SUMMARY SHEET
SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

May 13, 2021

( ) 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 March 1, 2021, through March 31, 2021.

III. **FACTS:** For the period of March 1, 2021 through March 31, 2021, Healthcare Quality reports two (2) Consent Order(s) totaling $1,885 in assessed monetary penalties, thirty-nine (39) Notices of Violation and Civil Penalty totaling $13,350 in assessed monetary penalties, and (1) Administrative Order.

Name of Bureau	Facility, Service, Provider, or Equipment Type	Notices of Violation and Civil Penalty	Administrative Orders	Consent Orders	Assessed Penalties
Bureau of Facilities Oversight	Community Residential Care Facility	34	0	0	$11,750
	Nursing Home	5	0	0	$1,350
	Body Piercing Facility	0	0	1	$0
Bureau of Radiological Health	Chiropractic Facility	0	0	1	$1,885
	Mammography Facility	0	1	0	$0
TOTAL		**39**	**1**	**2**	**$14,985**

Submitted By:

Gwendolyn C. Thompson

Gwen C. Thompson
Deputy Director
Healthcare Quality

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

May 13, 2021

Bureau of Facilities Oversight

1. Facilities in Violation of Public Health Order No. COVID-19-5

Violations: The Department found that the thirty-four (34) community residential care facilities (CRCFs) and five (5) nursing homes listed below failed to submit a weekly visitation report to the Department by the mandatory deadline. Failure to submit the report by the deadline is in violation of the Department's October 7, 2020, Public Health Order that requires all nursing homes and CRCFs licensed by the Department to submit a weekly report on their visitation status.

Enforcement Action: In March 2021, the Department issued Notices of Violation and Civil Penalty against thirty-four (34) CRCFs and five (5) nursing homes. All of the facilities listed below were required to pay the full amount of their accumulated penalties within twenty (20) days of the dated notices.

Name of Facility	Facility Type	Civil Penalty	Payment Received
Abundant Life Adult Care	CRCF	$250	Yes
Beard Residential Care Facility #1	CRCF	$350	Yes
Black's Drive Community Residence	CRCF	$350	Yes
Bostick's Adult Residential Care Facility	CRCF	$350	Yes
Brian's Residential Care	CRCF	$350	Yes
Brian's Residential Care II	CRCF	$250	Yes
Carson's Community Care	CRCF	$450	Yes
Cascades Verdae Assisted Living	CRCF	$250	Yes
Catherine's Manor II	CRCF	$250	Yes
Dayspring Assisted Living	CRCF	$250	No
Dayspring of Johns Island	CRCF	$250	No
Generations of Batesburg	CRCF	$350	Yes
Harborchase Of Aiken	CRCF	$250	Yes
Harborchase Of Columbia	CRCF	$250	Yes
Ladson's Residential Home Care	CRCF	$250	No
Lakeview Assisted Living	CRCF	$450	No
Lemonaide House	CRCF	$450	Yes
New Haven	CRCF	$250	Yes
Oakridge Community Care Home #1	CRCF	$1,000	Yes
Oakridge Community Care Home #2	CRCF	$450	Yes
Oaks of Loris	CRCF	$250	Yes
Pondview Residential Care Home #1	CRCF	$250	Yes
Pondview Residential Care Home #2	CRCF	$250	Yes

Name of Facility	Facility Type	Civil Penalty	Payment Received
Reese's Community Care Home #1	CRCF	$350	No
Reese's Community Care Home #2	CRCF	$350	No
Ridgeview Community Care Homes Unit B	CRCF	$350	No
Serenity Manor of Holly Hill	CRCF	$350	No
Stokes Residential Care	CRCF	$250	Yes
Westminster Memory Care-Lexington	CRCF	$250	Yes
Wildewood Downs Assisted Living Community	CRCF	$1,000	Yes
Williams Community Care Home	CRCF	$350	Yes
Willies II RCH	CRCF	$350	No
Woodland Place	CRCF	$350	No
John Edward Harter Nursing Center	Nursing Home	$250	Yes
Life Care Center of Hilton Head	Nursing Home	$250	No
Linville Courts at The Cascades Verdae	Nursing Home	$250	Yes
McCormick Rehabilitation and Healthcare Center	Nursing Home	$250	Yes
Wildewood Downs Nursing and Rehabilitation Center	Nursing Home	$350	Yes

Facility Type	Total # of Permitted Facilities
Body Piercing Facility	41

2. Raw Body Piercing – Columbia, SC

Inspections and Investigations: The Department conducted routine inspections in February 2019 and September 2020, and cited the facility for regulatory violations.

Violations: As a result of the inspections, the Department found the facility violated Regulation 61-109, *Standards for Permitting Body Piercing Facilities*, by failing to have an autoclave for proper sterilization, and failing to maintain proper documentation at the facility. The facility also repeatedly failed to submit its plans of correction for the cited violations.

Enforcement Action: The parties agreed to resolve the matter with a consent order. The facility agreed to probation until they satisfy the conditions described in the Consent Order. The facility agreed to schedule and attend a compliance assistance meeting with the Department. The facility also acknowledged the Department will conduct a follow-up inspection to determine compliance and whether the facility's probation status will be lifted.

Remedial Action: The parties have conducted the compliance assistance meeting. As of May 3, 2021, the Department's follow-up inspection has not yet taken place and the facility continues to be on probation.

Prior Enforcement Actions: None in the past five years.

Bureau of Radiological Health

Facility Type	Total # of Registered Facilities
Chiropractic Facility	487

3. Easterling Chiropractic – Hartsville, SC

Inspections and Investigations: The Department conducted routine inspections in November 2019 and discovered that the registrant was in violation of regulatory standards.

Violations: The Department found that the registrant failed to comply with Regulation 61-64, *X-Rays*, by failing to conduct its annual equipment performance testing. The last documented test was 2019 and the registrant provided additional records indicating that 2016 was the last year a test was performed before 2019. The registrant failed to submit a plan of corrections within the required timeframe.

Enforcement Action: The parties agreed to resolve the matter with a consent order. As a term of the Consent Order, the Department imposed a $1,885 monetary penalty against the registrant. The registrant is required to pay a total of $285 in eight (8) installments while the remaining $1,600 balance is stayed.

Remedial Action: The registrant has paid two (2) of the eight (8) installments.

Prior Enforcement Actions: None in the past five years.

Facility Type	Total # of Certified Facilities
Mammography Facilities	104

3. MUSC Hollings Cancer Center Mobile Mammography – Charleston, SC

Inspections and Investigations: This facility was accredited and certified to operate a mammography facility prior to the actions summarized herein. The facility had not been providing mammography services since October 2019. Because the facility maintained its accreditation and certification, it was still subject to applicable state and federal mammography facility requirements. The Department conducted federal and state inspections in September 2020 that resulted in regulatory violations. As a result of the Department's findings and at the Department's request, the accrediting body, the American College of Radiology, performed additional reviews in November 2020 and January 2021. The Department then investigated the American College of Radiology's additional findings.

Violations: The Department found the facility failed to comply with Regulation 61-64, *X-Rays*, by failing to perform ten quality control tests on the required frequency. Based on these quality control program violations, the Department requested the American College of Radiology perform an additional review. Upon performing additional review, the American College of Radiology determined the quality of mammography at the facility poses a "serious risk to human health" and revoked the facility's accreditation.

Enforcement Action: Following the Department's investigation into reasons for the American College of Radiology's revocation of accreditation, the Department suspended the facility's certificate effective February 24, 2021.

Remedial Action: The facility is suspended from performing mammography services and may no longer display the "SC DHEC Mammography Certificate" until the Department determines the emergency situation is no longer present and the facility has taken necessary action to obtain accreditation and compliance with applicable law.

Prior Enforcement Actions: None in the past five years.

SUMMARY SHEET
BOARD OF HEALTH AND ENVIRONMENTAL CONTROL
May 13, 2021

_____ 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 March 1, 2021, through March 31, 2021.

3. **FACTS:** For the reporting period of March 1, 2021, through March 31, 2021, the Office of Environmental Affairs issued twenty-seven (27) Consent Orders with total assessed civil penalties in the amount of fifty-five thousand, three hundred ten dollars ($55,310.00). Also, eighteen (17) Administrative Orders with total assessed civil penalties in the amount of twenty-five thousand, six hundred thirty dollars ($25,630.00) were reported during this period.

Bureau and Program Area	Administrative Orders	Assessed Penalties	Consent Orders	Assessed Penalties
Land and Waste Management				
UST Program	5	$18,105.00	4	$10,000.00
Aboveground Tanks	0	0	0	0
Solid Waste	1	$7,525.00	1	$2,100.00
Hazardous Waste	0	0	0	0
Infectious Waste	0	0	0	0
Mining	0	0	2	$3,000.00
SUBTOTAL	**6**	**$25,630.00**	**7**	**$15,100.00**
Water				
Recreational Water	0	0	4	$2,360.00
Drinking Water	0	0	5	$10,000.00
Water Pollution	0	0	7	$20,150.00
Dam Safety	1	0	0	0
SUBTOTAL	**1**	**0**	**16**	**$32,510.00**
Air Quality				
SUBTOTAL	**0**	**0**	**1**	**$4,000.00**
Environmental Health Services				
Food Safety	0	0	2	$2,200.00
Onsite Wastewater	10	0	1	$1,500.00
SUBTOTAL	**10**	**0**	**3**	**$3,700.00**
OCRM				
SUBTOTAL	**0**	**0**	**0**	**0**
TOTAL	**17**	**$25,630.00**	**27**	**$55,310.00**

Submitted by:

Myra C. Reece
Director of Environmental Affairs

ENVIRONMENTAL AFFAIRS ENFORCEMENT REPORT
BOARD OF HEALTH AND ENVIRONMENTAL CONTROL
April 8, 2021

BUREAU OF LAND AND WASTE MANAGEMENT

Underground Storage Tank Enforcement

1) Order Type and Number: Administrative Order 19-0257-UST
Order Date: March 10, 2021
Individual/Entity: **David Bilderback d.b.a. Carolina Country Store**
Facility: Carolina Country Store
Location: 11725 South Fraser Street, Georgetown, SC 29440
Mailing Address: Same
County: Georgetown
Previous Orders: None
Permit/ID Number: 19037
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs. 61-92, 280.40(a)(2) and 280.43(d) (2012 and Supp. 2019).

Summary: David Bilderback d.b.a. Carolina Country Store (Individual/Entity) is the owner of an underground storage tank (UST) located in Georgetown County, South Carolina. On June 18, 2019, the Department conducted a compliance inspection and issued a Notice of Alleged Violation. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to properly maintain release detection equipment; and failed to conduct proper release detection using an automatic tank gauge.

Action: The Individual/Entity is required to submit proof that the automatic tank gauge probes have been repaired and/or replaced and are in proper working order. The Individual/Entity shall submit all compliance documentation by May 29, 2021. The Department has assessed a total civil penalty in the amount of three thousand, thirty dollars ($3,030.00). The Individual/Entity shall pay a civil penalty in the amount of three thousand, thirty dollars **($3,030.00)** by May 29, 2021.

Updates: The Individual/Entity did not file a Request for Review.

2) Order Type and Number: Administrative Order 20-0216-UST
Order Date: March 10, 2021
Individual/Entity: **CD's Incorporated**
Facility: CD's
Location: 3271 Highway 9, Cheraw, SC 29520
Mailing Address: Same

County: Chesterfield
Previous Orders: None
Permit/ID Number: 10109
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. Code Ann. § 44-2-60(A) (2018).

Summary: CD's Incorporated (Individual/Entity) is the owner of underground storage tanks (USTs) located in Chesterfield County, South Carolina. On August 10, 2020, the Department issued a Notice of Alleged Violation due to unpaid annual tank registration fees for fiscal year 2021. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to pay annual underground storage tank registration fees.

Action: The Individual/Entity is required to pay annual tank registration fees and associated late fees for fiscal year 2021 in the amount of six hundred five dollars ($605.00) by May 25, 2021. 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)** by May 25, 2021.

Updates: The Individual/Entity did not file a Request for Review.

3) Order Type and Number: Administrative Order 20-0029-UST
Order Date: March 25, 2021
Individual/Entity: **Naya, Inc.**
Facility: Speedee Mart
Location: 730 West Main Street
Clinton, SC 29325
Mailing Address: 717 Providence Road
Gaffney, SC 29341
County: Laurens
Previous Orders: None
Permit/ID Number: 14492
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs. 61-92, 280.40(a) (2012 and Supp. 2019).

Summary: Naya, Inc. (Individual/Entity) is the owner of underground storage tanks (USTs) located in Laurens County, South Carolina. On December 17, 2019, the Department conducted a compliance inspection and issued a Notice of Alleged Violation. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to provide an adequate release detection method.

Action: The Individual/Entity corrected all violations prior to the issuance of the Order. The Department has assessed a total civil penalty in the amount of one thousand, five hundred dollars ($1,500.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand, five hundred dollars **($1,500.00)** by May 29, 2021.

Updates: The Individual/Entity submitted the required compliance documentation on January 15, 2021. The civil penalty has not been paid.

4) Order Type and Number: Administrative Order 20-0172-UST
Order Date: March 25, 2021
Individual/Entity: **Ankur Patel**
Facility: Little Mountain Corner Mart
Location: 2810 Highway 29 South
Anderson, SC 29624-6819
Mailing Address: P.O. Box 40
Piedmont, SC 29673-0040
County: Anderson
Previous Orders: None
Permit/ID Number: 15582
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. code Ann. § 44-2-140(A) et seq. (2018); and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs 61-92, 280.34(c), 280.36(a)(1)(i), 280.36(a)(1)(ii), 280.70(a), 280.242(b)(3), and 280.242(b)(4) (2012 & Supp 2019).

Summary: Ankur Patel (Individual/Entity) owns and operates underground storage tanks in Anderson County, South Carolina. The Department issued a Notice of Alleged Violation based on an inspection on July 14, 2020. The Individual/Entity violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to provide records to the Department upon request; failed to conduct monthly walk-though inspections; failed to conduct annual walk-through inspections; failed to maintain corrosion protection on a temporarily closed UST; failed to validate that monthly requirements have been performed; and failed to physically visit each facility once a quarter.

Action: The Individual/Entity is required to submit: proof that a Class A/B Operator log is being maintained; proof that a walkthrough log is being maintained; proof that Class C Operators have been trained and designated for the Facility; and current acceptable cathodic protection test results by May 26, 2021. The Department has assessed a total civil penalty in the amount of four thousand, five hundred seventy-five dollars ($4,575.00). The Individual/Entity shall pay a civil penalty in the amount of four thousand, five hundred seventy-five dollars **($4,575.00)** by May 26, 2021.

Updates: The Individual/Entity did not file a Request for Review.

5) Order Type and Number: Administrative Order 20-0182-UST
Order Date: March 25, 2021
Individual/Entity: **Beaufort Oil Co., Inc.**
Facility: Xpress Lane 5
Location: 1702 Sea Island Parkway
Saint Helena Island, SC 2929920
Mailing Address: 43 Old Jericho Road
Beaufort, SC 29906
County: Beaufort
Previous Orders: AO 19-0231-UST ($7,700.00)

Permit/ID Number: 00985
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. code Ann. § 44-2-140(A) et seq. (2018); and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs 61-92, 280.70(c) (2012 & Supp 2019).

Summary: Beaufort Oil Co., Inc. (Individual/Entity) owns and operates underground storage tanks in Beaufort County, South Carolina. The Department conducted file review and issued a Notice of Alleged Violation on July 9, 2020. The Individual/Entity violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to properly abandon a temporarily closed UST system after twelve (12) months if the UST system does not meet either performance standards in Section 280.20 for new UST systems or the upgrading requirements in Section 280.21.

Action: The Individual/Entity is required to: submit a completed UST Tank and Sludge Disposal Form by May 26, 2021; and, within sixty (60) days of the Department's approval of the UST Tank and Sludge Disposal Form, permanently close the USTs and submit an UST Closure and Assessment Report. The Department has assessed a total civil penalty in the amount of six thousand dollars ($6,000.00). The Individual/Entity shall pay a civil penalty in the amount of six thousand dollars **($6,000.00)** by May 26, 2021.

Updates: The Individual/Entity did not file a Request for Review.

6) Order Type and Number: Consent Order 20-0278-UST
Order Date: March 2, 2021
Individual/Entity: **Parmar Manharsinh**
Facility: Aniq, LLC
Location: 6058 Edmund Highway
Lexington, SC 29073
Mailing Address: Same
County: Lexington
Previous Orders: None
Permit/ID Number: 19237
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. code Ann. § 44-2-140(A) et seq. (2018); and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs 61-92, 280.10(d) (2012 & Supp 2019).

Summary: Parmar Manharsinh (Individual/Entity) owns and operates underground storage tanks in Lexington County, South Carolina. The Department conducted an inspection on October 30, 2020 and issued a Notice of Alleged Violation. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: introduced petroleum products to an UST system that was under Delivery Prohibition.

Action: The Individual/Entity corrected all violations prior to the issuance of the Order. 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)** by April 16, 2021.

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

closed.

7) Order Type and Number: Consent Order 21-0036-UST
Order Date: March 2, 2021
Individual/Entity: **Munisuvrat Inc.**
Facility: JK Food Mart
Location: 597 Ford Road
Gaffney, SC 29340
Mailing Address: 11229 Fountain Grove Drive
Charlotte, NC 28262
County: Cherokee
Previous Orders: N/A
Permit/ID Number: 09436
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., R.61-92 280.93(a) and 280.110(c) (2012 & Supp. 2018).

Summary: Munisuvrat Inc. (Individual/Entity) is the owner and operator of underground storage tanks located in Cherokee County, South Carolina. The Department conducted an inspection on November 30, 2020. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to maintain overfill prevention equipment.

Action: The Individual/Entity corrected the violation prior to the issuance of the Order. The Department 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)** by April 16, 2021.

Updates: The Individual/Entity paid the civil penalty in full on February 22, 2021. This Order has been closed.

8) Order Type and Number: Consent Order 21-0033-UST
Order Date: March 10, 2021
Individual/Entity: **Prakash Patel**
Facility: Short Trip 5
Location: 2227 Sumter Highway
Manning, SC 29102
Mailing Address: 500 1st St West
Hampton, SC 29102
County: Clarendon
Previous Orders: None
Permit/ID Number: 12708
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 & Supp. 2019).

Summary: Prakash Patel (Individual/Entity) owns underground storage tanks

(USTs) located in Clarendon County, South Carolina. Based on a January 15, 2021 inspection, the Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Control Regulation as follows: failed to maintain overfill prevention equipment.

Action: The Individual/Entity corrected the violation prior to the issuance of the Order. The Department assessed a total civil penalty in the amount of one thousand dollars ($1,000.00). The Individual/Entity is required to pay a civil penalty in the amount of one thousand dollars **($1,000)** by April 15, 2021.

Updates: A tank gauging stick was removed from the drop tube shutoff valve of the 8,000-gallon regular unleaded UST on January 15, 2021. A demand letter was issued for payment of the civil penalty with a deadline of May 17, 2021.

9) Order Type and Number: Consent Order 21-0041-UST
Order Date: March 25, 2021
Individual/Entity: **Bahuchar Mata, LLC**
Facility: Quick Pantry 19
Location: 1802 South Main Street
Greenwood, SC 29646
Mailing Address: 311 Oakmonte Circle
Greenwood, SC 29649
County: Greenwood
Previous Orders: None
Permit/ID Number: 04785
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), 280.40(a), 280.40(a)(2), 280.43(d), 280.45(b)(1), 280.50, 280.51, 280.52 (2012 & Supp. 2019).

Summary: Bahuchar Mata, LLC (Individual/Entity) owns underground storage tanks (USTs) located in Greenwood, South Carolina. Based on an October 30, 2020 inspection, the Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Control Regulation as follows: failed to provide records upon request; failed to provide an adequate release detection method; failed to properly maintain release detection equipment; failed to conduct proper release detection using an automatic tank gauge; failed to maintain records for at least one (1) year; failed to report a suspected release; failed to determine if the underground storage tank is the source of off-site impacts; and failed to investigate and confirm a suspected release within a reasonable time.

Action: The Individual/Entity is required to: conduct a tank tightness test and submit a current passing ATG test for the 4000-gallon regular unleaded UST; install a groundwater sampling monitoring well between the 4000-gallon regular unleaded UST and the adjacent creek; and submit a groundwater sampling report by May 10, 2021. The Department assessed a civil penalty in the amount of seven thousand dollars ($7,000.00). The Individual/Entity is required to pay a civil penalty in the amount of seven thousand dollars **($7,000.00)** by May 10, 2021.

Updates: The Individual/Entity submitted tank tightness test results on February 22, 2021 indicating failing results. The groundwater sampling report was received March 29,

2021.

Solid Waste Enforcement

10) Order Type and Number: Administrative Order 21-01-SW
Order Date: March 8, 2021
Individual/Entity: **Robert Fred Small**
Facility: N/A
Location: 101 Eagle Court
Union, SC 29379
Mailing Address: 1818 Jonesville Highway
Union, SC 29379
County: Union
Previous Orders: None
Permit/ID Number: N/A
Violations Cited: Solid Waste Policy and Management Act of 1991, S.C. Code Ann. 44-96-10 et seq. (Rev. 2018 & Supp. 2019); Solid Waste Management: Solid Waste Landfills and Structural Fill Regulations, S.C. Code Ann., Regs 61-107.19, Part IV.A.3. and Part V Subpart A.258.1(c) (Supp. 2018)

Summary: Robert Fred Small (Individual/Entity), owns property in Union, South Carolina. Based on a complaint, inspections were conducted on September 10, 2020 and October 12, 2020. The Individual/Entity has violated the Solid Waste Policy and Management Act and the Solid Waste Management: Solid Waste Landfills and Structural Fill Regulations as follows: failed to obtain a permit to operate a Class II and Class III Solid Waste Landfill from the Department before disposing of solid waste on the property.

Action: The Individual/Entity is required to: remove and dispose of the solid waste on the property at a permitted solid waste management at facility and provide disposal receipts to the Department. The Department has assessed a total civil penalty in the amount of seven thousand, five hundred twenty-five dollars ($7,525.00). The Individual/Entity shall pay a civil penalty in the amount of seven thousand, five hundred twenty-five dollars **($7,525.00).**

Updates: The Individual/Entity did not file a Request for Review.

11) Order Type and Number: Consent Order 20-29-SW
Order Date: March 2, 2021
Individual/Entity: **City of Greer**
Facility: 115 Leesburg Peak, Property
Location: 115 Leesburg Peak
Greenville County, SC
Mailing Address: 301 East Poinsett Street
Greer, SC 29651
County: Greenville
Previous Orders: None
Permit/ID Number: N/A
Violations Cited: South Carolina Solid Waste Policy and Management Act of 1991, S.C. Code Ann. §§ 44-96-290(A) (2018 & Supp.

2018) (Act) and the Solid Waste Management: Solid Waste Landfills and Structural Fill Regulation, R.61-107.19, Part II.B.1. (2002 and Supp. 2016) (Regulation)

Summary: City of Greer (Individual/Entity), owns property located in Greenville, South Carolina. Based on a complaint, the Department conducted an inspection on June 5, 2020. The Individual/Entity has violated the South Carolina Solid Waste Policy and Management Act and Solid Waste Management: Solid Waste Landfills and Structural Fill Regulation, as follows: failed to obtain a Department issued permit prior to engaging in structural fill activities.

Action: The Individual/Entity is required to: cease receipt and/or transport of solid waste debris onto the Site; complete closure activities to include, applying a two-foot thick final earth cover with a three-to-one (3:1) slope and seeding the finished surface area with native grasses or other suitable cover; record with the Register of Deeds a notation in the record of ownership of the property that will, in perpetuity, notify any potential purchaser of the property that the land, or a portion thereof, has been filled with solid waste debris; remove all loose solid waste material not compacted during closure activities from the Site, dispose of it at a permitted solid waste management facility, and submit disposal receipts to the Department. The Individual/Entity shall complete closure activities and removal of all loose solid waste material by August 29, 2021. The Department assessed a total civil penalty in the amount of two thousand, one hundred dollars ($2,100.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand, one hundred dollars **($2,100.00)** by April 16, 2021.

Updates: The civil penalty has been paid. The established due date for resolutions of violations is August 21, 2021.

Mining Enforcement

12)

Order Type and Number:	Consent Order 21-04-MSWM
Order Date:	March 25, 2021
Individual/Entity:	**A&A Structural fill**
Facility:	A&A Mine
Location:	0.4 mile northwest of the junction of US Highway 378 (E. Myrtle Beach Highway) and SC Secondary Highway S-21-34 (S. Friendfield Road), and 0.4 mile west of the junction of S. Friendfield Road and SC Secondary Highway S-21-729 (Bass Road).
Mailing Address:	2002 Manderley Court Charleston, SC 29414
County:	Florence
Previous Orders:	None
Permit/ID Number:	I-002002
Violations Cited:	The South Carolina Mining Act, S.C. code Ann. § 48-20-10 et seq. (2008 & Supp. 2018); South Carolina Mining Regulation (2012) R.89-280; and the Permit I-002002 Section IX.1.

Summary: A&A Structural Fill (Individual/Entity) owns and operates A&A Mine

in Florence County, South Carolina. Based on records review, the Department issued a Notice of Alleged Violation. The Individual/Entity violated the South Carolina Mining Act, the Mining Regulations, and the Permit, as follows: failed to submit the mining annual report and mining annual operating fees.

Action: The Individual/Entity is required to: submit the mining annual report; and pay mining annual operating fees and associated late fees in the amount of five hundred twenty-five dollars ($525.00) by May 9, 2021. 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)** by May 24, 2021.

Updates: The Individual/Entity paid annual operating fees and associated late fees on March 11, 2021. The civil penalty has been paid in full and the enforcement case closed.

13)

Order Type and Number:	Consent Order 21-06-MSWM
Order Date:	March 25, 2021
Individual/Entity:	**P Mining Co., Inc.**
Facilities:	Dewitt Mine/Coates Mine
Locations:	Off Half Pine Road/Off Pint Circle Longs, SC
Mailing Address:	1300 Highway 57 S Little River, SC 29566
County:	Horry
Previous Orders:	None
Permit/ID Number:	GP1-001952/GP1-001982
Violations Cited:	The South Carolina Mining Act (Act) S.C. Code Ann., § 48-20-10 et seq. (2008 and 2018); and South Carolina Mining Regulations, 9 S.C. Code Ann., Regs. Sections 89.10 (2012), R.89.340(B); R-89.280; R.89. 210; R.89.80; and Permit GP1-001952, Section IX.1.

Summary: P Mining Co., Inc. (Individual/Entity) owns the Dewitt Mine and Coates Mine located in Horry County, South Carolina. Based on a file review, the Department issued a Notice of Alleged Violation. The Individual/Entity has violated the ACT, the South Carolina Mining Regulations, and the Permits as follows: failed to pay Annual Operating Fees for FY21 and failed to submit the Annual Reclamation Report for FY21.

Action: The Individual/Entity is required to pay Annual Operating Fees and associated late fees for FY21 and submit the Annual Reclamation Report. The Department assessed a 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)**.

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

BUREAU OF WATER

Recreational Waters Enforcement

14) Order Type and Number: Consent Order 21-009-RW
Order Date: March 4, 2021
Individual/Entity: **Summer Knoll/Spring Knoll Homeowners Association, Inc.**
Facility: Summer Knoll
Location: 113 Arkhaven Court, Lexington, SC 29073
Mailing Address: P.O. Box 26844, Charlotte, SC 28221
County: Lexington
Previous Orders: None
Permit/ID Number: 32-1034C
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Summer Knoll/Spring Knoll Homeowners Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a kiddie pool located in Lexington County, South Carolina. The Department conducted inspections on June 19, 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 chlorine and pH levels were not within the acceptable range of water quality standards; the emergency notification device was not operational; the "No Lifeguard On Duty – Swim At Your Own Risk" signs did not have the correct wording; 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 March 24, 2021.

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

15) Order Type and Number: Consent Order 21-010-RW
Order Date: March 9, 2021
Individual/Entity: **DR Horton, Inc.**
Facility: Cobblestone Park Amenity Center
Location: 297 Links Crossing Drive, Blythewood, SC 29016
Mailing Address: 1298 University Parkway, Blythewood, SC 29016
County: Richland
Previous Orders: None
Permit/ID Number: 40-1079C
Violations Cited: S.C. Code Ann. Regs. 61-51.J.22

Summary: DR Horton, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a kiddie pool located in Richland County, South Carolina. The Department issued a Notice of Enforcement Conference on December 4, 2020, as a result of a review of inspection records. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: failed to fill in or remove the kiddie pool, which has been permanently closed for a period in excess of twenty-four consecutive months.

Action: The Individual/Entity is required to: submit to the Department for review and approval, a plan detailing the procedure and materials to be used to properly fill in or remove the kiddie pool by March 24, 2021; and complete the procedure in accordance with the plan and contact the Department to schedule an inspection to verify the completed work by June 22, 2021. The Department has assessed a total civil penalty in the amount of four hundred dollars ($400.00). The Individual/Entity shall pay a **stipulated penalty** in the amount of four hundred dollars **($400.00)** should any requirement of the Order not be met.

Updates: The Individual/Entity has submitted a plan and the plan has been approved.

16)

Order Type and Number:	Consent Order 21-011-RW
Order Date:	March 9, 2021
Individual/Entity:	PWRE2 Kay Street Apartments, LLC
Facility:	Colony East Apartments
Location:	3430 Kay Street Columbia, SC 29210
Mailing Address:	Same
County:	Richland
Previous Orders:	None
Permit/ID Number:	40-064-1
Violations Cited:	S.C. Code Ann. Regs. 61-51.J.22

Summary: PWRE2 Kay Street Apartments, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Richland County, South Carolina. The Department issued a Notice of Enforcement Conference on December 3, 2020, as a result of a review of inspection records. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: failed to fill in or remove the pool, which has been permanently closed for a period in excess of twenty-four consecutive months.

Action: The Individual/Entity is required to: correct all deficiencies and any upgrades required to bring the pool into compliance with Regulation 61-51 and contact the Department to schedule an inspection to verify the completed work by September 6, 2021. The Individual/Entity will be required to properly fill in or remove the pool by January 3, 2022, if the requirement to bring the pool into compliance with Regulation 61-51 is not met within the specified timeline. The Department has assessed a total civil penalty in the amount of four hundred dollars ($400.00). The Individual/Entity shall pay a **stipulated penalty** in the amount of four hundred dollars **($400.00)** should any requirement of the Order not be met.

Updates: On November 19, 2020, Department staff conducted a technical assistance inspection of the pool with the Individual/Entity to provide an inspection checklist of the deficiencies and required upgrades.

17) Order Type and Number: Consent Order 21-012-RW
Order Date: March 22, 2021
Individual/Entity: **NBVM-2, LLC**
Facility: Holiday Inn Express Greenville Airport
Location: 2681 Dry Pocket Road
Greer, SC 29650
Mailing Address: Same
County: Greenville
Previous Orders: None
Permit/ID Number: 23-469-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: NBVM-2, LLC (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 24, 2020, August 7, 2020, and December 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 no drinking water fountain; the chlorine and pH levels were not within the acceptable range of water quality standards; the log book was not properly bound and numbered and was not maintained on a daily basis; the cyanuric acid level was above the water quality standards acceptable limit; and the plaster on the pool floor was deteriorated.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of one thousand, six hundred eighty dollars ($1,680.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand, six hundred eighty dollars (**$1,680.00**) in three installments. Payments are due April 1, 2021, May 1, 2021, and June 1, 2021.

Updates: The first and second installments have been received.

Drinking Water Enforcement

18) Order Type and Number: Consent Order 21-008-DW
Order Date: March 10, 2021
Individual/Entity: **Gilbert Summit Rural Water District**
Facility: Gilbert Summit Rural Water District
Location: 136 Hampton Street
Gilbert, SC 29054
Mailing Address: P.O. Box 172
Gilbert, SC 29054
County: Lexington
Previous Orders: None
Permit/ID Number: 3220001
Violations Cited: S.C. Code Ann. Regs. 61-58.5.H(2)

Summary: Gilbert Summit Rural Water District (Individual/Entity) owns and is responsible for the proper operation and maintenance of a public water system (PWS) located in Lexington County, South Carolina. On December 21, 2020, a violation was issued as a result of review of monitoring records. The Individual/Entity has violated the State Primary Drinking Water Regulation as follows: the PWS exceeded the maximum contaminant level (MCL) for combined radium 226/228.

Action: The Individual/Entity is required to: submit a corrective action plan with a schedule to address the MCL violation by April 9, 2021. The Department has assessed a total civil penalty in the amount of four thousand dollars ($4,000.00). The Individual/Entity shall pay a **stipulated penalty** in the amount of four thousand dollars (**$4,000.00**) should any requirement of the Order not be met.

Updates: The Individual/Entity submitted a corrective action plan and the plan was approved.

19)

Order Type and Number:	Consent Order 21-009-DW
Order Date:	March 10, 2021
Individual/Entity:	**Fishing Line Enterprises, LLC**
Facility:	Fishing Line Enterprises
Location:	8 Whittle Lane Bluffton, SC 29910
Mailing Address:	27 Timber Lane Hilton Head, SC
County:	Beaufort
Previous Orders:	None
Permit/ID Number:	0760065
Violations Cited:	S.C. Code Ann. Regs. 61-58.7 & 61-58.8.B

Summary: Fishing Line Enterprises, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a public water system (PWS) located in Beaufort County, South Carolina. The Department conducted an inspection of the PWS on December 3, 2020, and it was rated unsatisfactory for failure to properly operate and maintain, and failure to provide an emergency preparedness plan. The Individual/Entity has violated the State Primary Drinking Water Regulation as follows: an emergency preparedness plan was not provided for Department review; a complete procedures manual with written programs and logs was not provided for Department review; there was dirt and debris covering the well pad; the sanitary seal was rusted; the wellhead piping did not have a screened vent; the pressure gauge was not working; the well did not have a wellhouse; and the sample tap was not functional.

Action: The Individual/Entity is required to: correct the deficiencies and submit to the Department for review and approval a complete procedures manual and an emergency preparedness plan by July 1, 2021. The Department has assessed a total civil penalty in the amount of eight thousand dollars ($8,000.00). The Individual/Entity shall pay a **stipulated penalty** in the amount of eight thousand dollars (**$8,000.00**) should any requirement of the Order not be met.

Updates: None

20) Order Type and Number: Consent Order 21-010-DW
Order Date: March 10, 2021
Individual/Entity: **McCormick Commission of Public Works**
Facility: McCormick CPW
Location: 912 South Main Street
McCormick, SC 29835
Mailing Address: Same
County: McCormick
Previous Orders: None
Permit/ID Number: 3510001
Violations Cited: S.C. Code Ann. Regs. 61-58.10.I(6)(b)(ii) & 61-58.6.E(3)(b)(iii)

Summary: McCormick Commission of Public Works (Individual/Entity) is responsible for the proper operation and maintenance of a public water system (PWS) located in McCormick County, South Carolina. On January 21, 2021, violations were issued as a result of review of monitoring and reporting records. The Individual/Entity has violated the State Primary Drinking Water Regulation as follows: the PWS exceeded the maximum contaminant level (MCL) for turbidity and the Individual/Entity failed to consult with the Department no later than twenty-four hours after it learned of the turbidity exceedance.

Action: The Individual/Entity is required to: submit a corrective action plan with a schedule to address the turbidity violation and a standard operating procedure to ensure compliance with notification requirements by April 10, 2021. The Department has assessed a total civil penalty in the amount of eight thousand dollars ($8,000.00). The Individual/Entity shall pay a civil penalty in the amount of eight thousand dollars **($8,000.00)** by April 10, 2021.

Updates: The civil penalty has been paid. The Individual/Entity submitted a corrective action plan and a standard operating procedure which were approved by the Department.

21) Order Type and Number: Consent Order 21-011-DW
Order Date: March 12, 2021
Individual/Entity: **Cendy Blackwell, Individually and d.b.a. Cendy's Café and Grocery**
Facility: Cendy's Café and Grocery
Location: 3267 Highway 11
Cleveland, SC 29635
Mailing Address: Same
County: Pickens
Previous Orders: None
Permit/ID Number: 3972000
Violations Cited: S.C. Code Ann. Regs. 61-58.7 & 61-58.8.B

Summary: Cendy Blackwell, Individually and d.b.a. Cendy's Café and Grocery (Individual/Entity) owns and is responsible for the proper operation and maintenance of a public water system (PWS) located in Pickens County, South Carolina. The Department conducted an inspection of the PWS on December 17, 2020, and it was rated unsatisfactory for failure to properly operate and maintain, and failure to provide an up-to-date emergency

preparedness plan. The Individual/Entity has violated the State Primary Drinking Water Regulation as follows: an up-to-date emergency preparedness plan was not provided for Department review; a complete procedures manual with written programs and logs was not provided for Department review; the current storage capacity was not the originally permitted amount; the sanitary seal was not flush to the casing; the casing vent did not meet regulatory standards; the well house door was not attached to its hinges; the sample tap for the wellhead piping was threaded; the water source did not have a sample tap; the electrical control box was on the ground; and the pressure switch box was not closed and the wires were exposed.

Action: The Individual/Entity is required to: correct the deficiencies and submit to the Department for review and approval a complete procedures manual and an up-to-date emergency preparedness plan by May 31, 2021. The Department has assessed a total civil penalty in the amount of seven thousand dollars ($7,000.00). The Individual/Entity shall pay a **stipulated penalty** in the amount of seven thousand dollars **($7,000.00)** should any requirement of the Order not be met.

Updates: None

22)

Order Type and Number:	Consent Order 21-012-DW
Order Date:	March 25, 2021
Individual/Entity:	**Jimalee Hanna Schmidt, Individually and d.b.a. Regency Square 2 MHP**
Facility:	Regency Square 2 MHP
Location:	5150 Platt Springs Road Lexington, SC 29073
Mailing Address:	755A Woodberry Road Lexington, SC 29073
County:	Lexington
Previous Orders:	None
Permit/ID Number:	3260170
Violations Cited:	S.C. Code Ann. Regs. 61-58.11.H(4)(d)(vi)(A); 61-58.11.G; & 61-58.11.C(5)(a)

Summary: Jimalee Hanna Schmidt, Individually and d.b.a. Regency Square 2 Mobile Home Park (Individual/Entity) owns and is responsible for the proper operation and maintenance of a public water system (PWS) located in Lexington County, South Carolina. On August 4, 2020, January 27, 2021, and February 1, 2021, violations were issued as a result of review of monitoring and reporting records. The Individual/Entity has violated the State Primary Drinking Water Regulation as follows: failed to conduct standard six month monitoring for lead and copper; failed to issue Public Education (PE) Information to its customers; and failed to submit to the Department an Optimal Corrosion Control Treatment (OCCT) Recommendation.

Action: The Individual/Entity is required to: continue standard six month monitoring for lead and copper; issue PE Information to its customers and submit a PE certification form to the Department by April 15, 2021; and submit an OCCT Recommendation and schedule to the Department for review and approval by May 15, 2021. The Department has assessed a total civil penalty in the amount of twelve thousand dollars ($12,000.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand dollars (**$2,000.00**) in four installments and pay a stipulated penalty in the amount

of ten thousand dollars ($10,000.00) should any requirement of the Order not be met. The four installments are due May 1, 2021, June 1, 2021, July 1, 2021, and August 1, 2021.

Updates: The Individual/Entity has resumed standard six-month monitoring, issued PE Information to its customers, and submitted a PE certification form to the Department. The first installment of the penalty payment has been received.

Water Pollution Enforcement

23) Order Type and Number: Consent Order 21-009-W
Order Date: March 2, 2021
Individual/Entity: **W/C GSP Lot 3 Owner VIII LLC**
Facility: Lister Road Borrow Mine
Location: 0 Lister Road
Greer, SC 29651
Mailing Address: 200 W Madison Street
Chicago, IL 60606
County: Spartanburg
Previous Orders: None
Permit/ID Number: SCG730767
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) (2011), and NPDES Permit SCG730767

Summary: W/C GSP Lot 3 Owner VIII LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a wastewater treatment facility in Spartanburg County, South Carolina. On November 30, 2020, a Notice of Alleged Violation was issued as a result of total suspended solids violations reported on discharge monitoring reports submitted to the Department. The Individual/Entity has violated the Pollution Control Act and Water Pollution Control Permits Regulations as follows: failed to comply with the Total Suspended Solids effluent limitations of its National Pollutant Discharge Elimination System (NPDES) permit.

Action: The Individual/Entity is required to: submit written notification of the completion date for all corrective actions necessary to resolve the violations by April 1, 2021; conduct a six (6) monitoring event compliance confirmation period upon completion of corrective actions; and, implement engineered upgrades to best management practices as determined by an engineering study should additional violations be observed during the compliance confirmation period. 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)** by April 1, 2021.

Updates: The Individual/Entity has submitted the corrective action completion notification and has paid the civil penalty.

24) Order Type and Number: Consent Order 21-010-W
Order Date: March 2, 2021
Individual/Entity: **City of Clemson**

Facility: Cochran Road WWTF
Location: Cochran Road
Clemson, SC 29631
Mailing Address: 300 Cochran Road
Clemson, SC 29631
County: Pickens
Previous Orders: 16-012-W ($1,700.00)
Permit/ID Number: NPDES Permit SC0020010
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: The City of Clemson (Individual/Entity) owns and is responsible for the proper operation and maintenance of a wastewater treatment facility located in Pickens County, South Carolina. On September 14, 2020, a Notice of Alleged Violation was issued as a result of biochemical oxygen demand (BOD) violations reported on discharge monitoring reports submitted to the Department. The Individual/Entity has violated the Pollution Control Act and Water Pollution Control Permits Regulation as follows: failed to comply with the effluent discharge limits of its National Pollutant Discharge Elimination System permit for BOD.

Action: The Individual/Entity is required to: submit a written notification of the completion date for all corrective actions necessary to resolve the violations by April 2, 2021; conduct a six (6) monitoring event compliance confirmation period upon completion of corrective actions; and, implement engineered upgrades to the WWTF should additional violations be observed during the compliance confirmation period. The Department has assessed a total civil penalty in the amount of two thousand, one hundred dollars ($2,100.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand, one hundred dollars **($2,100.00)** by April 2, 2021.

Updates: The Individual/Entity submitted a corrective action completion notification and has paid the civil penalty.

25) Order Type and Number: Consent Order 21-011-W
Order Date: March 19, 2021
Individual/Entity: **Thomas Nolan**
Facility: Nolan Services Incorporated
Location: 1674 Manville Wisacky Road
Bishopville, SC 29010
Mailing Address: Same
County: Lee
Previous Orders: None
Permit/ID Number: SCG160037
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), and NPDES Permit SCG160037

Summary: Thomas Nolan (Individual/Entity) owns and operates a pesticide application company in Lee County, South Carolina. On January 14, 2021, a Notice of Violation was issued for failure to reapply for permit coverage within one hundred eighty (180) days before the existing permit expires. The Individual/Entity has violated the

Pollution Control Act and Water Pollution Control Permits Regulations as follows: failed to submit an application for renewal of the National Pollutant Discharge Elimination System (NPDES) permit at least one hundred eighty (180) days before the existing permit expires.

Action: The Individual/Entity is required to: submit an administratively complete application for renewal of its NPDES permit by April 9, 2021 and continue operating the pesticide application company in accordance with the most recent NPDES permit until a new permit becomes effective. 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)** by April 19, 2021.

Updates: The Individual/Entity has submitted an administratively complete application for renewal of their permit and has paid the civil penalty.

26) Order Type and Number: Consent Order 21-012-W
Order Date: March 19, 2021
Individual/Entity: **Anita Inc.**
Facility: Budget Inn WWTF
Location: 5505 Highway 187
Anderson, SC 29625
Mailing Address: Same
County: Anderson
Previous Orders: None
Permit/ID Number: NPDES Permit SC0023311
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 (e) (2011).

Summary: Anita Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a wastewater treatment facility (WWTF) located in Pickens County, South Carolina. On January 31, 2020, a Notice of Violation was issued as a result of ammonia-nitrogen (ammonia), Escherichia coli (E.coli), total copper (copper) and chronic whole toxicity (CTOX) violations as reported on discharge monitoring reports submitted to the Department, and for failing to properly operate and maintain the WWTF in accordance with its National Pollutant Discharge Elimination System permit. The Individual/Entity has violated the Pollution Control Act and Water Pollution Control Permits Regulation as follows: failed to comply with the effluent discharge limits of its National Pollutant Discharge Elimination System permit for ammonia, E.coli, copper, CTOX, and failed to properly operate and maintain the WWTF.

Action: The Individual/Entity is required to: submit a written notification of the completion date for all corrective actions necessary to resolve the violations by April 19, 2021; conduct a six (6) monitoring event compliance confirmation period upon completion of corrective actions; and, implement engineered upgrades to the WWTF should additional violations be observed during the compliance confirmation period. The Department has assessed a total civil penalty in the amount of twenty thousand dollars ($20,000.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand dollars **($2,000.00)** by April 19, 2021, and a suspended penalty in the amount of eighteen thousand dollars ($18,000.00) if any requirement of the Order is not met.

Updates: The Individual/Entity has submitted the corrective action completion notification and has paid the civil penalty.

27) Order Type and Number: Consent Order 21-013-W
Order Date: March 19, 2021
Individual/Entity: **Orangeburg County**
Facility: Goodbys Creek WWTF
Location: 1 mile south of U.S. Hwy 301 and U.S. Highway 176 in Santee, SC
Mailing Address: P.O. Drawer 9000
Orangeburg, SC 29116
County: Orangeburg
Previous Orders: 20-031-W ($1,000.00)
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. 61-9.122.41 (a) (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 October 15, 2020, a Notice of Violation was issued as a result of ammonia-nitrogen (ammonia) violations reported on discharge monitoring reports submitted to the Department. The Individual/Entity has violated the Pollution Control Act and Water Pollution Control Permits Regulation as follows: failed to comply with the effluent discharge limits of its National Pollutant Discharge Elimination System permit for ammonia.

Action: The Individual/Entity is required to: submit written notification of the completion date for all corrective actions necessary to resolve the violations by April 19, 2021; conduct a six (6) monitoring event compliance confirmation period upon completion of corrective actions; and, implement engineered upgrades to the WWTF should additional violations be observed during the compliance confirmation period. The Department has assessed a total civil penalty in the amount of six thousand dollars ($6,000.00). The Individual/Entity shall pay a civil penalty in the amount of six thousand dollars **($6,000.00)** by April 19, 2021.

Updates: The Individual/Entity has paid the civil penalty. The Department has not received the written corrective action notification and has contacted the Individual/Entity regarding the past due submittal.

28) Order Type and Number: Consent Order 21-016-W
Order Date: March 30, 2021
Individual/Entity: **Ms. Shirley Cox Scott**
Facility: Cox Farms
Location: 452 High Hill Road
Dillon, SC
Mailing Address: P.O. Box 1242
Lake View, SC 29563
County: Dillon
Previous Orders: None

Permit/ID Number: N/A
Violations Cited: South Carolina Standards for the Permitting of Agricultural Animal Facilities, S.C. Code Ann. Regs. 61-43.200.130 (2) (2011)

Summary: Ms. Shirley Cox Scott (Individual/Entity) owns and is responsible for the proper operation and maintenance of an agricultural animal facility in Dillon County, South Carolina. On September 28, 2020 a Notice of Alleged Violation was issued for failure to cover a stockpile of manure for more than three (3) days. The Individual/Entity has violated the South Carolina Standards for the Permitting of Agricultural Animal Facilities as follows: stockpiled uncovered manure, not on a concrete or other approved pad, for more than three (3) days.

Action: The Individual/Entity is required to: ensure that any manure stockpiled at the agricultural animal facility is either properly covered, properly removed from the property, or, properly land applied by a permitted by April 9, 2021. The Department has assessed a total civil penalty in the amount of two thousand eight hundred and ninety dollars ($2,890.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand eight hundred and ninety dollars **($2,890.00)** by April 19, 2021.

Updates: The Individual/Entity has submitted documentation demonstrating the uncovered manure is no longer stockpiled at the property and has paid the civil penalty.

29) Order Type and Number: Consent Order 21-017-W
Order Date: March 30, 2021
Individual/Entity: **City of Rock Hill/Manchester Creek WWTF**
Facility: City of Rock Hill
Location: 310 Red River Road
Mailing Address: P.O. Box 11706
Rock Hill, SC 29731
County: York
Previous Orders: None
Permit/ID Number: SC0020443
Violations Cited: Pollution Control Act, S.C. Code Ann. § 48-1-110 (d) (2008 & Supp. 2019) and Water Pollution Control Permits Regulation, S.C. Code Ann Regs. 61-9.122.41(a) (2011), and NPDES SC0020443

Summary: The City of Rock Hill (Individual/Entity) owns and is responsible for the proper operation and maintenance of a wastewater treatment facility (WWTF) located in York County, South Carolina. On August 27, 2020, a Notice of Violation was issued as a result of Escherichia coli (E. coli) violations reported on discharge monitoring reports submitted to the Department. The Individual/Entity has violated the Pollution Control Act and Water Pollution Control Permits Regulation as follows: failed to comply with the effluent limitations for E. coli as contained in its National Pollutant Discharge Elimination System permit.

Action: The Individual/Entity is required to: submit written notification of the completion date for all corrective actions necessary to resolve the violations by April 30, 2021; conduct a six (6) monitoring event compliance confirmation period upon completion of corrective actions; and, implement engineered upgrades to the WWTF should additional violations be observed during the compliance confirmation period. The Department has

assessed a total civil penalty in the amount of three thousand three hundred and sixty dollars ($3,360.00). The Individual/Entity shall pay a civil penalty in the amount of three thousand three hundred and sixty dollars **($3,360.00)** by April 30, 2021.

Updates: The Individual/Entity has submitted the corrective action completion notification and has paid the civil penalty.

Dams Safety Enforcement

30) Order Type and Number: Administrative Order 21-014-W
Order Date: March 25, 2021
Individual/Entity: **Edith Joann Ackerman**
Facility: McGrady Dam
Location: Off of Cane Branch Road in Walterboro, SC
Mailing Address: 18 Edward Road Walterboro, SC 29488
County: Colleton
Previous Orders: Consent Agreement 17-076-W and Emergency Order dated October 14, 2016
Permit/ID Number: D 4934
Violations Cited: SC Dams and Reservoirs Safety Act, S.C. Code Ann. § 49-11-110, *et seq*., (2008) and Dams and Reservoirs Safety Act Regulation 72.1, *et seq*. (2012)

Summary: Edith Joann Ackerman (Individual/Entity) owns and is responsible for the proper operation and maintenance of a dam in Colleton County, South Carolina. A Notice of Violation was issued April 5, 2018, for failure to comply with the terms and conditions of Consent Agreement 17-076-W. The Department conducted a preliminary inspection on February 11, 2020, and issued a letter summarizing the findings on April 6, 2020. The letter was unclaimed by the Individual/Entity. The Individual/Entity has violated the SC Dams and Reservoirs Safety Act and the SC Dams and Reservoirs Safety Act Regulation as follows: failed to properly maintain the dam; failed to evaluate the structural safety and hydraulic capacity of the dam; failed to maintain a safe water level; and failed to submit a tree management plan.

Action: The Individual/Entity is required to: submit confirmation to the Department that an engineer has been retained to evaluate the Dam's structural safety and hydraulic capacity by May 25, 2021; maintain a safe water level until a Certificate of Completion has been issued by the Department; submit confirmation to the Department that large trees have been evaluated by an engineer by July 25, 2021; submit to the Department a permit application for the repair or removal of the Dam by August 25, 2021; within one (1) year from receiving a permit issued by the Department for the repair or removal of the Dam, complete all construction activities related to the repair or removal; and, request a final inspection by the Department within ten (10) days from completing all activities related to repair or removal of the Dam.

Updates: None

BUREAU OF AIR QUALITY

31) Order Type and Number: Consent Order 21-004-A
Order Date: March 22, 2021
Individual/Entity: **Kimura, Inc.**
Facility: Kimura, Inc.
Location: 102 Cherry Blossom Drive
Laurens, SC 29360
Mailing Address: Same
County: Greenwood
Previous Orders: None
Permit/ID Number: 1520-0096
Violations Cited: S.C. Code Ann. Regs. 61-62.1, Section II, Permit Requirements

Summary: Kimura, Inc. (Individual/Entity), manufactures steel pallets and containers at its facility located in Laurens County, South Carolina. The Department conducted an inspection on July 27, 2020 and issued a Notice of Violation on December 2, 2020. The Individual/Entity has violated South Carolina Air Pollution Control Regulation, as follows: failed to implement an inspection and replacement schedule for fabric filters associated with wet paint spray booth; failed to maintain documentation of maintenance checks performed on the afterburner and water spray system; failed to maintain an on-site implementation log; and, failed to conduct an annual facility equipment review.

Action: The Individual/Entity is required to: comply with all terms and conditions their permit. The Department has assessed a total civil penalty in the amount of four thousand dollars ($4,000.00). The Individual/Entity shall pay a civil penalty in the amount of four thousand dollars **($4,000.00)** by April 22, 2021.

Updates: The Individual/Entity has paid the assessed civil penalty.

BUREAU OF ENVIRONMENTAL HEALTH SERVICES

Food Safety Enforcement

32) Order Type and Number: Consent Order 2021-206-03-001
Order Date: March 1, 2021
Individual/Entity: **Mary Ann Keim and MAK's Meals, LLC**
Facility: Mary Ann Keim and MAK's Meals, LLC
Location: 429 South Main Street
Prosperity, SC 29127
Mailing Address: Same
County: Richland
Previous Orders: None

Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Mary Ann Keim and MAK's Meals, LLC (Individual/Entity) is a caterer located in Richland County, South Carolina. The Department issued warning letters on February 19, 2020, and October 27, 2020. The Department conducted an investigation on February 5, 2021. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: served food for public consumption without a Department issued Retail Food Establishment Permit.

Action: The Individual/Entity is required to cease all food service operations until a Retail Food Establishment Permit is obtained through 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)**.

Updates: The Individual/Entity has entered a payment plan with the Department. Department staff have received payments in accordance with the payment plan.

33) Order Type and Number: Consent Order 2021-206-04-001
Order Date: March 29, 2021
Individual/Entity: **Subway #8730**
Facility: Subway #8730
Location: 3745 Greeleyville Highway
Manning, SC 29102
Mailing Address: P.O. Box 728
Savannah, GA 31402
County: Clarendon
Previous Orders: None
Permit Number: 14-206-00612
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Subway #8730 (Individual/Entity) is a restaurant located in Clarendon County, South Carolina. The Department conducted inspections on October 1, 2020, January 15, 2021, January 25, 2021, February 4, 2021, and February 12, 2021. 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 Individual/Entity corrected all violations prior to the issuance of the Order. The Department has assessed a total civil penalty in the amount of one thousand, two hundred dollars ($1,200.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand, two hundred dollars **($1,200.00)** by March 29, 2021.

Updates: The Individual/Entity has met all requirements of the Order. This Order has been closed.

On Site Wastewater Enforcement

34) Order Type and Number: Administrative Order 21-013-OSWW
Order Date: March 2, 2021
Individual/Entity: **Katydid Properties, LLC**
Facility: Katydid Properties, LLC
Location: 345 Shelton Road
Travelers Rest, SC 29690
Mailing Address: P.O. Box 2001
Easley, SC 29641
County: Greenville
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: Katydid Properties, LLC (Individual/Entity) owns property located in Greenville County, South Carolina. The Department conducted an investigation on January 21, 2021, 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.

Updates: The Individual/Entity has met all requirements of the Order. This Order has been closed.

35) Order Type and Number: Administrative Order 21-012-OSWW
Order Date: March 8, 2021
Individual/Entity: **James J. Cravens, Jr. and Jo Beth Cravens**
Facility: James J. Cravens, Jr. and Jo Beth Cravens
Location: 305 Chafford Court
Simpsonville, SC 29681
Mailing Address: Same
County: Greenville
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: James J. Cravens, Jr. and Jo Beth Cravens (Individual/Entity) owns property located in Greenville County, South Carolina. The Department conducted an investigation on January 29, 2021, 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.

Updates: A contractor has been retained and is awaiting results from the soil classifier before repairs can be conducted.

36)	Order Type and Number:	Administrative Order 21-014-OSWW
	Order Date:	March 8, 2021
	Individual/Entity:	**Joyce Morrow and Troy Morrow**
	Facility:	Joyce Morrow and Troy Morrow
	Location:	240 Crooked Creek Road Seneca, SC 29672
	Mailing Address:	Same
	County:	Oconee
	Previous Orders:	None
	Permit Number:	None
	Violations Cited:	S.C. Code Ann. Regs. 61-56

Summary: Joyce Morrow and Troy Morrow (Individual/Entity) own property located in Oconee County, South Carolina. The Department conducted an investigation on January 27, 2021, 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.

Updates: The Individual/Entity has met all requirements of the Order. This Order has been closed.

37)	Order Type and Number:	Administrative Order 21-016-OSWW
	Order Date:	March 8, 2021
	Individual/Entity:	**Chassidy Morales**

Facility:	Chassidy Morales
Location:	3546 H. I. Taylor Road Williamston, SC 29697
Mailing Address:	120 Hadden Avenue Duncan, SC 29334
County:	Anderson
Previous Orders:	None
Permit Number:	None
Violations Cited:	S.C. Code Ann. Regs. 61-56

Summary: Chassidy Morales (Individual/Entity) owns property located in Anderson County, South Carolina. The Department conducted an investigation on January 27, 2021, 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.

Updates: Requested regional personnel revisit.

38)

Order Type and Number:	Administrative Order 20-015-OSWW
Order Date:	March 12, 2021
Individual/Entity:	**Callie Rae Scurry**
Facility:	Scurry Mobile Home Park
Location:	1428 Newberry Highway Saluda, SC 29138
Mailing Address:	Same
County:	Saluda
Previous Orders:	None
Permit Number:	None
Violations Cited:	S.C. Code Ann. Regs. 61-56

Summary: Callie Rae Scurry (Individual/Entity) owns property located in Saluda County, South Carolina. The Department conducted an investigation on December 7, 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 systems 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.

