.

South Carolina midwives, health department, and legislators worked together in the 1970's to develop a set of midwifery regulations that were the basis of excellent homebirth regulations in states across the nation. SC was cutting edge!

These regulations evolved over subsequent decades in mostly positive ways, but in the past 15 years, the health department has turned away from the wisdom of the midwives to rely on advice from professionals who have never even attended an out-of-hospital birth of any kind, or even worked in close conjunction with families who prefer to deliver their babies at home or birth center.

Physicians must NOT have veto power over homebirths. While their input is often important and helpful, they cannot be given the final word on where a woman gives birth.

Further more, VBAC moms deserve the same informed choice as any other moms. The majority of states where midwifery is legal clearly recognize this- why don't we?

Here is my personal story : I had my first c/s for a breech baby. My 2nd, 3rd and 4th babies were VBAC's in the hospital with a supportive OB. They weighed 10, 10.5 and 8.5 lbs. I am not nor was I ever a diabetic or gestational diabetic. My 5th was going to be a homebirth but was breech so I had another c/s. My 6th baby was to be a homebirth with a licensed midwife but toward the end of my pregnancy DHEC changed the midwives' regulations to prohibit midwives from attending VBAC's at home in SC. My husband and I prayerfully decided to have an unattended homebirth. She weighed 10 lbs. I am a nurse of 35 yrs. I knew the risks involved. I hated that it came to having an unattended birth when a skilled midwife COULD have attended.

I know that I don't know enough to give advice on every line of the 2020 proposed midwifery regulations- but I know that the current Licensed Midwives do, and the fact that they are being ignored on crucial aspects of these regulations is disturbing on many levels.

The proposed regulations as they now stand are insufficient and should be rewritten prior to submission for legislative review.

Misoprostol is a lifesaving medication for control of postpartum hemorrhage. It should NOT be banned from use by sc midwives. It is currently still being used quite regularly at Prisma Health Richland. If it is so unsafe I don't understand why it is being used there.

As a stakeholder I disagree with many of the regulations imposed upon the midwives of SC.

Sincerely,

Denese Norris

NAME	SECTION	DEPARTMENT RESPONSE
103.Gabriela Henderson	400, 900, 1100, 1200	Not Adopted. Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives. Not Adopted. S.C. 44-89-60(4) requires that a physician make a written determination that the planned birth is low risk. Adopted. Sections 900 and 1200. This regulation does not prohibit televisits according to South Carolina statute. Not Adopted. Misoprostol is not approved by the U.S. Food and Drug Administration for postpartum hemorrhaging. Any such use is considered an off-label use. This medication is also used in combination with another drug to end a pregnancy. The medication may also be used for induction of cervical

		softening and dilation in labor. The main problems cited for the medication are hyperstimulation, uterine rupture, and placental abruption. Oxytocin alone is the recommended uterotonic drug for the treatment of postpartum hemorrhage.

To Whom it May Concern,

I have many concerns about the proposed regulations regarding the future of Midwifery in the State of Sourh Carolina. Both as a homebirth client and a student midwife, I value the expertise of the midwives in this state. To be quite honest, it is incredibly difficult to convey the level of dedication these women have to their profession. With that being said, the dedication, training and hours these women put in make them some of the most trustworthy professionals in the birth world. They are a credit to the birth profession and vital in community-based health care.

The ongoing disregard of the state midwives and the Midwifery Advisory Council's advice concerning the updating of these regulations is insulting. I beseech you to listen to and trust these LICENSED MIDWIVES. They are THE SPECIALIST in out-of-hospital birth!

When considering Vaginal Birth After Cesarean Section (VBAC) DHEC should recognize a woman's bodily autonomy and her confidence in its ability to birth what it has grown and created. Many Obstetricians agree that a trial of labor should always be allowed. Licensed midwives have the ability and knowledge to decipher when a birth is not progressing as expected and make a last minute transfer. Homebirth VBAC should not be forbidden. The decision about where to birth should always be between a mother and her care providers, and include full informed consent even when it follows a cesarean. Across the state birthing women are choosing to have their babies unassisted due to these outrageous restrictions rather than give birth again in a hospital. No woman should be forced to choose between a homebirth without a provider and a hospital birth.

In more rural parts of the state, hospital care and delivery as well as physician examination are not as readily available. This creates disparity for lower income Caucasian and African American women thus creating a further divide in care. If our goal is really to save lives then we should allow women to seek medical consultations with already trusted medical professionals via telehealth. Making these provisions breaks down generational and financial barriers to proper prenatal care and allows women to seek care at their comfort level and give birth uninhibited in an environment surrounded by family and loved ones.

Additionally, I'm concerned that DHEC finds the need to prohibit midwives from administering Misoprostol, stating in proposed regulations that postpartum hemorrhage is an off-label use Misoprostol. Misoprostol is a life-saving drug used off-label in every hospital across the United States.

The article Uses of Misoprostol in Obstetrics and Gynecology found on PubMed states, "However, it remains an important option for treating postpartum hemorrhage when other agents are not available or fail. A descriptive study showed that 1000 μg of rectally administered misoprostol, when given to patients who failed to respond to oxytocin and ergotamine, controlled postpartum hemorrhage within 3 minutes."

As I'm sure you are aware, every second counts when stopping postpartum hemorrhages and the prohibition of this medication could mean the difference in life or death.

Finally, It is imperative that midwives be included in the perinatal levels of care for immediate access to the appropriate department. In the event of transfer minutes matter and subjecting laboring women to emergency room waiting rooms, exposing them to viruses and other unrelated emergencies is ridiculous and unnecessary. It would be more efficient for transfers to be take straight to labor and delivery.

I appreciate your time in hearing my concerns.

Sincerely,
Gabriela Henderson

NAME	SECTION	DEPARTMENT RESPONSE

104.Jessica Beck	400, 1200	Not Adopted. Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives. Not Adopted. Misoprostol is not approved by the U.S. Food and Drug Administration for postpartum hemorrhaging. Any such use is considered an off-label use. This medication is also used in combination with another drug to end a pregnancy. The medication may also be used for induction of cervical softening and dilation in labor. The main problems cited for the medication are hyperstimulation, uterine rupture, and placental abruption. Oxytocin alone is the recommended uterotonic drug for the treatment of postpartum hemorrhage.
see attached B.12		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
105.Lindsay Millwood Certified Birth Doula, herbalist, RBPR	400, 1200	Not Adopted. Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives. Not Adopted. Misoprostol is not approved by the U.S. Food and Drug Administration for postpartum hemorrhaging. Any such use is considered an off-label use. This medication is also used in combination with another drug to end a pregnancy. The medication may also be used for induction of cervical softening and dilation in labor. The main problems cited for the medication are hyperstimulation, uterine rupture, and placental abruption. Oxytocin alone is the recommended uterotonic drug for the treatment of postpartum hemorrhage. Clarification regarding Perinatal Levels of Care: This comment does not pertain to R.61-24. Perinatal levels of care are regulated within R.61-16.
see attachment B.13		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
106.Maria Dahl	400, 1200	Not Adopted. Not Adopted. Misoprostol is not approved by the U.S. Food and Drug Administration for postpartum hemorrhaging. Any such use is considered an off-label use. This medication is also used in combination with another drug to end a pregnancy. The medication may also be used for induction of cervical softening and dilation in labor. The main problems cited for the medication are hyperstimulation, uterine rupture, and placental abruption. Oxytocin alone is the recommended uterotonic drug for the treatment of postpartum hemorrhage. Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives.
To Whom it May Concern, I would like to share two concerns regarding the Proposed Regulations for Licensed Midwives		

(NPR_61-24).

First, I understand Section 1300 to restrict Licensed Midwives from obtaining and administering misoprostol for postpartum hemorrhage. Misoprostol is WHO approved and is often recommended for use in women who may not have access to hospitals for delivery. It follows that it should also be recommended for women who choose to birth in a location other than a hospital. To restrict its use among Licensed Midwives not only jeopardizes the woman's health but also reflects negatively on the state's view of a woman's autonomy; to choose a birthing location is an important and intimate decision. To restrict life-saving medication in only some birthing options (e.g. home birth attended by licensed midwife) communicates a lack of care by the state for its female population.

Second, I understand Section 400 to prohibit VBAC's in a home-birth setting. I would submit that VBAC's for low-risk mothers be allowed in a home birth setting, similar to other countries such as Germany, who allow women this freedom in low-risk cases.

I have recently moved to South Carolina and am very much enjoying residing in the state. I was very happy to discover the option of home birth as I start my family in South Carolina, and I would like to request that the options of women who desire a home birth and the dignity of the midwife profession not be compromised by new restrictions.

Thank you for your time!

Maria M. Dahl

NAME	SECTION	DEPARTMENT RESPONSE
107.Michelle Crooker	400, 1100	Not Adopted. Not Adopted. S.C. 44-89-60(4) requires that a physician make a written determination that the planned birth is low risk. Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives.

I did, I didn’t have much time so I just made it brief.

I have multiple concerns about the proposed regulation changes, starting with WHO is writing these and what knowledge of out-of-hospital birth do they have? What qualifications do they have to make these regulations from an informed place? Why is DHEC not listening the the Midwife Advisory Council, and is instead **reducing** their authority? Seems you are only providing lip service to giving women the options they want but actually trying to force all women into a one-size-fits-all system when it comes to their prenatal, birth & postpartum care.

Two big concerns: first- physicians should NOT get veto power over midwives. Midwives are qualified professionals who are more familiar with the patient, the situation and with physiological birth in general. Physicians have their roles but uncomplicated natural birth doesn’t need to be one.

Second- VBAC moms need options. Let women, their midwives and their consulting physicians make a decision about whether a mother is a good candidate for homebirth, we do not need a blanket HBAC ban.

As the COVID situation has shown, our medical model has many flaws and weaknesses— birth is one aspect of medical care that can certainly be removed from under the hospital’s umbrella in many cases. Many moms don’t want to expose themselves or their newborns to all kinds of diseases— ie birth in a

hospital. Let's allow PARENTS to make these decisions, not a random board who is not even listening to the midwives appointed to supposedly advise them. Thank you for your time, Michelle Crooker Campobello SC		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
108.Palmetto Association of Licensed Midwives	400	Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives.
see attachment B.14		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
109.Palmetto Association of Licensed Midwives	1200	Partially Adopted. Section 1200. (regarding Medications). A client has the right to self-administer any medications that her physician has prescribed. It is not within the scope of direct entry midwives to administer all medications available.
See Attachment B.15		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
110.Palmetto Association of Licensed Midwives	1100, 1300	Not Adopted. Not Adopted. Requiring a Physical Examination rather than a Medical Consultation is consistent with other regulations. Not Adopted. S.C. 44-89-60(4) requires that a physician make a written determination that the planned birth is low risk.
see attached B.16		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
111.Danielle Shealy	300, 1000, 1200, 1500, 1700, 1800	Not Adopted. Clarification: Regulation was changed to reflect S.C. Section 44-1-140. Not Adopted. Each client has the right to be informed of available midwifery services and of related charges. This is consistent with other Departmental regulations. Not Adopted. The Department determined this is not within the scope of direct entry midwifery. Routine antibiotic prophylaxis is not recommended for women with uncomplicated vaginal birth. Not Adopted. Misoprostol is not approved by the U.S. Food and Drug Administration for postpartum hemorrhaging. Any such use is considered an off-label use. This medication is also used in combination with another drug to end a pregnancy. The medication may also be used for induction of cervical softening and dilation in labor. The main problems cited for the medication are hyperstimulation, uterine rupture, and

		placental abruption. Oxytocin alone is the recommended uterotonic drug for the treatment of postpartum hemorrhage. Not Adopted. When events during intrapartum and/or postpartum move the pregnancy, birth, and/or condition of the client or neonate beyond the scope of midwifery care, the client and/or neonate are no longer considered low-risk and a transfer of care is required. Clients have the right to refuse care, treatment or services according to the laws of South Carolina. Not Adopted. The tuberculosis requirements are based on the Department's South Carolina's Tuberculosis Control Program and CDC guidelines. Not Adopted. (regarding the midwife advisory council) S.C. 44-1-60 lays out the process for appeals related to Department decisions . Per SC Code 44-1-140 the Department may promulgate and enforce rules and regulations for public health. The South Carolina Department of Health and Environmental Control ("DHEC" or "Department") develops regulations in accordance with the South Carolina Administrative Procedures Act ("APA"), S.C. Code Section 1-23-10 et seq. Regulation Development actions include promulgating new regulations, amending existing regulations, and repealing existing regulations.
see attachment B.17		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
112.Palmetto Association of Licensed Midwives	1800	Not Adopted. (regarding the midwife advisory council) S.C. 44-1-60 lays out the process for appeals related to Department decisions . Per SC Code 44-1-140 the Department may promulgate and enforce rules and regulations for public health. The South Carolina Department of Health and Environmental Control ("DHEC" or "Department") develops regulations in accordance with the South Carolina Administrative Procedures Act ("APA"), S.C. Code Section 1-23-10 et seq. Regulation Development actions include promulgating new regulations, amending existing regulations, and repealing existing regulations.
see attachment B.18		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
113.Palmetto Association of Licensed Midwives	1500	Not Adopted. Not Adopted. When events during intrapartum and/or postpartum move the pregnancy, birth, and/or condition of the client or neonate beyond the scope of midwifery care, the client and/or neonate are no longer considered low-risk and a transfer of care is required. Clients have the right to refuse care, treatment or services according to the laws of South Carolina.

		Clarification regarding Perinatal Levels of Care: This comment does not pertain to R.61-24. Perinatal levels of care are regulated within R.61-16.
see attached B.19		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
114.Robin Gause	n/a	Acknowledged
Good morning, to whom this may concern. My name is Robin Gause, and I am consumer of home birth midwives. My grandson was born at home. I do not agree with the regulations you are proposing. These midwives are thoroughly trained in what they do, but with what you are proposing will not allow them to function in the best interest of the consumers who use midwives. I believe in using medical doctors when needed, but normal birth is not a medical issue. Please vote no for these regulations, and let us the consumer continue to exercise our freedom of choice when it comes to child birth. I can be reached at this email address robingause50@gmail.com. or 803-450-3144. Sencerily, Robin Gause		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
115.Sarah Davis	400, 1200, 1300, 1500, 1800	Not Adopted. Not Adopted. (regarding the midwife advisory council) S.C. 44-1-60 lays out the process for appeals related to Department decisions . Per SC Code 44-1-140 the Department may promulgate and enforce rules and regulations for public health. The South Carolina Department of Health and Environmental Control ("DHEC" or "Department") develops regulations in accordance with the South Carolina Administrative Procedures Act ("APA"), S.C. Code Section 1-23-10 et seq. Regulation Development actions include promulgating new regulations, amending existing regulations, and repealing existing regulations. Not Adopted. Requiring a Physical Examination rather than a Medical Consultation is consistent with other regulations. Not Adopted. The requirement for client signature is consistent with other Department regulations. Not Adopted. When events during intrapartum and/or postpartum move the pregnancy, birth, and/or condition of the client or neonate beyond the scope of midwifery care, the client and/or neonate are no longer considered low-risk and a transfer of care is required. Clients have the right to refuse care, treatment or services according to the laws of South Carolina. Not Adopted. Misoprostol is not approved by the U.S. Food and Drug Administration for postpartum hemorrhaging. Any such use is considered an off-label use. This medication is also used in combination with another drug to end a pregnancy. The medication may also be used for induction of cervical softening and dilation in labor. The main problems cited for the medication are hyperstimulation, uterine rupture, and placental abruption. Oxytocin alone is the recommended

		uterotonic drug for the treatment of postpartum hemorrhage. Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives.

To whom it may concern,

I would like to submit my comments in response to the Notice of Proposed Regulation for Licensed Midwives. I have given birth twice, both in the comfort and safety of my home, and both without complications or unnecessary interventions. My midwife is a wealth of knowledge and competency, and I am disappointed that her profession is not more respected in the health field. I hope that my remarks can advocate for the profession of Midwifery the way that my Midwife has advocated for me as a client and a mother.

In regards to section 1800, I believe that the existence of the Midwife Advisory Council is essential to DHEC. Please do not change the current definition of MAC outlined in section 1800. I would like to see DHEC do a better job of listening to MAC about proposed regulations in the field.

In addition, the title of the Section 1100 MUST be changed from Physical Examination to Client Medical Consultation with no written, signed documentation required by regulation. Documentation in the chart is sufficient. Why am I, the client, being forced to receive a Physical Examination. In Section 1300, the requirement for Client's signature for a midwife consulting with a medical provider must be removed. The requirements for consultation with a physician in the new regs are extreme and would reduce access to community birth and inhibit the profession of Licensed Midwifery.

Under Section 1500- Transfer of Care I would like the requirement of my midwife to call 911 REMOVED. This is an action that is not necessarily in my best interest, and I, the patient should have full authority to make this decision or deny the option if I see fit. In addition, Licensed Midwives should be listed as a maternity provider within the Perinatal Levels of Care, and the families using a midwife should be given the same access to the emergency system as every other maternity provider in SC (physicians, smaller hospitals, college and prisons infirmaries have access to this Perinatal Level of Care transfer system).

Section 1300: Misoprostol needs to be incorporated as an emergency measure. It is a safe, very inexpensive and effective medication for postpartum hemorrhage. Ensuring that midwives can administer this medication might prevent an unnecessary transfer to hospital and it could save lives.

Under section 400, it is proposed that midwives be prohibited to perform a Vaginal Birth for someone who has had a previous Cesarean Section. Vaginal Birth After Cesarean, with a previous low transverse incision, should be considered low risk with assessment from the Licensed Midwife and after consultation with a physician. 400. D.2. Add: "classical" before cesarean.

Thank you for your time,

Sarah Davis

NAME	SECTION	DEPARTMENT RESPONSE
116.Jennifer Collins CNM	400, 1100, 1200, 1300	Partially Adopted.

		Not Adopted. S.C. 44-89-60(4) requires that a physician make a written determination that the planned birth is low risk. Partially Adopted. Section 1300. (regarding medical consultations and referrals). Any condition that requires consultation is considered to move the client beyond a low-risk pregnancy determination. The client has the right to consent to care that may possibly return her to a low-risk determination or to refuse the care. Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives. Not Adopted. Misoprostol is not approved by the U.S. Food and Drug Administration for postpartum hemorrhaging. Any such use is considered an off-label use. This medication is also used in combination with another drug to end a pregnancy. The medication may also be used for induction of cervical softening and dilation in labor. The main problems cited for the medication are hyperstimulation, uterine rupture, and placental abruption. Oxytocin alone is the recommended uterotonic drug for the treatment of postpartum hemorrhage.

To whom it may concern:

My name is Jennifer Collins, and I have been a practicing Certified Nurse Midwife since 2005. I have practiced in both in and out-of-hospital settings, and have attended over 1300 births.

I worked closely with the SC Licensed Midwives in a consulting capacity for years and found them to be safe and effective. There is a segment of our population that strongly desires the care offered by midwives in a home birth setting. Without them, I fear that women will choose to have an unattended birth and that could be disastrous.

The supervisory language in the proposed regulations- requiring care providers other than the CPM to have ultimate and repeated responsibility for determining the Client's risk status- is unnecessary and onerous for both Licensed Midwife, Consulting Care Provider and Client. In my experience, the LMs reach out when necessary, and care very much about the health and safety of their clients. I trust them.

As far as VBACs go- A respected doctor once told me that in four decades of practice the only uterine ruptures he witnessed were not TOLACS / VBAC's. The first was a woman in spontaneous labor with her third baby (no prior uterine surgery). The second a woman at 22 weeks being induced for fetal demise. The third woman was a previous cesarean sitting at home, not in labor, at 32 weeks who developed sudden pain. While this is anecdotal, it illustrates to me the rarity of the incident that is most concerning when contemplating VBACs.

Although I am a hospital-based midwife, or perhaps because I am a hospital-based midwife, I clearly recognize the challenges faced by women attempting to VBAC in an institutional setting. They should be able to have another choice, especially in SC where VBAC supportive hospitals are few and far between. The statistics do not support banning well-managed out-of-hospital VBACs.

I am happy to see sutures, IVs and Vitamin K administration being added to the LMs scope of practice.

I am concerned that there appears to be a push against the emergency use of misoprostol by an LM. Hemorrhage is a leading cause of morbidity and mortality. Every single person caring for women during delivery must be stocked with pitocin and misoprostol. The World Health Organization advised the

administration of prophylactic uterotonics during the third stage of labor by timely and appropriate management. In the richest country in the world, why would we allow our citizens to give birth in third world country conditions, i.e. sans effective and safe medications to prevent hemorrhage? I'm absolutely baffled by this.

I hope that you will consider the input by licensed midwives in this state. The goal should be to make birth more safe by listening to them, and by listening to women. Heed the words of your front line birth workers.

Thank you,
Jennifer Collins
CNM

NAME	SECTION	DEPARTMENT RESPONSE
117.Compassionate Care Doula Services	400, 900, 1200	Not Adopted. Not Adopted. Misoprostol is not approved by the U.S. Food and Drug Administration for postpartum hemorrhaging. Any such use is considered an off-label use. This medication is also used in combination with another drug to end a pregnancy. The medication may also be used for induction of cervical softening and dilation in labor. The main problems cited for the medication are hyperstimulation, uterine rupture, and placental abruption. Oxytocin alone is the recommended uterotonic drug for the treatment of postpartum hemorrhage. Not Adopted. In South Carolina the insertion of a catheter requires a physician's order, and is only within the scope of practice for a licensed registered nurse or an authorized healthcare provider as defined in the regulation. Adopted. Sections 900 and 1200. This regulation does not prohibit televisits according to South Carolina statute. Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives.

DHEC-

While I appreciate Health Licensing taking the time and effort to update Regulation 61-24 in such a way that would allow SC Licensed Midwives to offer more that is in their scope of practice, such as suturing and IVs and neonatal Vitamin K, I am very concerned that DHEC has left that important job of properly modernizing our LM's regulations only half completed. There are some glaring omissions in full access to tools such Misoprostol, in/out catheters, and clarification concerning televisits that need to be remedied.

Furthermore, denying the choice of midwifery care to mothers wishing to have a vaginal birth after a previous cesarean section outside of the hospital setting is unacceptable. OOH VBACs are legally and safely practiced in many states and countries, and DHEC has no right to attempt to deny that choice to SC mothers and families. It is a decision that needs to be made by a mother, her family, and her care providers- not dictated by the state.

I will also come out and protest on Bull st, if it's necessary. Please make decisions for the birthing mom.

Sincerely,

Dawn Oliver CDI(TDA)
Www.Compassionatecaredoula.com

NAME	SECTION	DEPARTMENT RESPONSE
118.Taj Cummings	400, 1100, 1300	Not Adopted. This comment partially refers to internal Department process rather than amendments to the regulation Not Adopted. S.C. 44-89-60(4) requires that a physician make a written determination that the planned birth is low risk. Not Adopted. (regarding the Physician's signature). S.C. Code 44-89-60(4) requires a physician to make a written determination that the planned birth is low risk. The requirement for signatures for verification are consistent with other Department regulations. Not Adopted. Any condition that requires consultation may move the client beyond a low-risk pregnancy, and a consultation is required to be obtained from an physician or other authorized healthcare provider in order to possibly return the client to a low-risk pregnancy determination. Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives.

DHEC-

At this point, I hope that you have received the letters of the many concerned voices that are making an effort to participate in our community. I also ask that you would please provide any and all research/studies that have informed the regulations proposed. This would help us to gain a sense of what evidence this regulation is proposed from.
Thank you for your efforts to protect the health of women and children- however, many sections of the newest set of proposed midwifery regulations appear to move beyond protection into control of women and families' medical freedoms, without nearly enough practical or scientific justification.

Informed consent and refusal are important in any health care setting- but the new proposed regulations include sections that seem to push beyond what are reasonable informed consent requirements. Furthermore, the new proposals do not appear to have taken the advice of the midwives- who are the experts in OOH (out of hospital) births and OOH clients- enough into account.
The practice of OOH midwifery cannot be inextricably tied to physicians (or the CNMs who work under them) granting a woman permission to birth at home, as is essentially outlined in Section 1100.2.A in the new proposed regulations. First- it is a conflict of interest. Second- physician concerns about liability will make this kind of written, signed "permission" very difficult to obtain.

Along the same lines, the requirements outlined Section 1300, in particular Section 1300 A, are overly onerous, and would be impossible in real life. This level of physician oversight described in those passages hinders the midwife from actually serving and helping mothers and babies. Midwives count on consultations and referrals to doctors, CNMs and hospitals, and most midwives have an ongoing relationship with at least one doctor or CNM, but the micromanagement described in Section 1300 would scare off any practitioner. The OOH-friendly providers cannot be available 24/7 and it is just too easy for a practitioner not familiar with OOH birth to insist on inappropriate and unnecessary transfers

of care.
This brings us to VBACs. According to the Healthy People 2020 goals, we should Reduce cesarean births among low-risk women giving birth with a prior cesarean birth . The goal for this is a 10% reduction. However, South Carolina needs to be a part of this goal.
With a proper informed consent contract- which DHEC could do an excellent job of writing, if they wished- a woman with a previous cesarean should be able to make her own choice- in conjunction with her family and care providers- about where she wants to give birth. This choice cannot and should not be dictated by the state.
Please support the licensed midwives and the families they serve. Give them regulations that actually help and not hinder their work.
Thank you-

Taj S. Cummings

NAME	SECTION	DEPARTMENT RESPONSE
119.K.Morgan	400	Not Adopted. VBACs are not low-risk deliveries, are not within the scope of practice in the current regulation, and are not included in the scope of practice in the NFR.

I feel this is infringing upon our rights to medical bodily autonomy. These midwives are certified and licensed to practice prenatal care. Taking this option away from women is going to push women to labor how they want to labor. This is against the constitution to say a woman, a mother, cannot have her baby the way she would like. DO NOT BAN HBAC/VBAC!

NAME	SECTION	DEPARTMENT RESPONSE
120.Wendy Bramble	n/a	Acknowledged.

Dear Sir or Madam:

I'm writing regarding the current plans by the South Carolina Department of Health to update the regulations under which Licensed Midwives are allowed to practice in the state. My daughter, Nicole Lavallee, a Certified Profession Midwife, has practiced in South Carolina for more than two decades and safely delivered more than 600 babies during that time. Many of the proposed changes would make her job more difficult for her and more dangerous for the patients she serves. Now in the time of the pandemic, when home births are especially desired by many, this seems foolhardy.

I can understand doctors' concern about home births, for I had it, too, as did my father, a family doctor who delivered thousands of babies while in practice. For many years we both were alarmed by my daughter's career choice, feeling out-of-hospital births dangerous. However, as Nicole's number of successful home births surged, I and, more importantly my dad, came to see how a trained, caring professional can bring a home birth to a positive and optimal outcome and how this option can be a responsible choice for informed parents. By the end of his life, he was proud of the work she does so well.

Most doctors have little experience with births outside hospitals and little education about the benefits of home birth. Often their initial reaction is to consider all such births dangerous. But doctors, like all of us, shouldn't have veto power over situations they don't always understand. Concern by any medical professional, including those who work both within and outside of hospital settings, about untrained, unlicensed birth attendants taking charge of birth situations is warranted. But establishing regulations to limit the ability of well-trained, licensed and competent midwives to practice effectively pushes expectant moms toward this most undesirable choice.

Informed consent and educated refusal of medical procedures is and should be a hallmark of all medical practices. The regulations as proposed would negatively impact pregnant women's ability to have options in this regard.

Just as important as the points above is a concern about making decisions to change important regulations pertaining to health matters in a time of Covid, when no open meetings can be safely held to get input from the broader public As a mother, I'm quite concerned about my daughter going to a open meeting where anti-maskers could expose her unnecessarily to illness. Please delay any discussion about the future of regulations covering midwives in South Carolina to a later date. It's a prudent and appropriate decision.

Sincerely,
Wendy Bramble

NAME	SECTION	DEPARTMENT RESPONSE
121.Faith Staton	400, 1200, 1500	Not Adopted. Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives. Not Adopted. Misoprostol is not approved by the U.S. Food and Drug Administration for postpartum hemorrhaging. Any such use is considered an off-label use. This medication is also used in combination with another drug to end a pregnancy. The medication may also be used for induction of cervical softening and dilation in labor. The main problems cited for the medication are hyperstimulation, uterine rupture, and placental abruption. Oxytocin alone is the recommended uterotonic drug for the treatment of postpartum hemorrhage. Not Adopted. When events during intrapartum and/or postpartum move the pregnancy, birth, and/or condition of the client or neonate beyond the scope of midwifery care, the client and/or neonate are no longer considered low-risk and a transfer of care is required. Clients have the right to refuse care, treatment or services according to the laws of South Carolina.

To whom it may concern:

I am a mother of two healthy boys. One was born at a hospital under the care of CNM and the other was born in the comfort and relaxation of home under the care of a Licensed Midwife. While I cherish both of my labors and births, my homebirth was by far more peaceful and enjoyable than my hospital birth despite receiving an epidural at the hospital.

As human beings with free will and bodily autonomy, we deserve the right to choose where we give birth and who we'd like to attend our birth. By enacting further restrictions on homebirth, you're only opening the door for women to give birth unassisted for fear of having to give birth in a hospital. So many women have PTSD from their hospital births and refuse to go through that again, especially mom's who've had unexpected cesareans. To automatically deny a woman the option to birth at home because of a previous cesarean is ignorant and unfounded. Up-to-date research and studies support the safety of VBAC.

DHEC should also ensure that LM have the ability to administer anti-hemorrhage medication in the event of postpartum hemorrhaging. It's unfathomable as to why 'misoprostol' is not on the list of medications for LM to administer. Furthermore, if an emergency transfer is required, mothers and midwives should be sent to labor & delivery and not through the ER just like any other laboring mother. Forcing a mother to wait in the ER rather than sending her to labor & delivery is unethical and discriminatory.

Thank you for your time and attention. Mothers and babies deserve options now more than ever.

NAME	SECTION	DEPARTMENT RESPONSE
122.Lisa Byrd	302, 901, 1000, 1100, 1200	Partially Adopted. 302.C - Adopted 901F - Adopted There is nothing preventing instruction from also being given postpartum 1000.D - Adopted Clarification: No section or part of the regulation were drafted by persons outside of DHEC. DHEC is solely responsible for the promulgation amending and repealing of healthcare regulations. 1100.B.2 - Not Adopted This is consistent with other regulations. 1200.B.5 - Partially Adopted. Section 1200. (regarding Medications). A client has the right to self-administer any medications that her physician has prescribed. It is not within the scope of direct entry midwives to administer all medications available. 1200.B.6 - Not Adopted Administering antibiotics is not within the midwife's scope of care 1200.B.8 - Not Adopted Administering anaphylaxis medications is not within the scope of midwifery care best practice

see attachment B.20

NAME	SECTION	DEPARTMENT RESPONSE
123.Tina Johnson Travelstead	400	Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives.

To whom it may concern:

Good afternoon. My name is Tina Travelstead and I am sending this to voice my opinion for midwives to be allowed to continue practicing excellent care for vbac patients such as myself. I am due in the beginning of December and have my heart set on a calm and peaceful home birth with the midwives I've chosen. With my first child I was urged into a c section and looking back now I wish I had known there were other options for me. My body felt very forced and the decision did not feel like my own, and I look back on it with more regret than I do a beautiful experience. With my second I got educated and went on to have a vaginal birth with absolutely no complications. Here I am now with a third and want nothing more than to let my body do what it was made for. Birth don't have to be a medical procedure, it can be a natural process, and with the help of an experienced midwife by your side it can and will give you a feeling of power. Being able to advocate for myself and birth how I want really makes a

difference for me. C sections are risky, it's a major surgery, and the rate of c sections are steadily climbing when they don't have to. Please consider not taking away a right that I have by choosing to allow midwives to aid me in bringing my beautiful baby into the world. Thank you for your time.

Sincerely,
Tina Travelstead

NAME	SECTION	DEPARTMENT RESPONSE
124.Alicia Adams	n/a	Acknowledged. Clarification: This comment partially does not pertain to amending R.61-24 but to the internal processes of the Department.

Please reconsider your proposed regulations and take the advise of the Midwifery Advisory Council (MAC). I've had 4 births with midwives, 2 at home. We need this option and right for women in our communities. Thank you.

Alicia Adams,
Greer, SC

NAME	SECTION	DEPARTMENT RESPONSE
125.Susan Smart LM	n/a	Acknowledged. Clarification: This comment partially does not pertain to amending R.61-24 but to the internal processes of the Department.

September 28, 2020

Re: Proposed Changes to Reg. 61-24

It is regrettable that, once again, SC DHEC has bypassed the avenue provided by legislation in Reg. 61-24 to utilize the expertise of the Midwifery Advisory Council. The Department has violated the intent of this regulation by using others outside the MAC whom the Department continues to refuse to identify despite direct requests for that information. There is a lack of transparency and an obvious intent to give only lip service to the MAC while trying to push through these proposed changes in the midst of a pandemic which limits the full exercise of citizens' rights to be fully able to respond. It is even more regrettable that DHEC is trying to further limit the purposes of the MAC in these proposed regulations to only licensing advice. It is evident in these proposed regulations that NO ONE at DHEC has knowledge of midwifery in the Community Birth Setting. The Midwifery Advisory Council was established in the initial Regulation for this very reason and rightly so.

In addition to the well documented problems that are being submitted by the Midwifery Advisory Council and the Palmetto Association of Licensed Midwives (PALM), the proposed regulations contain so many inappropriate changes to the safe functioning of midwives serving women and families, that is impossible for this proposed Regulation to move forward. The proposed regulation must return to the Midwifery Advisory Council and SC DHEC must listen to this Council. Then we can all work together to move forward a regulation that truly works for the health, safety, well being, and family support that midwifery clients are seeking.

Sincerely,

Susan Smart, Licensed Midwife		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
126.Sharon Finke	400, 1100	Not Adopted. Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives. Not Adopted. S.C. 44-89-60(4) requires that a physician make a written determination that the planned birth is low risk.
To whom it may concern- As a South Carolina resident and healthcare provider with a longtime affiliation with Licensed Midwives, it greatly concerns me to see our state's health department taking steps during a pandemic (especially during this pandemic we're many people can't show up in support of this) to undermine women's healthcare choices during pregnancy. My Body, My Child, My Family, My Choice Women and families should be able to make the final decisions about their healthcare at all times, in conjunction with information and advice from their doctors and other healthcare professionals. There is too much language in the newly proposed midwifery regulations that gives physicians too much ultimate control over a family's decision where and with whom to give birth. The revision needs to be rewritten with the input of the midwives. Out-of-hospital VBACs attended by Licensed Midwives should be an option for families who desire it. Thank You Sincerely, Sharon Finke		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
127.Midwife Alliance of North America	400, 1100, 1200	Not Adopted. Not Adopted. S.C. 44-89-60(4) requires that a physician make a written determination that the planned birth is low risk. Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives. Not Adopted. Misoprostol is not approved by the U.S. Food and Drug Administration for postpartum hemorrhaging. Any such use is considered an off-label use. This medication is also used in combination with another drug to end a pregnancy. The medication may also be used for induction of cervical softening and dilation in labor. The main problems cited for the medication are hyperstimulation, uterine rupture, and placental abruption. Oxytocin alone is the recommended uterotonic drug for the treatment of postpartum hemorrhage.
see attachment B.22		
NAME	**SECTION**	**DEPARTMENT RESPONSE**

128.Paul & Robina Wolf	n/a	Acknowledged. Clarification: This comment partially does not pertain to amending R.61-24 but to the internal processes of the Department.

Attention DHEC
I'm emailing to ask you to please avail yourselves of the advice of the Midwifery Advisory Committee (MAC). My own children and grandchild were birthed through mid-wives here in South Carolina and I was highly impressed with their thoroughness and professionalism. I would hate to see any regulation changes passed in South Carolina that would hinder their work or limit our freedom to choose our own health care options.

Please do not Change any regulations without the consultation and approval of the Midwifery Advisory Committee.

Sincerely,
Rev. Paul & Robina Wolff

NAME	SECTION	DEPARTMENT RESPONSE
129.Lisa Johnson	101, 302, 400, 700, 901, 1000, 1100, 1300, 1400, 1500, 1800	Partially Adopted. 101: Not Adopted. The term "Authorized Healthcare Provider" is used consistently in other Department regulations and defined for clarity across the healthcare community. The definition is based on SC Code of Laws 40-43-30 to clarify that only healthcare providers authorized by law may diagnose and prescribe drugs and devices. 101.X: Clarification. The client may take herbal products, vitamins, and nutritional supplements as she wishes. The Midwife is not allowed to administer these products per regulation. 302.C: Adopted. 30.2E: Adopted. Section 300. Clarification: Regulation was changed to reflect S.C. Section 44-1-140. Clarification regarding Violations: The S.C. Code of Laws allows the Department to implement penalties for enforcement. This is consistent with other regulations. 400.D.2: Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives. 700.B.1.a Not Adopted. (regarding face sheets) It is to allow for quick access to that information. 901.F: Nothing prevents the midwife from also providing instructions during postpartum. 1000.D Adopted 1100.A: This is consistent with other regulations. 1100.A.1 Not Adopted This does not restrict the timeframe for entry into care. 1100: Not Adopted. S.C. 44-89-60(4) requires that a physician make a written determination that the planned birth

		is low risk. 1100: Not Adopted. (regarding the Physician's signature). S.C. Code 44-89-60(4) requires a physician to make a written determination that the planned birth is low risk. The requirement for signatures for verification are consistent with other Department regulations. 1200 Not Adopted This is consistent with other regulations 1300 and 1400: This is consistent with the definition in other regulations and across the department. 1500: Not Adopted. When events during intrapartum and/or postpartum move the pregnancy, birth, and/or condition of the client or neonate beyond the scope of midwifery care, the client and/or neonate are no longer considered low-risk and a transfer of care is required. Clients have the right to refuse care, treatment or services according to the laws of South Carolina. 1800: Not Adopted. (regarding the midwife advisory council) S.C. 44-1-60 lays out the process for appeals related to Department decisions . Per SC Code 44-1-140 the Department may promulgate and enforce rules and regulations for public health. The South Carolina Department of Health and Environmental Control ("DHEC" or "Department") develops regulations in accordance with the South Carolina Administrative Procedures Act ("APA"), S.C. Code Section 1-23-10 et seq. Regulation Development actions include promulgating new regulations, amending existing regulations, and repealing existing regulations.
see attachment B.23		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
130.Allison Mugan	400, 1200	Not Adopted. Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives. Not Adopted. Misoprostol is not approved by the U.S. Food and Drug Administration for postpartum hemorrhaging. Any such use is considered an off-label use. This medication is also used in combination with another drug to end a pregnancy. The medication may also be used for induction of cervical softening and dilation in labor. The main problems cited for the medication are hyperstimulation, uterine rupture, and placental abruption. Oxytocin alone is the recommended uterotonic drug for the treatment of postpartum hemorrhage. Clarification regarding Perinatal Levels of Care: This comment does not pertain to R.61-24. Perinatal levels of care are regulated within R.61-16.
see attachment B.21		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
131.Shannon Fleming	n/a	Acknowledged.

