Date: February 8, 2024

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

From: Healthcare Quality

Re: Public Hearing for Notice of Final Regulation Amending R.61-16, *Minimum Standards for Licensing Hospitals and Institutional General Infirmaries*, Document No. 5265

I. Introduction

Healthcare Quality proposes the attached Notice of Final Regulation amending R.61-16, *Minimum Standards for Licensing Hospitals and Institutional General Infirmaries*. Legal authority resides in S.C. Code Sections 44-7-110 through 44-7-394, which requires the Department of Health and Environmental Control ("Department") to establish and enforce minimum standards for the licensure, maintenance, and operation of hospitals and institutional general infirmaries to ensure safe and appropriate treatment of persons served in this state. The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments.

II. Facts

1. Pursuant to S.C. Code Sections 44-7-250 and -260(A)(1), the Department establishes and enforces minimum standards for the licensure, maintenance, and operation of hospitals to ensure the safe and appropriate treatment of persons served in this state. The Department proposes amending R.61-16, *Minimum Standards for Licensing Hospitals and Institutional General Infirmaries*, to ensure alignment with current state laws and to update and revise definitions, license requirements and fees, staff and training, reporting, disaster management, accommodation for patients, patient care and services, design and construction, fire protection, prevention, and life safety, and policies and procedures.

2. The Department had a Notice of Drafting published in the July 28, 2023 *State Register*. This notice supersedes the Notice of Drafting that was published in *State Register* Volume 47, Issue 3 on March 24, 2023. The Department received public comments from 27 parties by August 28, 2023, close of the public comment period.

3. Department staff conducted stakeholder meetings on August 22, 2023, and October 25, 2023, to discuss the proposed amendments and/or to receive comments on the proposed amendments.

4. Appropriate Department staff conducted an internal review of the proposed amendments on October 9, 2023.

5. Upon receiving approval during the November 9, 2023 Board meeting, the Bureau had a Notice of Proposed Regulation published in the November 24, 2023 *State Register*. The Department received public comments from seven parties by December 27, 2023 close of the public comment period. Attachment B presents a summary of these public comments received and Department responses.

6. Department staff conducted another set of stakeholder meetings on December 15, 2023, and February 6, 2024, to discuss the proposed amendments and/or to receive comments on the proposed amendments.

7. After consideration of all timely received comments, staff has made substantive changes to the regulatory text of the Notice of Proposed Regulation approved by the Board in the November 9, 2023,

Board meeting and published in the November 24, 2023 *State Register*. Descriptions of the changes appear in Attachment B, Summary of Public Comments and Department Responses.

III. Request for Approval

Healthcare Quality respectfully requests the Board to find need and reasonableness of the attached proposed amendments of R.61-16, *Minimum Standards for Licensing Hospitals and Institutional General Infirmaries*, for submission to the General Assembly.

Gwendolyn C. Thompson

Charlene Bell

_____
Gwen C. Thompson
Deputy Director
Healthcare Quality

_____
Charlene Bell
Director, Hospital and Professional Services
Bureau of Healthcare Systems and Professionals
Healthcare Quality

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

ATTACHMENT A

STATE REGISTER NOTICE OF FINAL REGULATION
FOR R. 61-16, Minimum Standards for Licensing Hospitals and Institutional General Infirmaries

February 8, 2024

Document No. 5265
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Sections 44-7-110 through 44-7-394

61-16. Minimum Standards for Licensing Hospitals and Institutional General Infirmaries.

Synopsis:

Pursuant to S.C. Code Sections 44-7-250 and -260(A)(1), the Department of Health and Environmental Control ("Department") establishes and enforces minimum standards for the licensure, maintenance, and operation of hospitals to ensure the safe and appropriate treatment of persons served in this state. The Department proposes to amend the R.61-16 for consistency with current statutory requirements, update and revise definitions, licensure requirements, staff and training, reporting, disaster management, accommodations for patients, patient care and services, design and construction, fire protection and life safety, and policies and procedures. It contains a section-by-section discussion and justification for the proposed amendments. The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments.