Updates:

39) Order Type and Number: Administrative Order 20-017-OSWW
Order Date: March 25, 2021
Individual/Entity: **Dorniece Butler**
Facility: Dorniece Butler
Location: 132 Butler Corner Lane
Ridgeville, SC 29472
Mailing Address: 101 Brailsford Road
Summerville, SC 29485
County: Berkeley
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: Dorniece Butler (Individual/Entity) owns property located in Berkeley County, South Carolina. The Department conducted an investigation on February 21, 2021, 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.

Updates: Department personnel will revisit the site in the next two weeks to ensure the new repairs are appropriately working and the discharge of domestic wastewater to the surface of the ground has ceased.

40) Order Type and Number: Administrative Order 20-19-OSWW
Order Date: March 25, 2021
Individual/Entity: **Leng Keovongxay and Soy Keovongxay**
Facility: Leng Keovongxay and Soy Keovongxay
Location: 880 Beverly Drive
Spartanburg, SC 29303
Mailing Address: Same
County: Spartanburg
Previous Orders: None
Permit Number: None

Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: Leng Keovongxay and Soy Keovongxay (Individual/Entity) owns property located in Spartanburg County, South Carolina. The Department conducted an investigation on January 19, 2021, 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.

Updates: None.

41) Order Type and Number: Administrative Order 20-021-OSWW
Order Date: March 25, 2021
Individual/Entity: **SFR3-005, LLC**
Facility: SFR3-005, LLC
Location: 315 Jacquline Lane
Greenville, SC 29607
Mailing Address: 500 Westover Drive #14104
Sanford, NC 27330
228 Park Avenue South, Suite 73833
New York, NY 10003-1502
County: Greenville
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: SFR3-005, LLC (Individual/Entity) owns property located in Greenville County, South Carolina. The Department conducted an investigation on February 1, 2021, 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.

Updates: Invoice for connecting the Site to the public sewer has been provided. Waiting on the final approval for connection from the public sewer provider. Regional verification has been requested.

42) Order Type and Number: Administrative Order 20-022-OSWW
Order Date: March 25, 2021
Individual/Entity: **HASE Investments, Inc.**
Facility: HASE Investments, Inc.
Location: 29 Camelia Circle
Williamston, SC 29697
Mailing Address: Same
County: Anderson
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: HASE Investments, Inc. (Individual/Entity) owns property located in Anderson County, South Carolina. The Department conducted an investigation on February 12, 2021, 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.

Updates: None.

43) Order Type and Number: Administrative Order 21-020-OSWW
Order Date: March 31, 2021
Individual/Entity: **Beverly Oswald**
Facility: Beverly Oswald
Location: 133 Barnwell Court
Lexington, SC 29073
Mailing Address: 137 Barnwell Court
Lexington, SC 29073
County: Lexington
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: Beverly Oswald (Individual/Entity) owns property located in Lexington County, South Carolina. The Department conducted an investigation on February 23, 2021, 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.

Updates: None

44)

Order Type and Number:	Consent Order 21-006-OSWW
Order Date:	March 19, 2021
Individual/Entity:	**Orlando Santiago Gonzalez**
Facility:	La Roca Enterprises
Location:	10751 Ola Drive Indian Land, SC 29715
Mailing Address:	4412 Brittmore Court Charlotte, NC 28227
County:	Lancaster
Previous Orders:	None
Permit Number:	None
Violations Cited:	S.C. Code Ann. Regs. 61-56

Summary: Orlando Santiago Gonzalez, doing business as La Roca Enterprises, (Individual/Entity) attempted to make repairs to the OSWW system at property located in Lancaster County, South Carolina. The Department conducted an investigation on January 6, 2021 and determined that the Individual/Entity does not hold a Department issued license to construct and repair OSWW systems. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: they have engaged in the business of constructing and repairing onsite sewage treatment systems without first applying for, receiving, and subsequently maintaining a valid license to conduct such activities, as required by the Department.

Action: The Individual/Entity is required to cease and desist engaging in the business of constructing and repairing onsite sewage treatment systems without first applying for, receiving, and subsequently maintaining a valid license to conduct such activities, as required by the Department. The Department has assessed a total civil penalty in the amount of one thousand, five hundred dollars ($1,500.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand, five hundred dollars **($1,500.00)**.

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

* 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

May 13, 2021

(X) ACTION/DECISION
( ) INFORMATION

I. TITLE: Request for Removal of Samidorphan from Schedule II for Controlled Substances in South Carolina

II. SUBJECT: Removal of Samidorphan from Schedule II for Controlled Substances

III. 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 Acting Administrator of the Drug Enforcement Administration ("DEA") issued a final rule to remove samidorphan (3-carboxamido-4-hydroxy naltrexone) and its salts from the schedules of the Controlled Substances Act ("CSA"). This scheduling action is pursuant to the Controlled Substances Act which requires that such actions be made on the record after opportunity for a hearing through formal rulemaking. Prior to the effective date of this rule, samidorphan was a schedule II controlled substance because it can be derived from opium alkaloids. This action removes the regulatory controls and administrative, civil, and criminal sanctions applicable to controlled substances, including those specific to schedule II controlled substances, on persons who handle (manufacture, distribute, reverse distribute, dispense, conduct research, import, export, or conduct chemical analysis) or propose to handle samidorphan. This final rule became

effective April 19, 2021, *Federal Register*, Volume 86, Number 73, pages 20284-20286; *https://www.* *https://www.govinfo.gov/content/pkg/FR-2021-04-19/pdf/2021-07884.pdf*.

IV. ANALYSIS:

Under the CSA, each controlled substance is classified into one of five schedules based upon its potential for abuse, its currently accepted medical use in treatment in the United States, and the degree of dependence the drug or other substance may cause. 21 U.S.C. 812. The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c) and the current list of scheduled substances is published at 21 CFR part 1308. Pursuant to 21 U.S.C. 811(a)(2), the Attorney General may, by rule, ‘‘remove any drug or other substance from the schedules if he finds that the drug or other substance does not meet the requirements for inclusion in any schedule.’’ The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Acting Administrator of the DEA. 28 CFR 0.100.

The CSA provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General on the petition of any interested party. 21 U.S.C. 811(a)(3). This action was initiated by petition to remove samidorphan from the list of scheduled controlled substances of the CSA, and is supported by, among other things, a recommendation from the Assistant Secretary of the Health and Human Services (“HHS”) and an evaluation of all relevant data by DEA. This action removes the regulatory controls and administrative, civil, and criminal sanctions applicable to controlled substances, including those specific to schedule II controlled substances, on persons who handle or propose to handle samidorphan.

1) Background

Samidorphan (3-carboxamido-4- hydroxy naltrexone), is a chemical entity that is structurally similar to naltrexone, a mu (m)-opioid receptor antagonist. Samidorphan (other developmental code names: RDC–0313 or ALKS 33) is a mu-opioid receptor antagonist with a weak partial agonist activity at the kappa- and delta-opioid receptors. According to HHS, products containing samidorphan are currently being developed for medical use. Samidorphan is currently controlled in schedule II of the CSA, as defined in 21 CFR 1308.12(b)(l), because it can be derived from opium alkaloids. On April 14, 2014, DEA received a petition to initiate proceedings to amend 21 CFR 1308.12(b)(1) so as to decontrol samidorphan from schedule II of the CSA. The petition complied with the requirements of 21 CFR 1308.43(b) and was accepted for filing. The petitioner contended that samidorphan has been characterized as an opioid receptor antagonist, a class of drugs with no abuse potential.

2) DEA and HHS Eight Factor Analyses

Pursuant to 21 U.S.C. 811(b), DEA gathered the necessary data on samidorphan and forwarded the data, the sponsor’s petition, and a request for scheduling recommendation on samidorphan to HHS on April 24, 2015. On January 9, 2020, DEA received from HHS a scientific and medical evaluation (dated December 19, 2019) conducted by the Food and Drug Administration ("FDA”) 1 entitled ‘‘Basis for the Recommendation to Remove Samidorphan (3-Carboxamido-4- Hydroxy Naltrexone) and its Salts from All Schedules of Control Under the Controlled Substances Act’’ and a scheduling recommendation. Following consideration of the eight factors and findings related to the substance’s abuse potential, legitimate medical use, and dependence liability, HHS recommended that samidorphan and its salts be removed from all schedules of control of the CSA.

In response, DEA conducted its own eight factor analysis of samidorphan pursuant to 21 U.S.C. 811(c).

3) Determination to Decontrol Samidorphan

After a review of the available data, including the scientific and medical evaluation and the recommendation to decontrol samidorphan from HHS, the Acting Administrator of DEA published in the Federal Register a notice of proposed rulemaking ("NPRM") entitled ''Schedules of Controlled Substances: Removal of Samidorphan from Control'' which proposed removal of samidorphan and its salts from the schedules of the CSA. 85 FR 79450, December 10, 2020. The proposed rule provided an opportunity for interested persons to file a request for a hearing in accordance with DEA regulations by January 11, 2021. No requests for such a hearing were received by DEA. The NPRM also provided an opportunity for interested persons to submit written comments on the proposal on or before January 11, 2021. DEA received two comments on the proposed rule to remove samidorphan from control. Both commenters supported decontrol of samidorphan.

Based on the consideration of all comments, the scientific and medical evaluation and accompanying recommendation of HHS, and based on DEA's consideration of its own eight factor analysis, the Acting Administrator finds that these facts and all relevant data demonstrate that samidorphan does not meet the requirements for inclusion in any schedule, and will be removed from control under the CSA.

V. RECOMMENDATION:

The Department recommends removing this substance from Schedule II in the same manner as the federal Drug Enforcement Administration. The Acting Administrator of the Drug Enforcement Administration ("DEA") issued a final rule to remove samidorphan (3-carboxamido4-hydroxy naltrexone) and its salts from the schedules of the Controlled Substances Act.

Pursuant to South Carolina Code Section 44-53-160(C), the Department recommends the removal of samidorphan (3-carboxamido4-hydroxy naltrexone) and its salts, from Schedule II for controlled substances in South Carolina and the amendment of Section 44-53-210(B)(1) of the South Carolina Controlled Substances Act to include:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate, excluding Apomorphine, Nalbuphine, Naloxone, Naltrexone, and samidorphan, and their respective salts

Submitted by:

Lisa Thomson
Director
Bureau of Drug Control

Gwen Thompson
Deputy Director
Healthcare Quality

Attachment:
Federal Register, Volume 86, Number 73, April 19, 2021

PART 892—RADIOLOGY DEVICES

■ 10. The authority citation for part 892 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l,* 371.

■ 11. Amend § 892.2010 by revising paragraph (a) to read as follows:

§ 892.2010 Medical image storage device.

(a) *Identification:* A medical image storage device is a hardware device that provides electronic storage and retrieval functions for medical images. Examples include electronic hardware devices employing magnetic and optical discs, magnetic tapes, and digital memory.

* * * * *

■ 12. Amend § 892.2020 by revising paragraph (a) to read as follows:

§ 892.2020 Medical image communications device.

(a) *Identification.* A medical image communications device provides electronic transfer of medical image data between medical devices. It may include a physical communications medium, modems, and interfaces. It may provide simple image review software functionality for medical image processing and manipulation, such as grayscale window and level, zoom and pan, user delineated geometric measurements, compression, or user added image annotations. The device does not perform advanced image processing or complex quantitative functions. This does not include electronic transfer of medical image software functions.

* * * * *

■ 13. Amend § 892.2050 by revising the section heading and paragraph (a) to read as follows:

§ 892.2050 Medical image management and processing system.

(a) *Identification.* A medical image management and processing system is a device that provides one or more capabilities relating to the review and digital processing of medical images for the purposes of interpretation by a trained practitioner of disease detection, diagnosis, or patient management. The software components may provide advanced or complex image processing functions for image manipulation, enhancement, or quantification that are intended for use in the interpretation and analysis of medical images. Advanced image manipulation functions may include image segmentation, multimodality image registration, or 3D visualization. Complex quantitative functions may include semi-automated measurements or time-series measurements.

* * * * *

Dated: April 8, 2021.

Janet Woodcock,

Acting Commissioner of Food and Drugs.

Dated: April 13, 2021.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2021–07860 Filed 4–16–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–665]

Schedules of Controlled Substances: Removal of Samidorphan From Control

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Acting Administrator of the Drug Enforcement Administration removes samidorphan (3-carboxamido-4-hydroxy naltrexone) and its salts from the schedules of the Controlled Substances Act. This scheduling action is pursuant to the Controlled Substances Act which requires that such actions be made on the record after opportunity for a hearing through formal rulemaking. Prior to the effective date of this rule, samidorphan was a schedule II controlled substance because it can be derived from opium alkaloids. This action removes the regulatory controls and administrative, civil, and criminal sanctions applicable to controlled substances, including those specific to schedule II controlled substances, on persons who handle (manufacture, distribute, reverse distribute, dispense, conduct research, import, export, or conduct chemical analysis) or propose to handle samidorphan.

DATES: Effective April 19, 2021.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Drug & Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362–3261.

SUPPLEMENTARY INFORMATION:

Legal Authority

Under the Controlled Substances Act (CSA), each controlled substance is classified into one of five schedules based upon its potential for abuse, its currently accepted medical use in treatment in the United States, and the degree of dependence the drug or other substance may cause. 21 U.S.C. 812. The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c) and the current list of scheduled substances is published at 21 CFR part 1308.

Pursuant to 21 U.S.C. 811(a)(2), the Attorney General may, by rule, ''remove any drug or other substance from the schedules if he finds that the drug or other substance does not meet the requirements for inclusion in any schedule.'' The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Acting Administrator of the Drug Enforcement Administration (DEA). 28 CFR 0.100.

The CSA provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General on the petition of any interested party. 21 U.S.C. 811(a)(3). This action was initiated by one petition to remove samidorphan from the list of scheduled controlled substances of the CSA, and is supported by, *inter alia,* a recommendation from the Assistant Secretary of the HHS and an evaluation of all relevant data by DEA. This action removes the regulatory controls and administrative, civil, and criminal sanctions applicable to controlled substances, including those specific to schedule II controlled substances, on persons who handle or propose to handle samidorphan.

Background

Samidorphan (3-carboxamido-4-hydroxy naltrexone), is a chemical entity that is structurally similar to naltrexone, a mu (μ)-opioid receptor antagonist. Samidorphan (other developmental code names: RDC–0313 or ALKS 33) is a mu-opioid receptor antagonist with a weak partial agonist activity at the kappa- and delta-opioid receptors. According to HHS, products containing samidorphan are currently being developed for medical use. Samidorphan is currently controlled in schedule II of the CSA, as defined in 21 CFR 1308.12(b)(l), because it can be derived from opium alkaloids. On April 14, 2014, DEA received a petition to initiate proceedings to amend 21 CFR 1308.12(b)(1) so as to decontrol samidorphan from schedule II of the CSA. The petition complied with the requirements of 21 CFR 1308.43(b) and was accepted for filing. The petitioner contended that samidorphan has been characterized as an opioid receptor

antagonist, a class of drugs with no abuse potential.

DEA and HHS Eight Factor Analyses

Pursuant to 21 U.S.C. 811(b), DEA gathered the necessary data on samidorphan and forwarded the data, the sponsor's petition, and a request for scheduling recommendation on samidorphan to HHS on April 24, 2015.

On January 9, 2020, DEA received from HHS a scientific and medical evaluation (dated December 19, 2019) conducted by the Food and Drug Administration (FDA) [1] entitled ''Basis for the Recommendation to Remove Samidorphan (3-Carboxamido-4-Hydroxy Naltrexone) and its Salts from All Schedules of Control Under the Controlled Substances Act'' and a scheduling recommendation. Following consideration of the eight factors and findings related to the substance's abuse potential, legitimate medical use, and dependence liability, HHS recommended that samidorphan and its salts be removed from all schedules of control of the CSA. In response, DEA conducted its own eight factor analysis of samidorphan pursuant to 21 U.S.C. 811(c). Both DEA and HHS analyses are available in their entirety in the public docket of this rule (Docket Number DEA–665) at *http://www.regulations.gov* under ''Supporting and Related Material.''

Determination To Decontrol Samidorphan

After a review of the available data, including the scientific and medical evaluation and the recommendation to decontrol samidorphan from HHS, the Acting Administrator of DEA published in the **Federal Register** a notice of proposed rulemaking (NPRM) entitled ''Schedules of Controlled Substances: Removal of Samidorphan from Control'' which proposed removal of samidorphan and its salts from the schedules of the CSA. 85 FR 79450, December 10, 2020. The proposed rule provided an opportunity for interested persons to file a request for a hearing in accordance with DEA regulations by January 11, 2021. No requests for such a hearing were received by DEA. The NPRM also provided an opportunity for interested persons to submit written comments on the proposal on or before January 11, 2021.

Comments Received

DEA received two comments on the proposed rule to remove samidorphan from control. Both commenters supported decontrol of samidorphan.

Support

One commenter, a psychiatrist, clinical investigator and pain management expert, who participated as a principal investigator in clinical trials that examined the safety and efficacy of samidorphan and olanzapine combination product, stated that samidorphan counters weight gain associated with clinical use of olanzapine as antipsychotic medication and this combination product offers significant advancement relative to olanzapine alone, and thus supported this scheduling action.

Another commenter, on behalf of the sponsor of a samidorphan and olanzapine combination drug product currently under review by FDA for marketing approval, stated that samidorphan when combined with olanzapine has the potential to improve the safety profile of olanzapine by mitigating the weight gain associated with olanzapine treatment without altering its antipsychotic efficacy. This commenter agreed with DEA's conclusion that samidorphan lacks abuse or dependence potential and stated that samidorphan and its salts should be removed from the CSA schedules. This commenter further mentioned that the samidorphan and olanzapine combination product, which is currently under review by FDA for marketing approval, is an important new therapeutic option for patients and any delay in its availability for therapeutic use would negatively affect stakeholders, and therefore this final rule should be made effective immediately.

DEA Response: DEA appreciates the comments in support of this rulemaking.

Scheduling Conclusion

Based on the consideration of all comments, the scientific and medical evaluation and accompanying recommendation of HHS, and based on DEA's consideration of its own eight-factor analysis, the Acting Administrator finds that these facts and all relevant data demonstrate that samidorphan does not meet the requirements for inclusion in any schedule, and will be removed from control under the CSA.

Regulatory Analyses

Executive Orders 12866 and 13563

In accordance with 21 U.S.C. 811(a), this scheduling action is subject to formal rulemaking procedures done ''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 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.

Executive Order 12988

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 Civil Justice Reform 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

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 Federal government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175

This rule does not have tribal implications warranting the application of E.O. 13175. This rule 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 Acting Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612) (RFA), has reviewed this rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. The purpose of this rule is to remove samidorphan from the list of schedules of the CSA. This action removes regulatory controls and administrative, civil, and criminal sanctions applicable to controlled substances for handlers and proposed handlers of samidorphan. Accordingly, it has the potential for some economic impact in the form of cost savings.

This rule will affect all persons who would handle, or propose to handle,

[1] As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.

samidorphan. Samidorphan is not currently available or marketed in any country. Due to the wide variety of unidentifiable and unquantifiable variables that potentially could influence the distribution and dispensing rates, if any, of samidorphan, DEA is unable to determine the number of entities and small entities which might handle samidorphan. In some instances where a controlled pharmaceutical drug is removed from the schedules of the CSA, DEA is able to quantify the estimated number of affected entities and small entities because the handling of the drug is expected to be limited to DEA registrants even after removal from the schedules. In such instances, DEA's knowledge of its registrant population forms the basis for estimating the number of affected entities and small entities. However, DEA does not have a basis to estimate whether samidorphan is expected to be handled by persons who hold DEA registrations, by persons who are not currently registered with DEA to handle controlled substances, or both. Therefore, DEA is unable to estimate the number of entities and small entities who plan to handle samidorphan.

Although DEA does not have a reliable basis to estimate the number of affected entities and quantify the economic impact of this final rule, a qualitative analysis indicates that this rule is likely to result in some cost savings. Any person planning to handle samidorphan will realize cost savings in the form of saved DEA registration fees, and the elimination of physical security, recordkeeping, and reporting requirements. Because of these factors, DEA projects that this rule will not result in a significant economic impact on a substantial number of small entities.

Administrative Procedure Act

DEA finds that good cause exists for adopting this rule as a final rule with an immediate effective date under 5 U.S.C. 553(d) because this final rule relieves a restriction.

Unfunded Mandates Reform Act of 1995

On the basis of information contained in the RFA section above, DEA has determined and certifies pursuant to the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1501 *et seq.,* 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 provisions of UMRA.

Paperwork Reduction Act

This action does not impose a new collection of information requirement under the Paperwork Reduction Act, 44 U.S.C. 3501–3521. This action would 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 section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act (CRA)). This rule will 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 United States-based companies to compete with foreign-based companies in domestic and export markets. However, pursuant to the CRA, DEA is submitting a copy of this final rule to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

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

For the reasons set out above, 21 CFR part 1308 is amended to read 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. In § 1308.12, revise paragraph (b)(1) introductory text to read as follows:

§ 1308.12 Schedule II.

* * * * *

(b) * * *

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate excluding apomorphine, thebaine-derived butorphanol, dextrorphan, nalbuphine, naldemedine, nalmefene, naloxegol, naloxone, 6β-naltrexol, naltrexone, and samidorphan, and their respective salts, but including the following:

* * * * *

D. Christopher Evans,

Acting Administrator.

[FR Doc. 2021–07884 Filed 4–16–21; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF STATE

22 CFR Part 62

[Public Notice: 10818]

RIN 1400–AF03

Change to Certification Authority for the Alien Physician Category of the Exchange Visitor Program

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: The Department of State (Department) is changing the certification authority for alien physicians from the American Board of Medical Specialties (ABMS) to the Accreditation Council for Graduate Medical Education (ACGME).

DATES: This rule is effective May 19, 2021.

FOR FURTHER INFORMATION CONTACT: G. Kevin Saba, Director, Office of Policy and Program Support, Office of Private Sector Exchange, Bureau of Educational and Cultural Affairs, U.S. Department of State, SA–4E, 2201 C Street NW, Washington, DC 20522; email at *JExchanges@state.gov*; or, (202) 634–4710.

SUPPLEMENTARY INFORMATION: In 22 CFR 62.27(e)(1) and (e)(4)(i), there is a reference to the ''American Board of Medical Specialties'' (ABMS). These provisions, last amended in 1993, state that ABMS will perform certain certification functions for the Secretary of State.

ABMS no longer produces the publication, *Marquis Who's Who,* referenced in 22 CFR part 62. Furthermore, ABMS has confirmed that it is also no longer the appropriate organization to comment on programs of graduate medical education. The Department has confirmed that the Accreditation Council for Graduate Medical Education (ACGME) has responsibility to accredit and recognize institutions offering programs of graduate medical education, and is replacing the reference to the ABMS with the ACGME in § 62.27.

SUMMARY SHEET
SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

May 13, 2021

(X) ACTION/DECISION
( ) INFORMATION

I. **TITLE:** Request for Placement of 10 Specific Fentanyl-Related Substances in Schedule I for Controlled Substances in South Carolina

II. **SUBJECT:** Placement of 10 Specific Fentanyl-Related Substances in Schedule I 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 I substances are listed in Section 44-53-190 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.

On April 27, 2021, the Drug Enforcement Administration ("DEA") published a final rule which placed 10 specified fentanyl-related substances permanently in schedule I of the Controlled Substances Act. This final rule imposes permanent controls on 10 specified fentanyl-related substances, which will continue to be listed in schedule I of the Controlled Substances Act ("CSA"). These 10 fentanyl-related substances are: N-(1-(2-fluorophenethyl)piperidin4-yl)-N-(2-fluorophenyl)propionamide (2′-fluoro ortho-fluorofentanyl; 2′-fluoro 2-fluorofentanyl); N-(1-(4-methylphenethyl)piperidin4-yl)-N-phenylacetamide (4′-methyl acetyl fentanyl); N-(1-phenethylpiperidin-4-yl)-N,3- diphenylpropanamide (β′-phenyl fentanyl; beta′-Phenyl

fentanyl; 3- phenylpropanoyl fentanyl); N-phenyl-N-(1-(2- phenylpropyl)piperidin-4- yl)propionamide (β-methyl fentanyl); N-(2-fluorophenyl)-N-(1- phenethylpiperidin-4-yl)butyramide (ortho-fluorobutyryl fentanyl; 2- fluorobutyryl fentanyl); N-(2-methylphenyl)-N-(1- phenethylpiperidin-4-yl)acetamide (ortho-methyl acetyl fentanyl; 2-methylacetyl fentanyl); 2-methoxy-N-(2-methylphenyl)-N- (1-phenethylpiperidin-4-yl)acetamide (ortho-methyl methoxyacetylfentanyl; 2- methyl methoxyacetyl fentanyl); N-(4-methylphenyl)-N-(1- phenethylpiperidin-4-yl)propionamide (para-methylfentanyl; 4-methylfentanyl); N-(1-phenethylpiperidin-4-yl)-N-phenylbenzamide (phenyl fentanyl; benzoyl fentanyl); and N-(1-phenethylpiperidin-4-yl)-Nphenylthiophene-2-carboxamide (thiofuranyl fentanyl; 2-thiofuranyl fentanyl; thiophene fentanyl). The schedule I listing of these 10 fentanyl-related substances includes their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible. These 10 specific substances all fall within the definition of fentanyl-related substances set forth in a February 6, 2018, temporary scheduling order. Through the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act, which became law on February 6, 2020, Congress extended the temporary control of fentanyl-related substances until May 6, 2021. The regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle any of these 10 specified fentanyl-related substances will continue to be applicable permanently as a result of this action. This final rule became effective April 27, 2021, *Federal Register*, Volume 86, Number 79, pages 22113-22118; *https://www.govinfo.gov/content/pkg/FR-2021-04-27/pdf/2021-08720.pdf*.

III. ANALYSIS:

On July 2, 2020, Health and Human Services ("HHS") provided DEA with a scientific and medical evaluation and scheduling recommendation, prepared by the Food and Drug Administration ("FDA"), for 2′-fluoro ortho-fluorofentanyl, 4′-methyl acetyl fentanyl, b′-phenyl fentanyl, b-methyl fentanyl, ortho-fluorobutyryl fentanyl, ortho-methyl acetylfentanyl, orthomethyl methoxyacetyl fentanyl, paramethylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl and their salts. After considering the eight factors in 21 U.S.C. 811(c), each substance's abuse potential, lack of legitimate medical use in the United States, and lack of accepted safety for use under medical supervision pursuant to 21 U.S.C. 812(b), the Assistant Secretary recommended that these substances be placed in schedule I of the CSA. In response, DEA conducted its own eight factor analysis of 2′-fluoro orthofluorofentanyl, 4′-methyl acetyl fentanyl, b′-phenyl fentanyl, b-methyl fentanyl, ortho-fluorobutyryl fentanyl, ortho-methyl acetylfentanyl, orthomethyl methoxyacetyl fentanyl, paramethylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl.

After consideration of the analysis and recommendation of the Assistant Secretary and review of all other available data, the Acting Administrator, pursuant to 21 U.S.C. 811(a) and 812(b)(1), finds that 2′-Fluoro ortho-fluorofentanyl, 4′- methyl acetyl fentanyl, b′-phenyl fentanyl, b-methyl fentanyl, orthofluorobutyryl fentanyl, ortho-methyl acetylfentanyl, ortho-methyl methoxyacetyl fentanyl, paramethylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl have a high potential for abuse that is comparable to other schedule I substances such as acetyl fentanyl and furanyl fentanyl; have no currently accepted medical use in treatment in the United States; and a lack of accepted safety for use under medical supervision. Based on these findings, the Acting Administrator concludes that 2′-fluoro ortho-fluorofentanyl, 4′-methyl acetyl fentanyl, b′-phenyl fentanyl, bmethyl fentanyl, ortho-fluorobutyryl fentanyl, ortho-methyl acetylfentanyl, ortho-methyl methoxyacetyl fentanyl, para-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such

isomers, esters, ethers, and salts is possible, warrant continued control in schedule I of the CSA. 21 U.S.C. 812(b)(1).

IV. RECOMMENDATION:

Pursuant to S.C. Code Section 44-53-160(C), the Department recommends placing these 10-specific fentanyl-related substances in Schedule I in the same manner as the federal Drug Enforcement Administration. The listing of these 10 fentanyl-related substances includes their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible to schedule I for controlled substances in South Carolina and the amendment of Section 44-53-190(B) of the South Carolina Controlled Substances Act to include:

( ) beta-Methyl fentanyl (N-phenyl-N-(1-(2-phenylpropyl)piperidin-4-yl)propionamide; also known as b-methyl fentanyl);

( ) beta′-Phenyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N,3-diphenylpropanamide; also known as b′-phenyl fentanyl; 3- phenylpropanoyl fentanyl);

( ) 2′-Fluoro ortho-fluorofentanyl (N-(1-(2-fluorophenethyl)piperidin-4-yl)-N-(2-fluorophenyl)propionamide; also known as 2′- fluoro 2-fluorofentanyl);

( ) 4′-Methyl acetyl fentanyl (N-(1-(4-methylphenethyl)piperidin-4-yl)-N-phenylacetamide);

( ) ortho-Fluorobutyryl fentanyl (N-(2-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)butyramide; also known as 2-fluorobutyryl fentanyl);

( ) ortho-Methyl acetylfentanyl (N-(2-methylphenyl)-N-(1-phenethylpiperidin-4-yl)acetamide; also known as 2-methyl acetylfentanyl);

( ) ortho-Methyl methoxyacetyl fentanyl (2-methoxy-N-(2-methylphenyl)-N-(1-phenethylpiperidin-4-yl)acetamide; also known as 2-methyl methoxyacetyl fentanyl);

( ) para-Methylfentanyl (N-(4-methylphenyl)-N-(1-phenethylpiperidin-4-yl)propionamide; also known as 4-methylfentanyl);

( ) phenyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylbenzamide; also known as benzoyl fentanyl);

( ) thiofuranyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylthiophene-2-carboxamide; also known as 2-thiofuranyl fentanyl; thiophene fentanyl).

Submitted by:

Lisa Thomson
Director
Bureau of Drug Control

Gwen Thompson
Deputy Director
Healthcare Quality

Attachment:
Federal Register, Volume 86, Number 79, April 27, 2021

appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, New York ACO Branch, FAA; or TCCA; or Airbus Canada Limited Partnership's TCCA Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(k) Related Information

For more information about this AD, contact Deep Gaurav, Aerospace Engineer, Airframe and Propulsion Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; fax 516–794–5531; email *9-avs-nyaco-cos@faa.gov.*

(l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(3) The following service information was approved for IBR on May 4, 2021 (86 FR 20266, April 19, 2021).

(i) Transport Canada Civil Aviation (TCCA) AD CF–2021–10, dated March 18, 2021.

(ii) [Reserved]

(4) For TCCA AD CF–2021–10, contact TCCA, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; telephone 888–663–3639; email *AD-CN@tc.gc.ca;* internet *https://tc.canada.ca/en/aviation.*

(5) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. This material may be found in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0313.

(6) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fedreg.legal@nara.gov,* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on April 22, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–08760 Filed 4–23–21; 11:15 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–476]

Schedules of Controlled Substances: Placement of 10 Specific Fentanyl-Related Substances in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: In this rule, the Drug Enforcement Administration places 10 specified fentanyl-related substances permanently in schedule I of the Controlled Substances Act. These 10 specific substances all fall within the definition of fentanyl-related substances set forth in a February 6, 2018, temporary scheduling order. Through the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act, which became law on February 6, 2020, Congress extended the temporary control of fentanyl-related substances until May 6, 2021. The regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle any of these 10 specified fentanyl-related substances will continue to be applicable permanently as a result of this action.

DATES: Effective date: April 27, 2021.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION: This final rule imposes permanent controls on 10 specified fentanyl-related substances, which will continue to be listed in schedule I of the Controlled Substances Act (CSA). These 10 fentanyl-related substances are:

- *N*-(1-(2-fluorophenethyl)piperidin-4-yl)-*N*-(2-fluorophenyl)propionamide (2′-fluoro *ortho*-fluorofentanyl; 2′-fluoro 2-fluorofentanyl);
- *N*-(1-(4-methylphenethyl)piperidin-4-yl)-*N*-phenylacetamide (4′-methyl acetyl fentanyl);
- *N*-(1-phenethylpiperidin-4-yl)-*N*,3-diphenylpropanamide (β′-phenyl fentanyl; *beta*′-Phenyl fentanyl; 3-phenylpropanoyl fentanyl);
- *N*-phenyl-*N*-(1-(2-phenylpropyl)piperidin-4-yl)propionamide (β-methyl fentanyl);
- *N*-(2-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)butyramide (*ortho*-fluorobutyryl fentanyl; 2-fluorobutyryl fentanyl);
- *N*-(2-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)acetamide (*ortho*-methyl acetylfentanyl; 2-methyl acetylfentanyl);
- 2-methoxy-*N*-(2-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)acetamide (*ortho*-methyl methoxyacetylfentanyl; 2-methyl methoxyacetyl fentanyl);
- *N*-(4-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)propionamide (*para*-methylfentanyl; 4-methylfentanyl);
- *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbenzamide (phenyl fentanyl; benzoyl fentanyl); and
- *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylthiophene-2-carboxamide (thiofuranyl fentanyl; 2-thiofuranyl fentanyl; thiophene fentanyl).

The schedule I listing of these 10 fentanyl-related substances includes their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible.

Legal Authority

The CSA provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General (delegated to the Administrator of the Drug Enforcement Administration (DEA) pursuant to 28 CFR 0.100) on his own motion. 21 U.S.C. 811(a). This action is supported by, *inter alia,* a recommendation from the Assistant Secretary for Health of HHS (Assistant Secretary) and an evaluation of all relevant data by DEA. This action continues the imposition of the regulatory controls and administrative, civil, and criminal sanctions of schedule I controlled substances on any person who handles (manufactures, distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) or proposes to handle 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl.

Background

On February 6, 2018, pursuant to 21 U.S.C. 811(h)(1), DEA published a temporary scheduling order in the

Federal Register (83 FR 5188), temporarily placing fentanyl-related substances, as defined in that order, in schedule I of the CSA based upon a finding that these substances pose an imminent hazard to the public safety. That temporary order was effective upon the date of publication. Pursuant to 21 U.S.C. 811(h)(2), the temporary control of fentanyl-related substances, a class of substances as defined in the order, as well as the 10 specific substances already covered by that order, was set to expire on February 6, 2020. However, as explained in DEA's April 10, 2020, correcting amendment (85 FR 20155), Congress overrode and extended that expiration date until May 6, 2021, by enacting the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act (Pub. L. 116–114, sec. 2, 134 Stat. 103) (Feb. 6, 2020).

On March 3, 2021 (86 FR 12296), DEA published a notice of proposed rulemaking (NPRM) to permanently control 10 specific fentanyl-related substances: 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl in schedule I of the CSA. Specifically, DEA proposed to add these substances to the opiates list under 21 CFR 1308.11(b), and assign paragraph numbers 17, 18, 41, 50, 61, 62, 64, 69, 75, and 83 under paragraph (b) to *beta*-Methyl fentanyl, *beta*′-Phenyl fentanyl, 2′-Fluoro *ortho*-fluorofentanyl, 4′-Methyl acetyl fentanyl, *ortho*-Fluorobutyryl fentanyl, *ortho*-Methyl acetylfentanyl, *ortho*-Methyl methoxyacetyl fentanyl, *para*-Methylfentanyl, Phenyl fentanyl, and Thiofuranyl fentanyl, respectively.

Since the publication of this NPRM, DEA issued a correcting amendment which updated the numbering of all listed opiates in paragraph (b). See 86 FR 16667, March 31, 2021. As a result, this final rule assigns different paragraph numbers under paragraph (b) than originally proposed, to nine of the ten substances (though the numbering for *ortho*-Methyl acetylfentanyl remains the same). In addition, after publication of the NPRM, DEA discovered that the NPRM inadvertently assigned a duplicate drug code to 2′-fluoro *ortho*-fluorofentanyl (9829). As such, with this final rule, DEA hereby corrects this error by assigning a new drug code (9855) for 2′-fluoro *ortho*-fluorofentanyl.

DEA and HHS Eight Factor Analyses

On July 2, 2020, HHS provided DEA with a scientific and medical evaluation and scheduling recommendation, prepared by the Food and Drug Administration (FDA), for 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl and their salts.[1] After considering the eight factors in 21 U.S.C. 811(c), each substance's abuse potential, lack of legitimate medical use in the United States, and lack of accepted safety for use under medical supervision pursuant to 21 U.S.C. 812(b), the Assistant Secretary recommended that these substances be placed in schedule I of the CSA. In response, DEA conducted its own eight-factor analysis of 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl. Please note that both the DEA and HHS 8-Factor analyses and the Assistant Secretary's July 2, 2020, letter are available in their entirety under the tab ''Supporting Documents'' of the public docket for this action at *http://www.regulations.gov* under Docket Number ''DEA–476.''

Determination To Schedule Ten Specific Fentanyl-Related Substances

After review of the available data including the scientific and medical evaluation and the scheduling recommendations from HHS, DEA published an NPRM entitled ''Schedules of Controlled Substances: Placement of 10 Specific Fentanyl-Related Substances in Schedule I.'' 86 FR 12296, March 3, 2021. The NPRM provided an opportunity for interested persons to file a request for hearing in accordance with DEA regulations on or before April 2, 2021. No requests for such a hearing were received by DEA. The NPRM also provided an opportunity for interested persons to submit comments on the proposed rule on or before April 2, 2021.

[1] Although HHS also provided information on crotonyl fentanyl, this substance will not be discussed in this final rule since it was permanently placed in schedule I on October 2, 2020. 85 FR 62215.

Comments Received

DEA received ten comments on the proposed rule to control 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl in schedule 1 of the CSA. One submission was from a public health group called The Partnership for Safe Medicines, which is made up of more than 45 non-profit organizations committed to the safety of prescription drugs and protection of consumers against counterfeit or unsafe medicines. Other submissions were from individual or anonymous commenters. Nine of the commenters provided support for the rule, and one commenter did not state a position on the rule.

Rather, the latter commenter inquired about DEA's concern with synthetic opioids versus natural substances, and the possibility of reducing opioid addiction risks by managing pain differently without the use of prescribed opioid medications. This comment is outside the scope of this rulemaking. As such, this rule will not provide a response to this comment.

Support of the Proposed Rule

Nine commenters supported controlling 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl as schedule I controlled substances. These commenters indicated support for permanent scheduling of these substances for the reasons such as similarity in their abuse potential to fentanyl, safety concerns with fentanyl, such as deaths, overdoses, addiction, and trafficking, and the involvement of fentanyl and fentanyl-related substances in the current public health crisis associated with the opioid abuse epidemic. Most commenters indicated that DEA needs to impose the permanent control to help curb addiction and opioid overdose.

In addition to supporting control of these 10 substances, a commenter highlighted the need for more specific guidelines for regulatory controls and administrative, civil, and criminal sanctions specific to these substances. In particular, this commenter desired that DEA ensure that vulnerable populations (*e.g.,* those addicted to or dependent on opioids) would not be

unduly punished by broad convictions or sentencing guidelines, and advocated for no mandatory minimums for subsequent convictions (after the first conviction) related to simple possession or ''low level handling'' of the 10 fentanyl-related substances.

DEA Response. DEA appreciates the support for this rulemaking. Regarding the comment for more specific guidelines related to regulatory control for these 10 substances, this comment is outside the scope of this rulemaking since sentencing guidelines are set by the CSA.

Scheduling Conclusion

After consideration of the relevant matter presented through public comments, the scientific and medical evaluation and accompanying recommendation of HHS, and after its own eight-factor evaluation, DEA finds that these facts and all other relevant data constitute substantial evidence of the potential for abuse of 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl. DEA is therefore permanently scheduling these 10 specific fentanyl-related substances as controlled substances under the CSA.

Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA also outlines the findings required to place a drug or other substance in any particular schedule. 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Assistant Secretary and review of all other available data, the Acting Administrator, pursuant to 21 U.S.C. 811(a) and 812(b)(1), finds that:

(1) 2′-Fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl have a high potential for abuse that is comparable to other schedule I substances such as acetyl fentanyl and furanyl fentanyl.

(2) 2′-Fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl have no currently accepted medical use in treatment in the United States; [2] and

(3) There is a lack of accepted safety for use of 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl under medical supervision. Based on these findings, the Acting Administrator concludes that 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible, warrant continued control in schedule I of the CSA. 21 U.S.C. 812(b)(1).

Requirements for Handling 2′-Fluoro Ortho-Fluorofentanyl, 4′-Methyl Acetyl Fentanyl, β′-Phenyl Fentanyl, β-Methyl Fentanyl, Ortho-Fluorobutyryl Fentanyl, Ortho-Methyl Acetylfentanyl, Ortho-Methyl Methoxyacetyl Fentanyl, Para-Methylfentanyl, Phenyl Fentanyl, and Thiofuranyl Fentanyl

2′-Fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl will continue [3] to be subject to the CSA's regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, dispensing, importation, exportation, research, and conduct of instructional activities involving the handling of controlled 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), or who desires to handle, 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl 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.

2. *Security.* 2′-Fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl are subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, and in accordance with 21 CFR 1301.71–1301.76. Non-practitioners handling 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl also must comply with the employee screening requirements of 21 CFR 1301.90–1301.93.

3. *Labeling and Packaging.* All labels and labeling for commercial containers of 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl must be in compliance with 21 U.S.C. 825 and 958(e), and be in accordance with 21 CFR part 1302.

4. *Quota.* Only registered manufacturers are permitted to manufacture 2′-fluoro *ortho*-

[2] Although there is no evidence suggesting that 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl have a currently accepted medical use in treatment in the United States, it bears noting that a drug cannot be found to have such medical use unless DEA concludes that it satisfies a five-part test. Specifically, with respect to a drug that has not been approved by FDA, to have a currently accepted medical use in treatment in the United States, all of the following must be demonstrated: i. The drug's chemistry must be known and reproducible; ii. there must be adequate safety studies; iii. there must be adequate and well-controlled studies proving efficacy; iv. the drug must be accepted by qualified experts; and v. the scientific evidence must be widely available. 57 FR 10499 (1992), *pet. for rev. denied, Alliance for Cannabis Therapeutics* v. *DEA,* 15 F.3d 1131, 1135 (D.C. Cir. 1994).

[3] 2′-Fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl are covered by the February 6, 2018, temporary scheduling order, and are currently subject to schedule I controls on a temporary basis, pursuant to 21 U.S.C. 811(h). 83 FR 5188.

fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303.

5. *Inventory.* Any person registered with DEA to handle 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl must have an initial inventory of all stocks of controlled substances (including these substances) on hand on the date the registrant first engages in the handling of controlled substances pursuant to 21 U.S.C. 827 and 958, 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 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl) on hand every two years pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

6. *Records and Reports.* Every DEA registrant is required to maintain records and submit reports with respect to 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1301.74(b) and (c) and parts 1304, 1312, and 1317.

7. *Order Forms.* Every DEA registrant who distributes 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl must comply with the order form requirements, pursuant to 21 U.S.C. 828 and in accordance 21 CFR part 1305.

8. *Importation and Exportation.* All importation and exportation of 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl must be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

9. *Liability.* Any activity involving 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl not authorized by, or in violation of, the CSA or its implementing regulations is unlawful, and could subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)

In accordance with 21 U.S.C. 811(a), this final scheduling action is subject to formal rulemaking procedures done ''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 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.

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 the distribution of power and responsibilities among the various levels of government.

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 Acting Administrator, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601–602, has reviewed this rule and by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities. On February 6, 2018, DEA published an order to temporarily place fentanyl-related substances, as defined in the order, in schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). DEA estimates that all entities handling or planning to handle 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl have already established and implemented the systems and processes required to handle these substances which meet the definition of fentanyl-related substances.

There are currently 57 registrations authorized to handle the fentanyl-related substances as a class, which include 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl, as well as a number of registered analytical labs that are authorized to handle schedule I controlled substances generally. These 57 registrations represent 51 entities, of which eight are small entities. Therefore, DEA estimates eight small entities are affected by this final rule.

A review of the 57 registrations indicates that all entities that currently handle fentanyl-related substances, including 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl, also handle other schedule I controlled substances, and have established and implemented (or maintain) the systems and processes required to handle 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl

fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl. Therefore, DEA anticipates that this final rule will impose minimal or no economic impact on any affected entities, and thus will not have a significant economic impact on any of the eight affected small entities. Therefore, DEA has concluded that this rule will not have a significant effect on a substantial number of small entities.

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 and certifies 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 $100,000,000 or more (adjusted annually for inflation) in any 1 year. . . .'' Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Congressional Review Act

This rule is not a ''major rule'' as defined in the Congressional Review Act (CRA), 5 U.S.C. 804. However, DEA is submitting the required reports to the Government Accountability Office, the House, and the Senate under the CRA.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. This action would 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.

Determination To Make Rule Effective Immediately

As indicated above, this rule finalizes the schedule I control status of 10 substances that has already been in effect for over three years. These 10 substances all fall within the definition of fentanyl-related substances set forth in the February 6, 2018, temporary scheduling order (83 FR 5188). Through the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act, which became law on February 6, 2020, Congress extended the temporary control of fentanyl-related substances until May 6, 2021. The February 2018 order was effective on the date of publication, and was based on findings by the then-Acting Administrator that the temporary scheduling of the fentanyl-related substances was necessary to avoid an imminent hazard to the public safety pursuant to 21 U.S.C. 811(h)(1). Because this rule finalizes the control status of 10 substances that has already been in effect for over three years, it does not alter the legal obligations of any person who handles these substances. Rather, it merely makes permanent the current scheduling status and corresponding legal obligations. Therefore, DEA is making the rule effective on the date of publication in the **Federal Register**, as any delay in the effective date is unnecessary and would be contrary to the public interest.

List of Subjects in 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. In § 1308.11:

■ a. Redesignate paragraphs (b)(73) through (b)(76) as paragraphs (b)(83) through (b)(86);

■ b. Redesignate paragraphs (b)(66) through (b)(72) as paragraphs (b)(75) through (b)(81);

■ c. Redesignate paragraphs (b)(61) through (b)(65) as paragraphs (b)(69) through (b)(73);

■ d. Redesignate paragraphs (b)(57) through (b)(60) as paragraphs (b)(64) through (b)(67);

■ e. Redesignate paragraph (b)(56) as paragraph (b)(61);

■ f. Redesignate paragraphs (b)(46) through (b)(55) as paragraphs (b)(50) through (b)(59);

■ g. Redesignate paragraphs (b)(38) through (b)(45) as paragraphs (b)(41) through (b)(48);

■ h. Redesignate paragraphs (b)(19) through (b)(37) as paragraphs (b)(21) through (b)(39); and

■ i. Add new paragraphs (19), (20), (40), (49), (60), (62), (63), (68), (74), and (82).

The additions read as follows:

§ 1308.11 Schedule I.

* * * * *

(b) * * *

* * * * *

(19) *beta*-Methyl fentanyl (*N*-phenyl-*N*-(1-(2-phenylpropyl)piperidin-4-yl)propionamide; also known as β-methyl fentanyl) 9856

(20) *beta*′-Phenyl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*,3-diphenylpropanamide; also known as β′-phenyl fentanyl; 3-phenylpropanoyl fentanyl) 9842

* * * * * * *

(40) 2′-Fluoro *ortho*-fluorofentanyl (*N*-(1-(2-fluorophenethyl)piperidin-4-yl)-*N*-(2-fluorophenyl)propionamide; also known as 2′-fluoro 2-fluorofentanyl) 9855

* * * * * * *

(49) 4′-Methyl acetyl fentanyl (*N*-(1-(4-methylphenethyl)piperidin-4-yl)-*N*-phenylacetamide) 9819

* * * * * * *

(60) *ortho*-Fluorobutyryl fentanyl (*N*-(2-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)butyramide; also known as 2-fluorobutyryl fentanyl) 9846

* * * * * * *

(62) *ortho*-Methyl acetylfentanyl (*N*-(2-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)acetamide; also known as 2-methyl acetylfentanyl) 9848

(63) *ortho*-Methyl methoxyacetyl fentanyl (2-methoxy-*N*-(2-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)acetamide; also known as 2-methyl methoxyacetyl fentanyl) 9820

* * * * * * *

(68) *para*-Methylfentanyl (*N*-(4-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)propionamide; also known as 4-methylfentanyl) 9817

*	*	*	*	*	*	*
(74) Phenyl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbenzamide; also known as benzoyl fentanyl)						9841
*	*	*	*	*	*	*
(82) Thiofuranyl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylthiophene-2-carboxamide; also known as 2-thiofuranyl fentanyl; thiophene fentanyl)						9839

* * * * *

D. Christopher Evans,

Acting Administrator.

[FR Doc. 2021–08720 Filed 4–26–21; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF STATE

22 CFR Part 181

[Public Notice: 11408]

RIN 1400–AE98

Publication, Coordination, and Reporting of International Agreements

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: The Treaties and Other International Acts Series (TIAS) is the official treaty series of the United States and serves as evidence of the treaties, and international agreements other than treaties, in all courts of law and equity of the United States, and in public offices of the federal government and of the states, without any need of further authentication. Certain international agreements may be exempted from publication in TIAS, if the Department of State (the Department) provides notice in its regulations. This rule updates those regulations to clarify the scope of an existing exemption.

DATES: This rule is effective May 27, 2021.

FOR FURTHER INFORMATION CONTACT: Michael Mattler, Treaty Affairs, Office of the Legal Adviser, Department of State, Washington, DC 20520, (202) 647–1345, or at *treatyoffice@state.gov.*

SUPPLEMENTARY INFORMATION: This rule finalizes a proposed rule published by the Department of State on December 7, 2020. 85 FR 78813. The Department provided 60 days for comment; no relevant public comments were received.

Background

Pursuant to 1 U.S.C. 112a, the Secretary of State is required to cause to be published annually a compilation of all treaties and international agreements to which the United States is a party that were signed, proclaimed, or ''with reference to which any other final formality ha[d] been executed'' during the calendar year. The Secretary of State, however, may determine that publication of particular categories of agreements is not required if certain criteria are met (See 1 U.S.C. 112a(b)).

As explained in the NPRM, the Department is amending 22 CFR 181.8(a)(9) to read ''Agreements that have been given a national security classification pursuant to Executive Order No. 13526, its predecessors or successors, or are otherwise exempt from public disclosure pursuant to U.S. law.''

The scope of this new exemption includes agreements that have not been given a national security classification pursuant to Executive Order No. 13526, its predecessors or successors, but nonetheless are exempt from public disclosure pursuant to U.S. law. The principal category of agreements for which this clarification is relevant are agreements that are exempt from public disclosure pursuant to 10 U.S.C. 130c, which authorizes specified national security officials to withhold from public disclosure otherwise required by law sensitive information of foreign governments and international organizations.

Regulatory Analysis

Administrative Procedure Act

The Department issued the rule for comment in accordance with the Administrative Procedure Act (5 U.S.C. 553).

Regulatory Flexibility Act/Executive Order 13272: Small Business

This rulemaking is hereby certified as not expected to have a significant impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*

Congressional Review Act

This rulemaking does not constitute a major rule, as defined by 5 U.S.C. 804, for purposes of congressional review of agency rulemaking.

The Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1532, generally requires agencies to prepare a statement before proposing any rule that may result in an annual expenditure of $100 million or more by State, local, or tribal governments, or by the private sector. This rule will not result in any such expenditure nor would it significantly or uniquely affect small governments.

Executive Orders 12372 and 13132: Federalism and Executive Order 13175, Impact on Tribes

This rule will 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. Nor will the regulations have federalism implications warranting the application of Executive Orders 12372 and 13132. This rule will not have tribal implications, will not impose costs on Indian tribal governments, and will not pre-empt tribal law. Accordingly, the requirements of Executive Order 13175 do not apply to this rulemaking.

Executive Orders 12866 and 13563: Regulatory Review

This rule has been drafted in accordance with the principles of Executive Orders 12866 and 13563. This rule has been determined to be a significant rulemaking under section 3 of Executive Order 12866, but not economically significant. With respect to the costs and benefits of this rule, the Department notes that agreements addressed by the proposed clarification are, by definition, already exempt from public disclosure pursuant to U.S. law. The proposed rule is intended to provide greater clarity to the application of the existing rule rather than to effect a change in existing practices regarding the publication of agreements. For this reason, the Department does not anticipate any costs to the public from this rulemaking. Therefore, the Department believes that the benefits of this rulemaking outweigh any costs.

Executive Order 12988: Civil Justice Reform

This rule has been reviewed in light of sections 3(a) and 3(b)(2) of Executive Order 12988 to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

SUMMARY SHEET
SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

May 13, 2021

(X) ACTION/DECISION
( ) INFORMATION

I. TITLE: Request for Placement of Four Specific Fentanyl-Related Substances in Schedule I for Controlled Substances in South Carolina

II. SUBJECT: Placement of Four Specific Fentanyl-Related Substances in Schedule I 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 I substances are listed in Section 44-53-190 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.

On May 4, 2021, the Drug Enforcement Administration ("DEA") published a final rule which placed four specified fentanyl-related substances permanently in schedule I of the Controlled Substances Act. This final rule imposes permanent controls on four specified fentanyl-related substances, which will continue to be listed in schedule I of the Controlled Substances Act ("CSA"). These 4 fentanyl-related substances are: ethyl (1-phenethylpiperidin-4-yl)(phenyl)carbamate (fentanyl carbamate); N-(2-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)acrylamide (orthofluoroacryl fentanyl); N-(2-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide (orthofluoroisobutyryl fentanyl); and N-(4-fluorophenyl)-N-(1-

phenethylpiperidin-4-yl)furan-2-carboxamide (parafluoro furanyl fentanyl). The schedule I listing of these four fentanyl-related substances includes their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible. These four specific substances all fall within the definition of fentanyl-related substances set forth in a February 6, 2018, temporary scheduling order. Through the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act, which became law on February 6, 2020, Congress extended the temporary control of fentanyl-related substances until May 6, 2021. The regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle any of these four specified fentanyl-related substances will continue to be applicable permanently as a result of this action. This final rule became effective May 4, 2021, *Federal Register*, Volume 86, Number 84, pages 23602-23606; *https:// www. https://www.govinfo.gov/content/pkg/FR-2021-05-04/pdf/2021-09402.pdf*.

III. ANALYSIS:

On March 2, 2021, Health and Human Services provided DEA with a scientific and medical evaluation and scheduling recommendation, prepared by the Food and Drug Administration ("FDA"), for fentanyl carbamate, ortho-fluoroacryl fentanyl, ortho-fluoro isobutyryl fentanyl, and para-fluoro furanyl fentanyl in schedule I and their salts. After considering the eight factors in 21 U.S.C. 811(c), each substance's abuse potential, lack of legitimate medical use in the United States, and lack of accepted safety for use under medical supervision pursuant to 21 U.S.C. 812(b), the Assistant Secretary recommended that these substances be placed in schedule I of the CSA. In response, DEA conducted its own eight factor analysis of fentanyl carbamate, ortho-fluoroacryl fentanyl, ortho-fluoro isobutyryl fentanyl, and para-fluoro furanyl fentanyl in schedule I.

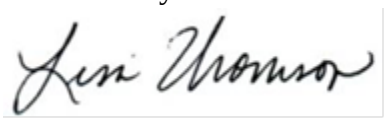
After consideration of the analysis and recommendation of the Assistant Secretary and review of all other available data, the Acting Administrator, pursuant to 21 U.S.C. 811(a) and 812(b)(1), finds that fentanyl carbamate, ortho-fluoroacryl fentanyl, ortho-fluoro isobutyryl fentanyl, and para-fluoro furanyl fentanyl have a high potential for abuse that is comparable to other schedule I substances such as acetyl fentanyl and furanyl fentanyl; have no currently accepted medical use in treatment in the United States; and a lack of accepted safety for use under medical supervision. Based on these findings, the Acting Administrator concludes that fentanyl carbamate, ortho-fluoroacryl fentanyl, ortho-fluoro isobutyryl fentanyl, and para-fluoro furanyl fentanyl, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible, warrant continued control in schedule I of the CSA. 21 U.S.C. 812(b)(1).

IV. RECOMMENDATION:

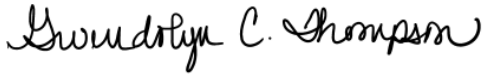
Pursuant to S.C. Code Section 44-53-160(C), the Department recommends placing these 4-specific fentanyl-related substances in Schedule I in the same manner as the federal Drug Enforcement Administration. The listing of these 4 fentanyl-related substances includes their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible to schedule I for controlled substances in South Carolina and the amendment of Section 44-53-190(B) of the South Carolina Controlled Substances Act to include:

( ) ethyl (1-phenethylpiperidin-4-yl)(phenyl)carbamate (fentanyl carbamate);
( ) N-(2-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)acrylamide (orthofluoroacryl fentanyl);
( ) N-(2-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide (orthofluoroisobutyryl fentanyl);
( ) N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)furan-2-carboxamide (parafluoro furanyl fentanyl)

Submitted by:



Lisa Thomson
Director
Bureau of Drug Control



Gwen Thompson
Deputy Director
Healthcare Quality

Attachment:
Federal Register, Volume 86, Number 84, May 4, 2021

5.B.(2)(a)*2,* of SB LEAP–1B–73–0038, related to the pressure transducer, until the PSS unit has accumulated 15 hours or more of electrical power within the previous 90 days; or

(ii) Before further flight, apply electrical power to the PSS unit in accordance with the Accomplishment Instructions, paragraph 5.A.(3)(a)*1,* of SB LEAP–1B–73–0038, until the PSS unit has accumulated 15 hours or more of electrical power within the past 90 days.

(2) For an engine in service on the effective date of this AD that has accumulated 15 hours or more of electrical power applied to the PSS unit within the previous 90 days, within 5 flight cycles of the effective date of this AD, perform a one-time check for the maintenance messages listed in the Accomplishment Instructions, paragraph 5.B.(2)(a)*2,* of SB LEAP–1B–73–0038, related to the pressure transducer.

(3) For an engine not in service on the effective date of this AD that has accumulated fewer than 15 hours of electrical power applied to the PSS unit within the past 90 days, before further flight, apply electrical power to the PSS unit in accordance with the Accomplishment Instructions, paragraph 5.A.(3)(a)*1,* of SB LEAP–1B–73–0038, until the PSS unit has accumulated 15 hours or more of electrical power within the previous 90 days.