		The Department acknowledges that Sandy Glenn submitted the contents of the online petition in full as a public comment. The description of the petition and the signatures can be found at: http://chngit/spJchrMY4L. Clarification regarding

To whom it may concern,

I am writing to you with concerns with potential legislature that could harm pregnant women and the birthing community of South Carolina.
I don't have time to cite studies and evidence but as a doula and a woman who has had two out-of-hospital births, restricting midwives' privileges and women's access to midwifery care will do more harm than good. I fear that by restricting midwives, you are restricting women's access to safe options. The ability to give birth in an environment where women feel safe is imperative to the success of vaginal birth. Many women just are not willing to go to the hospital because they do not feel safe there, for various personal reasons. Some of these women will give birth at home, regardless of whether or not they have a medical professional attending it. By restricting their access to legal midwifery care, you will be forcing these women into unsafe situations.
I implore you to consider the lives of thousands of mothers and babies and let midwives practice legally and safely in South Carolina.

Sincerely,
Shannon Fleming
Home birther and Doula

NAME	SECTION	DEPARTMENT RESPONSE
132.Sandy Glenn, LM, CPM	n/a	Acknowledged. The Department acknowledges that Sandy Glenn submitted the contents of the online petition in full as a public comment. The description of the petition and the signatures can be found at: http://chngit/spJchrMY4L. Clarification regarding Perinatal Levels of Care: This comment does not pertain to R.61-24. Perinatal levels of care are regulated within R.61-16.

In March over 4,000 people had signed the petition and the current number is almost 5000. The petition is directly related to this regulation revision and should be acknowledged as part of public comments. http://chng.it/spJchrMY4L

The petion statement is clear. As a matter of public safety, midwives should be added to the perinatal levels of care in reg 61-16 prior to any regulation revission for 61-24. "Instead of repairing the flawed regulation, DHEC's new proposal continues to restrict equal access for
the consumers of midwifery care."

The proposed regulation to 61-24 states:
A. The Midwife shall immediately initiate a Transfer of Care during intrapartum and postpartum by dialing 911.

These actions are not appropriate for midwife transfers and would be a step backward in are. For three years the Midwifery Advisory Council and other midwife organizations have been asking for The Department to repair an oversight in the hospital regulation that failed to recognize midwives and birth center as a maternity level of care. DHEC's failure with hospital reg. 61-16 is dangerous and should be repaired.

Instead of repairing the flawed regulation, DHEC's new proposal continues to restrict equal access for the consumers of midwifery care.

Earlier in 2020, bills were proposed in both the South Carolina House and Senate to remedy the oversight in Regulation 61-16 Minimum Standards for Licensing. Signatures from a petition in support of the legislative remedy are attached.

NAME	SECTION	DEPARTMENT RESPONSE
133.David Ellenburg	n/a	Acknowledged. The Department acknowledges that Sandy Glenn submitted the contents of the online petition in full as a public comment. The description of the petition and the signatures can be found at: http://chngit/spJchrMY4L. Clarification regarding

I am writing to ask that you listen to the Midwifery Advisory Committee in regards to the recent legislation.
Thanks,
Daivd

NAME	SECTION	DEPARTMENT RESPONSE
134.Brittany Arsenenko	Various Sections	Partially Adopted. PALM's comments were reviewed throughout the revision process and partially adopted.

Dear Sir:

I support the MAC and the PALM recommendations. And, there were too many problems for it to move forward to the next step of review of the DHEC board. They have a required series of steps they have to follow to move on to the legislators. They will try to say they requested input but really it was a sham process in which they didn't really listen to the most serious comments and just checked off a box. We need to let them that that won't work. My main comment was that it had too many problems to move forward and needed to be sent back for the advise from MAC to be incorporated.

Best Regards,

Brittany Arsenenko

NAME	SECTION	DEPARTMENT RESPONSE
135.Angela Springer, LM, CPM	300, 400, 1100, 1300	Partially Adopted. Not Adopted. Misoprostol is not approved by the U.S. Food and Drug Administration for postpartum hemorrhaging. Any such use is considered an off-label use. This medication is also used in combination with another drug to end a pregnancy. The medication may also be used for induction of cervical softening and dilation in labor. The main problems cited for the medication are hyperstimulation, uterine rupture, and placental abruption. Oxytocin alone is the recommended uterotonic drug for the treatment of postpartum hemorrhage. Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives. Adopted. 1100.A.1. (Regarding the timeframe for the Physical

		Examination). Clarification regarding Violations: The S.C. Code of Laws allows the Department to implement penalties for enforcement. This is consistent with other regulations.
Moved here because the reg. is super amazing and state is supportive of midwives. Imagine my surprise after moving here with the new regs seeming too restrictive. Mistocyn, I'm having trouble getting Pitocin, now you want to take away miso, what am I left with? That's a concerning question. If they're u sed so often by OBGYNs, why is it not okay for us to use if they write the prescription? Why would you have the authority to say that's not okay when they're the expert and we should be listening to them. They know what's appropriate and the best interests of our clients. Section 1100 A. The first part of that, number 1 says the client must undergo an initial physical exam at 14-20 weeks, why is it so specific? I'm not sure where that time frame came from. What if someone goes at 13 or 12 weeks, which is super common? Then you're saying it doesn't count? Or the other part that's concerning, the midwife may admit clients after 20 weeks provided the client has already had an examination. So now you're saying that someone who was planning an unassisted birth, but has now decided they wanted a midwife at 22 or 24 or 26 weeks. Because they did not see a physician before 20 weeks, they are stuck with an unassisted birth because they can't hire us because of this one sentence in the regulation. I think you would rather a midwife attend the birth than it be unassisted. Strike that line. The other part of that is that we have to have a written and signed statement by MD saying pregnancy is low risk. Going to be very difficult to get from a provider since they are not the care provider. In Conway, not a lot of home-birt VBAC – You guys are looking at outdated evidence. 2017 study shows that 93% were successful, no complications. How can we look at the real evidence and say VBACS are high risk, they're not. We have to look at all the factors. Section 302 – Violation thing – not sure why it's being added, I think a lot of midwives are confused as to what that means. Why are we being fined all of a sudden? Seems aggressive and punitive. It comes off as highly offensive and looks like your trying to get rid of home birth in SC. Joann is trying to say that because you can't find a physician to write and sign the form, you're making homebirths impossible and essentially illegal.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
136.International Cesarian Awareness Network of the Central Savannah River Area	400	Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives.
On behalf of ICAN SC - Read an exert from a physician's statement on midwives attending VBAC. 27 other states allow VBAC. Limiting access will put women at greater risk. A woman who wants to have a home birth after cesarean will have little options besides local hospitals. Country has the highest maternal mortality rate. SC has the 9th highest maternal mortality rate in the U.S. CA has the lowest maternal mortality rate; we believe their lesser restrictions on home births contribute to that. Opposes any restrictions on VBAC. The risk involved with HVAC does not change the human right of adults to make their decisions about their bodies. It violates their right to autonomy. Restrictions on VBAC in any setting are not ethical. Review your position and reconsider allowing hemorrhage medication.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**

137.Caitlin Charleton	400	Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives.
Midwives are experts in normal births. Not allowing midwives to attend VBAC births does not prevent women from having home births, it just removes the medical support of the midwife. Women should have safe options. It is not acceptable how women are treated after a cesarean. We should have choices. Safe choice makes positive difference in the statistics.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
138.Cyndia Rosenblatt Consumer	400	Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives.
Restricting midwives will not automatically make women go to the hospital. Referring to unassisted home births. The restrictions on VBAC, the restrictions on timing to seeing another provider and getting signed off – all these restrictions will result in unassisted deliveries. Consumers need access and options. It's not about safety when the result is less safe. The reg needs more midwifery input.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
139.Dana Patterson Mother, Doula, Childbirth Educator, ICAN Chapter Leader	400	Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives.
Very hard to find a doctor who will attend a home birth. I work with a lot of VBAC mothers. They want the choice of where they give birth and to choose who their attendant is. SC needs to consider the wishes of mothers. We also need to make sure we're going in the right direction with our cesarean rate (SC is 33.5%, higher than the national average). SC is double the recommended rate WHO suggests for cesarean. Home births have a cesarean rate of 5%, obviously those are transfers. Midwives really care, they don't have a hero complex and should be free to protect mothers with the correct medication, access to transfer their clients in if needed. Most women can birth at home with no complications. Even VBAC mothers, a midwife is a birth that most of them would choose.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
140.Danielle Shealy, CD(DONA), CPM, LM Member of PALM, Owner of LMLD Midwifery	1200	Not Adopted. Misoprostol is not approved by the U.S. Food and Drug Administration for postpartum hemorrhaging. Any such use is considered an off-label use. This medication is also used in combination with another drug to end a pregnancy. The medication may also be used for induction of cervical softening and dilation in labor. The main problems cited for the medication are hyperstimulation, uterine rupture, and placental abruption. Oxytocin alone is the recommended uterotonic drug for the treatment of postpartum hemorrhage.
We would like to see access to misoprostol. Very difficult to wrap our minds around a med. being denied for out-of-hospital use for delivery when it's being actively used in labor and delivery for post-partum hemorrhage. If it's being used off-label and we are unable to use, then perhaps OBGYNs and CNM in the hospitals shouldn't be allowed either.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**

141.Dawn Bingham, MD, MPH, FACOG	102, 600, 1100	Partially Adopted. Clarification regarding Perinatal Levels of Care: This comment does not pertain to R.61-24. Perinatal levels of care are regulated within R.61-16. Not Adopted. This regulation includes the requirement for each licensed midwife to pass the examination by the North American Registry of Midwives to be credentialed as a Certified Professional Midwife ("CPM"). The NARM CPM credential is a competency-based certification accredited by the National Commission on Certifying Agencies and is evaluated yearly for adherence to the national standards. Reporting Hospital Outcomes - This comment does not pertain to R.61-24. Hospitals are regulated though R.61-16. Not Adopted. This regulation includes the requirement for each licensed midwife to pass the examination by the North American Registry of Midwives to be credentialed as a Certified Professional Midwife ("CPM"). The NARM CPM credential is a competency-based certification accredited by the National Commission on Certifying Agencies and is evaluated yearly for adherence to the national standards. Partially Adopted. Section 1500. (regarding transfers to include an admitting Obstetrician). This regulation does not prohibit clients from preregistering and notifying the admitting physician of an emergent transfer.
* Gave oral comments focusing on maternal and neonatal out of hospital transfers from homes and birth centers, integration of homebirth midwives with the rest of the maternity care system, standardized and state approved protocols for client informed consent and collaboration and consult with hospital based obstetric providers with referral and transfer of care based on a pregnant woman's risk status, accredited education and training req. for midwives initial licensure and re-licensure, enforceful limits of ____ to normal, low risk pregnancy and new born care, improved documentation and reporting of out of hospital birth outcomes. In particular, our rec. for limit on out of hospitals setting for high risk pregnancy Seeks to avoid unwanted risks for mothers considering out of hospital births. Recommend detailed conversations about transfer protocols – state lacks a well developed system of dedicated maternity transfers. All home birth midwives would have accredited education training as well as collaborative arrangement with their maternity care providers aligns with the international standards that govern midwifery practices worldwide. Recommend midwives be required to follow the DHEC approved safety consult transfer and protocols that is used by the rest of the maternity care system and have a consulting collaborative arrangement with in-state hospital physicians and active obstetric. Is actually a recognition that when standards of education are not in common that optimal transfer agreements can break down.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
142.Ida Darragh Executie Director North American Registry of Midwives	400, 1100	Not Adopted. Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives. Not Adopted. S.C. 44-89-60(4) requires that a physician make a written determination that the planned birth is low risk.
Encourage you to look at CPM requirements while working on regulation and allow LMs to work and practice their training. Suturing and IVs do increase safety, but the most controversial part is the VBAC. CPMs are prepared to assess pros and cons of VBAC for each client and to attend VBACS at home with		

the understanding of which should be risked out and which are candidates for VBAC. Extremely rare in any state with licensure for a consumer to have to see a second provider during their pregnancy. Only two states (including SC) require this and there is no evidence that seeing this second provider changes outcomes or increases safety. The physician signed their comments is part of the external risk assessment that makes it impossible to comply with. To have a physician sign a statement that the client is low-risk or is approved for homebirth is an impossible thing to require. Encourage looking at other ways to document the requirement for physician assessment so it doesn't require a signed statement about that. States with licensure often just list antihemorrhagics in their medication formulary, but these states specifically approve Misoprostal for postpartum hemorrhage: CO, DE, KY, MD, NM, RI, SD, and WY.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
143.Jennifer O'Briant, CPM, LM	400, 1200	Not Adopted. Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives. Not Adopted. Misoprostol is not approved by the U.S. Food and Drug Administration for postpartum hemorrhaging. Any such use is considered an off-label use. This medication is also used in combination with another drug to end a pregnancy. The medication may also be used for induction of cervical softening and dilation in labor. The main problems cited for the medication are hyperstimulation, uterine rupture, and placental abruption. Oxytocin alone is the recommended uterotonic drug for the treatment of postpartum hemorrhage.
VBAC – sought out midwifery after providers were not approving VBAC – women will always come to home birth for whatever reasons. Restricting options will not force women to a hospital. We do not want to force women into a hospital, it will only encourage unassisted births. If I felt forced, I would've travelled or had an unassisted birth. We're seeing evidence of increased interest in home births. If you restrict access to skilled providers, we only make home birth less safe. Women will have unassisted births if they feel forced to go to the hospital or if they're not a good candidate because your restrictions keep us from attending to them. We appreciate the listed expansions of iv fluids and sutures. When an EMT is allowed to administer iv fluids and epinephrine, then that should absolutely be allowed for a certified professional midwife to do as well. There is a 1in3 chance having a cesarean at a hospital, (WHO suggests that number should be much lower) results in 1in3 multip consumers searching for VBAC or having to be either TOLAC patients or repeat cesarean PTs. I would encourage everyone involved to look at evidence of VBAC and the safety. Look at other states and how they handle VBAC and their success. Will submit rest of comment online. ... Misoprostol is a life-saving drug. It follows no logic that we would be allowed the expansion of administering fluids, but to restrict the means by which to control the hemorrhage, which is included in every crash cart.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
144.Jessica Beck Student Midwife, Consumer	1200	Partially Adopted. Section 1200. (regarding Medications). A client has the right to self-administer any medications that her physician has prescribed. It is not within the scope of direct entry midwives to administer all medications available.
I feel like some of the restrictions being imposed on midwifery care are going to make it harder for midwives to provide life-saving medications and life-saving measures. In an event of hemorrhage, you don't have time to make a phone call to your overseeing doctor to see about giving a medication to your client, you don't have that time. U.S. doesn't have a great maternal home birth rate. One of those		

reasons is the break down between the continuity of care of midwives and the hospital system. Give access to the medications and tools for midwives to be able to practice safely.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
145.Joann Gottschall	101, 400, 1100, 1200	Partially Adopted. Adopted. Section 101.B (regarding bias). Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives. Not Adopted. Misoprostol is not approved by the U.S. Food and Drug Administration for postpartum hemorrhaging. Any such use is considered an off-label use. This medication is also used in combination with another drug to end a pregnancy. The medication may also be used for induction of cervical softening and dilation in labor. The main problems cited for the medication are hyperstimulation, uterine rupture, and placental abruption. Oxytocin alone is the recommended uterotonic drug for the treatment of postpartum hemorrhage. Not Adopted. S.C. 44-89-60(4) requires that a physician make a written determination that the planned birth is low risk.
Section 101.B – listed who can train apprentice midwives and there's an inherent bias in how they're listed. This is a midwifery reg, so licensed midwives should be listed first. VBAC – 28 out of 35 states with regulated licensed midwives allow VBAC. Dr. Bingham spoke on the collaboration but living in Charleston I cannot find a single OB who would be willing to work on that relationship. Medication issue – ACOG, NIH, WHO, every hospital, nurses – misoprostol is the standard of care for hemorrhage. How the memo came about is that DHEC had a suspicion that a midwife was using it to induce labor which resulted in the memo. CPM's are trained to determine risk. I will put the rest of my comments in writing. ...How can you restrict our practice to match CNMs who cannot provide homebirth in SC? Because no OB, whom we must have supervise them will sign a collaborative agreement with them. Please follow updated national organizations and evidence, not an opinion of a Nursing board. ... (Regarding VBAC) How can you make our practice the same as CNM's, as they do not provide homebirth, so obviously they cannot do VBAC		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
146.Leandra Cail LMA	400, 1200	Not Adopted. Not Adopted. Misoprostol is not approved by the U.S. Food and Drug Administration for postpartum hemorrhaging. Any such use is considered an off-label use. This medication is also used in combination with another drug to end a pregnancy. The medication may also be used for induction of cervical softening and dilation in labor. The main problems cited for the medication are hyperstimulation, uterine rupture, and placental abruption. Oxytocin alone is the recommended uterotonic drug for the treatment of postpartum hemorrhage. Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives.
Super important for midwives to have everything available (referring to hemorrhage medications). Misoprostol is used all around the world for post-partum hemorrhage and it's important for us to have that available. Midwives should be allowed to attend low-risk VBAC births. If we don't allow that, women who maybe have an unnecessary first c-section, or even if it's emergent, it limits their ability and choice over their body and it's not right if the mom is low-risk.		

NAME	SECTION	DEPARTMENT RESPONSE
147.Lori Gibson, CPM, LM, MBC MAC Chair, PALM Secretary	400, 1200, 1800	Not Adopted. Not Adopted. Misoprostol is not approved by the U.S. Food and Drug Administration for postpartum hemorrhaging. Any such use is considered an off-label use. This medication is also used in combination with another drug to end a pregnancy. The medication may also be used for induction of cervical softening and dilation in labor. The main problems cited for the medication are hyperstimulation, uterine rupture, and placental abruption. Oxytocin alone is the recommended uterotonic drug for the treatment of postpartum hemorrhage. Not Adopted. (regarding the midwife advisory council) S.C. 44-1-60 lays out the process for appeals related to Department decisions . Per SC Code 44-1-140 the Department may promulgate and enforce rules and regulations for public health. The South Carolina Department of Health and Environmental Control ("DHEC" or "Department") develops regulations in accordance with the South Carolina Administrative Procedures Act ("APA"), S.C. Code Section 1-23-10 et seq. Regulation Development actions include promulgating new regulations, amending existing regulations, and repealing existing regulations. Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives.
Excited to have this conversation virtually to stay safe and that MAC has been involved in the process. There are some great proposals in the reg. but some things that are concerning. Want to make sure our profession is not being tightened, want to stay safe. Misoprostol is not FDA approved for a hemorrhage, but it's on every crash cart in the state. It's a simple solution to post-partum hemorrhage when the authorizing prescription providing provider has written the prescription. If we can't use that in the field, we'll be down to one medication which is limiting for PTs who can't take others. This regulation looks like our duties are being cut in half. .., (Regarding VBAC) Best practices would be for DHEC to look to OTHER CPM/ LM regulations in other states rather than CNM		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
148.Nicole Lavallee	400, 1100, 1300	Partially Adopted. Partially Adopted. Section 1300. (regarding medical consultations and referrals). Any condition that requires consultation is considered to move the client beyond a low-risk pregnancy determination. The client has the right to consent to care that may possibly return her to a low-risk determination or to refuse the care. Not Adopted. S.C. 44-89-60(4) requires that a physician make a written determination that the planned birth is low risk. Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives.
If I'm interpreting it correctly, it sounds like during an emergency, I need to call the doctor, get approval or sign off. It's impossible, it's too much oversight by the doctors. Happy about additions with the IVs, sutures, Vitamin K, but those additions don't mean anything if the physician oversight isn't addressed. Pretty sure the doctors know that this amendment is too much, we can't operate that way and		

that DHEC knows that as well. Most doctors are not willing to sign not just one, but two forms of a low risk pregnancy. It's not in their best interest. Consult language in 1300.A. – moms delivering before 42 weeks, but the physicians recommend induction because "nothing good comes from a baby staying in the womb past 40 weeks". If a doctor recommends the client gives birth, then we have to comply with that. A client is robbed of their informed refusal because every doctor is going to say "bring them in". VBAC is the epitome of the need for informed consent and refusal. DHEC should not ban VBACS. I wish someone would take the time to call Vicky Fisher Simpson about the unassisted birth certificate requests piling up on her desk.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
149.Rachel Hall, M.D.	1200	Not Adopted. If oxytocin doesn't work, emergency measures need to be taken.
Just to piggy back off Laurie Gibson and having more than one tool in the toolbox, for an emergency situation for a client who is not a candidate for methergine, if Pitocin doesn't work, you are in an emergent situation and you don't want anyone to be in that. You really need three tools (medications) to be able to be using the other two meds while planning the transfer. Hopefully one of the other two have worked while waiting on EMS. But if transfer is still needed, it'd be in a stable/guarded condition. Whereas if only one medication is available then it's putting a lot of risk on top of the situation		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
150.Sheila Dell	400	Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives.
The nursing boards opinion is outdated and does not match the American College of Midwives' statement. Opinions are not regulations. ACOG is full of opinions they put out all the time that influences regulations all the time. Unassisted rate is rising, I get calls every day. Book published in 2007 that woke CA up. Book called Push, lit CA up about modern maternity care. Opinion 68 is way outdated.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
151.Susan Smart	n/a	Clarification: This comment partially does not pertain to amending R.61-24 but to the internal processes of the Department.
No surprise the nursing board is getting involved. In '91 – DHEC decided none of the other professions can speak for midwives doing homebirths, they turned to the midwives. DHEC hasn't included midwives in this reg. DHEC needs to include MAC for approval on each change. They are listed as DHEC's advisory council, not the others. I advise you to collaborate with MAC or we have a long road ahead.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
152.Wesley Wilson Consumer	400, 1200	Not Adopted. Not Adopted. Misoprostol is not approved by the U.S. Food and Drug Administration for postpartum hemorrhaging. Any such use is considered an off-label use. This medication is also used in combination with another drug to end a pregnancy. The medication may also be used for induction of cervical softening and dilation in labor. The main problems cited for the medication are hyperstimulation, uterine rupture, and placental abruption. Oxytocin alone is the recommended

		uterotonic drug for the treatment of postpartum hemorrhage. Not Adopted. VBACs are not low-risk deliveries and therefore are outside the scope of practice for licensed midwives. Clarification: This regulation does not contain any distance limits.
Four items – Need to make sure reg is including midwives as maternity providers. For a lot of us that chose midwifery care, the midwife is the one that knows the family, the details, the case, etc. and they are looked at as a primary provider. The doctor is involved as well, but we need midwife counted as a provider with have full access. Allow midwives to attend low risk VBAC deliveries in consultation with the physician. Midwives need a full toolbox to preventing hemorrhage including Pitocin and misoprostol. Please remember some of us don't have a birth center, like us in Pickens County, so don't add distance restrictions; arbitrary distance reg. limits access to midwife care.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
153.Midwife Advisory Council	101.A	Not Adopted. The term "Authorized Healthcare Provider" is used consistently in other Department regulations and defined for clarity across the healthcare community. The definition is based on SC Code of Laws 40-43-30 to clarify that only healthcare providers authorized by law may diagnose and prescribe drugs and devices.
A. Authorized Healthcare Provider: Change Healthcare to Medical (and everywhere else in this regulation) Licensed Midwives are Healthcare providers. Physicians, physician assistants and nurses, as indiviuals licensed by LLR, are Medical Providers. Leaving Midwives out of the Authorized Healthare Provider definition is confusing.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
154.Midwife Advisory Council	101.D	Not Adopted. The term "Authorized Healthcare Provider" is used consistently in other Department regulations and defined for clarity across the healthcare community. The definition is based on SC Code of Laws 40-43-30 to clarify that only healthcare providers authorized by law may diagnose and prescribe drugs and devices.
D. Authorized Healthcare Provider: Change Healthcare to Medical (and everywhere else in this regulation) Licensed Midwives are Healthcare providers. Physicians, physician assistants and nurses are Medical Providers. Leaving Midwives out of the Authorized Healthare Provider definition is confusing. Changing "Healthcare" to "Medical" is accurate. We are authorized by the dept to provide healthcare maternity services.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
155.Midwife Advisory Council	101.E	Not Adopted. The definition for a Birthing Center is in S.C. Code 44-89-30.
E. Birthing Center: Remove "or other place" and "of the mother." Replace "the usual" with "a usual" There are situations when a pregnant person can neither give birth in their own homes nor have the		

option of using a birth center, in those situations they would be able to give birth in a residence in SC, not a facility.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
156.Midwife Advisory Council	101.P	Not Adopted. This is consistent with the definition of Birth Center as defined in SC 44-89-30
P: Home Birth: a birth planned out of hospital in the location of a usual residence. Remove "of the Client" There are situations when a pregnant person can neither give birth in their own homes nor have the option of using a birth center, in those situations they would be able to give birth in a residence in SC, not a facility. Defining this as just the place of the resident of the Client severly limits their choice in place of birth and birth attendant which can have negative emotional and financial impacts. The definition of Home Birth does not apply to Birth Centers.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
157.Midwife Advisory Council	101.W	Not Adopted. The term "Authorized Healthcare Provider" is used consistently in other Department regulations and defined for clarity across the healthcare community. The definition is based on SC Code of Laws 40-43-30 to clarify that only healthcare providers authorized by law may diagnose and prescribe drugs and devices.
W. Should read "makes contact with a physician or other "Authorized *Medical Provider" instead of authorized healthcare. provider. To be consistent throughout the regulation. LMs are authorized by the dept and provide healthcare for prospectively low risk women during pregnancy, birth and postpartum. The verbiage is confusing.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
158.Midwife Advisory Council	101.X	Clarification. The client may take herbal products, vitamins, and nutritional supplements as she wishes. The Midwife is not allowed to administer these products per regulation.
X. Strike: "herbal products, vitamins, and nutritional supplements." Medications are "classified" by the FDA as over the counter or prescriptive substances that use a chemical action or pharmocological action to override the body's natural inclinations and are federally regulated as "medications." The law does not define vitamins and herbs as medication. According to the FDA, "the law defines dietary supplements as products taken by mouth that contain a "dietary ingredient." Dietary ingredients include vitamins, minerals, amino acids, and herbs or botanicals, as well as other substances that can be used to supplement the diet." Supplements, herbs and vitamins are incorporated largely in study and training for CPMs and clients rely heavily on the Midwives' recommendtion for these items throughout their pregnancy and post partum period for a variety of issues. By including herbal supplements, vitamins, and nutritional supplements in this definition will surely set up midwives for being cited. Herbals, vitamins and nutritionals do not fit the definition of Medications per the FDA.https://www.fda.gov/consumers/consumer-updates/fda- 101-dietary-supplements.https://www.fda.gov/regulatory- information/search-fda-guidance-documents/classification-products-drugs-and- devices-and-additional-product-classification-issues		
NAME	**SECTION**	**DEPARTMENT RESPONSE**

159.Midwife Advisory Council	101.EE	Not Adopted. The term "Authorized Healthcare Provider" is used consistently in other Department regulations and defined for clarity across the healthcare community. The definition is based on SC Code of Laws 40-43-30 to clarify that only healthcare providers authorized by law may diagnose and prescribe drugs and devices.
EE. Physical Examination: Change to "Client Medical Consultation: consultations required of Client with Authorized Medical Provider in section 1100" To be consistent with changes for section 1100.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
160.Midwife Advisory Council	101.GG	Not Adopted. The term "Authorized Healthcare Provider" is used consistently in other Department regulations and defined for clarity across the healthcare community. The definition is based on SC Code of Laws 40-43-30 to clarify that only healthcare providers authorized by law may diagnose and prescribe drugs and devices.
GG. Prescription Medication: Remove "or is restricted to use by Physicians or other Authorized Healthcare Provider." OR change "Healthcare" to "Medical" "or restricted to use by physician or Authorized Healthcare provider only" is concerning language. Are Licensed Midwives authorized? What if Medical Provider writes a prescription medication for Licensed Midwives to administer such as pitocin, RhoGam or vitamin K? Restrictive language that could potentially be used against Licensed Midwives at some point. Should be in definitions that Licensed Midwives are an authorized Healthcare provider as an extension of our consulting APRN or physician.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
161.Midwife Advisory Council	101.II	Not Adopted. The term "Authorized Healthcare Provider" is used consistently in other Department regulations and defined for clarity across the healthcare community. The definition is based on SC Code of Laws 40-43-30 to clarify that only healthcare providers authorized by law may diagnose and prescribe drugs and devices.
II. Referral: Change "Healthcare" to "Medical" To be consistent with definition of Authorized Medical Provider.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
162.Midwife Advisory Council	101.MM	Not Adopted. The term "Authorized Healthcare Provider" is used consistently in other Department regulations and defined for clarity across the healthcare community. The definition is based on SC Code of Laws 40-43-30 to clarify that only healthcare providers authorized by law may diagnose and prescribe drugs and devices.
MM. Transfer of Care: Change "Healthcare" to "Medical" To be consistent with definition of Authorized Medical Provider.		

NAME	SECTION	DEPARTMENT RESPONSE
163.Midwife Advisory Council	101	Not Adopted. S.C. Department of Health and Environmental Control cannot opine on laws governing physicians' and authorized healthcare providers' scopes and standards of practice. A physician's scope of practice and prescribing considerations is beyond DHEC's authority, it appears that the S.C. Telemedicine Act, SC Code Section 40-47-37(C) allows for physical exams and evaluations to be performed via telehealth and certain prescriptions.
Line item for Telemed/ Telehealth: Virtual consultations and visits with Authorized Medical Provider Telemed/ telehealth consultations are now federally acceptible forms for means of communication and assessment by Authrorized Healthcare providers. These visits are reimbersilble by Medicaid and can help ease the burden both financially, as they cost less than in- person appointments, and scheduling as they lend themsleves to be more accesible for both the Client and the Authorized Healthcare provider. A client can follow through with this appointment without need of transportation or in the case of illness, loss of childcare etc. as currently demonstrated during the COVID 19 pandemic. This must be an option listed in regulation, as it would be at the preference of the Authorized Medical Provider https://www.ama-assn.org/practice- management/digital/5-huge-ways-pandemic-has-changed-telemedicine? gclid=CjwKCAjw8MD7BRArEiwAGZsrBQBnowe3C1AsWoOvFsUS5QqkqIx3qX 3dkATHUhtaWilfV4C--nUNmhoC_oMQAvD_BwE		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
164.Midwife Advisory Council	101	Not Adopted. The Department does not consider any vaginal/home births after cesarean to be low-risk.
Add line item for VBAC: Vaginal Birth After Cesaerean VBAC should be considered with prior low transverse incision, no prior classical incision and documented physician consultation explaining risks and informed consent.If it is prohibited by regulation then there will continue to be famlies who attempt to have a VBAC at home unattended or with improperly trained support. Certified Professional Midwives are the only providers trained in out of hospital birth, including VBAC. Referring to the Nursing board's opion #68 is not referencing an equivalent level of training. CPMs are with the client throughout the labor and monitoring throughout, nurses and CNMs are not. There is evidence and research that supports the statement that continuous fetal monitoring does not result in better, safer outcomes.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
165.Midwife Advisory Council	302.C	Adopted. 302.C
C. Strike the whole line item "or those that are against the best practices" This phrase is too open ended- this is defined by whom? Since this is a midwifery regulation, best practices must be defined within the regulations as structured by a midwifery organization, such as NARM or MAC, and not widely open to various interpretations.This must be clear and concise, or could be detrimental to midwifery in SC.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**

166.Midwife Advisory Council	302.E	Adopted. 302.E
E. The monetary penalties section is inaccurate due to missing punctuation. Specifically dashes in between the numerical ranges of the penalties. https://www.scstatehouse.gov/code/t44c001.php Not to exceed one thousand dollars a day for each violation.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
167.Midwife Advisory Council	302.E	Adopted. 302.E Clarification: The monetary penalty increases per additional violation.
E. Monetary Penalty https://www.scstatehouse.gov/code/t44c001.php Not to exceed one thousand dollars a day for each violation.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
168.Midwife Advisory Council	400.D.2	Not Adopted. The Department does not consider any vaginal/home births after cesarean to be low-risk.
D.2. Add: "classical" before cesarean. To be consistent with other department regulations. Exclusion of care for all women with prior c-sections is extreme according to current evidence. A thorough risk assessment by midwives and consulting Authorized Medical Provider would exclude those at high risk for home birth. Generally, women with a classical incision are not good candidates for homebirth but women with low transverse scars are not an absolute risk out criteria.If DHEC continues to exclude all VBAC (vaginal birth after cesarean) women, public health and safety will be severely impacted as women will continue to be forced into the corner of attempting an unassisted homebirth or choose to be attended by those who are not trained to avoid a forced repeat c-section. SC's c-secrion rates are much higher than they should be.Please refer to the scientific evidence offered by the professional midwifery organizations PALM, MANA, NARM, as well as ACNM and ACOG (position statement on planned home birth reaffirmed in 2020). Ultimately these organizations support a person's right to choose place of birth. All VBAC women are NOT high risk and should not be treated as such.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
169.Midwife Advisory Council	701.B.1.a	Not Adopted. It is to allow for quick access to that information.
B.1.a. Strike "name and address of Client's Physician" This information has nothing to do with our care and is consulting medical provider information, should not be recorded on a client's intake face sheet. When the client has her medical consultation with the Authorized Medical Provider, documentation of the visit in the Client's chart is sufficient.A face sheet is patient demographics, emergency contacts and insurance information.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
170.Midwife Advisory Council	701.B.1.n	Not Adopted. The term "Authorized Healthcare Provider" is used consistently in other Department regulations and defined for clarity across the healthcare community. The definition is

		based on SC Code of Laws 40-43-30 to clarify that only healthcare providers authorized by law may diagnose and prescribe drugs and devices.
B.1.n Change "Healthcare" to "Medical" To be consistent with definition of Authorized Medical Provider		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
171.Midwife Advisory Council	800	Not Adopted. This is consistent with other Departmental regulations for organizational and quality purposes. Any future proposed language for the "Reserved" sections would have to go through the same promulgation process.
Strike or add explanation for reserved/ unused section. As this regulation does not have an "Admissions" section, this section should be stricken. It is not best practice to have entire sections marked "Reserved" with no explanation. This seems to leave big holes in the regulations that could be potentially filled with adverse verbiage.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
172.Midwife Advisory Council	901.C	Partially Adopted. 901.C
Remove items: C.2, C.9, C.10 and C.11 No need to educate on or recommend these items at each prenatal visit as it creates redundancy. Documentation of discussion of these items as needed should be sufficient as reflected in 901.E.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
173.Midwife Advisory Council	901.D	Adopted. 901
D.1. The Midwife shall ensure and document in the Client's record that the following prenatal tests and screenings are completed by the Client between eight (8) weeks, zero (0) days and sixteen (16) weeks, zero (0) days gestation, (ADD) or upon initiation of midwifery services: Sometimes Clients come into care as "late entry" or beyond this section's parameter of 8 0/7 weeks to 16 0/7 weeks. Depending on the department's future interpretation of this section, if a woman comes into care at 16 1/7 weeks or beyond, we would be deemed to be out of compliance and open to citation for not "ensuring" this important testing was done in the stated timeframe.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
174.Midwife Advisory Council	1000	Not Adopted. This terminology is consistent with other regulations and across the Department.
A. Replace "or other Authorized Healthcare Provider" with Authorized "Medical" Provider. To be accurate and consistent throughout regulations		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
175.Midwife Advisory Council	1100	Not Adopted. S.C. 44-89-60(4) requires that a physician make a written determination that the planned birth is low risk. This regulation does not prohibit televisits according to South Carolina statute.

Change title of section to "Client Medical Consultations"
Replace Physical Examinations with "Client Medical Consultations" within this entire section. Licensed Midwives are assessing the Client for low risk at each appointment and some comsulting providers may prefer to use televisits for these appointments. By titling this section "Physical Examination" the Health Regulations Committee has removed that option for the client and Medical provider. Licensed Midwives cannot be held in regulation for another providers' (Authorized Medical Provider) preference. Additionally, a physical examshould be on a case by case basis to be determined by that medical provider at the client's appointment/consultation visit. https://www.acog.org/advocacy/-

/media/a211a70996ab47a28c3a0afdb43d2f86.ashxhttps://www.ncbi.nlm.nih.gov/pmc/articles/PMC7305486/

NAME	SECTION	DEPARTMENT RESPONSE
176.Midwife Advisory Council	1100.A	Partially Adopted. 1100.A

A.1. Change "Physical Examination" to "Medical Consultation." Strike: "The midwife may admit Clients after (20) weeks of gestation provided the client has undergone a Physical Examination that meets requirements of section 1100 A2."
Replace with: "The Midwife shall require the Client to undergo an initial Medical Consultation either in person or via televisit completed by a Physician or other Authorized Medical Provider, at the Authorized Medical Provider's discretion, within the first 2 trimesters."
Clients may not be able to obtain an appointment during that window of time (fourteen {14} to twenty {20} weeks) for various reasons including but not limited to lack of transportation, illness, limited availbility with Authorized Medical Provider, life circumstances, etc. In some cases a person may not know that they are pregnant until later in the second trimester. Likewise, some parents choose to go at 5 weeks of gestation.Licensed Midwives cannot deny maternity services based on that arbitrry time line alone. Due to our current Pandemic, Telemed/ telehealth visits are now federally accepted forms of medical appointments and are now reimbursible through Medicaid. When the Authorized Medical Provider has been given the client's prenatal flow chart and any lab reports to review, they can then advise the client appropriately. Any medications to be prescribed to Client can be written and sent to the chosen pharmacy by the Authorized Medical Provider at the time of appointment whether in person or virtual. It is the discretion of the Medical Provider as to how they choose to consult with the home birth Client.
This must be plainly stated in the regulations so as not to set up the Licensed Midwife for being at fault of the regulations due to another professional's action/ inaction. Another type of provider's plan of consultation cannot be dictated in License Midwife regulations.

NAME	SECTION	DEPARTMENT RESPONSE
177.Midwife Advisory Council	1100.A	Not Adopted S.C. 44-89-60(4) requires that a physician make a written determination that the planned birth is low risk.