The Department had a Notice of Drafting published in the July 28, 2023 *South Carolina State Register*.

Section-by-Section Discussion of Amendments:

Section	Type of Change	Purpose
Entire Regulation	Technical Corrections	Amended to clarify references to "Facilities" includes both Hospitals and Institutional General Infirmaries and references to "Hospitals" includes only hospitals. Amended to remove "DHEC" from references to certain Regulations – "DHEC Regulation 61-25". See, e.g., Section 1501.
Table of Contents	Technical Correction Reorganization	Amended language and sections to reflect technical corrections and reorganization proposed in regulation text.
101.E.1. Definitions. General Hospital.	Revision	Amended to be consistent with changes from 2023 Act No. 20.
101.E.2. Definitions. Specialized Hospital.	Revision	Amended to be consistent with changes from 2023 Act No. 20.

Section	Type of Change	Purpose
101. Definitions. Privately Owned Educational Institutional Infirmary.	Deletion	Deleted definition.
201. License Requirements. 201.F.	Addition	Added requirement to make payment of all fees prior to issuance of licenses.
201. License Requirements. 201.G.	Revision	Amended to clarify method of fee payment.
201. License Requirements. 201.H.3.	Technical Correction	Amended to delete the language "or replacement".
201. License Requirements. 201.H.4.	Technical Correction	Amended to delete the word "or".
201. License Requirements. 201.H.5.	Technical Correction	Amended to add the word "or".
201. License Requirements. 201.H.6.	Addition/Technical Correction	Added language to clarify an amended license shall be requested for move of a facility.
202. Exemptions to Licensing Standards.	Technical Correction/ Revision	Amended to replace "exemption" with "variance" and to add language to provide clarity regarding variances to licensing standards.
New 300. Enforcing Regulations and Enforcement Actions.	Revision/Deletion/ Reorganization	Amended to title section as Enforcing Regulations "and Enforcement Actions." Deleted former 400, Enforcement Actions, and recodified former 401, general, as 304, and former 402, violation classifications, as 305. Deleted former 401.B.
New 400. Policies and Procedures.	Addition/Technical Correction/Reorganization	Amended to create section specifically to address policy and procedures.
New 401. General.	Addition/Technical Correction/Reorganization	Amended to add clarifying language and to recodify the section.
New 402. Quality of Care.	Addition	Added requirements to have quality assessment and performance improvement program.
New 403. Security.	Revision/Reorganization	Reorganized to move previous Section 905 to Section 403, with certain minor amendments. .
502. Control.	Deletion/Revision	Removed language in section and revised to clarify governing body and control requirements.
503. Chief Executive Officer.	Revision	Amended for clarification.
504. Medical Staff	Revision/	Amended to remove and clarify

Section	Type of Change	Purpose
Appointment. (II)	Reorganization	language; amended to re-letter the section for consistency; amended to add Section 44-7-266(A) requirement .
505. Nursing Services. (II)	Deletion/Revision/ Reorganization/	Amended to remove and add language for clarification; amended to re-letter the section for consistency.
506. Employees. (II)	Deletion/Revision/ Reorganization/	Amended to remove and add language for clarification; amended to re-letter the section for consistency.
507. Job Orientation and In-Service Training.	Deletion/Reorganization	Amended and reorganized to remove and clarify language.
508. Plans and Training for Fires and Other Internal Emergencies. (II)	Deletion/ Reorganization	Amended to delete this section and move it to Section 2005.
604.A. Volunteer Workers. (II)	Revision	Amended to provide an exception to physical examination requirement for volunteers only administering vaccines.
701. Fire Report.	Deletion/Reorganization	Amended to delete this section and move it to new section 2003.
New 701. Incident Reports.	Revision/Reorganization	Amended to remove "accident and/or," and add "s" to end of reports in title; amended to add clarifying language and to recodify to section 701; amended to clarify and add reporting obligations to the Department and establish new timeframes for submitting reports.
New 702. Loss of Essential Services.	Addition	Added new language for reporting losses of essential services.
703. Facility Closure.	Revision	Amended to change lower case "f" in word facility to capital "F;" amended to remove and add language in last paragraph for clarification.
704. Zero Census.	Revision	Amended to change lower case "f" in word facility to capital "F;" amended by adding language to clarify numbers in writing; amended by deleting language.