(4) For an engine not in service on the effective date of this AD that has accumulated 15 hours or more of electrical power applied to the PSS unit within the previous 90 days, before further flight, perform a check for the engine maintenance messages using the Accomplishment Instructions, paragraphs 5.A.(3)(b)1 through 5, of SB LEAP–1B–73–0038, related to the pressure transducer.

(5) After accumulating 15 hours of electrical power on the PSS unit as required by paragraph (g)(1)(ii) or (g)(3) of this AD, before further flight, perform a check for the engine maintenance messages using the Accomplishment Instructions, paragraphs 5.A.(3)(b)*1* through *5,* of SB LEAP–1B–73–0038, related to the pressure transducer.

(6) If any engine maintenance messages are found by the checks required by paragraph (g)(1)(i), (2), (4), or (5) of this AD, before further flight, replace the PSS unit with a PSS unit eligible for installation.

(h) Definitions

(1) For the purpose of this AD, an ''in service'' engine is any of the following:

(i) An engine installed on an airplane that was delivered prior to November 18, 2020, that, as of the effective date of this AD, has completed the Operational Readiness Flight in accordance with paragraph (m) of FAA AD 2020–24–02 (85 FR 74560, November 20, 2020); or

(ii) An engine installed on an airplane delivered after November 18, 2020.

(2) For the purpose of this AD, hours of electrical power on the PSS unit is the total amount of time that voltage was applied to the PSS unit either on-wing or on a bench in segments of no less than 15 minutes. If the voltage-time is not available, use the run time of the engine on which the PSS unit is installed.

(3) For the purpose of this AD, a ''PSS unit eligible for installation'' is any of the following:

(i) A PSS unit that is cleared in accordance with the criteria in the Accomplishment Instructions, paragraph 5.B.(3), of SB LEAP–1B–73–0038; or

(ii) A PSS unit with an S/N not listed in Additional Information, Paragraph 6.A. Table 1 of SB LEAP–1B–73–0038.

(i) Installation Prohibition

After the effective date of this AD, do not install on any engine a PSS unit unless it is a PSS unit eligible for installation as defined in paragraph (h)(3) of this AD.

(j) Credit for Previous Actions

You may take credit for the actions required by paragraphs (g)(1)(ii) and (g)(2) through (6) of this AD if you performed these actions before the effective date of this AD using CFM SB LEAP–1B–73–00–0038–01A–930A–D, Issue 001, dated 2021–04–23.

(k) Special Flight Permit

A special flight permit may be issued in accordance with 14 CFR 21.197 and 21.199 to operate the airplane for up to 5 flight cycles prior to accomplishing paragraph (g)(3) of this AD provided engine maintenance messages are checked prior to each flight using the Accomplishment Instructions, paragraphs 5.A.(3)(b)*1-5,* of SB LEAP–1B 73–0038, and no engine maintenance messages listed in the Accomplishment Instructions, paragraph 5.A.(3)(b)*5,* of SB LEAP–1B–73–0038, are detected. For all other requirements, special flight permits are prohibited.

(l) Alternative Methods of Compliance (AMOCs)

(1) The Manager, ECO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in Related Information. You may email your request to: *ANE-AD-AMOC@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(m) Related Information

For more information about this AD, contact Mehdi Lamnyi, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7743; fax: (781) 238–7199; email: *Mehdi.Lamnyi@faa.gov.*

(n) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) CFM Service Bulletin (SB) LEAP–1B–73–00–0038–01A–930A–D, Issue 002–00, dated 2021–04–25, excluding FADEC Alliance SB LEAP–1B/73–012, Issue 001, dated 2021–04–23 (which is attached to this CFM SB).

(ii) [Reserved]

(3) For CFM International, S.A. service information identified in this AD, contact CFM International, S.A., Aviation Operations Center, 1 Neumann Way, M/D Room 285, Cincinnati, OH 45125; phone: (877) 432–3272; fax: (877) 432–3329; email: *aviation.fleetsupport@ge.com.*

(4) You may view this service information at FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (781) 238–7759.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email: *fedreg.legal@nara.gov,* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on April 28, 2021.

Gaetano A. Sciortino,

Deputy Director for Strategic Initiatives, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–09507 Filed 4–30–21; 4:15 pm]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–806]

Schedules of Controlled Substances: Placement of Four Specific Fentanyl-Related Substances in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration places four specified fentanyl-related substances permanently in schedule I of the Controlled Substances Act. These four specific substances fall within the definition of fentanyl-related substances set forth in the February 6, 2018, temporary scheduling order. Through the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act, which became law on February 6, 2020, Congress extended the temporary control of fentanyl-related substances until May 6, 2021. The regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who

handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle any of these four specified fentanyl-related substances will continue to be applicable permanently as a result of this action.

DATES: Effective date: May 4, 2021.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION: This final rule imposes permanent controls on four specified fentanyl-related substances, which will continue to be listed in schedule I of the Controlled Substances Act (CSA). These four fentanyl-related substances are:

- Ethyl (1-phenethylpiperidin-4-yl)(phenyl)carbamate (fentanyl carbamate);
- *N*-(2-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)acrylamide (*ortho*-fluoroacryl fentanyl);
- *N*-(2-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)isobutyramide (*ortho*-fluoroisobutyryl fentanyl); and
- *N*-(4-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)furan-2-carboxamide (*para*-fluoro furanyl fentanyl).

The schedule I listing of these four fentanyl-related substances includes their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible.

Legal Authority

The Controlled Substances Act (CSA) provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General (delegated to the Administrator of the Drug Enforcement Administration (DEA) pursuant to 28 CFR 0.100) on his own motion. 21 U.S.C. 811(a). This action is supported by, *inter alia,* a recommendation from the Assistant Secretary for Health of the Department of Health and Human Services (Assistant Secretary for HHS or Assistant Secretary) and an evaluation of all relevant data by DEA. This action continues the imposition of the regulatory controls and administrative, civil, and criminal sanctions of schedule I controlled substances on any person who handles (manufactures, distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) or proposes to handle fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl fentanyl.

Background

On February 6, 2018, pursuant to 21 U.S.C. 811(h)(1), DEA published a temporary scheduling order in the **Federal Register** (83 FR 5188) temporarily placing fentanyl-related substances, as defined in that order, in schedule I of the CSA based upon a finding that these substances pose an imminent hazard to the public safety. That temporary order was effective upon the date of publication. Pursuant to 21 U.S.C. 811(h)(2), the temporary control of fentanyl-related substances, a class of substances as defined in the order, as well as the four specific substances already covered by that order, was set to expire on February 6, 2020. However, as explained in DEA's April 10, 2020, correcting amendment (85 FR 20155), Congress overrode and extended that expiration date until May 6, 2021, by enacting the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act (Pub. L. 116–114, sec. 2, 134 Stat. 103) (Feb. 6, 2020).

On March 18, 2021 (86 FR 14707), DEA published a notice of proposed rulemaking (NPRM) to permanently control four specific fentanyl-related substances: fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl fentanyl in schedule I of the CSA. Specifically, DEA proposed to add these substances to the opiates list under 21 CFR 1308.11(b), and assign paragraph numbers 39, 62, 66, and 73 under paragraph (b) to Fentanyl carbamate, *ortho*-Fluoroacryl fentanyl, *ortho*-Fluoro isobutyryl fentanyl, and *para*-Fluoro furanyl fentanyl, respectively. Since the publication of this NPRM, DEA issued a correcting amendment which updated the numbering of all listed opiates in paragraph (b). See 86 FR 16667, March 31, 2021. As a result, this final rule assigns different paragraph numbers under paragraph (b), than originally proposed, to three of the four fentanyl-related substances (though the numbering for Fentanyl carbamate remains the same).

DEA and HHS Eight Factor Analyses

On March 2, 2021, HHS provided DEA with a scientific and medical evaluation and scheduling recommendation, prepared by the Food and Drug Administration (FDA), for fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl fentanyl and their salts. After considering the eight factors in 21 U.S.C. 811(c), each substance's abuse potential, lack of legitimate medical use in the United States, and lack of accepted safety for use under medical supervision pursuant to 21 U.S.C. 812(b), the Assistant Secretary recommended that these substances be placed in schedule I of the CSA. In response, DEA conducted its own eight-factor analysis of fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl fentanyl. Please note that both the DEA and HHS 8-Factor analyses and the Assistant Secretary's March 2, 2021, letter are available in their entirety under the tab ''Supporting Documents'' of the public docket for this action at *http://www.regulations.gov* under Docket Number ''DEA–806.''

Determination To Schedule Four Specific Fentanyl-Related Substances

After review of the available data including the scientific and medical evaluation and the scheduling recommendations from HHS, DEA published an NPRM entitled ''Schedules of Controlled Substances: Placement of Four Specific Fentanyl-Related Substances in Schedule I.'' 86 FR 14707, March 18, 2021. The NPRM provided an opportunity for interested persons to file a request for hearing in accordance with DEA regulations on or before April 19, 2021. No requests for such a hearing were received by DEA. The NPRM also provided an opportunity for interested persons to submit comments on the proposed rule on or before April 19, 2021.

Comments Received

DEA received 35 comments on the proposed rule to control fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl fentanyl in schedule 1 of the CSA. Submissions were from individual or anonymous commenters. Twenty-one commenters provided support for the rule. Three other commenters supported the proposal, but it is not clear whether they were referring to these specific four fentanyl-related substances or the class of fentanyl-related substances that was the subject of DEA's February 6, 2018, temporary scheduling order and that was extended until May 6, 2021 by legislation (Pub. L. 116–114, Sec. 2). Eleven other commenters did not state a position on the rule. Rather, these 11 commenters expressed adverse health concerns, including mortality associated with fentanyl and fentanyl-related

substances, and were mostly pleas to help save lives from grieving parents who had lost a child due to an ''accidental overdose of fentanyl'' or ''fentanyl poisoning.'' These 11 comments are not germane to this rulemaking. Therefore, DEA will not respond to these comments.

Support of the Proposed Rule

Comment. Twenty-one commenters supported controlling fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl fentanyl as schedule I controlled substances. These commenters indicated that permanent scheduling of these substances helps deter illicit manufacturing and trafficking of these substances. Further, commenters noted safety concerns with fentanyl, such as deaths, overdoses, addiction, and the involvement of fentanyl and fentanyl-related substances in the current public health crisis associated with the opioid abuse epidemic. Most commenters indicated that DEA needs to impose the permanent control on these substances to help curb addiction and opioid overdose. In addition to supporting control of these four substances, a commenter, who is a member of grief groups for parents who have lost a child due to an accidental overdose (particular drugs or substances not specified by the commenter), noted the fentanyl epidemic and growth of these groups. Specifically, this commenter stated that members have grown from about 4,000 to 12,000 during the ''pandemic''—which DEA interprets to mean, in context, the Coronavirus Disease 2019 (COVID–19) pandemic)—with no sign of decline.

DEA Response. DEA appreciates the support for this rulemaking.

Comment. Three commenters supported the proposal, but it is not clear whether they were referring to these specific four fentanyl-related substances or the class of fentanyl-related substances. Two of these commenters mentioned the dangers to health and safety from fentanyl, the illicit trafficking of fentanyl and fentanyl-related substances, and their desires that the temporary ban on the class of fentanyl-related substances—which they noted expires in May 2021—be made permanent. One of the two specifically requested that Congress ''pass the legislation'' to extend the temporary ban, and the other requested DEA's support in making the proposed temporary ban permanent. The third commenter did not mention the expiring legislation, and simply requested that efforts be continued to maintain the ban on fentanyl and fentanyl-related substances.

DEA Response. DEA agrees with the commenters on the importance that this temporary ban be extended or made permanent. However, as one of the three commenters correctly notes, for the scheduling of fentanyl-related substances to be made permanent by legislative action, Congress (rather than DEA) would have to take such action.

Scheduling Conclusion

After consideration of the relevant matter presented through public comments, the scientific and medical evaluation and accompanying recommendation of HHS, and after its own eight-factor evaluation, DEA finds that these facts and all other relevant data constitute substantial evidence of the potential for abuse of fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl fentanyl. DEA is therefore permanently scheduling these four specific fentanyl-related substances as controlled substances under the CSA.

Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA also outlines the findings required to place a drug or other substance in any particular schedule. 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Assistant Secretary and review of all other available data, the Acting Administrator, pursuant to 21 U.S.C. 811(a) and 812(b)(1), finds that:

(1) Fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl fentanyl have a high potential for abuse that is comparable to other schedule I substances such as acetyl fentanyl and furanyl fentanyl.

(2) Fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl fentanyl have no currently accepted medical use in treatment in the United States [1]; and

(3) There is a lack of accepted safety for use of fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl fentanyl under medical supervision. Based on these findings, the Acting Administrator concludes that fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl fentanyl, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible, warrant continued control in schedule I of the CSA. 21 U.S.C. 812(b)(1).

Requirements for Handling Fentanyl Carbamate, *Ortho*-Fluoroacryl Fentanyl, *Ortho*-Fluoro Isobutyryl Fentanyl, and *Para*-Fluoro Furanyl Fentanyl

Fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl fentanyl will continue [2] to be subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, dispensing, importation, exportation, research, and conduct of instructional activities involving the handling of controlled 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), or who desires to handle, fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl fentanyl 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.

2. *Security.* Fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl fentanyl are subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, and in accordance with 21 CFR 1301.71–1301.76. Non-practitioners handling fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl fentanyl also must comply with the employee

[1] Although there is no evidence suggesting that fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl fentanyl have a currently accepted medical use in treatment in the United States, it bears noting that a drug cannot be found to have such medical use unless DEA concludes that it satisfies a five-part test. Specifically, with respect to a drug that has not been approved by FDA, to have a currently accepted medical use in treatment in the United States, all of the following must be demonstrated:

i. The drug's chemistry must be known and reproducible;

ii. there must be adequate safety studies;

iii. there must be adequate and well-controlled studies proving efficacy;

iv. the drug must be accepted by qualified experts; and

v. the scientific evidence must be widely available.

57 FR 10499 (1992), *pet. for rev. denied, Alliance for Cannabis Therapeutics* v. *DEA,* 15 F.3d 1131, 1135 (D.C. Cir. 1994).

[2] Fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl fentanyl are covered by the February 6, 2018, temporary scheduling order, and are currently subject to schedule I controls on a temporary basis, pursuant to 21 U.S.C. 811(h). 83 FR 5188.

screening requirements of 21 CFR 1301.90–1301.93.

3. *Labeling and Packaging.* All labels and labeling for commercial containers of fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl fentanyl must be in compliance with 21 U.S.C. 825 and 958(e), and be in accordance with 21 CFR part 1302.

4. *Quota.* Only registered manufacturers are permitted to manufacture fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl fentanyl in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303.

5. *Inventory.* Any person registered with DEA to handle fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl fentanyl must have an initial inventory of all stocks of controlled substances (including these substances) on hand on the date the registrant first engages in the handling of controlled substances pursuant to 21 U.S.C. 827 and 958, 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 fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl fentanyl) on hand every two years pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

6. *Records and Reports.* Every DEA registrant is required to maintain records and submit reports with respect to fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl fentanyl, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1301.74(b) and (c) and parts 1304, 1312, and 1317.

7. *Order Forms.* Every DEA registrant who distributes fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl fentanyl must comply with the order form requirements, pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305.

8. *Importation and Exportation.* All importation and exportation of fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl fentanyl must be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

9. *Liability.* Any activity involving fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl fentanyl not authorized by, or in violation of, the CSA or its implementing regulations is unlawful, and could subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)

In accordance with 21 U.S.C. 811(a), this final scheduling action is subject to formal rulemaking procedures done ''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 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.

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 the distribution of power and responsibilities among the various levels of government.

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 Acting Administrator, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601–602, has reviewed this rule and by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities. On February 6, 2018, DEA published an order to temporarily place fentanyl-related substances, as defined in the order, in schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). DEA estimates that all entities handling or planning to handle fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl fentanyl have already established and implemented the systems and processes required to handle these substances which meet the definition of fentanyl-related substances.

There are currently 57 registrations authorized to handle the fentanyl-related substances as a class, which include fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl fentanyl, as well as a number of registered analytical labs that are authorized to handle schedule I controlled substances generally. These 57 registrations represent 51 entities, of which eight are small entities. Therefore, DEA estimates eight small entities are affected by this final rule.

A review of the 57 registrations indicates that all entities that currently handle fentanyl-related substances, including fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl fentanyl, also handle other schedule I controlled substances, and have established and implemented (or maintain) the systems and processes required to handle fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl fentanyl. Therefore, DEA anticipates that this final rule will impose minimal or no economic impact on any affected entities, and thus will not have a significant economic impact on any of the eight affected small entities. Therefore, DEA has concluded that this rule will not have a significant effect on a substantial number of small entities.

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 and certifies 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 $100,000,000 or more (adjusted annually for inflation) in any 1 year. . . .'' Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Congressional Review Act

This rule is not a ''major rule'' as defined in the Congressional Review Act (CRA), 5 U.S.C. 804. However, DEA is submitting the required reports to the Government Accountability Office, the House, and the Senate under the CRA.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. This action would 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.

Determination To Make Rule Effective Immediately

As indicated above, this rule finalizes the schedule I control status of four substances that has already been in effect for over three years. These four substances all fall within the definition of fentanyl-related substances set forth in the February 6, 2018, temporary scheduling order (83 FR 5188). Through the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act, which became law on February 6, 2020, Congress extended the temporary control of fentanyl-related substances until May 6, 2021. The February 2018 order was effective on the date of publication, and was based on findings by the then-Acting Administrator that the temporary scheduling of the fentanyl-related substances was necessary to avoid an imminent hazard to the public safety pursuant to 21 U.S.C. 811(h)(1). Because this rule finalizes the control status of four substances that has already been in effect for over three years, it does not alter the legal obligations of any person who handles these substances. Rather, it merely makes permanent the current scheduling status and corresponding legal obligations. Therefore, DEA is making the rule effective on the date of publication in the **Federal Register**, as any delay in the effective date is unnecessary and would be contrary to the public interest.

List of Subjects in 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. In § 1308.11:
■ a. Redesignate paragraphs (b)(67) through (86) as paragraphs (b)(71) through (90);
■ b. Redesignate paragraphs (b)(62) through (66) as paragraphs (b)(65) through (69);
■ c. Redesignate paragraphs (b)(60) and (61) as paragraphs (b)(62) and (63);
■ d. Redesignate paragraphs (b)(39) through (59) as paragraphs (b)(40) through (60); and
■ e. Add new paragraphs (b)(39), (61), (64), and (70).

The additions read as follows:

§ 1308.11 Schedule I.

* * * * *

(b) * * *

(39) Fentanyl carbamate (ethyl (1-phenethylpiperidin-4-yl)(phenyl)carbamate)	9851
* * * * *	
(61) *ortho*-Fluoroacryl fentanyl (*N*-(2-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)acrylamide)	9852
* * * * *	
(64) *ortho*-Fluoroisobutyryl fentanyl (*N*-(2-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)isobutyramide)	9853
* * * * *	
(70) *para*-Fluoro furanyl fentanyl (*N*-(4-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)furan-2-carboxamide)	9854

* * * * *

D. Christopher Evans,

Acting Administrator.

[FR Doc. 2021–09402 Filed 5–3–21; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF THE INTERIOR

Bureau of Safety and Environmental Enforcement

30 CFR Part 250

[Docket ID: BSEE–2021–0001; EEEE500000 21XE1700DX EX1SF0000.EAQ000]

RIN 1014–AA48

Oil and Gas and Sulfur Operations on the Outer Continental Shelf—Civil Penalty Inflation Adjustment

AGENCY: Bureau of Safety and Environmental Enforcement, Interior.

ACTION: Final rule.

SUMMARY: This final rule adjusts the level of the maximum daily civil monetary penalty contained in the Bureau of Safety and Environmental Enforcement (BSEE) regulations for violations of the Outer Continental Shelf Lands Act (OCSLA), in accordance with the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 and Office of Management and Budget (OMB) guidance. The civil penalty inflation adjustment, using a 1.01182 multiplier, accounts for one year of inflation based on the Consumer Price Index (CPI–U) spanning from October 2019 to October 2020.

DATES: This rule is effective May 4, 2021.

FOR FURTHER INFORMATION CONTACT: Janine Marie Tobias, Safety and Enforcement Division, Bureau of Safety and Environmental Enforcement, (202) 208–4657 or by email: *regs@bsee.gov*.

SUPPLEMENTARY INFORMATION:

I. Background and Legal Authority

The OCSLA, at 43 U.S.C. 1350(b)(1), directs the Secretary of the Interior (Secretary) to adjust the OCSLA maximum daily civil penalty amount at least once every three years to reflect any increase in the Consumer Price Index (CPI) to account for inflation. On November 2, 2015, the President signed into law the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of Pub. L. 114–74) (FCPIA of 2015). The FCPIA of 2015 required Federal agencies to adjust the level of civil monetary penalties found in their regulations with an initial ''catch-up'' adjustment through rulemaking, if warranted, and then to make subsequent annual adjustments for inflation. The purpose of these adjustments is to maintain the deterrent effect of civil penalties and to further the policy goals of the underlying statutes. Agencies were required to publish the first annual inflation adjustments in the **Federal Register** by no later than January 15, 2017 and must publish recurring annual inflation adjustments by no later than January 15 of each subsequent year.

BSEE last updated the maximum daily civil penalty amounts in BSEE's regulations for OCSLA violations by a final rule published and effective on March 4, 2020. (*See* 85 FR 12733). Consistent with OMB guidance, BSEE's final rule implemented the inflation

SUMMARY SHEET

SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

May 13, 2021

(X) ACTION/DECISION
( ) INFORMATION

I. TITLE: Request for Placement of Serdexmethylphenidate in Schedule IV for Controlled Substances in South Carolina

II. SUBJECT: Placement of Serdexmethylphenidate in Schedule IV for Controlled Substances

III. 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 IV substances are listed in Section 44-53-250 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 Code 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.

On March 2, 2021, the United States Food and Drug Administration ("FDA") approved a new drug application for AZSTARYS capsules for oral use, a combination drug product containing serdexmethylphenidate chloride and dexmethylphenidate hydrochloride, for the treatment of Attention Deficit Hyperactivity Disorder in patients six years of age or older. The Department of Health and Human Services ("HHS") provided the Drug Enforcement Administration ("DEA") with a scheduling recommendation to place serdexmethylphenidate and its salts in schedule IV of the Controlled Substances Act ("CSA"). In accordance with the CSA, as amended by the Improving Regulatory Transparency for New

Medical Therapies Act, Drug Enforcement Administration is hereby issuing an interim final rule placing serdexmethylphenidate, including its salts, isomers, and salts of isomers, in schedule IV of the Controlled Substances Act, thereby facilitating the commercial distribution of AZSTARYS as a lawful controlled substance, effective May 7, 2021. *Federal Register*, Volume 86, Number 87, pages 24487-24492; www.govinfo.gov/content/pkg/FR-2021-05-07/pdf/2021-09738.pdf.

IV. ANALYSIS:

Serdexmethylphenidate chloride (3-[[[(1S)-1-carboxy-2-hydroxyethyl]- amino]carbonyl]-1-[[[[(2R)-2-[(1R)-2-methoxy-2-oxo-1-phenylethyl]-1- piperidinyl]carbonyl]oxy]methyl]pyridinium chloride) is a new molecular entity ("NME") without central nervous system ("CNS") activity. According to HHS, because serdexmethylphenidate chloride ("SDX") is metabolized in the large intestine to dexmethylphenidate ("d-MPH"), a schedule II drug and a CNS stimulant, SDX is a prodrug of d-MPH.

On March 2, 2020, Commave Therapeutics S.A. submitted a New Drug Application ("NDA") to FDA, in partnership with KemPharm, Inc., for a combination drug product containing SDX and dMPH, both as chloride salts. On March 2, 2021, DEA received notification that FDA, on the same date, approved this NDA for AZSTARYS capsules for oral use, a combination drug product containing dexmethylphenidate hydrochloride and serdexmethylphenidate chloride, under section 505(c) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients six years of age or older. According to the FDA-approved product label, AZSTARYS contains 28mg/6mg, 42mg/9mg, or 56mg/12 mg of serdexmethylphenidate chloride/dexmethylphenidate hydrochloride (equivalent to 26.1 mg/5.2 mg, 39.2 mg/7.8 mg, and 52.3 mg/10.4 mg of serdexmethylphenidate/dexmethylphenidate, respectively).

On March 2, 2021, DEA received from HHS a scientific and medical evaluation entitled "Basis for the Recommendation to Control Serdexmethylphenidate and its Salts in schedule IV of the Controlled Substances Act" and a scheduling recommendation. Pursuant to 21 U.S.C. 811(b) and (c), this document contained an eight-factor analysis of the abuse potential, legitimate medical use, and dependence liability of serdexmethylphenidate, along with HHS's recommendation to control serdexmethylphenidate and its salts under schedule IV of the CSA.

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 pursuant to 21 U.S.C. 811(c). DEA concluded that SDX meets the 21 U.S.C. 812(b)(4) criteria for placement in schedule IV 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)(4), finds that:

1) Actual or Relative Potential for Abuse

   Serdexmethylphenidate has a low potential for abuse relative to the drugs or other substances in schedule III.

   Receptor binding studies demonstrate that SDX does not bind to dopamine and norepinephrine transporters and other receptors typically associated with abuse potential. Upon oral administration, SDX is metabolized to d-MPH, a schedule II drug, in the large intestine and showed an abuse potential lower than that of d-MPH, but similar to that of phentermine, a schedule IV drug. Results

from an observational animal behavioral study demonstrate that lower doses of SDX (12 and 25 mg/kg) did not produce any CNS effects and only the highest dose of SDX (50 mg/kg) increased CNS activity. In a HAP study, SDX at the therapeutic and supra-therapeutic doses produced positive subjective responses such as Drug Liking and Drug High similar to those of phentermine (schedule IV) and significantly higher than placebo. Furthermore, data from other clinical studies show that SDX produced abuse-related adverse events, namely euphoric mood and hypervigilance. Because SDX is similar to phentermine (schedule IV) in its abuse potential, SDX has a lower potential for abuse relative to the drugs or other substances in schedule III.

2) Accepted Medical Use in the United States.

Serdexmethylphenidate has a currently accepted medical use in the United States. On March 2, 2021, FDA approved the NDA for AZSTARYS capsules, a combination drug product containing d-MPH and SDX for the treatment of ADHD in patients six years of age or older. Thus, SDX has a currently accepted medical use for treatment in the United States.

3) Physical or Psychological Dependence

Serdexmethylphenidate may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

There were no animal studies performed to evaluate physical dependence of SDX. In clinical studies, SDX demonstrated no indication of physical dependence after abrupt discontinuation of the drug. In a HAP study, SDX increased drug-liking scores that were significantly greater than that of placebo and were similar to that of phentermine. In addition, SDX produced euphoria-related adverse events in a HAP study. These data collectively suggest that SDX abuse may lead to limited psychological dependence relative to drugs in schedule III and largely similar to that of schedule IV stimulants.

IV. RECOMMENDATION:

Pursuant to South Carolina Code Section 44-53-160(C), the Department recommends the addition of serdexmethylphenidate, including its salts, isomers, and salts of isomers, in Schedule IV for controlled substances in South Carolina and the amendment of Section 44-53-250 of the South Carolina Code of Laws to include:

( ) Serdexmethylphenidate.

Submitted by:

Lisa Thomson
Bureau Director
Bureau of Drug Control

Gwen Thompson
Deputy Director
Healthcare Quality

Attachment:
Federal Register, Volume 86, Number 87, May 7, 2021

that authority because it addresses an unsafe condition that is likely to exist or develop on helicopters identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect 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.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Will not affect intrastate aviation in Alaska, and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

2021–10–08 Bell Textron Canada Limited (Type Certificate Previously Held by Bell Helicopter Textron Canada Limited): Amendment 39–21541 Docket No. FAA–2006–25084; Project Identifier 2005–SW–38–AD.

(a) Effective Date

This airworthiness directive (AD) is effective June 11, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Bell Textron Canada Limited (type certificate previously held by Bell Helicopter Textron Canada Limited) Model 206L, 206L–1, 206L–3, and 206L–4 helicopters, certificated in any category, with a low fuel level detector switch unit (switch unit) part number (P/N) 206–063–613–003:

(1) With a switch unit serial number (S/N) 1413, 1414, 1415, 1424, 1428, 1430, 1432, or 1433 installed, or

(2) With a missing or illegible switch unit S/N or if the S/N cannot be determined, installed.

Note 1 to paragraph (c): Helicopters with a 206L–1+ designation are Model 206L–1 helicopters. Helicopters with a 206L–3+ designation are Model 206L–3 helicopters.

Note 2 to paragraph (c): The switch unit is located on the aft fuel boost pump assembly. The P/N and S/N for the switch unit could be on the outside face of the attachment flange, in the cross hatched area of the switch unit.

(d) Subject

Joint Aircraft Service Component (JASC) Code: 2842, Fuel Quantity Sensor.

(e) Unsafe Condition

This AD was prompted by a manufacturing flaw that could cause a switch unit to hang in the high position and fail to indicate a low fuel condition. The FAA is issuing this AD to prevent failure of the switch unit to indicate a low fuel condition that could lead to fuel exhaustion and which if not addressed, could result in a subsequent forced landing.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Required Actions

(1) For a switch unit identified in paragraph (c)(1) of this AD, on or before the next 100-hour time-in-service inspection after the effective date of this AD, remove the switch unit from service.

(2) For a switch unit identified in paragraph (c)(2) of this AD, on or before the next 100-hour time-in-service inspection after the effective date of this AD:

(i) Determine the color of the switch unit mounting flange. If the mounting flange color is any color other than red, determine the purchase date. If the purchase date of the switch unit is between April 19 and July 26, 2004, or cannot be determined, do an operational test.

(ii) If the switch unit fails the operational test, before further flight, remove the switch unit from service.

(3) As of the effective date of this AD, do not install a switch unit identified in paragraph (c)(1) of this AD on any helicopter.

(4) As of the effective date of this AD, do not install a switch unit identified in paragraph (c)(2) of this AD on any helicopter unless the actions in paragraphs (g)(2)(i) and (ii) of this AD have been accomplished.

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Validation Branch, send it to the attention of the person identified in paragraph (i)(1) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(i) Related Information

(1) For more information about this AD, contact Hal Jensen, Aerospace Engineer, Operational Safety Branch, FAA, 950 L'Enfant Plaza N SW, Washington, DC 20024; telephone (202) 267–9167; email *hal.jensen@faa.gov.*

(2) Bell Helicopter Textron Alert Service Bulletin No. 206L–04–132, Revision A, dated October 4, 2004, which is not incorporated by reference, contains additional information about the subject of this AD. For service information identified in this AD, contact Bell Textron Canada Limited, 12,800 Rue de l'Avenir, Mirabel, Quebec J7J1R4; telephone (450) 437–2862 or (800) 363–8023; fax (450) 433–0272; or at *https://www.bellcustomer.com.* You may view this referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

(3) The subject of this AD is addressed in Transport Canada AD CF–2004–24, dated November 24, 2004. You may view the Transport Canada AD on the internet at *https://www.regulations.gov* in Docket No. FAA–2006–25084.

(j) Material Incorporated by Reference

None.

Issued on April 28, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–09278 Filed 5–6–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–808]

Schedules of Controlled Substances: Placement of Serdexmethylphenidate in Schedule IV

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Interim final rule with request for comments.

SUMMARY: On March 2, 2021, the United States Food and Drug Administration approved a new drug application for AZSTARYS capsules for oral use, a combination drug product containing serdexmethylphenidate chloride and

dexmethylphenidate hydrochloride, for the treatment of Attention Deficit Hyperactivity Disorder in patients six years of age or older. The Department of Health and Human Services provided the Drug Enforcement Administration with a scheduling recommendation to place serdexmethylphenidate and its salts in schedule IV of the Controlled Substances Act. In accordance with the Controlled Substances Act, as amended by the Improving Regulatory Transparency for New Medical Therapies Act, Drug Enforcement Administration is hereby issuing an interim final rule placing serdexmethylphenidate, including its salts, isomers, and salts of isomers, in schedule IV of the Controlled Substances Act, thereby facilitating the commercial distribution of AZSTARYS as a lawful controlled substance.

DATES: The effective date of this rulemaking is May 7, 2021. 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 June 7, 2021. 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, together with a written statement of position on the matters of fact and law asserted in the hearing, must be received on or before June 7, 2021.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–808'' on all correspondence, including any attachments.

• *Electronic comments:* The Drug Enforcement Administration (DEA) 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/OALJ, 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: Terrence L. Boos, Drug & Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION: This interim final rule refers to the single entity, serdexmethylphenidate. The chloride salt of serdexmethylphenidate is chemically known as 3-[[[(1*S*)-1-carboxy-2-hydroxyethyl]-amino]carbonyl]-1-[[[[(2*R*)-2-[(1*R*)-2-methoxy-2-oxo-1-phenylethyl]-1-piperidinyl] carbonyl]oxy]methyl]pyridinium chloride. This rule places serdexmethylphenidate, including its salts, isomers, and salts of isomers, in schedule IV of the Controlled Substances Act (CSA), thereby facilitating the commercial distribution of AZSTARYS as a controlled substance.

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 are available at *http://www.regulations.gov* for easy reference.

Request for Hearing or Waiver of Participation in a Hearing

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. Such requests or notices must conform to the requirements of 21 CFR 1308.44(a) or (b), and 1316.47 or 1316.48, as applicable, and include a statement of the person's interests in the proceeding and the objections or issues, if any, concerning which the person desires to be heard. Any waiver must conform to the requirements of 21 CFR 1308.44(c) and may include a written statement regarding the interested

person's position on the matters of fact and law involved in any hearing.

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 CSA, as amended in 2015 by the Improving Regulatory Transparency for New Medical Therapies Act (section 2(b) of Pub. L. 114–89), DEA is required to commence an expedited scheduling action with respect to certain new drugs approved by the 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 HHS has advised DEA that a New Drug Application (NDA) has been submitted for a drug that has a stimulant, depressant, or hallucinogenic effect on the central nervous system (CNS), and that it appears that such drug has an abuse potential; and (2) the Secretary of HHS 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 interim final rule controlling the drug within 90 days.

Subsection (j)(2) states that the 90-day timeframe starts the later of (1) the date DEA receives HHS' scientific and medical evaluation/scheduling recommendation, or (2) the date DEA receives notice of the NDA approval by HHS. Subsection (j)(3) specifies that the rulemaking shall become immediately effective as an interim final rule without requiring DEA to demonstrate good cause therefore. 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)(3) further provides that the interim final rule 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 21 U.S.C. 811(b) through (d) and 812(b).

Serdexmethylphenidate chloride (3-[[[(1*S*)-1-carboxy-2-hydroxyethyl]-amino]carbonyl]-1-[[[[(2*R*)-2-[(1*R*)-2-methoxy-2-oxo-1-phenylethyl]-1-piperidinyl]carbonyl]oxy]methyl] pyridinium chloride) is a new molecular entity (NME) without CNS activity. However, according to HHS, because serdexmethylphenidate chloride (SDX) is metabolized in the large intestine to dexmethylphenidate (*d*-MPH), a schedule II drug and a CNS stimulant, SDX is a prodrug of *d*-MPH.

On March 2, 2020, Commave Therapeutics S.A. submitted an NDA to FDA, in partnership with KemPharm, Inc., for a combination drug product containing SDX and *d*-MPH, both as chloride salts. On March 2, 2021, DEA received notification that FDA, on the same date, approved this NDA for AZSTARYS capsules for oral use, a combination drug product containing dexmethylphenidate hydrochloride and serdexmethylphenidate chloride, under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FDCA), for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients six years of age or older. According to the FDA-approved product label, AZSTARYS contains 28 mg/6 mg, 42 mg/9 mg, or 56 mg/12 mg of serdexmethylphenidate chloride/dexmethylphenidate hydrochloride (equivalent to 26.1 mg/5.2 mg, 39.2 mg/7.8 mg, and 52.3 mg/10.4 mg of serdexmethylphenidate/dexmethylphenidate, respectively).[2]

The 90-day time frame, as stipulated to in subsection 811(j)(2) and discussed above, was triggered on March 2, 2021. Therefore, DEA must issue an interim final rule controlling serdexmethylphenidate on or before May 31, 2021.

Determination To Schedule Serdexmethylphenidate

On March 2, 2021, DEA received from HHS a scientific and medical evaluation entitled ''Basis for the Recommendation to Control Serdexmethylphenidate and its Salts in schedule IV of the Controlled Substances Act'' and a scheduling recommendation. Pursuant to 21 U.S.C. 811(b) and (c), this document contained an eight-factor analysis of the abuse potential, legitimate medical use, and dependence liability of serdexmethylphenidate, along with HHS's recommendation to control serdexmethylphenidate and its salts under schedule IV of the CSA.

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 pursuant to 21 U.S.C. 811(c). DEA concluded that SDX meets the 21 U.S.C. 812(b)(4) criteria for placement in schedule IV of the CSA.

Pursuant to subsection 811(j), and based on HHS' scheduling recommendation, the approval of the NDA by HHS/FDA, and DEA's determination, DEA is issuing this interim final rule to schedule SDX as a schedule IV 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 DEA and HHS analyses are available in their entirety under ''Supporting Documents'' in the public docket for this interim final rule at *http://www.regulations.gov,* under Docket Number ''DEA–808.'' 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

SDX is an NME that has not been marketed in the United States or any country. Thus, evidence regarding its diversion and actual abuse is lacking. SDX only recently became 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 SDX in the National Forensic Laboratory Information System (NFLIS),[3] which collects drug cases submitted to and analyzed by state and local forensic laboratories.

As stated by HHS, clinical studies show that SDX, when taken by the oral route, produces effects that are similar to other stimulant drugs in schedule IV, such as phentermine. The pharmacological mechanism of action of SDX is based on its prodrug characteristics, as it must be metabolized to *d*-MPH to exert its effects. In clinical studies, SDX demonstrated a lower potential for

[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] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/212994s000lbl.pdf.*

[3] 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% 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 March 4, 2021.

abuse when compared to *d*-MPH and similar potential for abuse when compared to phentermine. This evidence demonstrates that SDX is related in action and effect to the schedule IV substance phentermine, and can therefore be expected to have a similar potential for abuse.

2. Scientific Evidence of Its Pharmacological Effects, if Known

SDX itself has no CNS activity and must be metabolized to *d*-MPH to exert its effect. As HHS notes, *in vitro* binding studies demonstrated that SDX does not interact with dopamine and norepinephrine transporters, which are the sites of action for *d*-MPH, a schedule II drug. Moreover, SDX does not bind to any other receptor systems that are associated with drugs of abuse.

In a human abuse potential (HAP) study, therapeutic and supratherapeutic doses of SDX administered orally produced positive subjective responses such as Drug Liking and Drug High similar to those of phentermine and higher than placebo. In addition, abuse-related adverse events such as euphoric mood and hypervigilance occurred less frequently in SDX-treated subjects than in those treated with *d*-MPH. However, SDX-treated subjects reported more abuse-related adverse events than those treated with placebo. As concluded by HHS, results from preclinical and clinical studies indicate that SDX has abuse potential similar to phentermine, a schedule IV substance.

3. The State of Current Scientific Knowledge Regarding the Drug or Other Substance

SDX is an NME. It is chemically known as 3-[[[(1*S*)-1-carboxy-2-hydroxyethyl]-amino]carbonyl]-1-[[[[(2*R*)-2-[(1*R*)-2-methoxy-2-oxo-1-phenylethyl]-1-piperidinyl] carbonyl]oxy]methyl]pyridinium chloride. It is a white to off-white crystalline solid that is freely soluble in water at pH that was tested up to 6.8. On March 2, 2021, FDA approved the NDA for AZSTARYS, a combination drug product containing *d*-MPH and SDX for the treatment of ADHD in patients six years of age or older. Thus, SDX has an accepted medical use in the United States. SDX will be marketed in combination with *d*-MPH (SDX/*d*-MPH) as immediate-release capsules in three strengths of 28 mg/6 mg, 42 mg/9 mg, and 56 mg/12 mg.

4. Its History and Current Pattern of Abuse

There is no information on the history and current pattern of abuse for SDX, since it has not been marketed, legally or illegally, in the United States. HHS notes that SDX produces abuse-related signals, such as euphoric mood and hypervigilance, and abuse potential similar to that of schedule IV controlled substance phentermine. In March 2021, DEA searched the NFLIS database for SDX encounters. Consistent with the fact that SDX is an NME, this database had no records of encounters of SDX by law enforcement.

5. The Scope, Duration, and Significance of Abuse

SDX is not marketed in the United States, legally or illegally. Thus, information on the scope, duration, and significance of abuse for SDX is lacking. However, as stated by HHS, data from animal and human studies indicate that SDX has abuse potential similar to phentermine. Therefore, upon marketing, SDX scope of abuse is expected to be similar to phentermine.

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 preclinical and clinical studies showed that SDX has abuse potential similar to that of the schedule IV stimulant phentermine. Therefore, upon availability for marketing, SDX is likely to pose a public health risk to a degree similar to schedule IV stimulants, such as phentermine.

7. Its Psychic or Physiological Dependence Liability

As HHS notes, no animal studies were done to test physical dependence liability of SDX. A hallmark of physical dependence are withdrawal symptoms resulting from drug discontinuation. In clinical studies, there was no adverse events indicative of withdrawal from discontinuation of the SDX/*d*-MPH combination treatment.

SDX produced positive subjective responses to ratings of Drug Liking and Drug High in a HAP study. The responses were significantly higher than the placebo and similar to phentermine, a schedule IV stimulant. HHS concluded that SDX can produce psychic dependence to a similar extent as phentermine.

8. Whether the Substance Is an Immediate Precursor of a Substance Already Controlled Under the CSA

SDX is not an immediate precursor of any controlled substance, as defined by 21 U.S.C. 802(23).

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

Determination of Appropriate Schedule

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)(4), finds that:

1. *Serdexmethylphenidate has a low potential for abuse relative to the drugs or other substances in schedule III.*

Receptor binding studies demonstrate that SDX does not bind to dopamine and norepinephrine transporters and other receptors typically associated with abuse potential. Upon oral administration, SDX is metabolized to *d*-MPH, a schedule II drug, in the large intestine and showed an abuse potential lower than that of *d*-MPH, but similar to that of phentermine, a schedule IV drug. Results from an observational animal behavioral study demonstrate that lower doses of SDX (12 and 25 mg/kg) did not produce any CNS effects and only the highest dose of SDX (50 mg/kg) increased CNS activity. In a HAP study, SDX at the therapeutic and supra-therapeutic doses produced positive subjective responses such as Drug Liking and Drug High similar to those of phentermine (schedule IV) and significantly higher than placebo. Furthermore, data from other clinical studies show that SDX produced abuse-related adverse events, namely euphoric mood and hypervigilance. Because SDX is similar to phentermine (schedule IV) in its abuse potential, SDX has a lower potential for abuse relative to the drugs or other substances in schedule III.

2. *Serdexmethylphenidate has a currently accepted medical use in the United States.*

On March 2, 2021, FDA approved the NDA for AZSTARYS capsules, a combination drug product containing *d*-MPH and SDX for the treatment of ADHD in patients six years of age or older. Thus, SDX has a currently accepted medical use for treatment in the United States.

3. *Serdexmethylphenidate may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.*

There were no animal studies performed to evaluate physical dependence of SDX. In clinical studies,

SDX demonstrated no indication of physical dependence after abrupt discontinuation of the drug. In a HAP study, SDX increased drug-liking scores that were significantly greater than that of placebo and were similar to that of phentermine. In addition, SDX produced euphoria-related adverse events in a HAP study. These data collectively suggest that SDX abuse may lead to limited psychological dependence relative to drugs in schedule III and largely similar to that of schedule IV stimulants.

Based on these findings, the Acting Administrator of DEA concludes that SDX warrants control in schedule IV of the CSA. 21 U.S.C. 812(b)(4).

Requirements for Handling Serdexmethylphenidate

Serdexmethylphenidate is subject to the CSA's schedule IV 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 IV 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), or who desires to handle, serdexmethylphenidate, 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 serdexmethylphenidate and is not registered with DEA must submit an application for registration and may not continue to handle serdexmethylphenidate unless DEA has approved that application for registration, pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312. These registration requirements, however, are not applicable to patients (end users) who possess serdexmethylphenidate pursuant to a lawful prescription.

2. *Disposal of stocks.* Any person who obtains a schedule IV registration to handle serdexmethylphenidate but who subsequently does not desire or is not able to maintain such registration must surrender all quantities of serdexmethylphenidate or may transfer all quantities of serdexmethylphenidate to a person registered with DEA in accordance with 21 CFR part 1317, in additional to all other applicable Federal, state, local, and tribal laws.

3. *Security.* Serdexmethylphenidate is subject to schedule III–V security requirements for DEA registrants and it must be handled and stored in accordance with 21 CFR 1301.71–1301.77. Non-practitioners handling serdexmethylphenidate must also comply with the employee screening requirements of 21 CFR 1301.90–1301.93. These requirements, however, are not applicable to patients (end users) who possess serdexmethylphenidate pursuant to a lawful prescription.

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

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

Any person who becomes registered with DEA to handle serdexmethylphenidate must take an initial inventory of all stocks of controlled substances (including serdexmethylphenidate) 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 serdexmethylphenidate) 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. These requirements, however, are not applicable to patients (end users) who possess serdexmethylphenidate pursuant to a lawful prescription.

6. *Records and Reports.* DEA registrants must maintain records and submit reports for serdexmethylphenidate, pursuant to 21 U.S.C. 827, 832(a), and 958(e), and in accordance with 21 CFR 1301.74(b) and (c) and parts 1304, 1312, and 1317.

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

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

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

10. *Liability.* Any activity involving serdexmethylphenidate 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

Section 553 of the APA (5 U.S.C. 553) generally requires notice and comment for rulemakings. However, 21 U.S.C. 811(j) provides that in cases where a certain new drug is (1) approved by HHS, under section 505(c) of the FDCA and (2) HHS recommends control in CSA schedule II–V, DEA shall issue an interim final rule scheduling the drug within 90 days. As stated in the legal authority section, the 90-day time frame is the later of: (1) The date DEA receives HHS's scientific and medical evaluation/scheduling recommendation, or (2) the date DEA receives notice of the NDA approval by HHS. Additionally, subsection (j) specifies that the rulemaking shall become immediately effective as an interim final rule without requiring DEA to demonstrate good cause.

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)

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.

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.

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. As noted in the above discussion regarding the applicability of the APA, DEA is not required to publish a general notice of proposed rulemaking. Consequently, the RFA does not apply to this interim final rule.

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 $100,000,000 or more (adjusted annually for inflation) in any 1 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 would 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. However, pursuant to the CRA, DEA is submitting a copy of this interim final rule to both Houses of Congress and to the Comptroller General.

List of Subjects in 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 part 1308 continues to read as follows:

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

■ 2. In § 1308.14:
■ a. Redesignate paragraphs (f)(11) through (13) as (f)(12) through (14); and
■ b. Add new paragraph (f)(11).
The addition reads as follows:

§ 1308.14 Schedule IV.

* * * * *

(f) * * *

(11) Serdexmethylphenidate 1729

* * * * *

D. Christopher Evans,

Acting Administrator.

[FR Doc. 2021–09738 Filed 5–6–21; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2021–0215]

RIN 1625–AA08

Special Local Regulation; Clinch River, Oak Ridge, TN

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard establishes a temporary special local regulation for all navigable waters on the Clinch River from mile marker (MM) 48.5 to MM 52.0 during the U.S. Rowing Southeast Youth Championship. This special local regulation prohibits non-participant persons and vessels from entering, transiting through, anchoring in, or remaining within the race area and prohibits vessels from transiting at speeds that cause wake within the spectator area unless authorized by Captain of the Port Sector Ohio Valley or a designated representative.

DATES: This rule is effective from 6 a.m. until 6 p.m. from May 8, 2021, to May 9, 2021.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2021–0215 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Petty Officer First Class Nicholas Jones, Marine Safety Detachment Nashville, U.S. Coast Guard; telephone 615–736–5421, email *Nicholas.J.Jones@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. We must establish this temporary safety zone by May 8, 2021 and lack sufficient time to provide a reasonable comment period and then consider those comments before issuing the rule.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be contrary to the public

Date: May 13, 2021

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

From: Healthcare Quality

Re: Public Hearing for Notice of Final Regulation Amending R.61-63, *Radioactive Materials (Title A)*, Document No. 5036

I. Introduction

Healthcare Quality proposes the attached Notice of Final Regulation amending R.61-63, *Radioactive Materials (Title A)*, for publication in the May 28, 2021, *South Carolina State Register* ("*State Register*"). Legal authority resides in S.C. Code Section 13-7-40, which designates the Department as the responsible agency for the control and regulation of radiation sources. The Administrative Procedures Act, S.C. Code Section 1-23-120(H)(1), exempts these amendments from General Assembly review, as they are for compliance with federal law as required to maintain South Carolina's federal compatibility with the United States Nuclear Regulatory Commission ("NRC") as an Agreement State. The amendments will take legal effect as of the May 28, 2021, publication in the *State Register*.

II. Facts

1. The Department proposes amending R.61-63 to incorporate federal law as required to maintain South Carolina's federal compatibility with the United States Nuclear Regulatory Commission ("NRC") as an Agreement State.

2. The Department had a Notice of Drafting published in the October 23, 2020, *State Register*.

3. Healthcare Quality held a stakeholder meeting November 5, 2020. Two stakeholders attended the meeting. No public comments were given.

4. Appropriate Department staff conducted an internal review of the proposed amendments on December 16, 2020.

5. Upon receiving approval during the February 11, 2021, Board meeting, the Department had a Notice of Proposed Regulation published in the February 26, 2021, *State Register*. The Department received no public comments by the March 29, 2021 close of the public comment period.

6. Healthcare Quality held another stakeholder meeting March 18, 2021. Two stakeholders attended the meeting. No public comments were given.

7. Department staff provided the proposed amendments to the state Technical Advisory Radiation Control Council (TARCC) for review on December 9, 2020.

III. Request for Approval

Healthcare Quality respectfully requests the Board to find need and reasonableness of the attached proposed amendments of R.61-63, *Radioactive Materials (Title A)*, for legal effect as of the May 28, 2021, publication in the *State Register*.

Gwendolyn C. Thompson

Gwendolyn Thompson
Deputy Director
Healthcare Quality

Attachments:
A. Notice of Final Regulation

ATTACHMENT A

STATE REGISTER NOTICE OF FINAL REGULATION
FOR R. 61-63, *Radioactive Materials (Title A)*

May 13, 2021

Document No. 5036
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Sections 13-7-40 et seq.

61-63. Radioactive Materials (Title A).

Synopsis:

Pursuant to S.C. Code Sections 13-7-40 et seq., the Department of Health and Environmental Control ("Department") is responsible for the control and regulation of radiation sources, including disposal, use, reports, storage, and inspections relating to various uses of radioactive materials. The Department amends R.61-63 to incorporate federal law as required to maintain South Carolina's status with the United States Nuclear Regulatory Commission ("NRC") as an Agreement State.

The Administrative Procedures Act, S.C. Code Section 1-23-120(H)(1), exempted these amendments from General Assembly review, as the Department promulgates these amendments for compliance with federal law.

The Department had a Notice of Drafting published in the October 23, 2020, *South Carolina State Register*.

Instructions: Amend R.61-63 pursuant to each instruction provided with the text of the amendments below.

Text:

~~Indicates Matter Stricken~~
Indicates New Matter

61-63. Radioactive Materials (Title A).

(Statutory Authority: Section 13-7-40 et seq., as amended, of the 1976 Code, namely the Atomic Energy and Radiation Control Act)

Amend the following Table of Contents sections to read:

SUBPART B General Administrative Requirements

RHA
4.13 Authority and Responsibilities for the Radiation Protection Program
4.14 Radiation Protection Program Changes
4.15 Supervision
4.17 Written Directives
4.18 Procedures for Administrations Requiring a Written Directive
4.19 Suppliers for Sealed Sources or Devices for Medical Use

SUBPART L Records

RHA

4.111 Records of Periodic Spot-Checks for Teletherapy Units
4.112 Records of Periodic Spot-Checks for Remote Afterloader Units
4.113 Records of Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units
4.114 Records of Additional Technical Requirements for Mobile Remote Afterloader Units
4.115 Records of Surveys of Therapeutic Treatment Units
4.116 Records of ~~5-Year Inspection~~Full-inspection Servicing for Teletherapy and Gamma Stereotactic Radiosurgery Units

SUBPART M Reports

RHA
4.117 Report and Notification of a Medical Event
4.118 Report and Notification of a Dose to an Embryo/Fetus or a Nursing Child
4.119 Report of a Leaking Source
4.120 Report and Notification for an Eluate Exceeding Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentrations

Amend 2.7.5.1.4 to read:

2.7.5.1.4 The applicant ~~satisfies~~commits to the following labeling requirements:

Amend 2.7.5.2.5.1 to read:

2.7.5.2.5.1 A copy of each individual's certification by a specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State as specified in ~~Part 4 of this Regulation with the written attestation signed by a preceptor as required by Part 4 of this Regulation~~RHA 4.22.1; or

Amend 2.7.5.4 to read:

2.7.5.4 A licensee shall satisfy the labeling requirements in paragraph 2.7.5.1.4 of this section.

2.7.5.~~4~~5 Nothing in this section relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

Amend 2.10.8 to read:

2.10.8 Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with RHA 4.38. The licensee shall record the results of each test and retain each record for 3 years after the record is made. The licensee shall report the results of any test that exceeds the permissible concentration listed in 4.38.1 of this chapter at the time of generator elution, in accordance with RHA 4.120 of this chapter.

Add 2.10.10:

2.10.10 Conditions of licenses.

2.10.10.1 Each license shall contain and be subject to the following conditions:

2.10.10.1.1 [Reserved]

2.10.10.1.2 No right to the special nuclear material shall be conferred by the license except as defined by the license;

2.10.10.1.3 Neither the license nor any right under the license shall be assigned or otherwise transferred in violation of the provisions of the Act;

2.10.10.1.4 [Reserved]

2.10.10.1.5 [Reserved]

2.10.10.1.6 [Reserved]

2.10.10.1.7 [Reserved]

2.10.10.1.8 The license shall be subject to and the licensee shall observe, all applicable rules, regulations, and orders of the Department.

2.10.10.1.9 Notification of Bankruptcy.

2.10.10.1.9.1 Each licensee shall notify the Department, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

2.10.10.1.9.1.1 The licensee;

2.10.10.1.9.1.2 An entity (as that term is defined in 11 U.S.C. 101(14)) controlling the licensee or listing the license or licensee as property of the estate; or

2.10.10.1.9.1.3 An affiliate (as that term is defined in 11 U.S.C. 101(a)) of the licensee.

2.10.10.1.9.2 The notification required in 2.10.10.1.9.1 must indicate:

2.10.10.1.9.2.1 The bankruptcy court in which the petition for bankruptcy was filed; and

2.10.10.1.9.2.2 The date of the filing of the petition.

Amend 4.2 to read:

4.2.1 “Address of use” means the building or buildings that are identified on the license and where radioactive material may be received, prepared, used, or stored.

4.2.2 “Agreement State” means any State with which the Nuclear Regulatory Commission (hereafter referred to as NRC) or the Atomic Energy Commission has entered into an effective agreement under subsection 274b of the Atomic Energy Act of 1954, as amended.

4.2.3 “Area of use” means a portion of an address of use that has been set aside for the purpose of receiving, preparing, using, or storing radioactive material.

4.2.4 "Associate Radiation Safety Officer" means an individual who—

4.2.4.1 Meets the requirements in RHA 4.20 and RHA 4.24; and

4.2.4.2 Is currently identified as an Associate Radiation Safety Officer for the types of use of radioactive material for which the individual has been assigned duties and tasks by the Radiation Safety Officer on—

4.2.4.2.1 A specific medical use license issued by the Nuclear Regulatory Commission or an Agreement State; or

4.2.4.2.2 A medical use permit issued by a Nuclear Regulatory Commission master material licensee.

4.2.~~4~~5 "Authorized medical physicist" means an individual who—

4.2.~~4~~5.1 Meets the requirements in RHA 4.21.1 and RHA 4.24; or

4.2.~~4~~5.2 Is identified as an authorized medical physicist or teletherapy physicist on—

4.2.~~4~~5.2.1 A specific medical use license issued by the NRC or an Agreement state;

4.2.~~4~~5.2.2 A medical use permit issued by an NRC master material licensee;

4.2.~~4~~5.2.3 A permit issued by an NRC or Agreement State broad scope medical use licensee; or

4.2.~~4~~5.2.4 A permit issued by an NRC master material license broad scope medical use permittee.

4.2.~~5~~6 "Authorized nuclear pharmacist" means a pharmacist who—

4.2.~~5~~6.1 Meets the requirements in RHA 4.22.1 and RHA 4.24; or

4.2.~~5~~6.2 Is identified as an authorized nuclear pharmacist on—

4.2.~~5~~6.2.1 A specific license issued by the NRC or Agreement State that authorizes medical use or the practice of nuclear pharmacy; or

4.2.~~5~~6.2.2 A permit issued by an NRC master material licensee that authorizes medical use or the practice of nuclear pharmacy; or

4.2.~~5~~6.2.3 A permit issued by an NRC or Agreement State broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or

4.2.~~5~~6.2.4 A permit issued by an NRC master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or

4.2.~~5~~6.3 Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

4.2.~~5~~6.4 Is designated as an authorized nuclear pharmacist in accordance with RHA 2.7.5.2.4.

4.2.~~6~~7 "Authorized user" means a physician, dentist, or podiatrist who—

4.2.~~6~~7.1 Meets the requirements in RHA 4.24 and RHA 4.36.1, RHA 4.39.1, RHA 4.43.1, RHA 4.44.1.1, RHA 4.45.1.1, RHA 4.54.1.1, RHA 4.57.1.1, or RHA 4.74.1.1; or

4.2.~~6~~7.2 Is identified as an authorized user on—

4.2.~~6~~7.2.1 An NRC or Agreement State license that authorizes the medical use of radioactive material;

4.2.~~6~~7.2.2 A permit issued by an NRC master material licensee that is authorized to permit the medical use of radioactive material;

4.2.~~6~~7.2.3 A permit issued by an NRC or Agreement State specific licensee of broad scope that is authorized to permit the medical use of radioactive material; or

4.2.~~6~~7.2.4 A permit issued by an NRC master material license broad scope permittee that is authorized to permit the medical use of radioactive material.