A. 2. Change "Physical Examination" to "Client Medical Consultation"

NAME	SECTION	DEPARTMENT RESPONSE
178.Midwife Advisory Council	1100.A	Not Adopted. S.C. Code 44-89-60(4) requires a physician to make a written determination that the planned birth is low risk. The requirement for signatures for verification are consistent with other Department regulations.

A.2.a. Strike entire line item
This section implies supervisory language while our current regulation requires consulting relationships with medical providers, respecting our role as Primary maternity providers for Clients.

Authorized Medical Providers who have an appointment/ Consultation with the Clients for those visits may not give a written and signed document. Licensed Midwives cannot make another provider write a document and it should not be in regulation to do so. Licensed midwives cannot be responsible for other providers, likewise Authorized Medical providers cannot be responsible for our Clients. The proposed language would put midwives at risk of being cited due to the potential inaction of the Authorized Medical Provider. This is very damaging proposed language.

SC Licensed Midwives are required to meet the North American Registry of Midwives requirements upon certification. This certification does not require the supervision of a Physician or other Medical Provider. Any changes or additions to Regulation 61-24 should align and reflect the North American Registry of Midwives best practices.

NAME	SECTION	DEPARTMENT RESPONSE
179.Midwife Advisory Council	1100.A	Not Adopted. Renumbering is not necessary.

A.2.b Change to A.2.a.

NAME	SECTION	DEPARTMENT RESPONSE
180.Midwife Advisory Council	1100.B	Not Adopted. The term "Authorized Healthcare Provider" is used consistently in other Department regulations and defined for clarity across the healthcare community. The definition is based on SC Code of Laws 40-43-30 to clarify that only healthcare providers authorized by law may diagnose and prescribe drugs and devices.

B. Change title from "Physical Examination" to "Client Medical Consultation"
To be consistent with title of section 1100
B 1. Change from "Physical Examination" to "Client Medical Consultation" and "Autorized Healthcare Provider" to "Authorized Medical Provider"
To be consistent with section definitions
B.2.Change from "Physical Examination" to "Client Medical Consultation"
B.2.Change from "Physical Examination" to "Client Medical Consultation"
To be consistent with title of section 1100 Not Adopted

NAME	SECTION	DEPARTMENT RESPONSE
181.Midwife Advisory Council	1100.B	Not Adopted. S.C. Code 44-89-60(4) requires a physician to make a written determination that the planned birth is low risk. The requirement for signatures for verification are consistent with other Department regulations.

B.2.a. Strike entire line item
This section implies supervisory language while our current regulation requires consulting relationships with medical providers, respecting our role as Primary maternity providers for Clients.

Authorized Medical Providers who have an appointment/ Consultation with the Clients for those visits

may not give a written and signed document. Licensed Midwives cannot make another provider write a document and it should not be in regulation to do so. Licensed midwives cannot be responsible for other providers, likewise Authorized Medical providers cannot be responsible for our Clients. The proposed language would put midwives at risk of being cited due to the potential inaction of the Authorized Medical Provider. This is very damaging proposed language.

SC Licensed Midwives are required to meet the North American Registry of Midwives requirements upon certification. This certification does not require the supervision of a Physician or other Medical Provider. Any changes or additions to Regulation 61-24 should align and reflect the North American Registry of Midwives best practices.

NAME	SECTION	DEPARTMENT RESPONSE
182.Midwife Advisory Council	1200.A	Not Adopted. Section 1200. (regarding Medications). A client has the right to self-administer any medications that her physician has prescribed. It is not within the scope of direct entry midwives to administer all medications available.

A. Strike: "in Section 1200 B and"
If a prescribing clinician has used their medical knowledge, expertise and wisdom, practicing their art of medicine, and has written a medication during their consult with a midwife's client, and that consult is a relationship between the clinician and the midwife, the midwife should be able to administer the medications.

NAME	SECTION	DEPARTMENT RESPONSE
183.Midwife Advisory Council	1200.B	Not Adopted. The term "Authorized Healthcare Provider" is used consistently in other Department regulations and defined for clarity across the healthcare community. The definition is based on SC Code of Laws 40-43-30 to clarify that only healthcare providers authorized by law may diagnose and prescribe drugs and devices.

B. Change: "Authorized Healthcare Provider" to "Authorized Medical Provider". Strike "The Midwife shall only administer the following Prescription Medications"

To be consistent with section definitions. The memo initiated bt DHEC was in response to a suspected use by " an upstate Midwife " to be using the drug to induce labor. See the FOIA email trail. Investigating this suspicion and citing that alleged midwife is how that should have been handled, not to deny all community midwives from life saving, accessible and affordable medication. To deny midwives the ability to administer a medication that has been prescribed to that Client by an Authorized Medical Provider is unethical. It is setting midwives up for a bad outcome, which should be placed on these regulations and not their skills and abilities. A quote from the US Department of Health and Human Services/ National Institutes of Health on a study regarding the use of misoprostol:
"Conclusions: Misoprostol has many applications in the practice of obstetrics and gynecology. Off-label use of approved medications is supported by the FDA as long as it is based on sound medical evidence. Researchers and providers must continue to work to further refine the indications for misoprostol in many areas. However, several indications are already supported by high-quality evidence. Given its low cost and ease of use, misoprostol has the potential to improve women's health worldwide."
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2760893/
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4973720/

NAME	SECTION	DEPARTMENT RESPONSE
184.Midwife Advisory Council	1200.B	Not Adopted. Misoprostol is not approved by the U.S. Food and Drug Administration for postpartum hemorrhaging. Any such use is considered an off-label use. This medication is also used in combination with another drug to end a pregnancy. The medication may also be used for induction of cervical softening and dilation in labor. The main problems cited for the medication are hyperstimulation, uterine rupture, and placental abruption. Oxytocin alone is the recommended uterotonic drug for the treatment of postpartum hemorrhage.
B. Strike as this statement is redundant to 1200 A. The memo initiated bt DHEC was in response to a suspected use of misoprotol by " an upstate Midwife " to be using the drug to induce labor. See the FOIA email trail. MAC, alongside the Department, investigating this suspicion and citing that midwife would have been the appropriate methond to handled this situation rather than refusing Midwife administration of a prescription medication that is life saving to the client to whom it was prescribed.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
185.Midwife Advisory Council	1200.B.3	Partially Adopted. 1200.B.3
B.3. Add "or Client's refusal shall be made in the Client's record" For consistency as with Section 1200 B.2.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
186.Midwife Advisory Council	1200.B	Not Adopted. Misoprostol is not approved by the U.S. Food and Drug Administration for postpartum hemorrhaging. Any such use is considered an off-label use. This medication is also used in combination with another drug to end a pregnancy. The medication may also be used for induction of cervical softening and dilation in labor. The main problems cited for the medication are hyperstimulation, uterine rupture, and placental abruption. Oxytocin alone is the recommended uterotonic drug for the treatment of postpartum hemorrhage.
Add line item B.10. for "other medications as prescribed by Authorized Medical Provider" Authorized Medical Providers may prescribe medications that work as an anti- hemmoragic in accordance with evidence based research and updated protocols in accordance with the World Health Organization and US Department of Health and Human Services/ National Institutes of Health. Efficent, appropriate and accepted medications include misoprostol and methergine in addition to synthetic oxytocin.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
187.Midwife Advisory Council	1300	Not Adopted. Section A requires the midwife to perform the consultation. The suggested change is not necessary.
Change title to "Midwife Medical Consultation" or "Professional Medical Consultation"		
NAME	**SECTION**	**DEPARTMENT RESPONSE**

188.Midwife Advisory Council	1300.A	Not Adopted. The term "Authorized Healthcare Provider" is used consistently in other Department regulations and defined for clarity across the healthcare community. The definition is based on SC Code of Laws 40-43-30 to clarify that only healthcare providers authorized by law may diagnose and prescribe drugs and devices.
A. Change: "Autorized Healthcare Provider" to "Authorized Medical Provider" To be consistent with Definition		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
189.Midwife Advisory Council	1300.A	Not Adopted. The requirement for client signature is consistent with other Department regulations.
A. Strike: "and time" as well as "and the Cient's decision, as authenticated by the Client's signature." Documentation in the chart of recommendations by the Authorized Medical Provider for the client is sufficient. A Client's Signature on the Informed Consent document upon the start of care should be evidence to confirm decision and recommendations upon medical consultation by the Licensed Midwife to the Authorized Medical Provider. This requirement is redundant and can be cumbersome.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
190.Midwife Advisory Council	1300	Not Adopted. The Department does not consider any vaginal/home births after cesarean to be low-risk.
Add line item: VBAC May be considered with prior low transverse incision, no prior classical incision and documented physician consultation explaining risks and informed consent. To be consistent with other department regulations.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
191.Midwife Advisory Council	1300.B	Adopted. 1300.B
B.2.e. Add "with non-reassuring fetal heart tones" Appears that suggestion was added to line item B.2.d. instead of B.2.e		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
192.Midwife Advisory Council	1300.B	Not Adopted. Meconium-stained amniotic fluid is a condition that requires the notification and availability of an appropriately credentialed team with full resuscitation skills, including endotracheal intubation.
B.4.j. Strike "Meconium staining." Meconium staining, alone, of a newborn is not a reason to consult, it is a normal finding		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
193.Midwife Advisory Council	1300.B	Not Adopted. Research shows that 99% of infants pass meconium in the first

		twenty-four (24) hours. Not passing meconium during this time could be indicative of a blockage.
B.4.k. Change to "... or meconium within the first forty-eight (48) hours"		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
194.Midwife Advisory Council	1300.B	Not Adopted. The Mayo Clinic states that the method of taking the temperature rectally is the most accurate method.
B.4.n. Strike "Rectal"		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
Midwife Advisory Council	1400	Not Adopted. The term "Authorized Healthcare Provider" is used consistently in other Department regulations and defined for clarity across the healthcare community. The definition is based on SC Code of Laws 40-43-30 to clarify that only healthcare providers authorized by law may diagnose and prescribe drugs and devices.
195.The Midwife shall immediately Discharge a Client during antepartum when care required for the Client is outside the Midwife's scope of practice pursuant to Section 400, the Client refuses the initial or second Physical Examination, or the Client refuses a Referral as recommended by Midwife or Authorized Medical Provider To be consistent with definition		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
196.Midwife Advisory Council	1500	Not Adopted. The term "Authorized Healthcare Provider" is used consistently in other Department regulations and defined for clarity across the healthcare community. The definition is based on SC Code of Laws 40-43-30 to clarify that only healthcare providers authorized by law may diagnose and prescribe drugs and devices.
Authorized Medical Provider during a Medical Consultation.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
197.Midwife Advisory Council	1500.B	Not Adopted. This is not consistent with S.C. 44-61-70.
B. Strike " Upon arrival of the emergency medical services personnel, Physician, or other Authorized Healthcare Provider, the midwife shall transfer the care of the Client to the emergency medical services personnel, Physician or other Authorized Healthcare Provider. " Leave "The midwife shall provide information as requested by the emergency medical services personnel, Physician or other Authorized Medical Provider." EMS providers are not ideally equipped nor are they trained to take over care in an obstetric emergency. Also, emergent transport via private car is often more expedient in some situations. Additionally, Licensed Midwives cannot rely on clients to have copiers or printers which in turn does not provide for printing in the field. Written summaries can be faxed to the receiving provider and/ or hand delivered by the transferring midwife at the receiving hospital for copies of the chart to be made at the time of report		

of situation to the receiving provider. By transferring care to one of the proposed persons disrupts Continuity of Care which is unique to CPM/ LM credentialling. CPMs/LMs will often continue post partum care with the transported client, as a hallmark of community midwifery care (Midwivery Model of Care). Receiving Medical Providers (especially EMS) do not offer Continuity of Care/ post partum follow up.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
198.Midwife Advisory Council	1500.B	Not Adopted. A client outside of the scope of care of midwifery must be transferred.
B. Add Continuity of Care. When referring a patient to a physician, the midwife shall remain in consultation with the physician until the resolution of the situation. It is appropriate for the midwife to maintain care of her patient to the greatest degree possible, in accordance with the patient's wishes, remaining present through delivery if possible To remain consistent with the current regulations. Continuity of Care is the hallmark of community midwifery. This is the biggest reason that clients choose to give birth with a licensed midwife. This is the reason that community midwives have great out comes. This is also referred to as Midwives Model of Care. https://www.citizensformidwifery.org/mmoc		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
199.Midwife Advisory Council	1700	Not Adopted. The tuberculosis requirements are based on the Department's South Carolina's Tuberculosis Control Program and CDC guidelines.
1701.A. Add "or submit yearly CDC Symptom Screening/ Baseline Individual Risk Assessment". Change "Authorized Healthcare Provider" to "Authorized Medical Provider" Per updated CDC guidelines/ Baseline Individual Risk Assessment. "Annual TB testing of health care personnel is not recommended unless there is a known exposure or ongoing transmission at a healthcare facility." https://www.cdc.gov/tb/topic/testing/healthcareworkers.htm#:-:text=All% 20health%20care%20personnel%20with,after%20the%20last%20known% 20exposure		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
200.Midwife Advisory Council	1800	Not Adopted. S.C. 44-1-60 lays out the process for appeals related to Department decisions . Per SC Code 44-1-140 the Department may promulgate and enforce rules and regulations for public health. The South Carolina Department of Health and Environmental Control ("DHEC" or "Department") develops regulations in accordance with the South Carolina Administrative Procedures Act ("APA"), S.C. Code Section 1-23-10 et seq. Regulation Development actions include promulgating new regulations, amending existing regulations, and repealing existing regulations.
Suggested Edit/ Addition: MIDWIFERY ADVISORY COUNCIL The Department shall appoint a Midwifery Advisory Council to advise the Department regarding licensing, practice, regulations, inspections and disciplinary actions, including an appeal process when disciplinary action was taken, of Midwives. The Council shall meet at least annually. The Council shall consist of three (3) licensed Midwives, one (1) consumer of midwife care, two (2) Certified Nurse-Midwives, one (1) Physician active in perinatal care, and one (1) member-at-large. Each member shall		

be appointed for a three (3) year term of office.

The regulation updates should not in any way diminish the duties of the Midwifery Advisory Council, though the most recent NPR does just that. As the proposed verbiage is written, this cuts the responsibilities in half. While Licensed Midwives are not licensed under LLR, the Health Regulations Committee has cited LLR as rationale for some changes in the most recent NPR_61-24. For consistency of using that rationale, we must look at who comprises the Boards in LLR and their roles. Boards under LLR are composed of a majority of those who work in the designated profession, as those working in that field are the only experts, while there are typically 1-2 "general public" members. For example, there are currently 5 RNs and 2 General Public members on of the Nursing Board with 2 LNP and 2 RN seats empty; 8 Chiropractors and 1 General Public member of the Board of Chiropractic Examiners; and 9 MD and 1 DO with 3 vacant Public Member seats on the Board of Medical Examiners.

As defined by LLR, the role of the Board of Nursing: "The mission of the State Board of Nursing for South Carolina is the protection of public health, safety and welfare by assuring safe and competent practice of nursing.

This mission is accomplished by assuring safe initial practice as well as continuing competency in the practice of nursing and by promoting nursing excellence in the areas of education and practice. The Board licenses qualified individuals as licensed practical nurses, registered nurses or advanced practice registered nurses. Complaints against nurses are investigated and disciplinary action taken when necessary. Schools of nursing (pre-licensure programs) are surveyed and approved to ensure quality education for future nurses."

For the Board of Chiropractic Examiners: "The SC Board of Chiropractic Examiners licenses and regulates Chiropractors and the practice of chiropractic in the state of South Carolina."

Finally, regarding the Board of Medical Examiners, in addition to licensing professionals, is responsible for "investigating and disciplining licensees found to be engaged in misconduct as defined in the professions' respective practice acts. This includes illegal, unethical or incompetent conduct."

It must be noted that as of 2013, all new LM applicants must have passed the North American Registry of Midwives' examination. Given this, it behooves the Department to incorporate NARM's course of action when there is a complaint. The process is to select a Complaint Review Committee Chair, who is a CPM. The Chair then appoints CPMs to form the Complaint Review committee. It is through this peer review process that unbiased and educated decisions will be made regarding course of action.

This suggestion to Section 1800 does not disrupt the makeup of MAC members, rather it urges that the Health Regulations Committee not remove their major function. The only way to have a true system of checks and balances within a profession is through peer review and guidance. The only way to ensure that for Licensed Midwives is to adopt the suggestion as the definition of Midwifery Advisory Council

for the proposed draft and utilize the Council as fully defined without conflict as well as with consistency with other Department/ Health Regulations Committee rationale. This creates a stronger relationship between the Department, the Licensed Midwives and the public.		
NAME	**SECTION**	**DEPARTMENT RESPONSE**
201.Midwife Advisory Council	1900, 2000, 2100, 2200, 2200, 2400, 2500, 2600	Not Adopted. This is consistent with other regulations for organizational and quality purposes. Any future proposed language for the "Reserved" sections would have to go through the same promulgation process.
Strike or add explanation for reserved/ unused section. As this regulation does not have an "Admissions" section, this section should be strickenIt is not best practice to have entire sections marked "Reserved" with no explanation. This seems to leave big holes in the regulations that could be potentially filled with adverse verbiage.		

ATTACHMENT B.1

SUPPLEMENTAL DOCUMENTATION FOR PUBLIC COMMENT # 60

To whom it may concern.

My name is Savannah Messer. Local to Horry County SC. I'm writing in concern for the midwife restrictions that are being revised. The most concerning to me as a mother is restricting midwives and mother's from a natural home birth for VBAC mother's. I'm a Mother of almost three children as I'm due to give birth any day with my third child due at the end of September. I am a VBAC mother.
In December of 2015 I gave birth via cesarean section to my first child due to breech fetal position at Waccamaw hospital in Georgetown County. I knew from that moment when I was ready to have a second child I wanted to have an all natural vaginal delivery. I was scared, I had no idea who would listen to my needs and wishes, who would take me on as a patient and allow me to give birth the way my body intended. As I spent a year or more educating myself, I learned that it is safer for VBAC mother's to feel safe in the environment they're birthing in and have as little medical intervention as possible during labor and delivery.

In 2017 I found out that I was pregnant with my second child. I was mentally prepared to reach out, stand up for myself and find a provider that would take me as a patient. I was successful in finding an OBGYN in my area but was nervous about how they would respond to my desire to have a VBAC. I presented them with all the research I had done myself. Letting them know the benefits of VBAC and they were supportive of my decision. My doctor's had informed me that being a VBAC mother they would not be allowing an induction for any reason, that an epidural was highly discouraged and to labor at home for as long as possible to make sure there were little risk of medical intervention.

The day I went into labor I followed exactly as they recommended. I went in to labor spontaneously without intervention at home at 40 weeks and 1 day. I labored at home for 27 hours before deciding it was time to head to the hospital. I knew at the time things were getting more intense and I would be meeting my baby soon. Upon arrival, I was in very active labor. I had so many people in and out of my room. They were throwing paper work in my face, asking questions and I felt so overwhelmed and so did my baby. I was hooked up to very uncomfortable monitors that kept me in bed. Which is not ideal for a laboring mother. They tried to recommend another cesarean section which was unnecessary and not at all what I wanted. I weighed my options at that time and refused. I continued to labor in the bed for another six hours. It was very uncomfortable. I had to wear monitors to go to the restroom and I couldn't really change positions. This made labor more painful however I was successful with my VBAC.

Here we are in 2020. As a successful VBAC mother, I have advocated and supported many women who were also successful with their VBAC. South Carolina is one of the few states trying to keep licensed midwives from providing for VBAC mothers who would be more comfortable giving birth at home. In my years of research as well as my personal opinion it is much safer and more comfortable to birth at home. If the pregnancy is low risk and there are no health concerns a VBAC at home should be an option. It should be the mother and the providers decision where it is safest to birth.

In my current pregnancy I have a planned second VBAC. This time I plan to remain at home and giving birth where I feel the safest. I will not have experience paper work, or the pressure to have another cesarean. I'm a perfect candidate for home birth and for VBAC.

Before finding a provider that would accept me as a patient, I considered having an unassisted home birth which means I would have been giving birth in my home without anyone to monitor me and baby through labor, I wouldn't have anyone to help deliver my baby or suggest a hospital transfer in the case of an emergency. This situation could have been life threatening for myself and my baby. I knew I had to figure something else out as I didn't really want to take those risk but I also didn't want to experience being in the hospital again while also in the midst of a pandemic with Covid -19.

In conclusion, VBAC mother's should have the right to choose what type of care they receive. They should have the right to choose to birth at home if they wish. I hope my experience along with my concern helps play a role in the decision to allow our midwives to provide care to VBAC mothers and allowing us to birth at home safely.

Thank you.

ATTACHMENT B.2

SUPPLEMENTAL DOCUMENTATION FOR PUBLIC COMMENT # 61

The proposed amendment to the regulations of Licensed Midwives in Section 400 D 2 prohibits the provision of care for clients with a previous cesarean section. A quick review of recent scientific studies proves that this restriction is not an evidence based decision, but rather a political one. In a 2017 study of midwife-attended planned community births, women with a history of both cesarean and vaginal birth fared better than first-time mothers across all outcomes. 93% of women that attempted a VBAC at home did not need an unplanned repeat 1 cesarean and had a vaginal birth.
ACOG says, "In addition to fulfilling a patient's preference for vaginal delivery, at an individual 2 level, VBAC is associated with decreased maternal morbidity and a decreased risk of complications in future pregnancies as well as a decrease in the overall cesarean delivery rate." Yet mothers report, "When their provider expressed an opinion (72% of the time), it was 3 typically in favor of a cesarean (88%)." ACOG says, 1 "The preponderance of evidence suggests that most women with one previous cesarean delivery with a low-transverse incision are candidates for and should be counseled about and offered TOLAC." Yet, 2 "A total of 97% of mothers with a prior cesarean indicated there had been at least some discussion with their provider over why they should have a repeat cesarean, but only 60% indicated there had been any discussion about why they should have a VBAC." And, 3 "Moreover, almost one-third of respondents (32%) indicated that the discussion was not framed as a matter of choice."
ACOG says, 1 "The decision to attempt TOLAC is a preference-sensitive decision, and eliciting patient values and preferences is a key element of counseling." Yet, 2 "Of women with a previous cesarean, 48% were interested in the option of a VBAC, but many of these women (46%) were denied that option." "In most cases (93%) the mother received a repeat cesarean." And, "Among women who had a repeat cesarean, 46% indicated they had had an interest in 4 having a VBAC. This level of interest is notable in the environment of persistent repeat cesarean rates of nearly 9 in 10. We asked women who had an interest whether they had had the option of planning a VBAC, and almost half (48%) reported that they had not had the option. When asked about reasons for not having the option of planning a VBAC (and to "choose all that apply"), more than 6 in 10 (62%) reported that their provider and nearly 1 in 6 stated that their

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1 Bovjberg, M. L., Cheyney, M. Brown, J., et al. (2017). "Perspectives on risk: Assessment of risk profiles and outcomes among women planning community birth in the United States." Birth 44(3): 209-221. https://pubmed.ncbi.nlm.nih.gov/28332220/ 2 American College of Obstetricians and Gynecologists (2019). Vaginal birth after cesarean delivery. ACOG Practice Bulletin No. 205. Obstet Gynecol, 133, e110–27. https://pubmed.ncbi.nlm.nih.gov/30681543/ 3 Declercq, E. R., Sakala, C., Corry, M. P., et al. (2013). Listening to MothersSM III: Pregnancy and Birth. New York: Childbirth Connection. https://www.nationalpartnership.org/our-work/resources/health-care/maternity/listening-to-mothers-iii-pregnancy-andbirth-2013.pdf 4 Sakala, C., Braveman, P., et al. (2018). Listening to Mothers in California. National Partnership for Women & Families. https://www.nationalpartnership.org/our-work/health/listening-to-mothers-ca/report/

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hospital (17%) did not allow VBAC, while 39% identified a need for a cesarean for their recent birth"

And who is "allowed" to have a VBAC? Is the decision influenced by race, socio-economic status, and insurance coverage? Sadly, the answer is yes. "About 1 in 6 pregnant women in California (17%) approached their most recent birth having had at least one prior cesarean. Among those, just 1 in 7 (15%) had a VBAC, while 85% had a repeat cesarean. VBAC rates varied by subgroups. Across

racial/ethnic groups, VBAC rates ranged from just 8% among Black women to 16% among White women (16%) ($p < .01$). Women with Medi-Cal coverage had a lower rate of VBAC (13%) than women with private insurance (17% rate) ($p < .01$). We found large differences in VBAC rates between women who primarily had an obstetrician (14%) and those who primarily had a midwife (33%) for prenatal care ($p < .02$). This may reflect a commitment of many midwives to support planned VBAC and of women with an interest in VBAC who choose midwifery care, as well as greater need for cesarean in women with obstetrical care." 3

So, what are policymakers to do? Should they continue down the road of restricting access to VBACs? Should they be the sole determiners of who is a good candidate for TOLAC? Or rather, should they listen to the midwives that are trained in birth? Should they listen to the mothers that want to experience the "decreased maternal morbidity and a decreased risk of complications in future pregnancies as well as a decrease in the overall cesarean delivery rate" that VBAC offers and ACOG promotes? Perhaps they should start by reviewing the current literature on VBACs and particularly planned VBACs at home.

Ultimately, the question is this - "Who decides what happens with a woman's body?" Does being pregnant cause her to lose her autonomy? Does she no longer have the right to informed consent? Is she unable to make medical decisions for herself? These are important questions to consider when making any decisions regarding restricting access to care.

The women of South Carolina deserve better.

Respectfully,

Angela Springer, LM, CPM

ATTACHMENT B.3

SUPPLEMENTAL DOCUMENTATION FOR PUBLIC COMMENT # 62

To Whom it May Concern,

I am writing to you on behalf of all South Carolina chapters of the International Cesarean Awareness Network (ICAN). The South Carolina chapters of ICAN and the national ICAN organization have issued position statements regarding regulations that inhibit access to VBACs. Please see the attached position statements.

We look forward to speaking with you at the stakeholder meeting tomorrow. Thank you for your consideration!

--
ICAN of the CSRA
csra.sc@ican-online.org
1-800-686-ICAN ext. 287

Dear Members of the South Carolina Board of Health and Environmental Control,
At one time, South Carolina was the leader in licensing direct entry midwives. In 1976, SC became the first state in the U.S. to provide licensure for direct entry midwives. However, since then, SC has fallen behind the curve. 27 of the 34 other states (79%) that license direct entry midwives allow home births after cesarean (HBAC). Take, for example, California. Not only does California allow their licensed midwives to attend HBACs, they also allow home births after multiple cesareans (HBAMCs) with very reasonable guidelines. They provide statistics on all the HBACs in their annual report. The most recently published annual report from 2018 1 demonstrates an 80.7% success rate for their HBACs, with zero uterine ruptures.
Another example of a state leading the nation in reasonable HBAC regulations is Minnesota. The Minnesota Council of Certified Professional Midwives has published an extensive paper titled, "Clinical Guideline: Vaginal Birth After Cesarean in the Out-of-Hospital Setting". This 2 paper covers the risks, benefits, statistics, and practice guidelines for HBACs. It should be required reading for all policy makers regulating Midwifery, homebirth, and vaginal birth after cesarean (VBAC).
By limiting access to trained and licensed midwives, you are putting women and babies at greater risk. Imagine for a second that a woman wants to have an HBAC, but of course there are no licensed midwives that can legally attend her birth. What options does she have? The next best thing would be one of the few birth centers in SC. Except you have prohibited VBAC there as well. The next option is her local hospital. Except, as of 2009, there were official or de 3 facto VBAC bans in over 43% of SC hospitals. So, now a woman's options are a completely unnecessary surgery, where she has a five times greater risk of dying , or an unassisted 4 homebirth, which she does not want either. She has been pushed into a corner by your regulations, and you are responsible for whatever bad outcomes she may encounter.
Our country is in a maternal mortality crisis. We have the highest maternal mortality rate of any 5 developed country, and we are the only developed country where the maternal mortality rate is

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1 https://www.mbc.ca.gov/Licensees/Midwives/#Annual 2
https://static1.squarespace.com/static/5aafe10dcc8fed691c9f767e/t/5e83e83c6b1f390209755a6a/158570
2972855/Minnesota+Council+of+Certified+Professional+Midwives+VBAC+Guideline+Final+Draft+Feb
+2 020.pdf 3 https://scdhec.gov/sites/default/files/docs/Health/docs/BCVBACMEMO20101214.pdf 4
https://www.euro.who.int/__data/assets/pdf_file/0006/277737/Cesarean-Section-or-Vaginal-Delivery-in-
th e-21st-

Century.pdf?ua=1#:~:text=Maternal%20mortality%20and%20morbidity%20is,4000%20(2%2C%20 3). 5 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7067092/ rising. South Carolina has the 9th highest maternal mortality rate in the U.S. Meanwhile, 6 California (with their reasonable HBAC policies) has the lowest maternal mortality rate in the U.S. We believe that it is not a coincidence that access to VBACs attended by skilled professionals (in all settings) is correlated with better health outcomes.

We have chosen to take an active role in improving these statistics by leading local chapters of the International Cesarean Awareness Network (ICAN). ICAN is a non-profit organization whose mission is to improve maternal-child health by reducing preventable cesareans through education, supporting cesarean recovery, and advocating for vaginal birth after cesarean (VBAC). Our ICAN chapters serve families in Aiken, Greenville, Spartanburg, Fort Mill, Rock Hill, and surrounding areas. Since there are currently no active ICAN chapters in Columbia, Charleston, or Myrtle Beach, our chapters often support families in those areas as well.

We would like to echo several sentiments from the national ICAN Midwifery Licensure Position Statement dated August 14, 2020 (attached). South Carolina women are capable of weighing 7 the risks and benefits of their birthing options and are willing to take responsibility for those decisions. The risk involved with HBAC does not change the human right of a decisionally capable adult to make their own healthcare decisions. Birthing families in South Carolina should not be forced by their legislators or rule-makers to have a certain type of care provider, nor birth location, as it violates their rights and autonomy.

We, as the ICAN chapters serving South Carolina families, categorically oppose any proposed licensure of midwives that in any way restricts the access of anyone desiring midwifery support for a planned VBAC. Restrictions on VBAC in any setting are not ethically enforceable, and restrictions on VBAC work against our shared goal of improving maternal health outcomes.

Sincerely,

Caitlin Tarleton
Chapter Leader, ICAN of the CSRA
Brittany Williamson
Past Chapter Leader, ICAN of the CSRA
Dana Patterson
Chapter Leader, ICAN of Upstate SC
Megan Stark Chapter
Co-Leader, ICAN of
Charlotte Sarah Dyer Chapter Co-Leader, ICAN of Charlotte

6 https://worldpopulationreview.com/state-rankings/maternal-mortality-rate-by-state 7 https://www.ican-online.org/wp-content/uploads/2020/08/ICAN-Midwifery-Position-Statement.pdf

Midwifery Licensure Position Statement
International Cesarean Awareness Network
August 14, 2020

ICAN supports efforts to increase availability of midwifery care for all, regardless of where they plan to give birth. Restricting the ability of midwives to practice independently by forcing restrictive collaborative agreements or legislating physician consultations is an abuse of power differentials, a conflict of interest, and reduces already limited access to care. With regard to people with a previous cesarean or cesareans, research is clear that planning a vaginal birth after cesarean (VBAC) is a low-risk option for many. There are risks and benefits to all options; it should be up to the family to make an informed decision, as no birth is risk free, and risk level does not change the human right of a decisionally capable adult to make their own healthcare choices. Midwives are trained to respond to rare, life-threatening complications.

A spontaneous, physiological labor after cesarean typically results in a VBAC and does not represent a special procedure. Given that, worldwide, one in five will undergo a surgical delivery, the population of people who may consider VBAC for a subsequent pregnancy is large and expected to continue to increase. Since finding support for a VBAC within the hospital system is difficult, or even impossible in many communities, out-of-hospital care for people desiring a VBAC is essential to any serious effort to reduce the cesarean rate and its associated maternal and fetal consequences. Further, as autonomous beings, pregnant people have the right to make informed choices. The American College of Obstetrics and Gynecology describes the importance of informed choice and autonomy in their Committee Opinion, titled: Informed Consent. People should not be forced by legislators to have a certain type of care provider, nor birth location, as it violates their rights and autonomy.

ICAN categorically opposes any proposed licensure or regulation of midwives that in any way restricts the access of anyone desiring midwifery support for a planned VBAC. We believe such restrictions are short-sighted and will ultimately restrain the trade of midwifery and increase the access to care gap that families with a prior cesarean already experience. Legislative VBAC restrictions consign a significant number of people to preventable repeat surgery, increasing maternal and fetal morbidity and mortality. There are those who will birth out of hospital, for cultural, religious, or personal reasons and any restrictions of this sort could lead to families birthing unattended, without the desire to do so. Restrictions on VBAC are strictly the result of political maneuvering and conflicts of interest, and are not ethically enforceable. This abuse of power differentials violates the human rights of the constituents which legislators serve.

Passing legislation that codifies restrictions on VBAC only serves the interests of the medical establishment by further limiting access to the midwifery-model of care. ICAN urges those working on licensure issues to stop using VBAC as a negotiating tool and rather put energy into educating legislators on the need for VBAC access as part of the larger effort to educate on the benefit of the midwifery-model of care. ICAN as an organization does not support any efforts that place restrictions on VBAC access. Statute limitations on VBAC are never acceptable and criminalizing midwives who attend VBACs is never progress. There are no mitigating circumstances or rationalizations that justify these restrictions. Support is always available for any efforts to educate and advocate for VBAC as an option for those with a previous cesarean or cesareans, consistent with our Mission Statement: To improve maternal-child health by reducing preventable cesareans through education, supporting cesarean recovery, and advocating for Vaginal Birth After Cesarean (VBAC).

Brianna Barker – President
Justen Alexander - Vice President
Kelly Hufnagel - Treasurer
Samantha Wall - Secretary
Brittany Healy - Chapter Director

ATTACHMENT B.4

SUPPLEMENTAL DOCUMENTATION FOR PUBLIC COMMENT # 73

September 15, 2020

Healthcare Quality

S.C. Department of Health and Environmental Control

2600 Bull Street

Columbia, S.C. 29201

RE: Proposed Rulemaking Comment, 61 - 24. Licensed Midwives.

The purpose of this letter is to request amendment of language in the proposed rules of the Department of Health and Environmental Control ("Department").

I. Proposed Rule Language

102. Licensure E.4. & License Renewal H.3. “Evidence of a valid cardiopulmonary resuscitation certificate by the American Red Cross or American Heart Association and Neonatal Resuscitation Program certificate, or other American Academy of Pediatric neonatal resuscitation certification;”

Requested Amendment
102. Licensure E.4. & License Renewal H.3. “Evidence of a valid cardiopulmonary resuscitation certificate by the American Red Cross, or the American Heart Association or the Health & Safety Institute and Neonatal Resuscitation Program certificate, or other American Academy of Pediatric neonatal resuscitation certification;”

Reasons for Requesting Amendment

The American Heart Association®, Inc. (“AHA”), the American National Red Cross (“ARC”) and The Health and Safety Institute (“HSI”) are the largest providers of CPR training in the United States.[1], [2]
HSI is comprised of four emergency care training program brands; including the American Safety and Health Institute (“ASHI”), MEDIC First Aid®, EMS Safety Services and 24-7 EMS & Fire. These four brands of training programs include a range of courses covering first aid and CPR training for the community and workplace as well as both basic and advanced life support training for healthcare providers.
ASHI’s CPR training program is codified in South Carolina law.[3]
ASHI is currently approved by the Department as a valid CPR credential for Emergency Medical Technicians. [4]
ASHI is currently approved by the Department as a training provider for Body Piercing Technicians. [5]
Like the AHA and ARC, HSI is nationally accredited by the Commission on Accreditation of Pre-Hospital Continuing Education (“CAPCE”). CAPCE is the national accrediting body for Emergency Medical Services continuing education courses and course providers.
Like the AHA and ARC, HSI’s ASHI CPR/Basic Life Course is approved by the North American Registry of Midwives (“NARM”).[6]
The training business units of the HSI, AHA and ARC are similar.

i. Each corporation develops and markets commercially available, proprietary training programs, products, and services to their approved Training Centers; either directly or via distributors.

ii. The business structures of the approved Training Centers include sole proprietorships, partnerships, corporations, LLCs, non-profits, as well as both large and small government agencies.

iii. Instructors are authorized to certify course participants. Certification requires instructor evaluation of hands-on skills to verify skill competency.

As proposed, the rule language:

i. Unfairly fixes a bias for the proprietary CPR training programs, products and services of the AHA; its Approved Training Centers and for-profit CPR training company[7] and the ARC and its Licensed Training Providers - all whom have a vested economic interest in CPR training - particularly where it is required for occupational licensing; and

ii. Will have an inequitable cost impact on licensees by denying them the use of a substantially equivalent means of compliance and potentially lower cost CPR training alternative, and by preventing greater choice in CPR training vendor selection, quality, and service, and by imposing the inconvenience and additional costs associated with superfluous AHA or ARC CPR training and certification, and

iii. Will have an adverse business impact on HSI Training Centers in South Carolina, many of which are small or micro businesses employing or independently contracting with HSI Authorized Instructors, by preventing competition on equal and fair terms; and

iv. Harms HSI's reputation as an equivalent, bona fide, state and nationally recognized and accredited training organization.

Additional Facts

HSI's emergency care training programs brands are also currently accepted, approved or recognized as an industry credential meeting the requirements of more than 7000 US state regulatory agencies, occupational licensing boards, national associations, commissions and councils in more than 550 occupations and professions.

HSI publishes and administers a set of quality assurance standards designed to monitor and improve the performance of HSI, its approved Training Centers and Authorized Instructors so that the products and services provided meet or exceed the requirements of regulatory authorities and other approvers.

HSI is a member of the Council on Licensure, Enforcement and Regulation (CLEAR), the international resource for professional regulation stakeholders. HSI Quality Assurance representatives are Nationally Certified Regulatory Investigators.

HSI is a member of the American National Standards Institute (ANSI) and ASTM International (ASTM) – both globally recognized leaders in the development and delivery of international voluntary consensus standards.

Conclusion

The AHA, ARC and HSI are the largest providers of CPR training in the United States. The requested amendment will encourage full and free competition while achieving the goal of maintaining the quality measures necessary to protect public health and safety. We support regulations that do not harm employment, competition, or innovation. We value, believe in, and promote successful completion of a

valid CPR program as an important component in protecting public safety, health, and welfare. We look forward to helping the Department protect the health and safety of the citizens of South Carolina.