Section	Type of Change	Purpose
705. Joint Annual Report.	Revision	Amended to clarify language.
706. Hospital Infections Disclosure Act (HIDA) & Reporting Requirements. (I)	Revision	Amended to clarify language.
New 900. Emergency Preparedness.	Revision	Amended to re-name section to specifically address hazardous events outside those considered a disaster.
New 901. All-Hazards Emergency Operations Plan.	Revision/Technical Correction/Reorganization	Amended to change title of section from Emergency Evacuation; amended to remove and clarify language; amended to add language for clarification; amended to re-letter the section for consistency; added subsection F regarding communication with local emergency agencies.
902. Internal Medical Surge.	Technical Correction/Revision/ Reorganization	Amended to change lower case "f" in word facility to capital "F;" amended to remove and clarify language; amended to add language for clarification; amended to re-letter the section for consistency.
903. External Medical Surge.	Technical Correction/Revision/ Reorganization	Amended to remove and clarify language; amended to add language for clarification; amended to re-letter this section for consistency.
904. Emergency Call Data. (I)	Deletion	Amended to remove and clarify language.
905. Security.	Technical Correction/Reorganization	Amended to delete this section and move it to Section 403.
1001. Maximum Number of Beds.	Addition	Amended to add language for regarding the Facility's ability to setup beds.
1002. Location of Beds.	Revision	Amended to add language for clarification.
1105. Contents.	Revision/Technical Correction/Reorganization	Amended to remove and clarify language; amended to add language regarding race and ethnicity and for clarification; amended to re-number this section for consistency.
Section 1200. Patient Care and Services.	Revision/Reorganization	Amended Section 1200 to have 1201 addressing basic facility functions and 1202 addressing optional hospital services.

Section	Type of Change	Purpose
New 1201.A. Pharmaceutical Services.	Revision/Technical Correction/Reorganization	Added pharmaceutical services which incorporates applicable federal Medicare standards; reorganized to delete and relocate some of the provisions in former 1201, Medications, 1204, Pharmacy Services, 1205, Drug Distribution and Control, 1206, Physical Facilities and Storage, and 1207, labeling of medications.
New 1201.B. Radiological Services.	Revision/Technical Correction/Reorganization	Added radiological services which incorporates applicable federal Medicare standards; deleted former 1203, Radiology.
New 1201.C. Laboratory Services.	Revision/Technical Correction/Reorganization	Added laboratory services which incorporates applicable federal Medicare standards; deleted former 1202, Laboratory.
New 1201.D. Emergency Services.	Revision/Technical Correction/Reorganization	Amended to add language regarding hospitals' provision of emergency services, including classification of such services the provision of off-campus emergency services, and address diversion. Reorganized to delete and relocate some of the standards at former 1214, Emergency Services .
New 1201.E. Central Supply.	Technical Correction/Reorganization	Amended to relocate former 1208, Central Supply, to Section 1201.E; amended to re-number the section for consistency.
New 1202.A. Surgical Services.	Revision/Technical Correction/Reorganization	Added surgical services which incorporates applicable federal Medicare standards and parts of former 1209, surgery; partially relocated former 1211, Equipment, to 1202.A.2.g; deletes former 1210, facilities, and 1216, dental surgery;amended to add language for clarification; amended to re-letter the section for consistency.
New 1202.B. Anesthesia Services.	Revision/Technical Correction/Reorganization	Added anesthesia services which incorporates applicable federal Medicare standards with certain exceptions; deleted former 1212,