4.2.~~7~~8 "Brachytherapy" means a method of radiation therapy in which sources are used to deliver a radiation dose at a distance of up to a few centimeters by surface, intracavitary, intraluminal, or interstitial application.

4.2.~~8~~9 "Brachytherapy source" means a radioactive source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

4.2.~~9~~10 "Client's address" means the area of use or a temporary job site for the purpose of providing mobile medical service in accordance with RHA 4.33.

4.2.1~~0~~1 "Consortium" means an association of medical use licensees and a PET radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution or a Federal facility or a medical facility.

4.2.1~~1~~2 "Dedicated check source" means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years.

4.2.1~~2~~3 "Dentist" means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice dentistry.

4.2.1~~3~~4 "High dose-rate remote afterloader," as used in this part, means a brachytherapy device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

4.2.1~~4~~5 "Low dose-rate remote afterloader," as used in this part, means a brachytherapy device that remotely delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the point or surface where the dose is prescribed.

4.2.1~~5~~6 "Management" means the chief executive officer or other individual having the authority to manage, direct, or administer the licensee's activities, or those persons' delegate or delegates.

4.2.1~~6~~7 “Manual brachytherapy,” as used in this part, means a type of brachytherapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually placed topically on or inserted either into the body cavities that are in close proximity to a treatment site or directly into the tissue volume.

4.2.1~~7~~8 “Medical event” means an event that meets the criteria in RHA 4.117.1.

4.2.1~~8~~9 “Medical institution” means an organization in which more than one medical discipline is practiced.

4.2.~~19~~20 “Medical use” means the intentional internal or external administration of radioactive material or the radiation from radioactive material to patients or human research subjects under the supervision of an authorized user.

4.2.2~~0~~1 “Medium dose-rate remote afterloader,” as used in this part, means a brachytherapy device that remotely delivers a dose rate of greater than 2 gray (200 rads), but less than 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

4.2.2~~1~~2 “Mobile medical service” means the transportation of radioactive material to and its medical use at the client’s address.

4.2.23 “Ophthalmic physicist” means an individual who—

4.2.23.1 Meets the requirements in RHA 4.52.1.2 and RHA 4.24; and

4.2.23.2 Is identified as an ophthalmic physicist on a—

4.2.23.2.1 Specific medical use license issued by the Nuclear Regulatory Commission or an Agreement State;

4.2.23.2.2 Permit issued by a Nuclear Regulatory Commission or Agreement State broad scope medical use licensee;

4.2.23.2.3 Medical use permit issued by a Nuclear Regulatory Commission master material licensee; or

4.2.23.2.4 Permit issued by a Nuclear Regulatory Commission master material licensee broad scope medical use permittee.

4.2.2~~2~~4 “Output” means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a brachytherapy source or a teletherapy, remote afterloader, or gamma stereotactic radiosurgery unit for specified set of exposure conditions.

4.2.2~~3~~5 “Patient intervention” means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

4.2.2~~4~~6 “Pharmacist” means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.

4.2.2~~5~~7 “Physician” means a medical doctor or doctor of osteopathy licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine.

4.2.2~~6~~8 “Podiatrist” means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice podiatry.

4.2.2~~7~~9 “Positron Emission Tomography (PET) radionuclide production facility” means a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

4.2.~~28~~30 “Preceptor” means an individual who provides, directs or verifies the training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a Radiation Safety Officer.

4.2.~~29~~31 “Prescribed dosage” means the specified activity or range of activity of unsealed radioactive material as documented—

4.2.~~29~~31.1 In a written directive; or

4.2.~~29~~31.2 In accordance with the directions of the authorized user for procedures performed pursuant to RHA 4.35 and 4.37.

4.2.~~30~~32 “Prescribed dose” means—

4.2.~~30~~32.1 For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

4.2.~~30~~32.2 For teletherapy, the total dose and dose per fraction as documented in the written directive;

4.2.~~30~~32.3 For manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or

4.2.~~30~~32.4 For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

4.2.3~~1~~3 “Pulsed dose-rate remote afterloader,” as used in this part, means a special type of remote afterloading brachytherapy device that uses a single source capable of delivering dose rates in the “high dose-rate” range, but—

4.2.3~~1~~3.1 Is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and

4.2.3~~1~~3.2 Is used to simulate the radiobiology of a low dose-rate treatment by inserting the source for a given fraction of each hour.

4.2.3~~2~~4 “Radiation Safety Officer” means an individual who—

4.2.3~~2~~4.1 Meets the requirements in RHA 4.20.1 or 4.20.3 and RHA 4.24; or

4.2.3~~2~~4.2 Is identified as a Radiation Safety Officer on—

4.2.3~~2~~4.2.1 A specific medical use license issued by the NRC or Agreement State; or

4.2.3~~2~~4.2.2 A medical use permit issued by an NRC master material licensee.

4.2.3~~3~~5 "Sealed source" means any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

4.2.3~~4~~6 "Sealed Source and Device Registry" means the national registry that contains all the registration certificates, generated by both NRC and the Agreement States, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

4.2.3~~5~~7 "Stereotactic radiosurgery" means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a therapeutic dose to a tissue volume.

4.2.3~~6~~8 "Structured educational program" means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

4.2.3~~7~~9 "Teletherapy," as used in this part, means a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject.

4.2.~~38~~40 "Temporary job" means a location where mobile medical services are conducted other than those location(s) of use authorized on the license.

4.2.~~39~~41 "Therapeutic dosage" means a dosage of unsealed radioactive material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

4.2.4~~0~~2 "Therapeutic dose" means a radiation dose delivered from a source containing radioactive material to a patient or human research subject for palliative or curative treatment.

4.2.4~~1~~3 "Treatment site" means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

4.2.4~~2~~4 "Type of use" means use of radioactive material under RHA 4.35, 4.37, 4.40, 4.46, 4.56 4.58 or 4.88.

4.2.4~~3~~5 "Unit dosage" means a dosage prepared for medical use for administration as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

4.2.4~~4~~6 "Written directive" means an authorized user's written order for the administration of radioactive material or radiation from radioactive material to a specific patient or human research subject, as specified in RHA 4.17.

Amend 4.7.2.1 to read:

4.7.2.1 Filing an original of DHEC Form 0813, "Application for Radioactive Material License," that includes the facility diagram, equipment, and training and experience qualifications of the Radiation Safety Officer, Associate Radiation Safety Officer(s), authorized user(s), authorized medical physicist(s), ophthalmic physicist(s), and authorized nuclear pharmacist(s); and

Amend 4.7.3.1.2 to read:

4.7.3.1.2 A letter ~~requesting the amendment or renewal~~containing all information required by DHEC Form 0813; and

Amend 4.7.4 to read:

4.7.4 In addition to the requirements in RHA 4.7.2 and 4.7.3 of this section an application for a license or amendment for medical use of radioactive material as described in RHA 4.88 must also include ~~information regarding any radiation safety aspects of the medical use of the material that is not addressed in Subparts A through C of this part.~~:

4.7.4.1 ~~The applicant shall also provide specific information on:~~ Any additional aspects of the medical use of the material that are applicable to radiation safety that are not addressed in, or differ from, subparts A through C, L, and M of this part;

4.7.4.2 Identification of and commitment to follow the applicable radiation safety program requirements in subparts D through H of this part that are appropriate for the specific RHA 4.88 medical use;

4.7.4.3 Any additional specific information on --

4.7.4.~~1~~3.1 Radiation safety precautions and instructions;

4.7.4.~~1~~3.2 Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

4.7.4.~~1~~3.3 Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety~~.~~; and

4.7.4.~~2~~4 ~~The applicant or licensee shall also provide a~~Any other information requested by the Department in its review of the application.

Amend 4.8 to read:

A licensee shall apply for and must receive a license amendment—

4.8.1 Before it receives, prepares, or uses radioactive material for a type of use that is permitted under this part, but that is not authorized on the licensee's current license issued under this part;

4.8.2 Before it permits anyone to work as an authorized user, ~~authorized nuclear pharmacist, or~~ authorized medical physicist, ophthalmic physicist, or authorized nuclear pharmacist under the license, except—

4.8.2.1 For an authorized user, an individual who meets the requirements in RHA 4.24, ~~RHA~~ 4.36.1, 4.39.1, 4.43.1, 4.44.1.1, 4.45.1.1, 4.54.1.1, 4.57.1.1, and 4.74.1.1~~, 4.76, 4.77, 4.78, 4.79, 4.80, 4.81, 4.82, 4.83 or 4.84 and RHA 4.24~~;

4.8.2.2 For an authorized nuclear pharmacist, an individual who meets the requirements in RHA 4.22.1 ~~or 4.86~~ and RHA 4.24;

4.8.2.3 For an authorized medical physicist, an individual who meets the requirements in RHA 4.21.1 ~~or 4.85~~ and RHA 4.24~~;~~

4.8.2.4 An individual who is identified as an authorized user, an authorized nuclear pharmacist, ~~or~~ authorized medical physicist, or an ophthalmic physicist—

4.8.2.4.1 On an NRC or Agreement State license or other equivalent permit or license recognized by the Department that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy;

4.8.2.4.2 On a license issued by an NRC or Agreement State specific license of broad scope that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy;

4.8.2.4.3 On a license issued by an NRC master material licensee that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy; or

4.8.2.4.4 By a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists.

4.8.3 Before it changes Radiation Safety Officers, except as provided in RHA 4.13.3;

4.8.4 Before it permits anyone to work as an Associate Radiation Safety Officer, or before the Radiation Safety Officer assigns duties and tasks to an Associate Radiation Safety Officer that differ from those for which this individual is authorized on the license;

4.8.4~~5~~ Before it receives radioactive material in excess of the amount or in a different form, or receives a different radionuclide than is authorized on the license;

4.8.5~~6~~ Before it adds to or changes the areas of use identified in the application or on the license, except for areas of use where radioactive material is used only in accordance with either RHA 4.35 or 4.37;

4.8.6~~7~~ Before it changes the address(es) of use identified in the application or on the license; ~~and~~

4.8.7~~8~~ Before it revises procedures required by RHA 4.61, 4.67, 4.68 and 4.69, as applicable, where such revision reduces radiation safety~~.~~; and

4.8.9 Before it receives a sealed source from a different manufacturer or of a different model number than authorized by its license unless the sealed source is used for manual brachytherapy, is listed in the Sealed Source and Device Registry, and is in a quantity and for an isotope authorized by the license.

Amend 4.9 to read:

~~4.9.1 A licensee shall provide the Department a copy of the board certification, the NRC or Agreement State license, the permit issued by an NRC master material licensee, the permit issued by an NRC or Agreement State licensee of broad scope, or the permit issued by an NRC master material license broad scope permittee for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist, under RHA 4.8.2.1 through 4.8.2.4.~~

~~4.9.2 A licensee shall notify the Department by letter no later than 30 days after:~~

~~4.9.2.1 An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer, or an authorized medical physicist permanently discontinues performance of duties under the license or has a name change;~~

~~4.9.2.2 The licensee's mailing address changes;~~

~~4.9.2.3 The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in RHA 2.15; or~~

~~4.9.2.4 The licensee has added to or changed the areas of use identified in the application or on the license where radioactive material is used in accordance with either RHA 4.35 or 4.37.~~

~~4.9.3 The licensee shall mail the documents required in this section to the appropriate address identified in RHA 1.13.~~

4.9.1 A licensee shall provide the Department, no later than 30 days after the date that the licensee permits an individual to work under the provisions of RHA 4.8.2 as an authorized user, authorized medical physicist, ophthalmic physicist, or authorized nuclear pharmacist—

4.9.1.1 A copy of the board certification and, as appropriate, verification of completion of:

4.9.1.1.1 Training for the authorized medical physicist under RHA 2.21.4;

4.9.1.1.2 Any additional case experience required in RHA 4.43.2.2.7 for an authorized user under RHA 4.40; or

4.9.1.1.3 Device specific training in RHA 4.74.1.5 for the authorized user under RHA 4.58; or

4.9.2 A copy of the Nuclear Regulatory Commission or Agreement State license, the permit issued by a Nuclear Regulatory Commission master material licensee, the permit issued by a Nuclear Regulatory Commission or Agreement State licensee of broad scope, the permit issued by a Nuclear Regulatory Commission master material license broad scope permittee, or documentation that only accelerator-produced radioactive materials, discrete sources of radium-226, or both, were used for medical use or in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the Nuclear Regulatory Commission for each individual whom the licensee permits to work under the provisions of this section.

4.9.2.1 A licensee shall notify the Department no later than 30 days after:

4.9.2.1.1 An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer, an Associate Radiation Safety Officer, an authorized medical physicist, or ophthalmic physicist permanently discontinues performance of duties under the license or has a name change;

4.9.2.1.2 The licensee permits an individual qualified to be a Radiation Safety Officer under RHA 4.20 and 4.24 to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer in accordance with RHA 4.13.3;

4.9.2.1.3 The licensee's mailing address changes;

4.9.2.1.4 The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in RHA 2.10.2.1 of this chapter;

4.9.2.1.5 The licensee has added to or changed the areas of use identified in the application or on the license where radioactive material is used in accordance with either RHA 4.35 or RHA 4.37 if the change does not include addition or relocation of either an area where PET radionuclides are produced or a PET radioactive drug delivery line from the PET radionuclide/PET radioactive drug production area; or

4.9.2.1.6 The licensee obtains a sealed source for use in manual brachytherapy from a different manufacturer or with a different model number than authorized by its license for which it did not require a license amendment as provided in RHA 4.8.9. The notification must include the manufacturer and model number of the sealed source, the isotope, and the quantity per sealed source.

4.9.3 The licensee shall send the documents required in this section to the appropriate address identified in RHA 1.13.

Amend 4.10.3 and 4.10.5 to read:

4.10.3 The provisions of RHA 4.8.~~5~~6 regarding additions to or changes in the areas of use at the addresses identified in the application or on the license;

4.10.5 The provisions of RHA 4.9.2.1.1 for an authorized user, an authorized nuclear pharmacist, ~~or an~~ authorized medical physicist, or an ophthalmic physicist;

Amend 4.13.2 and 4.13.3 to read:

4.13.2 A licensee's management shall appoint a Radiation Safety Officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. A licensee's management may appoint, in writing, one or more Associate Radiation Safety Officers to support the Radiation Safety Officer. The Radiation Safety Officer, with written agreement of the licensee's management, must assign the specific duties and tasks to each Associate Radiation Safety Officer. These duties and tasks are restricted to the types of use for which the Associate Radiation Safety Officer is listed on a license. The Radiation Safety Officer may delegate duties and tasks to the Associate Radiation Safety Officer but shall not delegate the authority or responsibilities for implementing the radiation protection program.

4.13.3 For up to 60 days each year, a licensee may permit ~~an authorized user or~~ an individual qualified to be a Radiation Safety Officer, under RHA 4.20 and 4.24, to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in RHA 4.13.7 of this section, if the licensee takes the actions required in RHA 4.13.2, 4.13.3, 4.13.7 and 4.13.8 of this section and notifies the Department in accordance with RHA 4.9.2.

Amend 4.17.2.5 and 4.17.2.6 to read:

4.17.2.5 For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; ~~or~~

4.17.2.6 For permanent implant brachytherapy:

4.17.2.6.1 Before implantation: The treatment site, the radionuclide, and the total source strength; and

4.17.2.6.2 After implantation but before the patient leaves the post-treatment recovery area: The treatment site, the number of sources implanted, the total source strength implanted, and the date; or

4.17.2.~~6~~7 For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:

4.17.2.~~6~~7.1 Before implantation: The treatment site, ~~the~~ radionuclide, and dose; and

4.17.2.~~6~~7.2 After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose), and date.

Amend 4.18.2 to read:

4.18.2 At a minimum, the procedures required by RHA 4.18.1 must address the following items that are applicable to the licensee's use of radioactive material—

4.18.2.1 Verifying the identity of the patient or human research subject;

4.18.2.2 Verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive;

4.18.2.3 Checking both manual and computer-generated dose calculations; ~~and~~

4.18.2.4 Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by RHA 4.58~~.~~ or RHA 4.88;

4.18.2.5 Determining if a medical event, as defined in RHA 4.117, has occurred; and

4.18.2.6 Determining, for permanent implant brachytherapy, within 60 calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented.

Amend 4.20 to read:

RHA 4.20. Training for Radiation Safety Officers and Associate Radiation Safety Officer

Except as provided in RHA 4.23, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer or an individual assigned duties and tasks as an Associate Radiation Safety Officer as provided in RHA 4.13 to be an individual who—

4.20.1 Is certified by a specialty board whose certification process has been recognized by the ~~NRC~~Nuclear Regulatory Commission or an Agreement State and who meets the requirements in paragraphs 4.20.4 and 4.20.5 of this section. ~~(The names of board certifications, which have been recognized by the NRC or an Agreement State, will be posted on the NRC's Web page, www.nrc.gov.)~~The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page.

4.20.1.1 To have its certification process recognized, a specialty board shall require all candidates for certification to:

4.20.1.1.1 Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

4.20.1.1.2 Have 5 or more years of professional experience in health physics (graduate training may be substituted for no more than 2 years of the required experience) including at least 3 years in applied health physics; and

4.20.1.1.3 Pass an examination administered by diplomats of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

4.20.1.2.1 Hold a master's or ~~doctorate~~doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

4.20.1.2.2 Have 2 years of full-time practical training and/or supervised experience in medical physics:

4.20.1.2.2.1 Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the ~~NRC~~Nuclear Regulatory Commission or an Agreement State; or

4.20.1.2.2.2 In clinical nuclear medicine facilities providing diagnostic ~~and/~~or therapeutic services under the direction of physicians who meet the requirements for authorized users in RHA 4.23, 4.39 or RHA 4.43~~.~~; and

4.20.1.2.3 Pass an examination, administered by diplomats of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

4.20.2 Has completed a structured educational program consisting of both:

4.20.2.1 200 hours of classroom and laboratory training in the following areas—

4.20.2.1.1 Radiation physics and instrumentation;

4.20.2.1.2 Radiation protection;

4.20.2.1.3 Mathematics pertaining to the use and measurement of radioactivity;

4.20.2.1.4 Radiation biology; and

4.20.2.1.5 Radiation dosimetry; and

4.20.2.2 One year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Office on ~~NRC~~Nuclear Regulatory Commission or Agreement State license or on a permit issued by an ~~NRC~~Nuclear Regulatory Commission master material licensee that authorizes similar type(s) of use(s) of radioactive material ~~involving the following—~~. An Associate Radiation Safety Officer may provide supervision for those areas for which the Associate Radiation Safety Officer is authorized on a Nuclear Regulatory Commission or an Agreement State license or permit issued

by a Nuclear Regulatory Commission master material licensee. The full-time radiation safety experience must involve the following—

4.20.2.2.1 Shipping, receiving, and performing related radiation surveys;

4.20.2.2.2 Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;

4.20.2.2.3 Securing and controlling radioactive material;

4.20.2.2.4 Using administrative controls to avoid mistakes in the administration of radioactive material;

4.20.2.2.5 Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

4.20.2.2.6 Using emergency procedures to control radioactive material; and

4.20.2.2.7 Disposing of radioactive material; and

4.20.2.3 This individual must obtain a written attestation, signed by a preceptor Radiation Safety Officer or Associate Radiation Safety Officer who has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual is seeking approval as a Radiation Safety Officer or an Associate Radiation Safety Officer. The written attestation must state that the individual has satisfactorily completed the requirements in paragraphs RHA 4.20.2 and RHA 4.20.4 of this section, and is able to independently fulfill the radiation safety-related duties as a Radiation Safety Officer or as an Associate Radiation Safety Officer for a medical use license; or

~~4.20.3 Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State under RHA 4.21 and has experience in radiation safety for similar types of use of radioactive material for which the licensee is seeking the approval of the individual as Radiation Safety Officer and who meets the requirements RHA 4.20.4 and 4.20.5; or~~

~~4.20.3.1 Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has Radiation Safety Officer responsibilities; and~~

4.20.3 Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State under RHA 4.21.1, has experience with the radiation safety aspects of similar types of use of radioactive material for which the licensee seeks the approval of the individual as Radiation Safety Officer or an Associate Radiation Safety Officer, and meets the requirements in paragraph 4.20.4 of this section; or

4.20.3.1 Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on a Nuclear Regulatory Commission or an Agreement State license, a permit issued by a Nuclear Regulatory Commission master material licensee, a permit issued by a Nuclear Regulatory Commission or an Agreement State licensee of broad scope, or a permit issued by a Nuclear Regulatory Commission master material license broad scope permittee, has experience with the radiation safety aspects of similar types of use of radioactive material for which the licensee seeks the approval of the individual as the Radiation Safety Officer or Associate Radiation Safety Officer, and meets the requirements in paragraph 4.20.4 of this section; or

4.20.3.2 Has experience with the radiation safety aspects of the types of use of radioactive material for which the individual is seeking simultaneous approval both as the Radiation Safety Officer and the authorized user on the same new medical use license or new medical use permit issued by a Nuclear Regulatory Commission master material license. The individual must also meet the requirements in paragraph 4.20.4 of this section.

~~4.20.4 Has obtained written attestation, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in RHA 4.20.5, and 4.20.1.1.1 and 4.20.1.1.2, or 4.20.1.2.1 and 4.20.1.2.2 or 4.20.3 or 4.20.3.1 and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; and~~

4.20.~~5~~4 Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a Radiation Safety Officer, an Associate Radiation Safety Officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

Amend 4.21 to read:

Except as provided in RHA 4.23, the licensee shall require the authorized medical physicist to be an individual who—

4.21.1 Is certified by a specialty board whose certification process has been recognized by the ~~NRC~~Nuclear Regulatory Commission or an Agreement State and who meets the requirements in paragraph~~s~~ ~~4.21.3 and~~ 4.21.4 of this section. ~~(The names of board certifications which have been recognized by the NRC or an Agreement State will be posted on the NRC's Web page, www.nrc.gov.)~~ The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

4.21.1.1 Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university.

4.21.1.2 Have 2 years of full-time practical training and/or supervised experience in medical physics—

4.21.1.2.1 Under the supervision of a medical physicist who is certified in medical physics by a specialty board whose certification process has been recognized under this section by the Nuclear Regulatory Commission or an Agreement State; or

4.21.1.2.2 In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in RHA 4.23, 4.54 or 4.74; and

4.21.1.3 Pass an examination, administered by diplomats of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or

4.21.2 Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed 1 year of full-time training in medical physics and an additional year of full-time work experience under the

supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services and must include:

4.21.2.1 Performing sealed source leak tests and inventories;

4.21.2.2 Performing decay corrections;

4.21.2.3 Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

4.21.2.4 Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

4.21.~~3~~2.5 Has obtained written attestation that the individual has satisfactorily completed the requirements in RHA ~~4.21.4 and 4.21.1.1 and 4.21.1.2 or~~ 4.21.2 and 4.21.~~4~~3 of this section, and ~~has achieved a level of competency sufficient to function independently~~ is able to independently fulfill the radiation safety-related duties as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in RHA 4.21 or 4.23, or equivalent ~~NRC~~Nuclear Regulatory Commission or Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status~~; and~~.

4.21.~~4~~3 Has training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

Amend 4.22.1 and 4.22.3 to read:

4.22.1 Is certified ~~as a nuclear pharmacist~~ by a specialty board whose certification process has been recognized by the ~~NRC~~Nuclear Regulatory Commission or an Agreement State ~~and who meets the requirements in paragraph 4.22.3 of this section. (The names of board certifications which have been recognized by the NRC or an Agreement State will be posted on the NRC's Web page, www.nrc.gov.)~~ The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit webpage. To have its certification process recognized, a specialty board shall require all candidates for certification to:

4.22.3 Has obtained written attestation signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in RHA 4.22.2 of this section and ~~has achieved a level of competency sufficient to function independently~~is able to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist.

Amend 4.23 to read:

RHA 4.23. Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized Medical Physicist, Authorized User, Nuclear Pharmacist, and Authorized Nuclear Pharmacist.

~~4.23.1 An individual identified as a Radiation Safety Officer, a teletherapy or medical physicist, an authorized medical physicist, a nuclear pharmacist or an authorized nuclear pharmacist on an NRC or Agreement State license or a permit issued by an NRC or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope before April 29, 2005, need not comply with the training requirements of RHA 4.20, 4.21 or 4.22, respectively.~~

~~4.23.2 Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the NRC or Agreement State, a permit issued by an NRC master material licensee, a permit issued by an NRC or Agreement State broad scope licensee, or a permit issued by an NRC master material license broad scope permittee April 29, 2005, who perform only those medical uses for which they were authorized on that date need not comply with the training requirements of Subparts D-H of this part.~~

~~4.23.3 Individuals who need not comply with training requirements as described in this section may serve as preceptors for, and supervisors of, applicants seeking authorization on NRC or Agreement State licenses for the same uses for which these individuals are authorized.~~

4.23.1 Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, and Nuclear Pharmacist.

4.23.1.1 An individual identified on a Nuclear Regulatory Commission or an Agreement State license or a permit issued by a Nuclear Regulatory Commission or an Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope as a Radiation Safety Officer, a teletherapy or medical physicist, an authorized medical physicist, a nuclear pharmacist or an authorized nuclear pharmacist on or before January 14, 2019, need not comply with the training requirements of RHA 4.20, RHA 4.21, or RHA 4.22, respectively, except the Radiation Safety Officers and authorized medical physicists identified in this paragraph must meet the training requirements in RHA 4.20.4 or RHA 4.21.3, as appropriate, for any material or uses for which they were not authorized prior to this date.

4.23.1.2 Any individual certified by the American Board of Health Physics in Comprehensive Health Physics; American Board of Radiology; American Board of Nuclear Medicine; American Board of Science in Nuclear Medicine; Board of Pharmaceutical Specialties in Nuclear Pharmacy; American Board of Medical Physics in radiation oncology physics; Royal College of Physicians and Surgeons of Canada in nuclear medicine; American Osteopathic Board of Radiology; or American Osteopathic Board of Nuclear Medicine on or before October 24, 2005, need not comply with the training requirements of RHA 4.20 to be identified as a Radiation Safety Officer or as an Associate Radiation Safety Officer on a Nuclear Regulatory Commission or an Agreement State license or Nuclear Regulatory Commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2005.

4.23.1.3 Any individual certified by the American Board of Radiology in therapeutic radiological physics, Roentgen ray and gamma ray physics, x-ray and radium physics, or radiological physics, or certified by the American Board of Medical Physics in radiation oncology physics, on or before October 24, 2005, need not comply with the training requirements for an authorized medical physicist described in RHA 4.21, for those materials and uses that these individuals performed on or before October 24, 2005.

4.23.1.4 A Radiation Safety Officer, a medical physicist, or a nuclear pharmacist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses or in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the Nuclear Regulatory Commission, need not comply with the training requirements of RHA 4.20, RHA 4.21, or RHA 4.22, respectively, when performing the same uses. A nuclear pharmacist, who prepared only radioactive drugs containing accelerator-produced radioactive materials, or a medical physicist, who used only accelerator-produced radioactive materials, at the locations and during the time period identified in this paragraph, qualifies as an authorized nuclear pharmacist or an authorized medical physicist, respectively, for those materials and uses performed before these dates, for the purposes of this chapter.

4.23.2 Training for Experienced Authorized User

4.23.2.1 Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the Nuclear Regulatory Commission or an Agreement State, a permit issued by a Nuclear Regulatory Commission master material licensee, a permit issued by a Nuclear Regulatory Commission or an Agreement State broad scope licensee, or a permit issued by a Nuclear Regulatory Commission master material license broad scope permittee on or before January 14, 2019, who perform only those medical uses for which they were authorized on or before that date need not comply with the training requirements of subparts D through H of this part.

4.23.2.2 Physicians, dentists, or podiatrists not identified as authorized users for the medical use of radioactive material on a license issued by the Nuclear Regulatory Commission or an Agreement State, a permit issued by a Nuclear Regulatory Commission master material licensee, a permit issued by a Nuclear Regulatory Commission or an Agreement State broad scope licensee, or a permit issued by a Nuclear Regulatory Commission master material license of broad scope on or before October 24, 2005, need not comply with the training requirements of subparts D through H of this part for those materials and uses that these individuals performed on or before October 24, 2005, as follows:

4.23.2.2.1 For uses authorized under RHA 4.35 or RHA 4.37, or oral administration of sodium iodide I–131 requiring a written directive for imaging and localization purposes, a physician who was certified on or before October 24, 2005, in nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology by the American Board of Radiology; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or American Osteopathic Board of Nuclear Medicine in nuclear medicine;

4.23.2.2.2 For uses authorized under RHA 4.40, a physician who was certified on or before October 24, 2005, by the American Board of Nuclear Medicine; the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or the American Osteopathic Board of Radiology after 1984;

4.23.2.2.3 For uses authorized under RHA 4.46 or RHA 4.58, a physician who was certified on or before October 24, 2005, in radiology, therapeutic radiology or radiation oncology by the American Board of Radiology; radiation oncology by the American Osteopathic Board of Radiology; radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; and

4.23.2.2.4 For uses authorized under RHA 4.56, a physician who was certified on or before October 24, 2005, in radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology

or radiology by the American Osteopathic Board of Radiology; or nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

4.23.2.3 Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses performed at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the Nuclear Regulatory Commission, need not comply with the training requirements of subparts D through H of this part when performing the same medical uses. A physician, dentist, or podiatrist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses at the locations and time period identified in this paragraph, qualifies as an authorized user for those materials and uses performed before these dates, for the purposes of this chapter.

Amend 4.28 to read:

Any person authorized by RHA 4.6 for medical use of radioactive material may receive, possess, and use any of the following radioactive material for check, calibration, transmission, and reference use.

4.28.1 Sealed sources, not exceeding 1.11 GBq (30 mCi) each, manufactured and distributed by a person licensed under RHA 2.7.7 of this chapter or equivalent NRC or Agreement State regulations.

4.28.2 Sealed sources, not exceeding 1.11 GBq (30 mCi) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under RHA 2.7.7 of this chapter or equivalent Nuclear Regulatory Commission or Agreement State regulations, providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions.

4.28.3 Any radioactive material with a half-life not longer than 120 days in individual amounts not to exceed 0.56 GBq (15 mCi).

4.28.4 Any radioactive material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 7.4 MBq (200 uCi) or 1000 times the quantities in Appendix C, RHA 3.54, of Part III of these regulations.

4.28.5 Technetium-99m in amounts as needed.

4.28.6 Radioactive material in sealed sources authorized by this provision shall not be:

4.28.6.1 Used for medical use as defined in RHA 4.2 except in accordance with the requirements in RHA 4.56 or

4.28.6.2 Combined (i.e., bundled or aggregated) to create an activity greater than the maximum activity of any single sealed source authorized under this section.

4.28.6.3 A licensee using calibration, transmission, and reference sources in accordance with the requirements in this section need not list these sources on a specific medical use license.

Amend the title of 4.35 to read:

RHA 4.35. Use of Unsealed ~~Byproduct~~Radioactive Material for Uptake, Dilution, and Excretion Studies for Which a Written Directive is not Required.

Amend 4.36 to read:

Except as provided in RHA 4.23, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under RHA 4.35 to be a physician who—

4.36.1 Is certified by a medical specialty board whose certification process has been recognized by the ~~NRC~~Nuclear Regulatory Commission or an Agreement State ~~and who meets the requirements in paragraph 4.36.4 of this section. (~~. The names of board certifications ~~which~~that have been recognized by the NRC or an Agreement State ~~will be~~are posted on the NRC's ~~Web page, www.nrc.gov.)~~Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

4.36.1.1 Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies that includes the topics listed in paragraphs 4.36.3 through 4.36.3.2.6 of this section; and
4.36.1.2 Pass an examination, administered by diplomats of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

4.36.2 Is an authorized user under RHA 4.39 or 4.43 or equivalent NRC requirements; or 4.36.3—

4.36.3 Has completed 60 hours of training and experience, including a minimum of 8 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience must include—

4.36.3.1 Classroom and laboratory training in the following areas—

4.36.3.1.1 Radiation physics and instrumentation;

4.36.3.1.2 Radiation protection;

4.36.3.1.3 Mathematics pertaining to the use and measurement of radioactivity;

4.36.3.1.4 Chemistry of radioactive material for medical use; and

4.36.3.1.5 Radiation biology; and

4.36.3.2 Work experience, under the supervision of an authorized user who meets the requirements in RHA 4.23, 4.36, 4.39 or 4.43 or equivalent NRC requirements, involving—

4.36.3.2.1 Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

4.36.3.2.2 Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

4.36.3.2.3 Calculating, measuring, and safely preparing patient or human research subject dosages;

4.36.3.2.4 Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

4.36.3.2.5 Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

4.36.3.2.6 Administering dosages of radioactive drugs to patients or human research subjects; and

4.36.3.3 ~~Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in RHA 4.23, 4.36, 4.39 or 4.43 or equivalent NRC requirements, that the individual has satisfactorily completed the requirements in RHA 4.36.1.1 or 4.36.3 and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under RHA 4.35.~~ Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph 4.36.3 of this section and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under 4.35. The attestation must be obtained from either:

4.36.3.3.1 A preceptor authorized user who meets the requirements in RHA 4.23, 4.36, 4.39, or 4.43, or equivalent Agreement State requirements; or

4.36.3.3.2 A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in RHA 4.23, 4.36, 4.39, or 4.43, or equivalent Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraph 4.36.3 of this section.

~~4.36.4 Has obtained written certification, signed by a preceptor authorized user who meets the requirements in RHA 4.36, 4.39 or 4.43 or equivalent NRC requirements, that the individual has satisfactorily completed the requirements in RHA 4.36.3 and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under RHA 4.35.~~

Amend 4.38 to read:

RHA 4.38. Permissible Molybdenum-99, ~~Concentration~~Strontium-82, and Strontium-85 Concentrations.

4.38.1 A licensee may not administer to humans a radiopharmaceutical that contains:

4.38.1.1 More than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m); or

4.38.1.2 More than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02 microcurie of strontium-82 per millicurie of rubidium-82 chloride); or more than 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 microcurie of strontium-85 per millicurie of rubidium-82).

4.38.2 A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration ~~of the first eluate after receipt of a~~in each eluate from a generator to demonstrate compliance with RHA 4.38.1.

4.38.3 A licensee that uses a strontium-82/rubidium-82 generator for preparing a rubidium-82 radiopharmaceutical shall, before the first patient use of the day, measure the concentration of radionuclides strontium-82 and strontium-85 to demonstrate compliance with RHA 4.38.1.

4.38.~~3~~4 If a licensee is required to measure the molybdenum-99 concentration, the licensee shall retain a record of each measurement in accordance with RHA 4.101.

4.38.5 The licensee shall report any measurement that exceeds the limits in RHA 4.38.1 of this section at the time of generator elution, in accordance with RHA 4.120.

Amend 4.39 to read:

Except as provided in RHA 4.23, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under RHA 4.37 to be a physician who—

4.39.1 Is certified by a medical specialty board whose certification process has been recognized by the ~~NRC~~Nuclear Regulatory Commission or an Agreement State~~and who meets the requirements in paragraph 4.39.3 of this section. (~~. The names of board certifications ~~which~~that have been recognized by the ~~NRC~~Nuclear Regulatory Commission or an Agreement State ~~will be~~are posted on the NRC's ~~Web page.)~~Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

4.39.1.1 Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for imaging and localization studies that includes the topics listed in paragraphs RHA 4.39.3 through 4.39.3.2.7; and

4.39.1.2 Pass an examination, administered by diplomats of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

4.39.2 Is an authorized user under RHA 4.43 and meets the requirements in RHA 4.39.3.2.7 or equivalent NRC requirements; or

4.39.3 Has completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. The training and experience must include, at a minimum,-

4.39.3.1 Classroom and laboratory training in the following areas—

4.39.3.1.1 Radiation physics and instrumentation;

4.39.3.1.2 Radiation protection;

4.39.3.1.3 Mathematics pertaining to the use and measurement of radioactivity;

4.39.3.1.4 Chemistry of radioactive material for medical use;

4.39.3.1.5 Radiation biology; and

4.39.3.2 Work experience, under the supervision of an authorized user~~,~~ who meets the requirements in RHA 4.23, 4.39 or 4.43 and 4.39.3.2.7 or equivalent NRC or Agreement State requirements~~, involving~~ . An authorized nuclear pharmacist who meets the requirements in RHA 4.22 or RHA 4.23 may provide the supervised work experience for paragraph 4.39.3.2.7 of this section. Work experience must involve—

4.39.3.2.1 Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

4.39.3.2.2 Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

4.39.3.2.3 Calculating, measuring, and safely preparing patient or human research subject dosages;

4.39.3.2.4 Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

4.39.3.2.5 Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

4.39.3.2.6 Administering dosages of radioactive drugs to patients or human research subjects; and

4.39.3.2.7 Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

4.39.3.3 ~~Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in RHA 4.23, 4.39 or 4.43 and 4.39.3.2.7, or equivalent NRC requirements, that the individual has satisfactorily completed the requirements in RHA 4.39.1 or 4.39.3 through 4.39.3.2.7 and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under RHA 4.35 and 4.37.~~ Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph 4.39.3 of this section and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under RHA 4.35 and 4.37. The attestation must be obtained from either:

4.39.3.3.1 A preceptor authorized user who meets the requirements in RHA 4.23, RHA 4.39, or RHA 4.43 and RHA 4.39.3.2.7, or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

4.39.3.3.2 A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in RHA 4.23, RHA 4.39, or RHA 4.43 and RHA 4.39.3.2.7, or equivalent Nuclear Regulatory Commission or Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraph 4.39.3 of this section.

Amend the title of Subpart E to read:

SUBPART E
Unsealed ~~Byproduct~~Radioactive Material–Written Directive Required

Amend the title and introductory paragraph of 4.40 to read:

RHA 4.40. Use of Unsealed ~~Byproduct~~Radioactive Material for Which a Written Directive is Required.

A licensee may use any unsealed ~~byproduct~~radioactive material identified in RHA 4.43.2.2.7 prepared for medical use and for which a written directive is required that is—

Amend 4.43 to read:

Except as provided in RHA 4.23, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under RHA 4.40 to be a physician who—

4.43.1 Is certified by a medical specialty board whose certification process has been recognized by the ~~NRC~~Nuclear Regulatory Commission or an Agreement State and who meets the requirements in paragraphs 4.43.2.2.7 ~~and 4.43.3~~ of this section. ~~(Specialty boards whose certification processes~~ The names of board certifications that have been recognized by the ~~NRC~~Nuclear Regulatory Commission or an Agreement State ~~will be~~are posted on the NRC's ~~Web page, www.nrc.gov.)~~Medical Uses Licensee Toolkit Web page. To be recognized, a specialty board shall require all candidates for certification to:

4.43.1.1 Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in paragraphs 4.43.2.1 through 4.43.2.2.5 of this section. Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association; and

4.43.1.2 Pass an examination, administered by diplomats of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed radioactive material for which a written directive is required; or

4.43.2 Has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. The training and experience must include—

4.43.2.1 Classroom and laboratory training in the following areas—

4.43.2.1.1 Radiation physics and instrumentation;

4.43.2.1.2 Radiation protection;

4.43.2.1.3 Mathematics pertaining to the use and measurement of radioactivity;

4.43.2.1.4 Chemistry of radioactive material for medical use; and

4.43.2.1.5 Radiation biology; and

4.43.2.2 Work experience, under the supervision of an authorized user who meets the requirements in RHA 4.23, 4.43, or equivalent NRC requirements. A supervising authorized user, who meets the requirements in RHA 4.43.2, must also have experience in administering dosages in the same dosage

category or categories (i.e., RHA 4.43.2.2.7) as the individual requesting authorized user status. The work experience must involve—

4.43.2.2.1 Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

4.43.2.2.2 Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

4.43.2.2.3 Calculating, measuring, and safely preparing patient or human research subject dosages;

4.43.2.2.4 Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

4.43.2.2.5 Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

4.43.2.2.6 [Reserved]

4.43.2.2.7 ~~Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status –~~ Administering dosages of radioactive drugs to patients or research subjects from the three categories in this paragraph. Radioactive drugs containing radionuclides in categories not included in this paragraph are regulated under RHA 4.88. This work experience must involve a minimum of three cases in each of the following categories for which the individual is requesting authorized user status--

4.43.2.2.7.1 Oral administration of less than or equal to 1.22 ~~G~~gigabecquerels (33 millicuries) of sodium iodide I-131, for which a written directive is required;

4.43.2.2.7.2 Oral administration of greater than 1.22 ~~G~~gigabecquerels (33 millicuries) of sodium iodide I-131;[2]

4.43.2.2.7.3 ~~Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required; and/or~~ Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required; and

~~4.43.2.2.7.4 Parenteral administration of any other radionuclide, for which a written directive is required; and~~

~~4.43.3 Has obtained written attestation that the individual has satisfactorily completed the requirements in RHA 4.43.1 and 4.43.2.2.7 or 4.43.2 and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under RHA 4.40. The written attestation must be signed by a preceptor authorized user who meets the requirements in RHA 4.23, 4.43, or equivalent NRC requirements. The preceptor authorized user, who meets the requirements in RHA 4.43.2, must have experience in administering dosages in the same dosage category or categories (i.e., RHA 4.43.2.2.7) as the individual requesting authorized user status.~~

4.43.2.3 Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph 4.43.2 of this section and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under RHA 4.40 for which the individual is requesting authorized user status. The attestation must be obtained from either:

4.43.2.3.1 A preceptor authorized user who meets the requirements in 4.23, 4.43, or equivalent Nuclear Regulatory Commission or Agreement State requirements and has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status; or

4.43.2.3.2 A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in 4.23, 4.43, or equivalent Nuclear Regulatory Commission or Agreement State requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraph 4.43.2 of this section.

4.43.~~4~~3 Training for the parenteral administration of unsealed byproduct material requiring a written directive.

4.43.3.1 Except as provided in RHA 4.23, the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who—

4.43.~~4~~3.1.1 Is an authorized user under RHA 4.43 uses listed in RHA 4.43.2.2.7.3 ~~or 4.43.2.2.7.4~~ or equivalent NRC or Agreement State requirements; or

4.43.~~4~~3.1.~~1~~2 Is an authorized user under RHA 4.~~46~~54, 4.74, or equivalent NRC or Agreement State requirements and who meets the requirements in RHA 4.43.~~4~~3.2 of this section; or

4.43.~~4~~3.1.~~2~~3 Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State under RHA 4.~~46~~54 or 4.74, and who meets the requirements in RHA 4.43.~~4~~3.2 of this section.

4.43.3.2 The Physician--

4.43.~~4~~3.2.1 Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, ~~for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required~~listed in RHA 4.43.2.2.7.3. The training must include—

4.43.~~4~~3.2.1.1 Radiation physics and instrumentation;

4.43.~~4~~3.2.1.2 Radiation protection;

4.43.~~4~~3.2.1.3 Mathematics pertaining to the use and measurement of radioactivity;

4.43.~~4~~3.2.1.4 Chemistry of radioactive material for medical use; and

4.43.~~4~~3.2.1.5 Radiation biology; and

4.43.~~4.~~3.2.2 Has work experience, under the supervision of an authorized user who meets the requirements in RHA 4.23, 4.43, 4.43.~~4~~3 or equivalent NRC or Agreement State requirements, in the parenteral administration~~, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required~~listed in RHA 4.43.2.2.7.3. A supervising authorized user who meets the requirements in RHA 4.43, 4.43.3, or equivalent Nuclear Regulatory Commission or Agreement State requirements must have experience in administering dosages ~~as specified in RHA 4.43.2.2.7.3 and/or RHA 4.43.2.2.7.4~~in the same category or categories as the individual requesting authorized user status. The work experience must involve—

4.43.~~4.~~3.~~1~~2.2.1 Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;

4.43.~~4.~~3.2.2.2 Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

4.43.~~4.~~3.~~3~~2.2.3 Calculating, measuring, and safely preparing patient or human research subject dosages;

4.43.~~4.~~3.~~4~~2.2.4 Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

4.43.~~4.~~3.~~5~~2.2.5 Using procedures to contain spilled radioactive material safely, and using proper decontamination procedures; and

4.43.~~4.~~3.~~6~~2.2.6 Administering dosages to patients or human research subjects, that include at least ~~3~~three cases ~~involving the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV and/or at least 3 cases involving the parenteral administration of any other radionuclide, for which a written directive is required~~ of parenteral administrations as specified in RHA 4.43.2.2.7.3; and

~~4.43.4.4 Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs 4.43.4.1.1 and 4.43.4.1.2 of this section, and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed radioactive material requiring a written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in RHA 4.23, 4.43, 4.43.4, or equivalent NRC or Agreement State requirements. A preceptor authorized user, who meets the requirements in RHA 4.43, must have experience in administering dosages as specified in RHA 4.43.2.2.7.3 and/or RHA 4.43.2.2.7.4.~~

4.43.3.3 Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs 4.43.3.2.1 and 4.43.3.2.2 of this section, and is able to independently fulfill the radiation safety-related duties as an authorized user for the parenteral administration of unsealed radioactive material requiring a written directive. The attestation must be obtained from either:

4.43.3.3.1 A preceptor authorized user who meets the requirements in RHA 4.23, RHA 4.43, RHA 4.43.3, or equivalent Nuclear Regulatory Commission or Agreement State requirements. A preceptor authorized user who meets the requirements in RHA 4.43, RHA 4.43.3, or equivalent Nuclear Regulatory Commission or Agreement State requirements, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status; or

4.43.3.3.2 A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in RHA 4.23, RHA 4.43, RHA 4.43.3, or equivalent Nuclear Regulatory Commission or Agreement State requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs 4.43.3.2.1 and 4.43.3.2.2 of this section.

[2]Experience with at least ~~3~~three cases in RHA 4.43.2.2.7.2 also satisfies the requirement in RHA 4.43.2.2.7.1.

Amend 4.44 to read:

~~4.44.1~~ Except as provided in RHA 4.23, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries), to be a physician who—

— 4.44.1.~~1~~ Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs 4.44.1.3 and 4.44.1.4 of this section and whose certification process has been recognized by the ~~NRC~~Nuclear Regulatory Commission or an Agreement State~~and who meets the requirements in paragraph 4.44.1.5 of this section. (~~.The names of board certifications ~~which~~that have been recognized by the ~~NRC~~Nuclear Regulatory Commission or an Agreement State ~~will be~~are posted on the NRC's ~~Web page, www.nrc.gov.)~~Medical Uses Licensee Toolkit Web page; or

— 4.44.~~1.~~2 Is an authorized user under RHA 4.43, for uses listed in RHA 4.43.2.2.7.1 or 4.43.2.2.7.2, RHA 4.45, or equivalent NRC requirements; or

— 4.44.~~1.~~3 Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include—

— 4.44.~~1.~~3.1 Radiation physics and instrumentation;

— 4.44.~~1.~~3.2 Radiation protection;

— 4.44.~~1.~~3.3 Mathematics pertaining to the use and measurement of radioactivity;

— 4.44.~~1.~~3.4 Chemistry of radioactive material for medical use; and

— 4.44.~~1.~~3.5 Radiation biology; and

4.44.~~1.4~~3.6 Has work experience, under the supervision of an authorized user who meets the requirements in RHA 4.23, 4.43, RHA 4.44, RHA 4.45, or equivalent NRC requirements. A supervising authorized user who meets the requirements in RHA 4.43.2 must have experience in administering dosages as specified in RHA 4.43.2.2.7.1 or 4.43.2.2.7.2. The work experience must involve—

4.44.~~1.4.1~~3.6.1 Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

4.44.~~1.4.2~~3.6.2 Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;

4.44.~~1.4.3~~3.6.3 Calculating, measuring, and safely preparing patient or human research subject dosages;

4.44.~~1.4.4~~3.6.4 Using administrative controls to prevent a medical event involving the use of radioactive material;

4.44.~~1.4.5~~3.6.5 Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

4.44.~~1.4.6~~3.6.6 Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131; and

4.44.~~1.5~~3.7 ~~Has obtained written attestation that the individual has satisfactorily completed the requirements in RHA 4.44.1.3 and 4.44.1.4 and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under RHA 4.40. The written attestation must be signed by a preceptor authorized user who meets the requirements in RHA 4.23, 4.43, 4.44, 4.45 or equivalent NRC requirements. A preceptor authorized user, who meets the requirement in RHA 4.43.2, must have experience in administering dosages as specified in RHA 4.43.2.2.7.1 or 4.43.2.2.7.2.~~ Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs 4.44.3 of this section, and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I–131 for medical uses authorized under RHA 4.40. The attestation must be obtained from either:

4.44.3.7.1 A preceptor authorized user who meets the requirements in RHA 4.23, RHA 4.43, RHA 4.44, RHA 4.45, or equivalent Nuclear Regulatory Commission or Agreement State requirements and has experience in administering dosages as specified in RHA 4.43.2.2.7.1 or RHA 4.43.2.2.7.2; or

4.44.3.7.2 A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in RHA 4.23, RHA 4.43, RHA 4.44, RHA 4.45, or equivalent Agreement State requirements, has experience in administering dosages as specified in RHA 4.43.2.2.7.1 or RHA 4.43.2.2.7.2, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs 4.44.1.3 and 4.44.1.4 of this section.

Amend 4.45 to read:

~~4.45.1~~ Except as provided in RHA 4.23, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries), to be a physician who—

— 4.45.1.1 Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs 4.45.1.3 and 4.45.1.4 of this section, and whose certification has been recognized by the NRCNuclear Regulatory Commission or an Agreement State, and who meets the requirements in paragraph 4.45.1.5 of this section. (The names of board certifications whichthat have been recognized by the NRCNuclear Regulatory Commission or an Agreement State will beare posted on the NRC's Web page, www.nrc.gov.)Medical Uses Licensee Toolkit Web page.; or

— 4.45.1.2 Is an authorized user under RHA 4.43.1, 4.43.2 for uses listed in RHA 4.43.2.2.7.2, or equivalent NRC requirements; or

— 4.45.1.3 Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include—

— 4.45.1.3.1 Radiation physics and instrumentation;

— 4.45.1.3.2 Radiation protection;

— 4.45.1.3.3 Mathematics pertaining to the use and measurement of radioactivity;

— 4.45.1.3.4 Chemistry of radioactive material for medical use; and

— 4.45.1.3.5 Radiation biology; and

— 4.45.1.43.6 Has work experience, under the supervision of an authorized user who meets the requirements in RHA 4.23, 4.43, 4.45, or equivalent NRC requirements. A supervising authorized user, who meets the requirements in RHA 4.43.2, must also have experience in administering dosages as specified in RHA 4.43.2.2.7.2. The work experience must involve—

— 4.45.1.4.13.6.1 Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

— 4.45.1.4.23.6.2 Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;

— 4.45.1.4.33.6.3 Calculating, measuring, and safely preparing patient or human research subject dosages;

— 4.45.1.4.43.6.4 Using administrative controls to prevent a medical event involving the use of radioactive material;

— 4.45.1.4.53.6.5 Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

— 4.45.1.4.63.6.6 Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131; and

— 4.45.1.53.7 Has obtained written attestation that the individual has satisfactorily completed the requirements in RHA 4.45.1.3 and 4.45.1.4 and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under RHA 4.40. The written attestation

~~must be signed by a preceptor authorized user who meets the requirements in RHA 4.23, 4.43, RHA 4.45 or equivalent NRC requirements. A preceptor authorized user, who meets the requirements in RHA 4.43.2, must have experience in administering dosages as specified in RHA 4.43.2.2.7.2.~~ Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs 4.45.3 of this section, and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of greater than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I–131 for medical uses authorized under RHA 4.40. The attestation must be obtained from either:

— 4.45.3.7.1 A preceptor authorized user who meets the requirements in RHA 4.23, 4.43, 4.45, or equivalent Nuclear Regulatory Commission or Agreement State requirements and has experience in administering dosages as specified in 4.43.2.2.7.2; or

— 4.45.3.7.2 A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in RHA 4.23, 4.43, 4.45, or equivalent Nuclear Regulatory Commission or Agreement State requirements, has experience in administering dosages as specified in 4.43.2.2.7.2, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs 4.45.3 of this section.

Amend 4.46 to read:

4.46.1 A licensee ~~shall~~must use only brachytherapy sources ~~for therapeutic medical uses~~:

4.46.1.1 ~~As approved in the Sealed Source and Device Registry~~Approved in the Sealed Source and Device Registry for manual brachytherapy medical use. The manual brachytherapy sources may be used for manual brachytherapy uses that are not explicitly listed in the Sealed Source and Device Registry, but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

4.46.1.2 ~~In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of~~ In research to deliver therapeutic doses for medical use in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of RHA 4.19.1 are met.

Amend 4.52 to read:

RHA 4.52. ~~Decay of Strontium-90 Sources for Ophthalmic Treatments~~Strontium-90 Sources for Ophthalmic Treatments.

~~4.52.1 Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under RHA 4.51.~~

~~4.52.2 A licensee shall retain a record of the activity of each strontium-90 source in accordance with RHA 4.106.~~

4.52.1 Licensees who use strontium-90 for ophthalmic treatments must ensure that certain activities as specified in 4.52.2 of this section are performed by either:

4.52.1.1 An authorized medical physicist; or

4.52.1.2 An individual who:

4.52.1.2.1 Is identified as an ophthalmic physicist on a specific medical use license issued by the Nuclear Regulatory Commission or an Agreement State; permit issued by a Nuclear Regulatory Commission or Agreement State broad scope medical use licensee; medical use permit issued by a Nuclear Regulatory Commission master material licensee; or permit issued by a Nuclear Regulatory Commission master material licensee broad scope medical use permittee; and

4.52.1.2.2 Holds a master's or doctor's degree in physics, medical physics, other physical sciences, engineering, or applied mathematics from an accredited college or university; and

4.52.1.2.3 Has successfully completed 1 year of full-time training in medical physics and an additional year of full-time work experience under the supervision of a medical physicist; and

4.52.1.2.4 Has documented training in:

4.52.1.2.4.1 The creation, modification, and completion of written directives;

4.52.1.2.4.2 Procedures for administrations requiring a written directive; and

4.52.1.2.4.3 Performing the calibration measurements of brachytherapy sources as detailed in RHA 4.51.

4.52.2 The individuals who are identified in 4.52.1 of this section must:

4.52.2.1 Calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under RHA 4.51; and

4.52.2.2 Assist the licensee in developing, implementing, and maintaining written procedures to provide high confidence that the administration is in accordance with the written directive. These procedures must include the frequencies that the individual meeting the requirements in 4.52.1 of this section will observe treatments, review the treatment methodology, calculate treatment time for the prescribed dose, and review records to verify that the administrations were in accordance with the written directives.

4.52.3 Licensees must retain a record of the activity of each strontium-90 source in accordance with RHA 4.106.

Amend 4.54 to read:

~~4.54.1~~ Except as provided in RHA 4.23, the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under RHA 4.46 to be a physician who—

~~—~~ 4.54.1.~~1~~ Is certified by a medical specialty board whose certification process has been recognized by the ~~NRC~~Nuclear Regulatory Commission or an Agreement State~~,~~. ~~and who meets the requirements in paragraph 4.54.1.4 of this section. (~~The names of board certifications ~~which~~that have been recognized by the ~~NRC~~Nuclear Regulatory Commission or an Agreement State ~~will be~~are posted on the NRC's ~~Web page.)~~Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

— 4.54.1.1.~~1~~ Successfully complete a minimum of 3 years of residency training in a radiation oncology program approved by the Residency Review committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

— 4.54.1.~~1.~~2 Pass an examination, administered by diplomats of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or

— 4.54.~~1.~~2 Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes—

— 4.54.~~1.~~2.1 200 hours of classroom and laboratory training in the following areas:

— 4.54.~~1.~~2.1.1 Radiation physics and instrumentation;

— 4.54.~~1.~~2.1.2 Radiation protection;

— 4.54.~~1.~~2.1.3 Mathematics pertaining to the use and measurement of radioactivity; and

— 4.54.~~1.~~2.1.4 Radiation biology; and

— 4.54.~~1.~~2.2 500 hours of work experience, under the supervision of an authorized user who meets the requirements in RHA 4.23, 4.54, or equivalent NRC or Agreement State requirements at a medical ~~institution~~facility authorized to use radioactive material under RHA 4.46, involving—

— 4.54.~~1.~~2.2.1 Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

— 4.54.~~1.~~2.2.2 Checking survey meters for proper operation;

— 4.54.~~1.~~2.2.3 Preparing, implanting, and removing brachytherapy sources;

— 4.54.~~1.~~2.2.4 Maintaining running inventories of material on hand;

— 4.54.~~1.~~2.2.5 Using administrative controls to prevent a medical event involving the use of radioactive material;

— 4.54.~~1.~~2.2.6 Using emergency procedures to control radioactive material; and

— 4.54.~~1~~2.3 Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in RHA 4.23, 4.54 or equivalent NRC requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by RHA 4.54.~~1.~~2.2; and

— 4.54.~~1~~2.4 ~~Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in RHA 4.23, 4.54 or equivalent NRC requirements, that the individual has satisfactorily~~

~~completed the requirements in RHA 4.54.1.1 or 4.54.1.2 and RHA 4.54.1.3 and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under RHA 4.46.~~ Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs 4.54.2.1 and 4.54.2.2 of this section and is able to independently fulfill the radiation safety-related duties as an authorized user of manual brachytherapy sources for the medical uses authorized under RHA 4.46. The attestation must be obtained from either:

4.54.2.4.1 A preceptor authorized user who meets the requirements in RHA 4.23, RHA 4.54, or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

4.54.2.4.2 A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in RHA 4.23, RHA 4.54, or equivalent Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs 4.54.2.1 and 4.54.2.2 of this section.

Amend 4.55 to read:

~~4.55.1~~ Except as provided in RHA 4.23, the licensee shall require the authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who—

— 4.55.~~1.~~1 Is an authorized user under RHA 4.54 or equivalent NRC requirements; or

— 4.55.~~1.~~2 Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include—

— 4.55.~~1.~~2.1 Radiation physics and instrumentation;

— 4.55.~~1.~~2.2 Radiation protection;

— 4.55.~~1.~~2.3 Mathematics pertaining to the use and measurement of radioactivity; and

— 4.55.~~1.~~2.4 Radiation biology; and

— 4.55.~~1.~~3 Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve—

— 4.55.~~1.~~3.1 Examination of each individual to be treated;

— 4.55.~~1.~~3.2 Calculation of the dose to be administered;

— 4.55.~~1.~~3.3 Administration of the dose; and

— 4.55.~~1.~~3.4 Follow up and review of each individual's case history; and

— 4.55.~~1.~~4 Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in RHA 4.23, 4.54, 4.55, or equivalent NRC or Agreement State requirements, that the

individual has satisfactorily completed the requirements in ~~RHA 4.55.1.1 and 4.55.1.2~~ paragraphs 4.55.2 and 4.55.3 of this section and ~~has achieved a level of competency sufficient to function independently~~is able to independently fulfill the radiation safety-related duties as an authorized user of strontium-90 for ophthalmic use.