Respectfully,

Ralph M. Shenefelt

Senior Vice President

Health and Safety Institute

[1]Anderson ML, et al. Rates of cardiopulmonary resuscitation training in the United States. JAMA Intern Med. 2014 Feb 1;174(2):194-201 doi: 10.1001/jamainternmed.2013.11320. [Retrieved 09/15/2020]

[2]Virani S, et al. Heart Disease and Stroke Statistics- 2020 Update. A Report from the American Heart Association Circulation. 020; 141:00–00. Clinical Statements and Guidelines. Awareness and Treatment, pg. e318 (Large file). Available: https://www.ahajournals.org/doi/pdf/10.1161/CIR.0000000000000757 [Retrieved 09/15/2020]

[3] South Carolina Automated External Defibrillator Act. Available: https://www.scstatehouse.gov/code/t44c076.php [Retrieved 9/15/2020]

[4] Emergency Medical Technician (EMT) Certification Requirements. Available: https://scdhec.gov/health-regulation/emergency-medical-technician-emt-certification-requirements [Retrieved 9/15/2020]

[5] Body Piercing. Approved Training Providers. Available: https://scdhec.gov/body-piercing-0 [Retrieved 9/15/2020]

[6] NARM Neonatal Resuscitation and CPR Requirements. Available: http://narm.org/news/news-title-2/ [Retrieved 09/09/2020]

[7] Dallas-based American Heart Association to spin off a CPR training company, July 5, 2018 Available: https://www.dallasnews.com/business/health-care/2018/06/29/dallas-based-american-heart-association-spin-off-cpr-training-company. [Retrieved 09/09/2020]

ATTACHMENT B.5

SUPPLEMENTAL DOCUMENTATION FOR PUBLIC COMMENT #75

Dear Members of the DHEC Board,

The DHEC Proposed transfer regulations is prejudicial and does not protect the safety of women and children in South Carolina.

The Licensed Midwife proposed regulation is asking midwives to call 911 to initiate a transfer of care instead of calling directly in to the Regional Perinatal Care system. This mandate would be a dangerous practice and a government disparity placed directly upon the consumers of midwifery care. Transfer of care protocols for maternity patients are already detailed in DHEC regulation 61-16. Community Births that occur at home, birth center or in a physician's office are considered a basic level of care (level I) and should be incorporated into the perinatal system.

Smooth and expedient transfer of care with direct provider-to-provider communication improves outcomes. Licensed Midwife providers and their clients are entitled to the same system of care that is available to every other maternity patient in South Carolina.

As you can see by the attached information, the consensus is overwhelming. To limit access when a higher need arises does not serve to improve healthy birth outcomes and should be immediately abandoned by The Department.

Attached please find:
SC Midwifery Advisory Council RPC Support Letter
Mapping integration of midwives journal study
Equal Patient Access to Perinatal Levels of Care in South
Carolina Midwifery Advisory Council Letter of Support
South Carolina's Perinatal Regionalized System of Care Integration Goals
to Reducing Premature Births and Infant Mortality
PALM Position Statement Equal Patient Access
American College of Obstetrics and Gynecologist Levels of Maternal Care
Obstetric Care Consensus
Best Practice Guidelines:
Transfer from Planned Home Birth to Hospital
SUPPORTING HEALTHY AND NORMAL PHYSIOLOGIC CHILDBIRTH: A CONSENSUS STATEMENT BY ACNM, MANA, AND NACPM SC NACPM letter requesting these corrections since 2018.

Sandy Glenn, LM CPM MBC
Carolina Birth Center
864-329-0010

PROPOSED CHANGE:
A. The Midwife shall immediately initiate a Transfer of Care during intrapartum and postpartum by dialing 911 when the care required is outside the Midwife’s scope of practice pursuant to Section 400, as recommended by a Physician or other Authorized Healthcare Provider during a Medical Consultation, or for any event during labor that compromises the health of the Client or Neonate and/or normally requires emergency intervention.

CURRENT MIDWIFE REGULATION:
J. Referral to Physician.

1. Recognition of Problems. The midwife must be able at all times to recognize the warning signs of abnormal or potentially abnormal conditions necessitating referral to a physician. It shall be the midwife's duty to consult with a physician whenever there are significant deviations from the normal. The midwife's training and practice must reflect a particular emphasis on thorough risk assessment.

2. Continuity of Care. When referring a patient to a physician, the midwife shall remain in consultation with the physician until the resolution of the situation. It is appropriate for the midwife to maintain care of her patient to the greatest degree possible, in accordance with the patient's wishes, remaining present through delivery if possible.

CURRENT HOSPITAL REGULATION:
Code of Regulations CHAPTER 61.Department of Health and Environmental
Control SECTION 16.
Minimum Standards for Licensing Hospitals and Institutional General Infirmaries.
SECTION 1306
D. Regional Perinatal Center with Neonatal Intensive Care Units (Level III) (RPC). In addition to complying with all requirements of Sections 1306.A through 1306.C, the RPC shall provide consultative, outreach, and support services to Level I, II, and III hospitals in the region. The RPC shall manage no less than an average of 2000 deliveries annually, calculated over the previous three years. Personnel qualified to manage obstetric or neonatal emergencies shall be in-house. A board-certified maternal-fetal medicine specialist (perinatologist) shall be in the hospital or on site within 30 minutes for supervision and consultation, 24 hours a day. The RPC shall participate in residency programs for obstetrics, pediatrics, and/or family practice. Physician-to-physician consultation shall be available 24 hours a day for Level I, II, and III hospitals. Regional Perinatal Centers shall coordinate the development and implementation of professional continuing education to maintain competency and provide education to other facilities within the region, facilitate transport from the perinatal centers to the regional perinatal center and back transport when possible, and collect data on long-term outcomes to evaluate the effectiveness of delivery of perinatal care services and the efficacy of new therapies. The RPC shall provide a perinatal transport system that operates 24 hours a day, seven days a week, and return transports neonates to lower level perinatal hospitals when the neonates' condition and care requirements are within the capability of those hospitals.

ATTACHMENT B.6

SUPPLEMENTAL DOCUMENTATION FOR PUBLIC COMMENT #76

Dear Health Regulation Committee,

Thank you for your tireless efforts in the proposed revisions for regulation 61-24, Licensed Midwives. Upon review of the proposed revisions, I would like to bring to your attention a few sections that will need to be revised from the current proposals.

Please find attached my recommendations, and thank you, again for your hard work and dedication.

Jami Morris, LM, CPM, MBC

REGULATION 61-24 PROPOSED REGULATION REVISIONS SUGGESTIONS

PROPOSED SECTION 300 – ENFORCEMENT ACTIONS

E. When imposing a monetary penalty, the Department may invoke South Carolina Code Section 44-1-140 to determine the dollar amount or may utilize the following schedule:

REQUESTED CHANGE: THE FINES LISTED ON THE TABLE OF FINES FOR CLASS I, II, AND III VIOLATIONS ARE CITED UNDER SECTION 44-1-140, HOWEVER; THIS SECTION PERTAINS TO SANITATION PRACTICES, INFECTIOUS DISEASES, DISPOSITION OF GARBAGE, ETC. IN ADDITION, THE AMOUNTS LISTED AS FINES DO NOT APPEAR TO BE LEGITIMATE FIGURES. REQUEST FOR CLEARLY IDENTIFIED FINES PER CLASS VIOLATION NOT TO EXCEED $1000.00.

SECTION 1000 – INFORMED CONSENT (II)

C. Disclosure of fees for all care and services provided; and

REQUESTED CHANGE: OMIT THIS REQUIREMENT. FEES CHARGED TO CLIENTS ARE NOT PART OF SC DHEC'S REGULATORY AUTHORITY

SECTION 1100 – PHYSICAL EXAMINATIONS (I)

REQUESTED CHANGE: STRIKE SECTION 1100

RATIONALE: Out of the 35 states that license Certified Professional Midwives, only 2 states require Physician or health provider examinations during any of the trimesters of pregnancy unless a consult is required. The conditions requiring consultations are clearly identified in Regulation 61-24. The Physicians and health care providers rely on the knowledge and training of the midwives to identify them and refer appropriately. There is no documented evidence that confirms the safety of care from the two states who require Physician or health provider examination. As hospitals become more and more monopolized, and physician and health provider practices are merged into their monopoly, midwives cannot be responsible for what a physician or heath care provider agrees or disagrees to comply with.

Midwives are required to meet the North American Registry of Midwives requirements upon certification. This certification does not require the oversight of a Physician or other Healthcare

Provider. Any changes or additions to Regulation 61-24 should align and reflect the North American Registry of Midwives scope of practice.

SECTION 1200 – PRESCRIPTION MEDICATION ADMINISTRATION (I)

REQUESTED CHANGE: IN ADDITION TO THE APPROVED AUTHORIZED PRESCRIBED MEDICATIONS, CURRENT PRESCRIPTIONS FOR GROUP B STREPTOCOCCUS AS WELL AS OTHER ANTI HEMORRHAGIC MEDICATIONS PRESCRIBED TO THE CLIENT BY THE AUTHORIZED HEALTH CARE PROVIDER SHOULD BE ADDED TO THE LANGUAGE.

SECTION 1500 – TRANSFER OF CARE (I)

A. The Midwife shall immediately initiate a Transfer of Care during intrapartum and postpartum by dialing 911 when the care required is outside the Midwife's scope of practice pursuant to Section 400, as recommended by a Physician or other Authorized Healthcare Provider during a Medical Consultation, or for any event during labor that compromises the health of the Client or Neonate and/or normally requires emergency intervention.

B. Upon arrival of the emergency medical services personnel, Physician, or other Authorized Healthcare Provider, the Midwife shall transfer the care of the Client to the emergency medical services personnel, Physician, or other Authorized Healthcare Provider. The Midwife shall provide information as requested by the emergency medical services personnel, Physician, or other Authorized Healthcare Provider.

REQUESTED CHANGE: UPON TRANSFER OF CARE TO PHYSICIAN OR OTHER AUTHORIZED HEALTHCARE PROVIDER, DIRECTIVES FROM THE PHYSICIAN OR AUTHORIZED HEALTHCARE PROVIDER MAY NOT REQUIRE EMERGENCY MEDICAL SERVICES (911). TRANSFERS MAY BE INITIATED, BUT FROM A NON EMERGENT STATUS. DISPATCHING EMS FOR NON EMERGENT TRANSFERS, IS NOT RELEVANT TO THE SITUATION, IS NOT COST EFFECTIVE FOR THE CLIENT, HAS A HISTORY OF LONG TRANSFER DELAYS, AND EMS HAS LESS TRAINING THAN MIDWIVES REGARDING THE COURSE OF ACTION TO EMPLOY ONCE THE CLIENT HAS BEEN TRANSFERRED INTO THEIR CARE.

SECTION 1700 – INFECTION CONTROL

1702. Tuberculosis Screening. (I)

D. Annual Tuberculosis Training. Midwives and Apprentice Midwives shall receive annual training regarding tuberculosis to include risk factors and signs and symptoms of tuberculosis disease. The Midwife and Apprentice Midwife shall maintain documentation of the annual tuberculosis training.

REQUESTED CHANGE: TUBERCULOSIS TRAINING IS INCLUDED IN THE CURRICULA OF APPRENTICE MIDWIVES AND SCREENED FOR COMPETENCY DURING INITIAL LICENSURE TESTING. ANNUAL TRAINING IS UNNECESSARY AND REDUNDANT.

SECTION 1800 – MIDWIFERY ADVISORY COUNCIL

The Department shall appoint a Midwifery Advisory Council to advise the Department regarding licensing and Inspection of Midwives. The Council shall meet at least annually. The Council shall consist of three (3) licensed Midwives, one (1) consumer of midwife care, two (2) Certified Nurse-Midwives, one

(1) Physician active in perinatal care, and one (1) member-at-large. Each member shall be appointed for a three (3) year term of office.

REQUESTED CHANGE: THE DEPARTMENT SHALL UTILIZE THE CURRENT STANDARDS OF THE MIDWIFERY ADVISORY COUNCIL TO ADVISE THE DEPARTMENT IN MATTERS SUCH AS, BUT NOT LIMITED TO: LICENSING MIDWIVES, INSPECTION OF MIDWIVES, LIASON FOR THE DEPARTMENT WITH COMMUNICATION AND SUGGESTIONS TO THE MIDWIVES, LIASON FOR THE MIDWIVES WITH COMMUNICATION AND SUGGESTIONS TO THE DEPARTMENT, REGULATION REVISIONS, VIOLATION CITATIONS INITIATED BY THE DEPARTMENT, ETC. THE COUNCIL SHALL CONSIST OF THREE(3) LICENSED MIDWIVES, ONE (1) CONSUMER OF MIDWIFERY CARE, TWO (2) CERTIFIED NURSE MIDWIVES, ONE (1) PHYSICIAN TRAINED IN PERINATAL CARE, AND ONE (1) MEMBER AT LARGE. EACH MEMBER SHALL BE APPOINTED FOR A THREE (3) YEAR TERM OF OFFICE. A BI-ANNUAL MEETING SHALL BE HELD TO IMPLEMENT COMMUNICATIONS BETWEEN THE DEPARTMENT AND THE MIDWIVES.

RATIONALE: THE MIDWIFERY ADVISORY COUNCIL CONSISTS OF PROFESSIONALS THAT ARE INVOLVED IN, BUT NOT LMITED TO OUT OF HOSPITAL MATERNITY CARE. THE PRACTICE OF MIDWIFERY CANNOT NOR SHOULD IT BE REGULATED BY PROFESSIONALS THAT DO NOT HAVE TRAINING NOR PRACTICE OUTSIDE OF THE HOSPITAL SETTING. THE MIDWIFERY ADVISORY COUNCIL SHOULD BE THE INITIAL AND PRIMARY GOVERNING BODY TO ADVISE THE DEPARTMENT REGARDING OUT OF HOSPITAL MIDWIFERY CARE.

ATTACHMENT B.7

SUPPLEMENTAL DOCUMENTATION FOR PUBLIC COMMENT #78

Dear Health Regulation Committee,

The proposed regulation to 61-24 states:
A. The Midwife shall immediately initiate a Transfer of Care during intrapartum and postpartum by dialing 911.

These actions are not appropriate for midwife transfers and would be a step backward in care.

The individual names and public comments are below and attached.Please add each of the 200+ comments to the public comments regarding the revision of Licensed Midwife Regulations.

Petition:Protect pregnant women's and newborns' access to emergency care
http://chng.it/spJchrMY4L
The South Carolina state legislature must protect pregnant women, mothers and newborn babies by passing the Equal Access to Hospital Doors Bill H-4966, officially called the Perinatal Integration Act of 2020. A similar bill in the senate is also pending. The South Carolina Department of Health and Environmental Control also must not pass retaliatory regulations to further restrict midwives.

In 2014, the South Carolina Department of Health and Environmental Control (DHEC) wrote a regulation that specifically omitted patients of midwives and specifically outborn babies (babies who are not born in a hospital) from being able to automatically transfer care to a higher resource facility in an emergency. The regulation painstakingly lists every perinatal care facility type in the state, including prison infirmaries, except for Licensed Midwives and birth centers. Therefore,in an emergency, midwife and birth center patients may be refused smooth transfers into higher resource facilities in an emergency, which could create life or death situations for mother and/or baby. Instead, these patients are sometimes referred to an emergency room and lose precious time while waiting for their turn and for the slower process of admittance to take place.

It is unlikely this is a simple oversight because there is an easy fix. All DHEC must do is agree to add in "licensed midwives and outborn babies" to the language, and all of these mothers and babies would suddenly be protected as well. DHEC has refused. Two years ago, the Palmetto Association of Licensed Midwives and the Midwifery Advisory Committee (whose job it is to advise DHEC) approached DHEC and also wrote a statement in favor of the change. Instead, DHEC went to the OB task force, which also agreed with MAC, yet DHEC continued to do nothing to change this except to say it was looking for stakeholders and would then talk to the Hospital Association. Two years later, nothing has changed.

DHEC could also offer a quick and temporary solution to the problem by providing a provider-wide exception, position statement or memo. However, DHEC is also unwilling to do this. As recently as January 2020, MAC asked DHEC to provide this temporary solution, but DHEC stated that they have no plans to make such a resolution, according to representatives who were present at that meeting. They stated that the Licensed Midwife regulation is now scheduled for revisions, but they have no current plans to revise regulations 61-16, which is the regulation regarding perinatal levels of care. The midwifery groups have asked DHEC numerous times why they instated and maintained this omission, but no reason has ever been given.

Therefore, in order to protect these mothers and babies who choose the safe and attentive care of licensed midwives in the state of South Carolina, the House of Representatives has introduced the Equal Access to Hospital Doors bill. As of March 1 2020, that bill had 15 co-sponsors already, and a mirrored senate bill was pending.

On February 26 2020, in what appears to be retaliation to the pending legislation, DHEC formally announced that it was opening midwife regulations. The midwives believe this is not to fix the omission because historically DHEC has done this specifically to further limit and restrict midwives' freedoms. The public comment period for the Notice of Drafting for this new Regulation 61-24 runs through Monday, March 30. Public comments regarding this regulation can be submitted via email to healthregcomm@dhec.sc.gov or by completing an online public comment form. A stakeholder meeting for the DHEC regulations on Tuesday,March 17, 2020 at 10 a.m. in the DHEC Columbia Mills Building, conference room 2407. A conference line to join the meeting is at 800-753-1965, access code 6671491. Even though they opened the regulations, DHEC would not tell the South Carolina midwives why theywant to update them. In the past, DHEC has tried to put in supervisory language, meaning licensed midwives would have to have a supervising physician and agreements with the hospitals.

Why do I care? I personally had an incredible home birth with a licensed midwife on Feb. 26, 2019 -- exactly one year to the day before DHEC decided to open midwife regulations for potentially more restrictions. It was the most amazing, beautiful, empowering and loving experience of my life, and I strongly believe that anyone should have access to this experience if they so desire and they meet the safety parameters to have a home birth or to work with a licensed midwife. My highly trained and experienced midwife ensured my baby and I were safe at all times. At one point in labor, she was concerned I may not be dilating appropriately due to scar tissue, so she kept careful watch on the situation. Fortunately, right after she discovered the potential problem, I quickly fully dilated and birthed a healthy baby girl just an hour and a half later. However, if my cervix continued to be "stuck" due to scar tissue, I would have had to transfer to the hospital. It would have been crucial for me to have a smooth transition to a higher resource facility and NOT be stuck waiting in an emergency room. My midwife did her job perfectly, but DHEC's prejudice against midwives, birth centers and their patients could have led to a life or death situation, had my body not cooperated that day.

Please sign this petition to urge DHEC to drop any additional restrictive regulations, fix the omission of midwives in equal access to hospital transfers, and for state legislators to sponsor and sign this bill so that no matter what kind of maternal and perinatal care a woman chooses, ALL mothers and babies are protected, even in an emergency.

PROPOSED CHANGE:
A. The Midwife shall immediately initiate a Transfer of Care during intrapartum and postpartum by dialing 911 when the care required is outside the Midwife's scope of practice pursuant to Section 400, as recommended by a Physician or other Authorized Healthcare Provider during a Medical Consultation, or for any event during labor that compromises the health of the Client or
Neonate and/or normally requires emergency intervention.

CURRENT MIDWIFE REGULATION:
J. Referral to Physician.
1. Recognition of Problems. The midwife must be able at all times to recognize the warning signs of abnormal or potentially abnormal conditions necessitating referral to a physician. It shall be the midwife's duty to consult with a physician whenever there are significant deviations from the normal. The midwife's training and practice must reflect a particular emphasis on thorough risk assessment.
2. Continuity of Care. When referring a patient to a physician, the midwife shall remain in consultation with the physician until the resolution of the situation. It is appropriate for the midwife to maintain care of

her patient to the greatest degree possible, in accordance with the patient’s wishes, remaining present through delivery if possible.

CURRENT HOSPITAL REGULATION:
Code of Regulations CHAPTER 61.Department of Health and Environmental Control SECTION 16.
Minimum Standards for Licensing Hospitals and Institutional General Infirmaries.
SECTION 1306
D. Regional Perinatal Center with Neonatal Intensive Care Units (Level III) (RPC). In addition to complying with all requirements of Sections 1306.A through 1306.C, the RPC shall provide consultative, outreach, and support services to Level I, II, and III hospitals in the region. The RPC shall manage no less than an average of 2000 deliveries annually, calculated over the previous three years. Personnel qualified to manage obstetric or neonatal emergencies shall be in-house. A board-certified maternal-fetal medicine specialist (perinatologist) shall be in the hospital or on site within 30 minutes for supervision and consultation, 24 hours a day. The RPC shall participate in residency programs for obstetrics, pediatrics, and/or family practice. Physician-to-physician consultation shall be available 24 hours a day for Level I, II, and III hospitals. Regional Perinatal Centers shall coordinate the development and implementation of professional continuing education to maintain competency and provide education to other facilities within the region, facilitate transport from the perinatal centers to the regional perinatal center and back transport when possible, and collect data on long-term outcomes to evaluate the effectiveness of delivery of perinatal care services and the efficacy of new therapies. The RPC shall provide a perinatal transport system that operates 24 hours a day, seven days a week, and return transports neonates to lower level perinatal hospitals when the neonates' condition and care requirements are within the capability of those hospitals.

NameComment
Marian Gordon "Wen should be allowed equal rights under the law. Discrimination against birthingother's in any form is against our constitutional rights. Birth is a natural bodily function and a requirement for the furtherance of our species. Government should not dictate when, why or how birth happens. It is the right of the individual to choose this. Denying care or charging fees as a form of punishment and manipulation is inexcusable. Equality is to provide equal care to all birthing mother's and their chosen providers in SC." Amanda DiPietro "I’m signing because I had two home-births made less safe by DHEC. Restricting midwives does not reflect evidence based safety measures and can result in loss of life and unnecessary trauma. 13 counties in South Carolina do not have OB’s serving them. Midwives fill a crucial gap in care for both those in poverty and those seeking out of hospital care." Sandy Carolina"As a midwife, I am proud to offer an exceptional service and provide this safe alternative to qualifying women.I am appalled that ANYONE would delay care from a mother or baby; especially our licencing agency whose purpose is to protect the health, safety, and general well being of our citizens.Such actions are not only dangerous but they are prejudicialwhich is a violation of YOUR CONSTITUTIONAL RIGHTS." Audrey Montgomery "Mothers and babies matter. Why on earth would anyone deny immediate medical care to mothers and their newborns?" Jaleesa Poston"Every mother and women have a right to decide how they and their babies are cared for. No one else’s opinion matters!" Megan Sanders "I have been beyond blessed by midwifery care." Scarlett Hernkersman"Please protect our access to trained midwives!" Brandy Langley"Midwifery care should stay an option and be supported so women have the options they choose but can still be cared for appropriately during an emergency. Midwives should be upheld and respected." Emileigh Thynes "I safely birthed children at home and will never willingly birth in another hospital because of the difference on care I received. Women need the final decision on where they safely give birthto their children." Lauren Small"Women and babies should have access to healthcare,no matter where they choose to birth" Oliver Troche "All women deserve access to competent, affordable midwifery care of their choice. Where do you think the knowledge of birth came

from? Do you remember not very long ago, if an expectingmother didn't have insurance she wasn't allowed in the hospital. Every study done comparing the safety of hospital birth versus home birth or birthing center births in low risk mothers, has always shown that out of hospital births are as safe if not safer than hospital births, for both mother and baby." Rebecca Brosius "Extremely important issue for women in SC!!!"Rebecca Brosius "Extremely important issue for women in SC!!!" Rebecca Brosius "Extremely important issue for women in SC!!!"Rebecca Brosius "Extremely important issue for women in SC!!!" Rebecca Brosius "Extremely important issue for women in SC!!!" Lori Heffner Gibson "Once upon a time I was a consumer of midwifery care. Now I am a midwife. I am a mother who may have children one day choose home birth midwifery I want to ensure easy access for my clients and my own children. It is a very logical request." Emily Wright"If “my body, my choice” can be used in some fashions, it needs to be used in ALL fashions. Including safely birthing a baby where and with whom you choose. Government doesn’t belong in birth." Lauren Hood "Every woman, every person, should never be denied medical care. Period." Brittany Cox"All women and babies deserve access to healthcare, no mater where they choose to birth. What this will lead to us women still choosing birth outside of hospital with no safe place to turn if they need further emergency help. Every study done comparing the safety of hospital birth versus home birth or birthing center births in low risk mothers, has shown that out of hospital births are as safe if not safer than hospital births, for both mother and baby." Janice Cooper "ALL babies and mothers have the right to Hospital and emergency care." Emily Graham"Restricting access to midwifery care is a detriment to public health and autonomy in personal health care." Angie Huechtker "Women’s rights" Hannah Dale Freeland"This is so incredibly important!" Greg Ryan "Stop medical tyranny upon the public. To refuse a newborn and the mom is utter hypocrisy and is in direct conflict of the Hippocratictaken by doctors." Christina Szrama"I believe women & babies warrant protection, not hospitals nor their “shareholders.”" Kristi Williams "I want to protect medical freedom for families and to protect women’s health by providing equal care for those choosing midwives." Kassie Morgan "I support women’s choice.They should be able to birth THEIR children how they want!" Cammy Benton MD "Because it is the write thing to do" Sarah Williams"I believe all women have a right to choose quality care for themselves and their unborn children. Licensed midwifery should be an option to any low risk expectant mother. In the event of emergent circumstances, transfers should be smooth and respectful." cherith colling "Women should have the ability to choose where and how to birth their children." Hannah Himes"Women should have access to the kid of care they deserve during birth." Isaiah Glenn"Women and Babies rights need to be protected and the hospital's game of "The business of being born," has gone on long enough." Jackie Borsick"Jackie Borsick" Kelley Appleton "As a mom who has safely delivered two children at home in SC, I personally have been at rest knowing that if plans changed andmy attending midwives brought me to the hospital, I would be immediatelyadmitted and attended to. This law would put moms and babies at unnecessary risks of infection and even death for lack of immediate attention." Stephanie Dasher"I believe women have the right to decide who their provider will be, and rage providers need to be able to practice all the skills that will keep women healthy and safe. Removing rights from midwives, limits access and removes the rights of women." Katie Boling"I had two out of my three boys with a midwife. My experiences with my midwife were amazing! I will never have another baby in a hospital unless medically necessary. This is nothing more than discrimination. Shame on DHEC!" Leslie Norman "DHEC has constantly obstructed safe and legal home births in SC for years. There are always fights to be had with them regarding OUR RIGHTS as women and the rights of our precious babies to be born in a calm, loving, quiet setting, in our own bacterial environment instead of in a setting with harsh cleansing chemicals and scents, and the of bacteria from hundreds of people and their bodily fluids in a hospital." Brittney Tassin "Women should be able to transition to a hospital settingseamlessly should an emergency situation arises that requires a higher level of care.The law as it currently stands jeopardizes the health and safety of mothers and their babies." Teena slawson "My best friend had huge success with midwives for her pregnancy and I know a couple other women who use them as well." Karla Hall"If women can have the right to kill their innocent unborn, then they surely should have the right to choose how to bring this precious life into this

world!" Lateysha Black"I support this accident method." Jessica Patterson "Women have every right to choose where they give birth and shouldn't be discriminated against for doing so. This could potentially kill moms and unborn babies." Tamara Sawyer "As a homebirth mother myself I would hope I received The same respect treatment and access to care as anyone else transfer into the hospital from previous medical care" Justin Voshell"All women and babies should have access to the best healthcare and deserve to be all treated equally regardless of money or insurance." Anna Daniels"I believe in the cause and women's right to equal care." Elbert Hubbard"Licensed midwives should be empowered not restricted." Monika Julian "people who need care need care" Lisa Lee"I support midwives and home births." miriam leister"I believe pregnant women should have access to great healthcare in emergency situations, even though they choose to use midwifes and have at home births. My daughter-in -law would have been affected had this restriction been in effect on her second birth." Stephanie Miller"I have had three midwife attended births.Midwifery is equal, if not better than conventional healthcare and we as mothersdeserve access to emergency care if needed." Keisha LockhartBecause mothers and babies (especially of color) continue to die at astronomically high, ridiculous rates in the current system." Natalie Walker"I want to help." Katherine Jackson "All mothers and babies deserve equal access to high-quality emergency care when needed. The state should support MORE options, NOT FEWER, for women in labor!" Lauren Brasington "women and children should be allowed to access the higher level of care if needed, no matter where or how they chose to birth." Tiffany Gregg "Everyone deserves fair medical treatment! Babies do not need to be exposed to unnecessary germs in an ER." Casey Bridges "Home births are the best!!!" shelly kennedy"Shelly Kennedy" Jen Salvatore "Midwives are the best and most natural way to assist mothers in welcoming their baby(use) into this world!" Sharon Watson "All people deserve to have proper healthcare no matter how they choose to birth their baby." Leanna Taylor "Why would you leave out these mothers and babies?? They deserve emergency care just as much as anyone else!" Stephanie Gillam"Mothers are monitored closely by midwives throughout pregnancy just as they are with an obgyn. They can only attempt to birth at home if low risk and everything progressing well. If a transfer needs to happen, why wouldn't a transfer be allowed? I support all woman's choice to birth how they feel most comfortable, including transfers." Bridget Soliman "Every woman has a right to decide how to have her baby. This tries to force women to only have their babies in hospitals. Unfair" Alia Al-Humaidhi"I believe in every human's right to health care and every human's right to choose what care is right for them. It is not the states role to make these decisions not punish a person for choosing home birth. Midwives are highly trained and loving individuals. They and their clients deserve support and access to all the care that is extended to those people who choose to give birth in a hospital and may very well also experience complications." Chelsea Lawrence"This is crucial and women need to have and deserve options!" Taylor Aluisio"We are a home birth family and support equal access to higher care" lisa byrd "Equal access for all women coming from a South Carolina DHEC Licensed provider... Including Midwives. I'm not even sure why were still having this conversation after 2 years. It's a simple fix and a professional recommendation by 2 separate SC midwife organizations and also the Midwifery Advisory Counsel to DHEC. DHEC holds the power to fix it. But now we have to enact legislation to get this injustice to our precious clients resolved. Please make your voice heard!!" TERIE BOLES "Emily is a Matrona Sister and I believe in her cause" Tori Smith"All Mothers and newborn babies need emergency access to care quickly in an emergency situation after birthing outside of a hospital." Andrea Sandifer "Every women should have a choice for how she decides to give birth...and should not be denied if further emergency care is needed" Jacqueline Kuschner "Midwives deserve respect and less control by departments that are not educated in the Midwifery Model of Care and how very critical is the need for Midwife led Midwifery Boards!!" Jennifer stewart"I'm signing because the families of SC need MORE access to high quality out-of-hospital care, and not less. Give midwives the freedom to practice the evidence-based way we have a history of." Linda Weaver"Having had a home birth myself and helping families do the same over the past 20+ years, I know they safety of moms and babies can be dependent on seamless transfers. Let's all work together." Debora Carroll"Women have the right to choose how they want their baby to be born!" Bethany Wilkinson "I believe in women's rights to birth

where you they choose and with whom." Stephanie Spake "I have a beautiful homebirth baby and I deserve options." Mackenzie Ruppe "How sad that hospitals wouldn't want to help and protect babies and mothers in an emergency situation where we need them... just because the mothers' preference is to deliver outside of the hospital because of her low risk pregnancy. We are not against hospitals. Thank God for all the options we have to bring about the best outcome for our births, and moms/babies. We need emergency care available to us if needed. Thank you." Catherine Goodman "I have had 2 babies with midwives and had excellent care.Midwives treat the whole woman and encourage healthy habits for their clients.They thoroughly screen their clients and ensure they are low risk." Savannah luna "Fully integrating midwives into our health care system provides better outcomes for mothers and infants" David Stewart "It is important" Sharon Thunder"This assault on women and birthing needs to stop" Mary Locklair "Whywould they not change the wording in this bill to protect ALL women and babies? Aren't they the department of health and their job is to keep the public safe and healthy!? Please DHEC, do the right thing this is ridiculous!!" Lisa Johnson"I have been practicing as a licensed midwife in SC for over 11 years and have had the honor of serving hundreds of families during that time. Having the ability to transfer a mother/baby to ahospital when necessary is an integral part of practicing safely and ensuring good outcomes. It just doesn't make any sense what DHEC is doing." Paris Henry "Women and their babies should not be punished by preventing life saving care because they chose home birth." Chloe Clauser "I believe mothers and newborns should have the right to access any and all types of medical care without restrictions." Michelle Meyers "Midwives have safely delivered babies in a thousand risky places (swamps, during war, refugee camps, on the Underground Railroad, on boats, in rural indigenous housing) for centuries before hospitals existed. Why not keep that as a SAFE, reasonable option for those who desire a safe, reasonable, non-hospital birth?" Deborah McCarson"Women should be able to chose the provider that is right for their birth and to have that provider have immediate access to higher care if needed." Danna Ancrum"I 1000% support the cause!" Keirra Loud "I'm a Mom" Eva Carroll "There is so much research about how birthing under the care of midwives results in less intervention and better outcomes for baby and momma (including the mental health of the mother). It's insane that they try to restrict it. Join the other countries of the world who romote midwives as a great choice for care and protect women and babies who need extra help!" Barb Machina"As a beneficiary of excellent midwifery care in various settings, I believe women should have as few barriers to safe and healthy birthing options as possible. The system that is in place to provide emergency medical care should do so, without restriction, especially considering their own statistics under the same circumstances." Jennifer Kenway "I had a safe and peaceful birth with my son, watched over and attended to by my amazing Midwife. I knew the hospital was down the road if an emergency arose. Not allowing birthing mothers and/or their infants to have hospital transport or emergency services care is UNCONSCIONABLE and blatantly anti-woman. It is discriminatory and potentially life-threatening. I stand with our capable, knowledge licensed midwives in South Carolina; I also stand with pregnant women in exercising their right to the type of maternal care and healthy birth scenario they desire." Hannah Pratt"My babies were birthed in a birthing center and the freedom of choice to give birth NO one should take away. Emotionally,mentally, physically it is freeing knowing you get to make the choice to have your baby in the best environment to bring them into the world." Hannah Pratt"My babies were birthed in a birthing center and thefreedom of choice to give birth NO one should take away. Emotionally, mentally, physically it is freeing knowing you get to make the choice to ave your baby in the best environment to bring them into the world."Hannah Pratt"My babies were birthed in a birthing center and the reedom of choice to give birth NO one should take away. 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Natalie Mudd"It is of upmost importance that all women and babies have access to medical care if and when they need it, regardless of where they choose to give birth."Norma Bourne"This access is important." Megan Carter"Every woman has the right to give birth how she chooses and every hospital should admit in a timely manner all women and babies in medical emergency situations." Marina Grebennikova "When time is so critical, women and their babies should have easy access to medical personal." Tiffany Miller"All mothers and babies need midwives, but some will also need hospital OB care." Shelly Jones"Midwifery is safe and effective.A much needed resource for women who want these services.Allow women to choose how and where they will birth." Shawna Noel "FREEDOM! Home birth is relaxing and beautiful! Risks are in hospital births as well, but the care providers prepare as best they can. Ler midwives do what they have trained to do!" Julie Brashear"Having had a safe homebirth myself, I was very glad to know I could have transferred care to a hospital should the need have arisen." Mandy Holley"Hospitals shouldn't be allowed to refuse care to anyone, for any reason. I stand with a woman's right to choose." Elizabeth Bradway "passing the Equal Access to Hospital Doors Bill H-4966, officially called the Perinatal Integration Act of 2020 will ensure liberty and maternal Freedoms. *AllBirthsMatter* We need to protect our Ancestral Wisdoms from being stolen by profit-minded policies. A human in peril should not be treated ill; because they have Faith in the natural process of birth. They want to experience the full radiant spectrum of their bodies design. Any athlete who opens up on a preplanned course, and has a crash is treated with dignity at hospitals. Umm SuperDave is risky...Birth is Normal. when the less then 2% of issues arise; fate has chosen the miracles of sciences to work on the Creators behalf. Individual Birth Sovereignty is not up for debate now or later. Remove the rhetoric against Midwives; the keepers of our Primitive Survival Skills cannot be lost to Profit agendas." Layla Angulo"My mother was a midwife. I had to be transferred to a hospital during labor because my baby had meconium leaking out before she was born and that meant major stress, fortunately the midwives knew. I was quickly transferred to a hospital. They saved my life. All of them did.I'm thankful for all the midwives, including my mother (who against her beliefs, caught her grand baby in a hospital) as well as all the hospital staff there that day 22 years ago." Noel Yaun "Supporting my sister in law." Melissa Pemble"I am signing because, women and children deserve and need the right to be able to access health care no matter what stage of life they are in, regardless of financials or their personal choices." Rachael Wilson"Mothers and out born babies deserve to receive a smooth transition into the hospital in the event that additional care is needed. Birth under the care of a midwife is perfectly safe in most cases and in the rare cases where a transfer is necessary, a smooth transition is imperative to the continued health and safety of mother and baby." Anna Chappell "I enjoyed the empowerment that giving birth on my terms allowed for me and my baby. We were better for it and our midwife was with us the entire way!" Heather Davis "I've had 5 wonderful births with two different wonderful midwives. So much better than my 4 hospital births. They need to be supported." Abby Maples "Everyone woman should be able to birth where she is comfortable and confident." Bonnie Hawk "Pro Life" Kaitlyn Bell"As someone who wants a natural home birth in the future, this has effects me in every way" Kia Martin"I believe that this is a matter of life and death!!!" Teresa Gearing"What is wrong with you people who banInnocent babies and midwives from hospitals? Women should have a choice where to deliver their babies and those who choose to deliver in their own home or birthing centers should still have access to the hospitals which their tax money supports." Becky Kolb"All babies and mothers deserve equal emergency care when needed and without wait/hang ups that could cause stress or harm to the mother and baby." erin freeman"Women and infants

have a right to care!" Tanya Park"Tanya Park" Keith Hunter"I'm signing because two of my grandsons were born out of hospital (like it has been for centuries)." Jen Thomason"I believe women have the right to a safe transfer and a birth place of their choosing."
Mary G

ATTACHMENT B.8

SUPPLEMENTAL DOCUMENTATION FOR PUBLIC COMMENT #79
Dear Health Regulation Committee,

22 September 2020

Dear Healthcare Quality Committee,

We are writing to share our comments regarding South Carolina Regulation 61-24, Licensed Midwives. While we agree that these regulations should be amended and updated to reflect current standards and practice while providing the utmost protection of the public, we have concerns about some of the proposed amendments.