Section	Type of Change	Purpose
		Anesthesia
New 1202.C. Nuclear Medicine Services.	Addition	Added nuclear medicine services which incorporates applicable federal Medicare standards.
New 1202.D. Outpatient Services.	Revision/Technical Correction/Reorganization	Added outpatient services which incorporates applicable federal Medicare standards; deletes former 1213, outpatient services.
New 1202.E. Rehabilitation Services.	Revision/Technical Correction/Reorganization	Added rehabilitation services which incorporates applicable federal Medicare standards; deletes former 1217, physical therapy, and 1218, occupational therapy.
New 1202.F. Psychiatric Services.	Revision/Technical Correction/Reorganization	Added psychiatric services which incorporates applicable federal Medicare standards; relocates former 1219, psychiatric services, to 1202.F.
New 1202.G. Respiratory Care Services.	Addition	Added respiratory care services which incorporates applicable federal Medicare standards.
New 1202.H. Inpatient Dialysis Services.	Revision/Technical Correction/Reorganization	Relocated former 1215, inpatient dialysis services, to 1202.H, and adds language regarding quality of care.
New 1202.I. Chemical and Substance Abuse Treatment Services.	Revision/Technical Correction/Reorganization	Relocated former 1220, chemical and substance abuse treatment services, to 1202.I, and adds language regarding quality of care.
New 1202.J. Pediatric Services.	Revision/Technical Correction/Reorganization	Relocated former 1221, pediatrics, to 1202.J, and adds language regarding quality of care.
New 1202.K. Cardiovascular Care Services.	Addition	Added requirements for the offering of certain cardiovascular care services.
1801.B.3. General [Infection Control].	Revision	Added World Health Organization's Moments of Hand Hygiene Guidelines as an infection control guideline.
1804. Live Animals.	Revision	Amended to delete and add language regarding service animals in facilities.
1900. Design, Construction, Repairs, Alterations, and Additions.	Revision/Technical Correction	Amended to create new title for section – Design, Construction, Repairs, Alterations, and

Section	Type of Change	Purpose
		Additions.
1901. General.	Revision	Amended to delete and add language for clarification.
1902. Codes and Standards.	Revision	Amended to delete and add language for clarification of applicable codes.
1903. Submission of Plans.	Revision/Addition	Amended to delete and add language for clarification of the Department's review of certain construction projects.
1904. Constriction Inspections.	Technical Correction/Revision	Amended to remove inspections and add permits to title; amended to delete and add language for clarification.
1905. Patient Rooms.	Revision	Amended to delete and add language for clarification.
1907. Nurses Station.	Revision	Amended to delete and add language for clarification.
1908. Utility Rooms.	Revision/Addition	Amended to delete and add language for clarification; added provision regarding nourishment rooms.
1909. Temperature and Humidity.	Deletion	Deleted this section as it is covered under mechanical section.
New 2003. Fire Reports.	Revision/reorganization	Amended to add language from former 701, fire report.
New 2004. Fire Safety.	Addition	Added language regarding compliance with adopted codes concerning fire safety.
New 2005. Plans and Training for Fires.	Revision/reorganization	Amended to add language from former 508, plans and training for fires and other internal emergencies, and clarify certain requirements.
New 2006. Tests and Inspections.	Addition	Added language regarding testing and maintenance of fire systems.
New 2007. Gases.	Addition	Added language regarding safety precautions for administration of oxygen.
New 2008. Furnishings and Equipment.	Addition	Added language regarding maintenance of furnishings/equipment and fire safety.
Section 2100. Preventive Maintenance of Life Support Equipment.	Revision	Amended for correct grammar/spelling.

Section	Type of Change	Purpose
Section 2200. General.	Deletion	Deleted section.

Instructions:

Print the regulation as shown above. All other items remain unchanged.

~~Indicates Matter Stricken~~
Indicates New Matter

Text:

61-16. Minimum Standards for Licensing Hospitals and Institutional General Infirmaries.