Amend 4.56 to read:

RHA 4.56. Use of Sealed Sources and Medical Devices for Diagnosis.

~~A licensee shall use only sealed sources for diagnostic medical uses as approved in the NRC Sealed Source and Device Registry.~~

4.56.1 A licensee must use only sealed sources that are not in medical devices for diagnostic medical uses if the sealed sources are approved in the Sealed Source and Device Registry for diagnostic medicine. The sealed sources may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

4.56.2 A licensee must only use medical devices containing sealed sources for diagnostic medical uses if both the sealed sources and medical devices are approved in the Sealed Source and Device Registry for diagnostic medical uses. The diagnostic medical devices may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

4.56.3 Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of RHA 4.19.1 are met.

Amend 4.57 to read:

RHA 4.57. Training for Use of Sealed Sources and Medical Devices for Diagnosis.

~~4.57.1~~ Except as provided in RHA 4.23, the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under RHA 4.56 to be a physician, dentist, or podiatrist who—

~~4.57.1.1 Is certified by a specialty board whose certification process includes all of the requirements in RHA 4.57.1.2 and 4.57.1.3 and whose certification has been recognized by the NRC or an Agreement State; or~~

4.57.1 Is certified by a medical specialty board whose certification process includes all of the requirements in RHA 4.57.3 and 4.57.4 of this section and whose certification has been recognized by the Nuclear Regulatory Commission or an Agreement State. The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page; or

4.57.2 Is an authorized user for uses listed in RHA 4.37 or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

— 4.57.~~1.2~~3 Has had 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include—

— 4.57.~~1.2~~3.1 Radiation physics and instrumentation;

— 4.57.~~1.2~~3.2 Radiation protection;

— 4.57.~~1.2~~3.3 Mathematics pertaining to the use and measurement of radioactivity;

— 4.57.~~1.2~~3.4 Radiation biology; and

— 4.57.~~1.3~~4 Has completed training in the use of the device for the uses requested.

Amend 4.58 to read:

~~4.58.1 A licensee shall use sealed sources in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units for therapeutic medical uses:~~

~~4.58.1.1 As approved in the NRC Sealed Source and Device Registry; or~~

~~4.58.1.2 In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of RHA 4.19.1 are met.~~

4.58.1 A licensee must only use sealed sources:

4.58.1.1 Approved and as provided for in the Sealed Source and Device Registry in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units to deliver therapeutic doses for medical uses: or

4.58.1.2 In research involving photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of RHA 4.19.1 are met.

4.58.2 A licensee must use photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units:

4.58.2.1 Approved in the Sealed Source and Device Registry to deliver a therapeutic dose for medical use. These devices may be used for therapeutic medical treatments that are not explicitly provided for in the Sealed Source and Device Registry, but must be used in accordance with radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

4.58.2.2 In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of RHA 4.19.1 are met.

Amend 4.61.4 to read:

~~4.61.4 A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in~~

~~4.61.4.1 The procedures identified in RHA 4.61.1.4; and~~

~~4.61.4.2 The operating procedures for the unit.~~

4.61.4 Training and Instructions.

4.61.4.1 Prior to the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit, a licensee shall ensure that vendor operational and safety training is provided to all individuals who will operate the unit. The vendor operational and safety training must be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training.

4.61.4.2 A licensee shall provide operational and safety instructions initially and at least annually to all individuals who operate the unit at the facility, as appropriate to the individual's assigned duties. The instructions shall include instruction in—

4.61.4.2.1 The procedures identified in paragraph 4.61.1.4 of this section; and

4.61.4.2.2 The operating procedures for the unit.

Amend 4.61.7 to read:

4.61.7 A licensee shall retain a copy of the procedures required by RHA 4.61.1.4 and 4.61.4.2.2 of this section in accordance with RHA 4.108.

Amend the title of 4.72 to read:

RHA 4.72. ~~Five-Year Inspection~~Full-inspection Servicing for Teletherapy and Gamma Stereotactic Radiosurgery Units.

Amend 4.72.1 to read:

4.72.1 ~~A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement or at intervals not to exceed 5 years, whichever comes first, to assure proper functioning of the source exposure mechanism.~~A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during each source replacement to assure proper functioning of the source exposure mechanism and other safety components. The interval between each full-inspection servicing shall not exceed 5 years for each teletherapy unit and shall not exceed 7 years for each gamma stereotactic radiosurgery unit.

Amend 4.74 to read:

~~4.74.1~~ Except as provided in RHA 4.23, the licensee shall require an authorized user of a sealed source for a use authorized under RHA 4.58 to be a physician who—

~~—~~ 4.74.1.~~1~~ Is certified by a medical specialty board whose certification process has been recognized by the ~~NRC~~Nuclear Regulatory Commission or an Agreement State and who meets the requirements in paragraph~~s 4.74.1.4 and 4.74.1.5~~ 4.74.3 of this section. ~~(~~The names of board certifications ~~which~~that have been recognized by the ~~NRC~~Nuclear Regulatory Commission or an Agreement State ~~will be~~are posted on the NRC's Medical Uses Licensee Toolkit Web page~~, www.nrc.gov.)~~. To have its certification process recognized, a specialty board shall require all candidates for certification to:

~~—~~ 4.74.1.~~1.~~1 Successfully complete a minimum of 3 years of residency training in radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physician and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

— 4.74.1.~~1.~~2 Pass an examination, administered by diplomats of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders and external beam therapy; or

— 4.74.~~1.~~2 Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes—

— 4.74.~~1.~~2.1 200 hours of classroom and laboratory training in the following areas—

— 4.74.~~1.~~2.1.1 Radiation physics and instrumentation;

— 4.74.~~1.~~2.1.2 Radiation protection;

— 4.74.~~1.~~2.1.3 Mathematics pertaining to the use and measurement of radioactivity; and

— 4.74.~~1.~~2.1.4 Radiation biology; and

— 4.74.~~1.~~2.2 500 hours of work experience, under the supervision of an authorized user who meets the requirements in RHA 4.23, 4.74, or equivalent NRC or Agreement State requirements at a medical ~~institution~~facility that is authorized to use radioactive materials in RHA 4.58, involving—

— 4.74.~~1.~~2.2.1 Reviewing full calibration measurements and periodic spot-checks;

— 4.74.~~1.~~2.2.2 Preparing treatment plans and calculating treatment doses and times;

— 4.74.~~1.~~2.2.3 Using administrative controls to prevent a medical event involving the use of radioactive material;

— 4.74.~~1.~~2.2.4 Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

— 4.74.~~1.~~2.2.5 Checking and using survey meters; and

— 4.74.~~1.~~2.2.6 Selecting the proper dose and how it is to be administered; and

4.74.~~1~~2.3 Has completed 3 years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in RHA 4.23, 4.74, or equivalent NRC or Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by RHA 4.74.~~1.~~2.2; and

4.74.~~1~~2.4 ~~Has obtained written attestation that the individual has satisfactorily completed the requirements in RHA 4.74.1.1.1, or 4.74.1.2 and 4.74.1.3 and 4.74.1.5 and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be signed by a preceptor authorized user who meets the requirements in RHA 4.23, 4.74 or equivalent NRC requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status.~~Has obtained written attestation that the individual has satisfactorily completed the

requirements in paragraphs 4.74.2.1, 4.74.2.2, 4.74.2.3, and 4.74.3 of this section; and is able to independently fulfill the radiation safety-related duties as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The attestation must be obtained from either:

4.74.2.4.1 A preceptor authorized user who meets the requirements in RHA 4.23, 4.74, or equivalent Nuclear Regulatory Commission or Agreement State requirements for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status; or

4.74.2.4.2 A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in RHA 4.23, 4.74, or equivalent Nuclear Regulatory Commission or Agreement State requirements, for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs 4.74.2.1, 4.74.2.2, and 4.74.2.3 of this section.

— 4.74.~~1.5~~3 Has received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.

Add 4.89.3 to read:

4.89.3. For each Associate Radiation Safety Officer appointed under RHA 4.13.2, the licensee shall retain, for 5 years after the Associate Radiation Safety Officer is removed from the license, a copy of the written document appointing the Associate Radiation Safety Officer signed by the licensee's management.

Amend 4.102 to read:

A licensee shall maintain a record of safety instructions required by RHA 4.41, 4.49, and the operational and safety instructions required by RHA 4.61 for 3 years. The record must include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

Amend the title of 4.116 to read:

RHA 4.116. Records of ~~5-Year Inspection~~Full-inspection Servicing for Teletherapy and Gamma Stereotactic Radiosurgery Units.

Amend 4.116.1 to read:

4.116.1 A licensee shall maintain a record of the ~~5-year inspections~~full-inspection and servicing for teletherapy and gamma stereotactic radiosurgery units required by RHA 4.72 for the duration of use of the unit.

Amend 4.117.1 to read:

4.117.1 A licensee shall report any event as a medical event, except for an event that results from patient intervention, in which ~~the administration of radioactive material or radiation from radioactive material results in –~~

4.117.1.1 The administration of radioactive material or radiation from radioactive material, except permanent implant brachytherapy, results in –

4.117.1.1.1 A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and

4.117.1.1.1.1 The total dose delivered differs from the prescribed dose by 20 percent or more; or

4.117.1.1.1.2 The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

4.117.1.1.1.3 The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

4.117.1.1.2 A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following—

4.117.1.1.2.1 An administration of a wrong radioactive drug containing radioactive material; or

4.117.1.1.2.2 An administration of a radioactive drug containing radioactive material by the wrong route of administration; or

4.117.1.1.2.3 An administration of a dose or dosage to the wrong individual or human research subject; or

4.117.1.1.2.4 An administration of a dose or dosage delivered by the wrong mode of treatment; or

4.117.1.1.2.5 A leaking sealed source.

~~4.117.1.3 A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).~~

4.117.1.1.3 A dose to the skin or an organ or tissue other than the treatment site that exceeds by:

4.117.1.1.3.1 0.5 Sv (50 rem) or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and

4.117.1.1.3.2 50 percent or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration.

4.117.1.2 For permanent implant brachytherapy, the administration of radioactive material or radiation from radioactive material (excluding sources that were implanted in the correct site but migrated outside the treatment site) that results in—

4.117.1.2.1 The total source strength administered differing by 20 percent or more from the total source strength documented in the post-implantation portion of the written directive;

4.117.1.2.2 The total source strength administered outside of the treatment site exceeding 20 percent of the total source strength documented in the post-implantation portion of the written directive; or

4.117.1.2.3 An administration that includes any of the following:

4.117.1.2.3.1 The wrong radionuclide;

4.117.1.2.3.2 The wrong individual or human research subject;

4.117.1.2.3.3 Sealed source(s) implanted directly into a location discontiguous from the treatment site, as documented in the post-implantation portion of the written directive; or

4.117.1.2.3.4 A leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue.

Amend 4.117.7.1.2 to read:

4.117.7.1.2 ~~Social security number or other identification number, if one has been assigned,~~Identification number or if no other identification number is available, the social security number of the individual who is the subject of the event; and

Amend 4.118.6.1.2 to read:

4.118.6.1.2 ~~Social security number or other identification number, if one has been assigned,~~Identification number or if no other identification number is available, the social security number of the ~~pregnant individual or the nursing child~~individual who is the subject of the event; and

Add 4.120 to read:

RHA 4.120 Report and Notification for an Eluate Exceeding Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentrations.

4.120.1 The licensee shall notify by telephone the Department and the distributor of the generator within 7 calendar days after discovery that an eluate exceeded the permissible concentration listed in 4.38.1 at the time of generator elution. The telephone report to the Department must include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects, when the distributor was notified, and the action taken.

4.120.2 By an appropriate method listed in RHA 1.13 of this chapter, the licensee shall submit a written report to the Department within 30 calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The written report must include the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects; and the probable cause and an assessment of failure in

the licensee's equipment, procedures or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination; and the information in the telephone report as required by 4.120.1 of this section.

Amend 5.14 to read:

5.14.1 The licensee may not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each individual wears, on the trunk of the body, a direct reading dosimeter, an operating alarm rate meter and a personnel dosimeter ~~that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor~~. At permanent radiography facilities where other appropriate alarming or warning devices are in routine use, the wearing of an alarming rate meter is not required. Pocket dosimeters must have a range from zero to at least 200 milliroentgens and must be recharged at the start of each shift. Electronic personal dosimeters may only be used in place of ion-chamber pocket dosimeters. Each personnel dosimeter must be assigned to and worn by only one individual. Film badges must be replaced at least monthly and all other personnel dosimeters that require replacement must be replaced at least quarterly. All personnel dosimeters must be evaluated at least quarterly or promptly after replacement, whichever is more frequent.

5.14.2 Pocket dosimeters or electronic personal dosimeters must be read and exposures recorded at the beginning and end of each shift. The licensee shall retain each record of these exposures in accordance with RHA 5.14.7.1.

5.14.3 Pocket dosimeters or electronic personal dosimeters shall be checked at periods not to exceed one year for correct response to radiation. Acceptable dosimeters shall read within plus or minus 20 percent of the true radiation exposure. Records must be maintained in accordance with RHA 5.14.7.1.

5.14.4 If an individual's pocket chamber is found to be off scale, or if his or her electronic personal dosimeter reads greater than 2 millisieverts (200 millirems), and the possibility of radiation exposure cannot be ruled out as the cause, the individual's personnel dosimeter must be sent for processing within 24 hours. For personnel dosimeters that do not require processing, evaluation of the dosimeter must be started within 24 hours. In addition, the individual may not resume work associated with licensed material use until a determination of the individual's radiation exposure has been made. This determination must be made by the RSO or the RSO's designee. The results of this determination must be included in records to be maintained by the licensee until the Department terminates the license.

If the personnel dosimeter that is required by RHA 5.14.1 is lost or damaged, the worker shall cease work immediately until a replacement personnel dosimeter meeting the requirements is provided and the exposure is calculated for the time period from issuance to loss or damage of the personnel dosimeter. The results of the calculated exposure and the time period for which the personnel dosimeter was lost or damaged must be included in the records to be maintained until the Department terminates the license.

5.14.5 ~~Film badges must be replaced at periods not to exceed one month and other personnel dosimeters processed and evaluated by an accredited NVLAP processor must be replaced at periods not to exceed three months. After replacement, each personnel dosimeter must be processed as soon as possible. Dosimetry reports received from the accredited NVLAP personnel dosimeter processor must be retained in accordance with RHA 5.14.7.3. 3~~Dosimetry results must be retained in accordance with RHA 5.14.7.

5.14.6 Each alarm rate meter must:

5.14.6.1 Be checked to ensure that the alarm functions properly (sounds) prior to use at the start of each shift;

5.14.6.2 Be set to give an alarm signal at a preset dose rate of 500 mR/hr.;

5.14.6.3 Require special means to change the preset alarm function; and

5.14.6.4 Be calibrated at periods not to exceed one year for correct response to radiation: Acceptable rate meters must alarm within plus or minus 20 percent of the true radiation dose rate. Records of these calibrations must be maintained in accordance with RHA 5.14.7.2.

5.14.7 Each licensee shall maintain the following exposure records specified in RHA 5.14:

5.14.7.1 Direct reading dosimeter readings and yearly operability checks required by RHA 5.14.2 and 5.14.3 for 3 years after the record is made.

5.14.7.2 Records of alarm ratemeter calibrations for 3 years after the record is made.

5.14.7.3 Personnel dosimeter results ~~received from the accredited NVLAP processor~~ must be retained until the Department terminates the license.

5.14.7.4 Records of estimates of exposures as a result of: off-scale personal direct reading dosimeters, or lost or damaged personnel dosimeters until the Department terminates the license.

Amend 8.21.1 to read:

8.21.1 The licensee may not permit an individual to act as a logging supervisor or logging assistant unless that person wears~~,~~ a personnel dosimeter at all times during the handling of radioactive materials~~, a personnel dosimeter that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor~~. Each personnel dosimeter must be assigned to and worn by only one individual. Film badges must be replaced at least monthly and other personnel dosimeters that require replacement must be replaced at least quarterly. ~~After replacement, each personnel dosimeter must be promptly processed.~~All personnel dosimeters must be evaluated at least quarterly or promptly after replacement, whichever is more frequent.

Amend 11.20.1 to read:

11.20.1 Irradiator operators shall wear a personnel dosimeter while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The personnel dosimeter processor must be ~~accredited by the National Voluntary Laboratory Accreditation Program for~~capable of detecting high energy photons in the normal and accident dose ranges ~~(see RHA 3.16.3)~~. Each personnel dosimeter must be assigned to and worn by only one individual. Film badges must be processed at least monthly, and other personnel dosimeters must be processed at least quarterly. All personnel dosimeters must be evaluated at least quarterly or promptly after replacement, whichever is more frequent.

Amend 12.5.2.2 to read:

12.5.2.2 Each licensee shall name one or more individuals to be reviewing officials. After completing the background investigation on the reviewing official, the licensee shall provide under oath or affirmation, a certification that the reviewing official is deemed trustworthy and reliable by the licensee. Licensees shall provide oath or affirmation certificates to the Department. The fingerprints of the named reviewing official must be taken by a law enforcement agency, Federal or State agencies that provide fingerprinting services to the public, or commercial fingerprinting services authorized by a State to take fingerprints. The licensee

shall recertify that the reviewing official is deemed trustworthy and reliable every ten (10) years in accordance with RHA 12.6.3.

Amend 12.7.3 to read:

12.7.3.1 For the purpose of complying with this ~~S~~subpart ~~B~~, Department licensees shall use an appropriate method listed in 10 CFR 37.7 to submit to the U.S. Nuclear Regulatory Commission, Director Division of ~~Facilities and Security U.S NRC~~Physical and Cyber Security Policy, 11545 Rockville Pike, ATTN: Criminal History Program, Mail Stop T-8B20, Rockville, MD 20852~~ ATTN: Criminal History Program, Mail Stop TWB 05 B32M~~, one completed, legible standard fingerprint card (Form FD-258, ORIMDNRCOOOZ), electronic fingerprint scan or, where practicable, other fingerprint record for each individual requiring unescorted access to Category 1 or Category 2 quantities of radioactive material. Copies of these forms may be obtained by ~~writing the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, by calling 1-630-829-9565, or by email to~~e-mailing *~~FORMS.~~MAILSVS.Resource@nrc.gov*. Guidance on submitting electronic fingerprints can be found at ~~http://www.nrc.gov/site-help/e-submittals.html~~https://www.nrc.gov/security/chp.html.

12.7.3.2 Fees for the processing of fingerprint checks are due upon application. Licensees shall submit payment with the application for the processing of fingerprints through corporate check, certified check, cashier's check, money order, or electronic payment, made payable to "U.S. NRC." (For guidance on making electronic payments, contact the ~~Security Branch, Division of Facilities and Security at 301-415-7513~~Division of Physical and Cyber Security Policy by e-mailing Crimhist.Resource@nrc.gov.) Combined payment for multiple applications is acceptable. The Commission publishes the amount of the fingerprint check application fee on the NRC's public Web site. (To find the current fee amount, go to the ~~Electronic Submittals~~Licensee Criminal History Records Check & Firearms Background Check information page at ~~*http://www.nrc.gov/ site-help/e-submittals.html*~~https://www.nrc.gov/security/chp.html and see the link for ~~the Criminal History Program under Electronic Submission Systems.~~How do I determine how much to pay for the request?).

12.7.3.3 The U.S. Nuclear Regulatory Commission will forward to the submitting Department licensee all data received from the FBI as a result of the licensee's application(s) for criminal history records checks.

Amend 12.12.4 to read:

12.12.4 Protection of information.

12.12.4.1 Licensees authorized to possess Category 1 or Category 2 quantities of radioactive material shall limit access to and unauthorized disclosure of their security plan, implementing procedures, and the list of individuals that have been approved for unescorted access.

12.12.4.2 Efforts to limit access shall include the development, implementation, and maintenance of written policies and procedures for controlling access to, and for proper handling and protection against unauthorized disclosure of, the security plan ~~and~~, implementing procedures, and the list of individuals that have been approved for unescorted access.

12.12.4.3 Before granting an individual access to the security plan ~~or~~, implementing procedures, or the list of individuals that have been approved for unescorted access, licensees shall:

12.12.4.3.1 Evaluate an individual's need to know the security plan ~~or~~, implementing procedures, or the list of individuals that have been approved for unescorted access; and

12.12.4.3.2 If the individual has not been authorized for unescorted access to Category 1 or Category 2 quantities of radioactive material, safeguards information, or safeguards information modified handling, the licensee must complete a background investigation to determine the individual's trustworthiness and reliability. A trustworthiness and reliability determination shall be conducted by the reviewing official and shall include the background investigation elements contained in RHA 12.6.1.2 through 12.6.1.7.

12.12.4.4 Licensees need not subject the following individuals to the background investigation elements for protection of information:

12.12.4.4.1 The categories of individuals listed in RHA 12.8.1.1 through 12.8.1.13; or

12.12.4.4.2 Security service provider employees, provided written verification that the employee has been determined to be trustworthy and reliable, by the required background investigation in RHA 12.6.1.2 through 12.6.1.7, has been provided by the security service provider.

12.12.4.5 The licensee shall document the basis for concluding that an individual is trustworthy and reliable and should be granted access to the security plan ~~or,~~ implementing procedures, or the list of individuals that have been approved for unescorted access.

12.12.4.6 Licensees shall maintain a list of persons currently approved for access to the security plan ~~or,~~ implementing procedures, or the list of individuals that have been approved for unescorted access. When a licensee determines that a person no longer needs access to the security plan ~~or,~~ implementing procedures, or the list of individuals that have been approved for unescorted access or no longer meets the access authorization requirements for access to the information, the licensee shall remove the person from the approved list as soon as possible, but no later than 7 working days, and take prompt measures to ensure that the individual is unable to obtain the security plan ~~or,~~ implementing procedures, or the list of individuals that have been approved for unescorted access.

12.12.4.7 When not in use, the licensee shall store its security plan ~~and,~~ implementing procedures, and the list of individuals that have been approved for unescorted access in a manner to prevent unauthorized access. Information stored in nonremovable electronic form must be password protected.

12.12.4.8 The licensee shall retain as a record for 3 years after the document is no longer needed:

12.12.4.8.1 A copy of the information protection procedures; and

12.12.4.8.2 The list of individuals approved for access to the security plan ~~or,~~ implementing procedures, or the list of individuals that have been approved for unescorted access.

Amend 12.23.1.1 to read:

12.23.1.1 The notification must be made to the Department and to the office of each appropriate governor or governor's designee. The contact information, including telephone numbers and mailing addresses, of governors and governors' designees, is available on the NRC's Web site at https://scp.nrc.gov/special/designee.pdf. A list of the contact information is also available upon request from the Director, Division of Materials Safety, Security, State, and Tribal~~, and Rulemaking~~ Programs, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The notification to the Department may be made by email to RAMQC_shipments@dhec.sc.gov or by fax to 803-898-0391. Notifications to the Department must be to the Director, Division of Land & Waste Management, Bureau of Waste Management, 2600 Bull Street, Columbia, SC 29201.

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: 61-63, Radioactive Materials (Title A).

Purpose: The Department amends R.61-63 to incorporate federal law as required to maintain South Carolina's status with the United States Nuclear Regulatory Commission ("NRC") as an Agreement State.

Legal Authority: 1976 Code Sections 13-7-40 et seq.

Plan for Implementation: The amendments will take legal effect upon publication in the State Register. Department personnel will then take appropriate steps to inform the regulated community of the amendments. Additionally, a copy of the regulation will be posted on the Department's website, accessible at www.scdhec.gov/regulations-table. Printed copies may also be requested, 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 are required to be implemented for South Carolina to maintain its status through the NRC as an Agreement State and to ensure compatibility with federal regulations as required by Section 274 of the Atomic Energy Act of 1954. The amendments include revisions to medical event definitions, training and experience, individual monitoring devices, social security number fraud prevention, and general overall clarifications, miscellaneous corrections, and organization.

DETERMINATION OF COSTS AND BENEFITS:

Neither the state nor its political subdivisions will incur additional costs through implementation of these amendments. Existing staff and resources will be utilized to implement the revisions to the regulation. The amendments will not create any significant additional cost to the regulated community since requirements or changes to the regulations will be substantially consistent with the current guidelines and review guidelines utilized by the Department.

UNCERTAINTIES OF ESTIMATES:

None.

EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH:

These amendments seek to ensure an effective regulatory program for radioactive material users under state jurisdiction, and protection of the public and workers from unnecessary exposure to ionizing radiation.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED:

There is no anticipated detrimental effect on the environment.

South Carolina Board of Health and Environmental Control
Final Review Conference
May 13, 2021

Final Review Conference - Docket No. 21-RFR-27, Ridgeview Community Care Homes, Inc. – CRC-0559, Issuance of Notice of Violation and Civil Penalty for violation of Public Health Order No. COVID-19-5 by failing to submit a weekly report by the 5:00 PM deadline of Monday, March 8, 2021

Trish Daugherty for Ridgeview Community Care Homes, Inc.
Ashley Biggers for SCDHEC

Table of Contents

Note: Page #s for this record are located on the bottom of the page.

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

IN RE:
RIDGEVIEW COMMUNITY CARE HOMES UNIT A, CRC-0559
217 CHANDLER RD, GREER, SC
RIDGEVIEW COMMUNITY CARE HOMES INC, Licensee

NOTICE OF REPEAT VIOLATION AND CIVIL PENALTY

The South Carolina Department of Health and Environmental Control (Department) issued Public Health Order No. COVID-19-5 (attached hereto), pursuant to Section 44-1-140 of the South Carolina Code of Laws, on October 7, 2020, requiring all nursing homes and community residential care facilities (CRCFs) licensed by the Department to submit a weekly report, by no later than 5:00 pm each Monday, stating whether they are allowing visitation, and if not, providing the reason(s) for not allowing visitation. The weekly report must also include the number of residents who participated in a visit in the previous seven (7) days.

The Department notified RIDGEVIEW COMMUNITY CARE HOMES INC, of its first violation of Public Health Order No. COVID-19-5 by certified mail on OCTOBER 21, 2020.

The Department hereby notifies RIDGEVIEW COMMUNITY CARE HOMES INC, Licensee, that RIDGEVIEW COMMUNITY CARE HOMES UNIT A, License No. CRC-0559, violated Public Health Order No. COVID-19-5 a SECOND time by failing to submit a weekly report by the 5pm deadline of Monday, MARCH 1, 2021.

The Department hereby issues an additional civil penalty to RIDGEVIEW COMMUNITY CARE HOMES UNIT A in the amount of $350 for the aforementioned repeat violation, in accordance with Section 44-1-150(B) of the South Carolina Code of Laws. Section 44-1-150(B) provides for civil penalties not to exceed $1000.00 per day for each violation.

Payment of the additional $350 civil penalty is due within twenty (20) days of the date of this Notice of Repeat Violation and Civil Penalty. Instructions for payment are attached.

Failure to make timely payment of the civil penalty or further violation of Public Health Order No. COVID-19-5 may result in the Department taking further enforcement action.

Gwendolyn C. Thompson

03092021

Gwendolyn C. Thompson, Director
Healthcare Quality

Date

Attachments:
Public Health Order No. COVID-19-5
Instructions for Payment
Guide to Board Review

Healthy People. Healthy Communities.

SOUTH CAROLINA
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

PUBLIC HEALTH ORDER
No. COVID-19-5

WHEREAS, on March 13, 2020, Governor Henry McMaster declared a State of Emergency based on a determination that Coronavirus Disease 2019 (COVID-19) posed an actual or imminent public health emergency for the State of South Carolina; and

WHEREAS, on March 13, 2020, the Governor also directed the South Carolina Department of Health and Environmental Control (DHEC) to utilize and exercise any and all emergency powers, as set forth in the Emergency Health Powers Act, codified as amended in Title 44, Chapter 4 of the South Carolina Code of Laws, deemed necessary to promptly and effectively address the current public health emergency. In accordance with Section 44-4-500 of the South Carolina Code of Laws, as amended, the Governor ordered that DHEC shall "use every available means to prevent the transmission of infectious disease and to ensure that all cases of infectious disease are subject to proper control and treatment;" and

WHEREAS, on March 13, 2020, the President of the United States declared the ongoing COVID-19 outbreak a pandemic of sufficient severity and magnitude to warrant an emergency declaration for all states, tribes, territories, and the District of Columbia, pursuant to Section 501(b) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. §§ 5121-5207 ("Stafford Act"); and

WHEREAS, on March 24, 2020, the Governor requested that the President of the United States declare that a major disaster exists in the State of South Carolina pursuant to Section 401 of the Stafford Act; and

WHEREAS, on March 27, 2020, the President of the United States granted the Governor's request and declared that a major disaster exists in the State of South Carolina and ordered federal assistance to supplement state, tribal, and local recovery efforts in the areas affected by the COVID-19 pandemic, with an effective date retroactive to January 20, 2020, and continuing; and

WHEREAS, since declaring an initial State of Emergency on March 13, 2020, the Governor has subsequently declared a State of Emergency and directed DHEC to utilize and exercise any and all emergency powers, as set forth in the Executive Health Powers Act, codified in Title 44, Chapter 4 of the South Carolina Code of Laws, deemed necessary to promptly and effectively address the current public health emergency, in Executive Order Nos. 2020-15, 2020-23, 2020-29, 2020-35, 2020-38, 2020-40, 2020-42, 2020-44, 2020-48, 2020-53, 2020-56, 2020-59, and 2020-62; and

WHEREAS, as of October 7, 2020, COVID-19 is widespread throughout the state and in all 46 counties, with 148,334 total confirmed cases statewide and 3,300 total confirmed deaths; and

WHEREAS, DHEC is invested with all the rights and charged with all the duties pertaining to organizations of like character and is the sole advisor of the State in all questions involving the protection of the public health within its limits (S.C. Code Ann.§ 44-1-110); and

WHEREAS, DHEC must enforce or prescribe preventive measures as may be needed to suppress or prevent the spread of these diseases by proper quarantine or other measures of prevention, as may be necessary to protect citizens of the State (S.C. Code Ann. § 44-1-80(A)); and

WHEREAS, DHEC is granted the authority to make, adopt, promulgate and enforce reasonable rules and regulations from time to time requiring and providing for the thorough investigation and study of the causes of all diseases, epidemic and otherwise, in the State, the means for the prevention of contagious disease and the publication and distribution of such information as may contribute to the preservation of the public health and the prevention of disease (S.C. Code Ann.§ 44-1-140(12)); and

WHEREAS, DHEC may also make separate orders and rules to meet any emergency not provided for by general rules and regulations, for the purpose of suppressing nuisances dangerous to the public health and communicable, contagious and infectious diseases and other danger to the public life and health (S.C. Code Ann.§ 44-1-140); and

WHEREAS, in addition to its authority provided by statute or as otherwise provided for by regulation, DHEC may issue separate orders to enforce the provisions of S.C. Regulation 61-20 for the purpose of suppressing nuisances, Communicable, Contagious and Infectious Diseases, and other dangers to public health (S.C. Code Ann. Regs. 61-20 § 14(A)); and

WHEREAS, all entities shall comply with DHEC directives and orders to protect the public health from the spread of Communicable and Infectious Diseases (S.C. Code Ann. Regs. 61-20 § 4(D)); and

WHEREAS, during a public health emergency, DHEC must use every available means to prevent the transmission of infectious disease and ensure that all cases of infectious disease are subject to proper control and treatment (S.C. Code Ann.§ 44-4-500); and

WHEREAS, the Bill of Rights for Residents of Long-Term Care Facilities requires the legal guardian, family members, and other relatives of each resident of a long-term care facility

be allowed immediate access to that resident, subject to the resident's right to deny access or withdraw consent to access at any time, and requires each resident, without unreasonable delay or restrictions, be allowed to associate and communicate privately with persons of the resident's choice (S.C. Code Ann. § 44-81-40(K)); and

WHEREAS, nursing homes and community residential care facilities are required to comply with the Bill of Rights for Residents of Long-Term Care Facilities (S.C. Code Ann. Regs. 61-17, § 1101; S.C. Code Ann. Regs. 61-84 § 1001), and

WHEREAS, nursing homes shall encourage visitation of residents by family and friends with minimum restrictions and shall post visiting hours in accordance with facility policies and procedures (S.C. Code Ann. Regs. § 1003.J), and

WHEREAS, South Carolina is engaged in an all-hands effort to both reduce the spread of COVID-19 and to ensure safety of all South Carolinians, including residents of nursing homes and community residential care facilities; and

WHEREAS, the COVID-19 pandemic has created a need for nursing homes and community residential care facilities to prevent the spread of disease among residents and staff, and

WHEREAS, nursing homes and community residential care facilities are required by South Carolina law and regulation to allow for access to residents; however, the current State of Emergency requires changes and limitations to normal visitation policies and procedures in order to ensure residents, which are members of a vulnerable population, are protected from exposure to COVID-19; and

WHEREAS, as the Acting Director of Public Health, I have reviewed the data regarding confirmed COVID-19 cases, reported exposures among the population in South Carolina, including cases and reported exposures in vulnerable populations including residents of nursing homes and community residential care facilities, and

WHEREAS, I have determined that it is necessary to gather and monitor information regarding access to visitation for residents in nursing homes and community residential care facilities in order to ensure the safety of residents and staff and appropriate and reasonable compliance with applicable laws and regulations.

NOW, THEREFORE, IT IS HEREBY ORDERED, pursuant to section 44-1-140 of the South Carolina Code of Laws, that all nursing homes and community residential care facilities licensed by DHEC are required to submit a weekly report stating whether they are allowing

visitation, and if not, providing the reason(s) for not allowing visitation. Facilities must also report the number of residents who participated in a visit in the previous seven (7) days.

Each licensed Facility must submit a separate report to DHEC.

Facilities must complete their weekly report no later than 5:00 PM each Monday by completing and submitting the form on DHEC's webpage, https://scdhec.gov/visitation.

Should any nursing home or community residential care facility face human resource or information technology challenges in completing any requirement of this Order, the facility should notify DHEC immediately by contacting ACC-HealthReg@dhec.sc.gov.

IT IS FURTHER ORDERED, pursuant to section 44-1-150 of the South Carolina Code of Laws, that any facility that violates this Order may be subject to a civil penalty not to exceed one thousand (1,000) dollars a day for each violation.

This Order is effective immediately and shall remain in effect unless otherwise modified, amended, or rescinded by subsequent order.

AND IT IS SO ORDERED.

LB Traxler MD

L. Brannon Traxler, MD, MPH
Interim Director of Public Health

Date: 10/07/2020

Healthy People. Healthy Communities.

INSTRUCTIONS FOR PAYMENT

1. Make certified check or money order payable to S.C. Department of Health and Environmental Control and ensure to include your Facility's Name and License Number

2. Send payment to the following address:

   Attention: Angie Smith, Interim Director
   Bureau of Facilities Oversight/Healthcare Quality
   S.C. Department of Health and Environmental Control
   2600 Bull Street
   Columbia, SC 29201

South Carolina Board of Health and Environmental Control

Guide to Board Review

Pursuant to S.C. Code Ann. § 44-1-60

The decision of the South Carolina Department of Health and Environmental Control (Department) becomes the final agency decision fifteen (15) calendar days after notice of the decision has been mailed to the applicant, permittee, licensee and affected persons who have requested in writing to be notified, unless a written request for final review accompanied by a filing fee in the amount of $100 is filed with Department by the applicant, permittee, licensee or affected person.

Applicants, permittees, licensees, and affected parties are encouraged to engage in mediation or settlement discussions during the final review process.

If the Board declines in writing to schedule a final review conference, the Department's decision becomes the final agency decision and an applicant, permittee, licensee, or affected person may request a contested case hearing before the Administrative Law Court within thirty (30) calendar days after notice is mailed that the Board declined to hold a final review conference. In matters pertaining to decisions under the South Carolina Mining Act, appeals should be made to the South Carolina Mining Council.

I. Filing of Request for Final Review

1. A written Request for Final Review (RFR) and the required filing fee of one hundred dollars ($100) must be received by Clerk of the Board within fifteen (15) calendar days after notice of the staff decision has been mailed to the applicant, permittee, licensee, or affected persons. If the 15th day occurs on a weekend or State holiday, the RFR must be received by the Clerk on the next working day. RFRs will not be accepted after 5:00 p.m.
2. RFRs shall be in writing and should include, at a minimum, the following information:
   - The grounds for amending, modifying, or rescinding the staff decision;
   - a statement of any significant issues or factors the Board should consider in deciding how to handle the matter;
   - the relief requested;
   - a copy of the decision for which review is requested; and
   - mailing address, email address, if applicable, and phone number(s) at which the requestor can be contacted.
3. RFRs should be filed in person or by mail at the following address:
   South Carolina Board of Health and Environmental Control
   Attention: Clerk of the Board
   2600 Bull Street
   Columbia, South Carolina 29201
   Alternatively, RFR's may be filed with the Clerk by facsimile (803-898-3393) or by electronic mail (boardclerk@dhec.sc.gov).
4. The filing fee may be paid by cash, check or credit card and must be received by the 15th day.
5. If there is any perceived discrepancy in compliance with this RFR filing procedure, the Clerk should consult with the Chairman or, if the Chairman is unavailable, the Vice-Chairman. The Chairman or the Vice-Chairman will determine whether the RFR is timely and properly filed and direct the Clerk to (1) process the RFR for consideration by the Board or (2) return the RFR and filing fee to the requestor with a cover letter explaining why the RFR was not timely or properly filed. Processing an RFR for consideration by the Board shall not be interpreted as a waiver of any claim or defense by the agency in subsequent proceedings concerning the RFR.
6. If the RFR will be processed for Board consideration, the Clerk will send an Acknowledgement of RFR to the Requestor and the applicant, permittee, or licensee, if other than the Requestor. All personal and financial identifying information will be redacted from the RFR and accompanying documentation before the RFR is released to the Board, Department staff or the public.
7. If an RFR pertains to an emergency order, the Clerk will, upon receipt, immediately provide a copy of the RFR to all Board members. The Chairman, or in his or her absence, the Vice-Chairman shall based on the circumstances, decide whether to refer the RFR to the RFR Committee for expedited review or to decline in writing to schedule a Final Review Conference. If the Chairman or Vice-Chairman determines review by the RFR Committee is appropriate, the Clerk will forward a copy of the RFR to Department staff and Office of General Counsel. A Department response and RFR Committee review will be provided on an expedited schedule defined by the Chairman or Vice-Chairman.
8. The Clerk will email the RFR to staff and Office of General Counsel and request a Department Response within eight (8) working days. Upon receipt of the Department Response, the Clerk will forward the RFR and Department Response to all Board members for review, and all Board members will confirm receipt of the RFR to the Clerk by email. If a Board member does not confirm receipt of the RFR within a twenty-four (24) hour period, the Clerk will contact the Board member and confirm receipt. If a Board member believes the RFR should be considered by the RFR Committee, he or she will

respond to the Clerk's email within forty-eight (48) hours and will request further review. If no Board member requests further review of the RFR within the forty-eight (48) hour period, the Clerk will send a letter by certified mail to the Requestor, with copy by regular mail to the applicant, permittee, or licensee, if not the Requestor, stating the Board will not hold a Final Review Conference. Contested case guidance will be included within the letter.
NOTE: If the time periods described above end on a weekend or State holiday, the time is automatically extended to 5:00 p.m. on the next business day.

9. If the RFR is to be considered by the RFR Committee, the Clerk will notify the Presiding Member of the RFR Committee and the Chairman that further review is requested by the Board. RFR Committee meetings are open to the public and will be public noticed at least 24 hours in advance.
10. Following RFR Committee or Board consideration of the RFR, if it is determined no Conference will be held, the Clerk will send a letter by certified mail to the Requestor, with copy by regular mail to the applicant, permittee, or licensee, if not the Requestor, stating the Board will not hold a Conference. Contested case guidance will be included within the letter.

II. Final Review Conference Scheduling

1. If a Conference will be held, the Clerk will send a letter by certified mail to the Requestor, with copy by regular mail to the applicant, permittee, or licensee, if not the Requestor, informing the Requestor of the determination.
2. The Clerk will request Department staff provide the Administrative Record.
3. The Clerk will send Notice of Final Review Conference to the parties at least ten (10) days before the Conference. The Conference will be publically noticed and should:
   - include the place, date and time of the Conference;
   - state the presentation times allowed in the Conference;
   - state evidence may be presented at the Conference;
   - if the conference will be held by committee, include a copy of the Chairman's order appointing the committee; and
   - inform the Requestor of his or her right to request a transcript of the proceedings of the Conference prepared at Requestor's expense.
4. If a party requests a transcript of the proceedings of the Conference and agrees to pay all related costs in writing, including costs for the transcript, the Clerk will schedule a court reporter for the Conference.

III. Final Review Conference and Decision

1. The order of presentation in the Conference will, subject to the presiding officer's discretion, be as follows:
   - Department staff will provide an overview of the staff decision and the applicable law to include [10 minutes]:
     - Type of decision (permit, enforcement, etc.) and description of the program.
     - Parties
     - Description of facility/site
     - Applicable statutes and regulations
     - Decision and materials relied upon in the administrative record to support the staff decision.
   - Requestor(s) will state the reasons for protesting the staff decision and may provide evidence to support amending, modifying, or rescinding the staff decision. [15 minutes] *NOTE: The burden of proof is on the Requestor(s)*
   - Rebuttal by Department staff [15 minutes]
   - Rebuttal by Requestor(s) [10 minutes]

   Note: Times noted in brackets are for information only and are superseded by times stated in the Notice of Final Review Conference or by the presiding officer.
2. Parties may present evidence during the conference; however, the rules of evidence do not apply.
3. At any time during the conference, the officers conducting the Conference may request additional information and may question the Requestor, the staff, and anyone else providing information at the Conference.
4. The presiding officer, in his or her sole discretion, may allow additional time for presentations and may impose time limits on the Conference.
5. All Conferences are open to the public.
6. The officers may deliberate in closed session.
7. The officers may announce the decision at the conclusion of the Conference or it may be reserved for consideration.
8. The Clerk will mail the written final agency decision (FAD) to parties within 30 days after the Conference. The written decision must explain the basis for the decision and inform the parties of their right to request a contested case hearing before the Administrative Law Court or in matters pertaining to decisions under the South Carolina Mining Act, to request a hearing before the South Carolina Mining Council.. The FAD will be sent by certified mail, return receipt requested.
9. Communications may also be sent by electronic mail, in addition to the forms stated herein, when electronic mail addresses are provided to the Clerk.

The above information is provided as a courtesy; parties are responsible for complying with all applicable legal requirements.

Ridgeview Community Care Homes, Inc.

217 Chandler Rd ~ Greer, SC ~ 29651

March 17. 2021

South Carolina Board of Health and Environmental Control
Attention: Clerk of Court
2600 Bull Street
Columbia, SC 29201

RE: Written Request for Final Review

Dear Board Members,

We are submitting this written request for final review and a copy of the check payment of $100 for a final review of the decision to impose a civil penalty of $350 on each of our 4 facilities for submitting the weekly visitation report late. The check was sent Attn: Angie Smith, Interim Director.

The grounds for amending, modifying, or rescinding the staff decision:

After months of receiving Monday email reminders from DHEC to submit the weekly visitation reports, our facility did not receive email reminders from DHEC on Monday, March 8, to 0submit the weekly reports. This reminder email has become an integral part of our process to submit timely reports, and on March 8th we did not receive this reminder. Also, during this pandemic quarantine it is a financial hardship and unnecessary to impose a civil penalty for a report that was only 2 days late and did not put anyone in danger.

Significant issues the Board should consider in deciding how to handle the matter:

The weekly visitation report WAS FILED on Wednesday of that week, please see attached email confirmation.

I was working on financial paperwork for our facility's tax return and did not . I do not have anyone else in my office currently to train to submit the reports because there is no other administrative staff with online access right now.

Ridgeview Community Care Homes is made up of 4 licensed buildings so for us this second penalty of $350 is a penalty of $1,400, which is a tremendous financial hardship during this difficult time.

Please consider the many difficulties we have dealt with due to the COVID-19 pandemic. Financial difficulties such as reduced income due to inability to fill beds during quarantine, increased payroll expenses due to paying staff bonuses for continued service during the pandemic, increased food expenses due to ordering online to reduce staff exposure shopping for food items and increased recreational activity expenses for extra supplies and snacks ordered online to provide additional activities for our residents during quarantine to help improve their mental status. We can not survive

as a business with negative income. Additional expenses such as monetary penalties would be a financial hardship for us.

After last year's pandemic, filled with fear of illness and death, it is unnecessary for the Department to impose monetary penalties upon businesses that are caring for the most vulnerable population in our state. It has been challenging for our residents and staff to say the very least, a year full of new regulations, limited family visits, and no resident outings. Please take this into consideration and not add another financial burden to our business, or to any other facilities throughout the state who are suffering the same way. Our facility has not had any COVID-19 outbreaks among our residents or staff, we have followed the regulations and have received our vaccinations. Our residents' wellbeing comes first and at no time were they in a compromised position due to our report being submitted 2 days late so instead of imposing financial hardship on facilities, please show your support to the facilities that care for the ones that are most at risk and have been unable to have normal visits and outings with their loved ones.

The relief requested: We would like the civil penalty to be removed.

A copy of the decision for which the review is requested: Copies are attached.

Mailing address, email address and phone number the requestor can be contacted:

Trish Daugherty, Administrator
Ridgeview Community Care Homes
217 Chandler Road
Greer, SC 29651
ridgeview1@msn.com
Phone (864)877-8599 Fax (864)877-8704

We sincerely appreciate the opportunity to ask for a review of the decision to impose a civil penalty on our facility. If you have any questions please contact me at (864)877-8599.

Thank you,

Trish Daugherty
Administrator

Lee Daugherty
Assistant Administrator

The following copies are listed below/enclosed:

- Email confirmation that the weekly visitation reports were filed.
- Copy of the original notice of violation and civil penalty for one of our 4 facilities (all 4 of our facilities received the same notice so I am only enclosing one copy)

HealthRegComm <HealthRegComm@dhec.sc.gov>
Wed 3/10/2021 4:10 PM
To: RIDGEVIEW1@MSN.COM

Thank you for submitting your weekly visitation report for RIDGEVIEW COMMUNITY CARE HOMES UNIT A (CRC-0559).

Submission Summary:

Facility Type: Community Residential Care (CRC) Facility
Facility Name: RIDGEVIEW COMMUNITY CARE HOMES UNIT A (CRC-0559)

HealthRegComm <HealthRegComm@dhec.sc.gov>
Wed 3/10/2021 4:10 PM
To: RIDGEVIEW1@MSN.COM

Thank you for submitting your weekly visitation report for RIDGEVIEW COMMUNITY CARE HOMES UNIT B (CRC-0560).

Submission Summary:

Facility Type: Community Residential Care (CRC) Facility
Facility Name: RIDGEVIEW COMMUNITY CARE HOMES UNIT B (CRC-0560)

HealthRegComm <HealthRegComm@dhec.sc.gov>
Wed 3/10/2021 4:11 PM
To: RIDGEVIEW1@MSN.COM

Thank you for submitting your weekly visitation report for RIDGEVIEW COMMUNITY CARE HOMES UNIT C (CRC-0561).

Submission Summary:

Facility Type: Community Residential Care (CRC) Facility
Facility Name: RIDGEVIEW COMMUNITY CARE HOMES UNIT C (CRC-0561)

HealthRegComm <HealthRegComm@dhec.sc.gov>
Wed 3/10/2021 4:11 PM
To: RIDGEVIEW1@MSN.COM

Thank you for submitting your weekly visitation report for RIDGEVIEW COMMUNITY CARE HOMES UNIT D (CRC-0562).

Submission Summary:

Facility Type: Community Residential Care (CRC) Facility
Facility Name: RIDGEVIEW COMMUNITY CARE HOMES UNIT D (CRC-0562)

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

IN RE:
RIDGEVIEW COMMUNITY CARE HOMES UNIT A, CRC-0559
217 CHANDLER RD, GREER, SC
RIDGEVIEW COMMUNITY CARE HOMES INC, Licensee

NOTICE OF REPEAT VIOLATION AND CIVIL PENALTY

The South Carolina Department of Health and Environmental Control (Department) issued Public Health Order No. COVID-19-5 (attached hereto), pursuant to Section 44-1-140 of the South Carolina Code of Laws, on October 7, 2020, requiring all nursing homes and community residential care facilities (CRCFs) licensed by the Department to submit a weekly report, by no later than 5:00 pm each Monday, stating whether they are allowing visitation, and if not, providing the reason(s) for not allowing visitation. The weekly report must also include the number of residents who participated in a visit in the previous seven (7) days.

The Department notified RIDGEVIEW COMMUNITY CARE HOMES INC, of its first violation of Public Health Order No. COVID-19-5 by certified mail on OCTOBER 21, 2020.

The Department hereby notifies RIDGEVIEW COMMUNITY CARE HOMES INC, Licensee, that RIDGEVIEW COMMUNITY CARE HOMES UNIT A, License No. CRC-0559, violated Public Health Order No. COVID-19-5 a SECOND time by failing to submit a weekly report by the 5pm deadline of Monday, MARCH 8, 2021.

The Department hereby issues an additional civil penalty to RIDGEVIEW COMMUNITY CARE HOMES UNIT A in the amount of $350 for the aforementioned repeat violation, in accordance with Section 44-1-150(B) of the South Carolina Code of Laws. Section 44-1-150(B) provides for civil penalties not to exceed $1000.00 per day for each violation.

Payment of the additional $350 civil penalty is due within twenty (20) days of the date of this Notice of Repeat Violation and Civil Penalty. Instructions for payment are attached.

Failure to make timely payment of the civil penalty or further violation of Public Health Order No. COVID-19-5 may result in the Department taking further enforcement action.

Gwendolyn C. Thompson

Gwendolyn C. Thompson, Director
Healthcare Quality

03112021

Date

Attachments:
Public Health Order No. COVID-19-5
Instructions for Payment
Guide to Board Review

RECEIVED
APR 08 2021
Clerk, Board of Health
and Environmental Control

BEFORE THE BOARD OF HEALTH AND ENVIRONMENTAL CONTROL
STAFF RESPONSE TO REQUEST FOR FINAL REVIEW
Docket No. 21-RFR-27

Requestor: **Ridgeview Community Care Homes, Inc. (Licensee)**
Ridgeview Community Care Homes Unit A, License No. CRC-0559
(Ridgeview or Facility)
Re: **Notice of Repeat Violation and Civil Penalty**

Overview: This Request for Final Review (RFR) concerns a $350 civil monetary penalty imposed for a violation of Public Health Order No. COVID-19-5 (PHO) for failure to submit a mandatory weekly report on visitation status at the Facility. The Facility requests the violation be reviewed and removed. Staff requests the Board uphold the decision, which was issued in accordance with terms of the PHO and applicable statutory requirements.

I. Summary

Ridgeview Community Care Homes-Unit A is a licensed Community Residential Care Facility (CRCF) located in Greer, South Carolina, licensed for eleven (11) beds.

On March 13, 2020, Governor Henry McMaster declared a State of Emergency based on a determination that Coronavirus Disease 2019 (COVID-19) posed an actual or imminent public health emergency for the State of South Carolina.

On October 7, 2020, the South Carolina Department of Health and Environmental Control (DHEC or Department) issued the attached PHO, pursuant to section 44-1-140 of the South Carolina Code of Laws, requiring all licensed nursing homes and CRCFs to submit a weekly report stating whether they are allowing visitation, and if not, providing the reason(s) for not allowing visitation. *See* Exhibit 1. Facilities must also include in the weekly report the number of residents who participated in a visit in the previous seven (7) days. Facilities must submit their weekly report to DHEC no later than 5:00 PM each Monday by completing and submitting the form on the DHEC's webpage (https://scdhec.gov/visitation). The PHO further provides, pursuant to Section 44-1-150, that any facility violating the Order may be subject to a civil penalty not to exceed one thousand ($1,000) dollars a day for each violation.

DHEC sent Ridgeview Community Care Homes Unit-A, and other licensed CRCFs and nursing homes, notice of the PHO by email on October 8, 2020. *See* Exhibit 2. DHEC sent additional email reminders to the Facility and other licensed facilities following the initial notice, including three reminder emails on October 12, 2020, the first day of required reporting, and two reminder emails a week prior to the reporting deadline in subsequent weeks. The reminder emails are sent on Fridays and Mondays prior to the 5:00 PM Monday reporting deadline each week. *See* Exhibit 3 (reminder emails sent on March 5, 2021, and March 8, 2021).

For the week beginning March 1, 2021, the Department did not receive a weekly report, which was due March 8, 2021, from Ridgeview Community Care Homes Unit-A until March 10, 2021, at 4:10 PM. *See* Exhibit 4. The Department notified the Facility that it had violated the PHO by

failing to submit a weekly report by the 5PM deadline of Monday, March 8, 2021. *See* Exhibit 5. This was Ridgeway's second cited violation of the PHO reporting requirement. Therefore, the Department issued a penalty in the amount of $350 for the aforementioned violation, in accordance with Section 44-1-150(b) of the South Carolina Code of Laws. *Id.* Ridgeview Community Care Homes Unit-D, filed its RFR, requesting waiver of the penalty, on March 22, 2021.

II. Relevant Law

DHEC is vested with all the rights and charged with all the duties pertaining to organizations of like character and is the sole advisor of the State in all questions involving the protection of the public health within its limits. S.C. Code Ann. § 44-1-110. DHEC is granted the authority to make, adopt, promulgate and enforce reasonable rules and regulations from time to time requiring and providing for the thorough investigation and study of the causes of all diseases, epidemic and otherwise, in the State, the means for the prevention of contagious disease and the public and distribution of such information as may contribute to the preservation of the public health and the prevention of disease. S.C. Code Ann. § 44-1-140(12). During a public health emergency, DHEC must use every available means to prevent the transmission of infectious disease and ensure that all cases of infectious disease are subject to proper control and treatment. S.C. Code Ann. § 44-4-500. All entities shall comply with DHEC directives and orders to protect the public health from the spread of communicable and infectious diseases. S.C. Code Ann. Regs. 61-20 § 4(D).

The Bill of Rights for Residents of Long-Term Care Facilities requires the legal guardian, family members, and other relatives of each resident of a long-term care facility be allowed immediately access to that resident, subject to the resident's right to deny access or withdraw consent to access at any time, and requires each resident, without unreasonable delay or restrictions, be allowed to associate and communicate privately with persons of the residents' choice. S.C. Code Ann. § 44-81-40(K). Nursing homes and community residential care facilities are required to comply with the Bill of Rights for Residents of Long-Term Care Facilities. S.C. Code Ann. Regs. 61-17 § 1101; S.C. Code Ann. Regs 61-84 § 1001.

DHEC may make separate orders and rules to meet any emergency not provided for by general rules and regulations, for the purpose of suppressing nuisances dangerous to the public health and communicable, contagious and infectious diseases and other danger to the public life and health. S.C. Code Ann. § 44-1-140. A person who after notice violates an order of the department issued pursuant to Section 44-1-140 is subject to a civil penalty not to exceed one thousand dollars a day for each violation. S.C. Code Ann. § 44-1-150(b).

III. Response to Request for Review

The Facility does not dispute the Department's finding that it violated the PHO by failing to submit a weekly report by the deadline of 5:00 PM on March 8, 2021, for the week that began on March 1, 2021. Rather, the Facility requests the fine of $350 be waived because, "after months of receiving Monday email reminders from DHEC to submit the weekly visitation reports, our facility did not receive email reminders from DHEC on Monday, March 8th to submit the weekly reports. This reminder email has become an integral part of our process to submit timely reports, and on March 8th we did not receive this reminder. Also, during this pandemic quarantine it is a financial

hardship and unnecessary to impose a civil penalty for a report that was only two days late and did not put anyone in danger."

Staff respectfully requests the Board uphold the imposed $350 fine. The Department provided ample and repeated notices to the Facility of the PHO's reporting requirement and the 5:00 PM, March 8, 2021, reporting deadline, including email reminders on Friday, March 5, and Monday March 8, 2021. *See* Exhibit 3. Ridgeview Community Care Homes Unit-D is one of 499 community residential care facilities subject to the March 8, 2021, PHO reporting deadline, and one of fourteen that failed to submit a timely report by that week's deadline.[1] The Department is tracking compliance with the reporting requirement for hundreds of facilities and is treating all facilities subject to the PHO equally in terms of enforcement. The Department considered the Facility's compliance history with the reporting requirements when determining the monetary penalty amount. As with other similarly situated facilities that committed a second violation of the PHO for the week in question, Ridgeview Community Care Homes Unit-D was fined $350 – less than the maximum possible fine of $1,000 per violation. For these reasons, staff respectfully requests the Board uphold the issued fine.

IV. Requested Action

For the foregoing reasons, staff requests that the Board decline to conduct a final review conference and uphold the monetary penalty for violation of the PHO.