The South Carolina affiliate of the American College of Nurse-Midwives (SC-ACNM) is the professional organization for the over 130 certified nurse-midwives working in South Carolina. SC-ACNM and our members stand for improving access to midwifery care. We support policy solutions that ensure our patients have guaranteed health coverage and access to a full range of essential health services and providers under Medicare and Medicaid, as well as individual and family health insurance plans. As such, we proactively support state legislative and regulatory efforts that seek to expand access to certified nurse-midwives and midwifery-led care models.

SC-ACNM is a state affiliate of the ACNM; the professional association that represents advanced practice midwives in the United States. With roots dating to 1929, ACNM sets the standard for excellence in midwifery education and practice in the U.S. and strengthens the capacity of midwives in developing countries. Our members are highly trained primary health care professionals who provide care for women throughout the lifespan, with an emphasis on pregnancy, childbirth, gynecologic, and reproductive health care.

In the interest of public health and safety, any individual seeking to practice as a midwife in the United States should meet at a minimum the "International Definition of the Midwife"1 and "Global Standards for Midwifery Education"2 as defined by the International Confederation of Midwives (ICM). Only pathways to midwifery practice that are consistent with these standards are sufficient to produce qualified licensed midwives. These standards include the following:

1. Completion of a midwifery education program consistent with ICM's "Essential Competencies for Basic Midwifery Practice" and "Global Standards for Midwifery Education."

2. Periodic external review of midwifery education programs. In the United States this is accomplished through accreditation by an organization recognized by the U.S. Department of Education (USDE).

3. Passing a national certification examination. Currently such examinations are offered by the American Midwifery Certification Board (AMCB) and the North American Registry of Midwives (NARM). a. It is ACNM's position that the certifying examination should be developed using processes approved by the Institute for Credentialing Excellence (ICE).

4. Licensure in the jurisdiction in which the midwife practices. 1 International Confederation of Midwives. International definition of the midwife.

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https://www.internationalmidwives.org/assets/files/definitions-files/2018/06/eng-definition_of_the_midwife2017.pdf. Published April 2018. Accessed September 21, 2020. 2

International Confederation of Midwives. Global standards for midwifery education 2010, Amended2013. https://www.internationalmidwives.org/assets/files/general-files/2018/04/icm-standards-guidelines_ammended2013.pdf . Published April 2018. Accessed September 21, 2020.

Please consider revising the following:

• Under Section 100, Definitions and Licensure, 101, G. Certified Nurse-Midwives; the certifying body is the American Midwifery Certification Board, not the American College of Nurse-Midwives.

• Under Section 100, Definitions and Licensure, 101, H. Certified Professional Midwives; this amendment should state that this is a professional midwifery practitioner who has completed an educational program or pathway accredited by the Midwifery Education Accreditation Council (MEAC) and has been certified by the North American Registry of Midwives. The current proposed language could be interpreted to mean that persons who meet the standards for certification but have not passed the certification exam and been certified by NARM could practice in South Carolina. It also lacks adherence to the recommendations outlined by the United States Midwifery Education, Regulation and Association (US MERA) coalition, comprised of representatives of national midwifery associations, credentialing bodies and education accreditation agencies. According to US MERA the following should be included in any new regulatory language:

o For CPMs who obtained certification through an educational pathway not accredited by MEAC:

CPMs certified before January 1, 2020, through a non-accredited pathway will be required to obtain the Midwifery Bridge Certificate issued by the North American Registry of Midwives (NARM) in order to apply for licensure in states using the US MERA language for licensure, or

CPMs who have maintained licensure in a state that does not require an accredited education may obtain the Midwifery Bridge Certificate regardless of the date of their certification in order to apply for licensure in a state that includes the US MERA language.3

ACNM is committed to establishing the midwifery model of care as the standard of care for all women. The principles of this model guide the involvement of midwives in legislative and regulatory actions at the state and federal levels and have resulted in recent efforts to create a more cohesive midwifery presence in the United States.

Please contact Sharon Bond (sharonmbond@gmail.com/843-270-6828) or Linda George (skzmmsss@gmail.com /843-307-3774) if you have any questions. Thank you for working to ensure access to safe, high-quality maternity care in South Carolina.

Sincerely,
Linda J George, MSN, CNM
President, SC Affiliate of ACNM

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1 United States Midwifery Education, Regulation and Association. Statement on the Licensure of Certified Professional Midwives. http://www.usmera.org/index.php/2015/07/01/statement-on-the-licensure-of-certified-professionalmidwives-cpm/ . Published July 1, 2015. Accessed September 21, 2020.
1 International Confederation of Midwives. International definition of the midwife. https://www.internationalmidwives.org/assets/files/definitions-files/2018/06/engdefinition_of_the_midwife-2017.pdf. Published April 2018. Accessed September 21,

2020. 1 International Confederation of Midwives. Global standards for midwifery education 2010, Amended2013. https://www.internationalmidwives.org/assets/files/general-files/2018/04/icm-standardsguidelines_ammended2013.pdf . Published April 2018. Accessed September 21, 2020.

ATTACHMENT B.9

SUPPLEMENTAL DOCUMENTATION FOR PUBLIC COMMENT #80

Office of the South Carolina Section Chair
Amy H. Crockett, MD, FACOG

September 28, 2020

SC Department of Health and Environmental Control
Healthcare Quality Public Comments: R. 61-24 Licensed Midwives To Whom it May Concern:
The South Carolina Section of the American College of Obstetricians and Gynecologists welcomes the opportunity to submit comments on the DHEC proposed regulations amending R. 61-24, Licensed Midwives. State licensure laws and regulations should serve as a reliable authority for consumers and regulators to understand and assess the quality and safety of services, including home births attended by midwives. DHEC can serve a vital function including (1) verification that midwives meet minimum accredited education and training requirements; (2) collection and reporting of safety measures and outcomes for out-of-hospital births; and (3) monitoring and acting promptly on peer review and consumer complaints.

In the proposed regulations, our comments focus on the following:
▪maternal and neonatal out-of-hospital (OOH) transfers from homes and birth centers;
▪integration of home birth midwives with the rest of the maternity care system;
▪standardized, state-approved protocols for client informed consent, collaboration and consult with hospital-based and privileged obstetric providers, and referral and transfer of care based on a pregnant woman's risk status;
▪accredited education and training requirements for a midwife's initial licensure and re-licensure;
▪enforceable limits on scope of care to normal, low-risk pregnancy and newborn care;
▪and improved documentation and reporting of OOH birth outcomes.

Our recommendations for limits on out-of-hospital settings for high-risk pregnancies seek to avoid unwarranted risk to expecting mothers who may consider home birth. Perinatal mortality for home births appears to be higher in the US compared with other high-resource countries that have greater numbers of home births. These countries have better integrated health care systems with national guidelines that govern midwifery practice including patient eligibility criteria, planned birth location, and transfers to higher levels of care. In contrast, most US and SC home births are attended by CPM midwives who lack formal education and adequate clinical training, and practice outside of the rest of the maternity care system.

Our recommendations on transfer of care protocols recognize that our state not only has '911' emergency services, but also a highly developed perinatal regionalization system that ensures pregnant women reach the appropriate level of hospital care, safekeeping both pregnant women and newborns. Unfortunately, Licensed Midwives currently practice outside of and in insolation from this important safety net, putting lives at risk. In an emergency involving a pregnant or postpartum woman, or her newborn, DHEC should require a Licensed Midwife to arrange for prompt transport of mother and/or neonate to a hospital with emergency obstetric capability in accordance with system-wide safety protocols, accompany her client to the hospital and provide records of client care.

Our recommendation that all Licensed Midwives have accredited education and training – as well as collaborative arrangements with other maternity care providers – aligns with the international midwifery standards that govern midwifery practice worldwide. Since 2015, states here in the US have modernized their licensure laws and regulations to require accredited education and training that meets the worldwide, baseline midwifery education standard. Why not here in South Carolina?

Our recommendation that midwives be required to follow standard, DHEC approved safety, consult, transfer, and transport protocols in use by the rest of the maternity care system – and have a consulting, collaborative arrangement with an in-state, hospital-privileged physician with active obstetric admitting privileges – are a recognition that when standards of education and practice are not held in common, optimal consult, transfer and transport systems break down.

Here, we provide comments directly referencing the notice of proposed regulation:

SECTION 100 – DEFINITIONS AND LICENSURE
101.Definitions.
Item H – CPM. Recommend inserting language requiring training from accredited programs here as follows: "A professional midwifery practitioner who has met the accreditation standards for certification set by the North American Registry of Midwives." NARM offers certification for midwives who have either accredited OR non-accredited, apprenticeship-style education and training which does not meet international standards.

Item L – Continuing education. This should specify "accredited" education. Insert accredited directly in the text as follows: "Participation in an accredited organized learning experience….".

Item N – Discharge. This term does not seem to be appropriate; LM clients should be transferred to the care of another healthcare provider and not discharged from care. This seems like abandonment. This seems to be different from Transfer of Care and is confusing. LM should have a responsibility to transfer care, and not abandon patients.

Item CC – North American Registry of Midwives. Accreditation is an issue here. Suggest inserting as follows: " National organization that provides and maintains an evaluative process for multiple routes of midwifery education and training including education and training programs that do not meet USDOE accreditation standards and develops and administers a standardized examination system for CPM credentialing."

Item EE – Physical Examination. This lacks specificity, and the more appropriate description of the service being requested is consultation. This should include not only a physical exam, but a review of the patient's medical, surgical, social and obstetric history as well as an individualized assessment regarding risks of home birth. We recommend specifying that the consulting physician has obstetric training, and active obstetric admitting privileges to a hospital in South Carolina.

Item FF – Physician. Recommend that this specifies that this person holds an active license. Additionally, this physician should have formal obstetric training and have active obstetric admitting privileges for a hospital in South Carolina.

Item OO – Variance. This is alarmingly open-ended. Variance from regulations should only be permitted in very rare circumstances.

102.Licensure. (II)

E. 2. To ensure patient safety and the best possible care for women who are pregnant, South Carolina and the midwives in our state should join the rest of the world's midwives and other states here in the US in support of accredited education and training for all Licensed Midwives.
There are three separate midwifery credentials in the US: certified nurse-midwives (CNM), certified midwives (CM,) and certified professional midwives (CPM). Each credential accepts different levels of education, training and experience. Marked variation in qualifications also exists among midwives who use the CPM designation. Unlike academically trained and credentialed CNMs/CMs, the majority of CPMs have only a high-school diploma or equivalent and are trained in one-on-one apprenticeships and self-study models, with no university or hospital-based education or training. In fact, the CPM apprenticeship training model does not meet US accreditation standards of the US Department of Education (USDE). Notably, CPMs who are apprentice-trained and CPMs who have some university–affiliated, formal training use the CPM designation without distinction.

All references to midwife training, licensure, re-licensure and continuing education should specify that all training programs should be accredited, in this section and in others.

ACOG Position:
•Accredited education should be a licensure prerequisite. Licensure laws and regulations should assure that all midwives have graduated from an accredited program and guarantee continuing competency through recertification.
•Accredited education and professional certification preceding licensure are essential to ensure skilled providers at all levels of care.
•In 2015, ACOG endorsed the International Confederation of Midwives' (ICM) worldwide standards for midwifery education and training – as the baseline for midwives in the US. ACOG believes all midwives – including those educated through non-accredited pathways and licensed and credentialed years ago – should meet the ICM standards.

ACOG Policy:
oPolicy Statement on Midwifery Education and Certification, 2014
oJoint Statement on Practice Relations with ACNM, 2018
oStatement Endorsing the ICM Standards for Midwifery Education, Training, Licensure and Regulation, 2015

H. 2. License renewal. In the 2nd bullet, insert accredited as follows: "Evidence of completion of forty-five
(45) accredited Contact Hours…."

Section 500 – Continuing Education also specifies requirements for re-licensing that would benefit from specifying accredited educational programs. We suggest adding the word accredited in two more places as follows: (1) in the opening paragraph after, "…. forty-five (45) accredited Continuing Education Contact Hours…." and (2) "The Midwife shall ensure all accredited Continuing Education training…."

103.Apprentice Midwife Permit. (II)
104. Variance.

SECTION 200 – ENFORCEMENT OF REGULATIONS
201.General.
202.Inspections and Investigations. 203. Compliance Meetings.

Current limitations in the collection and reporting of data on home births can severely compromise DHEC's oversight role and any analysis of safety and outcomes data on which legislators and regulators rely when enforcing licensure and scope of practice laws. Improved data collection and reporting of patient safety and outcomes data on midwife-assisted home births is needed in our state.

▪Hospitals should be required to report all out-of-hospital birth transfers they receive to the DHEC, or similar entity, as they do for transfers from free-standing surgical centers. This will help improve the collection of accurate home birth outcomes data and strengthen the state oversight/licensure role.

▪Midwives should report their OOH birth case outcomes on an annual basis to the DHEC state oversight board and outcomes reporting should be tied to mandatory peer review.

▪Adverse incident reporting in OOH births. All maternity care providers should be required to report specified adverse incidents in an OOH birth, as Florida now requires with passage in 2018 of the first-of-its-kind OOH birth adverse incident reporting law.

▪Peer review should be specified, mandatory for all transfers, and ideally, tied to case outcomes reporting requirements. Participants in the peer review should include other members of the maternity care team.

SECTION 300 – ENFORCEMENT ACTIONS
This section is a huge improvement and was much needed. It would be helpful to specify who can submit concerns about violation of standards. At one point DHEC would not accept physician complaints about midwife actions, only accepted complaints directly from clients. Physicians receiving transfers of care may have the best perspective on the quality of care and adherence to DHEC licensing regulations.

301.General.
302.Violation Classifications.

SECTION 400 – SCOPE OF PRACTICE (I)
C. Consumer safety concerns warrant restrictions on high-risk births at home, including episiotomy or laceration repair, vaginal birth after cesarean (VBAC), and use of certain medications including methergine, lidocaine, antibiotics, epinephrine and IV fluids.

We strongly oppose this expansion of scope of practice; the current regulations adequately describe care for uncomplicated low-risk laboring women and newborns. Episiotomy, which includes intentional incision of the complex pelvic floor muscles, should not be routinely performed and is only indicated in the case of an emergency. The patient should be transported to a hospital if there is a situation in which maternal fatigue or fetal intolerance of labor arises which would require an episiotomy. Additionally, obstetric lacerations and episiotomy can be quite complex to repair. Obstetric lacerations and episiotomy which are improperly repaired can result in lifelong disability, including chronic pain and incontinence of both urine and stool. They can result in severe and life-threatening infection. CPM do not have adequate training in female pelvic anatomy to perform episiotomy, recognize and repair complex lacerations.

It is also important to specify that even if CPM obtain nursing credentials (which would include obtaining intravenous access, for example) their scope of practice should not be expanded unless they re- credential as Certified Nurse Midwives through the nursing board. This is included in the legislative language in Colorado and is a good model for our regulations. There is no reason that a healthy normally laboring patient would need intravenous fluids during labor in the out of hospital setting where she is typically still allowed to consume liquids by mouth during her labor course.

D.2. The specific prohibition of care for women with a previous cesarean section is much needed and an important improvement to these regulations.

There are well-founded patient safety concerns with attempting a vaginal birth after cesarean section (VBAC) delivery at home regardless of the training of the birth attendant. The National Institutes of Health (NIH) 2010 Consensus Development Conference on VBAC summarized an imposing list of life-threatening complications to both mother and baby that can occur even in women who undertake a trial of labor in a high-volume, fully staffed hospital labor and delivery unit. NIH recommends that VBAC should be done in well-equipped facilities ready to perform an emergent cesarean delivery with surgeons, anesthesia personnel, surgical nurses, operating rooms, blood transfusions, and post- operative care. See National Institutes of Health Consensus Development Conference Statement, "Vaginal Birth After Cesarean: New Insights," March 8-10, 2010.
http://consensus.nih.gov/2010/images/vbac/vbac_statement.pdf.

SECTION 500 – CONTINUING EDUCATION (II)
A.We appreciate that this regulation specifies that continuing education for Licensed Midwives must be from accredited educational programs. We recommend expanding the requirement for accredited educational pathways to initial licensing.

SECTION 600 – REPORTING
601.Incidents.
B.We recommend including specific language here requiring reporting any pregnancy ending in miscarriage/stillbirth/fetal death and not just neonatal or maternal death. We also recommend extending the reporting period related to the death of client or neonate within 30 days of discharge, transfer or termination of care.

602.Quarterly Report Forms. 603.Reporting Mortalities.
604.Registration of Birth.

SECTION 700 – CLIENT AND NEONATE RECORDS SECTION 800 – [RESERVED]
SECTION 900 – CLIENT CARE AND SERVICES (I)

New safety data from Oregon on out-of-hospital births supports restrictions on high-risk out-of- hospital births, and better state oversight of safety protocols to protect home birth consumers. Oregon ranks among the top ten states in the percentage of births that occur out-of-hospital. In 2011, the Oregon Legislature passed an ACOG–backed bill (HB 2380), requiring the state public health division to collect data on planned place of birth and planned birth attendant, and report annually on the outcomes of these births. The 2012 summary report of the Oregon Health Authority, Public Health Division analyzed the data and found a much higher mortality rate for out-of-hospital births

http://public.health.oregon.gov/BirthDeathCertificates/VitalStatistics/birth/Pages/planned-birth-place.aspx:

"Sixty-two term fetal and 30 early neonatal deaths occurred in Oregon during 2012; of these 8 (4 fetal, 4 early neonatal) occurred among planned out-of-hospital births. The term perinatal mortality rate for planned out-of-hospital births (4.0/1,000 pregnancies) was nearly twice that of in-hospital births (2.1/1,000). …6 of 8 pregnancies did not meet low risk criteria. These pregnancies included: more than 40 weeks gestation (4); twin gestation (2); morbid obesity (1). Planned attendants among these 6: CNMs (1), licensed DEMs (3), unlicensed midwife (1) and ND (1)."

901. Prenatal Care.
C.Please specify that this assessment should be done at every visit, not just every "prenatal visit." Visits which are scheduled for education only, or for a problem visit and not a prenatal visit are just as important to document vitals and assess maternal and infant well-being.

D.1. j. All women planning an out of hospital birth should be screened for gestational diabetes, not just those at high risk. Screening with history looking for risk factors may be appropriate (it is still a screen), but very few women do not have any risk factors and most benefit from glucose challenge testing. Undiagnosed or untreated gestational diabetes confers additional risk during delivery and the immediate peripartum period to both the pregnant woman and infant.

D. 3.a. Requiring Group B Streptococcus screening for all women is an important inclusion and a good improvement to these regulations.

902. Intrapartum Care.

903. Postpartum Care.
A.5. There should not be an expansion of scope of practice to allow for suturing of first or second- degree perineal or vaginal lacerations. Obstetric lacerations can be quite complex to repair. Obstetric lacerations which are improperly repaired can result in lifelong disability, including chronic pain, fistula formation between the vagina and other pelvic organs like the rectum or bladder, and incontinence of both urine and stool. Even a well-performed repair can also result in severe and life-threatening infection. CPM do not have adequate training in female pelvic anatomy to recognize and repair complex lacerations.

904. Newborn Care.
B.These regulations should specify that newborn hearing screening and congenital heart disease screening are also required, in addition to the metabolic screening. Newborn screening aims to identify newborns who may be at risk for hidden conditions. If left undetected and untreated, these conditions can lead to illness, physical disability, developmental delay, or death. A screening test is not a diagnostic test. It identifies individuals who may have a condition so that follow-up testing can be offered. Midwives in our state should be familiar with the components of newborn screening, follow state mandates, and consistently utilize educational materials regarding the importance of newborn screening designed for both providers and their clients. To improve newborn health outcomes in South Carolina, rates of newborn screening should be reported by delivery setting. Data from other states (eg, Utah) shows that recommended newborn congenital heart defect screening, hearing screening and heel stick screening was performed less often for neonates born at home or a birth center.

SECTION 1000 – INFORMED CONSENT (II)

SECTION 1100 – PHYSICAL EXAMINATIONS (I)
This section is really mis-named. It seems as though the request is not just for physical examination from a physician, but a consultation that should include a review of medical, surgical, social and obstetric history as well as an evaluation of risk factors for out of hospital birth.

It should be specified that this physician must be licensed to practice medicine or nursing in the State of South Carolina. It should furthermore be required this healthcare provider has current obstetric admitting privileges at a hospital in South Carolina, or is part of a practice or call pool with partners who have current obstetric admitting privileges at a hospital in South Carolina. South Carolina Licensed Midwives should be working in collaboration with South Carolina physicians.

Additionally, the “second physical exam” should be performed by the same physician or certified nurse midwife, or another physician or certified nurse midwife within the same practice group or call pool. This section could be further strengthened by requiring all women to pre-register their intended out of hospital birth at the nearest hospital with emergency obstetric capability, which is ideally the hospital in which their consulting physician has active obstetric admitting privileges. Preregistration may help

emotionally prepare the woman for the possibility of a transfer, speed the transfer process, and give the hospital the opportunity to provide educational materials to help inform patient decision-making. Safety concerns are greater in states where there is no requirement for home birth midwives to work collaboratively with hospital-based and privileged providers or under state-approved practice guidelines and safety and transport protocols. Placing more formal expectations around the interface between Licensed Midwives and the rest of the healthcare system will improve outcomes for women and infants experiencing unexpected emergencies.

SECTION 1200 – PRESCRIPTION MEDICATION ADMINISTRATION (I)
4.We do not support allow methergine to be administered in out of hospital settings. Oxytocin is an excellent first-line drug to control hemorrhage; it can easily be given via intramuscular injection, and it will serve well to stabilize women while transportation to a hospital can be arranged. There is no need for CPM to have access to additional medications. When the first drug is needed to control hemorrhage, the birth is no longer low risk and immediate arrangements for transfer should be made. This is consistent with legislation governing CPM practice in other States (Utah). Methylergometrine (Methergine) can cause hypertensive crisis and stroke in women with blood pressure elevations and is not safe for use outside of a monitored environment.

5.We do not support the use of injected lidocaine in out of hospital settings. Intravascular Lidocaine can cause life threatening hypotension, arrhythmias and cardiac arrest. I would support the use of topical Lidocaine in the out of hospital setting, but injection of Lidocaine is risky and should not be required in the setting of a normal, uncomplicated birth. The only reason injected lidocaine would be required is if women have complex perineal lacerations and for these repairs should be transferred to the hospital for surgical evaluation.

6.We do not support the use of penicillin or other antibiotics in the out of hospital setting. It is no longer a normal uncomplicated pregnancy if a patient required antibiotics. There are risks of anaphylaxis with administration of intravenous antibiotics which could be life threatening in the out of hospital setting. If a patient is GBS positive and requires prophylactic antibiotics, this is an indication for an in-hospital delivery due to the risk for early or late onset neonatal sepsis. These infants benefit from additional time for observation and monitoring of vital signs after birth which is not permitted in the out of hospital setting in which midwives typically do not monitor longer than 2 hours.

7.We do not support the use of lactated ringers or normal saline in the outpatient setting. There is no reason that a healthy normally laboring patient would need intravenous fluids during labor in the out of hospital setting where she is typically still allowed to consume liquids by mouth during her labor course. It is also important to specify that even if CPM obtain nursing credentials (which would include obtaining intravenous access, for example) their scope of practice should not be expanded unless they re- credential as Certified Nurse Midwives through the nursing board. This is included in the legislative language in Colorado and is a good model for our regulations.

8.We do not support the use of epinephrine in the out of hospital setting. This is a medication only indicated in the setting of circulatory collapse. Training for licensed midwives is not adequate to treat either women or neonates who are in cardiac arrest. Licensed Midwives should activate EMS and emergently transfer the patient to the hospital. If a licensed midwife is doing an appropriate job with monitoring fetal heart tones during labor, transfer to a hospital should be accomplished long before any situation like this evolves.

SECTION 1300 – MEDICAL CONSULTATION AND REFERRAL (I)
B.1.k. “Elevated blood glucose levels” is not specific enough. Any suspicion of gestational diabetes or glucose intolerance in pregnancy. Abnormal results on diabetes screening tests, such as 1-hour 50

gram glucose tolerance test >140, and any fasting blood glucose level >90 should require medical consultation for management of gestational diabetes.

B.2.e. Any meconium staining should be an indication for transfer to the hospital, not just moderate or severe meconium staining.

B.3.c. Any postpartum fever over 101.5 should be an immediate referral. Endometritis untreated for >24 hours can result in life-threatening sepsis, ICU admission and even emergent hysterectomy to treat an uncontrolled infection.

SECTION 1400 – DISCHARGE

SECTION 1500 – TRANSFER OF CARE (I)
A.Facilitating safe transfer from home or birth center to hospitals is a shared goal. Safety concerns are greater in states where there is no requirement for home birth midwives to work collaboratively with hospital-based and privileged providers or under state-approved practice guidelines and safety and transport protocols.

Emergency transfers: In an emergency, DHEC should require a midwife to arrange for prompt transport of mother and/or neonate to a hospital with emergency obstetric capability in accordance with system-wide safety protocols. The best way to ensure that Licensed Midwife clients receive the highest level of care in the event of an emergency is if there is a pre-established plan in place for emergency transfers. Ideally, this would have been arranged during prenatal care and the pregnant woman would have an established relationship with a physician with active admitting obstetric privileges at a hospital within 15-30 minutes of the location of the planned home birth. The pregnant woman would have pre-registered at this hospital, and perhaps even toured it as part of her preparation for childbirth. There should also be arrangements in place for the transfer and admission of neonatal emergencies. There is precedent for this; Washington state requires Licensed Midwives to submit a plan for consultation, emergency transfer and transport annually at the time of license renewal.

Non-emergent transfers: When a home birth patient's condition and risk status changes, care of the patient should be transferred to another provider to assure continuity of care and in accordance with previously agreed-upon protocols. Again, it is ideal if this plan would have been arranged during prenatal care and the pregnant woman would have an established relationship with a physician with active admitting obstetric privileges at a hospital within 15 -30 minutes of the location of the planned home birth. The pregnant woman would have pre-registered at this hospital, and perhaps even toured it as part of her preparation for childbirth.

We call on DHEC to support and implement strategies such as:
- ▪defined model practices for midwives, hospital providers and staff and hospitals/hospital systems like maternal levels of care;
- ▪improved documentation of maternal and newborn transfers to support assessment of planned home birth outcomes;
- ▪consistent use of standard transfer forms to facilitate communication;
- ▪use of transfer feedback tools to voluntarily collect feedback on the transfer process from both hospital staff and midwives;
- ▪mandatory peer review for all transfers; and
- ▪state oversight of safety protocols to protect home birth and birth center consumers.

SECTION 1600 – MAINTENANCE OF EQUIPMENT SECTION 1700 – INFECTION CONTROL
1701. Infection Control Practices. 1702. Tuberculosis Screening. (I)

SECTION 1800 – MIDWIFERY ADVISORY COUNCIL
We recommend disbanding the Midwifery Advisory Council. Instead, it should be replaced with a Board of Licensed Midwifery in the same model as the Board of Nursing or Board of Medicine at SC LLR. This would align with the mission of DHEC to protect public health, safety and welfare by assuring safe and competent practice of Licensed Midwifery.

The revised Board of Licensed Midwifery would be responsible for licensing qualified individuals, investigate complaints and take disciplinary action when necessary. Licensure pathways could be surveyed and approved to ensure high-quality, accredited education for future Licensed Midwives. It would be able to serve in a meaningful peer review capacity.

If the Midwifery Advisory Council will remain in its current incarnation, the designation of the physician member of the Council as being "active in perinatal care" is unclear. We urge DHEC to specify that the physician member have current obstetric admitting privileges or at a minimum hold an active license in good standing in South Carolina. The SC Section of ACOG would be willing to assist in identifying individuals who are qualified to serve in this position. Additionally, the Midwifery Advisory Council would be strengthened by the addition of a second physician member with training in pediatrics.

Thank you for your consideration.

Dr. Amy Crockett, MD, MSPH
Chair, South Carolina Section of ACOG

ATTACHMENT B.10

SUPPLEMENTAL DOCUMENTATION FOR PUBLIC COMMENT #88

I am a Birth Center owner and the rationale of changing the Licensed Midwife regulations to be consistent with Birth Center regulations is incorrect.

Proposed Section 1100 is not consistent with other Department regulations. N Other regulations do not require:
a client to undergo an initial Physical Exam by a physician
a client to be seen by a physician between 14-20 weeks gestation
a written signed statement by a physician at an initial physician visit
a statement of vertex presentation
orders needed for medications needed for intrapartum

Not only are these mandates not consistent with other Departmental regulations; there are some serious flaws in the logic of these mandates.
1) If the department wished to provide consistency with other Department regulations; the first change to the LM regulation should be to update the definition of low risk VBAC:

Regulation 61-102 Standards for Licensing Birthing Centers for Deliveries by Midwives "D. Professional Care (1) Limitation of Services Offered by Birthing Center: (I)

In order to be delivered in a birthing center, the woman and/or her infant shall exhibit no evidence of:... (m) previous caesarean delivery with classical incision;"

2) Physical examination is undefined and could intel intrusions upon the personal rights of the client.

3) Midwives have no authority over a physician to require them to provide such services to her clients. If the department wishes to require such stringent guidelines for midwifery clients than they should require that their health departments or public clinics provide such services. Requiring the midwives to get a physician's signature without requiring the publicly paid physicians to offer such services is an infringement upon the trade of midwifery and a bias toward the profession and consumers served by this regulation.

4) There is no rationale for requiring a visit between 14-20 weeks.
Only two states require a physician visit of any kind; but restricting the visit into an arbitrary time frame would needlessly restrict care especially to Medicaid recipients and breastfeeding mothers. It is common for a breastfeeding mother to not have regular menstrual cycles and be unaware of early pregnancy. Additionally, low income mothers have found that Medicaid backlogs can take an extended amount of time to qualify. While the midwife may agree to see the client prior to Medicaid approval, the client could be subject to the cost of the physician, labs and ultrasounds if these timelines are mandated. The financial burden could cost Medicaid clients thousands of dollars and likely disqualify a large portion of health mothers from midwifery care.

5) Even birth centers are not required to have a written letter from a physician at an initial visit. A client who is healthy at 14 weeks may not be healthy at 36 weeks and therefore there is no rationale reason for an initial letter.

Birth centers can be owned by anyone and it is not uncommon for them to be affiliated with a physician

which makes getting a written statement more attainable.

Birth centers deliver in the same location for every delivery. While the written letter is burdensome for the centers it could be impossible for a home birth midwife who travels for deliveries because she comes in contact with different areas and may not be as widely recognized because her base is disbursed over a large geographical area.

Although birth centers are required to get a written letter from a physician at the end of pregnancy; this is distinctly different from what is being required in the propose Licensed Midwife Regulations. "...that he or she has determined to the best of his or her ability that the pregnancy is a Low Risk Pregnancy as defined by this regulation." This statement implies a correlation between midwife and physician that is similar to an employer/employee relationship. Licensed Midwives are independent providers with distinctly different training an criteria for out-of-hospital delivery. In order to provide the best care to clients, midwives can not be subject to supervision by physicians.

6) A physician can't sign a statement of vertex presentation unless he preforms a 3rd trimester ultrasound. This is yet another financial burden to the family with no rationale. A baby can change position at any time and it is common for a baby to be breech at 34 weeks gestation. Additionally, many midwives have extended training in breech delivery and the parents should be the ones who make the final decision regarding the route of delivery for their baby based upon their individual benefits and risks.

7) 6) As a midwife, I can say that the statement, "b. orders needed for medications needed for intrapartum" is horribly flawed. It is obvious that the Department needed the advice of MAC to formulate these regulations. There are no intrapartum medications used by Licensed Midwives; however, we do use POSTPARTUM medications.

Birth centers also do not get individual orders for each patient. The patients get prescriptions in their name and the midwives give them PRN. Requiring written orders further reduces the ability of a midwife to fully comply with the proposed regulation and inhibits otherwise healthy women from choosing a community birth with a Licensed Midwife.

SOUTH CAROLINA STATE REGISTERY Rationale:
Section 1100. Physical Examination, added for consistency with other Department regulations
1100.A re-codified prior F.1 amended for clarity.
1100.B re-codified prior F.1 amended for clarity.

Proposed Regulation:
SECTION 1100 – PHYSICAL EXAMINATIONS (I)

A. Initial Physical Examination:

1. The Midwife shall require the Client to undergo an initial Physical Examination completed by a Physician or other Authorized Healthcare Provider between fourteen (14) weeks and twenty (20) weeks of gestation. The Midwife may admit Clients after twenty (20) weeks gestation provided the Client has undergone a Physical Examination that meets the requirements in Section 1100.A.2.

2. The Midwife shall ensure the initial Physical Examination of the Client is documented in the Client’s record and includes:

a. A written and signed statement by the Physician or other Authorized Healthcare Provider that he or she has determined to the best of his or her ability that the pregnancy is a Low Risk Pregnancy as defined by this regulation; and

b. Identification of special conditions and/or care required.

B. Second Physical Examination:

1. The Midwife shall require the Client to undergo a second Physical Examination completed by a Physician or other Authorized Healthcare Provider after thirty four (34) weeks of gestation.

2. The Midwife shall ensure the second Physical Examination of the Client is documented in the Client's record and includes:

a. A written and signed statement from the Physician or other Authorized ealthcare Provider that the pregnancy remains a Low Risk
Pregnancy and the fetus is in the vertex position; and

b. Orders for Medications needed for intrapartum

ATTACHMENT B.11

SUPPLEMENTAL DOCUMENTATION FOR PUBLIC COMMENT #100

I have been involved in the natural birth community for almost 30 years. As a past home birth consumer in the state of South Carolina, and the mother of a home birth consumer, I have a vested interest in the regulations that keep home birth midwives practicing legally and safely in SC.

While I think it is ill-advised to pursue changes to the midwifery regulations at this time due to the complications of holding public meetings in the midst of a pandemic, I and many other families who believe strongly in the right to self-determination – which includes adult women making informed decisions about their preferred care providers and place of birth – have every intention of attending in person if this revision of the licensed midwife regulations moves forward without extensive and substantive changes. The proposed revisions demonstrate a lack of understanding of logical consequences. Inadequate notice to the public, failure to involve the Licensed Midwives and concerned stakeholders, specifically the home birth consumers, and disregard for the Midwifery Advisory Council in the revision process from the beginning have resulted in a poorly executed document that does nothing to improve the health outcomes of mothers or babies in SC.

101.
D. Authorized Healthcare Provider: Should include wording regarding providers licensed in contiguous states.
E. Birthing Center: Wording should be revised to exclude listed facilities and also any location specified under P. Home Birth setting.
G. Certified Nurse Midwife: Should include wording regarding providers licensed in contiguous states.
J. Compliance Meeting: Provision needs to be made for the Licensee to include representatives of their choice.
P. Home Birth: Should be expanded to include other locations that may serve as a temporary residential setting such as a friend or family member's home or a rental space like a hotel, which may be necessary or desirable for various reasons including proximity to a hospital or evacuation destination.
W. Medical Consultation: Wording should be changed to remove Physician and only reference Authorized Healthcare Provider as already defined under D.
DD. Nurse Practitioner: Should include wording regarding providers licensed in contiguous states.
EE. Physical Examination: Wording should be changed to remove Physician and only reference Authorized Healthcare Provider as already defined under D.
FF. Physician: Should include wording regarding providers licensed in contiguous states.
GG. Prescription Medication: Wording should be changed to remove Physician and only reference Authorized Healthcare Provider as already defined under D.
II. Referral: Wording should be changed to remove Physician and only reference Authorized Healthcare Provider as already defined under D.
MM. Transfer of Care: This wording seems to preclude the current standard of Continuity of Care (J.2. in current regulations). Continuity of Care is an important concept and should be maintained to the degree possible.

202.
B. Minimum timeframe, such as 30 days, should be specified. e.g., The Midwife shall provide the Department all requested records and documentation in the manner and within the timeframe specified by the Department, but not fewer than 30 days. (I)

301.

Concern 1: There is no mention of the Midwifery Advisory Council's role in addressing appropriate practice. Is all oversight and judgment being invested in hired or appointed Department staff with no practical experience in provision of home birth midwifery care?
Concern 2: There is no language addressing appeals or administrative hearings in response to purported violations as determined by Department staff.

400.
D. 2: Given the high rate of cesarean section birth, it is an unreasonable standard to prohibit all attendance at home births for clients wishing to exercise their right to informed consent by choosing an attended home birth. Most cesareans are performed for non-recurrent reasons and subsequent pregnancies should be evaluated for the appropriateness of home birth on a case-by-case basis by the midwife in consultation with authorized healthcare providers. Specific factors to be considered may include reason(s) for the previous cesarean(s); prior history of vaginal birth; current health of client; and verification of placental placement in relation to uterine scarring.
Given the resistance of some hospitals and providers to VBAC, a blanket prohibition on midwife-attended home births will result in a further increase of unassisted deliveries and negatively impact the health of SC mothers and babies.

700.
B.1.n. Wording should be changed to remove Physician and only reference Authorized Healthcare Provider.

901.
A. Scheduled Prenatal Visits: Wording should be amended to state "Upon acceptance as a Client, the Midwife or Authorized Healthcare Provider shall conduct prenatal visits…"
B. Home Visit: Wording should be amended to state "…at least one (1) of the prenatal visits to the Client's planned location of delivery during the last six (6) weeks…"
C. Wording should be amended to encompass potential for televisits. Potential revision could state: "The Midwife shall document each prenatal visit in the Client's record and include the format of visit and all relevant care provided, which may include the following:"
D. Depending on acceptance of Client to midwifery care, such specific dates of testing may not be applicable. Wording should be revised to indicate that upon acceptance of Client to midwifery care, midwife will ensure and document in the Client's record that all tests and screenings under sections 1 and 2 are completed prior to birth and screenings under section 3 are completed or informed refusal is obtained prior to birth.

1100.
A.1. Prohibiting access to midwifery care for clients who did not receive early prenatal care is counterproductive to optimizing health outcomes for SC mothers and babies. There are many reasons mothers may not obtain early prenatal care, including financial concerns, lack of pregnancy knowledge, past trauma by care providers, or simply not realizing they are pregnant until later in gestation. There are also mothers who deliberately plan unassisted delivery from the beginning of a pregnancy who may be persuaded to change their minds and permit attendance of a skilled midwife later in pregnancy. Stipulating that midwives may not accept care of these patients is more likely to result in zero care than in sudden compliance with a hospital-based care provider's prenatal care schedule.
A.2.a. A written and signed statement by an authorized healthcare provider certifying a pregnancy as low-risk raises the specter of legal liability that is not realistic. The only possible practical intent of this stipulation is to render home birth midwifery care legally unattainable in practice.
B.3.a. Again, a written statement certifying a pregnancy as low-risk is not a reasonable expectation and will effectively render home birth midwifery illegal, with a likely result of an influx of unlicensed and underground practitioners from this and other states.