Respectfully submitted:

Angie Smith

Angie Smith, Interim Director
Bureau of Facilities Oversight
Director, Community Oversight Care Division
Healthcare Quality

Ashley Biggers

Ashley Biggers, Esq.
Chief Counsel for Healthcare Quality
Office of General Counsel

March 2021

Exhibit 1 – October 7, 2020, PHO
Exhibit 2 – October 8, 2020, Email Notice of PHO
Exhibit 3 – March 5 and March 8, 2021, Email Reminder of March 8, 2021, Reporting Deadline
Exhibit 4 – Confirmation of Receipt of Report
Exhibit 5 – March 9, 2021, Notice of Violation and Civil Penalty

[1] Of the 499 community residential care facilities subject to the PHO reporting requirement on March 8, 2021, only fourteen failed to submit a weekly report and were sent a notice of violation and civil penalty

EXHIBIT 1

October 7, 2020
Public Health Order (PHO)

SOUTH CAROLINA
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

PUBLIC HEALTH ORDER
No. COVID-19-5

WHEREAS, on March 13, 2020, Governor Henry McMaster declared a State of Emergency based on a determination that Coronavirus Disease 2019 (COVID-19) posed an actual or imminent public health emergency for the State of South Carolina; and

WHEREAS, on March 13, 2020, the Governor also directed the South Carolina Department of Health and Environmental Control (DHEC) to utilize and exercise any and all emergency powers, as set forth in the Emergency Health Powers Act, codified as amended in Title 44, Chapter 4 of the South Carolina Code of Laws, deemed necessary to promptly and effectively address the current public health emergency. In accordance with Section 44-4-500 of the South Carolina Code of Laws, as amended, the Governor ordered that DHEC shall "use every available means to prevent the transmission of infectious disease and to ensure that all cases of infectious disease are subject to proper control and treatment;" and

WHEREAS, on March 13, 2020, the President of the United States declared the ongoing COVID-19 outbreak a pandemic of sufficient severity and magnitude to warrant an emergency declaration for all states, tribes, territories, and the District of Columbia, pursuant to Section 501(b) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. §§ 5121-5207 ("Stafford Act"); and

WHEREAS, on March 24, 2020, the Governor requested that the President of the United States declare that a major disaster exists in the State of South Carolina pursuant to Section 401 of the Stafford Act; and

WHEREAS, on March 27, 2020, the President of the United States granted the Governor's request and declared that a major disaster exists in the State of South Carolina and ordered federal assistance to supplement state, tribal, and local recovery efforts in the areas affected by the COVID-19 pandemic, with an effective date retroactive to January 20, 2020, and continuing; and

WHEREAS, since declaring an initial State of Emergency on March 13, 2020, the Governor has subsequently declared a State of Emergency and directed DHEC to utilize and exercise any and all emergency powers, as set forth in the Executive Health Powers Act, codified in Title 44, Chapter 4 of the South Carolina Code of Laws, deemed necessary to promptly and effectively address the current public health emergency, in Executive Order Nos. 2020-15, 2020-23, 2020-29, 2020-35, 2020-38, 2020-40, 2020-42, 2020-44, 2020-48, 2020-53, 2020-56, 2020-59, and 2020-62; and

WHEREAS, as of October 7, 2020, COVID-19 is widespread throughout the state and in all 46 counties, with 148,334 total confirmed cases statewide and 3,300 total confirmed deaths; and

WHEREAS, DHEC is invested with all the rights and charged with all the duties pertaining to organizations of like character and is the sole advisor of the State in all questions involving the protection of the public health within its limits (S.C. Code Ann.§ 44-1-110); and

WHEREAS, DHEC must enforce or prescribe preventive measures as may be needed to suppress or prevent the spread of these diseases by proper quarantine or other measures of prevention, as may be necessary to protect citizens of the State (S.C. Code Ann. § 44-1-80(A)); and

WHEREAS, DHEC is granted the authority to make, adopt, promulgate and enforce reasonable rules and regulations from time to time requiring and providing for the thorough investigation and study of the causes of all diseases, epidemic and otherwise, in the State, the means for the prevention of contagious disease and the publication and distribution of such information as may contribute to the preservation of the public health and the prevention of disease (S.C. Code Ann.§ 44-1-140(12)); and

WHEREAS, DHEC may also make separate orders and rules to meet any emergency not provided for by general rules and regulations, for the purpose of suppressing nuisances dangerous to the public health and communicable, contagious and infectious diseases and other danger to the public life and health (S.C. Code Ann.§ 44-1-140); and

WHEREAS, in addition to its authority provided by statute or as otherwise provided for by regulation, DHEC may issue separate orders to enforce the provisions of S.C. Regulation 61-20 for the purpose of suppressing nuisances, Communicable, Contagious and Infectious Diseases, and other dangers to public health (S.C. Code Ann. Regs. 61-20 § 14(A)); and

WHEREAS, all entities shall comply with DHEC directives and orders to protect the public health from the spread of Communicable and Infectious Diseases (S.C. Code Ann. Regs. 61-20 § 4(D)); and

WHEREAS, during a public health emergency, DHEC must use every available means to prevent the transmission of infectious disease and ensure that all cases of infectious disease are subject to proper control and treatment (S.C. Code Ann.§ 44-4-500); and

WHEREAS, the Bill of Rights for Residents of Long-Term Care Facilities requires the legal guardian, family members, and other relatives of each resident of a long-term care facility

be allowed immediate access to that resident, subject to the resident's right to deny access or withdraw consent to access at any time, and requires each resident, without unreasonable delay or restrictions, be allowed to associate and communicate privately with persons of the resident's choice (S.C. Code Ann. § 44-81-40(K)); and

WHEREAS, nursing homes and community residential care facilities are required to comply with the Bill of Rights for Residents of Long-Term Care Facilities (S.C. Code Ann. Regs. 61-17, § 1101; S.C. Code Ann. Regs. 61-84 § 1001), and

WHEREAS, nursing homes shall encourage visitation of residents by family and friends with minimum restrictions and shall post visiting hours in accordance with facility policies and procedures (S.C. Code Ann. Regs. § 1003.J), and

WHEREAS, South Carolina is engaged in an all-hands effort to both reduce the spread of COVID-19 and to ensure safety of all South Carolinians, including residents of nursing homes and community residential care facilities; and

WHEREAS, the COVID-19 pandemic has created a need for nursing homes and community residential care facilities to prevent the spread of disease among residents and staff, and

WHEREAS, nursing homes and community residential care facilities are required by South Carolina law and regulation to allow for access to residents; however, the current State of Emergency requires changes and limitations to normal visitation policies and procedures in order to ensure residents, which are members of a vulnerable population, are protected from exposure to COVID-19; and

WHEREAS, as the Acting Director of Public Health, I have reviewed the data regarding confirmed COVID-19 cases, reported exposures among the population in South Carolina, including cases and reported exposures in vulnerable populations including residents of nursing homes and community residential care facilities, and

WHEREAS, I have determined that it is necessary to gather and monitor information regarding access to visitation for residents in nursing homes and community residential care facilities in order to ensure the safety of residents and staff and appropriate and reasonable compliance with applicable laws and regulations.

NOW, THEREFORE, IT IS HEREBY ORDERED, pursuant to section 44-1-140 of the South Carolina Code of Laws, that all nursing homes and community residential care facilities licensed by DHEC are required to submit a weekly report stating whether they are allowing

visitation, and if not, providing the reason(s) for not allowing visitation. Facilities must also report the number of residents who participated in a visit in the previous seven (7) days.

Each licensed Facility must submit a separate report to DHEC.

Facilities must complete their weekly report no later than 5:00 PM each Monday by completing and submitting the form on DHEC's webpage, https://scdhec.gov/visitation.

Should any nursing home or community residential care facility face human resource or information technology challenges in completing any requirement of this Order, the facility should notify DHEC immediately by contacting ACC-HealthReg@dhec.sc.gov.

IT IS FURTHER ORDERED, pursuant to section 44-1-150 of the South Carolina Code of Laws, that any facility that violates this Order may be subject to a civil penalty not to exceed one thousand (1,000) dollars a day for each violation.

This Order is effective immediately and shall remain in effect unless otherwise modified, amended, or rescinded by subsequent order.

AND IT IS SO ORDERED.

L. Brannon Traxler, MD, MPH
Interim Director of Public Health

Date: 10/07/2020

EXHIBIT 2

October 8, 2020
Email Notice of PHO

Healthy People. Healthy Communities.

Good afternoon,

DHEC issued a Public Health Order on October 7, 2020 that is available to read here.

This Order requires all licensed nursing homes and community residential care facilities to submit a weekly report to DHEC regarding visitation.

Facilities are required to send their respective weekly reports by submitting a response in DHEC's Visitation Reporting Form. The first weekly report is due on this **upcoming Monday, October 12, 2020, by 5:00 pm.**

If you are filling out the survey on behalf of more than one licensed facility, then **you are required to fill out a separate weekly report for each individual facility**. Failure to comply with the mandatory weekly reporting to DHEC may result in a civil penalty not to exceed $1,000 a day for each violation.

Submit weekly reports via the Visitation Reporting Form.

Weekly reports are due each Monday by 5:00 pm.

The Visitation Reporting Form requires all licensed nursing homes and community residential care facilities to report whether they are allowing visitation and, if not, to provide the reason(s) for not allowing visitation; facilities allowing visitation must also report the number of residents who participated in a visit in the previous 7 days.

DHEC plans to publish updated visitation guidelines tomorrow, October 9, 2020, on both outdoor and indoor visitation.

DHEC's Visitation Reporting Form and relevant information will be available on our new Long-Term Care Facilities Visitation (COVID-19) page, which can also be reached by going directly to scdhec.gov/visitation. The forthcoming updated visitation guidance and other resources will be posted on this page.

We thank all licensed nursing homes and community residential care facilities for their cooperation, timely responses, and invaluable care of all residents, staff, and visitors.

Facilities can reach out to acc-healthreg@dhec.sc.gov with any questions at all.

Thank you,

Healthcare Quality
S.C. Dept. of Health & Environmental Control
Connect: www.scdhec.gov Facebook Twitter

EXHIBIT 3

Email Reminders-Reporting Deadline

March 5, 2021
March 8, 2021

Wilson, Gloria

From: ACC-HealthReg <ACC-HealthReg@dhec.sc.gov>
Sent: Friday, March 5, 2021 2:13 PM
To: Gregory, Aramis L.
Subject: Weekly Visitation Report Due Monday by 5 pm!

Healthy People. Healthy Communities.

Good Afternoon,

This email serves as a reminder that all nursing homes and community residential care facilities are required to send their weekly visitation report via DHEC's **Visitation Reporting Form** **no later than Monday, March 8, by 5 p.m.** If you experience technical difficulties (i.e., internet outage) while trying to submit the **Visitation Reporting Form** prior to Monday's deadline, you may call 803-365-3468, to provide the information over the phone to a DHEC staff member. This phone number is reserved for extenuating circumstances involving an internet outage prior to Monday's 5 p.m. deadline.

In order to ensure that we always have the most current information, DHEC strongly encourages facilities to submit one report per reporting week and to submit them between Sunday at 5 p.m. and Monday at 5 p.m. If you are filling out the survey on behalf of more than one licensed facility, then you are required to fill out a separate weekly report for each individual facility.

Facilities that fail to comply with the mandatory weekly reporting are subject to a civil penalty not to exceed $1,000 a day for each violation.

In situations of technical difficulty submitting the form, call 803-365-3468 prior to 5 p.m. on Monday and provide the weekly visitation information over the phone.

Please feel free to contact **acc-healthreg@dhec.sc.gov** with any questions at all.

Thank you!

Healthcare Quality
S.C. Dept. of Health & Environmental Control
Connect: www.scdhec.gov Facebook Twitter

Healthcare Quality | DHEC, 301 Gervais Street, Columbia, SC 29214

Wilson, Gloria

From: ACC-HealthReg <ACC-HealthReg@dhec.sc.gov>
Sent: Monday, March 8, 2021 1:36 PM
To: Gregory, Aramis L.
Subject: Reminder: Weekly Visitation Report Due Today by 5pm!

Healthy People. Healthy Communities.

Good Afternoon,

This email serves as a reminder that all nursing homes and community residential care facilities are required to send their weekly visitation report via DHEC's Visitation Reporting Form no later than today, Monday, March 8th, by 5:00 pm. If you experience technical difficulties (i.e., internet outage) while trying to submit the Visitation Reporting Form prior to today's deadline, you may call 803-365-3468, to provide the information over the phone to a DHEC staff member. This phone number is reserved for extenuating circumstances involving an internet outage prior to today's 5 p.m. deadline.

In order to ensure that we always have the most current information, **DHEC strongly encourages facilities to submit one report per reporting week and to submit them between Sunday at 5:00 pm and Monday at 5:00 pm.** If you are filling out the survey on behalf of more than one licensed facility, then **you are required to fill out a separate weekly report for each individual facility**.

Facilities that fail to comply with the mandatory weekly reporting are subject to a civil penalty not to exceed $1,000 a day for each violation.

In situations of technical difficulty submitting the form, call 803-365-3468 prior to 5 p.m. today and provide the weekly visitation information over the phone.

Please feel free to contact acc-healthreg@dhec.sc.gov with any questions at all.

Thank you!

Healthcare Quality
S.C. Dept. of Health & Environmental Control
Connect: www.scdhec.gov Facebook Twitter

Healthcare Quality | DHEC, 301 Gervais Street, Columbia, SC 29201

EXHIBIT 4

Facility's Confirmation of Receipt of Report

Wilson, Gloria

From: HealthRegComm <HealthRegComm@dhec.sc.gov>
Sent: Tuesday, March 30, 2021 2:44 PM
To: Gregory, Aramis L.
Subject: Fw: Weekly Visitation Report Received (Reference ID:16058)

Healthcare Quality
S.C. Dept. of Health & Environmental Control
Connect: www.scdhec.gov Facebook Twitter

From: HealthRegComm
Sent: Wednesday, March 10, 2021 4:11 PM
To: RIDGEVIEW1@MSN.COM <RIDGEVIEW1@MSN.COM>
Subject: Weekly Visitation Report Received (Reference ID:16058)

Thank you for submitting your weekly visitation report for RIDGEVIEW COMMUNITY CARE HOMES UNIT D (CRC-0562).

Submission Summary:

Facility Type: Community Residential Care (CRC) Facility
Facility Name: RIDGEVIEW COMMUNITY CARE HOMES UNIT D (CRC-0562)
Facility Contact Email: ridgeview1@msn.com
Allowing Visitation: Yes
Type of Visitation: ["Indoor visitation"]
Participation: 1
Reason(s) for not allowing visitation:

EXHIBIT 5

March 9, 2021
Notice of Violation and Civil Penalty

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

IN RE:
RIDGEVIEW COMMUNITY CARE HOMES UNIT D, CRC-0562
217 CHANDLER RD, GREER, SC
RIDGEVIEW COMMUNITY CARE HOMES INC, Licensee

NOTICE OF REPEAT VIOLATION AND CIVIL PENALTY

The South Carolina Department of Health and Environmental Control (Department) issued Public Health Order No. COVID-19-5 (attached hereto), pursuant to Section 44-1-140 of the South Carolina Code of Laws, on October 7, 2020, requiring all nursing homes and community residential care facilities (CRCFs) licensed by the Department to submit a weekly report, by no later than 5:00 pm each Monday, stating whether they are allowing visitation, and if not, providing the reason(s) for not allowing visitation. The weekly report must also include the number of residents who participated in a visit in the previous seven (7) days.

The Department notified RIDGEVIEW COMMUNITY CARE HOMES INC, of its first violation of Public Health Order No. COVID-19-5 by certified mail on OCTOBER 21, 2020.

The Department hereby notifies RIDGEVIEW COMMUNITY CARE HOMES INC, Licensee, that RIDGEVIEW COMMUNITY CARE HOMES UNIT D, License No. CRC-0562, violated Public Health Order No. COVID-19-5 a SECOND time by failing to submit a weekly report by the 5pm deadline of Monday, MARCH 8, 2021.

The Department hereby issues an additional civil penalty to RIDGEVIEW COMMUNITY CARE HOMES UNIT D in the amount of $350 for the aforementioned repeat violation, in accordance with Section 44-1-150(B) of the South Carolina Code of Laws. Section 44-1-150(B) provides for civil penalties not to exceed $1000.00 per day for each violation.

Payment of the additional $350 civil penalty is due within twenty (20) days of the date of this Notice of Repeat Violation and Civil Penalty. Instructions for payment are attached.

Failure to make timely payment of the civil penalty or further violation of Public Health Order No. COVID-19-5 may result in the Department taking further enforcement action.

Gwendolyn C. Thompson

Gwendolyn C. Thompson, Director
Healthcare Quality

03112021

Date

Attachments:
Public Health Order No. COVID-19-5
Instructions for Payment
Guide to Board Review

ACKNOWLEDGMENT OF REQUEST FOR FINAL REVIEW

TO: Ridgeview Community Care Homes, Inc., Permittee/Requestor

Ashley Biggers, Attorney for the Department

FROM: M. Denise Crawford, Clerk of the Board

RE: **Docket No. 21-RFR-27, Ridgeview Community Care Homes, Inc. – CRC-0559**
Issuance of Notice of Violation and Civil Penalty for violation of Public Health Order No. COVID-19-5 by failing to submit a weekly report by the 5:00 PM deadline of Monday, March 8, 2020.

DATE: March 30, 2021

A Request for Final Review of the above-referenced decision was filed on March 22, 2021. A copy of the request is attached. The Board of Health and Environmental Control will notify you by mail as to whether it will conduct a final review conference in this matter.

The Board has 60 days from the date of receipt of a Request for Final Review to conduct a final review conference. If a final review conference is scheduled, all parties will be given at least 10 calendar days' written notice of the conference.

Procedures for final review conferences and requesting further review are provided in S.C. Code Section 44-1-60. Additional information on procedures will be provided to you after the Board decides whether to conduct a final review conference in this matter.

The above information is provided as a courtesy; parties are responsible for complying with all applicable legal requirements.

CERTIFICATE OF SERVICE

I, M. Denise Crawford, Clerk of the South Carolina Board of Health and Environmental Control and an employee of the South Carolina Department of Health Environmental Control, hereby certify that I have this 30th day of March 2021, served the foregoing Acknowledgment of Request for Final Review and Notice of Procedures – Docket No. 21-RFR-27.

Via Electronic Delivery
Ridgeview Community Care Homes, Inc.
Attn: Trish Daugherty
Administrator
Email: ridgeview1@msn.com
217 Chandler Road
Greer, SC 29651

Via Electronic Delivery
Ashley Biggers, Esquire
Email biggerac@dhec.sc.gov
SCHEC – Office of General Counsel
2600 Bull Street
Columbia, SC 29201

M. Denise Crawford

March 30, 2021
Columbia, South Carolina

April 29, 2021

Via Electronic Mail and US Mail Certified 9214 8969 0099 9790 1419 4710 13
Ridgeview Community Care Homes, Inc.
Attn: Trish Daugherty
Administrator
Email: ridgeview1@msn.com
217 Chandler Road
Greer, SC 29651

Via Electronic Mail Delivery
Ashley Biggers, Esquire
Email biggerac@dhec.sc.gov
SCHEC – Office of General Counsel
2600 Bull Street
Columbia, SC 29201

RE: Docket No. 21-RFR-27, Ridgeview Community Care Homes, Inc. – CRC-0559
Issuance of Notice of Violation and Civil Penalty for violation of Public Health Order No. COVID-19-5 by failing to submit a weekly report by the 5:00 PM deadline of Monday, March 8, 2021

Ms. Daugherty and Counsel of Record:

The South Carolina Board of Health and Environmental Control will hold a Final Review Conference on Thursday, May 13, 2021, at 11:00 a.m. in the Board Room (3420), South Carolina Department of Health and Environmental Control, 2600 Bull Street, Columbia, South Carolina, on the above referenced matter.

The Board has approved the following outline of procedures for conferences:

- Swear all witnesses
- Presentation by parties
  - Order of presentation:
    - DHEC Staff - **10 minutes**
    - Requestor/Owner – Ridgeview Community Care Home, Inc. - **15 minutes**

    Rebuttal:
    - DHEC Staff - **15 minutes**
    - Requestor/Owner – Ridgeview Community Care Home, Inc. - **5 minutes**

- Parties may present evidence; rules of admissibility of evidence do not apply
- At any time during conference, officers conducting conference may request additional information and may question parties and anyone providing information
- Burden of proof is on Requestor(s)
- Presiding officer may impose time limits
- Conference is open to the public
- Officers may deliberate in closed session
- Officers may announce decision at conclusion of conference or may reserve consideration

If either party would like to have a transcript of the review conference, please notify (by e-mail or mail at the above address) the Clerk of Board by Monday, May 10, 2021 so that arrangements can be made to have a reporter present for the conference. The parties requesting a court reporter will be responsible for payment of the court reporter.

Sincerely,

M. Denise Crawford
Clerk of the Board

South Carolina Board of Health and Environmental Control
Final Review Conference
May 13, 2021

Final Review Conference - Docket No. 21-RFR-28, Ridgeview Community Care Homes, Inc. – CRC-0560, Issuance of Notice of Violation and Civil Penalty for violation of Public Health Order No. COVID-19-5 by failing to submit a weekly report by the 5:00 PM deadline of Monday, March 8, 2021

Trish Daugherty for Ridgeview Community Care Homes, Inc.
Ashley Biggers for SCDHEC

Table of Contents

Note: Page #s for this record are located on the bottom of the page.

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

IN RE:
RIDGEVIEW COMMUNITY CARE HOMES UNIT B, CRC-0560
217 CHANDLER RD, GREER, SC
RIDGEVIEW COMMUNITY CARE HOMES INC, Licensee

NOTICE OF REPEAT VIOLATION AND CIVIL PENALTY

The South Carolina Department of Health and Environmental Control (Department) issued Public Health Order No. COVID-19-5 (attached hereto), pursuant to Section 44-1-140 of the South Carolina Code of Laws, on October 7, 2020, requiring all nursing homes and community residential care facilities (CRCFs) licensed by the Department to submit a weekly report, by no later than 5:00 pm each Monday, stating whether they are allowing visitation, and if not, providing the reason(s) for not allowing visitation. The weekly report must also include the number of residents who participated in a visit in the previous seven (7) days.

The Department notified RIDGEVIEW COMMUNITY CARE HOMES INC, of its first violation of Public Health Order No. COVID-19-5 by certified mail on OCTOBER 21, 2020.

The Department hereby notifies RIDGEVIEW COMMUNITY CARE HOMES INC, Licensee, that RIDGEVIEW COMMUNITY CARE HOMES UNIT B, License No. CRC-0560, violated Public Health Order No. COVID-19-5 a SECOND time by failing to submit a weekly report by the 5pm deadline of Monday, MARCH 1, 2021.

The Department hereby issues an additional civil penalty to RIDGEVIEW COMMUNITY CARE HOMES UNIT B in the amount of $350 for the aforementioned repeat violation, in accordance with Section 44-1-150(B) of the South Carolina Code of Laws. Section 44-1-150(B) provides for civil penalties not to exceed $1000.00 per day for each violation.

Payment of the additional $350 civil penalty is due within twenty (20) days of the date of this Notice of Repeat Violation and Civil Penalty. Instructions for payment are attached.

Failure to make timely payment of the civil penalty or further violation of Public Health Order No. COVID-19-5 may result in the Department taking further enforcement action.

Gwendolyn C. Thompson

Gwendolyn C. Thompson, Director
Healthcare Quality

03092021

Date

Attachments:
Public Health Order No. COVID-19-5
Instructions for Payment
Guide to Board Review

Healthy People. Healthy Communities.

SOUTH CAROLINA
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

PUBLIC HEALTH ORDER
No. COVID-19-5

WHEREAS, on March 13, 2020, Governor Henry McMaster declared a State of Emergency based on a determination that Coronavirus Disease 2019 (COVID-19) posed an actual or imminent public health emergency for the State of South Carolina; and

WHEREAS, on March 13, 2020, the Governor also directed the South Carolina Department of Health and Environmental Control (DHEC) to utilize and exercise any and all emergency powers, as set forth in the Emergency Health Powers Act, codified as amended in Title 44, Chapter 4 of the South Carolina Code of Laws, deemed necessary to promptly and effectively address the current public health emergency. In accordance with Section 44-4-500 of the South Carolina Code of Laws, as amended, the Governor ordered that DHEC shall "use every available means to prevent the transmission of infectious disease and to ensure that all cases of infectious disease are subject to proper control and treatment;" and

WHEREAS, on March 13, 2020, the President of the United States declared the ongoing COVID-19 outbreak a pandemic of sufficient severity and magnitude to warrant an emergency declaration for all states, tribes, territories, and the District of Columbia, pursuant to Section 501(b) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. §§ 5121-5207 ("Stafford Act"); and

WHEREAS, on March 24, 2020, the Governor requested that the President of the United States declare that a major disaster exists in the State of South Carolina pursuant to Section 401 of the Stafford Act; and

WHEREAS, on March 27, 2020, the President of the United States granted the Governor's request and declared that a major disaster exists in the State of South Carolina and ordered federal assistance to supplement state, tribal, and local recovery efforts in the areas affected by the COVID-19 pandemic, with an effective date retroactive to January 20, 2020, and continuing; and

WHEREAS, since declaring an initial State of Emergency on March 13, 2020, the Governor has subsequently declared a State of Emergency and directed DHEC to utilize and exercise any and all emergency powers, as set forth in the Executive Health Powers Act, codified in Title 44, Chapter 4 of the South Carolina Code of Laws, deemed necessary to promptly and effectively address the current public health emergency, in Executive Order Nos. 2020-15, 2020-23, 2020-29, 2020-35, 2020-38, 2020-40, 2020-42, 2020-44, 2020-48, 2020-53, 2020-56, 2020-59, and 2020-62; and

WHEREAS, as of October 7, 2020, COVID-19 is widespread throughout the state and in all 46 counties, with 148,334 total confirmed cases statewide and 3,300 total confirmed deaths; and

WHEREAS, DHEC is invested with all the rights and charged with all the duties pertaining to organizations of like character and is the sole advisor of the State in all questions involving the protection of the public health within its limits (S.C. Code Ann.§ 44-1-110); and

WHEREAS, DHEC must enforce or prescribe preventive measures as may be needed to suppress or prevent the spread of these diseases by proper quarantine or other measures of prevention, as may be necessary to protect citizens of the State (S.C. Code Ann. § 44-1-80(A)); and

WHEREAS, DHEC is granted the authority to make, adopt, promulgate and enforce reasonable rules and regulations from time to time requiring and providing for the thorough investigation and study of the causes of all diseases, epidemic and otherwise, in the State, the means for the prevention of contagious disease and the publication and distribution of such information as may contribute to the preservation of the public health and the prevention of disease (S.C. Code Ann.§ 44-1-140(12)); and

WHEREAS, DHEC may also make separate orders and rules to meet any emergency not provided for by general rules and regulations, for the purpose of suppressing nuisances dangerous to the public health and communicable, contagious and infectious diseases and other danger to the public life and health (S.C. Code Ann.§ 44-1-140); and

WHEREAS, in addition to its authority provided by statute or as otherwise provided for by regulation, DHEC may issue separate orders to enforce the provisions of S.C. Regulation 61-20 for the purpose of suppressing nuisances, Communicable, Contagious and Infectious Diseases, and other dangers to public health (S.C. Code Ann. Regs. 61-20 § 14(A)); and

WHEREAS, all entities shall comply with DHEC directives and orders to protect the public health from the spread of Communicable and Infectious Diseases (S.C. Code Ann. Regs. 61-20 § 4(D)); and

WHEREAS, during a public health emergency, DHEC must use every available means to prevent the transmission of infectious disease and ensure that all cases of infectious disease are subject to proper control and treatment (S.C. Code Ann.§ 44-4-500); and

WHEREAS, the Bill of Rights for Residents of Long-Term Care Facilities requires the legal guardian, family members, and other relatives of each resident of a long-term care facility

be allowed immediate access to that resident, subject to the resident's right to deny access or withdraw consent to access at any time, and requires each resident, without unreasonable delay or restrictions, be allowed to associate and communicate privately with persons of the resident's choice (S.C. Code Ann. § 44-81-40(K)); and

WHEREAS, nursing homes and community residential care facilities are required to comply with the Bill of Rights for Residents of Long-Term Care Facilities (S.C. Code Ann. Regs. 61-17, § 1101; S.C. Code Ann. Regs. 61-84 § 1001), and

WHEREAS, nursing homes shall encourage visitation of residents by family and friends with minimum restrictions and shall post visiting hours in accordance with facility policies and procedures (S.C. Code Ann. Regs. § 1003.J), and

WHEREAS, South Carolina is engaged in an all-hands effort to both reduce the spread of COVID-19 and to ensure safety of all South Carolinians, including residents of nursing homes and community residential care facilities; and

WHEREAS, the COVID-19 pandemic has created a need for nursing homes and community residential care facilities to prevent the spread of disease among residents and staff, and

WHEREAS, nursing homes and community residential care facilities are required by South Carolina law and regulation to allow for access to residents; however, the current State of Emergency requires changes and limitations to normal visitation policies and procedures in order to ensure residents, which are members of a vulnerable population, are protected from exposure to COVID-19; and

WHEREAS, as the Acting Director of Public Health, I have reviewed the data regarding confirmed COVID-19 cases, reported exposures among the population in South Carolina, including cases and reported exposures in vulnerable populations including residents of nursing homes and community residential care facilities, and

WHEREAS, I have determined that it is necessary to gather and monitor information regarding access to visitation for residents in nursing homes and community residential care facilities in order to ensure the safety of residents and staff and appropriate and reasonable compliance with applicable laws and regulations.

NOW, THEREFORE, IT IS HEREBY ORDERED, pursuant to section 44-1-140 of the South Carolina Code of Laws, that all nursing homes and community residential care facilities licensed by DHEC are required to submit a weekly report stating whether they are allowing

visitation, and if not, providing the reason(s) for not allowing visitation. Facilities must also report the number of residents who participated in a visit in the previous seven (7) days.

Each licensed Facility must submit a separate report to DHEC.

Facilities must complete their weekly report no later than 5:00 PM each Monday by completing and submitting the form on DHEC's webpage, https://scdhec.gov/visitation.

Should any nursing home or community residential care facility face human resource or information technology challenges in completing any requirement of this Order, the facility should notify DHEC immediately by contacting ACC-HealthReg@dhec.sc.gov.

IT IS FURTHER ORDERED, pursuant to section 44-1-150 of the South Carolina Code of Laws, that any facility that violates this Order may be subject to a civil penalty not to exceed one thousand (1,000) dollars a day for each violation.

This Order is effective immediately and shall remain in effect unless otherwise modified, amended, or rescinded by subsequent order.

AND IT IS SO ORDERED.

LB Traxler MD

L. Brannon Traxler, MD, MPH
Interim Director of Public Health

Date: 10/07/2020

Healthy People. Healthy Communities.

INSTRUCTIONS FOR PAYMENT

1. Make certified check or money order payable to S.C. Department of Health and Environmental Control and ensure to include your Facility's Name and License Number

2. Send payment to the following address:

   Attention: Angie Smith, Interim Director
   Bureau of Facilities Oversight/Healthcare Quality
   S.C. Department of Health and Environmental Control
   2600 Bull Street
   Columbia, SC 29201

South Carolina Board of Health and Environmental Control

Guide to Board Review

Pursuant to S.C. Code Ann. § 44-1-60

The decision of the South Carolina Department of Health and Environmental Control (Department) becomes the final agency decision fifteen (15) calendar days after notice of the decision has been mailed to the applicant, permittee, licensee and affected persons who have requested in writing to be notified, unless a written request for final review accompanied by a filing fee in the amount of $100 is filed with Department by the applicant, permittee, licensee or affected person.

Applicants, permittees, licensees, and affected parties are encouraged to engage in mediation or settlement discussions during the final review process.

If the Board declines in writing to schedule a final review conference, the Department's decision becomes the final agency decision and an applicant, permittee, licensee, or affected person may request a contested case hearing before the Administrative Law Court within thirty (30) calendar days after notice is mailed that the Board declined to hold a final review conference. In matters pertaining to decisions under the South Carolina Mining Act, appeals should be made to the South Carolina Mining Council.

I. Filing of Request for Final Review

1. A written Request for Final Review (RFR) and the required filing fee of one hundred dollars ($100) must be received by Clerk of the Board within fifteen (15) calendar days after notice of the staff decision has been mailed to the applicant, permittee, licensee, or affected persons. If the 15th day occurs on a weekend or State holiday, the RFR must be received by the Clerk on the next working day. RFRs will not be accepted after 5:00 p.m.
2. RFRs shall be in writing and should include, at a minimum, the following information:
   - The grounds for amending, modifying, or rescinding the staff decision;
   - a statement of any significant issues or factors the Board should consider in deciding how to handle the matter;
   - the relief requested;
   - a copy of the decision for which review is requested; and
   - mailing address, email address, if applicable, and phone number(s) at which the requestor can be contacted.
3. RFRs should be filed in person or by mail at the following address:
   South Carolina Board of Health and Environmental Control
   Attention: Clerk of the Board
   2600 Bull Street
   Columbia, South Carolina 29201
   Alternatively, RFR's may be filed with the Clerk by facsimile (803-898-3393) or by electronic mail (boardclerk@dhec.sc.gov).
4. The filing fee may be paid by cash, check or credit card and must be received by the 15th day.
5. If there is any perceived discrepancy in compliance with this RFR filing procedure, the Clerk should consult with the Chairman or, if the Chairman is unavailable, the Vice-Chairman. The Chairman or the Vice-Chairman will determine whether the RFR is timely and properly filed and direct the Clerk to (1) process the RFR for consideration by the Board or (2) return the RFR and filing fee to the requestor with a cover letter explaining why the RFR was not timely or properly filed. Processing an RFR for consideration by the Board shall not be interpreted as a waiver of any claim or defense by the agency in subsequent proceedings concerning the RFR.
6. If the RFR will be processed for Board consideration, the Clerk will send an Acknowledgement of RFR to the Requestor and the applicant, permittee, or licensee, if other than the Requestor. All personal and financial identifying information will be redacted from the RFR and accompanying documentation before the RFR is released to the Board, Department staff or the public.
7. If an RFR pertains to an emergency order, the Clerk will, upon receipt, immediately provide a copy of the RFR to all Board members. The Chairman, or in his or her absence, the Vice-Chairman shall based on the circumstances, decide whether to refer the RFR to the RFR Committee for expedited review or to decline in writing to schedule a Final Review Conference. If the Chairman or Vice-Chairman determines review by the RFR Committee is appropriate, the Clerk will forward a copy of the RFR to Department staff and Office of General Counsel. A Department response and RFR Committee review will be provided on an expedited schedule defined by the Chairman or Vice-Chairman.
8. The Clerk will email the RFR to staff and Office of General Counsel and request a Department Response within eight (8) working days. Upon receipt of the Department Response, the Clerk will forward the RFR and Department Response to all Board members for review, and all Board members will confirm receipt of the RFR to the Clerk by email. If a Board member does not confirm receipt of the RFR within a twenty-four (24) hour period, the Clerk will contact the Board member and confirm receipt. If a Board member believes the RFR should be considered by the RFR Committee, he or she will

respond to the Clerk's email within forty-eight (48) hours and will request further review. If no Board member requests further review of the RFR within the forty-eight (48) hour period, the Clerk will send a letter by certified mail to the Requestor, with copy by regular mail to the applicant, permittee, or licensee, if not the Requestor, stating the Board will not hold a Final Review Conference. Contested case guidance will be included within the letter.
NOTE: If the time periods described above end on a weekend or State holiday, the time is automatically extended to 5:00 p.m. on the next business day.

9. If the RFR is to be considered by the RFR Committee, the Clerk will notify the Presiding Member of the RFR Committee and the Chairman that further review is requested by the Board. RFR Committee meetings are open to the public and will be public noticed at least 24 hours in advance.
10. Following RFR Committee or Board consideration of the RFR, if it is determined no Conference will be held, the Clerk will send a letter by certified mail to the Requestor, with copy by regular mail to the applicant, permittee, or licensee, if not the Requestor, stating the Board will not hold a Conference. Contested case guidance will be included within the letter.

II. Final Review Conference Scheduling

1. If a Conference will be held, the Clerk will send a letter by certified mail to the Requestor, with copy by regular mail to the applicant, permittee, or licensee, if not the Requestor, informing the Requestor of the determination.
2. The Clerk will request Department staff provide the Administrative Record.
3. The Clerk will send Notice of Final Review Conference to the parties at least ten (10) days before the Conference. The Conference will be publically noticed and should:
   - include the place, date and time of the Conference;
   - state the presentation times allowed in the Conference;
   - state evidence may be presented at the Conference;
   - if the conference will be held by committee, include a copy of the Chairman's order appointing the committee; and
   - inform the Requestor of his or her right to request a transcript of the proceedings of the Conference prepared at Requestor's expense.
4. If a party requests a transcript of the proceedings of the Conference and agrees to pay all related costs in writing, including costs for the transcript, the Clerk will schedule a court reporter for the Conference.

III. Final Review Conference and Decision

1. The order of presentation in the Conference will, subject to the presiding officer's discretion, be as follows:
   - Department staff will provide an overview of the staff decision and the applicable law to include [10 minutes]:
     - Type of decision (permit, enforcement, etc.) and description of the program.
     - Parties
     - Description of facility/site
     - Applicable statutes and regulations
     - Decision and materials relied upon in the administrative record to support the staff decision.
   - Requestor(s) will state the reasons for protesting the staff decision and may provide evidence to support amending, modifying, or rescinding the staff decision. [15 minutes] *NOTE: The burden of proof is on the Requestor(s)*
   - Rebuttal by Department staff [15 minutes]
   - Rebuttal by Requestor(s) [10 minutes]

   Note: Times noted in brackets are for information only and are superseded by times stated in the Notice of Final Review Conference or by the presiding officer.
2. Parties may present evidence during the conference; however, the rules of evidence do not apply.
3. At any time during the conference, the officers conducting the Conference may request additional information and may question the Requestor, the staff, and anyone else providing information at the Conference.
4. The presiding officer, in his or her sole discretion, may allow additional time for presentations and may impose time limits on the Conference.
5. All Conferences are open to the public.
6. The officers may deliberate in closed session.
7. The officers may announce the decision at the conclusion of the Conference or it may be reserved for consideration.
8. The Clerk will mail the written final agency decision (FAD) to parties within 30 days after the Conference. The written decision must explain the basis for the decision and inform the parties of their right to request a contested case hearing before the Administrative Law Court or in matters pertaining to decisions under the South Carolina Mining Act, to request a hearing before the South Carolina Mining Council.. The FAD will be sent by certified mail, return receipt requested.
9. Communications may also be sent by electronic mail, in addition to the forms stated herein, when electronic mail addresses are provided to the Clerk.

The above information is provided as a courtesy; parties are responsible for complying with all applicable legal requirements.

Ridgeview Community Care Homes, Inc.

217 Chandler Rd ~ Greer, SC ~ 29651

March 23, 2021

South Carolina Board of Health and Environmental Control
Attention: Clerk of Court
2600 Bull Street
Columbia, SC 29201

RE: Written Request for Final Review, CRC-0560 Unit B

Dear Board Members,

We are submitting this written request for final review of the decision to impose a civil penalty of $350 on our facility CRC-0560, for submitting the weekly visitation report late. The payment of $100 was made over the phone.

The grounds for amending, modifying, or rescinding the staff decision:

After months of receiving Monday email reminders from DHEC to submit the weekly visitation reports, our facility did not receive email reminders from DHEC on Monday, March 8, to submit the weekly reports. This reminder email has become an integral part of our process to submit timely reports, and on March 8th we did not receive this reminder. Also, during this pandemic quarantine it is a financial hardship and unnecessary to impose a civil penalty for a report that was only 2 days late and did not put anyone in danger.

Significant issues the Board should consider in deciding how to handle the matter:

The weekly visitation report WAS FILED on Wednesday of that week, please see attached email confirmation.

I was working on financial paperwork for our facility's tax return. I do not have anyone else in my office currently to train to submit the reports because there is no other administrative staff with online access right now.

Ridgeview Community Care Homes is made up of 4 licensed buildings so for us this second penalty of $350 is a total penalty of $1,400, which is a tremendous financial hardship during this difficult time.

Please consider the many difficulties we have dealt with due to the COVID-19 pandemic. Financial difficulties such as reduced income due to inability to fill beds during quarantine, increased payroll expenses due to paying staff bonuses for continued service during the pandemic, increased food expenses due to ordering online to reduce staff exposure shopping for food items and increased recreational activity expenses for extra supplies and snacks ordered online to provide additional

activities for our residents during quarantine to help improve their mental status. We can not survive as a business with negative income. Additional expenses such as monetary penalties would be a financial hardship for us.

After last year's pandemic, filled with fear of illness and death, it is unnecessary for the Department to impose monetary penalties upon businesses that are caring for the most vulnerable population in our state. It has been challenging for our residents and staff to say the very least, a year full of new regulations, limited family visits, and no resident outings. Please take this into consideration and not add another financial burden to our business, or to any other facilities throughout the state who are suffering the same way. Our facility has not had any COVID-19 outbreaks among our residents or staff, we have followed the regulations and have received our vaccinations. Our residents' wellbeing comes first and at no time were they in a compromised position due to our report being submitted 2 days late so instead of imposing financial hardship on facilities, please show your support to the facilities that care for the ones that are most at risk and have been unable to have normal visits and outings with their loved ones.

The relief requested: We would like the civil penalty to be removed.

A copy of the decision for which the review is requested: Copies are attached.

Mailing address, email address and phone number the requestor can be contacted:

Trish Daugherty, Administrator
Ridgeview Community Care Homes
217 Chandler Road
Greer, SC 29651
ridgeview1@msn.com
Phone (864)877-8599 Fax (864)877-8704

We sincerely appreciate the opportunity to ask for a review of the decision to impose a civil penalty on our facility. If you have any questions please contact me at (864)877-8599.

Thank you,

Trish Daugherty

Trish Daugherty
Administrator
Authorized digital signature

Lee Daugherty

Lee Daugherty
Assistant Administrator
Authorized digital signature

The following copies are enclosed below:

- Email confirmation that the weekly visitation reports were filed.
- Copy of the original notice of violation and civil penalty for CRC-0560.

HealthRegComm <HealthRegComm@dhec.sc.gov>
Wed 3/10/2021 4:10 PM
To: RIDGEVIEW1@MSN.COM

Thank you for submitting your weekly visitation report for RIDGEVIEW COMMUNITY CARE HOMES UNIT B (CRC-0560).

Submission Summary:

Facility Type: Community Residential Care (CRC) Facility
Facility Name: RIDGEVIEW COMMUNITY CARE HOMES UNIT B (CRC-0560)

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

IN RE:
RIDGEVIEW COMMUNITY CARE HOMES UNIT B, CRC-0560
217 CHANDLER RD, GREER, SC
RIDGEVIEW COMMUNITY CARE HOMES INC, Licensee

NOTICE OF REPEAT VIOLATION AND CIVIL PENALTY

The South Carolina Department of Health and Environmental Control (Department) issued Public Health Order No. COVID-19-5 (attached hereto), pursuant to Section 44-1-140 of the South Carolina Code of Laws, on October 7, 2020, requiring all nursing homes and community residential care facilities (CRCFs) licensed by the Department to submit a weekly report, by no later than 5:00 pm each Monday, stating whether they are allowing visitation, and if not, providing the reason(s) for not allowing visitation. The weekly report must also include the number of residents who participated in a visit in the previous seven (7) days.

The Department notified RIDGEVIEW COMMUNITY CARE HOMES INC, of its first violation of Public Health Order No. COVID-19-5 by certified mail on OCTOBER 21, 2020.

The Department hereby notifies RIDGEVIEW COMMUNITY CARE HOMES INC, Licensee, that RIDGEVIEW COMMUNITY CARE HOMES UNIT B, License No. CRC-0560, violated Public Health Order No. COVID-19-5 a SECOND time by failing to submit a weekly report by the 5pm deadline of Monday, MARCH 8, 2021.

The Department hereby issues an additional civil penalty to RIDGEVIEW COMMUNITY CARE HOMES UNIT B in the amount of $350 for the aforementioned repeat violation, in accordance with Section 44-1-150(B) of the South Carolina Code of Laws. Section 44-1-150(B) provides for civil penalties not to exceed $1000.00 per day for each violation.

Payment of the additional $350 civil penalty is due within twenty (20) days of the date of this Notice of Repeat Violation and Civil Penalty. Instructions for payment are attached.

Failure to make timely payment of the civil penalty or further violation of Public Health Order No. COVID-19-5 may result in the Department taking further enforcement action.

Gwendolyn C. Thompson

03112021

Gwendolyn C. Thompson, Director
Healthcare Quality

Date

Attachments:
Public Health Order No. COVID-19-5
Instructions for Payment
Guide to Board Review

RECEIVED
APR 08 2021
Clerk, Board of Health
and Environmental Control

BEFORE THE BOARD OF HEALTH AND ENVIRONMENTAL CONTROL
STAFF RESPONSE TO REQUEST FOR FINAL REVIEW
Docket No. 21-RFR-28

Requestor: **Ridgeview Community Care Homes, Inc. (Licensee)**
Ridgeview Community Care Homes Unit B, License No. CRC-0560
(Ridgeview or Facility)
Re: **Notice of Repeat Violation and Civil Penalty**

Overview: This Request for Final Review (RFR) concerns a $350 civil monetary penalty imposed for a violation of Public Health Order No. COVID-19-5 (PHO) for failure to submit a mandatory weekly report on visitation status at the Facility. The Facility requests the violation be reviewed and removed. Staff requests the Board uphold the decision, which was issued in accordance with terms of the PHO and applicable statutory requirements.

I. Summary

Ridgeview Community Care Homes-Unit B is a licensed Community Residential Care Facility (CRCF) located in Greer, South Carolina, licensed for ten (10) beds.

On March 13, 2020, Governor Henry McMaster declared a State of Emergency based on a determination that Coronavirus Disease 2019 (COVID-19) posed an actual or imminent public health emergency for the State of South Carolina.

On October 7, 2020, the South Carolina Department of Health and Environmental Control (DHEC or Department) issued the attached PHO, pursuant to section 44-1-140 of the South Carolina Code of Laws, requiring all licensed nursing homes and CRCFs to submit a weekly report stating whether they are allowing visitation, and if not, providing the reason(s) for not allowing visitation. *See* Exhibit 1. Facilities must also include in the weekly report the number of residents who participated in a visit in the previous seven (7) days. Facilities must submit their weekly report to DHEC no later than 5:00 PM each Monday by completing and submitting the form on the DHEC's webpage (https://scdhec.gov/visitation). The PHO further provides, pursuant to Section 44-1-150, that any facility violating the Order may be subject to a civil penalty not to exceed one thousand ($1,000) dollars a day for each violation.

DHEC sent Ridgeview Community Care Homes Unit-B, and other licensed CRCFs and nursing homes, notice of the PHO by email on October 8, 2020. *See* Exhibit 2. DHEC sent additional email reminders to the Facility and other licensed facilities following the initial notice, including three reminder emails on October 12, 2020, the first day of required reporting, and two reminder emails a week prior to the reporting deadline in subsequent weeks. The reminder emails are sent on Fridays and Mondays prior to the 5:00 PM Monday reporting deadline each week. *See* Exhibit 3 (reminder emails sent on March 5, 2021, and March 8, 2021).

For the week beginning March 1, 2021, the Department did not receive a weekly report, which was due March 8, 2021, from Ridgeview Community Care Homes Unit-B until March 10, 2021, at 4:10 PM. *See* Exhibit 4. The Department notified the Facility that it had violated the PHO by

failing to submit a weekly report by the 5PM deadline of Monday, March 8, 2021. *See* Exhibit 5. This was Ridgeway's second cited violation of the PHO reporting requirements. Therefore, the Department issued a penalty in the amount of $350 for the aforementioned violation, in accordance with Section 44-1-150(b) of the South Carolina Code of Laws. *Id.* Ridgeview Community Care Homes Unit-B, filed its RFR, requesting waiver of the penalty, on March 22, 2021.

II. Relevant Law

DHEC is vested with all the rights and charged with all the duties pertaining to organizations of like character and is the sole advisor of the State in all questions involving the protection of the public health within its limits. S.C. Code Ann. § 44-1-110. DHEC is granted the authority to make, adopt, promulgate and enforce reasonable rules and regulations from time to time requiring and providing for the thorough investigation and study of the causes of all diseases, epidemic and otherwise, in the State, the means for the prevention of contagious disease and the public and distribution of such information as may contribute to the preservation of the public health and the prevention of disease. S.C. Code Ann. § 44-1-140(12). During a public health emergency, DHEC must use every available means to prevent the transmission of infectious disease and ensure that all cases of infectious disease are subject to proper control and treatment. S.C. Code Ann. § 44-4-500. All entities shall comply with DHEC directives and orders to protect the public health from the spread of communicable and infectious diseases. S.C. Code Ann. Regs. 61-20 § 4(D).

The Bill of Rights for Residents of Long-Term Care Facilities requires the legal guardian, family members, and other relatives of each resident of a long-term care facility be allowed immediately access to that resident, subject to the resident's right to deny access or withdraw consent to access at any time, and requires each resident, without unreasonable delay or restrictions, be allowed to associate and communicate privately with persons of the residents' choice. S.C. Code Ann. § 44-81-40(K). Nursing homes and community residential care facilities are required to comply with the Bill of Rights for Residents of Long-Term Care Facilities. S.C. Code Ann. Regs. 61-17 § 1101; S.C. Code Ann. Regs 61-84 § 1001.

DHEC may make separate orders and rules to meet any emergency not provided for by general rules and regulations, for the purpose of suppressing nuisances dangerous to the public health and communicable, contagious and infectious diseases and other danger to the public life and health. S.C. Code Ann. § 44-1-140. A person who after notice violates an order of the department issued pursuant to Section 44-1-140 is subject to a civil penalty not to exceed one thousand dollars a day for each violation. S.C. Code Ann. § 44-1-150(b).

III. Response to Request for Review

The Facility does not dispute the Department's finding that it violated the PHO by failing to submit a weekly report by the deadline of 5:00 PM on March 8, 2021, for the week that began on March 1, 2021. Rather, the Facility requests the fine of $350 be waived because, "after months of receiving Monday email reminders from DHEC to submit the weekly visitation reports, our facility did not receive email reminders from DHEC on Monday, March 8th to submit the weekly reports. This reminder email has become an integral part of our process to submit timely reports, and on March 8th we did not receive this reminder. Also, during this pandemic quarantine it is a financial

hardship and unnecessary to impose a civil penalty for a report that was only two days late and did not put anyone in danger."

Staff respectfully requests the Board uphold the imposed $350 fine. The Department provided ample and repeated notices to the Facility of the PHO's reporting requirement and the 5:00 PM, March 8, 2021, reporting deadline, including email reminders on Friday, March 5, and Monday March 8, 2021. *See* Exhibit 3. Ridgeview Community Care Homes Unit-B is one of 499 community residential care facilities subject to the March 8, 2021, PHO reporting deadline, and one of fourteen that failed to submit a timely report by that week's deadline.[1] The Department is tracking compliance with the reporting requirement for hundreds of facilities and is treating all facilities subject to the PHO equally in terms of enforcement. The Department considered the Facility's compliance history with the reporting requirements when determining the monetary penalty amount. As with other similarly situated facilities that committed a second violation of the PHO for the week in question, Ridgeview Community Care Homes Unit-B was fined $350 – less than the maximum possible fine of $1,000 per violation. For these reasons, staff respectfully requests the Board uphold the issued fine.

IV. Requested Action

For the foregoing reasons, staff requests that the Board decline to conduct a final review conference and uphold the monetary penalty for violation of the PHO.

Respectfully submitted:

Angie Smith

Angie Smith, Interim Director
Bureau of Facilities Oversight
Director, Community Oversight Care Division
Healthcare Quality

Ashley Biggers

Ashley Biggers, Esq.
Chief Counsel for Healthcare Quality
Office of General Counsel

March 2021

Exhibit 1 – October 7, 2020, PHO
Exhibit 2 – October 8, 2020, Email Notice of PHO
Exhibit 3 – March 5 and March 8, 2021, Email Reminder of March 8, 2021, Reporting Deadline
Exhibit 4 – Confirmation of Receipt of Report
Exhibit 5 – March 9, 2021, Notice of Violation and Civil Penalty

[1] Of the 499 community residential care facilities subject to the PHO reporting requirement on March 8, 2021, only fourteen failed to submit a weekly report and were sent a notice of violation and civil penalty

EXHIBIT 1

October 7, 2020
Public Health Order (PHO)

SOUTH CAROLINA
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

PUBLIC HEALTH ORDER
No. COVID-19-5

WHEREAS, on March 13, 2020, Governor Henry McMaster declared a State of Emergency based on a determination that Coronavirus Disease 2019 (COVID-19) posed an actual or imminent public health emergency for the State of South Carolina; and

WHEREAS, on March 13, 2020, the Governor also directed the South Carolina Department of Health and Environmental Control (DHEC) to utilize and exercise any and all emergency powers, as set forth in the Emergency Health Powers Act, codified as amended in Title 44, Chapter 4 of the South Carolina Code of Laws, deemed necessary to promptly and effectively address the current public health emergency. In accordance with Section 44-4-500 of the South Carolina Code of Laws, as amended, the Governor ordered that DHEC shall "use every available means to prevent the transmission of infectious disease and to ensure that all cases of infectious disease are subject to proper control and treatment;" and

WHEREAS, on March 13, 2020, the President of the United States declared the ongoing COVID-19 outbreak a pandemic of sufficient severity and magnitude to warrant an emergency declaration for all states, tribes, territories, and the District of Columbia, pursuant to Section 501(b) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. §§ 5121-5207 ("Stafford Act"); and

WHEREAS, on March 24, 2020, the Governor requested that the President of the United States declare that a major disaster exists in the State of South Carolina pursuant to Section 401 of the Stafford Act; and

WHEREAS, on March 27, 2020, the President of the United States granted the Governor's request and declared that a major disaster exists in the State of South Carolina and ordered federal assistance to supplement state, tribal, and local recovery efforts in the areas affected by the COVID-19 pandemic, with an effective date retroactive to January 20, 2020, and continuing; and

WHEREAS, since declaring an initial State of Emergency on March 13, 2020, the Governor has subsequently declared a State of Emergency and directed DHEC to utilize and exercise any and all emergency powers, as set forth in the Executive Health Powers Act, codified in Title 44, Chapter 4 of the South Carolina Code of Laws, deemed necessary to promptly and effectively address the current public health emergency, in Executive Order Nos. 2020-15, 2020-23, 2020-29, 2020-35, 2020-38, 2020-40, 2020-42, 2020-44, 2020-48, 2020-53, 2020-56, 2020-59, and 2020-62; and

WHEREAS, as of October 7, 2020, COVID-19 is widespread throughout the state and in all 46 counties, with 148,334 total confirmed cases statewide and 3,300 total confirmed deaths; and

WHEREAS, DHEC is invested with all the rights and charged with all the duties pertaining to organizations of like character and is the sole advisor of the State in all questions involving the protection of the public health within its limits (S.C. Code Ann.§ 44-1-110); and

WHEREAS, DHEC must enforce or prescribe preventive measures as may be needed to suppress or prevent the spread of these diseases by proper quarantine or other measures of prevention, as may be necessary to protect citizens of the State (S.C. Code Ann. § 44-1-80(A)); and

WHEREAS, DHEC is granted the authority to make, adopt, promulgate and enforce reasonable rules and regulations from time to time requiring and providing for the thorough investigation and study of the causes of all diseases, epidemic and otherwise, in the State, the means for the prevention of contagious disease and the publication and distribution of such information as may contribute to the preservation of the public health and the prevention of disease (S.C. Code Ann.§ 44-1-140(12)); and

WHEREAS, DHEC may also make separate orders and rules to meet any emergency not provided for by general rules and regulations, for the purpose of suppressing nuisances dangerous to the public health and communicable, contagious and infectious diseases and other danger to the public life and health (S.C. Code Ann.§ 44-1-140); and

WHEREAS, in addition to its authority provided by statute or as otherwise provided for by regulation, DHEC may issue separate orders to enforce the provisions of S.C. Regulation 61-20 for the purpose of suppressing nuisances, Communicable, Contagious and Infectious Diseases, and other dangers to public health (S.C. Code Ann. Regs. 61-20 § 14(A)); and

WHEREAS, all entities shall comply with DHEC directives and orders to protect the public health from the spread of Communicable and Infectious Diseases (S.C. Code Ann. Regs. 61-20 § 4(D)); and

WHEREAS, during a public health emergency, DHEC must use every available means to prevent the transmission of infectious disease and ensure that all cases of infectious disease are subject to proper control and treatment (S.C. Code Ann.§ 44-4-500); and

WHEREAS, the Bill of Rights for Residents of Long-Term Care Facilities requires the legal guardian, family members, and other relatives of each resident of a long-term care facility

be allowed immediate access to that resident, subject to the resident's right to deny access or withdraw consent to access at any time, and requires each resident, without unreasonable delay or restrictions, be allowed to associate and communicate privately with persons of the resident's choice (S.C. Code Ann. § 44-81-40(K)); and

WHEREAS, nursing homes and community residential care facilities are required to comply with the Bill of Rights for Residents of Long-Term Care Facilities (S.C. Code Ann. Regs. 61-17, § 1101; S.C. Code Ann. Regs. 61-84 § 1001), and

WHEREAS, nursing homes shall encourage visitation of residents by family and friends with minimum restrictions and shall post visiting hours in accordance with facility policies and procedures (S.C. Code Ann. Regs. § 1003.J), and

WHEREAS, South Carolina is engaged in an all-hands effort to both reduce the spread of COVID-19 and to ensure safety of all South Carolinians, including residents of nursing homes and community residential care facilities; and

WHEREAS, the COVID-19 pandemic has created a need for nursing homes and community residential care facilities to prevent the spread of disease among residents and staff, and

WHEREAS, nursing homes and community residential care facilities are required by South Carolina law and regulation to allow for access to residents; however, the current State of Emergency requires changes and limitations to normal visitation policies and procedures in order to ensure residents, which are members of a vulnerable population, are protected from exposure to COVID-19; and

WHEREAS, as the Acting Director of Public Health, I have reviewed the data regarding confirmed COVID-19 cases, reported exposures among the population in South Carolina, including cases and reported exposures in vulnerable populations including residents of nursing homes and community residential care facilities, and

WHEREAS, I have determined that it is necessary to gather and monitor information regarding access to visitation for residents in nursing homes and community residential care facilities in order to ensure the safety of residents and staff and appropriate and reasonable compliance with applicable laws and regulations.

NOW, THEREFORE, IT IS HEREBY ORDERED, pursuant to section 44-1-140 of the South Carolina Code of Laws, that all nursing homes and community residential care facilities licensed by DHEC are required to submit a weekly report stating whether they are allowing

visitation, and if not, providing the reason(s) for not allowing visitation. Facilities must also report the number of residents who participated in a visit in the previous seven (7) days.

Each licensed Facility must submit a separate report to DHEC.

Facilities must complete their weekly report no later than 5:00 PM each Monday by completing and submitting the form on DHEC's webpage, https://scdhec.gov/visitation.