1200.
A. Wording should be changed to remove Physician and only reference Authorized Healthcare Provider.
B. Wording should be changed to remove Physician and only reference Authorized Healthcare Provider. Given the definition of medication under 101.X, this appears to restrict the ability of the midwife to administer over-the-counter or herbal preparations without a written order from an Authorized Healthcare Provider. This is an unreasonable standard that would effectively prevent use of Tums or aromatherapy. The first sentence of this section needs to be removed (which would eliminate redundancy with the previous section anyway). Ex. B. The Midwife shall only administer the following prescription medications:
B.2. Wording should be clear on use of informed refusal. Ex. 2. Eye prophylactic, within one (1) hour of birth, unless written informed refusal is obtained from the Client. Documentation of the administration or Client's refusal shall be made in the Client's record;
B.3. Wording should be clear on use of informed refusal. Ex. 3. Vitamin K, unless written informed refusal is obtained from the Client. Documentation of the administration or Client's refusal shall be made in the Client's record;
B.4. Recommend replacing "Oxytocin or Methergine" with "Common medications utilized to arrest hemorrhage, such as oxytocin and methergine" to permit the use of additional drugs (such as misoprostol) at the authorized healthcare provider's discretion.

1300.
A. Wording should be changed to remove Physician and only reference Authorized Healthcare Provider. The level of documentation described is excessive. This is onerous under non-urgent circumstances and will be impossible to manage under urgent or emergent circumstances where decisions must be made quickly.

1400.
Wording should be changed to remove Physician and only reference Authorized Healthcare Provider. Requiring the midwife to discharge the client solely based on intervention recommended by an Authorized Healthcare Provider is antithetical to the concept of informed consent. If such circumstances are not outside the midwife's scope of practice outlined in section 400, it is clearly within the client's purview to decline recommendations and continue with midwifery care. An example is the opinion of many hospital-based obstetrical providers that induction without indication is acceptable and even desirable at 39 weeks (and it was 37 weeks until Medicaid quit paying for all the NNICU stays). In the face of such a recommendation, it is clearly the client's right to refuse and to continue with midwifery care with the intention of birthing at home. This section seems to indicate that this would not be the client's decision any longer once an Authorized Healthcare Provider states induction as a recommended course of action.

1500.
A. While it is within the midwife's purview to call 911, this should not be a requirement. Each situation needs to be evaluated independently to determine whether this course of action is safer or more expedient than other options. Rural EMS units may be a significant distance away and transport may be accomplished sooner in a private vehicle. EMTs are not appropriately trained to manage all potential complications of the mother or baby and at times have caused more trauma, both physically and emotionally. Circumstances might dictate that a non-emergent transport be made to a specific hospital, while EMS rules typically dictate that transport be made to the nearest hospital. Clients without health insurance may refuse to accept an ambulance ride in a non-emergent situation and should not be burdened with unnecessary expense. A calm, orderly transfer of birth locations during labor is preferable whenever possible, and this is best accomplished by relying on the judgment of the midwife, in consultation with the client whenever feasible.

B. While it is appropriate that care is transferred to another provider when necessary, the statement as written does not address continuity of care with the midwife remaining involved as a member of the care team.

1800.
The Midwifery Advisory Council should be participating in revising regulations, addressing reported violations, serving as an appeals body, and otherwise guiding the Department as subject matter experts. The revised language appears to relegate the MAC to a nominal body with zero weight or responsibility. While this does reflect how the Department has treated the MAC in recent years, this should not be codified as the official expectation.

Sincerely,

Cyndi Rosenblatt

ATTACHMENT B.12

SUPPLEMENTAL DOCUMENTATION FOR PUBLIC COMMENT #104

To Whom it May Concern,

I have many concerns about the proposed regulations regarding the future of Midwifery in the State of Sourh Carolina. Both as a homebirth client and a student midwife, I value the expertise of the midwives in this state. To be quite honest it is incredibly difficult to convey the level of dedication these women have to their profession. With that being said, the dedication, training and hours these women put in make them some of the most trustworthy professionals in the birth world. They are a credit to the birth profession and vital in community-based health care.

The ongoing disregard of the state midwives and the Midwifery Advisory Council's advice concerning the updating of these regulations is insulting. I beseech you to listen to and trust these LICENSED MIDWIVES. They are THE SPECIALIST in out-of-hospital birth!

When considering Vaginal Birth After Cesarean Section (VBAC) DHEC should recognize a woman's bodily autonomy and her confidence in its ability to birth what it has grown and created. Many Obstetricians agree that a trial of labor should always be allowed. Licensed midwives have the ability and knowledge to decipher when a birth is not progressing as expected and make a last minute transfer. Homebirth VBAC should not be forbidden. The decision about where to birth should always be between a mother and her care providers, and include full informed consent even when it follows a cesarean. Across the state birthing women are choosing to have their babies unassisted due to these outrageous restrictions rather than give birth again in a hospital. No woman should be forced to choose between a homebirth without a provider and a hospital birth.

In more rural parts of the state, hospital care and delivery as well as physician examination are not as readily available. This creates disparity for lower income Caucasian and African American women thus creating a further divide in care. If our goal is really to save lives then we should allow women to seek medical consultations with already trusted medical professionals via telehealth. Making these provisions breaks down generational and financial barriers to proper prenatal care and allows women to seek care at their comfort level and give birth uninhibited in an environment surrounded by family and loved ones.

Additionally, I'm concerned that DHEC finds the need to prohibit midwives from administering Misoprostol, stating in proposed regulations that postpartum hemorrhage is an off-label use Misoprostol. Misoprostol is a life-saving drug used off-label in every hospital across the United States.

The article Uses of Misoprostol in Obstetrics and Gynecology found on PubMed states, "However, it remains an important option for treating postpartum hemorrhage when other agents are not available or fail. A descriptive study showed that 1000 μg of rectally administered misoprostol, when given to patients who failed to respond to oxytocin and ergotamine, controlled postpartum hemorrhage within 3 minutes."

As I'm sure you are aware, every second counts when stopping postpartum hemorrhages and the prohibition of this medication could mean the difference in life or death.

Finally, It is imperative that midwives be included in the perinatal levels of care for immediate access to the appropriate department. In the event of transfer minutes matter and subjecting laboring women to emergency room waiting rooms, exposing them to viruses and other unrelated emergencies is ridiculous and unnecessary. It would be more efficient for transfers to be take straight to labor and delivery.

I appreciate your time in hearing my concerns.

ATTACHMENT B.13

SUPPLEMENTAL DOCUMENTATION FOR PUBLIC COMMENT #105

September 24, 2020
DHEC

RE: Midwifery Regulations

To Whom it May Concern,
I have many concerns about the proposed regulations regarding the future of Midwifery in the State of Sourh Carolina. Both as a homebirth client and a student midwife, I value the expertise of the midwives in this state. To be quite honest it is incredibly difficult to convey the level of dedication these women have to their profession. With that being said, the dedication, training and hours these women put in make them some of the most trustworthy professionals in the birth world. They are a credit to the birth profession and vital in community-based health care.

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In more rural parts of the state, hospital care and delivery as well as physician examination are not as readily available. This creates disparity for lower income Caucasian and African American women thus creating a further divide in care. If our goal is really to save lives then we should allow women to seek medical consultations with already trusted medical professionals via telehealth. Making these provisions breaks down generational and financial barriers to proper prenatal care and allows women to seek care at their comfort level and give birth uninhibited in an environment surrounded by family and loved ones. Additionally, I'm concerned that DHEC finds the need to prohibit midwives from administering Misoprostol, stating in proposed regulations that postpartum hemorrhage is an off-label use Misoprostol. Misoprostol is a life-saving drug used off-label in every hospital across the United States.

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Finally, It is imperative that midwives be included in the perinatal levels of care for immediate access to the appropriate department. In the event of transfer minutes matter and subjecting laboring women to emergency room waiting rooms, exposing them to viruses and other unrelated emergencies is ridiculous and unnecessary. It would be more efficient for transfers to be take straight to labor and delivery.

I appreciate your time in hearing my concerns.

Sincerely,
Lindsay Millwood

Best Wishes,

Lindsay Millwood
Certified Birth Doula, herbalist, RBPR

ATTACHMENT B.14

SUPPLEMENTAL DOCUMENTATION FOR PUBLIC COMMENT #108

Dear Members of the South Carolina Board of Health and Environmental Control,

The Memorandum to Licensed Midwives concerning Vaginal Birth After Cesarean (VBAC) in2006 is based on what is now out-of-date research. Please consider looking at more recentstudies and statements on VBAC.

Of the 35 states with licensure or statutory authority for the legal practice of CPMs, only sevenstates do not allow VBAC by licensed midwives at home. Not surprisingly, these states havehigh rates of cesarean sections and low rates of VBAC. South Carolina is one of them. SouthCarolina continues to have cesarean rates higher than the national average (33.5% vs 31.9%)and VBAC rates lower than the national average (12.0% vs 13.3%). Our state must do better.1

The ACOG guidelines which mandate that a physician and anesthesiologist be "immediatelyavailable" during a trial of labor were found to be the main reason for the low rates of VBAC in a2011 study. Additionally, fear of liability was a central reason for obstetricians and midwives to2avoid attending VBACs, rather than evidence based decision making. Midwives were oftenfurther marginalized due to restrictive policies.

The US Department of Health & Human Services concluded in 2010 that there was a low levelof evidence for the requirement for "immediately available" surgical and anesthesia personnel inthe current ACOG guidelines. Furthermore, they recommended that policymakers find ways to3"mitigate or even eliminate current barriers to trial of labor." Yet, the intention of SCpolicymakers is to increase the barriers women face to find providers that allow a trial of labor.

The evidence does support giving women greater access to VBAC, including giving birth athome for low-risk women. Women that have had a cesarean section and a vaginal birth,regardless of the order, are considered viable candidates for VBAC. 2017 study ofmidwife-attended planned community births, women with a history of both cesarean and vaginalbirth fared better than first-time mothers across all outcomes. The risk status of women with a4history of both cesarean and vaginal birth is similar to the risk status of a woman with a historyof only vaginal birth. 93% of women that attempted a VBAC at home did not need anunplanned repeat cesarean and had a vaginal birth.

When understanding risk status we must look not at relative risk but rather at absolute risk. Therelative risk of neonatal death is higher with VBAC than with Elective Repeat Cesarean (ERC)(0.13% vs 0.05%) but both have a very low absolute risk. The relative risk of maternal death isreversed with a higher risk for an ERC than with a VBAC (0.013% vs 0.004%) but again both

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1 https://www.cesareanrates.org/vbac2 Cox, K. J. (2011). Providers' perspectives on the vaginal birth after cesarean guidelines in Florida, United States: aqualitative study. BMC pregnancy and childbirth, 11, 72. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3203084/3 US Department of Health & Human Services - National Institutes of Health, NIH Consensus DevelopmentConference on Vaginal Birth After Cesarean: New Insights. March 8–10, 2010. Bethesda, Maryland. Final PanelStatement. https://consensus.nih.gov/2010/vbacstatement.htm4 Bovjberg, M. L., Cheyney, M. Brown, J., et al. (2017). "Perspectives on risk: Assessment of risk profiles andoutcomes among women planning community birth in the United States." Birth 44(3): 209-221.https://pubmed.ncbi.nlm.nih.gov/28332220/5

Guise, J.-M., Eden, K., Emeis, C., et al. (2010). Vaginal Birth After Cesarean: New Insights. EvidenceReport/Technology Assessment No.191. https://pubmed.ncbi.nlm.nih.gov/20629481/

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have a very low absolute risk. So, we can see that women should have a choice between VBACand ERC since their own health is more at risk with an ERC and their baby's health with aVBAC, but ultimately both risks are actually low.

Studies have also shown that we can predict which women are likely to have a successfulVBAC. A previous vaginal delivery, spontaneous labor, and a neonate birth weight less than4000g have been shown to reduce risks. Homebirth can actually increase the odds of a6successful VBAC since we always start births with spontaneous labor and not artificialinductions.

Unassisted homebirth is on the rise in South Carolina. When women are denied access to thecare they desire, you (are encouraging) encourage them to birth unassisted.

The Palmetto Association of Licensed Midwives oppose any policy (the proposed revision) restricting access to a trial of labor for birthing women in SouthCarolina. Our training already includes providing care for VBACs at home. Denying access toquality midwifery care is a huge step backwards for South Carolina.

ATTACHMENT B.15

SUPPLEMENTAL DOCUMENTATION FOR PUBLIC COMMENT #109

PROPOSED CHANGE SECTION 1200 : PRESCRIPTION MEDICATION ADMINISTRATION (I)

A. The Midwife shall Administer only the Prescription Medications in Section 1200.B and in accordance with the orders and directions of a Physician or other Authorized Medical Provider. The Midwife shall only Administer Prescription Medications to the Client and/or Neonate for whom the prescription is ordered. The Midwife shall maintain documentation in the Client record of all Medications Administered and shall include the time of administration, the quantity and/or dosage, and any adverse effects.

B. The Midwife shall only Administer Medications as prescribed by the Physician or other Authorized Medical Provider. The Midwife shall only Administer the following Prescription Medications:

1. Oxygen;

2. Eye prophylactic, within one (1) hour of birth, unless written refusal is obtained from the Client. Documentation of the administration or Client's refusal shall be made in the Client's record;

3. Vitamin K to the Neonate with documented informed consent from the Client;

4. Oxytocin, Methergine or other anti hemorrhagic

5. Lidocaine;

6. Penicillin or other antibiotic;

7. Lactated Ringers or Normal Saline;

8. Epinephrine; and

9. Rho(D) immune globulin to the Client within seventy-two (72) hours of delivery.

REQUESTED CHANGE: #4 ADD MISOPROSTAL or other antihemorrhagics , SUCH THAT IT READS AS FOLLOWS;

4. Oxytocin, Misoprostol , Methergine or other antihemorrhgics

RATIONALE: Postpartum Hemorrhage (PPH) is the leading cause of maternal morbidity in the United States. In fact it is the leading cause of maternal death in the world. Every seven minutes, a woman dies of PPH. Approximately 25% of all maternal deaths are from PPH. Uterine atony causes 70-80% of cases of PPH, it remains the single most common cause and it appears to be increasing. Because of these statistics, *Active Management of the Third Stage of Labor (AMTSL)* recommendations were developed, with (Step 1) being the administration of a uterotonic immediately following birth. It has been established that routine use of prophylactic uterotonics causes the uterus to contract firmly decreasing the risk of a PPH. A recent multi-centered World Health Organization (WHO) clinical trial concluded that the administration of the uterotonic was the most important component of the AMTSL.

Oxytocin has long been established as the first line uterotonic to be administered in the incidence of a PPH. It has been determined that in 3-25% of cases a second uterotonic is required. Multiple uterotonic agents are commonly used, assuming no contraindications, and should be used in rapid succession. It has also been determined that Oxytocin in combination with methergine, misoprostol, or other antihemorrhagics appears to be more effective than oxytocin alone. Methergine is sensitive to temperature change, must be refrigerated, difficult to obtain due to history of multiple shortages and may cause severe hypertension. These facts caused the administration of methergine to be moved down in the recommended algorithm of uterotonic meds.

In numerous randomized controlled trials, antihemorrhagics including misoprostol has been associated with significant decrease in the rate of PPH including severe hemorrhage of >1000ml, which may prove fatal.

In 2013 a review of studies concluded that antihemorrhagics including misoprostol can be administered safely in the home birth setting. Efforts to utilize AMTSL with the administration by midwives of antihemorrhagics including misoprostol can ensure that nearly 100% of all women giving birth are protected. The establishment of uterotonic use in the prevention of PPH, as the most important intervention

,is justification enough to change Regulation 61-24, to allow midwives to administer antihemorrhagics including misoprostol. In light of the current evidence, now is the time to ensure that every woman who gives birth is provided with high-quality uterotonics, regardless of where she chooses to give birth.

ATTACHMENT B.16

SUPPLEMENTAL DOCUMENTATION FOR PUBLIC COMMENT #110

PROPOSED CHANGE: SECTION 1100 – PHYSICAL EXAMINATIONS (I)
A. Initial Physical Examination:

1. The Midwife shall require the Client to undergo an initial Physical Examination completed by a Physician or other Authorized Healthcare Provider between fourteen (14) weeks and twenty (20) weeks of gestation. The Midwife may admit Clients after twenty (20) weeks gestation provided the Client has undergone a Physical Examination that meets the requirements in Section 1100.A.2.

2. The Midwife shall ensure the initial Physical Examination of the Client is documented in the Client's record and includes:

a. A written and signed statement by the Physician or other Authorized Healthcare Provider that he or she has determined to the best of his or her ability that the pregnancy is a Low Risk Pregnancy as defined by this regulation; and

b. Identification of special conditions and/or care required.

B. Second Physical Examination:

1. The Midwife shall require the Client to undergo a second Physical Examination completed by a Physician or other Authorized Healthcare Provider after thirty-four (34) weeks of gestation.

2. The Midwife shall ensure the second Physical Examination of the Client is documented in the Client's record and includes:

a. A written and signed statement from the Physician or other Authorized Healthcare Provider that the pregnancy remains a Low Risk Pregnancy and the fetus is in the vertex position; and

b. Orders for Medications needed for intrapartum.
REQUESTED CHANGE: Replace PHYSICIAN EXAMINATION with MEDICAL CONSULTATION for the heading

PROPOSED CHANGE: SECTION 1100 MEDICAL CONSULTATION (I)
A. Initial : Medical Consultation

1. The Midwife shall require the Client to have an initial Medical Consultation completed by a Physician or other Authorized Medical Provider within the first two (2) trimesters of pregnancy.

2. The Midwife shall ensure the initial Medical Consultation is documented in the Client's record..
Second Medical Consultation:

1. The Midwife shall require the Client to have a second Medical Consultation completed by a Physician or other Authorized Medical Provider after thirty-four (34) weeks of gestation.

2. The Midwife shall ensure the second Medical Consultation is documented in the Client's record.

RATIONALE: Out of the 35 states that license Certified Professional Midwives, only 2 states require Physician or other medical provider examinations during any of the trimesters of pregnancy unless a consult is required. The conditions requiring consultations are clearly identified in Regulation 61-24. The Physicians and other medical providers rely on the knowledge and training of the midwives to identify any conditions and refer appropriately. The North American Registry of Midwives credentials Certified Professional Midwives and does not require the oversight of a Physician or other Medical Provider.
There is no documented evidence that confirms increased safety of healthcare from the two states who require Physician or other medical provider examination.

While mapping integration of midwives across the United States, current evidence suggests that scope of practice laws, as well as other aspects of state policy and regulation, may be reducing the maternity care workforce and access to services. An integrated maternity system facilitates the full exercise of scope of practice, autonomy, self-regulation, and collaboration across disciplines.

As hospitals become more and more monopolized, and physician and other medical provider practices are merged into their monopoly, midwives cannot be responsible for what a physician or other medical provider agrees or disagrees to comply with. More and more physicians and other medical care providers are opting for virtual office visits with their patients especially during Pandemic periods. The Medical Consultation verbiage will allow for those types of visits.

ATTACHMENT B.17

SUPPLEMENTAL DOCUMENTATION FOR PUBLIC COMMENT #111

REGULATION 61-24 PROPOSED REGULATION REVISIONS SUGGESTIONS

PROPOSED SECTION 300 – ENFORCEMENT ACTIONS
E. When imposing a monetary penalty, the Department may invoke South Carolina Code Section 44-1-140 to determine the dollar amount or may utilize the following schedule:
REQUESTED CHANGE: THE FINES LISTED ON THE TABLE OF FINES FOR CLASS I, II, AND III VIOLATIONS ARE CITED UNDER SECTION 44-1-140, HOWEVER; THIS SECTION PERTAINS TO SANITATION PRACTICES, INFECTIOUS DISEASES, DISPOSITION OF GARBAGE, ETC. IN ADDITION, THE AMOUNTS LISTED AS FINES DO NOT APPEAR TO BE LEGITIMATE FIGURES. REQUEST FOR CLEARLY IDENTIFIED FINES PER CLASS VIOLATION NOT TO EXCEED $1000.00.
SECTION 1000 – INFORMED CONSENT (II)
C. Disclosure of fees for all care and services provided; and
REQUESTED CHANGE: OMIT THIS REQUIREMENT. FEES CHARGED TO CLIENTS ARE NOT PART OF SC DHEC'S REGULATORY AUTHORITY
SECTION 1100 – PHYSICAL EXAMINATIONS (I)
REQUESTED CHANGE: STRIKE SECTION 1100
RATIONALE: Out of the 35 states that license Certified Professional Midwives, only 2 states require Physician or health provider examinations during any of the trimesters of pregnancy unless a consult is required. The conditions requiring consultations are clearly identified in Regulation 61-24. The Physicians and health care providers rely on the knowledge and training of the midwives to identify them and refer appropriately. There is no documented evidence that confirms the safety of care from the two states who require Physician or health provider examination. As hospitals become more and more monopolized, and physician and health provider practices are merged into their monopoly, midwives cannot be responsible for what a physician or heath care provider agrees or disagrees to comply with. Midwives are required to meet the North American Registry of Midwives requirements upon certification. This certification does not require the oversight of a Physician or other Healthcare Provider. Any changes or additions to Regulation 61-24 should align and reflect the North American Registry of Midwives scope of practice.

SECTION 1200 – PRESCRIPTION MEDICATION ADMINISTRATION (I)
REQUESTED CHANGE: IN ADDITION TO THE APPROVED AUTHORIZED PRESCRIBED MEDICATIONS, CURRENT PRESCRIPTIONS FOR GROUP B STREPTOCOCCUS AS WELL AS OTHER ANTI HEMORRHAGIC MEDICATIONS PRESCRIBED TO THE CLIENT BY THE AUTHORIZED HEALTH CARE PROVIDER SHOULD BE ADDED TO THE LANGUAGE.
SECTION 1500 – TRANSFER OF CARE (I)
A. The Midwife shall immediately initiate a Transfer of Care during intrapartum and postpartum by dialing 911 when the care required is outside the Midwife's scope of practice pursuant to Section 400, as recommended by a Physician or other Authorized Healthcare Provider during a Medical Consultation, or for any event during labor that compromises the health of the Client or Neonate and/or normally requires emergency intervention.
B. Upon arrival of the emergency medical services personnel, Physician, or other Authorized Healthcare Provider, the Midwife shall transfer the care of the Client to the emergency medical services personnel, Physician, or other Authorized Healthcare Provider. The Midwife shall provide information as requested by the emergency medical services personnel, Physician, or other Authorized Healthcare Provider.

REQUESTED CHANGE: UPON TRANSFER OF CARE TO PHYSICIAN OR OTHER AUTHORIZED HEALTHCARE PROVIDER, DIRECTIVES FROM THE PHYSICIAN OR AUTHORIZED HEALTHCARE PROVIDER MAY NOT REQUIRE EMERGENCY MEDICAL SERVICES (911). TRANSFERS MAY BE INITIATED, BUT FROM A NON EMERGENT STATUS. DISPATCHING EMS FOR NON EMERGENT TRANSFERS, IS NOT RELEVANT TO THE SITUATION, IS NOT COST EFFECTIVE FOR THE CLIENT, HAS A HISTORY OF LONG TRANSFER DELAYS, AND EMS HAS LESS TRAINING THAN MIDWIVES REGARDING THE COURSE OF ACTION TO EMPLOY ONCE THE CLIENT HAS BEEN TRANSFERRED INTO THEIR CARE.

SECTION 1700 – INFECTION CONTROL

1702. Tuberculosis Screening. (I)

D. Annual Tuberculosis Training. Midwives and Apprentice Midwives shall receive annual training regarding tuberculosis to include risk factors and signs and symptoms of tuberculosis disease. The Midwife and Apprentice Midwife shall maintain documentation of the annual tuberculosis training.

REQUESTED CHANGE: TUBERCULOSIS TRAINING IS INCLUDED IN THE CURRICULA OF APPRENTICE MIDWIVES AND SCREENED FOR COMPETENCY DURING INITIAL LICENSURE TESTING. ANNUAL TRAINING IS UNNECESSARY AND REDUNDANT.

SECTION 1800 – MIDWIFERY ADVISORY COUNCIL

The Department shall appoint a Midwifery Advisory Council to advise the Department regarding licensing and Inspection of Midwives. The Council shall meet at least annually. The Council shall consist of three (3) licensed Midwives, one (1) consumer of midwife care, two (2) Certified Nurse-Midwives, one (1) Physician active in perinatal care, and one (1) member-at-large. Each member shall be appointed for a three (3) year term of office.

REQUESTED CHANGE: THE DEPARTMENT SHALL UTILIZE THE CURRENT STANDARDS OF THE MIDWIFERY ADVISORY COUNCIL TO ADVISE THE DEPARTMENT IN MATTERS SUCH AS, BUT NOT LIMITED TO: LICENSING MIDWIVES, INSPECTION OF MIDWIVES, LIASON FOR THE DEPARTMENT WITH COMMUNICATION AND SUGGESTIONS TO THE MIDWIVES, LIASON FOR THE MIDWIVES WITH COMMUNICATION AND SUGGESTIONS TO THE DEPARTMENT, REGULATION REVISIONS, VIOLATION CITATIONS INITIATED BY THE DEPARTMENT, ETC. THE COUNCIL SHALL CONSIST OF THREE(3) LICENSED MIDWIVES, ONE (1) CONSUMER OF MIDWIFERY CARE, TWO (2) CERTIFIED NURSE MIDWIVES, ONE (1) PHYSICIAN TRAINED IN PERINATAL CARE, AND ONE (1) MEMBER AT LARGE. EACH MEMBER SHALL BE APPOINTED FOR A THREE (3) YEAR TERM OF OFFICE. A BI-ANNUAL MEETING SHALL BE HELD TO IMPLEMENT COMMUNICATIONS BETWEEN THE DEPARTMENT AND THE MIDWIVES.

RATIONALE: THE MIDWIFERY ADVISORY COUNCIL CONSISTS OF PROFESSIONALS THAT ARE INVOLVED IN, BUT NOT LMITED TO OUT OF HOSPITAL MATERNITY CARE. THE PRACTICE OF MIDWIFERY CANNOT NOR SHOULD IT BE REGULATED BY PROFESSIONALS THAT DO NOT HAVE TRAINING NOR PRACTICE OUTSIDE OF THE HOSPITAL SETTING. THE MIDWIFERY ADVISORY COUNCIL SHOULD BE THE INITIAL AND PRIMARY GOVERNING BODY TO ADVISE THE DEPARTMENT REGARDING OUT OF HOSPITAL MIDWIFERY CARE.

ATTACHMENT B.18

SUPPLEMENTAL DOCUMENTATION FOR PUBLIC COMMENT #112

Suggested Edit/ Addition for SECTION 1800- MIDWIFERY ADVISORY COUNCIL

The Department shall appoint a Midwifery Advisory Council to advise the Department regarding ***licensing, practice, regulations, inspections and disciplinary actions, including an appeal process when disciplinary action was taken*****,** of Midwives. The Council shall meet at least annually. The Council shall consist of three (3) licensed Midwives, one (1) consumer of midwife care, two (2) Certified Nurse-Midwives, one (1) Physician active in perinatal care, and one (1) member-at-large. Each member shall be appointed for a three (3) year term of office.

Rationale:

The regulation updates should not in any way diminish the duties of the Midwifery Advisory Council, though the most recent NPR does just that. As the proposed verbiage is written, this cuts the responsibilities in half. While Licensed Midwives are not licensed under LLR, the Health Regulations Committee has cited LLR as rationale for some changes in the most recent NPR_61-24. For consistency of using that rationale, we must look at who comprises the Boards in LLR and their roles. Boards under LLR are composed of a majority of those who work in the designated profession, as those working in that field are the only experts, while there are typically 1-2 "general public" members. For example, there are currently 5 RNs and 2 General Public members on of the Nursing Board with 2 LNP and 2 RN seats empty; 8 Chiropractors and 1 General Public member of the Board of Chiropractic Examiners; and 9 MD and 1 DO with 3 vacant Public Member seats on the Board of Medical Examiners.

As defined by LLR, the role of the Board of Nursing: *"The mission of the State Board of Nursing for South Carolina is the protection of public health, safety and welfare by assuring safe and competent practice of nursing.*

This mission is accomplished by assuring safe initial practice as well as continuing competency in the practice of nursing and by promoting nursing excellence in the areas of education and practice. The Board licenses qualified individuals as licensed practical nurses, registered nurses or advanced practice registered nurses. Complaints against nurses are investigated and disciplinary action taken when necessary. Schools of nursing (pre-licensure programs) are surveyed and approved to ensure quality education for future nurses."

For the Board of Chiropractic Examiners: *"The SC Board of Chiropractic Examiners licenses and regulates Chiropractors and the practice of chiropractic in the state of South Carolina."*

Finally, regarding the Board of Medical Examiners, in addition to licensing professionals, is responsible for *"investigating and disciplining licensees found to be engaged in misconduct as defined in the professions' respective practice acts. This includes illegal, unethical or incompetent conduct."*

It must be noted that as of 2013, all new LM applicants must have passed the North American Registry of Midwives' examination. Given this, it behooves the Department to incorporate NARM's course of action when there is a complaint. The process is to select a Complaint Review Committee Chair, who is a CPM. The Chair then appoints CPMs to form the Complaint Review committee. It is through this peer review process that unbiased and educated decisions will be made regarding course of action.

The above suggestion to Section 1800 does not disrupt the makeup of MAC members, rather it urges that the Health Regulations Committee not remove their major function. The only way to have a true system of checks and balances within a profession is through peer review and guidance. The only way to ensure that for Licensed Midwives is to adopt the suggestion as the definition of Midwifery Advisory Council for the proposed draft and utilize the Council as fully defined without conflict as well as with consistency with other Department/ Health Regulations Committee rationale. This creates a stronger relationship between the Department, the Licensed Midwives and the public.

Current Regulation

1. Midwifery Advisory Council.

a. The Commissioner of DHEC shall appoint a Midwifery Advisory Council which shall meet at least annually for the purpose of reviewing and advising the Department regarding matters pertaining to the training, practices, and regulation of midwives in South Carolina. The Council shall consist of three licensed midwives, one consumer of midwife care, two certified nurse-midwives, one physician active in perinatal care, and one member-at-large. Each member shall be appointed for a three-year term of office.

b. The Council shall establish a committee for peer review to consult with midwives in questions of ethics, competency and performance, and to serve as an appeal committee when disciplinary action has been taken. The committee may recommend denying, suspending, or revoking a license, or may recommend specific educational objectives, apprenticeship or other improvement measures as necessary.

Proposed Regulation Change in NPR_R.61-24 8/13/2020

SECTION 1800 – MIDWIFERY ADVISORY COUNCIL

The Department shall appoint a Midwifery Advisory Council to advise the Department regarding licensing and Inspection of Midwives. The Council shall meet at least annually. The Council shall consist of three (3) licensed Midwives, one (1) consumer of midwife care, two (2) Certified Nurse-Midwives, one (1) Physician active in perinatal care, and one (1) member-at-large. Each member shall be appointed for a three (3) year term of office.

ATTACHMENT B.19

SUPPLEMENTAL DOCUMENTATION FOR PUBLIC COMMENT #113

> Dear Members of the Health Regulation Committee:

The Members of the Palmetto Association of Licensed Midwives respectfully submits the following revisions for the proposed Regulation revision 61-24, Section 1500.
>
>
> The Licensed Midwife proposed regulation is asking midwives to call 911 to initiate a transfer of care instead of calling directly in to the Regional Perinatal Care system. This mandate would be a dangerous practice and a government disparity placed directly upon the consumers of midwifery care. Transfer of care protocols for maternity patients are already detailed in DHEC regulation 61-16. Community Births that occur at home, birth center or in a physician's office are considered a basic level of care (level I) and should be incorporated into the perinatal system.
>
> Smooth and expedient transfer of care with direct provider-to-provider communication improves outcomes. Licensed Midwife providers and their clients are entitled to the same system of care that is available to every other maternity patient in South Carolina.
>
> As you can see by the attached information, the consensus is overwhelming. To limit access when a higher need arises does not serve to improve healthy birth outcomes and should be immediately abandoned by The Department.
>
> Attached please find:

> SC Midwifery Advisory Council RPC Support Letter
> Mapping integration of midwives journal study
> Equal Patient Access to Perinatal Levels of Care in South
> Carolina Midwifery Advisory Council Letter of Support
> South Carolina's Perinatal Regionalized System of Care Integration Goals to Reducing Premature Births and Infant Mortality
> PALM Position Statement Equal Patient Access
> American College of Obstetrics and Gynecologist Levels of Maternal Care
> Obstetric Care Consensus
> Best Practice Guidelines:
> Transfer from Planned Home Birth to Hospital
> SUPPORTING HEALTHY AND NORMAL PHYSIOLOGIC CHILDBIRTH:
> A CONSENSUS STATEMENT BY ACNM, MANA, AND NACPM
> SC NACPM letter requesting these corrections since 2018.
>
>
>
> PROPOSED CHANGE:
> A. The Midwife shall immediately initiate a Transfer of Care during intrapartum and postpartum by
> dialing 911 when the care required is outside the Midwife’s scope of practice pursuant to Section 400, as
> recommended by a Physician or other Authorized Healthcare Provider during a Medical Consultation, or

> for any event during labor that compromises the health of the Client or Neonate and/or normally requires
> emergency intervention.
>
> CURRENT MIDWIFE REGULATION:
> J. Referral to Physician.
> 1. Recognition of Problems. The midwife must be able at all times to recognize the warning signs of abnormal or potentially abnormal conditions necessitating referral to a physician. It shall be the midwife's duty to consult with a physician whenever there are significant deviations from the normal. The midwife's training and practice must reflect a particular emphasis on thorough risk assessment.
> 2. Continuity of Care. When referring a patient to a physician, the midwife shall remain in consultation with the physician until the resolution of the situation. It is appropriate for the midwife to maintain care of her patient to the greatest degree possible, in accordance with the patient's wishes, remaining present through delivery if possible.
>
> CURRENT HOSPITAL REGULATION:
> Code of Regulations CHAPTER 61.Department of Health and Environmental Control SECTION 16.
> Minimum Standards for Licensing Hospitals and Institutional General Infirmaries.
> SECTION 1306
> D. Regional Perinatal Center with Neonatal Intensive Care Units (Level III) (RPC). In addition to complying with all requirements of Sections 1306.A through 1306.C, the RPC shall provide consultative, outreach, and support services to Level I, II, and III hospitals in the region. The RPC shall manage no less than an average of 2000 deliveries annually, calculated over the previous three years. Personnel qualified to manage obstetric or neonatal emergencies shall be in-house. A board-certified maternal-fetal medicine specialist (perinatologist) shall be in the hospital or on site within 30 minutes for supervision and consultation, 24 hours a day. The RPC shall participate in residency programs for obstetrics, pediatrics, and/or family practice. Physician-to-physician consultation shall be available 24 hours a day for Level I, II, and III hospitals. Regional Perinatal Centers shall coordinate the development and implementation of professional continuing education to maintain competency and provide education to other facilities within the region, facilitate transport from the perinatal centers to the regional perinatal center and back transport when possible, and collect data on long-term outcomes to evaluate the effectiveness of delivery of perinatal care services and the efficacy of new therapies. The RPC shall provide a perinatal transport system that operates 24 hours a day, seven days a week, and return transports neonates to lower level perinatal hospitals when the neonates' condition and care requirements are within the capability of those hospitals.

ATTACHMENT B.20

SUPPLEMENTAL DOCUMENTATION FOR PUBLIC COMMENT #122

As a current member of the SC DHEC Midwifery Advisory Council (MAC), a CPM and practicing Licensed Midwife in SC since 2004, I would like to go on record to state that I DO NOT SUPPORT THIS PROPOSED REGULATION AS A WHOLE. There are too many problems with it, as proposed.

The proposed 61-24 regulation revision appears to be an attempt by DHEC and other undisclosed, regulation writing "stakeholders"(likely medical and nursing professional organizations who may also be maternity care competitors), to reduce the number of practicing midwives in SC.

This proposal exhibits bias, attempting to limit women's access to SC Licensed Midwives and placing an undue burden on midwives who already consult and refer to medicine for situations outside of our scope of practice.

RESTRAINT OF TRADE is written into this revision and is blatantly obvious by requiring our competitors, aka institutional based medical providers to supervise our community level midwifery practices. Midwives can not require medical providers to comply with midwifery regulations, which would effectively shut down community level midwives in the State of SC.

We are currently and effectively under regulatory obligation to consult and refer, as appropriate, for women who need a higher level of services. Supervisory language does not improve outcomes when comparing maternal/infant morbidity and mortality rates with states with better overall outcomes than SC.

It is my strong recommendation as an individual member of MAC, for DHEC to scrap this whole proposal and start again by including the MAC from the beginning of the drafting process. This simple inclusion would help DHEC avoid the current general consensus in the midwifery community and among our consumers that this current NPR proposal is not workable.

Important note: Consumers of midwifery care would be adversely affected, are very vocal throughout the state and are ready to protest, en masse, at the November 12th DHEC Board meeting should this NPR move forward for board approval with the proposed restrictive language.

Lisa Byrd LM, CPM, MBC LMW-032
9/28/2020

My concerns are as follows:

101.A. LM, CPMs are Healthcare Providers and authorized by the Dept. Orders or prescriptions come from Authorized "Medical" Providers with prescriptive authority. Verbiage should change to "Physician or other Authorized *Medical Provider" regarding prescriptions and all things medical throughout this proposal.

101.D. Authorized Healthcare Provider should be changed to Authorized MEDICAL Provider to avoid confusion. Licensed Midwives provide for the "health" care of our clients, not their medical care as stated in this definition and throughout the proposal. We are authorized by the dept to provide healthcare maternity services.

101.W. Should read "makes contact with a physician or other "Authorized *Medical Provider" instead of authorized healthcare provider. LMs are authorized by the dept and provide healthcare for prospectively low risk women during pregnancy, birth and postpartum. The verbiage is confusing.

101.X. Herbal products, vitamins and nutritional supplements are not specifically defined as medications, are used to support the body's natural processes and most importantly, are not regulated by the FDA. Medications are "classified" as over the counter or prescriptive substances that use a chemical action or pharmocological action to override the body's natural inclinations and are federally regulated as "medications." OTC medications, biologicals and prescriptive meds apply to this definition. Herbals, vitamins and nutritionals do not fit the definition of Medications per the FDA. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/classification-products-drugs-and-devices-and-additional-product-classification-issues

101.EE. Should read "or other authorized *medical provider" to provide clarity. Midwives are authorized healthcare providers but not authorized medical providers.

101.II. should read "or other medical provider" to provide clarity for referrals. Midwives are authorized healthcare providers.

101.MM. We transfer care to an "Authorized Medical Provider." Verbiage should be changed to provide clarity. Midwives are authorized healthcare providers but not authorized medical providers.

302.C. phrase "those that are against the best practices" as defined by whom? Since this is a midwifery regulation, best practices should be defined by a midwifery organization such as MAC, MANA or NARM and not widely open to various interpretations.

302.E. The monetary penalties section is inaccurate due to missing punctuation. Specifically dashes in between the numerical ranges of the penalties. Ex: 1st offense class 1 should read $200-$1000 not $2,001,000. The dashes are missing throughout this section.

The monetary amounts are extreme based on SC Code 44-1-151 which sets limits between $200-$1000. This regulation exceeds those legal limitations.

As a matter of note, I question why monetary penalties were stricken from the 2013 version of 61-24 and are now being added back in? Did DHEC change its mind? What is the legal precedent for that?

IF there is legal precedent for adding monetary penalties back in to 61-24, I strongly advise DHEC to omit Class 3 violations since the definition of this class is wide open to interpretation.

At a minimum, CLEARLY define what would constitute a class 3 violation as stated in my comments in 302.C. using a midwifery standard such as MAC, MANA or NARM to define “best practice."

400.D.2. Exclusion of care for all women with prior c-sections is extreme according to current evidence. A thorough risk assessment by midwives and our consulting physicians would exclude those at high risk.

Generally women with a classical incision are not good candidates for homebirth but women with low transverse scars are not an absolute risk-out criteria. As stated by others, if DHEC continues to exclude all VBAC (vaginal birth after cesarean) women, public health and safety will be severely impacted as women will continue to be forced into the corner of attempting an unassisted homebirth to avoid a repeat c-section.

Please refer to the scientific evidence and rationale offered by the professional midwifery organizations PALM, SC NACPM and NARM regarding VBACs. All VBAC women are NOT high risk and should not be treated as such.

I recommend that DHEC change this section to specify, "Provision of care for Client with a previous *classical cesarean section.

I defer to the VBAC statement (below) submitted by the Palmetto Association of Licensed Midwives (PALM) for rationale and scientific citations already submitted by our state professional organization.

Dear Members of the South Carolina Board of Health and Environmental Control,
The Memorandum to Licensed Midwives concerning Vaginal Birth After Cesarean (VBAC) in 2006 is based on what is now out-of-date research. Please consider looking at more recent studies and statements on VBAC.
Of the 35 states with licensure or statutory authority for the legal practice of CPMs, only seven states do not allow VBAC by licensed midwives at home. Not surprisingly, these states have high rates of cesarean sections and low rates of VBAC. South Carolina is one of them. South Carolina continues to have cesarean rates higher than the national average (33.5% vs 31.9%) and VBAC rates lower than the national average (12.0% vs 13.3%). Our state must do better.
The ACOG guidelines which mandate that a physician and anesthesiologist be "immediately available" during a trial of labor were found to be the main reason for the low rates of VBAC in a 2011 study. Additionally, fear of liability was a central reason for obstetricians and midwives to avoid attending VBACs, rather than evidence based decision making. Midwives were often further marginalized due to restrictive policies.
The US Department of Health & Human Services concluded in 2010 that there was a low level of evidence for the requirement for “immediately available” surgical and anesthesia personnel in the current ACOG guidelines. Furthermore, they recommended that policymakers find ways to “mitigate or even eliminate current barriers to trial of labor.” Yet, the intention of SC policymakers is to increase the barriers women face to find providers that allow a trial of labor.
The evidence does support giving women greater access to VBAC, including giving birth at home for low-risk women. Women that have had a cesarean section and a vaginal birth, regardless of the order, are considered viable candidates for VBAC. 2017 study of midwife-attended planned community births, women with a history of both cesarean and vaginal birth fared better than first-time mothers across all outcomes. The risk status of women with a history of both cesarean and vaginal birth is similar to the risk status of a woman with a history of only vaginal birth. 93% of women that attempted a VBAC at home did not need an unplanned repeat cesarean and had a vaginal birth.
When understanding risk status we must look not at relative risk but rather at absolute risk. The relative risk of neonatal death is higher with VBAC than with Elective Repeat Cesarean (ERC) (0.13% vs 0.05%) but both have a very low absolute risk. The relative risk of maternal death is reversed with a higher risk for an ERC than with a VBAC (0.013% vs 0.004%) but again both have a very low absolute risk. So, we can see that women should have a choice between VBAC and ERC since their own health is more at risk with an ERC and their baby’s health with a VBAC, but ultimately both risks are actually low.

Studies have also shown that we can predict which women are likely to have a successful VBAC. A previous vaginal delivery, spontaneous labor, and a neonate birth weight less than 4000g have been shown to reduce risks. Homebirth can actually increase the odds of a successful VBAC since we always start births with spontaneous labor and not artificial inductions.

Unassisted homebirth is on the rise in South Carolina. When women are denied access to the care they desire, you (are encouraging) encourage them to birth unassisted.

The Palmetto Association of Licensed Midwives oppose any policy (the proposed revision) restricting access to a trial of labor for birthing women in South Carolina. Our training already includes providing care for VBACs at home. Denying access to quality midwifery care is a huge step backwards for South Carolina.

https://www.cesareanrates.org/vbac
Cox, K. J. (2011). Providers' perspectives on the vaginal birth after cesarean guidelines in Florida, United States: a qualitative study. BMC pregnancy and childbirth, 11, 72. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3203084/
US Department of Health & Human Services - National Institutes of Health, NIH Consensus Development Conference on Vaginal Birth After Cesarean: New Insights. March 8–10, 2010. Bethesda, Maryland. Final Panel Statement. https://consensus.nih.gov/2010/vbacstatement.htm
Bovjberg, M. L., Cheyney, M. Brown, J., et al. (2017). "Perspectives on risk: Assessment of risk profiles and outcomes among women planning community birth in the United States." Birth 44(3): 209-221. https://pubmed.ncbi.nlm.nih.gov/28332220/
Guise, J.-M., Eden, K., Emeis, C., et al. (2010). Vaginal Birth After Cesarean: New Insights. Evidence Report/Technology Assessment No.191. https://pubmed.ncbi.nlm.nih.gov/20629481/
Landon et al. (2016). "What We Have Learned About Trial of Labor After Cesarean Delivery from the Maternal-Fetal Medicine Units Cesarean Registry." Seminar Perinatol Aug;40(5):281-6. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4983226/

700.B.1.a. The clients face sheet should not include name and address of client's physician, midwife or midwife apprentice information. A face sheet is patient demographics, emergency contacts and insurance information. Please omit that verbiage as many of us use electronic health record systems and have no ability to override our current systems to include these items.

800. Why is this section reserved?

901.D.1. When a client comes into care, prenatal testing is either performed or obtained from the client's prior provider's records. Sometimes women come into care as "late entry" or beyond this section's parameter of 8 0/7 weeks to 16 0/7 weeks. Depending on the department's future interpretation of this section, if a woman comes into care at 16 1/7 weeks or beyond, we would be deemed to be out of compliance and open to citation for not "ensuring" this important testing was done in the stated timeframe. I advise changing the verbiage to state "upon coming into care" instead of 8-16 weeks when testing would ideally be done.

901.F. While written postpartum instructions and education are important components of midwifery care, these are generally included in the immediate postpartum period, before the midwife leaves the family's home. Postpartum *education is wise to include antenatally but to require postpartum instructions to be given antenatally is not appropriate timing as pregnant client's are primarily focused on the upcoming labor, comfort measures and tools to accomplish their goals of natural childbirth. Written postpartum instructions should be given in the early postpartum period for maximum impact, clarity and retention by the new parents.

1000.A. For continuity and clarity, please replace "or other Authorized Healthcare Provider" with Authorized Medical Provider. LMs are healthcare providers authorized to perform midwifery care in SC.

1000.D .Midwives are proponents of full evidence based informed consent and informed refusals regarding prenatal testing. If this section is to remain it should read, "explanation of the benefits and *risks of having an anatomic ultrasound. Why is this even under this section? Should be under prenatal testing section, not informed consent for clarity.

1100.A. Recommended change to "Initial Client Medical Consultation" The performing medical provider should be the decision maker as to whether the client needs a full physical or not. This should be on a case by case basis to be determined by that medical provider at the client's appointment/consultation visit.

1100.A.1. Recommended change-The Midwife shall require the Client to be evaluated with an initial Client Medical Consultation completed by a Physician or other Authorized MEDICAL Provider within the first two (2) trimesters of pregnancy.

Perfectly healthy pregnant women sometimes enter into care late for various reasons. Ideally and most often, they enter into care in the first trimester but not always. To restrict the timeframe for entry into care leaves many women without a care provider at all and potentially falling through the cracks as far as maternity care goes. Our goal is to improve outcomes in SC, not restrict entry to care, as has been the practice of many OB groups.

1100.A.2. As stated in 1100.A. above, Recommended change to "Initial Client Medical Consultation" The performing medical provider should be the decision maker as to whether the client needs a full physical or not. This should be on a case by case basis to be determined by that medical provider at the client's appointment/consultation visit.

1100.A.2.a.
THIS section (1100) contains language that causes me to reject the entire proposal.

This proposed language places LMs directly under supervisory language and has the high probability of forcing midwives out of practice.

As this language was included in the original drafting (prior to MACs involvement) and DHEC has avoided repeated questions requesting the names and credentials of the original draft writers, one can only assume that competing professionals in the maternity care field acted as DHEC's consultants in the writing process.

This section wreaks of implicit bias and appears to be an attempt at restraint of trade.

This section implies supervisory language while our current regulation requires appropriate consulting, referral and collaborative relationships with medical providers.

Please strongly consider the PALM statement-
Out of the 35 states that license Certified Professional Midwives, only 2 states require Physician or health provider examinations during any of the trimesters of pregnancy unless a consult is required. The conditions requiring consultations are clearly identified in Regulation 61-24. The Physicians and medical care providers rely on the knowledge and training of the midwives to identify them and refer appropriately.
There is no documented evidence that confirms the safety of care from the two states who require Physician or medical provider examination.
While mapping integration of midwives across the Unite States, current evidence suggests that scope of practice laws, as well as other aspects of state policy and regulation, may be reducing the maternity care workforce and access to services. An integrated maternity system facilitates the full exercise of scope of practice, autonomy, self-regulation, and collaboration across disciplines.
As hospitals become more and more monopolized, and physician and medical provider practices are merged into their monopoly, midwives cannot be responsible for what a physician or medical care provider agrees or disagrees to comply with. More and more physicians and other authorized medical

care providers are opting for virtual office visits with their patients especially during Pandemic periods. The Client Consultation verbiage will allow for those types of visits.
Midwives are required to meet the North American Registry of Midwives requirements upon certification. This certification does not require the supervision of a Physician or other Medical Care Provider. Any changes or additions to Regulation 61-24 should align and reflect the North American Registry of Midwives best practices.
Reducing the number of community level providers of midwifery care will only make SC's numbers worse! Please refer to:
https://journals.plos.org/plosone/article/file?id=10.1371/journal.pone.0192523&type=printable
1100.B. Recommended change to "Second Client Medical Consultation" The performing medical provider should be the decision maker as to whether the client needs a full physical or not. This should be on a case by case basis to be determined by that medical provider at the client's appointment/consultation visit.
1100.B.1. Recommended edit- "The midwife shall require the client to undergo a second *medical consultation completed by a physician or other Authorized *Medical provider after 34 weeks of gestation." As stated above, the term Authorized Healthcare Provider is confusing and should be replace throughout this document to reflect the fact that midwives are authorized by the department as healthcare providers and that this section, among others, should stipulate a consultation with a medical provider for clarity.

1100.B.2. recd edit, change verbiage to clarify, "…shall ensure the second *Medical Consultation is documented…"

1100.B.2.a. "A written and signed statement from a physician or other authorized healthcare provider…" is unachievable for many SC midwives. Midwives can not require medical professionals to adheare to our proposed regulations and this proposal would leave many midwives in SC in a position of being out of compliance and at risk for citation and penalties. This is an undue burden to place on midwives who cannot control the actions of medical providers.

1200.A. Section verbiage should be changed to "or other Authorized *Medical Provider…" to provide clarity. LMs are authorized "health"care providers by DHEC in the state of SC under Health Licensing.

1200.B. Section verbiage should be changed to "or other Authorized *Medical Provider…" to provide clarity. LMs are authorized "health"care providers by DHEC in the state of SC under Health Licensing.

1200.B.4. Recommended edit- Change to Antihemmorhagics to allow for changes in professional standards over the duration that this proposed regulation would be in effect. Specific medications or brand names listed over the life of this regulation may change.

Physicians and Authorized Medical Providers should be prescribing based on best practice at the time. DHEC should not limit the prescriptive authority of those working in the field of maternity care. To do so puts mothers at higher risk for bad outcomes and leaves midwives, medical providers and DHEC at risk of liability for not providing the generally accepted maternity standard of care.

Regarding the Misoprostol memo generated by DHEC in xxxx, (can't currently find it on the DHEC Midwives page where it existed in the past) I defer to the statement submitted by the Palmetto Association of Licensed Midwives (PALM) on the topic of Misoprostol for use in severe postpartum hemorrhages.

While I believe that specific medications and brand names should be omitted and classes of medications should replace them, I do strongly advise DHEC to reconsider the standard of care worldwide, regarding

the use of misoprostol in cases of severe postpartum hemorrhage. If LMs are disallowed from providing for the standard of midwifery care in emergency situations, using a cheap and effective lifesaving medication, women are at higher risk of mortality and LMs, our medical consultants and DHEC is at high risk of liability.

By tying our consulting physician's hands to prescribe and practice according to the maternity standard of care, DHEC is effectively increasing risk to mothers and creating barriers that are obvious public health and safety issues. Isn't that opposite of DHEC's stated purpose?

1200.B.5. Recommended edit- Change to "Local Anesthesia for the purpose of perineal repairs" to allow for changes in professional standards over the duration that this proposed regulation would be in effect. Specific medications or brand names listed over the life of this regulation may change.

Physicians and Authorized Medical Providers should be prescribing based on best practice at the time. DHEC should not limit the prescriptive authority of those working in the field of maternity care. To do so puts mothers at higher risk for bad outcomes and leaves midwives, medical providers and DHEC at risk of liability for not providing the generally accepted maternity standard of care.

1200.B.6. Recommended edit- Change to "Antibiotics for the purpose of GBS prophylaxis" to allow for changes in professional standards over the duration that this proposed regulation would be in effect. Specific medications or brand names listed over the life of this regulation may change.

Physicians and Authorized Medical Providers should be prescribing based on best practice at the time. DHEC should not limit the prescriptive authority of those working in the field of maternity care. To do so puts mothers at higher risk for bad outcomes and leaves midwives, medical providers and DHEC at risk of liability for not providing the generally accepted maternity standard of care.

1200.B.8 Recommended edit- Change to "Emergency Anaphylaxis medications" to allow for changes in professional standards over the duration that this proposed regulation would be in effect. Specific medications or brand names listed over the life of this regulation may change.

Physicians and Authorized Medical Providers should be prescribing based on best practice at the time. DHEC should not limit the prescriptive authority of those working in the field of maternity care. To do so puts mothers at higher risk for bad outcomes and leaves midwives, medical providers and DHEC at risk of liability for not providing the generally accepted maternity standard of care.

1300.A. Recommended edit- change "or Authorized healthcare provider" to "Authorized Medical Provider" to provide clarity. LMs are authorized by the Dept under health licensing as maternity care providers, thus are Authorized Healthcare Providers.

1400. DISCHARGE- Recommended edit 1)- change "or Authorized healthcare provider" to "Authorized Medical Provider" to provide clarity. LMs are authorized by the Dept under health licensing as maternity care providers, thus are Authorized Healthcare Providers.

Recommended edit 2)- change "…the client refuses the initial or second physical examination…" to "…the client refuses the initial or second medical consultation visit" as referenced in section 1100 above.

The performing medical provider should be the decision maker as to whether the client needs a full physical or not. This should be on a case by case basis to be determined by that medical provider at the client's appointment/consultation visit.

1500.A. Recd edit- STRIKE “by dialing 911” EMS providers are not equipped, nor are they trained to take over care in an obstetric emergency.

In some situations and in the current state of pandemic, midwife ride-alongs are being disallowed by EMS and hospital infection control policies. In this type of situation, by being mandated to call 911, we could be dumping client’s on EMS who are not ideally equipped for an obstetric emergency. They are “generalists”, midwives are more suited to manage transitional care no matter the mode of transportation to a specialist.

Initiation of transfer of care should start with a provider to provider consultation and referral, ideally to an RPC. Mode of transportation should be on a case by case basis decided by the medical provider and the Licensed Midwife.

To correct this deficiency, in 2018, MAC submitted an advisory statement to DHEC which I will reference below. In the interest of public health and safety, DHEC *should be proponents of adding SC Licensed Midwives to the definition regarding Perinatal Levels of Care as Level 1, Community Midwives.

Why has this request for support from DHEC fallen on deaf ears for years? I question again, is there internal bias regarding LMs as community level providers?

Correcting the Perinatal Levels of Care deficiency will provide for smoother transitions and provide for more expedient services when a higher level of care is warranted. Mandating calling 911 is a bandaid and will not.

MAC 2018 Letter to DHEC

Equal Patient Access to Perinatal Levels of Care in South
Carolina Midwifery Advisory Council Letter of Support
December 7,
2018
The Midwifery Advisory Council supports equal access to Perinatal Levels of Care for all patients of South Carolina Licensed Midwives and Licensed Facilities. The access should include patients enrolled in the services of a DHEC Licensed Midwife and/or Licensed Facility.
Nationwide, perinatal systems designed to facilitate smooth transfers of care are being implemented on state levels and supported by major perinatal organizations such as American College of Obstetrics and Gynecology, National Association of Certified Professional Midwives and Home Birth Summit (which includes collaboration with ACOG). See supporting documents.
DHEC Hospital Regulation 61-16 was amended in 2015 to include revisions to the Perinatal Services section based on the latest version of the Guidelines for Perinatal Care, but did not include the same access to care for Licensed Midwife and Licensed Facility patients as were provided for obstetrical patients of hospital/infirmary-to-hospital transfer patients. An item to note is that the RPC is an inhibiting factor to safe transport, see citations below.
DHEC reg. 61-16 Regional Perinatal Center with Neonatal Intensive Care Units (Level III)
(RPC): “... the
RPC shall provide consultative, outreach, and support services to Level I, II, and III hospitals in the region.
”

SCDHEC reg 61-16 1306. B. “A Level II hospital shall not admit outborn neonates into its nursery without
prior concurrence with the
RPC.”
This Council advises the Department to provide regulations/interpretations that encourage congruency in the care for transferring any perinatal patient no matter which Licensed Midwife or Licensed Birth Center from which the patient originated. This Council advises access for Licensed Midwife and Licensed Facility patients to the levels of perinatal care as supported by national organizations to ensure timely and safe transfers of care.
Respectively Submitted, Midwifery Advisory Council Rebecca Creel- Chair, Consumer Member; Geoffrey Chamber- Member-at-Large; Dr. Rachel Hall- Physician Member; Lisa Byrd, LM, CPM; Joanne Gottschall, LM, CPM; Lori Gibson, CPM, LM, MBC; Tom Chappell, CNM; Judy Fry, CNM
Attachments: ACOG Consensus of Levels of Care, February 2015 Midwifery Integration Scoring System Graph and Explanation (MISS) Home Birth Summit Best Practice Guidelines Published 2013 Supporting Healthy and Normal Physiologic Childbirth: A Consensus Statement by ACNM, MANA, and NACPM. 2012 Example of failed access: A letter from a local RPC denying equal access to neonatal transport team, re: Baby w/undiagnosed Downs Syndrome

1500.B. Recd edit- STRIKE “Emergency Medical Services personnel” written twice in this section. Please see rationale in section 1500.A. above.

Transferring care to EMS in an obstetric emergency does not provide a higher level of care as EMS providers are not maternity specialists, but emergency “generalists.” This section, as written, increases health risk to mothers and babies and increases liability risks for midwives, consulting physicians and DHEC.

For continuity and clarity, please replace “or other Authorized Healthcare Provider” with “ or other Authorized Medical Provider. LMs are healthcare providers authorized to perform midwifery care in SC.

1702.A. For continuity and clarity, please replace “or other Authorized Healthcare Provider” with “ or other Authorized Medical Provider. LMs are healthcare providers authorized to perform midwifery care in SC.

1702.B.3. For continuity and clarity, please replace “or other Authorized Healthcare Provider” with “ or other Authorized Medical Provider. LMs are healthcare providers authorized to perform midwifery care in SC.

1800- Recd edit- STRIKE the proposed section regarding the Midwifery Advisory Council (MAC) as written and REPLACE with the current 61-24 language regarding MAC, as copied and pasted below.

The prior/current regulation should not be minimized to reduce input from the MAC on matters of training, practices and regulation of midwives in SC, among other things. See below.

Licensed Midwives are experts in the field of out of hospital and physiologic birth and are uniquely suited to advise DHEC on midwifery professional matters, as in the past.

Recommendation-REPLACE THE PROPOSED NPR (section 1800) WITH THE CURRENT LANGUAGE IN 61-24
1. Midwifery Advisory Council.
a. The Commissioner of DHEC shall appoint a Midwifery Advisory Council which shall meet at least annually for the purpose of reviewing and advising the Department regarding matters pertaining to the

training, practices, and regulation of midwives in South Carolina. The Council shall consist of three licensed midwives, one consumer of midwife care, two certified nurse-midwives, one physician active in perinatal care, and one member-at-large. Each member shall be appointed for a three-year term of office.

b. The Council shall establish a committee for peer review to consult with midwives in questions of ethics, competency and performance, and to serve as an appeal committee when disciplinary action has been taken. The committee may recommend denying, suspending, or revoking a license, or may recommend specific educational objectives, apprenticeship or other improvement measures as necessary.

1900-2700- What are these sections Reserved for?

2800 Recd edit- “in accordance with the best practices as interpreted by the department” should be revised to include a professional midwifery organization such as MAC, MANA or NARM as the determiner of “best practice” for matters relating to the profession of midwifery.

To leave this statement open ended is invitation for biased interpretation.

Suggested language edit- “Conditions that have not been addressed in this regulation shall be managed in accordance with the best practices, as determined by the MANA Standards and Qualifications for the Art and Practice of Midwifery, as interpreted by the Department."

Standards and Qualifications | Midwives Alliance of North America
https://mana.org/about-us/standards-and-qualifications

ATTACHMENT B.21

SUPPLEMENTAL DOCUMENTATION FOR PUBLIC COMMENT #130

September 29, 2020
DHEC

RE: Midwifery Regulations

To Whom it May Concern,
I have many concerns about the proposed regulations regarding the future of Midwifery in the State of Sourh Carolina. I believe in medical freedom and am truly concerned at having my medical freedoms removed, such as the choice to birth children at home. I value the expertise of the midwives in this state, as I have birthed 2 children under midwifery care. I also birthed 1 child under the care of an Ob/Gyn. I would birth more children strictly with midwifery care. To be quite honest it is incredibly difficult to convey the level of dedication these women have to their profession. With that being said, the dedication, training and hours these women put in make them some of the most trustworthy professionals. They are vital to birthing mothers.
The ongoing disregard of the state midwives and the Midwifery Advisory Council's advice concerning the updating of these regulations is insulting. From a birthing mother, I urge you to remember a mother's medical freedom.

When considering Vaginal Birth After Cesarean Section (VBAC) DHEC should recognize a woman's bodily autonomy and her confidence in its ability to birth what it has grown and created. Many Obstetricians agree that a trial of labor should always be allowed. Licensed midwives have the ability and knowledge to decipher when a birth is not progressing as expected and make a last minute transfer. Homebirth VBAC should not be forbidden. The decision about where to birth should always be between a mother and her care providers, and include full informed consent even when it follows a cesarean. Across the state birthing women are choosing to have their babies unassisted due to these outrageous restrictions rather than give birth again in a hospital. No woman should be forced to choose between a homebirth without a provider and a hospital birth. I personally have had one child via VBAC and was forced to deliver in the hospital, where the nurses could have cared less as they were having loud conversations, laughing, etc. as I was focused on birthing my child naturally. Please listen to us women who use midwifery care and hear us in that we want the choice as to where we birth, whether it be at home, birthing center, or hospital!

In more rural parts of the state, hospital care and delivery as well as physician examination are not as readily available. This creates disparity for lower income Caucasian and African American women thus creating a further divide in care. If our goal is really to save lives then we should allow women to seek medical consultations with already trusted medical professionals via telehealth. Making these provisions breaks down generational and financial barriers to proper prenatal care and allows women to seek care at their comfort level and give birth uninhibited in an environment surrounded by family and loved ones.

Additionally, I'm concerned that DHEC finds the need to prohibit midwives from administering Misoprostol, stating in proposed regulations that postpartum hemorrhage is an off-label use Misoprostol. Misoprostol is a life-saving drug used off-label in every hospital across the United States.

The article Uses of Misoprostol in Obstetrics and Gynecology found on PubMed states, "However, it remains an important option for treating postpartum hemorrhage when other agents are not available or

fail. A descriptive study showed that 1000 μg of rectally administered misoprostol, when given to patients who failed to respond to oxytocin and ergotamine, controlled postpartum hemorrhage within 3 minutes." As I'm sure you are aware, every second counts when stopping postpartum hemorrhages and the prohibition of this medication could mean the difference in life or death.
Finally, It is imperative that midwives be included in the perinatal levels of care for immediate access to the appropriate department. In the event of transfer minutes matter and subjecting laboring women to emergency room waiting rooms, exposing them to viruses and other unrelated emergencies is ridiculous and unnecessary. It would be more efficient for transfers to be taken straight to labor and delivery.

I appreciate your time in hearing my concerns.

Sincerely from a mother who has received top-care from midwives,
Allison Mugan

ATTACHMENT B.22

SUPPLEMENTAL DOCUMENTATION FOR PUBLIC COMMENT #127

September 28, 2020
To: South Carolina Midwifery Advisory Council
Re: Update of Rules and Regulations for Certified Professional Midwives
Dear Council Members,
The Midwives Alliance of North America (MANA) is a recognized professional organization whose mission is to unite, strengthen, support and advocate for the midwifery community and to promote educational, economic and cultural sustainability of the midwifery profession.
The MANA executive board of directors was asked by members who practice in South Carolina to review and respond to recent proposed updates to their Rules and Regulations. Our overall response is positive with the following four comments:

1. CPMs, like all midwives, are well trained in the ability to assess risk status of a pregnancy, labor, delivery and postpartum period. There is no evidence that additional benefit would be gained from placing a requirement for a physician to determine the risk of a midwife's client. There is the reality that the requirement would create a barrier to assessing midwifery care especially for families without health insurance.
2. There is no evidence to limit consumer autonomy by restricting midwives from providing care to families seeking vaginal birth after cesarean except when the history includes a previous classical incision. We recommend that this history be the only limitation listed.
3. The use of Misoprostol for postpartum hemorrhage management is well-documented and is recommended by national certification courses including Advanced Life Support in Obstetrics.
4. As national midwifery leaders, the MANA Board appreciates a fully engaged Midwifery Advisory Council and applaud your dedication to maintaining quality while improving access to midwifery care in your state.

Thank you again for your consideration and your dedication to the families who choose midwifery care.
MANA Board of Directors
Sarita Bennett, DO, CPM – President

ATTACHMENT B.23

SUPPLEMENTAL DOCUMENTATION FOR PUBLIC COMMENT #129

As a practicing SC Licensed Midwife since 2009, I would like to go on record to state that I DO NOT SUPPORT THIS PROPOSED REGULATION IN GENERAL. The proposed regulations are restrictive for practicing midwives which in turn will restrict the availability of midwives to consumers.

The proposed 61-24 regulation revision appears to be an attempt by DHEC and other undisclosed, regulation writing "stakeholders"(likely medical and nursing professional organizations who may also be maternity care competitors), to reduce the number of practicing midwives in SC.

This proposal also exhibits bias, attempting to limit women's access to SC Licensed Midwives and placing an undue burden on midwives who already consult and refer to medicine for situations outside of our scope of practice.

RESTRAINT OF TRADE is written into this revision and is blatantly obvious by requiring our competitors, aka institutional based medical providers to supervise our community level midwifery practices. Midwives cannot require medical providers to comply with midwifery regulations, which would effectively shut down community level midwives in the State of SC.

We are currently and effectively under regulatory obligation to consult and refer, as appropriate, for women who need a higher level of services. Supervisory language does not improve outcomes when comparing maternal/infant morbidity and mortality rates with states with better overall outcomes than SC.

It is my concern that if these proposed revisions were to be put into place I would be forced to close my practice due to the restrictive supervisory physician requirements. I have been practicing in my community for over a decade and the physician relationships I have established for consulting purposes took a long time to develop and were difficult to find. The new proposed language for physicians would put a great amount of liability on the physician, which would inevitably force the physicians to end their professional relationship with me. There aren't any physicians in my area that would be willing to sign off that a woman is low risk for a home birth or take on the responsibility that would be required in the proposed language for consulting.

I hope you will strongly consider all of the comments I am submitting for the revisions being proposed for the 61-24 regulation, as I would like to continue serving the women in my community with good quality home birth services as a SC Licensed Midwife.

Lisa Johnson LM, CPM, LMW-0043
9/28/2020

My detailed concerns are as follows:

101.A. LM, CPMs are Healthcare Providers and authorized by the Dept. Orders or prescriptions come from Authorized "Medical" Providers with prescriptive authority. Verbiage should change to "Physician or other Authorized *Medical Provider" regarding prescriptions and all things medical throughout this proposal.

101.D. Authorized Healthcare Provider should be changed to Authorized MEDICAL Provider to avoid confusion. Licensed Midwives provide for the "health" care of our clients, not their medical care as stated in this definition and throughout the proposal. We are authorized by the dept to provide healthcare maternity services.

101.W. Should read "makes contact with a physician or other "Authorized *Medical Provider" instead of authorized healthcare provider. LMs are authorized by the dept and provide healthcare for prospectively low risk women during pregnancy, birth and postpartum. The verbiage is confusing.

101.X. Herbal products, vitamins and nutritional supplements are not specifically defined as medications, are used to support the body's natural processes and most importantly, are not regulated by the FDA. Medications are "classified" as over the counter or prescriptive substances that use a chemical action or pharmocological action to override the body's natural inclinations and are federally regulated as "medications." OTC medications, biologicals and prescriptive meds apply to this definition. Herbals, vitamins and nutritionals do not fit the definition of Medications per the FDA. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/classification-products-drugs-and-devices-and-additional-product-classification-issues

101.EE. Should read "or other authorized *medical provider" to provide clarity. Midwives are authorized healthcare providers but not authorized medical providers.

101.II. should read "or other medical provider" to provide clarity for referrals. Midwives are authorized healthcare providers.

101.MM. We transfer care to an "Authorized Medical Provider." Verbiage should be changed to provide clarity. Midwives are authorized healthcare providers but not authorized medical providers.

302.C. phrase "those that are against the best practices" as defined by whom? Since this is a midwifery regulation, best practices should be defined by a midwifery organization such as MAC, MANA or NARM and not widely open to various interpretations.

302.E. The monetary penalties section is inaccurate due to missing punctuation. Specifically dashes in between the numerical ranges of the penalties. Ex: 1st offense class 1 should read $200-$1000 not $2,001,000. The dashes are missing throughout this section.

The monetary amounts are extreme based on SC Code 44-1-151 which sets limits between $200-$1000. This regulation exceeds those legal limitations.

As a matter of note, I question why monetary penalties were stricken from the 2013 version of 61-24 and are now being added back in? Did DHEC change its mind? What is the legal precedent for that?

IF there is legal precedent for adding monetary penalties back in to 61-24, I strongly advise DHEC to omit Class 3 violations since the definition of this class is wide open to interpretation.

At a minimum, CLEARLY define what would constitute a class 3 violation as stated in my comments in 302.C. using a midwifery standard such as MAC, MANA or NARM to define “best practice."

400.D.2. Exclusion of care for all women with prior c-sections is extreme according to current evidence. A thorough risk assessment by midwives and our consulting physicians would exclude those at high risk.

Generally women with a classical incision are not good candidates for homebirth but women with low transverse scars are not an absolute risk-out criteria. As stated by others, if DHEC continues to exclude all VBAC (vaginal birth after cesarean) women, public health and safety will be severely impacted as women will continue to be forced into the corner of attempting an unassisted homebirth to avoid a repeat c-section.

Please refer to the scientific evidence and rationale offered by the professional midwifery organizations PALM, SC NACPM and NARM regarding VBACs. All VBAC women are NOT high risk and should not be treated as such.

I recommend that DHEC change this section to specify, "Provision of care for Client with a previous *classical cesarean section.

I defer to the VBAC statement (below) submitted by the Palmetto Association of Licensed Midwives (PALM) for rationale and scientific citations already submitted by our state professional organization.

Dear Members of the South Carolina Board of Health and Environmental Control,
The Memorandum to Licensed Midwives concerning Vaginal Birth After Cesarean (VBAC) in 2006 is based on what is now out-of-date research. Please consider looking at more recent studies and statements on VBAC.
Of the 35 states with licensure or statutory authority for the legal practice of CPMs, only seven states do not allow VBAC by licensed midwives at home. Not surprisingly, these states have high rates of cesarean sections and low rates of VBAC. South Carolina is one of them. South Carolina continues to have cesarean rates higher than the national average (33.5% vs 31.9%) and VBAC rates lower than the national average (12.0% vs 13.3%). Our state must do better.
The ACOG guidelines which mandate that a physician and anesthesiologist be "immediately available" during a trial of labor were found to be the main reason for the low rates of VBAC in a 2011 study. Additionally, fear of liability was a central reason for obstetricians and midwives to avoid attending VBACs, rather than evidence based decision making. Midwives were often further marginalized due to restrictive policies.
The US Department of Health & Human Services concluded in 2010 that there was a low level of evidence for the requirement for “immediately available” surgical and anesthesia personnel in the current ACOG guidelines. Furthermore, they recommended that policymakers find ways to “mitigate or even eliminate current barriers to trial of labor.” Yet, the intention of SC policymakers is to increase the barriers women face to find providers that allow a trial of labor.
The evidence does support giving women greater access to VBAC, including giving birth at home for low-risk women. Women that have had a cesarean section and a vaginal birth, regardless of the order, are considered viable candidates for VBAC. 2017 study of midwife-attended planned community births, women with a history of both cesarean and vaginal birth fared better than first-time mothers across all outcomes. The risk status of women with a history of both cesarean and vaginal birth is similar to the risk status of a woman with a history of only vaginal birth. 93% of women that attempted a VBAC at home did not need an unplanned repeat cesarean and had a vaginal birth.
When understanding risk status we must look not at relative risk but rather at absolute risk. The relative risk of neonatal death is higher with VBAC than with Elective Repeat Cesarean (ERC) (0.13% vs 0.05%) but both have a very low absolute risk. The relative risk of maternal death is reversed with a higher risk for an ERC than with a VBAC (0.013% vs 0.004%) but again both have a very low absolute risk. So, we can see that women should have a choice between VBAC and ERC since their own health is more at risk with an ERC and their baby’s health with a VBAC, but ultimately both risks are actually low.

Studies have also shown that we can predict which women are likely to have a successful VBAC. A previous vaginal delivery, spontaneous labor, and a neonate birth weight less than 4000g have been

shown to reduce risks. Homebirth can actually increase the odds of a successful VBAC since we always start births with spontaneous labor and not artificial inductions.

Unassisted homebirth is on the rise in South Carolina. When women are denied access to the care they desire, you (are encouraging) encourage them to birth unassisted.
The Palmetto Association of Licensed Midwives oppose any policy (the proposed revision) restricting access to a trial of labor for birthing women in South Carolina. Our training already includes providing care for VBACs at home. Denying access to quality midwifery care is a huge step backwards for South Carolina.

https://www.cesareanrates.org/vbac
Cox, K. J. (2011). Providers' perspectives on the vaginal birth after cesarean guidelines in Florida, United States: a qualitative study. BMC pregnancy and childbirth, 11, 72. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3203084/
US Department of Health & Human Services - National Institutes of Health, NIH Consensus Development Conference on Vaginal Birth After Cesarean: New Insights. March 8–10, 2010. Bethesda, Maryland. Final Panel Statement. https://consensus.nih.gov/2010/vbacstatement.htm
Bovjberg, M. L., Cheyney, M. Brown, J., et al. (2017). "Perspectives on risk: Assessment of risk profiles and outcomes among women planning community birth in the United States." Birth 44(3): 209-221. https://pubmed.ncbi.nlm.nih.gov/28332220/
Guise, J.-M., Eden, K., Emeis, C., et al. (2010). Vaginal Birth After Cesarean: New Insights. Evidence Report/Technology Assessment No.191. https://pubmed.ncbi.nlm.nih.gov/20629481/
Landon et al. (2016). "What We Have Learned About Trial of Labor After Cesarean Delivery from the Maternal-Fetal Medicine Units Cesarean Registry." Seminar Perinatol Aug;40(5):281-6. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4983226/

700.B.1.a. The clients face sheet should not include name and address of client's physician, midwife or midwife apprentice information. A face sheet is patient demographics, emergency contacts and insurance information. Please omit that verbiage as many of us use electronic health record systems and have no ability to override our current systems to include these items.

800. Why is this section reserved?

901.D.1. When a client comes into care, prenatal testing is either performed or obtained from the client's prior provider's records. Sometimes women come into care as "late entry" or beyond this section's parameter of 8 0/7 weeks to 16 0/7 weeks. Depending on the department's future interpretation of this section, if a woman comes into care at 16 1/7 weeks or beyond, we would be deemed to be out of compliance and open to citation for not "ensuring" this important testing was done in the stated timeframe. I advise changing the verbiage to state "upon coming into care" instead of 8-16 weeks when testing would ideally be done.

901.F. While written postpartum instructions and education are important components of midwifery care, these are generally included in the immediate postpartum period, before the midwife leaves the family's home. Postpartum *education is wise to include antenatally but to require postpartum instructions to be given antenatally is not appropriate timing as pregnant client's are primarily focused on the upcoming labor, comfort measures and tools to accomplish their goals of natural childbirth. Written postpartum instructions should be given in the early postpartum period for maximum impact, clarity and retention by the new parents.

1000.A. For continuity and clarity, please replace "or other Authorized Healthcare Provider" with Authorized Medical Provider. LMs are healthcare providers authorized to perform midwifery care in SC.