Should any nursing home or community residential care facility face human resource or information technology challenges in completing any requirement of this Order, the facility should notify DHEC immediately by contacting ACC-HealthReg@dhec.sc.gov.

IT IS FURTHER ORDERED, pursuant to section 44-1-150 of the South Carolina Code of Laws, that any facility that violates this Order may be subject to a civil penalty not to exceed one thousand (1,000) dollars a day for each violation.

This Order is effective immediately and shall remain in effect unless otherwise modified, amended, or rescinded by subsequent order.

AND IT IS SO ORDERED.

LB Traxler MD

Date: 10/07/2020

L. Brannon Traxler, MD, MPH
Interim Director of Public Health

EXHIBIT 2

October 8, 2020
Email Notice of PHO

Healthy People. Healthy Communities.

Good afternoon,

DHEC issued a Public Health Order on October 7, 2020 that is available to read here.

This Order requires all licensed nursing homes and community residential care facilities to submit a weekly report to DHEC regarding visitation.

Facilities are required to send their respective weekly reports by submitting a response in DHEC's Visitation Reporting Form. The first weekly report is due on this **upcoming Monday, October 12, 2020, by 5:00 pm.**

If you are filling out the survey on behalf of more than one licensed facility, then **you are required to fill out a separate weekly report for each individual facility**. Failure to comply with the mandatory weekly reporting to DHEC may result in a civil penalty not to exceed $1,000 a day for each violation.

Submit weekly reports via the Visitation Reporting Form.

Weekly reports are due each Monday by 5:00 pm.

The Visitation Reporting Form requires all licensed nursing homes and community residential care facilities to report whether they are allowing visitation and, if not, to provide the reason(s) for not allowing visitation; facilities allowing visitation must also report the number of residents who participated in a visit in the previous 7 days.

DHEC plans to publish updated visitation guidelines tomorrow, October 9, 2020, on both outdoor and indoor visitation.

DHEC's Visitation Reporting Form and relevant information will be available on our new Long-Term Care Facilities Visitation (COVID-19) page, which can also be reached by going directly to scdhec.gov/visitation. The forthcoming updated visitation guidance and other resources will be posted on this page.

We thank all licensed nursing homes and community residential care facilities for their cooperation, timely responses, and invaluable care of all residents, staff, and visitors.

Facilities can reach out to acc-healthreg@dhec.sc.gov with any questions at all.

Thank you,

Healthcare Quality
S.C. Dept. of Health & Environmental Control
Connect: www.scdhec.gov Facebook Twitter

EXHIBIT 3

Email Reminders-Reporting Deadline

March 5, 2021
March 8, 2021

Wilson, Gloria

From: ACC-HealthReg <ACC-HealthReg@dhec.sc.gov>
Sent: Friday, March 5, 2021 2:13 PM
To: Gregory, Aramis L.
Subject: Weekly Visitation Report Due Monday by 5 pm!

Healthy People. Healthy Communities.

Good Afternoon,

This email serves as a reminder that all nursing homes and community residential care facilities are required to send their weekly visitation report via DHEC's **Visitation Reporting Form** **no later than Monday, March 8, by 5 p.m.** If you experience technical difficulties (i.e., internet outage) while trying to submit the **Visitation Reporting Form** prior to Monday's deadline, you may call 803-365-3468, to provide the information over the phone to a DHEC staff member. This phone number is reserved for extenuating circumstances involving an internet outage prior to Monday's 5 p.m. deadline.

In order to ensure that we always have the most current information, DHEC strongly encourages facilities to submit one report per reporting week and to submit them between Sunday at 5 p.m. and Monday at 5 p.m. If you are filling out the survey on behalf of more than one licensed facility, then you are required to fill out a separate weekly report for each individual facility.

Facilities that fail to comply with the mandatory weekly reporting are subject to a civil penalty not to exceed $1,000 a day for each violation.

In situations of technical difficulty submitting the form, call 803-365-3468 prior to 5 p.m. on Monday and provide the weekly visitation information over the phone.

Please feel free to contact **acc-healthreg@dhec.sc.gov** with any questions at all.

Thank you!

Healthcare Quality
S.C. Dept. of Health & Environmental Control
Connect: www.scdhec.gov Facebook Twitter

Healthcare Quality | DHEC, 301 Gervais Street, Columbia, SC 29214

Wilson, Gloria

From: ACC-HealthReg <ACC-HealthReg@dhec.sc.gov>
Sent: Monday, March 8, 2021 1:36 PM
To: Gregory, Aramis L.
Subject: Reminder: Weekly Visitation Report Due Today by 5pm!

Healthy People. Healthy Communities.

Good Afternoon,

This email serves as a reminder that all nursing homes and community residential care facilities are required to send their weekly visitation report via DHEC's Visitation Reporting Form no later than today, Monday, March 8th, by 5:00 pm. If you experience technical difficulties (i.e., internet outage) while trying to submit the **Visitation Reporting Form** prior to today's deadline, you may call 803-365-3468, to provide the information over the phone to a DHEC staff member. This phone number is reserved for extenuating circumstances involving an internet outage prior to today's 5 p.m. deadline.

In order to ensure that we always have the most current information, **DHEC strongly encourages facilities to submit one report per reporting week and to submit them between Sunday at 5:00 pm and Monday at 5:00 pm.** If you are filling out the survey on behalf of more than one licensed facility, then **you are required to fill out a separate weekly report for each individual facility**.

Facilities that fail to comply with the mandatory weekly reporting are subject to a civil penalty not to exceed $1,000 a day for each violation.

In situations of technical difficulty submitting the form, call 803-365-3468 prior to 5 p.m. today and provide the weekly visitation information over the phone.

Please feel free to contact acc-healthreg@dhec.sc.gov with any questions at all.

Thank you!

Healthcare Quality
S.C. Dept. of Health & Environmental Control
Connect: www.scdhec.gov Facebook Twitter

EXHIBIT 4

Facility's Confirmation of Receipt of Report

Wilson, Gloria

From: HealthRegComm <HealthRegComm@dhec.sc.gov>
Sent: Tuesday, March 30, 2021 2:44 PM
To: Gregory, Aramis L.
Subject: Fw: Weekly Visitation Report Received (Reference ID:16056)

Healthcare Quality
S.C. Dept. of Health & Environmental Control
Connect: www.scdhec.gov Facebook Twitter

From: HealthRegComm
Sent: Wednesday, March 10, 2021 4:10 PM
To: RIDGEVIEW1@MSN.COM <RIDGEVIEW1@MSN.COM>
Subject: Weekly Visitation Report Received (Reference ID:16056)

Thank you for submitting your weekly visitation report for RIDGEVIEW COMMUNITY CARE HOMES UNIT B (CRC-0560).

Submission Summary:

Facility Type: Community Residential Care (CRC) Facility
Facility Name: RIDGEVIEW COMMUNITY CARE HOMES UNIT B (CRC-0560)
Facility Contact Email: ridgeview1@msn.com
Allowing Visitation: Yes
Type of Visitation: ["Indoor visitation"]
Participation: 1
Reason(s) for not allowing visitation:

EXHIBIT 5

March 9, 2021
Notice of Violation and Civil Penalty

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

IN RE:
RIDGEVIEW COMMUNITY CARE HOMES UNIT B, CRC-0560
217 CHANDLER RD, GREER, SC
RIDGEVIEW COMMUNITY CARE HOMES INC, Licensee

NOTICE OF REPEAT VIOLATION AND CIVIL PENALTY

The South Carolina Department of Health and Environmental Control (Department) issued Public Health Order No. COVID-19-5 (attached hereto), pursuant to Section 44-1-140 of the South Carolina Code of Laws, on October 7, 2020, requiring all nursing homes and community residential care facilities (CRCFs) licensed by the Department to submit a weekly report, by no later than 5:00 pm each Monday, stating whether they are allowing visitation, and if not, providing the reason(s) for not allowing visitation. The weekly report must also include the number of residents who participated in a visit in the previous seven (7) days.

The Department notified RIDGEVIEW COMMUNITY CARE HOMES INC, of its first violation of Public Health Order No. COVID-19-5 by certified mail on OCTOBER 21, 2020.

The Department hereby notifies RIDGEVIEW COMMUNITY CARE HOMES INC, Licensee, that RIDGEVIEW COMMUNITY CARE HOMES UNIT B, License No. CRC-0560, violated Public Health Order No. COVID-19-5 a SECOND time by failing to submit a weekly report by the 5pm deadline of Monday, MARCH 8, 2021.

The Department hereby issues an additional civil penalty to RIDGEVIEW COMMUNITY CARE HOMES UNIT B in the amount of $350 for the aforementioned repeat violation, in accordance with Section 44-1-150(B) of the South Carolina Code of Laws. Section 44-1-150(B) provides for civil penalties not to exceed $1000.00 per day for each violation.

Payment of the additional $350 civil penalty is due within twenty (20) days of the date of this Notice of Repeat Violation and Civil Penalty. Instructions for payment are attached.

Failure to make timely payment of the civil penalty or further violation of Public Health Order No. COVID-19-5 may result in the Department taking further enforcement action.

Gwendolyn C. Thompson

03112021

Gwendolyn C. Thompson, Director
Healthcare Quality

Date

Attachments:
Public Health Order No. COVID-19-5
Instructions for Payment
Guide to Board Review

ACKNOWLEDGMENT OF REQUEST FOR FINAL REVIEW

TO: Ridgeview Community Care Homes, Inc., Permittee/Requestor

Ashley Biggers, Attorney for the Department

FROM: M. Denise Crawford, Clerk of the Board

RE: **Docket No. 21-RFR-28, Ridgeview Community Care Homes, Inc. – CRC-0560**
Issuance of Notice of Violation and Civil Penalty for violation of Public Health Order No. COVID-19-5 by failing to submit a weekly report by the 5:00 PM deadline of Monday, March 8, 2020.

DATE: March 30, 2021

A Request for Final Review of the above-referenced decision was filed on March 24, 2021. A copy of the request is attached. The Board of Health and Environmental Control will notify you by mail as to whether it will conduct a final review conference in this matter.

The Board has 60 days from the date of receipt of a Request for Final Review to conduct a final review conference. If a final review conference is scheduled, all parties will be given at least 10 calendar days' written notice of the conference.

Procedures for final review conferences and requesting further review are provided in S.C. Code Section 44-1-60. Additional information on procedures will be provided to you after the Board decides whether to conduct a final review conference in this matter.

The above information is provided as a courtesy; parties are responsible for complying with all applicable legal requirements.

CERTIFICATE OF SERVICE

I, M. Denise Crawford, Clerk of the South Carolina Board of Health and Environmental Control and an employee of the South Carolina Department of Health Environmental Control, hereby certify that I have this 30th day of March 2021, served the foregoing Acknowledgment of Request for Final Review and Notice of Procedures – Docket No. 21-RFR-28.

Via Electronic Delivery
Ridgeview Community Care Homes, Inc.
Attn: Trish Daugherty
Administrator
Email: ridgeview1@msn.com
217 Chandler Road
Greer, SC 29651

Via Electronic Delivery
Ashley Biggers, Esquire
Email biggerac@dhec.sc.gov
SCHEC – Office of General Counsel
2600 Bull Street
Columbia, SC 29201

M. Denise Crawford

March 30, 2021
Columbia, South Carolina

April 29, 2021

Via Electronic Mail and US Mail Certified 9214 8969 0099 9790 1419 4716 55
Ridgeview Community Care Homes, Inc.
Attn: Trish Daugherty
Administrator
Email: ridgeview1@msn.com
217 Chandler Road
Greer, SC 29651

Via Electronic Mail Delivery
Ashley Biggers, Esquire
Email biggerac@dhec.sc.gov
SCHEC – Office of General Counsel
2600 Bull Street
Columbia, SC 29201

RE: Docket No. 21-RFR-28, Ridgeview Community Care Homes, Inc. – CRC-0560
Issuance of Notice of Violation and Civil Penalty for violation of Public Health Order No. COVID-19-5 by failing to submit a weekly report by the 5:00 PM deadline of Monday, March 8, 2021

Ms. Daugherty and Counsel of Record:

The South Carolina Board of Health and Environmental Control will hold a Final Review Conference on Thursday, May 13, 2021, at 11:00 a.m. in the Board Room (3420), South Carolina Department of Health and Environmental Control, 2600 Bull Street, Columbia, South Carolina, on the above referenced matter.

The Board has approved the following outline of procedures for conferences:

- Swear all witnesses
- Presentation by parties
  - Order of presentation:
    - DHEC Staff - **10 minutes**
    - Requestor/Owner – Ridgeview Community Care Home, Inc. - **15 minutes**

    Rebuttal:
    - DHEC Staff - **15 minutes**
    - Requestor/Owner – Ridgeview Community Care Home, Inc. - **5 minutes**

- Parties may present evidence; rules of admissibility of evidence do not apply
- At any time during conference, officers conducting conference may request additional information and may question parties and anyone providing information
- Burden of proof is on Requestor(s)
- Presiding officer may impose time limits
- Conference is open to the public
- Officers may deliberate in closed session
- Officers may announce decision at conclusion of conference or may reserve consideration

If either party would like to have a transcript of the review conference, please notify (by e-mail or mail at the above address) the Clerk of Board by Monday, May 10, 2021 so that arrangements can be made to have a reporter present for the conference. The parties requesting a court reporter will be responsible for payment of the court reporter.

Sincerely,

M. Denise Crawford
Clerk of the Board

South Carolina Board of Health and Environmental Control
Final Review Conference
May 13, 2021

Final Review Conference - Docket No. 21-RFR-29, Ridgeview Community Care Homes, Inc. – CRC-0561, Issuance of Notice of Violation and Civil Penalty for violation of Public Health Order No. COVID-19-5 by failing to submit a weekly report by the 5:00 PM deadline of Monday, March 8, 2021

Trish Daugherty for Ridgeview Community Care Homes, Inc.
Ashley Biggers for SCDHEC

Table of Contents

Note: Page #s for this record are located on the bottom of the page.

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

IN RE:
RIDGEVIEW COMMUNITY CARE HOMES UNIT C, CRC-0561
217 CHANDLER RD, GREER, SC
RIDGEVIEW COMMUNITY CARE HOMES INC, Licensee

NOTICE OF REPEAT VIOLATION AND CIVIL PENALTY

The South Carolina Department of Health and Environmental Control (Department) issued Public Health Order No. COVID-19-5 (attached hereto), pursuant to Section 44-1-140 of the South Carolina Code of Laws, on October 7, 2020, requiring all nursing homes and community residential care facilities (CRCFs) licensed by the Department to submit a weekly report, by no later than 5:00 pm each Monday, stating whether they are allowing visitation, and if not, providing the reason(s) for not allowing visitation. The weekly report must also include the number of residents who participated in a visit in the previous seven (7) days.

The Department notified RIDGEVIEW COMMUNITY CARE HOMES INC, of its first violation of Public Health Order No. COVID-19-5 by certified mail on OCTOBER 21, 2020.

The Department hereby notifies RIDGEVIEW COMMUNITY CARE HOMES INC, Licensee, that RIDGEVIEW COMMUNITY CARE HOMES UNIT C, License No. CRC-0561, violated Public Health Order No. COVID-19-5 a SECOND time by failing to submit a weekly report by the 5pm deadline of Monday, MARCH 1, 2021.

The Department hereby issues an additional civil penalty to RIDGEVIEW COMMUNITY CARE HOMES UNIT C in the amount of $350 for the aforementioned repeat violation, in accordance with Section 44-1-150(B) of the South Carolina Code of Laws. Section 44-1-150(B) provides for civil penalties not to exceed $1000.00 per day for each violation.

Payment of the additional $350 civil penalty is due within twenty (20) days of the date of this Notice of Repeat Violation and Civil Penalty. Instructions for payment are attached.

Failure to make timely payment of the civil penalty or further violation of Public Health Order No. COVID-19-5 may result in the Department taking further enforcement action.

Gwendolyn C. Thompson

03092021

Gwendolyn C. Thompson, Director
Healthcare Quality

Date

Attachments:
Public Health Order No. COVID-19-5
Instructions for Payment
Guide to Board Review

Healthy People Healthy Communities

SOUTH CAROLINA
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

PUBLIC HEALTH ORDER
No. COVID-19-5

WHEREAS, on March 13, 2020, Governor Henry McMaster declared a State of Emergency based on a determination that Coronavirus Disease 2019 (COVID-19) posed an actual or imminent public health emergency for the State of South Carolina; and

WHEREAS, on March 13, 2020, the Governor also directed the South Carolina Department of Health and Environmental Control (DHEC) to utilize and exercise any and all emergency powers, as set forth in the Emergency Health Powers Act, codified as amended in Title 44, Chapter 4 of the South Carolina Code of Laws, deemed necessary to promptly and effectively address the current public health emergency. In accordance with Section 44-4-500 of the South Carolina Code of Laws, as amended, the Governor ordered that DHEC shall "use every available means to prevent the transmission of infectious disease and to ensure that all cases of infectious disease are subject to proper control and treatment;" and

WHEREAS, on March 13, 2020, the President of the United States declared the ongoing COVID-19 outbreak a pandemic of sufficient severity and magnitude to warrant an emergency declaration for all states, tribes, territories, and the District of Columbia, pursuant to Section 501(b) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. §§ 5121-5207 ("Stafford Act"); and

WHEREAS, on March 24, 2020, the Governor requested that the President of the United States declare that a major disaster exists in the State of South Carolina pursuant to Section 401 of the Stafford Act; and

WHEREAS, on March 27, 2020, the President of the United States granted the Governor's request and declared that a major disaster exists in the State of South Carolina and ordered federal assistance to supplement state, tribal, and local recovery efforts in the areas affected by the COVID-19 pandemic, with an effective date retroactive to January 20, 2020, and continuing; and

WHEREAS, since declaring an initial State of Emergency on March 13, 2020, the Governor has subsequently declared a State of Emergency and directed DHEC to utilize and exercise any and all emergency powers, as set forth in the Executive Health Powers Act, codified in Title 44, Chapter 4 of the South Carolina Code of Laws, deemed necessary to promptly and effectively address the current public health emergency, in Executive Order Nos. 2020-15, 2020-23, 2020-29, 2020-35, 2020-38, 2020-40, 2020-42, 2020-44, 2020-48, 2020-53, 2020-56, 2020-59, and 2020-62; and

WHEREAS, as of October 7, 2020, COVID-19 is widespread throughout the state and in all 46 counties, with 148,334 total confirmed cases statewide and 3,300 total confirmed deaths; and

WHEREAS, DHEC is invested with all the rights and charged with all the duties pertaining to organizations of like character and is the sole advisor of the State in all questions involving the protection of the public health within its limits (S.C. Code Ann.§ 44-1-110); and

WHEREAS, DHEC must enforce or prescribe preventive measures as may be needed to suppress or prevent the spread of these diseases by proper quarantine or other measures of prevention, as may be necessary to protect citizens of the State (S.C. Code Ann. § 44-1-80(A)); and

WHEREAS, DHEC is granted the authority to make, adopt, promulgate and enforce reasonable rules and regulations from time to time requiring and providing for the thorough investigation and study of the causes of all diseases, epidemic and otherwise, in the State, the means for the prevention of contagious disease and the publication and distribution of such information as may contribute to the preservation of the public health and the prevention of disease (S.C. Code Ann.§ 44-1-140(12)); and

WHEREAS, DHEC may also make separate orders and rules to meet any emergency not provided for by general rules and regulations, for the purpose of suppressing nuisances dangerous to the public health and communicable, contagious and infectious diseases and other danger to the public life and health (S.C. Code Ann.§ 44-1-140); and

WHEREAS, in addition to its authority provided by statute or as otherwise provided for by regulation, DHEC may issue separate orders to enforce the provisions of S.C. Regulation 61-20 for the purpose of suppressing nuisances, Communicable, Contagious and Infectious Diseases, and other dangers to public health (S.C. Code Ann. Regs. 61-20 § 14(A)); and

WHEREAS, all entities shall comply with DHEC directives and orders to protect the public health from the spread of Communicable and Infectious Diseases (S.C. Code Ann. Regs. 61-20 § 4(D)); and

WHEREAS, during a public health emergency, DHEC must use every available means to prevent the transmission of infectious disease and ensure that all cases of infectious disease are subject to proper control and treatment (S.C. Code Ann.§ 44-4-500); and

WHEREAS, the Bill of Rights for Residents of Long-Term Care Facilities requires the legal guardian, family members, and other relatives of each resident of a long-term care facility

be allowed immediate access to that resident, subject to the resident's right to deny access or withdraw consent to access at any time, and requires each resident, without unreasonable delay or restrictions, be allowed to associate and communicate privately with persons of the resident's choice (S.C. Code Ann. § 44-81-40(K)); and

WHEREAS, nursing homes and community residential care facilities are required to comply with the Bill of Rights for Residents of Long-Term Care Facilities (S.C. Code Ann. Regs. 61-17, § 1101; S.C. Code Ann. Regs. 61-84 § 1001), and

WHEREAS, nursing homes shall encourage visitation of residents by family and friends with minimum restrictions and shall post visiting hours in accordance with facility policies and procedures (S.C. Code Ann. Regs. § 1003.J), and

WHEREAS, South Carolina is engaged in an all-hands effort to both reduce the spread of COVID-19 and to ensure safety of all South Carolinians, including residents of nursing homes and community residential care facilities; and

WHEREAS, the COVID-19 pandemic has created a need for nursing homes and community residential care facilities to prevent the spread of disease among residents and staff, and

WHEREAS, nursing homes and community residential care facilities are required by South Carolina law and regulation to allow for access to residents; however, the current State of Emergency requires changes and limitations to normal visitation policies and procedures in order to ensure residents, which are members of a vulnerable population, are protected from exposure to COVID-19; and

WHEREAS, as the Acting Director of Public Health, I have reviewed the data regarding confirmed COVID-19 cases, reported exposures among the population in South Carolina, including cases and reported exposures in vulnerable populations including residents of nursing homes and community residential care facilities, and

WHEREAS, I have determined that it is necessary to gather and monitor information regarding access to visitation for residents in nursing homes and community residential care facilities in order to ensure the safety of residents and staff and appropriate and reasonable compliance with applicable laws and regulations.

NOW, THEREFORE, IT IS HEREBY ORDERED, pursuant to section 44-1-140 of the South Carolina Code of Laws, that all nursing homes and community residential care facilities licensed by DHEC are required to submit a weekly report stating whether they are allowing

visitation, and if not, providing the reason(s) for not allowing visitation. Facilities must also report the number of residents who participated in a visit in the previous seven (7) days.

Each licensed Facility must submit a separate report to DHEC.

Facilities must complete their weekly report no later than 5:00 PM each Monday by completing and submitting the form on DHEC's webpage, https://scdhec.gov/visitation.

Should any nursing home or community residential care facility face human resource or information technology challenges in completing any requirement of this Order, the facility should notify DHEC immediately by contacting ACC-HealthReg@dhec.sc.gov.

IT IS FURTHER ORDERED, pursuant to section 44-1-150 of the South Carolina Code of Laws, that any facility that violates this Order may be subject to a civil penalty not to exceed one thousand (1,000) dollars a day for each violation.

This Order is effective immediately and shall remain in effect unless otherwise modified, amended, or rescinded by subsequent order.

AND IT IS SO ORDERED.

L. Brannon Traxler, MD, MPH
Interim Director of Public Health

Date: 10/07/2020

dhec
Healthy People. Healthy Communities.

INSTRUCTIONS FOR PAYMENT

1. Make certified check or money order payable to S.C. Department of Health and Environmental Control and ensure to include your Facility's Name and License Number

2. Send payment to the following address:

   Attention: Angie Smith, Interim Director
   Bureau of Facilities Oversight/Healthcare Quality
   S.C. Department of Health and Environmental Control
   2600 Bull Street
   Columbia, SC 29201

South Carolina Board of Health and Environmental Control

Guide to Board Review

Pursuant to S.C. Code Ann. § 44-1-60

The decision of the South Carolina Department of Health and Environmental Control (Department) becomes the final agency decision fifteen (15) calendar days after notice of the decision has been mailed to the applicant, permittee, licensee and affected persons who have requested in writing to be notified, unless a written request for final review accompanied by a filing fee in the amount of $100 is filed with Department by the applicant, permittee, licensee or affected person.

Applicants, permittees, licensees, and affected parties are encouraged to engage in mediation or settlement discussions during the final review process.

If the Board declines in writing to schedule a final review conference, the Department's decision becomes the final agency decision and an applicant, permittee, licensee, or affected person may request a contested case hearing before the Administrative Law Court within thirty (30) calendar days after notice is mailed that the Board declined to hold a final review conference. In matters pertaining to decisions under the South Carolina Mining Act, appeals should be made to the South Carolina Mining Council.

I. Filing of Request for Final Review

1. A written Request for Final Review (RFR) and the required filing fee of one hundred dollars ($100) must be received by Clerk of the Board within fifteen (15) calendar days after notice of the staff decision has been mailed to the applicant, permittee, licensee, or affected persons. If the 15th day occurs on a weekend or State holiday, the RFR must be received by the Clerk on the next working day. RFRs will not be accepted after 5:00 p.m.
2. RFRs shall be in writing and should include, at a minimum, the following information:
   - The grounds for amending, modifying, or rescinding the staff decision;
   - a statement of any significant issues or factors the Board should consider in deciding how to handle the matter;
   - the relief requested;
   - a copy of the decision for which review is requested; and
   - mailing address, email address, if applicable, and phone number(s) at which the requestor can be contacted.
3. RFRs should be filed in person or by mail at the following address:
   South Carolina Board of Health and Environmental Control
   Attention: Clerk of the Board
   2600 Bull Street
   Columbia, South Carolina 29201
   Alternatively, RFR's may be filed with the Clerk by facsimile (803-898-3393) or by electronic mail (boardclerk@dhec.sc.gov).
4. The filing fee may be paid by cash, check or credit card and must be received by the 15th day.
5. If there is any perceived discrepancy in compliance with this RFR filing procedure, the Clerk should consult with the Chairman or, if the Chairman is unavailable, the Vice-Chairman. The Chairman or the Vice-Chairman will determine whether the RFR is timely and properly filed and direct the Clerk to (1) process the RFR for consideration by the Board or (2) return the RFR and filing fee to the requestor with a cover letter explaining why the RFR was not timely or properly filed. Processing an RFR for consideration by the Board shall not be interpreted as a waiver of any claim or defense by the agency in subsequent proceedings concerning the RFR.
6. If the RFR will be processed for Board consideration, the Clerk will send an Acknowledgement of RFR to the Requestor and the applicant, permittee, or licensee, if other than the Requestor. All personal and financial identifying information will be redacted from the RFR and accompanying documentation before the RFR is released to the Board, Department staff or the public.
7. If an RFR pertains to an emergency order, the Clerk will, upon receipt, immediately provide a copy of the RFR to all Board members. The Chairman, or in his or her absence, the Vice-Chairman shall based on the circumstances, decide whether to refer the RFR to the RFR Committee for expedited review or to decline in writing to schedule a Final Review Conference. If the Chairman or Vice-Chairman determines review by the RFR Committee is appropriate, the Clerk will forward a copy of the RFR to Department staff and Office of General Counsel. A Department response and RFR Committee review will be provided on an expedited schedule defined by the Chairman or Vice-Chairman.
8. The Clerk will email the RFR to staff and Office of General Counsel and request a Department Response within eight (8) working days. Upon receipt of the Department Response, the Clerk will forward the RFR and Department Response to all Board members for review, and all Board members will confirm receipt of the RFR to the Clerk by email. If a Board member does not confirm receipt of the RFR within a twenty-four (24) hour period, the Clerk will contact the Board member and confirm receipt. If a Board member believes the RFR should be considered by the RFR Committee, he or she will

respond to the Clerk's email within forty-eight (48) hours and will request further review. If no Board member requests further review of the RFR within the forty-eight (48) hour period, the Clerk will send a letter by certified mail to the Requestor, with copy by regular mail to the applicant, permittee, or licensee, if not the Requestor, stating the Board will not hold a Final Review Conference. Contested case guidance will be included within the letter.
NOTE: If the time periods described above end on a weekend or State holiday, the time is automatically extended to 5:00 p.m. on the next business day.

9. If the RFR is to be considered by the RFR Committee, the Clerk will notify the Presiding Member of the RFR Committee and the Chairman that further review is requested by the Board. RFR Committee meetings are open to the public and will be public noticed at least 24 hours in advance.
10. Following RFR Committee or Board consideration of the RFR, if it is determined no Conference will be held, the Clerk will send a letter by certified mail to the Requestor, with copy by regular mail to the applicant, permittee, or licensee, if not the Requestor, stating the Board will not hold a Conference. Contested case guidance will be included within the letter.

II. Final Review Conference Scheduling

1. If a Conference will be held, the Clerk will send a letter by certified mail to the Requestor, with copy by regular mail to the applicant, permittee, or licensee, if not the Requestor, informing the Requestor of the determination.
2. The Clerk will request Department staff provide the Administrative Record.
3. The Clerk will send Notice of Final Review Conference to the parties at least ten (10) days before the Conference. The Conference will be publically noticed and should:
   - include the place, date and time of the Conference;
   - state the presentation times allowed in the Conference;
   - state evidence may be presented at the Conference;
   - if the conference will be held by committee, include a copy of the Chairman's order appointing the committee; and
   - inform the Requestor of his or her right to request a transcript of the proceedings of the Conference prepared at Requestor's expense.
4. If a party requests a transcript of the proceedings of the Conference and agrees to pay all related costs in writing, including costs for the transcript, the Clerk will schedule a court reporter for the Conference.

III. Final Review Conference and Decision

1. The order of presentation in the Conference will, subject to the presiding officer's discretion, be as follows:
   - Department staff will provide an overview of the staff decision and the applicable law to include [10 minutes]:
     - Type of decision (permit, enforcement, etc.) and description of the program.
     - Parties
     - Description of facility/site
     - Applicable statutes and regulations
     - Decision and materials relied upon in the administrative record to support the staff decision.
   - Requestor(s) will state the reasons for protesting the staff decision and may provide evidence to support amending, modifying, or rescinding the staff decision. [15 minutes] *NOTE: The burden of proof is on the Requestor(s)*
   - Rebuttal by Department staff [15 minutes]
   - Rebuttal by Requestor(s) [10 minutes]

   Note: Times noted in brackets are for information only and are superseded by times stated in the Notice of Final Review Conference or by the presiding officer.
2. Parties may present evidence during the conference; however, the rules of evidence do not apply.
3. At any time during the conference, the officers conducting the Conference may request additional information and may question the Requestor, the staff, and anyone else providing information at the Conference.
4. The presiding officer, in his or her sole discretion, may allow additional time for presentations and may impose time limits on the Conference.
5. All Conferences are open to the public.
6. The officers may deliberate in closed session.
7. The officers may announce the decision at the conclusion of the Conference or it may be reserved for consideration.
8. The Clerk will mail the written final agency decision (FAD) to parties within 30 days after the Conference. The written decision must explain the basis for the decision and inform the parties of their right to request a contested case hearing before the Administrative Law Court or in matters pertaining to decisions under the South Carolina Mining Act, to request a hearing before the South Carolina Mining Council.. The FAD will be sent by certified mail, return receipt requested.
9. Communications may also be sent by electronic mail, in addition to the forms stated herein, when electronic mail addresses are provided to the Clerk.

The above information is provided as a courtesy; parties are responsible for complying with all applicable legal requirements.

Ridgeview Community Care Homes, Inc.

217 Chandler Rd ~ Greer, SC ~ 29651

March 23, 2021

South Carolina Board of Health and Environmental Control
Attention: Clerk of Court
2600 Bull Street
Columbia, SC 29201

RE: Written Request for Final Review, CRC-0561 Unit C

Dear Board Members,

We are submitting this written request for final review of the decision to impose a civil penalty of $350 on our facility CRC-0561, for submitting the weekly visitation report late. The payment of $100 was made over the phone.

The grounds for amending, modifying, or rescinding the staff decision:

After months of receiving Monday email reminders from DHEC to submit the weekly visitation reports, our facility did not receive email reminders from DHEC on Monday, March 8, to submit the weekly reports. This reminder email has become an integral part of our process to submit timely reports, and on March 8th we did not receive this reminder. Also, during this pandemic quarantine it is a financial hardship and unnecessary to impose a civil penalty for a report that was only 2 days late and did not put anyone in danger.

Significant issues the Board should consider in deciding how to handle the matter:

The weekly visitation report WAS FILED on Wednesday of that week, please see attached email confirmation.

I was working on financial paperwork for our facility's tax return. I do not have anyone else in my office currently to train to submit the reports because there is no other administrative staff with online access right now.

Ridgeview Community Care Homes is made up of 4 licensed buildings so for us this second penalty of $350 is a total penalty of $1,400, which is a tremendous financial hardship during this difficult time.

Please consider the many difficulties we have dealt with due to the COVID-19 pandemic. Financial difficulties such as reduced income due to inability to fill beds during quarantine, increased payroll expenses due to paying staff bonuses for continued service during the pandemic, increased food expenses due to ordering online to reduce staff exposure shopping for food items and increased recreational activity expenses for extra supplies and snacks ordered online to provide additional

activities for our residents during quarantine to help improve their mental status. We can not survive as a business with negative income. Additional expenses such as monetary penalties would be a financial hardship for us.

After last year's pandemic, filled with fear of illness and death, it is unnecessary for the Department to impose monetary penalties upon businesses that are caring for the most vulnerable population in our state. It has been challenging for our residents and staff to say the very least, a year full of new regulations, limited family visits, and no resident outings. Please take this into consideration and not add another financial burden to our business, or to any other facilities throughout the state who are suffering the same way. Our facility has not had any COVID-19 outbreaks among our residents or staff, we have followed the regulations and have received our vaccinations. Our residents' wellbeing comes first and at no time were they in a compromised position due to our report being submitted 2 days late so instead of imposing financial hardship on facilities, please show your support to the facilities that care for the ones that are most at risk and have been unable to have normal visits and outings with their loved ones.

The relief requested: We would like the civil penalty to be removed.

A copy of the decision for which the review is requested: Copies are attached.

Mailing address, email address and phone number the requestor can be contacted:

Trish Daugherty, Administrator
Ridgeview Community Care Homes
217 Chandler Road
Greer, SC 29651
ridgeview1@msn.com
Phone (864)877-8599 Fax (864)877-8704

We sincerely appreciate the opportunity to ask for a review of the decision to impose a civil penalty on our facility. If you have any questions please contact me at (864)877-8599.

Thank you,

Trish Daugherty

Trish Daugherty
Administrator
Authorized digital signature

Lee Daugherty

Lee Daugherty
Assistant Administrator
Authorized digital signature

The following copies are enclosed below:

- Email confirmation that the weekly visitation reports were filed.
- Copy of the original notice of violation and civil penalty for CRC-0561.

HealthRegComm <HealthRegComm@dhec.sc.gov>
Wed 3/10/2021 4:11 PM
To: RIDGEVIEW1@MSN.COM

Thank you for submitting your weekly visitation report for RIDGEVIEW COMMUNITY CARE HOMES UNIT C (CRC-0561).

Submission Summary:

Facility Type: Community Residential Care (CRC) Facility
Facility Name: RIDGEVIEW COMMUNITY CARE HOMES UNIT C (CRC-0561)

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

IN RE:
RIDGEVIEW COMMUNITY CARE HOMES UNIT C, CRC-0561
217 CHANDLER RD, GREER, SC
RIDGEVIEW COMMUNITY CARE HOMES INC, Licensee

NOTICE OF REPEAT VIOLATION AND CIVIL PENALTY

The South Carolina Department of Health and Environmental Control (Department) issued Public Health Order No. COVID-19-5 (attached hereto), pursuant to Section 44-1-140 of the South Carolina Code of Laws, on October 7, 2020, requiring all nursing homes and community residential care facilities (CRCFs) licensed by the Department to submit a weekly report, by no later than 5:00 pm each Monday, stating whether they are allowing visitation, and if not, providing the reason(s) for not allowing visitation. The weekly report must also include the number of residents who participated in a visit in the previous seven (7) days.

The Department notified RIDGEVIEW COMMUNITY CARE HOMES INC, of its first violation of Public Health Order No. COVID-19-5 by certified mail on OCTOBER 21, 2020.

The Department hereby notifies RIDGEVIEW COMMUNITY CARE HOMES INC, Licensee, that RIDGEVIEW COMMUNITY CARE HOMES UNIT C, License No. CRC-0561, violated Public Health Order No. COVID-19-5 a SECOND time by failing to submit a weekly report by the 5pm deadline of Monday, MARCH 8, 2021.

The Department hereby issues an additional civil penalty to RIDGEVIEW COMMUNITY CARE HOMES UNIT C in the amount of $350 for the aforementioned repeat violation, in accordance with Section 44-1-150(B) of the South Carolina Code of Laws. Section 44-1-150(B) provides for civil penalties not to exceed $1000.00 per day for each violation.

Payment of the additional $350 civil penalty is due within twenty (20) days of the date of this Notice of Repeat Violation and Civil Penalty. Instructions for payment are attached.

Failure to make timely payment of the civil penalty or further violation of Public Health Order No. COVID-19-5 may result in the Department taking further enforcement action.

Gwendolyn C. Thompson

Gwendolyn C. Thompson, Director
Healthcare Quality

03112021

Date

Attachments:
Public Health Order No. COVID-19-5
Instructions for Payment
Guide to Board Review

RECEIVED
APR 08 2021
Clerk, Board of Health and Environmental Control

BEFORE THE BOARD OF HEALTH AND ENVIRONMENTAL CONTROL
STAFF RESPONSE TO REQUEST FOR FINAL REVIEW
Docket No. 21-RFR-29

Requestor: **Ridgeview Community Care Homes, Inc. (Licensee)**
Ridgeview Community Care Homes Unit C, License No. CRC-0561
(Ridgeview or Facility)
Re: **Notice of Repeat Violation and Civil Penalty**

Overview: This Request for Final Review (RFR) concerns a $350 civil monetary penalty imposed for a violation of Public Health Order No. COVID-19-5 (PHO) for failure to submit a mandatory weekly report on visitation status at the Facility. The Facility requests the violation be reviewed and removed. Staff requests the Board uphold the decision, which was issued in accordance with terms of the PHO and applicable statutory requirements.

I. Summary

Ridgeview Community Care Homes-Unit C is a licensed Community Residential Care Facility (CRCF) located in Greer, South Carolina, licensed for eleven (11) beds.

On March 13, 2020, Governor Henry McMaster declared a State of Emergency based on a determination that Coronavirus Disease 2019 (COVID-19) posed an actual or imminent public health emergency for the State of South Carolina.

On October 7, 2020, the South Carolina Department of Health and Environmental Control (DHEC or Department) issued the attached PHO, pursuant to section 44-1-140 of the South Carolina Code of Laws, requiring all licensed nursing homes and CRCFs to submit a weekly report stating whether they are allowing visitation, and if not, providing the reason(s) for not allowing visitation. *See* Exhibit 1. Facilities must also include in the weekly report the number of residents who participated in a visit in the previous seven (7) days. Facilities must submit their weekly report to DHEC no later than 5:00 PM each Monday by completing and submitting the form on the DHEC's webpage (https://scdhec.gov/visitation). The PHO further provides, pursuant to Section 44-1-150, that any facility violating the Order may be subject to a civil penalty not to exceed one thousand ($1,000) dollars a day for each violation.

DHEC sent Ridgeview Community Care Homes Unit-C, and other licensed CRCFs and nursing homes, notice of the PHO by email on October 8, 2020. *See* Exhibit 2. DHEC sent additional email reminders to the Facility and other licensed facilities following the initial notice, including three reminder emails on October 12, 2020, the first day of required reporting, and two reminder emails a week prior to the reporting deadline in subsequent weeks. The reminder emails are sent on Fridays and Mondays prior to the 5:00 PM Monday reporting deadline each week. *See* Exhibit 3 (reminder emails sent on March 5, 2021, and March 8, 2021).

For the week beginning March 1, 2021, the Department did not receive a weekly report, which was due March 8, 2021, from Ridgeview Community Care Homes Unit-C until March 10, 2021, at 4:11 PM. *See* Exhibit 4. The Department notified the Facility that it had violated the PHO by

failing to submit a weekly report by the 5PM deadline of Monday, March 8, 2021. *See* Exhibit 5. This was Ridgeway's second cited violation of the PHO reporting requirement. Therefore, the Department issued a penalty in the amount of $350 for the aforementioned violation, in accordance with Section 44-1-150(b) of the South Carolina Code of Laws. *Id.* Ridgeview Community Care Homes Unit-C, filed its RFR, requesting waiver of the penalty, on March 22, 2021.

II. Relevant Law

DHEC is vested with all the rights and charged with all the duties pertaining to organizations of like character and is the sole advisor of the State in all questions involving the protection of the public health within its limits. S.C. Code Ann. § 44-1-110. DHEC is granted the authority to make, adopt, promulgate and enforce reasonable rules and regulations from time to time requiring and providing for the thorough investigation and study of the causes of all diseases, epidemic and otherwise, in the State, the means for the prevention of contagious disease and the public and distribution of such information as may contribute to the preservation of the public health and the prevention of disease. S.C. Code Ann. § 44-1-140(12). During a public health emergency, DHEC must use every available means to prevent the transmission of infectious disease and ensure that all cases of infectious disease are subject to proper control and treatment. S.C. Code Ann. § 44-4-500. All entities shall comply with DHEC directives and orders to protect the public health from the spread of communicable and infectious diseases. S.C. Code Ann. Regs. 61-20 § 4(D).

The Bill of Rights for Residents of Long-Term Care Facilities requires the legal guardian, family members, and other relatives of each resident of a long-term care facility be allowed immediately access to that resident, subject to the resident's right to deny access or withdraw consent to access at any time, and requires each resident, without unreasonable delay or restrictions, be allowed to associate and communicate privately with persons of the residents' choice. S.C. Code Ann. § 44-81-40(K). Nursing homes and community residential care facilities are required to comply with the Bill of Rights for Residents of Long-Term Care Facilities. S.C. Code Ann. Regs. 61-17 § 1101; S.C. Code Ann. Regs 61-84 § 1001.

DHEC may make separate orders and rules to meet any emergency not provided for by general rules and regulations, for the purpose of suppressing nuisances dangerous to the public health and communicable, contagious and infectious diseases and other danger to the public life and health. S.C. Code Ann. § 44-1-140. A person who after notice violates an order of the department issued pursuant to Section 44-1-140 is subject to a civil penalty not to exceed one thousand dollars a day for each violation. S.C. Code Ann. § 44-1-150(b).

III. Response to Request for Review

The Facility does not dispute the Department's finding that it violated the PHO by failing to submit a weekly report by the deadline of 5:00 PM on March 8, 2021, for the week that began on March 1, 2021. Rather, the Facility requests the fine of $350 be waived because, "after months of receiving Monday email reminders from DHEC to submit the weekly visitation reports, our facility did not receive email reminders from DHEC on Monday, March 8th to submit the weekly reports. This reminder email has become an integral part of our process to submit timely reports, and on March 8th we did not receive this reminder. Also, during this pandemic quarantine it is a financial

hardship and unnecessary to impose a civil penalty for a report that was only two days late and did not put anyone in danger."

Staff respectfully requests the Board uphold the imposed $350 fine. The Department provided ample and repeated notices to the Facility of the PHO's reporting requirement and the 5:00 PM, March 8, 2021, reporting deadline, including email reminders on Friday, March 5, and Monday, March 8, 2021. *See* Exhibit 3. Ridgeview Community Care Homes Unit-C is one of 499 community residential care facilities subject to the March 8, 2021, PHO reporting deadline, and one of fourteen that failed to submit a timely report by that week's deadline.[1] The Department is tracking compliance with the reporting requirement for hundreds of facilities and is treating all facilities subject to the PHO equally in terms of enforcement. The Department considered the Facility's compliance history with the reporting requirements when determining the monetary penalty amount. As with other similarly situated facilities that committed a second violation of the PHO for the week in question, Ridgeview Community Care Homes Unit-C was fined $350 – less than the maximum possible fine of $1,000 per violation. For these reasons, staff respectfully requests the Board uphold the issued fine.

IV. Requested Action

For the foregoing reasons, staff requests that the Board decline to conduct a final review conference and uphold the monetary penalty for violation of the PHO.

Respectfully submitted:

Angie Smith

Angie Smith, Interim Director
Bureau of Facilities Oversight
Director, Community Oversight Care Division
Healthcare Quality

Ashley Biggers

Ashley Biggers, Esq.
Chief Counsel for Healthcare Quality
Office of General Counsel

March 2021

Exhibit 1 – October 7, 2020, PHO
Exhibit 2 – October 8, 2020, Email Notice of PHO
Exhibit 3 – March 5 and March 8, 2021, Email Reminder of March 8, 2021, Reporting Deadline
Exhibit 4 – Confirmation of Receipt of Report
Exhibit 5 – March 9, 2021, Notice of Violation and Civil Penalty

[1] Of the 499 community residential care facilities subject to the PHO reporting requirement on March 8, 2021, only fourteen failed to submit a weekly report and were sent a notice of violation and civil penalty

EXHIBIT 1

October 7, 2020
Public Health Order (PHO)

SOUTH CAROLINA
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

PUBLIC HEALTH ORDER
No. COVID-19-5

WHEREAS, on March 13, 2020, Governor Henry McMaster declared a State of Emergency based on a determination that Coronavirus Disease 2019 (COVID-19) posed an actual or imminent public health emergency for the State of South Carolina; and

WHEREAS, on March 13, 2020, the Governor also directed the South Carolina Department of Health and Environmental Control (DHEC) to utilize and exercise any and all emergency powers, as set forth in the Emergency Health Powers Act, codified as amended in Title 44, Chapter 4 of the South Carolina Code of Laws, deemed necessary to promptly and effectively address the current public health emergency. In accordance with Section 44-4-500 of the South Carolina Code of Laws, as amended, the Governor ordered that DHEC shall "use every available means to prevent the transmission of infectious disease and to ensure that all cases of infectious disease are subject to proper control and treatment;" and

WHEREAS, on March 13, 2020, the President of the United States declared the ongoing COVID-19 outbreak a pandemic of sufficient severity and magnitude to warrant an emergency declaration for all states, tribes, territories, and the District of Columbia, pursuant to Section 501(b) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. §§ 5121-5207 ("Stafford Act"); and

WHEREAS, on March 24, 2020, the Governor requested that the President of the United States declare that a major disaster exists in the State of South Carolina pursuant to Section 401 of the Stafford Act; and

WHEREAS, on March 27, 2020, the President of the United States granted the Governor's request and declared that a major disaster exists in the State of South Carolina and ordered federal assistance to supplement state, tribal, and local recovery efforts in the areas affected by the COVID-19 pandemic, with an effective date retroactive to January 20, 2020, and continuing; and

WHEREAS, since declaring an initial State of Emergency on March 13, 2020, the Governor has subsequently declared a State of Emergency and directed DHEC to utilize and exercise any and all emergency powers, as set forth in the Executive Health Powers Act, codified in Title 44, Chapter 4 of the South Carolina Code of Laws, deemed necessary to promptly and effectively address the current public health emergency, in Executive Order Nos. 2020-15, 2020-23, 2020-29, 2020-35, 2020-38, 2020-40, 2020-42, 2020-44, 2020-48, 2020-53, 2020-56, 2020-59, and 2020-62; and

WHEREAS, as of October 7, 2020, COVID-19 is widespread throughout the state and in all 46 counties, with 148,334 total confirmed cases statewide and 3,300 total confirmed deaths; and

WHEREAS, DHEC is invested with all the rights and charged with all the duties pertaining to organizations of like character and is the sole advisor of the State in all questions involving the protection of the public health within its limits (S.C. Code Ann.§ 44-1-110); and

WHEREAS, DHEC must enforce or prescribe preventive measures as may be needed to suppress or prevent the spread of these diseases by proper quarantine or other measures of prevention, as may be necessary to protect citizens of the State (S.C. Code Ann. § 44-1-80(A)); and

WHEREAS, DHEC is granted the authority to make, adopt, promulgate and enforce reasonable rules and regulations from time to time requiring and providing for the thorough investigation and study of the causes of all diseases, epidemic and otherwise, in the State, the means for the prevention of contagious disease and the publication and distribution of such information as may contribute to the preservation of the public health and the prevention of disease (S.C. Code Ann.§ 44-1-140(12)); and

WHEREAS, DHEC may also make separate orders and rules to meet any emergency not provided for by general rules and regulations, for the purpose of suppressing nuisances dangerous to the public health and communicable, contagious and infectious diseases and other danger to the public life and health (S.C. Code Ann.§ 44-1-140); and

WHEREAS, in addition to its authority provided by statute or as otherwise provided for by regulation, DHEC may issue separate orders to enforce the provisions of S.C. Regulation 61-20 for the purpose of suppressing nuisances, Communicable, Contagious and Infectious Diseases, and other dangers to public health (S.C. Code Ann. Regs. 61-20 § 14(A)); and

WHEREAS, all entities shall comply with DHEC directives and orders to protect the public health from the spread of Communicable and Infectious Diseases (S.C. Code Ann. Regs. 61-20 § 4(D)); and

WHEREAS, during a public health emergency, DHEC must use every available means to prevent the transmission of infectious disease and ensure that all cases of infectious disease are subject to proper control and treatment (S.C. Code Ann.§ 44-4-500); and

WHEREAS, the Bill of Rights for Residents of Long-Term Care Facilities requires the legal guardian, family members, and other relatives of each resident of a long-term care facility

be allowed immediate access to that resident, subject to the resident's right to deny access or withdraw consent to access at any time, and requires each resident, without unreasonable delay or restrictions, be allowed to associate and communicate privately with persons of the resident's choice (S.C. Code Ann. § 44-81-40(K)); and

WHEREAS, nursing homes and community residential care facilities are required to comply with the Bill of Rights for Residents of Long-Term Care Facilities (S.C. Code Ann. Regs. 61-17, § 1101; S.C. Code Ann. Regs. 61-84 § 1001), and

WHEREAS, nursing homes shall encourage visitation of residents by family and friends with minimum restrictions and shall post visiting hours in accordance with facility policies and procedures (S.C. Code Ann. Regs. § 1003.J), and

WHEREAS, South Carolina is engaged in an all-hands effort to both reduce the spread of COVID-19 and to ensure safety of all South Carolinians, including residents of nursing homes and community residential care facilities; and

WHEREAS, the COVID-19 pandemic has created a need for nursing homes and community residential care facilities to prevent the spread of disease among residents and staff, and

WHEREAS, nursing homes and community residential care facilities are required by South Carolina law and regulation to allow for access to residents; however, the current State of Emergency requires changes and limitations to normal visitation policies and procedures in order to ensure residents, which are members of a vulnerable population, are protected from exposure to COVID-19; and

WHEREAS, as the Acting Director of Public Health, I have reviewed the data regarding confirmed COVID-19 cases, reported exposures among the population in South Carolina, including cases and reported exposures in vulnerable populations including residents of nursing homes and community residential care facilities, and

WHEREAS, I have determined that it is necessary to gather and monitor information regarding access to visitation for residents in nursing homes and community residential care facilities in order to ensure the safety of residents and staff and appropriate and reasonable compliance with applicable laws and regulations.

NOW, THEREFORE, IT IS HEREBY ORDERED, pursuant to section 44-1-140 of the South Carolina Code of Laws, that all nursing homes and community residential care facilities licensed by DHEC are required to submit a weekly report stating whether they are allowing

visitation, and if not, providing the reason(s) for not allowing visitation. Facilities must also report the number of residents who participated in a visit in the previous seven (7) days.

Each licensed Facility must submit a separate report to DHEC.

Facilities must complete their weekly report no later than 5:00 PM each Monday by completing and submitting the form on DHEC's webpage, https://scdhec.gov/visitation.

Should any nursing home or community residential care facility face human resource or information technology challenges in completing any requirement of this Order, the facility should notify DHEC immediately by contacting ACC-HealthReg@dhec.sc.gov.

IT IS FURTHER ORDERED, pursuant to section 44-1-150 of the South Carolina Code of Laws, that any facility that violates this Order may be subject to a civil penalty not to exceed one thousand (1,000) dollars a day for each violation.

This Order is effective immediately and shall remain in effect unless otherwise modified, amended, or rescinded by subsequent order.

AND IT IS SO ORDERED.

LB Traxler MD

Date: 10/07/2020

L. Brannon Traxler, MD, MPH
Interim Director of Public Health

EXHIBIT 2

October 8, 2020
Email Notice of PHO

Healthy People. Healthy Communities.

Good afternoon,

DHEC issued a Public Health Order on October 7, 2020 that is available to read here.

This Order requires all licensed nursing homes and community residential care facilities to submit a weekly report to DHEC regarding visitation.

Facilities are required to send their respective weekly reports by submitting a response in DHEC's Visitation Reporting Form. The first weekly report is due on this **upcoming Monday, October 12, 2020, by 5:00 pm.**

If you are filling out the survey on behalf of more than one licensed facility, then **you are required to fill out a separate weekly report for each individual facility**. Failure to comply with the mandatory weekly reporting to DHEC may result in a civil penalty not to exceed $1,000 a day for each violation.

Submit weekly reports via the Visitation Reporting Form.

Weekly reports are due each Monday by 5:00 pm.

The Visitation Reporting Form requires all licensed nursing homes and community residential care facilities to report whether they are allowing visitation and, if not, to provide the reason(s) for not allowing visitation; facilities allowing visitation must also report the number of residents who participated in a visit in the previous 7 days.

DHEC plans to publish updated visitation guidelines tomorrow, October 9, 2020, on both outdoor and indoor visitation.

DHEC's Visitation Reporting Form and relevant information will be available on our new Long-Term Care Facilities Visitation (COVID-19) page, which can also be reached by going directly to scdhec.gov/visitation. The forthcoming updated visitation guidance and other resources will be posted on this page.

We thank all licensed nursing homes and community residential care facilities for their cooperation, timely responses, and invaluable care of all residents, staff, and visitors.

Facilities can reach out to acc-healthreg@dhec.sc.gov with any questions at all.

Thank you,

Healthcare Quality
S.C. Dept. of Health & Environmental Control
Connect: www.scdhec.gov Facebook Twitter

EXHIBIT 3

Email Reminders-Reporting Deadline

March 5, 2021
March 8, 2021

Wilson, Gloria

From: ACC-HealthReg <ACC-HealthReg@dhec.sc.gov>
Sent: Friday, March 5, 2021 2:13 PM
To: Gregory, Aramis L.
Subject: Weekly Visitation Report Due Monday by 5 pm!

Good Afternoon,

This email serves as a reminder that all nursing homes and community residential care facilities are required to send their weekly visitation report via DHEC's **Visitation Reporting Form** **no later than Monday, March 8, by 5 p.m.** If you experience technical difficulties (i.e., internet outage) while trying to submit the **Visitation Reporting Form** prior to Monday's deadline, you may call 803-365-3468, to provide the information over the phone to a DHEC staff member. This phone number is reserved for extenuating circumstances involving an internet outage prior to Monday's 5 p.m. deadline.

In order to ensure that we always have the most current information, DHEC strongly encourages facilities to submit one report per reporting week and to submit them between Sunday at 5 p.m. and Monday at 5 p.m. If you are filling out the survey on behalf of more than one licensed facility, then you are required to fill out a separate weekly report for each individual facility.

Facilities that fail to comply with the mandatory weekly reporting are subject to a civil penalty not to exceed $1,000 a day for each violation.

In situations of technical difficulty submitting the form, call 803-365-3468 prior to 5 p.m. on Monday and provide the weekly visitation information over the phone.

Please feel free to contact **acc-healthreg@dhec.sc.gov** with any questions at all.

Thank you!

Healthcare Quality
S.C. Dept. of Health & Environmental Control
Connect: www.scdhec.gov Facebook Twitter

Healthcare Quality | DHEC, 301 Gervais Street, Columbia, SC 29214

Wilson, Gloria

From: ACC-HealthReg <ACC-HealthReg@dhec.sc.gov>
Sent: Monday, March 8, 2021 1:36 PM
To: Gregory, Aramis L.
Subject: Reminder: Weekly Visitation Report Due Today by 5pm!

Healthy People. Healthy Communities.

Good Afternoon,

This email serves as a reminder that all nursing homes and community residential care facilities are required to send their weekly visitation report via DHEC's Visitation Reporting Form no later than today, Monday, March 8th, by 5:00 pm. If you experience technical difficulties (i.e., internet outage) while trying to submit the **Visitation Reporting Form** prior to today's deadline, you may call 803-365-3468, to provide the information over the phone to a DHEC staff member. This phone number is reserved for extenuating circumstances involving an internet outage prior to today's 5 p.m. deadline.

In order to ensure that we always have the most current information, **DHEC strongly encourages facilities to submit one report per reporting week and to submit them between Sunday at 5:00 pm and Monday at 5:00 pm.** If you are filling out the survey on behalf of more than one licensed facility, then **you are required to fill out a separate weekly report for each individual facility**.

Facilities that fail to comply with the mandatory weekly reporting are subject to a civil penalty not to exceed $1,000 a day for each violation.

In situations of technical difficulty submitting the form, call 803-365-3468 prior to 5 p.m. today and provide the weekly visitation information over the phone.

Please feel free to contact acc-healthreg@dhec.sc.gov with any questions at all.

Thank you!

Healthcare Quality
S.C. Dept. of Health & Environmental Control
Connect: www.scdhec.gov Facebook Twitter

Healthcare Quality | DHEC, 301 Gervais Street, Columbia, SC 29201

EXHIBIT 4

Facility's Confirmation of Receipt of Report

Wilson, Gloria

From: HealthRegComm <HealthRegComm@dhec.sc.gov>
Sent: Tuesday, March 30, 2021 2:44 PM
To: Gregory, Aramis L.
Subject: Fw: Weekly Visitation Report Received (Reference ID:16057)

Healthcare Quality
S.C. Dept. of Health & Environmental Control
Connect: www.scdhec.gov Facebook Twitter

From: HealthRegComm
Sent: Wednesday, March 10, 2021 4:11 PM
To: RIDGEVIEW1@MSN.COM <RIDGEVIEW1@MSN.COM>
Subject: Weekly Visitation Report Received (Reference ID:16057)

Thank you for submitting your weekly visitation report for RIDGEVIEW COMMUNITY CARE HOMES UNIT C (CRC-0561).