1000.D .Midwives are proponents of full evidence based informed consent and informed refusals regarding prenatal testing. If this section is to remain it should read, “explanation of the benefits and *risks of having an anatomic ultrasound. Why is this even under this section? Should be under prenatal testing section, not informed consent for clarity.

1100.A. Recommended change to "Initial Client Medical Consultation” The performing medical provider should be the decision maker as to whether the client needs a full physical or not. This should be on a case by case basis to be determined by that medical provider at the client’s appointment/consultation visit.

1100.A.1. Recommended change-The Midwife shall require the Client to be evaluated with an initial Client Medical Consultation completed by a Physician or other Authorized MEDICAL Provider within the first two (2) trimesters of pregnancy.

Perfectly healthy pregnant women sometimes enter into care late for various reasons. Ideally and most often, they enter into care in the first trimester but not always. To restrict the timeframe for entry into care leaves many women without a care provider at all and potentially falling through the cracks as far as maternity care goes. Our goal is to improve outcomes in SC, not restrict entry to care, as has been the practice of many OB groups.

1100.A.2. As stated in 1100.A. above, Recommended change to "Initial Client Medical Consultation” The performing medical provider should be the decision maker as to whether the client needs a full physical or not. This should be on a case by case basis to be determined by that medical provider at the client’s appointment/consultation visit.

1100.A.2.a.
THIS section (1100) contains language that causes me to reject the entire proposal.

This proposed language places LMs directly under supervisory language and has the high probability of forcing midwives out of practice.

As this language was included in the original drafting (prior to MACs involvement) and DHEC has avoided repeated questions requesting the names and credentials of the original draft writers, one can only assume that competing professionals in the maternity care field acted as DHEC’s consultants in the writing process.

This section wreaks of implicit bias and appears to be an attempt at restraint of trade.

This section implies supervisory language while our current regulation requires appropriate consulting, referral and collaborative relationships with medical providers.

Please strongly consider the PALM statement-
Out of the 35 states that license Certified Professional Midwives, only 2 states require Physician or health provider examinations during any of the trimesters of pregnancy unless a consult is required. The conditions requiring consultations are clearly identified in Regulation 61-24. The Physicians and medical care providers rely on the knowledge and training of the midwives to identify them and refer appropriately.
There is no documented evidence that confirms the safety of care from the two states who require Physician or medical provider examination.
While mapping integration of midwives across the Unite States, current evidence suggests that scope of practice laws, as well as other aspects of state policy and regulation, may be reducing the maternity care

workforce and access to services. An integrated maternity system facilitates the full exercise of scope of practice, autonomy, self-regulation, and collaboration across disciplines.
As hospitals become more and more monopolized, and physician and medical provider practices are merged into their monopoly, midwives cannot be responsible for what a physician or medical care provider agrees or disagrees to comply with. More and more physicians and other authorized medical care providers are opting for virtual office visits with their patients especially during Pandemic periods. The Client Consultation verbiage will allow for those types of visits.
Midwives are required to meet the North American Registry of Midwives requirements upon certification. This certification does not require the supervision of a Physician or other Medical Care Provider. Any changes or additions to Regulation 61-24 should align and reflect the North American Registry of Midwives best practices.
Reducing the number of community level providers of midwifery care will only make SC's numbers worse! Please refer to:
https://journals.plos.org/plosone/article/file?id=10.1371/journal.pone.0192523&type=printable
1100.B. Recommended change to "Second Client Medical Consultation" The performing medical provider should be the decision maker as to whether the client needs a full physical or not. This should be on a case by case basis to be determined by that medical provider at the client's appointment/consultation visit.
1100.B.1. Recommended edit- "The midwife shall require the client to undergo a second *medical consultation completed by a physician or other Authorized *Medical provider after 34 weeks of gestation." As stated above, the term Authorized Healthcare Provider is confusing and should be replace throughout this document to reflect the fact that midwives are authorized by the department as healthcare providers and that this section, among others, should stipulate a consultation with a medical provider for clarity.

1100.B.2. recd edit, change verbiage to clarify, "…shall ensure the second *Medical Consultation is documented…"

1100.B.2.a. "A written and signed statement from a physician or other authorized healthcare provider…" is unachievable for many SC midwives. Midwives can not require medical professionals to adheare to our proposed regulations and this proposal would leave many midwives in SC in a position of being out of compliance and at risk for citation and penalties. This is an undue burden to place on midwives who cannot control the actions of medical providers.

1200.A. Section verbiage should be changed to "or other Authorized *Medical Provider…" to provide clarity. LMs are authorized "health"care providers by DHEC in the state of SC under Health Licensing.

1200.B. Section verbiage should be changed to "or other Authorized *Medical Provider…" to provide clarity. LMs are authorized "health"care providers by DHEC in the state of SC under Health Licensing.

1200.B.4. Recommended edit- Change to Antihemmorhagics to allow for changes in professional standards over the duration that this proposed regulation would be in effect. Specific medications or brand names listed over the life of this regulation may change.

Physicians and Authorized Medical Providers should be prescribing based on best practice at the time. DHEC should not limit the prescriptive authority of those working in the field of maternity care. To do so puts mothers at higher risk for bad outcomes and leaves midwives, medical providers and DHEC at risk of liability for not providing the generally accepted maternity standard of care.

Regarding the Misoprostol memo generated by DHEC in xxxx, (can't currently find it on the DHEC Midwives page where it existed in the past) I defer to the statement submitted by the Palmetto

Association of Licensed Midwives (PALM) on the topic of Misoprostol for use in severe postpartum hemorrhages.

While I believe that specific medications and brand names should be omitted and classes of medications should replace them, I do strongly advise DHEC to reconsider the standard of care worldwide, regarding the use of misoprostol in cases of severe postpartum hemorrhage. If LMs are disallowed from providing for the standard of midwifery care in emergency situations, using a cheap and effective lifesaving medication, women are at higher risk of mortality and LMs, our medical consultants and DHEC is at high risk of liability.

By tying our consulting physician's hands to prescribe and practice according to the maternity standard of care, DHEC is effectively increasing risk to mothers and creating barriers that are obvious public health and safety issues. Isn't that opposite of DHEC's stated purpose?

1200.B.5. Recommended edit- Change to "Local Anesthesia for the purpose of perineal repairs" to allow for changes in professional standards over the duration that this proposed regulation would be in effect. Specific medications or brand names listed over the life of this regulation may change.

Physicians and Authorized Medical Providers should be prescribing based on best practice at the time. DHEC should not limit the prescriptive authority of those working in the field of maternity care. To do so puts mothers at higher risk for bad outcomes and leaves midwives, medical providers and DHEC at risk of liability for not providing the generally accepted maternity standard of care.

1200.B.6. Recommended edit- Change to "Antibiotics for the purpose of GBS prophylaxis" to allow for changes in professional standards over the duration that this proposed regulation would be in effect. Specific medications or brand names listed over the life of this regulation may change.

Physicians and Authorized Medical Providers should be prescribing based on best practice at the time. DHEC should not limit the prescriptive authority of those working in the field of maternity care. To do so puts mothers at higher risk for bad outcomes and leaves midwives, medical providers and DHEC at risk of liability for not providing the generally accepted maternity standard of care.

1200.B.8 Recommended edit- Change to "Emergency Anaphylaxis medications" to allow for changes in professional standards over the duration that this proposed regulation would be in effect. Specific medications or brand names listed over the life of this regulation may change.

Physicians and Authorized Medical Providers should be prescribing based on best practice at the time. DHEC should not limit the prescriptive authority of those working in the field of maternity care. To do so puts mothers at higher risk for bad outcomes and leaves midwives, medical providers and DHEC at risk of liability for not providing the generally accepted maternity standard of care.

1300.A. Recommended edit- change "or Authorized healthcare provider" to "Authorized Medical Provider" to provide clarity. LMs are authorized by the Dept under health licensing as maternity care providers, thus are Authorized Healthcare Providers.

1400. DISCHARGE- Recommended edit 1)- change "or Authorized healthcare provider" to "Authorized Medical Provider" to provide clarity. LMs are authorized by the Dept under health licensing as maternity care providers, thus are Authorized Healthcare Providers.

Recommended edit 2)- change "…the client refuses the initial or second physical examination…" to "…the client refuses the initial or second medical consultation visit" as referenced in section 1100 above.

The performing medical provider should be the decision maker as to whether the client needs a full physical or not. This should be on a case by case basis to be determined by that medical provider at the client's appointment/consultation visit.

1500.A. Recd edit- STRIKE "by dialing 911" EMS providers are not equipped, nor are they trained to take over care in an obstetric emergency.

In some situations and in the current state of pandemic, midwife ride-alongs are being disallowed by EMS and hospital infection control policies. In this type of situation, by being mandated to call 911, we could be dumping client's on EMS who are not ideally equipped for an obstetric emergency. They are "generalists", midwives are more suited to manage transitional care no matter the mode of transportation to a specialist.

Initiation of transfer of care should start with a provider to provider consultation and referral, ideally to an RPC. Mode of transportation should be on a case by case basis decided by the medical provider and the Licensed Midwife.

To correct this deficiency, in 2018, MAC submitted an advisory statement to DHEC which I will reference below. In the interest of public health and safety, DHEC *should be proponents of adding SC Licensed Midwives to the definition regarding Perinatal Levels of Care as Level 1, Community Midwives.

Why has this request for support from DHEC fallen on deaf ears for years? I question again, is there internal bias regarding LMs as community level providers?

Correcting the Perinatal Levels of Care deficiency will provide for smoother transitions and provide for more expedient services when a higher level of care is warranted. Mandating calling 911 is a bandaid and will not.

MAC 2018 Letter to DHEC

Equal Patient Access to Perinatal Levels of Care in South
Carolina Midwifery Advisory Council Letter of Support
December 7,
2018
The Midwifery Advisory Council supports equal access to Perinatal Levels of Care for all patients of South Carolina Licensed Midwives and Licensed Facilities. The access should include patients enrolled in the services of a DHEC Licensed Midwife and/or Licensed Facility.
Nationwide, perinatal systems designed to facilitate smooth transfers of care are being implemented on state levels and supported by major perinatal organizations such as American College of Obstetrics and Gynecology, National Association of Certified Professional Midwives and Home Birth Summit (which includes collaboration with ACOG). See supporting documents.
DHEC Hospital Regulation 61-16 was amended in 2015 to include revisions to the Perinatal Services section based on the latest version of the Guidelines for Perinatal Care, but did not include the same access to care for Licensed Midwife and Licensed Facility patients as were provided for obstetrical

patients of hospital/infirmary-to-hospital transfer patients. An item to note is that the RPC is an inhibiting factor to safe transport, see citations below.
DHEC reg. 61-16 Regional Perinatal Center with Neonatal Intensive Care Units (Level III) (RPC): "... the
RPC shall provide consultative, outreach, and support services to Level I, II, and III hospitals in the region.
"
SCDHEC reg 61-16 1306. B. "A Level II hospital shall not admit outborn neonates into its nursery without
prior concurrence with the
RPC."
This Council advises the Department to provide regulations/interpretations that encourage congruency in the care for transferring any perinatal patient no matter which Licensed Midwife or Licensed Birth Center from which the patient originated. This Council advises access for Licensed Midwife and Licensed Facility patients to the levels of perinatal care as supported by national organizations to ensure timely and safe transfers of care.
Respectively Submitted, Midwifery Advisory Council Rebecca Creel- Chair, Consumer Member; Geoffrey Chamber- Member-at-Large; Dr. Rachel Hall- Physician Member; Lisa Byrd, LM, CPM; Joanne Gottschall, LM, CPM; Lori Gibson, CPM, LM, MBC; Tom Chappell, CNM; Judy Fry, CNM
Attachments: ACOG Consensus of Levels of Care, February 2015 Midwifery Integration Scoring System Graph and Explanation (MISS) Home Birth Summit Best Practice Guidelines Published 2013 Supporting Healthy and Normal Physiologic Childbirth: A Consensus Statement by ACNM, MANA, and NACPM. 2012 Example of failed access: A letter from a local RPC denying equal access to neonatal transport team, re: Baby w/undiagnosed Downs Syndrome

1500.B. Recd edit- STRIKE "Emergency Medical Services personnel" written twice in this section. Please see rationale in section 1500.A. above.

Transferring care to EMS in an obstetric emergency does not provide a higher level of care as EMS providers are not maternity specialists, but emergency "generalists." This section, as written, increases health risk to mothers and babies and increases liability risks for midwives, consulting physicians and DHEC.

For continuity and clarity, please replace "or other Authorized Healthcare Provider" with " or other Authorized Medical Provider. LMs are healthcare providers authorized to perform midwifery care in SC.

1702.A. For continuity and clarity, please replace "or other Authorized Healthcare Provider" with " or other Authorized Medical Provider. LMs are healthcare providers authorized to perform midwifery care in SC.

1702.B.3. For continuity and clarity, please replace "or other Authorized Healthcare Provider" with " or other Authorized Medical Provider. LMs are healthcare providers authorized to perform midwifery care in SC.

1800- Recd edit- STRIKE the proposed section regarding the Midwifery Advisory Council (MAC) as written and REPLACE with the current 61-24 language regarding MAC, as copied and pasted below.

The prior/current regulation should not be minimized to reduce input from the MAC on matters of training, practices and regulation of midwives in SC, among other things. See below.

Licensed Midwives are experts in the field of out of hospital and physiologic birth and are uniquely suited to advise DHEC on midwifery professional matters, as in the past.

Recommendation-REPLACE THE PROPOSED NPR (section 1800) WITH THE CURRENT LANGUAGE IN 61-24

1. Midwifery Advisory Council.

a. The Commissioner of DHEC shall appoint a Midwifery Advisory Council which shall meet at least annually for the purpose of reviewing and advising the Department regarding matters pertaining to the training, practices, and regulation of midwives in South Carolina. The Council shall consist of three licensed midwives, one consumer of midwife care, two certified nurse-midwives, one physician active in perinatal care, and one member-at-large. Each member shall be appointed for a three-year term of office.

b. The Council shall establish a committee for peer review to consult with midwives in questions of ethics, competency and performance, and to serve as an appeal committee when disciplinary action has been taken. The committee may recommend denying, suspending, or revoking a license, or may recommend specific educational objectives, apprenticeship or other improvement measures as necessary.

1900-2700- What are these sections Reserved for?

2800 Recd edit- “in accordance with the best practices as interpreted by the department” should be revised to include a professional midwifery organization such as MAC, MANA or NARM as the determiner of “best practice” for matters relating to the profession of midwifery.

To leave this statement open ended is invitation for biased interpretation.

Suggested language edit- “Conditions that have not been addressed in this regulation shall be managed in accordance with the best practices, as determined by the MANA Standards and Qualifications for the Art and Practice of Midwifery, as interpreted by the Department."

Standards and Qualifications | Midwives Alliance of North America
https://mana.org/about-us/standards-and-qualifications

ATTACHMENT C

SUMMARY OF ADVISORY COUNCIL COMMENTS AND DEPARTMENT RESPONSES

R.61-24, *Licensed Midwives*

Comments received by the Midwifery Advisory Council on July 21, 2020

SECTION	COMMENT	DEPARTMENT RESPONSE
101: Definitions	B. Authorized Healthcare Provider: add Licensed Midwives as extension of medical providers	**Not Adopted.** These are individuals licensed by LLR and are authorized by statute to provide treatment and services that midwives are not authorized to provide. Section 1200 of this regulation authorizes Midwives to administer certain prescription medications to Clients.
Additional Comment:	Licensed Midwives must be added here for the scenarios when they will be administering prescription medications to Clients that were prescribed by the medical providers. See current definition of FF. and suggested change below.	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
101: Definitions	H: Consultation: change this to "Meeting"	**Partially Adopted.** Changed to "Compliance Meeting" for clarity.
Additional Comment:	The definition of Consultation for healthcare professionals is in reference to having a conversation about a Client with another professional for medical advice. By using consultation in reference to having a meeting with DHEC can be confusing, especially since 101.V. is entitiled "Medical Consultation"	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
101: Definitions	I: Amended License: add space between name, address	**Adopted.**
Additional Comment:		

SECTION	COMMENT	DEPARTMENT RESPONSE
101: Definitions	O: Home Birth: a birth planned out of hospital in the location of a residence	**Not Adopted.** The Birthing Center Licensure Act defines "Birthing center" as "a facility or other place where human births are planned to occur. This does not include the usual residence of the mother or any facility which is licensed as a hospital." (S.C. 44-89-30). Therefore, a planned delivery at a location other than the mother's usual residence falls within the statutory definition of a "birthing center" and would require a license as such.
Additional Comment:	There are situations when a pregnant person can neither give birth in their own homes nor have the option of using a birth center, in those situations they would be able to give birth in a residence in SC. Defining this as just the place of the resident of the Client severly limits their choice in place of birth and birth attendant which can have negative emotional and financial impacts.	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
101: Definitions	U. Low Risk pregnancy: Pregnancy in which there are no active complications and that there are no maternal or fetal factors that place the pregnancy at increased risk for complications.	**Partially Adopted.** DHEC will use the definition from The Birthing Center Act, S.C. 44-89-30. Low risk "means normal, uncomplicated prenatal course as determined by adequate prenatal care and prospects for a normal, uncomplicated birth as defined by reasonable and generally accepted criteria of maternal and fetal health."
Additional Comment:	"Medical intervention" should be removed as it could be interpreted as something as simple as antibiotics for a UTI, this does not place a pregnant person into a high risk category. Could be a dangerous open ended statement	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
101: Definitions	EE. Physician.	**Adopted.**
Additional Comment:	Consider using LLR's definition or "licensed by the sc board of medical examiners to practice medicine in SC"	

SECTION	COMMENT	DEPARTMENT RESPONSE
101: Definitions	FF. Prescription Medication	**Not Adopted.** Definition is from statute (Section 40-43-30). The requested change would contradict statute. This regulation authorizes Midwives to administer certain Prescription Medications to Clients.
Additional Comment:	"or restricted to use by physician or Authorized Healthcare provider only" is concerning language. Are Licensed Midwives authorized? What if they write for medications for Licensed Midwives to administer? Restrictive language that could potentially be used against Licensed MIdwives at some point. Should be in definitions that Licensed Midwives are an authorized Healthcare provider as an extension of our consulting APRN or physician.	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
101: Definitions	LL. Transfer of Care. Change "Higher medical authority" to "relinquishes care to another medical professional."	**Partially Adopted.** Changed to Authorized Healthcare Provider or Emergency Medical Services Personnel.
Additional Comment:	Deminishes the professionalism, scope and skill of the licensed midwife.	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
101: Definitions	Add Line item for Telemed/ Telehealth: Virtual consultations and visits with Authorized Healthcare Provider	**Not Adopted.** We do not regulate whether or not a physician/authorized healthcare professional is allowed to use telehealth.
Additional Comment:	Telemed/ telehealth consultations are now federally acceptible forms for means of communication and assessment by Authrorized Healthcare providers. These visits are reimbersilble by Medicaid and can help ease the burden both financially, as they cost less than in- person appointments, and scheduling as they lend themsleves to be more accesible for both the Client and the Authorized Healthcare provider. A client can follow through with this appointment without need of transportation or in the case of illness, loss of childcare etc. as currently demonstrated during the COVID 19 pandemic.	

SECTION	COMMENT	DEPARTMENT RESPONSE
101: Definitions	Add line item for VBAC: Vaginal Birth After Cesaerean	**Not Adopted.** We are consistent with LLR's Boards of Nursing Advisory Opinion #68.
Additional Comment:	There are only 6 other states that prohibit VBAC at home. The other 28 states that regulate midwives allow for and have successfully high rates of home vaginal birth after cesaerean. Pregnant people with prior low transverse incision should be allowed trial of labor in the setting that they feel most comfortable with the professional birth team that they choose. Clients who are given these options are more likely to have a vaginal birth with decreased risk of maternal and neonatal morbidity. For some of these people, home is the safest and best option for them. If it is prohibited by regulation then there will continue to be famlies who attempt to have a VBAC at home unattended or with improperly trained support. VBAC should be considered with prior low transverse incision, no prior classical incision and documented physician consultation explaining risks and informed consent.	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
102 Licensure Requirements	Correct typo to read "...the expiration of license by…"	**Adopted.**
Additional Comment:		
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
102 Licensure Requirements	C.3. Strike twenty-four (24) and replace with "A License for a Midwife shall be effective for a thirty-six (36) month period following the date of issue."	**Adopted.**
Additional Comment:	Renewal should be three (3) year period to coincide with NARM to ease burden on DHEC and on licensed midwives	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
102 Licensure Requirements	F. Licenseing Fees: $225 every three years	**Adopted.**
Additional Comment:	To coincide with three (3) year renewal	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
102 Licensure Requirements	H. License Renewal. The Midwife shall renew his or her License every thirty-six (36) months…	**Adopted.**
Additional Comment:	Renewal should be three (3) year period to coincide with NARM to ease burden on DHEC and on licensed midwives	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
201 General	Add "Licensed" before the second Midwife and Midwife Apprentice.	**Adopted.**
Additional Comment:	It reads a bit confusing as it is currently written	

SECTION	COMMENT	DEPARTMENT RESPONSE
203 Consultations	Change "consultations" to “Meetings" as per the suggestion in the definitions above	**Partially Adopted.** Changed to "Compliance Meeting" for clarity.
Additional Comment:	Using "consultations" for meetings with DHEC can lend itself to being confusing.	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
302 Violations of Classifications	Is there statutory basis to collect fines?	**S.C. 44-1-140**
Additional Comment:		
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
400 Scope of Practice	C.3. Strike "first-degree and second-degree"	**Adopted.**
Additional Comment:	episiotomies are not classified as first degree and second degree, just episiotomy	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
400 Scope of Practice	D.2. Provision of care for Client with a previous classical cesarean section	**Not Adopted.** We are consistent with LLR's Boards of Nursing Advisory Opinion #68.
Additional Comment:	Pregnant people must be given the choice and autonomy to have trial of labor after cesarean section with the provider of choice and in the place that they feel safest. A client with a previous c-section with a low transverse incision may be assessed prenatally and considered appropriate for out of hospital birth, with informed consent, with a Licensed Midwife. See definitions above.	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
500 Continuing Education	B. 1.c. strike “first-degree and second-degree”	**Adopted.**
Additional Comment:	episiotomies are not classified as first degree and second degree, just episiotomy	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
601 Incident	A. Add "when transport ends in maternal or neonatal death."	**Not Adopted.** This is consistent with other Departmental regulations regarding transfer of clients, patients, and residents out of a licensed program.
Additional Comment:	Coordinated transfers of care should be appropriately reported on quarterly reports. This 48 hour incident report for transfers places undue reporting burden on Midwives for clients who have been appropriately cared for.	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
603 Reporting Mortalities	Strike section	**Not Adopted.** It is a different department.
Additional Comment:	Redundant to section 601 B unless this is referring to a different department than in section 601 B	

SECTION	COMMENT	DEPARTMENT RESPONSE
701 Content	B.1.a. Strike race	**Adopted.**
Additional Comment:	Some clients decline to report race on intake and on birth certificates.	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
701 Content	B.1.a. Strike "name and address of Physician to be contacted in the event of emergency"	**Partially Adopted.** This was edited for clarity.
Additional Comment:	This is consulting healthcare provider information, not generally recorded on a client's intake face sheet	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
701 Content	B.1.e. add "unless client refuses GDM testing (as listed in 900 d 1j if at high risk for...)." Remove and create a new line item for syphilis testing	**Partially Adopted.**
Additional Comment:	Clients at low risk for gestational diabetes often decline traditional testing in lieu of alternate nutritional agreements.	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
701 Content	B.1.k. Strike "estimated amount"	**Partially Adopted.** Changed to "Estimated amount (small, moderate, or large)..."
Additional Comment:	no way to measure amniotic fluid	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
701 Content	B 1.l. Where is the line item?	**Adopted.**
Additional Comment:		
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
701 Content	B.1.m. Strike the word “and”	**Adopted.**
Additional Comment:		
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
701 Content	B.1.p. Should read “breast-feeding” resources	**Adopted.**
Additional Comment:		
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
701 Content	B.2.a. Strike race	**Adopted.**
Additional Comment:	Some clients decline to report race on intake and on birth certificates	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
701 Content	B.2.d. Change “resuscitations” to “resuscitation”	**Adopted.**
Additional Comment:		

SECTION	COMMENT	DEPARTMENT RESPONSE
800	What is section 800 “reserved” for?	The Department is creating consistency among regulations to align sections among its regulations within Healthcare Quality. Other regulations use this section for Admissions. This regulation does not have an Admissions section.
Additional Comment:		
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
901 Prenatal Care	Create a separate section for items: C.2, C.9, C.10 and C.11	**Adopted.**
Additional Comment:	No need to educate on or recommend these items at each prenatal visit as it creates redundancy. Documentation of discussion of these items as needed should be sufficient.	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
901 Prenatal Care	C.4. Strike line item	**Adopted.**
Additional Comment:	Not evidence based to dip urine at each appointment, only as needed.	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
901 Prenatal Care	C.8. Change “yones” to “tones”	**Adopted.**
Additional Comment:		
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
901 Prenatal Care	D.1. Change "twelve (12) weeks" to "eight (8) weeks"	**Adopted.**
Additional Comment:	Some clients begin as early as 8 weeks and need to or prefer to have blood work done at that time. This helps us potentially detect issues (such as low hemoglobin) as soon as 8 weeks and simply broadens our window for treatment of issue.	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
901 Prenatal Care	D.1.h. add "Optional, with informed consent from the Client"	**Adopted.**
Additional Comment:	this test should be optional	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
901 Prenatal Care	D.2. Definition: change to "thirty-five (35) weeks zero (0) days to thirty-seven (37) weeks zero (0) days"	**Adopted.**
Additional Comment:	Ensures that the window of time is sufficeint enough to not have to obtain tests more than needed.	

SECTION	COMMENT	DEPARTMENT RESPONSE
901 Prenatal Care	D.2.a. Change to "Council Client regarding Screening for Group B Streptococcus per current CDC guidelines and recommendations."	**Not Adopted.** Evidenced-based practice, Group B Streptococcus is the most common cause of life-threatening infections in newborns.
Additional Comment:	This test should be optional. Despite evidence-based education, some clients will decline GBS screening	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
901 Prenatal Care	D.2.b. Create and move to a new section for twenty-four (24) to twenty- eight (28) weeks, remove from this section	**Adopted.**
Additional Comment:	This labwork should be obtained and reviewed closer to 24-28 weeks, when the maternal blood volume has expanded and hemodilution has occurred.	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
901 Prenatal Care	D.2.c. Add "Assess and offer for Clients with lifestyle risk factors"	**Adopted.**
Additional Comment:	The majority of home birth clients are monogamous and this could be a financial burden. Additionally, Repeat STI screening should be reserved for those with lifestyle risk factors	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
901 Prenatal Care	E. Strike “the written instructions signed and dated by the Client”	**Adopted.**
Additional Comment:	Documentation in the chart that these items were given should be sufficient. While documentation is necessary, signature during antepartum or postpartum instructions would be often forgotten. Post partum instructions during initial postpartum care provides for more favorable retention of information. A signature for these items is overkill	

SECTION	COMMENT	DEPARTMENT RESPONSE
902 Intrapartum Care	A. Either keep verbiage as it is written in the current regulations or change to "Assess and monitor Client vital signs according to the standard of care. Assess, evaluate, and document the status of labor and the Client and fetal conditions throughout the labor and birth process, including Client vital signs and fetal heart tones in accord with sound obstetric and neonatal practice"	**Adopted.**
Additional Comment:	Home birth is not a medical event, it is a normal bodily function, the frequency of vitals collections should not be in regulation as this is policy and procedure. Mandatory collection of vitals every hour is excessive and is an interferance with and intervention of the normal function of labor.	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
903 Postpartum Care	A.1. change to "Assess, monitor and document Client and Newborn vital signs according to the standard of care during the first 2 hours and upon discharge.	**Adopted.**
Additional Comment:	Home birth is not a medical event it is a normal bodily function, the frequency of vitals collections should not be in regulations as this is a policy and procedure. Mandatory collection of vitals every hour is excessive and is an interferance with and intervention of the normal transition of client and newborn immediately following the birth.	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
904 Newborn Care	A 3. Strike this line item	**Not Adopted.** Added "if necessary" for clarity.
Additional Comment:	This is arbitrary. Why do we need to have in regulation to chart how we are providing for warmth and stimulation? Most home born babies do not need stimulation. Blankets and heating pads are on the list of supplies for the Client to have available for each birth. This is an unneccessary item for regulation.	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
904 Newborn Care	B. Newborn Screening: add "If the specimen is not collected by the midwife or is not collected within three (3) days..."	**Not Adopted.** This is copied from statute. This corrects the error in the current regulation.
Additional Comment:	Many clients with traditional insurance opt to have the newborn screen collected by their pediatrician to activate their insurance instead of being out of pocket for midwifery collection processed by DHEC lab	

SECTION	COMMENT	DEPARTMENT RESPONSE
1000 Informed Consent	D. Strike this line item	**Adopted**
Additional Comment:	Anatomic ultrasounds are generally performed between 18 and 22 weeks of pregnancy. With reliable dating, early ultrasound is unwarranted and introduces unnecessary risk factors to the fetus. Late ultrasound is unreliable for dating or fetal size and only indicated in higher risk situations or questions of presentation.	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
1100 Physical Examinations	Change title of section from Physical Examinations to “Client Medical Consultations”	**Not Adopted.**
Additional Comment:	Replace Physical Examinations with “Client Medical Consultations” within this entire section.	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
1100 Physical Examinations	A.1. Change “Physical Examination” to “Medical Consultation.” "The Midwife shall require the Client to undergo an initial Medical Consultation either in person or via telemedicine completed by a Physician or other Authorized Medical Provider, at the Provider's discretion, within the first 2 trimesters."	**Not Adopted.** This is consistent with evidence-based practice. Nothing in this regulation prohibits televisits. The S.C. Department of Health and Environmental Control cannot opine on laws governing physicians' and authorized healthcare providers' scopes and standards of practice.
Additional Comment:	Clients may not be able to obtain an appointment during that window of time (fourteen {14} to twenty {20} weeks) for various reasons including but not limited to lack of transportation, illness, limited availbility with Authorized Heatlhcare Provider, life circumstances, etc. Due to our current Pandemic, Telemed/ telehealth visits are now federally accepted forms of medical appointments and are now reimbursible through Medicaid. When the Authorized Healthcare Provider has been given the client's prenatal flow chart and any lab reports to review, they can then advise the client appropriately. Any medications to be prescribed to Client can be written and sent to the chosen pharmacy by the Authorized Healthcare Provider at the time of appointment whether in person or virtual. Licensed Midwives are assessing the Client for low risk at each appointment.	

SECTION	COMMENT	DEPARTMENT RESPONSE
1100 Physical Examinations	A.2.a. Strike entire line item	Not Adopted. The Birthing center statute requires the physician shall make a determination that the birth is low risk. Consistent with other regulations
Additional Comment:	Providers who have an appointment with the Clients for those visit may not give a written and signed document. We cannot make another provider write a document. Licensed Midwives palpate for fetal position at every prenatal visit, some medical providers who see for these visits do not perform uterine palpation. Licensed midwives cannot be responsible for other providers, likewise Authorized Healthcare providers cannot be responsible for our Clients.	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
1100 Physical Examinations	B 1. Change title from "Physical Examination" to "Client Medical Consultation"	**Not Adopted.** This is consistent with evidence-based practice.
Additional Comment:		
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
1100 Physical Examinations	Change to read "after thirty-four (34) weeks of gestation	**Adopted.**
Additional Comment:	It can be difficult to find a medical provider and schedule an appointment in that short time frame for various reasons including but not limited to lack of transportation, illness, no availbility with Authorized Medical Provider, life circumstances, etc. Due to the current Pandemic, Telemed/ telehealth visits are now federally accepted forms of medical appointments and are now reimbursible through Medicaid.When the Authorized Medical Provider has been given the client's prenatal flow chart and any lab reports to review, they can then advise the client appropriately. Any medications to be prescribed to Client can be written and sent to the chosen pharmacy at the time of appointment whether in person or virtual.	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
1200 Prescription Medication Administration	B 2… where is this line item?	**Adopted.** This item is the eye prophylactic as required by statute.
Additional Comment:		

SECTION	COMMENT	DEPARTMENT RESPONSE
1200 Prescription Medication Administration	B.7. Add"or alternative antibiotic, as deemed appropriate and prescribed by Authorized Medical Provider in accordance with current CDC guidelines"	**Adopted.**
Additional Comment:	For cases of penicillin allergy alternative antibiotics must be availble	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
1200 Prescription Medication Administration	B.8. Change to read "IV fluids"	**Adopted.**
Additional Comment:	Lactated Ringer's or Normal Saline would be appropriate here.	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
1200 Prescription Medication Administration	Add line item for "other anti-hemorrhagic medications as prescribed by Authorized Medical Provider"	**Partially adopted.** Misoprostol is not FDA-approved as a post-hemorrhagic medication.
Additional Comment:	Authorized Medical Providers may prescribe anti-hemmoragic medications in accordance with evidence based research and updated protocols in accordance with the World Health Organization. Efficent, appropriate and accepted medications include misoprostol and methergine in addition to synthetic oxytocin.	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
1300 Medical Consultation	Change title to “Midwife Medical Consultation”	**Not Adopted.**
Additional Comment:		
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
1300 Medical Consultation	A. Strike: “ and the Cient’s decision, as evidenced by the Client’s signature.”	**Not Adopted.** This is consistent with other Departmental regulations requiring evidence that a Client has received relevant information about their care from the licensed facility or provider.
Additional Comment:	When the Licensed Midwife should need to consult with a medical provider, the client may not necessarily be present. Medical consultation by midwife to Authorized Healthcare Provider may take place virtually or over the phone at any time. Physicians don’t always record the time of their appointment or any consultations with midwives. Documentation in the chart of recommendations by the Authorized Healthcare Provider for the client is sufficient. Signature to confirm decision and recommendations upon medical consultation by the Licensd Midwife to the Authorized Healthcare Provider should be evidence on the informed consent document upon the start of care. This requirement is redundant.	

SECTION	COMMENT	DEPARTMENT RESPONSE
1300 Medical Consultation	B.1.n Strike "Failure to gain weight" or add "without adequate nutrition." to the end of the line item	**Adopted.**
Additional Comment:	Obese clients who are committed to excellent nutrition often exhibit low weight gain due to nutritional choices being optimized	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
1300 Medical Consultation	Add line item: VBAC	**Not Adopted.** We are consistent with LLR's Boards of Nursing Advisory Opinion #68.
Additional Comment:	May be considered with prior low transverse incision, no prior classical incision and documented physician consultation explaining risks and informed consent.	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
1300 Medical Consultation	B.2.a. Add "greater than 24 hours."	**Adopted**
Additional Comment:	As it is written, it is too vague and leaves it open to interrpretation	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
1300 Medical Consultation	B.2.e. Add "with non-reassuring fetal heart tones"	**Adopted.**
Additional Comment:		
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
1300 Medical Consultation	B.4.h Change to more than ten (10) pounds	**Adopted.**
Additional Comment:	Well nourished, healthy Clients can give birth uneventfully to babies who weigh more than 9 pounds without signs of hypoglycemia or other issues.	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
1300 Medical Consultation	B.4.j. Strike line item	**Adopted.**
Additional Comment:	No need to consult for post maturity unless the baby has an abnormal newborn exam	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
1300 Medical Consultation	B.4.k. Strike "Meconium staining." Change the remaining line item to "does not urininate within first twenty-four (24) hours or meconium within the first forty-eight (48) hours	**Partially Adopted.** “Does not urinate or pass meconium in the first twenty-four (24) hours following birth;”
Additional Comment:		

SECTION	COMMENT	DEPARTMENT RESPONSE
1300 Medical Consultation	B.4.n. Strike "Rectal" Change one hundred six (106) to one hundred and six tenths (100.6)	**Adopted.** Correction was made.
Additional Comment:	Rectal temperatures are no longer recommended. Fever in neonate is not 106degrees F, it is 100.6 degrees F	
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
1500 Transfer of Care	A. Strike "by dialing 911"	**Not Adopted.**
Additional Comment:		
SECTION	**COMMENT**	**DEPARTMENT RESPONSE**
1500 Transfer of Care	B. Strike " Upon arrival of the emergency medical services personnel, Physician, or other Authorized Healthcare Provider, the midwife shall transfer the care of the Client to the emergency medical services personnel, Physician or other Authorized Healthcare Provider. "	**Not Adopted.** Nothing is preventing the Client or responsible party from refusing the emergency care when it arrives and driving their own vehicle.
Additional Comment:	EMS providers are not ideally equipped nor are they trained to take over care in an obstetric emergency. Also, emergent transport via private car is often more expedient in some situations. Additionally, Licensed Midwives cannot rely on clients to have copiers or printers which in turn does not provide for printing in the field. Written summaries can be faxed to the receiving provider and/ or hand delivered by the transferring midwife at the receiving hospital for copies of the chart to be made at the time of report of situation to the receiving provider.	

SECTION	COMMENT	DEPARTMENT RESPONSE
1800 Midwifery Advisory Council	Currently the MAC is an appeal committee for DHEC actions. This should remain in the regulations. It provides the opportunity to have members of the profession review actions related to these regulations. Members of this committee are in a good position to keep the public safe. The council shall establish a committee for peer review to consult with midwives on questions of ethics, competency, licensure and performance, and to serve as an appeals committee for disciplinary action under this regulation. A licensed midwife or midwife apprentice shall have 30 days to provide notice of appeal by letter directed to the Midwife Advisory Council. Upon reciept of a request for appeal of agency action, the MAC shall schedule an appeal at the next available meeting. Only actions of the department that fall under this regulation may be appealed before the MAC. A licensed midwife may be represented by an attorney in a appeal before the MAC.	**Not Adopted.** This contradicts S.C. 44-1-60. The prior regulation was enacted before this statute was changed.
Additional Comment:		

SECTION	COMMENT	DEPARTMENT RESPONSE
N/A	What are the following sections reserved for? SECTION 1900 – [RESERVED] SECTION 2000 – [RESERVED] SECTION 2100 – [RESERVED] SECTION 2200 – [RESERVED] SECTION 2400 – [RESERVED] SECTION 2500 – [RESERVED] SECTION 2600 – [RESERVED]	Generally used for Design and Construction, which is not applicable to this regulation. Fire Protection, Prevention, and Life Safety, which is not applicable to this regulation. General Construction, which is not applicable to this regulation. Exits, which is not applicable to this regulation. Electrical, which is not applicable to this regulation. HVAC, which is not applicable to this regulation. Physical Plant, which is not applicable to this regulation.
Additional Comment:		