Submission Summary:

Facility Type: Community Residential Care (CRC) Facility
Facility Name: RIDGEVIEW COMMUNITY CARE HOMES UNIT C (CRC-0561)
Facility Contact Email: ridgeview1@msn.com
Allowing Visitation: Yes
Type of Visitation: ["Indoor visitation"]
Participation: 0
Reason(s) for not allowing visitation:

EXHIBIT 5

March 9, 2021
Notice of Violation and Civil Penalty

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

IN RE:
RIDGEVIEW COMMUNITY CARE HOMES UNIT C, CRC-0561
217 CHANDLER RD, GREER, SC
RIDGEVIEW COMMUNITY CARE HOMES INC, Licensee

NOTICE OF REPEAT VIOLATION AND CIVIL PENALTY

The South Carolina Department of Health and Environmental Control (Department) issued Public Health Order No. COVID-19-5 (attached hereto), pursuant to Section 44-1-140 of the South Carolina Code of Laws, on October 7, 2020, requiring all nursing homes and community residential care facilities (CRCFs) licensed by the Department to submit a weekly report, by no later than 5:00 pm each Monday, stating whether they are allowing visitation, and if not, providing the reason(s) for not allowing visitation. The weekly report must also include the number of residents who participated in a visit in the previous seven (7) days.

The Department notified RIDGEVIEW COMMUNITY CARE HOMES INC, of its first violation of Public Health Order No. COVID-19-5 by certified mail on OCTOBER 21, 2020.

The Department hereby notifies RIDGEVIEW COMMUNITY CARE HOMES INC, Licensee, that RIDGEVIEW COMMUNITY CARE HOMES UNIT C, License No. CRC-0561, violated Public Health Order No. COVID-19-5 a SECOND time by failing to submit a weekly report by the 5pm deadline of Monday, MARCH 8, 2021.

The Department hereby issues an additional civil penalty to RIDGEVIEW COMMUNITY CARE HOMES UNIT C in the amount of $350 for the aforementioned repeat violation, in accordance with Section 44-1-150(B) of the South Carolina Code of Laws. Section 44-1-150(B) provides for civil penalties not to exceed $1000.00 per day for each violation.

Payment of the additional $350 civil penalty is due within twenty (20) days of the date of this Notice of Repeat Violation and Civil Penalty. Instructions for payment are attached.

Failure to make timely payment of the civil penalty or further violation of Public Health Order No. COVID-19-5 may result in the Department taking further enforcement action.

Gwendolyn C. Thompson

Gwendolyn C. Thompson, Director
Healthcare Quality

03112021

Date

Attachments:
Public Health Order No. COVID-19-5
Instructions for Payment
Guide to Board Review

ACKNOWLEDGMENT OF REQUEST FOR FINAL REVIEW

TO: Ridgeview Community Care Homes, Inc., Permittee/Requestor

Ashley Biggers, Attorney for the Department

FROM: M. Denise Crawford, Clerk of the Board

RE: **Docket No. 21-RFR-29, Ridgeview Community Care Homes, Inc. – CRC-0561**
Issuance of Notice of Violation and Civil Penalty for violation of Public Health Order No. COVID-19-5 by failing to submit a weekly report by the 5:00 PM deadline of Monday, March 8, 2020.

DATE: March 30, 2021

A Request for Final Review of the above-referenced decision was filed on March 24, 2021. A copy of the request is attached. The Board of Health and Environmental Control will notify you by mail as to whether it will conduct a final review conference in this matter.

The Board has 60 days from the date of receipt of a Request for Final Review to conduct a final review conference. If a final review conference is scheduled, all parties will be given at least 10 calendar days' written notice of the conference.

Procedures for final review conferences and requesting further review are provided in S.C. Code Section 44-1-60. Additional information on procedures will be provided to you after the Board decides whether to conduct a final review conference in this matter.

The above information is provided as a courtesy; parties are responsible for complying with all applicable legal requirements.

CERTIFICATE OF SERVICE

I, M. Denise Crawford, Clerk of the South Carolina Board of Health and Environmental Control and an employee of the South Carolina Department of Health Environmental Control, hereby certify that I have this 30th day of March 2021, served the foregoing Acknowledgment of Request for Final Review and Notice of Procedures – Docket No. 21-RFR-29.

Via Electronic Delivery
Ridgeview Community Care Homes, Inc.
Attn: Trish Daugherty
Administrator
Email: ridgeview1@msn.com
217 Chandler Road
Greer, SC 29651

Via Electronic Delivery
Ashley Biggers, Esquire
Email biggerac@dhec.sc.gov
SCHEC – Office of General Counsel
2600 Bull Street
Columbia, SC 29201

M. Denise Crawford

March 30, 2021
Columbia, South Carolina

April 29, 2021

Via Electronic Mail and US Mail Certified 9214 8969 0099 9790 1419 4719 38
Ridgeview Community Care Homes, Inc.
Attn: Trish Daugherty
Administrator
Email: ridgeview1@msn.com
217 Chandler Road
Greer, SC 29651

Via Electronic Mail Delivery
Ashley Biggers, Esquire
Email biggerac@dhec.sc.gov
SCHEC – Office of General Counsel
2600 Bull Street
Columbia, SC 29201

RE: Docket No. 21-RFR-29, Ridgeview Community Care Homes, Inc. – CRC-0561
Issuance of Notice of Violation and Civil Penalty for violation of Public Health Order No. COVID-19-5 by failing to submit a weekly report by the 5:00 PM deadline of Monday, March 8, 2021

Ms. Daugherty and Counsel of Record:

The South Carolina Board of Health and Environmental Control will hold a Final Review Conference on Thursday, May 13, 2021, at 11:00 a.m. in the Board Room (3420), South Carolina Department of Health and Environmental Control, 2600 Bull Street, Columbia, South Carolina, on the above referenced matter.

The Board has approved the following outline of procedures for conferences:

- Swear all witnesses
- Presentation by parties
  - Order of presentation:
    - DHEC Staff - **10 minutes**
    - Requestor/Owner – Ridgeview Community Care Home, Inc. - **15 minutes**

    Rebuttal:
    - DHEC Staff - **15 minutes**
    - Requestor/Owner – Ridgeview Community Care Home, Inc. - **5 minutes**

- Parties may present evidence; rules of admissibility of evidence do not apply
- At any time during conference, officers conducting conference may request additional information and may question parties and anyone providing information
- Burden of proof is on Requestor(s)
- Presiding officer may impose time limits
- Conference is open to the public
- Officers may deliberate in closed session
- Officers may announce decision at conclusion of conference or may reserve consideration

If either party would like to have a transcript of the review conference, please notify (by e-mail or mail at the above address) the Clerk of Board by Monday, May 10, 2021 so that arrangements can be made to have a reporter present for the conference. The parties requesting a court reporter will be responsible for payment of the court reporter.

Sincerely,

M. Denise Crawford
Clerk of the Board

South Carolina Board of Health and Environmental Control
Final Review Conference
May 13, 2021

Final Review Conference - Docket No. 21-RFR-30, Ridgeview Community Care Homes, Inc. – CRC-0562, Issuance of Notice of Violation and Civil Penalty for violation of Public Health Order No. COVID-19-5 by failing to submit a weekly report by the 5:00 PM deadline of Monday, March 8, 2021

Trish Daugherty for Ridgeview Community Care Homes, Inc.
Ashley Biggers for SCDHEC

Table of Contents

Note: Page #s for this record are located on the bottom of the page.

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

IN RE:
RIDGEVIEW COMMUNITY CARE HOMES UNIT D, CRC-0562
217 CHANDLER RD, GREER, SC
RIDGEVIEW COMMUNITY CARE HOMES INC, Licensee

NOTICE OF REPEAT VIOLATION AND CIVIL PENALTY

The South Carolina Department of Health and Environmental Control (Department) issued Public Health Order No. COVID-19-5 (attached hereto), pursuant to Section 44-1-140 of the South Carolina Code of Laws, on October 7, 2020, requiring all nursing homes and community residential care facilities (CRCFs) licensed by the Department to submit a weekly report, by no later than 5:00 pm each Monday, stating whether they are allowing visitation, and if not, providing the reason(s) for not allowing visitation. The weekly report must also include the number of residents who participated in a visit in the previous seven (7) days.

The Department notified RIDGEVIEW COMMUNITY CARE HOMES INC, of its first violation of Public Health Order No. COVID-19-5 by certified mail on OCTOBER 21, 2020.

The Department hereby notifies RIDGEVIEW COMMUNITY CARE HOMES INC, Licensee, that RIDGEVIEW COMMUNITY CARE HOMES UNIT D, License No. CRC-0562, violated Public Health Order No. COVID-19-5 a SECOND time by failing to submit a weekly report by the 5pm deadline of Monday, MARCH 1, 2021.

The Department hereby issues an additional civil penalty to RIDGEVIEW COMMUNITY CARE HOMES UNIT D in the amount of $350 for the aforementioned repeat violation, in accordance with Section 44-1-150(B) of the South Carolina Code of Laws. Section 44-1-150(B) provides for civil penalties not to exceed $1000.00 per day for each violation.

Payment of the additional $350 civil penalty is due within twenty (20) days of the date of this Notice of Repeat Violation and Civil Penalty. Instructions for payment are attached.

Failure to make timely payment of the civil penalty or further violation of Public Health Order No. COVID-19-5 may result in the Department taking further enforcement action.

Gwendolyn C. Thompson

03092021

Gwendolyn C. Thompson, Director
Healthcare Quality

Date

Attachments:
Public Health Order No. COVID-19-5
Instructions for Payment
Guide to Board Review

Healthy People. Healthy Communities.

SOUTH CAROLINA
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

PUBLIC HEALTH ORDER
No. COVID-19-5

WHEREAS, on March 13, 2020, Governor Henry McMaster declared a State of Emergency based on a determination that Coronavirus Disease 2019 (COVID-19) posed an actual or imminent public health emergency for the State of South Carolina; and

WHEREAS, on March 13, 2020, the Governor also directed the South Carolina Department of Health and Environmental Control (DHEC) to utilize and exercise any and all emergency powers, as set forth in the Emergency Health Powers Act, codified as amended in Title 44, Chapter 4 of the South Carolina Code of Laws, deemed necessary to promptly and effectively address the current public health emergency. In accordance with Section 44-4-500 of the South Carolina Code of Laws, as amended, the Governor ordered that DHEC shall "use every available means to prevent the transmission of infectious disease and to ensure that all cases of infectious disease are subject to proper control and treatment;" and

WHEREAS, on March 13, 2020, the President of the United States declared the ongoing COVID-19 outbreak a pandemic of sufficient severity and magnitude to warrant an emergency declaration for all states, tribes, territories, and the District of Columbia, pursuant to Section 501(b) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. §§ 5121-5207 ("Stafford Act"); and

WHEREAS, on March 24, 2020, the Governor requested that the President of the United States declare that a major disaster exists in the State of South Carolina pursuant to Section 401 of the Stafford Act; and

WHEREAS, on March 27, 2020, the President of the United States granted the Governor's request and declared that a major disaster exists in the State of South Carolina and ordered federal assistance to supplement state, tribal, and local recovery efforts in the areas affected by the COVID-19 pandemic, with an effective date retroactive to January 20, 2020, and continuing; and

WHEREAS, since declaring an initial State of Emergency on March 13, 2020, the Governor has subsequently declared a State of Emergency and directed DHEC to utilize and exercise any and all emergency powers, as set forth in the Executive Health Powers Act, codified in Title 44, Chapter 4 of the South Carolina Code of Laws, deemed necessary to promptly and effectively address the current public health emergency, in Executive Order Nos. 2020-15, 2020-23, 2020-29, 2020-35, 2020-38, 2020-40, 2020-42, 2020-44, 2020-48, 2020-53, 2020-56, 2020-59, and 2020-62; and

WHEREAS, as of October 7, 2020, COVID-19 is widespread throughout the state and in all 46 counties, with 148,334 total confirmed cases statewide and 3,300 total confirmed deaths; and

WHEREAS, DHEC is invested with all the rights and charged with all the duties pertaining to organizations of like character and is the sole advisor of the State in all questions involving the protection of the public health within its limits (S.C. Code Ann.§ 44-1-110); and

WHEREAS, DHEC must enforce or prescribe preventive measures as may be needed to suppress or prevent the spread of these diseases by proper quarantine or other measures of prevention, as may be necessary to protect citizens of the State (S.C. Code Ann. § 44-1-80(A)); and

WHEREAS, DHEC is granted the authority to make, adopt, promulgate and enforce reasonable rules and regulations from time to time requiring and providing for the thorough investigation and study of the causes of all diseases, epidemic and otherwise, in the State, the means for the prevention of contagious disease and the publication and distribution of such information as may contribute to the preservation of the public health and the prevention of disease (S.C. Code Ann.§ 44-1-140(12)); and

WHEREAS, DHEC may also make separate orders and rules to meet any emergency not provided for by general rules and regulations, for the purpose of suppressing nuisances dangerous to the public health and communicable, contagious and infectious diseases and other danger to the public life and health (S.C. Code Ann.§ 44-1-140); and

WHEREAS, in addition to its authority provided by statute or as otherwise provided for by regulation, DHEC may issue separate orders to enforce the provisions of S.C. Regulation 61-20 for the purpose of suppressing nuisances, Communicable, Contagious and Infectious Diseases, and other dangers to public health (S.C. Code Ann. Regs. 61-20 § 14(A)); and

WHEREAS, all entities shall comply with DHEC directives and orders to protect the public health from the spread of Communicable and Infectious Diseases (S.C. Code Ann. Regs. 61-20 § 4(D)); and

WHEREAS, during a public health emergency, DHEC must use every available means to prevent the transmission of infectious disease and ensure that all cases of infectious disease are subject to proper control and treatment (S.C. Code Ann.§ 44-4-500); and

WHEREAS, the Bill of Rights for Residents of Long-Term Care Facilities requires the legal guardian, family members, and other relatives of each resident of a long-term care facility

be allowed immediate access to that resident, subject to the resident's right to deny access or withdraw consent to access at any time, and requires each resident, without unreasonable delay or restrictions, be allowed to associate and communicate privately with persons of the resident's choice (S.C. Code Ann. § 44-81-40(K)); and

WHEREAS, nursing homes and community residential care facilities are required to comply with the Bill of Rights for Residents of Long-Term Care Facilities (S.C. Code Ann. Regs. 61-17, § 1101; S.C. Code Ann. Regs. 61-84 § 1001), and

WHEREAS, nursing homes shall encourage visitation of residents by family and friends with minimum restrictions and shall post visiting hours in accordance with facility policies and procedures (S.C. Code Ann. Regs. § 1003.J), and

WHEREAS, South Carolina is engaged in an all-hands effort to both reduce the spread of COVID-19 and to ensure safety of all South Carolinians, including residents of nursing homes and community residential care facilities; and

WHEREAS, the COVID-19 pandemic has created a need for nursing homes and community residential care facilities to prevent the spread of disease among residents and staff, and

WHEREAS, nursing homes and community residential care facilities are required by South Carolina law and regulation to allow for access to residents; however, the current State of Emergency requires changes and limitations to normal visitation policies and procedures in order to ensure residents, which are members of a vulnerable population, are protected from exposure to COVID-19; and

WHEREAS, as the Acting Director of Public Health, I have reviewed the data regarding confirmed COVID-19 cases, reported exposures among the population in South Carolina, including cases and reported exposures in vulnerable populations including residents of nursing homes and community residential care facilities, and

WHEREAS, I have determined that it is necessary to gather and monitor information regarding access to visitation for residents in nursing homes and community residential care facilities in order to ensure the safety of residents and staff and appropriate and reasonable compliance with applicable laws and regulations.

NOW, THEREFORE, IT IS HEREBY ORDERED, pursuant to section 44-1-140 of the South Carolina Code of Laws, that all nursing homes and community residential care facilities licensed by DHEC are required to submit a weekly report stating whether they are allowing

visitation, and if not, providing the reason(s) for not allowing visitation. Facilities must also report the number of residents who participated in a visit in the previous seven (7) days.

Each licensed Facility must submit a separate report to DHEC.

Facilities must complete their weekly report no later than 5:00 PM each Monday by completing and submitting the form on DHEC's webpage, https://scdhec.gov/visitation.

Should any nursing home or community residential care facility face human resource or information technology challenges in completing any requirement of this Order, the facility should notify DHEC immediately by contacting ACC-HealthReg@dhec.sc.gov.

IT IS FURTHER ORDERED, pursuant to section 44-1-150 of the South Carolina Code of Laws, that any facility that violates this Order may be subject to a civil penalty not to exceed one thousand (1,000) dollars a day for each violation.

This Order is effective immediately and shall remain in effect unless otherwise modified, amended, or rescinded by subsequent order.

AND IT IS SO ORDERED.

L. Brannon Traxler, MD, MPH
Interim Director of Public Health

Date: 10/07/2020

Healthy People. Healthy Communities.

INSTRUCTIONS FOR PAYMENT

1. Make certified check or money order payable to S.C. Department of Health and Environmental Control and ensure to include your Facility's Name and License Number

2. Send payment to the following address:

   Attention: Angie Smith, Interim Director
   Bureau of Facilities Oversight/Healthcare Quality
   S.C. Department of Health and Environmental Control
   2600 Bull Street
   Columbia, SC 29201

South Carolina Board of Health and Environmental Control

Guide to Board Review

Pursuant to S.C. Code Ann. § 44-1-60

The decision of the South Carolina Department of Health and Environmental Control (Department) becomes the final agency decision fifteen (15) calendar days after notice of the decision has been mailed to the applicant, permittee, licensee and affected persons who have requested in writing to be notified, unless a written request for final review accompanied by a filing fee in the amount of $100 is filed with Department by the applicant, permittee, licensee or affected person.

Applicants, permittees, licensees, and affected parties are encouraged to engage in mediation or settlement discussions during the final review process.

If the Board declines in writing to schedule a final review conference, the Department's decision becomes the final agency decision and an applicant, permittee, licensee, or affected person may request a contested case hearing before the Administrative Law Court within thirty (30) calendar days after notice is mailed that the Board declined to hold a final review conference. In matters pertaining to decisions under the South Carolina Mining Act, appeals should be made to the South Carolina Mining Council.

I. Filing of Request for Final Review

1. A written Request for Final Review (RFR) and the required filing fee of one hundred dollars ($100) must be received by Clerk of the Board within fifteen (15) calendar days after notice of the staff decision has been mailed to the applicant, permittee, licensee, or affected persons. If the 15th day occurs on a weekend or State holiday, the RFR must be received by the Clerk on the next working day. RFRs will not be accepted after 5:00 p.m.
2. RFRs shall be in writing and should include, at a minimum, the following information:
   - The grounds for amending, modifying, or rescinding the staff decision;
   - a statement of any significant issues or factors the Board should consider in deciding how to handle the matter;
   - the relief requested;
   - a copy of the decision for which review is requested; and
   - mailing address, email address, if applicable, and phone number(s) at which the requestor can be contacted.
3. RFRs should be filed in person or by mail at the following address:
   South Carolina Board of Health and Environmental Control
   Attention: Clerk of the Board
   2600 Bull Street
   Columbia, South Carolina 29201
   Alternatively, RFR's may be filed with the Clerk by facsimile (803-898-3393) or by electronic mail (boardclerk@dhec.sc.gov).
4. The filing fee may be paid by cash, check or credit card and must be received by the 15th day.
5. If there is any perceived discrepancy in compliance with this RFR filing procedure, the Clerk should consult with the Chairman or, if the Chairman is unavailable, the Vice-Chairman. The Chairman or the Vice-Chairman will determine whether the RFR is timely and properly filed and direct the Clerk to (1) process the RFR for consideration by the Board or (2) return the RFR and filing fee to the requestor with a cover letter explaining why the RFR was not timely or properly filed. Processing an RFR for consideration by the Board shall not be interpreted as a waiver of any claim or defense by the agency in subsequent proceedings concerning the RFR.
6. If the RFR will be processed for Board consideration, the Clerk will send an Acknowledgement of RFR to the Requestor and the applicant, permittee, or licensee, if other than the Requestor. All personal and financial identifying information will be redacted from the RFR and accompanying documentation before the RFR is released to the Board, Department staff or the public.
7. If an RFR pertains to an emergency order, the Clerk will, upon receipt, immediately provide a copy of the RFR to all Board members. The Chairman, or in his or her absence, the Vice-Chairman shall based on the circumstances, decide whether to refer the RFR to the RFR Committee for expedited review or to decline in writing to schedule a Final Review Conference. If the Chairman or Vice-Chairman determines review by the RFR Committee is appropriate, the Clerk will forward a copy of the RFR to Department staff and Office of General Counsel. A Department response and RFR Committee review will be provided on an expedited schedule defined by the Chairman or Vice-Chairman.
8. The Clerk will email the RFR to staff and Office of General Counsel and request a Department Response within eight (8) working days. Upon receipt of the Department Response, the Clerk will forward the RFR and Department Response to all Board members for review, and all Board members will confirm receipt of the RFR to the Clerk by email. If a Board member does not confirm receipt of the RFR within a twenty-four (24) hour period, the Clerk will contact the Board member and confirm receipt. If a Board member believes the RFR should be considered by the RFR Committee, he or she will

respond to the Clerk's email within forty-eight (48) hours and will request further review. If no Board member requests further review of the RFR within the forty-eight (48) hour period, the Clerk will send a letter by certified mail to the Requestor, with copy by regular mail to the applicant, permittee, or licensee, if not the Requestor, stating the Board will not hold a Final Review Conference. Contested case guidance will be included within the letter.
NOTE: If the time periods described above end on a weekend or State holiday, the time is automatically extended to 5:00 p.m. on the next business day.

9. If the RFR is to be considered by the RFR Committee, the Clerk will notify the Presiding Member of the RFR Committee and the Chairman that further review is requested by the Board. RFR Committee meetings are open to the public and will be public noticed at least 24 hours in advance.
10. Following RFR Committee or Board consideration of the RFR, if it is determined no Conference will be held, the Clerk will send a letter by certified mail to the Requestor, with copy by regular mail to the applicant, permittee, or licensee, if not the Requestor, stating the Board will not hold a Conference. Contested case guidance will be included within the letter.

II. Final Review Conference Scheduling

1. If a Conference will be held, the Clerk will send a letter by certified mail to the Requestor, with copy by regular mail to the applicant, permittee, or licensee, if not the Requestor, informing the Requestor of the determination.
2. The Clerk will request Department staff provide the Administrative Record.
3. The Clerk will send Notice of Final Review Conference to the parties at least ten (10) days before the Conference. The Conference will be publically noticed and should:
   - include the place, date and time of the Conference;
   - state the presentation times allowed in the Conference;
   - state evidence may be presented at the Conference;
   - if the conference will be held by committee, include a copy of the Chairman's order appointing the committee; and
   - inform the Requestor of his or her right to request a transcript of the proceedings of the Conference prepared at Requestor's expense.
4. If a party requests a transcript of the proceedings of the Conference and agrees to pay all related costs in writing, including costs for the transcript, the Clerk will schedule a court reporter for the Conference.

III. Final Review Conference and Decision

1. The order of presentation in the Conference will, subject to the presiding officer's discretion, be as follows:
   - Department staff will provide an overview of the staff decision and the applicable law to include [10 minutes]:
     - Type of decision (permit, enforcement, etc.) and description of the program.
     - Parties
     - Description of facility/site
     - Applicable statutes and regulations
     - Decision and materials relied upon in the administrative record to support the staff decision.
   - Requestor(s) will state the reasons for protesting the staff decision and may provide evidence to support amending, modifying, or rescinding the staff decision. [15 minutes] *NOTE: The burden of proof is on the Requestor(s)*
   - Rebuttal by Department staff [15 minutes]
   - Rebuttal by Requestor(s) [10 minutes]

   Note: Times noted in brackets are for information only and are superseded by times stated in the Notice of Final Review Conference or by the presiding officer.
2. Parties may present evidence during the conference; however, the rules of evidence do not apply.
3. At any time during the conference, the officers conducting the Conference may request additional information and may question the Requestor, the staff, and anyone else providing information at the Conference.
4. The presiding officer, in his or her sole discretion, may allow additional time for presentations and may impose time limits on the Conference.
5. All Conferences are open to the public.
6. The officers may deliberate in closed session.
7. The officers may announce the decision at the conclusion of the Conference or it may be reserved for consideration.
8. The Clerk will mail the written final agency decision (FAD) to parties within 30 days after the Conference. The written decision must explain the basis for the decision and inform the parties of their right to request a contested case hearing before the Administrative Law Court or in matters pertaining to decisions under the South Carolina Mining Act, to request a hearing before the South Carolina Mining Council.. The FAD will be sent by certified mail, return receipt requested.
9. Communications may also be sent by electronic mail, in addition to the forms stated herein, when electronic mail addresses are provided to the Clerk.

The above information is provided as a courtesy; parties are responsible for complying with all applicable legal requirements.

Ridgeview Community Care Homes, Inc.

217 Chandler Rd ~ Greer, SC ~ 29651

March 23, 2021

South Carolina Board of Health and Environmental Control
Attention: Clerk of Court
2600 Bull Street
Columbia, SC 29201

RE: Written Request for Final Review, CRC-0562 Unit D

Dear Board Members,

We are submitting this written request for final review of the decision to impose a civil penalty of $350 on our facility CRC-0562, for submitting the weekly visitation report late. The payment of $100 was made over the phone.

The grounds for amending, modifying, or rescinding the staff decision:

After months of receiving Monday email reminders from DHEC to submit the weekly visitation reports, our facility did not receive email reminders from DHEC on Monday, March 8, to submit the weekly reports. This reminder email has become an integral part of our process to submit timely reports, and on March 8th we did not receive this reminder. Also, during this pandemic quarantine it is a financial hardship and unnecessary to impose a civil penalty for a report that was only 2 days late and did not put anyone in danger.

Significant issues the Board should consider in deciding how to handle the matter:

The weekly visitation report WAS FILED on Wednesday of that week, please see attached email confirmation.

I was working on financial paperwork for our facility's tax return. I do not have anyone else in my office currently to train to submit the reports because there is no other administrative staff with online access right now.

Ridgeview Community Care Homes is made up of 4 licensed buildings so for us this second penalty of $350 is a total penalty of $1,400, which is a tremendous financial hardship during this difficult time.

Please consider the many difficulties we have dealt with due to the COVID-19 pandemic. Financial difficulties such as reduced income due to inability to fill beds during quarantine, increased payroll expenses due to paying staff bonuses for continued service during the pandemic, increased food expenses due to ordering online to reduce staff exposure shopping for food items and increased recreational activity expenses for extra supplies and snacks ordered online to provide additional

activities for our residents during quarantine to help improve their mental status. We can not survive as a business with negative income. Additional expenses such as monetary penalties would be a financial hardship for us.

After last year's pandemic, filled with fear of illness and death, it is unnecessary for the Department to impose monetary penalties upon businesses that are caring for the most vulnerable population in our state. It has been challenging for our residents and staff to say the very least, a year full of new regulations, limited family visits, and no resident outings. Please take this into consideration and not add another financial burden to our business, or to any other facilities throughout the state who are suffering the same way. Our facility has not had any COVID-19 outbreaks among our residents or staff, we have followed the regulations and have received our vaccinations. Our residents' wellbeing comes first and at no time were they in a compromised position due to our report being submitted 2 days late so instead of imposing financial hardship on facilities, please show your support to the facilities that care for the ones that are most at risk and have been unable to have normal visits and outings with their loved ones.

The relief requested: We would like the civil penalty to be removed.

A copy of the decision for which the review is requested: Copies are attached.

Mailing address, email address and phone number the requestor can be contacted:

Trish Daugherty, Administrator
Ridgeview Community Care Homes
217 Chandler Road
Greer, SC 29651
ridgeview1@msn.com
Phone (864)877-8599 Fax (864)877-8704

We sincerely appreciate the opportunity to ask for a review of the decision to impose a civil penalty on our facility. If you have any questions please contact me at (864)877-8599.

Thank you,

Trish Daugherty

Trish Daugherty
Administrator
Authorized digital signature

Lee Daugherty

Lee Daugherty
Assistant Administrator
Authorized digital signature

The following copies are enclosed below:

- Email confirmation that the weekly visitation reports were filed.
- Copy of the original notice of violation and civil penalty for CRC-0562.

HealthRegComm <HealthRegComm@dhec.sc.gov>
Wed 3/10/2021 4:11 PM
To: RIDGEVIEW1@MSN.COM

Thank you for submitting your weekly visitation report for RIDGEVIEW COMMUNITY CARE HOMES UNIT D (CRC-0562).

Submission Summary:

Facility Type: Community Residential Care (CRC) Facility
Facility Name: RIDGEVIEW COMMUNITY CARE HOMES UNIT D (CRC-0562)

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

IN RE:
RIDGEVIEW COMMUNITY CARE HOMES UNIT D, CRC-0562
217 CHANDLER RD, GREER, SC
RIDGEVIEW COMMUNITY CARE HOMES INC, Licensee

NOTICE OF REPEAT VIOLATION AND CIVIL PENALTY

The South Carolina Department of Health and Environmental Control (Department) issued Public Health Order No. COVID-19-5 (attached hereto), pursuant to Section 44-1-140 of the South Carolina Code of Laws, on October 7, 2020, requiring all nursing homes and community residential care facilities (CRCFs) licensed by the Department to submit a weekly report, by no later than 5:00 pm each Monday, stating whether they are allowing visitation, and if not, providing the reason(s) for not allowing visitation. The weekly report must also include the number of residents who participated in a visit in the previous seven (7) days.

The Department notified RIDGEVIEW COMMUNITY CARE HOMES INC, of its first violation of Public Health Order No. COVID-19-5 by certified mail on OCTOBER 21, 2020.

The Department hereby notifies RIDGEVIEW COMMUNITY CARE HOMES INC, Licensee, that RIDGEVIEW COMMUNITY CARE HOMES UNIT D, License No. CRC-0562, violated Public Health Order No. COVID-19-5 a SECOND time by failing to submit a weekly report by the 5pm deadline of Monday, MARCH 8, 2021.

The Department hereby issues an additional civil penalty to RIDGEVIEW COMMUNITY CARE HOMES UNIT D in the amount of $350 for the aforementioned repeat violation, in accordance with Section 44-1-150(B) of the South Carolina Code of Laws. Section 44-1-150(B) provides for civil penalties not to exceed $1000.00 per day for each violation.

Payment of the additional $350 civil penalty is due within twenty (20) days of the date of this Notice of Repeat Violation and Civil Penalty. Instructions for payment are attached.

Failure to make timely payment of the civil penalty or further violation of Public Health Order No. COVID-19-5 may result in the Department taking further enforcement action.

Gwendolyn C. Thompson

03112021

Gwendolyn C. Thompson, Director
Healthcare Quality

Date

Attachments:
Public Health Order No. COVID-19-5
Instructions for Payment
Guide to Board Review

BEFORE THE BOARD OF HEALTH AND ENVIRONMENTAL CONTROL
STAFF RESPONSE TO REQUEST FOR FINAL REVIEW
Docket No. 21-RFR-30

Requestor: **Ridgeview Community Care Homes, Inc. (Licensee)**
Ridgeview Community Care Homes Unit D, License No. CRC-0562 (Ridgeview or Facility)
Re: **Notice of Repeat Violation and Civil Penalty**

Overview: This Request for Final Review (RFR) concerns a $350 civil monetary penalty imposed for a violation of Public Health Order No. COVID-19-5 (PHO) for failure to submit a mandatory weekly report on visitation status at the Facility. The Facility requests the violation be reviewed and removed. Staff requests the Board uphold the decision, which was issued in accordance with terms of the PHO and applicable statutory requirements.

I. Summary

Ridgeview Community Care Homes Unit-D is a licensed Community Residential Care Facility (CRCF) located in Greer, South Carolina, licensed for eleven (11) beds.

On March 13, 2020, Governor Henry McMaster declared a State of Emergency based on a determination that Coronavirus Disease 2019 (COVID-19) posed an actual or imminent public health emergency for the State of South Carolina.

On October 7, 2020, the South Carolina Department of Health and Environmental Control (DHEC or Department) issued the attached PHO, pursuant to section 44-1-140 of the South Carolina Code of Laws, requiring all licensed nursing homes and CRCFs to submit a weekly report stating whether they are allowing visitation, and if not, providing the reason(s) for not allowing visitation. *See* Exhibit 1. Facilities must also include in the weekly report the number of residents who participated in a visit in the previous seven (7) days. Facilities must submit their weekly report to DHEC no later than 5:00 PM each Monday by completing and submitting the form on the DHEC's webpage (https://scdhec.gov/visitation). The PHO further provides, pursuant to Section 44-1-150, that any facility violating the Order may be subject to a civil penalty not to exceed one thousand ($1,000) dollars a day for each violation.

DHEC sent Ridgeview Community Care Homes Unit-D, and other licensed CRCFs and nursing homes, notice of the PHO by email on October 8, 2020. *See* Exhibit 2. DHEC sent additional email reminders to the Facility and other licensed facilities following the initial notice, including three reminder emails on October 12, 2020, the first day of required reporting, and two reminder emails a week prior to the reporting deadline in subsequent weeks. The reminder emails are sent on Fridays and Mondays prior to the 5:00 PM Monday reporting deadline each week. *See* Exhibit 3 (reminder emails sent on March 5, 2021, and March 8, 2021).

For the week beginning March 1, 2021, the Department did not receive a weekly report, which was due March 8, 2021, from Ridgeview Community Care Homes Unit-D until March 10, 2021, at 4:11 PM. *See* Exhibit 4. The Department notified the Facility that it had violated the PHO by

failing to submit a weekly report by the 5PM deadline of Monday, March 8, 2021. *See* Exhibit 5. This was Ridgeway's second cited violation of the PHO reporting requirement. Therefore, the Department issued a penalty in the amount of $350 for the aforementioned violation, in accordance with Section 44-1-150(b) of the South Carolina Code of Laws. *Id.* Ridgeview Community Care Homes Unit-D, filed its RFR, requesting waiver of the penalty, on March 22, 2021.

II. Relevant Law

DHEC is vested with all the rights and charged with all the duties pertaining to organizations of like character and is the sole advisor of the State in all questions involving the protection of the public health within its limits. S.C. Code Ann. § 44-1-110. DHEC is granted the authority to make, adopt, promulgate and enforce reasonable rules and regulations from time to time requiring and providing for the thorough investigation and study of the causes of all diseases, epidemic and otherwise, in the State, the means for the prevention of contagious disease and the public and distribution of such information as may contribute to the preservation of the public health and the prevention of disease. S.C. Code Ann. § 44-1-140(12). During a public health emergency, DHEC must use every available means to prevent the transmission of infectious disease and ensure that all cases of infectious disease are subject to proper control and treatment. S.C. Code Ann. § 44-4-500. All entities shall comply with DHEC directives and orders to protect the public health from the spread of communicable and infectious diseases. S.C. Code Ann. Regs. 61-20 § 4(D).

The Bill of Rights for Residents of Long-Term Care Facilities requires the legal guardian, family members, and other relatives of each resident of a long-term care facility be allowed immediately access to that resident, subject to the resident's right to deny access or withdraw consent to access at any time, and requires each resident, without unreasonable delay or restrictions, be allowed to associate and communicate privately with persons of the residents' choice. S.C. Code Ann. § 44-81-40(K). Nursing homes and community residential care facilities are required to comply with the Bill of Rights for Residents of Long-Term Care Facilities. S.C. Code Ann. Regs. 61-17 § 1101; S.C. Code Ann. Regs 61-84 § 1001.

DHEC may make separate orders and rules to meet any emergency not provided for by general rules and regulations, for the purpose of suppressing nuisances dangerous to the public health and communicable, contagious and infectious diseases and other danger to the public life and health. S.C. Code Ann. § 44-1-140. A person who after notice violates an order of the department issued pursuant to Section 44-1-140 is subject to a civil penalty not to exceed one thousand dollars a day for each violation. S.C. Code Ann. § 44-1-150(b).

III. Response to Request for Review

The Facility does not dispute the Department's finding that it violated the PHO by failing to submit a weekly report by the deadline of 5:00 PM on March 8, 2021, for the week that began on March 1, 2021. Rather, the Facility requests the fine of $350 be waived because, "after months of receiving Monday email reminders from DHEC to submit the weekly visitation reports, our facility did not receive email reminders from DHEC on Monday, March 8th to submit the weekly reports. This reminder email has become an integral part of our process to submit timely reports, and on March 8th we did not receive this reminder. Also, during this pandemic quarantine it is a financial

hardship and unnecessary to impose a civil penalty for a report that was only two days late and did not put anyone in danger."

Staff respectfully requests the Board uphold the imposed $350 fine. The Department provided ample and repeated notices to the Facility of the PHO's reporting requirement and the 5:00 PM, March 8, 2021, reporting deadline, including email reminders on Friday, March 5, and Monday March 8, 2021. *See* Exhibit 3. Ridgeview Community Care Homes Unit-D is one of 499 community residential care facilities subject to the March 8, 2021, PHO reporting deadline, and one of fourteen that failed to submit a timely report by that week's deadline.[1] The Department is tracking compliance with the reporting requirement for hundreds of facilities and is treating all facilities subject to the PHO equally in terms of enforcement. The Department considered the Facility's compliance history with the reporting requirements when determining the monetary penalty amount. As with other similarly situated facilities that committed a second violation of the PHO for the week in question, Ridgeview Community Care Homes Unit-D was fined $350 – less than the maximum possible fine of $1,000 per violation. For these reasons, staff respectfully requests the Board uphold the issued fine.

IV. Requested Action

For the foregoing reasons, staff requests that the Board decline to conduct a final review conference and uphold the monetary penalty for violation of the PHO.

Respectfully submitted:

Angie Smith

Angie Smith, Interim Director
Bureau of Facilities Oversight
Director, Community Oversight Care Division
Healthcare Quality

Ashley Biggers

Ashley Biggers, Esq.
Chief Counsel for Healthcare Quality
Office of General Counsel

March 2021

Exhibit 1 – October 7, 2020, PHO
Exhibit 2 – October 8, 2020, Email Notice of PHO
Exhibit 3 – March 5 and March 8, 2021, Email Reminder of March 8, 2021, Reporting Deadline
Exhibit 4 – Confirmation of Receipt of Report
Exhibit 5 – March 9, 2021, Notice of Violation and Civil Penalty

[1] Of the 499 community residential care facilities subject to the PHO reporting requirement on March 8, 2021, only fourteen failed to submit a weekly report and were sent a notice of violation and civil penalty

EXHIBIT 1

October 7, 2020
Public Health Order (PHO)

SOUTH CAROLINA
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

PUBLIC HEALTH ORDER
No. COVID-19-5

WHEREAS, on March 13, 2020, Governor Henry McMaster declared a State of Emergency based on a determination that Coronavirus Disease 2019 (COVID-19) posed an actual or imminent public health emergency for the State of South Carolina; and

WHEREAS, on March 13, 2020, the Governor also directed the South Carolina Department of Health and Environmental Control (DHEC) to utilize and exercise any and all emergency powers, as set forth in the Emergency Health Powers Act, codified as amended in Title 44, Chapter 4 of the South Carolina Code of Laws, deemed necessary to promptly and effectively address the current public health emergency. In accordance with Section 44-4-500 of the South Carolina Code of Laws, as amended, the Governor ordered that DHEC shall "use every available means to prevent the transmission of infectious disease and to ensure that all cases of infectious disease are subject to proper control and treatment;" and

WHEREAS, on March 13, 2020, the President of the United States declared the ongoing COVID-19 outbreak a pandemic of sufficient severity and magnitude to warrant an emergency declaration for all states, tribes, territories, and the District of Columbia, pursuant to Section 501(b) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. §§ 5121-5207 ("Stafford Act"); and

WHEREAS, on March 24, 2020, the Governor requested that the President of the United States declare that a major disaster exists in the State of South Carolina pursuant to Section 401 of the Stafford Act; and

WHEREAS, on March 27, 2020, the President of the United States granted the Governor's request and declared that a major disaster exists in the State of South Carolina and ordered federal assistance to supplement state, tribal, and local recovery efforts in the areas affected by the COVID-19 pandemic, with an effective date retroactive to January 20, 2020, and continuing; and

WHEREAS, since declaring an initial State of Emergency on March 13, 2020, the Governor has subsequently declared a State of Emergency and directed DHEC to utilize and exercise any and all emergency powers, as set forth in the Executive Health Powers Act, codified in Title 44, Chapter 4 of the South Carolina Code of Laws, deemed necessary to promptly and effectively address the current public health emergency, in Executive Order Nos. 2020-15, 2020-23, 2020-29, 2020-35, 2020-38, 2020-40, 2020-42, 2020-44, 2020-48, 2020-53, 2020-56, 2020-59, and 2020-62; and

WHEREAS, as of October 7, 2020, COVID-19 is widespread throughout the state and in all 46 counties, with 148,334 total confirmed cases statewide and 3,300 total confirmed deaths; and

WHEREAS, DHEC is invested with all the rights and charged with all the duties pertaining to organizations of like character and is the sole advisor of the State in all questions involving the protection of the public health within its limits (S.C. Code Ann.§ 44-1-110); and

WHEREAS, DHEC must enforce or prescribe preventive measures as may be needed to suppress or prevent the spread of these diseases by proper quarantine or other measures of prevention, as may be necessary to protect citizens of the State (S.C. Code Ann. § 44-1-80(A)); and

WHEREAS, DHEC is granted the authority to make, adopt, promulgate and enforce reasonable rules and regulations from time to time requiring and providing for the thorough investigation and study of the causes of all diseases, epidemic and otherwise, in the State, the means for the prevention of contagious disease and the publication and distribution of such information as may contribute to the preservation of the public health and the prevention of disease (S.C. Code Ann.§ 44-1-140(12)); and

WHEREAS, DHEC may also make separate orders and rules to meet any emergency not provided for by general rules and regulations, for the purpose of suppressing nuisances dangerous to the public health and communicable, contagious and infectious diseases and other danger to the public life and health (S.C. Code Ann.§ 44-1-140); and

WHEREAS, in addition to its authority provided by statute or as otherwise provided for by regulation, DHEC may issue separate orders to enforce the provisions of S.C. Regulation 61-20 for the purpose of suppressing nuisances, Communicable, Contagious and Infectious Diseases, and other dangers to public health (S.C. Code Ann. Regs. 61-20 § 14(A)); and

WHEREAS, all entities shall comply with DHEC directives and orders to protect the public health from the spread of Communicable and Infectious Diseases (S.C. Code Ann. Regs. 61-20 § 4(D)); and

WHEREAS, during a public health emergency, DHEC must use every available means to prevent the transmission of infectious disease and ensure that all cases of infectious disease are subject to proper control and treatment (S.C. Code Ann.§ 44-4-500); and

WHEREAS, the Bill of Rights for Residents of Long-Term Care Facilities requires the legal guardian, family members, and other relatives of each resident of a long-term care facility

be allowed immediate access to that resident, subject to the resident's right to deny access or withdraw consent to access at any time, and requires each resident, without unreasonable delay or restrictions, be allowed to associate and communicate privately with persons of the resident's choice (S.C. Code Ann. § 44-81-40(K)); and

WHEREAS, nursing homes and community residential care facilities are required to comply with the Bill of Rights for Residents of Long-Term Care Facilities (S.C. Code Ann. Regs. 61-17, § 1101; S.C. Code Ann. Regs. 61-84 § 1001), and

WHEREAS, nursing homes shall encourage visitation of residents by family and friends with minimum restrictions and shall post visiting hours in accordance with facility policies and procedures (S.C. Code Ann. Regs. § 1003.J), and

WHEREAS, South Carolina is engaged in an all-hands effort to both reduce the spread of COVID-19 and to ensure safety of all South Carolinians, including residents of nursing homes and community residential care facilities; and

WHEREAS, the COVID-19 pandemic has created a need for nursing homes and community residential care facilities to prevent the spread of disease among residents and staff, and

WHEREAS, nursing homes and community residential care facilities are required by South Carolina law and regulation to allow for access to residents; however, the current State of Emergency requires changes and limitations to normal visitation policies and procedures in order to ensure residents, which are members of a vulnerable population, are protected from exposure to COVID-19; and

WHEREAS, as the Acting Director of Public Health, I have reviewed the data regarding confirmed COVID-19 cases, reported exposures among the population in South Carolina, including cases and reported exposures in vulnerable populations including residents of nursing homes and community residential care facilities, and

WHEREAS, I have determined that it is necessary to gather and monitor information regarding access to visitation for residents in nursing homes and community residential care facilities in order to ensure the safety of residents and staff and appropriate and reasonable compliance with applicable laws and regulations.

NOW, THEREFORE, IT IS HEREBY ORDERED, pursuant to section 44-1-140 of the South Carolina Code of Laws, that all nursing homes and community residential care facilities licensed by DHEC are required to submit a weekly report stating whether they are allowing

visitation, and if not, providing the reason(s) for not allowing visitation. Facilities must also report the number of residents who participated in a visit in the previous seven (7) days.

Each licensed Facility must submit a separate report to DHEC.

Facilities must complete their weekly report no later than 5:00 PM each Monday by completing and submitting the form on DHEC's webpage, https://scdhec.gov/visitation.

Should any nursing home or community residential care facility face human resource or information technology challenges in completing any requirement of this Order, the facility should notify DHEC immediately by contacting ACC-HealthReg@dhec.sc.gov.

IT IS FURTHER ORDERED, pursuant to section 44-1-150 of the South Carolina Code of Laws, that any facility that violates this Order may be subject to a civil penalty not to exceed one thousand (1,000) dollars a day for each violation.

This Order is effective immediately and shall remain in effect unless otherwise modified, amended, or rescinded by subsequent order.

AND IT IS SO ORDERED.

L. Brannon Traxler, MD, MPH
Interim Director of Public Health

Date: 10/07/2020

EXHIBIT 2

October 8, 2020
Email Notice of PHO

Healthy People. Healthy Communities.

Good afternoon,

DHEC issued a Public Health Order on October 7, 2020 that is available to read here.

This Order requires all licensed nursing homes and community residential care facilities to submit a weekly report to DHEC regarding visitation.

Facilities are required to send their respective weekly reports by submitting a response in DHEC's Visitation Reporting Form. The first weekly report is due on this **upcoming Monday, October 12, 2020, by 5:00 pm.**

If you are filling out the survey on behalf of more than one licensed facility, then **you are required to fill out a separate weekly report for each individual facility**. Failure to comply with the mandatory weekly reporting to DHEC may result in a civil penalty not to exceed $1,000 a day for each violation.

Submit weekly reports via the Visitation Reporting Form.

Weekly reports are due each Monday by 5:00 pm.

The Visitation Reporting Form requires all licensed nursing homes and community residential care facilities to report whether they are allowing visitation and, if not, to provide the reason(s) for not allowing visitation; facilities allowing visitation must also report the number of residents who participated in a visit in the previous 7 days.

DHEC plans to publish updated visitation guidelines tomorrow, October 9, 2020, on both outdoor and indoor visitation.

DHEC's Visitation Reporting Form and relevant information will be available on our new Long-Term Care Facilities Visitation (COVID-19) page, which can also be reached by going directly to scdhec.gov/visitation. The forthcoming updated visitation guidance and other resources will be posted on this page.

We thank all licensed nursing homes and community residential care facilities for their cooperation, timely responses, and invaluable care of all residents, staff, and visitors.

Facilities can reach out to acc-healthreg@dhec.sc.gov with any questions at all.

Thank you,

Healthcare Quality
S.C. Dept. of Health & Environmental Control
Connect: www.scdhec.gov Facebook Twitter

EXHIBIT 3

Email Reminders-Reporting Deadline

March 5, 2021
March 8, 2021

Wilson, Gloria

From: ACC-HealthReg <ACC-HealthReg@dhec.sc.gov>
Sent: Friday, March 5, 2021 2:13 PM
To: Gregory, Aramis L.
Subject: Weekly Visitation Report Due Monday by 5 pm!

Healthy People. Healthy Communities.

Good Afternoon,

This email serves as a reminder that all nursing homes and community residential care facilities are required to send their weekly visitation report via DHEC's **Visitation Reporting Form** **no later than Monday, March 8, by 5 p.m.** If you experience technical difficulties (i.e., internet outage) while trying to submit the **Visitation Reporting Form** prior to Monday's deadline, you may call 803-365-3468, to provide the information over the phone to a DHEC staff member. This phone number is reserved for extenuating circumstances involving an internet outage prior to Monday's 5 p.m. deadline.

In order to ensure that we always have the most current information, DHEC strongly encourages facilities to submit one report per reporting week and to submit them between Sunday at 5 p.m. and Monday at 5 p.m. If you are filling out the survey on behalf of more than one licensed facility, then you are required to fill out a separate weekly report for each individual facility.

Facilities that fail to comply with the mandatory weekly reporting are subject to a civil penalty not to exceed $1,000 a day for each violation.

In situations of technical difficulty submitting the form, call 803-365-3468 prior to 5 p.m. on Monday and provide the weekly visitation information over the phone.

Please feel free to contact **acc-healthreg@dhec.sc.gov** with any questions at all.

Thank you!

Healthcare Quality
S.C. Dept. of Health & Environmental Control
Connect: www.scdhec.gov Facebook Twitter

Healthcare Quality | DHEC, 301 Gervais Street, Columbia, SC 29214

Wilson, Gloria

From: ACC-HealthReg <ACC-HealthReg@dhec.sc.gov>
Sent: Monday, March 8, 2021 1:36 PM
To: Gregory, Aramis L.
Subject: Reminder: Weekly Visitation Report Due Today by 5pm!

dhec
Healthy People. Healthy Communities.

Good Afternoon,

This email serves as a reminder that all nursing homes and community residential care facilities are required to send their weekly visitation report via DHEC's Visitation Reporting Form no later than today, Monday, March 8th, by 5:00 pm. If you experience technical difficulties (i.e., internet outage) while trying to submit the Visitation Reporting Form prior to today's deadline, you may call 803-365-3468, to provide the information over the phone to a DHEC staff member. This phone number is reserved for extenuating circumstances involving an internet outage prior to today's 5 p.m. deadline.

In order to ensure that we always have the most current information, **DHEC strongly encourages facilities to submit one report per reporting week and to submit them between Sunday at 5:00 pm and Monday at 5:00 pm.** If you are filling out the survey on behalf of more than one licensed facility, then **you are required to fill out a separate weekly report for each individual facility**.

Facilities that fail to comply with the mandatory weekly reporting are subject to a civil penalty not to exceed $1,000 a day for each violation.

In situations of technical difficulty submitting the form, call 803-365-3468 prior to 5 p.m. today and provide the weekly visitation information over the phone.

Please feel free to contact acc-healthreg@dhec.sc.gov with any questions at all.

Thank you!

Healthcare Quality
S.C. Dept. of Health & Environmental Control
Connect: www.scdhec.gov Facebook Twitter

Healthcare Quality | DHEC, 301 Gervais Street, Columbia, SC 29201

EXHIBIT 4

Facility's Confirmation of Receipt of Report

Wilson, Gloria

From: HealthRegComm <HealthRegComm@dhec.sc.gov>
Sent: Tuesday, March 30, 2021 2:44 PM
To: Gregory, Aramis L.
Subject: Fw: Weekly Visitation Report Received (Reference ID:16058)

Healthcare Quality
S.C. Dept. of Health & Environmental Control
Connect: www.scdhec.gov Facebook Twitter

From: HealthRegComm
Sent: Wednesday, March 10, 2021 4:11 PM
To: RIDGEVIEW1@MSN.COM <RIDGEVIEW1@MSN.COM>
Subject: Weekly Visitation Report Received (Reference ID:16058)

Thank you for submitting your weekly visitation report for RIDGEVIEW COMMUNITY CARE HOMES UNIT D (CRC-0562).

Submission Summary:

Facility Type: Community Residential Care (CRC) Facility
Facility Name: RIDGEVIEW COMMUNITY CARE HOMES UNIT D (CRC-0562)
Facility Contact Email: ridgeview1@msn.com
Allowing Visitation: Yes
Type of Visitation: ["Indoor visitation"]
Participation: 1
Reason(s) for not allowing visitation:

EXHIBIT 5

March 9, 2021
Notice of Violation and Civil Penalty

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

IN RE:
RIDGEVIEW COMMUNITY CARE HOMES UNIT D, CRC-0562
217 CHANDLER RD, GREER, SC
RIDGEVIEW COMMUNITY CARE HOMES INC, Licensee

NOTICE OF REPEAT VIOLATION AND CIVIL PENALTY

The South Carolina Department of Health and Environmental Control (Department) issued Public Health Order No. COVID-19-5 (attached hereto), pursuant to Section 44-1-140 of the South Carolina Code of Laws, on October 7, 2020, requiring all nursing homes and community residential care facilities (CRCFs) licensed by the Department to submit a weekly report, by no later than 5:00 pm each Monday, stating whether they are allowing visitation, and if not, providing the reason(s) for not allowing visitation. The weekly report must also include the number of residents who participated in a visit in the previous seven (7) days.

The Department notified RIDGEVIEW COMMUNITY CARE HOMES INC, of its first violation of Public Health Order No. COVID-19-5 by certified mail on OCTOBER 21, 2020.

The Department hereby notifies RIDGEVIEW COMMUNITY CARE HOMES INC, Licensee, that RIDGEVIEW COMMUNITY CARE HOMES UNIT D, License No. CRC-0562, violated Public Health Order No. COVID-19-5 a SECOND time by failing to submit a weekly report by the 5pm deadline of Monday, MARCH 8, 2021.

The Department hereby issues an additional civil penalty to RIDGEVIEW COMMUNITY CARE HOMES UNIT D in the amount of $350 for the aforementioned repeat violation, in accordance with Section 44-1-150(B) of the South Carolina Code of Laws. Section 44-1-150(B) provides for civil penalties not to exceed $1000.00 per day for each violation.

Payment of the additional $350 civil penalty is due within twenty (20) days of the date of this Notice of Repeat Violation and Civil Penalty. Instructions for payment are attached.

Failure to make timely payment of the civil penalty or further violation of Public Health Order No. COVID-19-5 may result in the Department taking further enforcement action.

Gwendolyn C. Thompson

03112021

Gwendolyn C. Thompson, Director
Healthcare Quality

Date

Attachments:
Public Health Order No. COVID-19-5
Instructions for Payment
Guide to Board Review

ACKNOWLEDGMENT OF REQUEST FOR FINAL REVIEW

TO: Ridgeview Community Care Homes, Inc., Permittee/Requestor

Ashley Biggers, Attorney for the Department

FROM: M. Denise Crawford, Clerk of the Board

RE: **Docket No. 21-RFR-30, Ridgeview Community Care Homes, Inc. – CRC-0562**
Issuance of Notice of Violation and Civil Penalty for violation of Public Health Order No. COVID-19-5 by failing to submit a weekly report by the 5:00 PM deadline of Monday, March 8, 2020.

DATE: March 30, 2021

A Request for Final Review of the above-referenced decision was filed on March 24, 2021. A copy of the request is attached. The Board of Health and Environmental Control will notify you by mail as to whether it will conduct a final review conference in this matter.

The Board has 60 days from the date of receipt of a Request for Final Review to conduct a final review conference. If a final review conference is scheduled, all parties will be given at least 10 calendar days' written notice of the conference.

Procedures for final review conferences and requesting further review are provided in S.C. Code Section 44-1-60. Additional information on procedures will be provided to you after the Board decides whether to conduct a final review conference in this matter.

The above information is provided as a courtesy; parties are responsible for complying with all applicable legal requirements.

CERTIFICATE OF SERVICE

I, M. Denise Crawford, Clerk of the South Carolina Board of Health and Environmental Control and an employee of the South Carolina Department of Health Environmental Control, hereby certify that I have this 30th day of March 2021, served the foregoing Acknowledgment of Request for Final Review and Notice of Procedures – Docket No. 21-RFR-30.

Via Electronic Delivery
Ridgeview Community Care Homes, Inc.
Attn: Trish Daugherty
Administrator
Email: ridgeview1@msn.com
217 Chandler Road
Greer, SC 29651

Via Electronic Delivery
Ashley Biggers, Esquire
Email biggerac@dhec.sc.gov
SCHEC – Office of General Counsel
2600 Bull Street
Columbia, SC 29201

M. Denise Crawford

March 30, 2021
Columbia, South Carolina

April 29, 2021

Via Electronic Mail and US Mail Certified 9214 8969 0099 9790 1419 4722 49
Ridgeview Community Care Homes, Inc.
Attn: Trish Daugherty
Administrator
Email: ridgeview1@msn.com
217 Chandler Road
Greer, SC 29651

Via Electronic Mail Delivery
Ashley Biggers, Esquire
Email biggerac@dhec.sc.gov
SCHEC – Office of General Counsel
2600 Bull Street
Columbia, SC 29201

RE: Docket No. 21-RFR-30, Ridgeview Community Care Homes, Inc. – CRC-0562
Issuance of Notice of Violation and Civil Penalty for violation of Public Health Order No. COVID-19-5 by failing to submit a weekly report by the 5:00 PM deadline of Monday, March 8, 2021

Ms. Daugherty and Counsel of Record:

The South Carolina Board of Health and Environmental Control will hold a Final Review Conference on Thursday, May 13, 2021, at 11:00 a.m. in the Board Room (3420), South Carolina Department of Health and Environmental Control, 2600 Bull Street, Columbia, South Carolina, on the above referenced matter.

The Board has approved the following outline of procedures for conferences:

- Swear all witnesses
- Presentation by parties
  - Order of presentation:
    - DHEC Staff - **10 minutes**
    - Requestor/Owner – Ridgeview Community Care Home, Inc. - **15 minutes**

    Rebuttal:
    - DHEC Staff - **15 minutes**
    - Requestor/Owner – Ridgeview Community Care Home, Inc. - **5 minutes**

- Parties may present evidence; rules of admissibility of evidence do not apply
- At any time during conference, officers conducting conference may request additional information and may question parties and anyone providing information
- Burden of proof is on Requestor(s)
- Presiding officer may impose time limits
- Conference is open to the public
- Officers may deliberate in closed session
- Officers may announce decision at conclusion of conference or may reserve consideration

If either party would like to have a transcript of the review conference, please notify (by e-mail or mail at the above address) the Clerk of Board by Monday, May 10, 2021 so that arrangements can be made to have a reporter present for the conference. The parties requesting a court reporter will be responsible for payment of the court reporter.

Sincerely,

M. Denise Crawford
Clerk of the Board