(Statutory Authority: 1976 Code Sections 44-7-110 through 44-7-394, 44-37-40, 44-37-50, and 63-7-40)

Table of Contents

SECTION 700. REPORTING
701. ~~Fire Report.~~
~~702. Accident and/or~~ Incident Report<u>s</u>.
<u>702. Loss of Essential Services.</u>
703. Facility Closure.
704. Zero Census.
705. Joint Annual Report.
706. Hospital Infections Disclosure Act (HIDA) & Reporting Requirements.
SECTION 800. REQUIREMENTS OF THE LEWIS BLACKMAN ACT
801. Compliance.
SECTION 900. ~~DISASTER MANAGEMENT~~<u>EMERGENCY PREPAREDNESS</u>
901. ~~Emergency Evacuation.~~ <u>All-Hazards Emergency Operations Plan.</u>
902. Internal Medical Surge.
903. External Medical Surge.
904. Emergency Call Data.
~~905. Security.~~
SECTION 1000. ACCOMMODATIONS FOR PATIENTS
1001. Maximum Number of Beds.
1002. Location of Beds.
SECTION 1100. MEDICAL RECORDS
1101. Physician's Responsibility.
1102. Organization.
1103. Indexing.
1104. Ownership.
1105. Contents.
1106. Orders for Medication and Treatment.
1107. Storage.
1108. Information to be Provided to Other Health Care Providers.
1109. Maintenance and Disposal.
1110. Access to Medical Records.
SECTION 1200. PATIENT CARE AND SERVICES
1201. ~~Medications~~<u>Basic Facility Functions</u>.
~~1202. Laboratory.~~
~~1203. Radiology.~~
~~1204. Pharmacy Services.~~
~~1205. Drug Distribution and Control.~~
~~1206. Physical Facilities and Storage.~~
~~1207. Labeling of Medications.~~
~~1208. Central Supply.~~
<u>1202. Optional Hospital Services.</u>
~~1209. Surgery.~~
~~1210. Facilities.~~
~~1211. Equipment.~~
~~1212. Anesthesia.~~
~~1213. Outpatient Services.~~
~~1214. Emergency Services.~~
~~1215. Inpatient Dialysis Services.~~
~~1216. Dental Surgery.~~
~~1217. Physical Therapy.~~
~~1218. Occupational Therapy.~~
~~1219. Psychiatric Services.~~

~~1220. Chemical and Substance Abuse Treatment Services.~~
~~1221. Pediatrics.~~
SECTION 1300. PERINATAL SERVICES
1301. Newborn Hearing Screening.
1302. Shaking Infant Video & Infant CPR Information for Parents and Caregivers of Newborn Infants and Adoptive Parents.
1303. Providing a Safe Haven for Abandoned Babies.
1304. Paternity – In-Hospital Voluntary Paternity Acknowledgement Program.
1305. Perinatal Organization.
1306. Designation of Inpatient Perinatal Care Services.
1307. Personnel.
1308. Neonatal Intensive Care Nurse Staffing.
1309. General Facility and Care Requirements.
1310. Neonatal Care.
1311. Neonatal Resuscitation.
1312. Inter-hospital Care of the Perinatal Patient (Transport).
1313. Evaluation of Perinatal Care.
SECTION 1400. VITAL STATISTICS
1401. General.
1402. Birth Certificates.
1403. Death Certificates.
SECTION 1500. FOOD AND NUTRITION SERVICE
1501. Approval.
1502. Services.
1503. Management.
1504. Personnel.
1505. Diets.
1506. Planning of Menus and Food Supplies.
1507. Preparation and Serving of Food.
1508. Dietary and Food Sanitation.
1509. Meal Service.
1510. Ice and Drinking Water.
SECTION 1600. MAINTENANCE
SECTION 1700. HOUSEKEEPING AND REFUSE DISPOSAL
1701. Housekeeping.
1702. Refuse Disposal.
SECTION 1800. INFECTION CONTROL
1801. General.
1802. Infection Control Training.
1803. Patient/Public Education and Disclosure.
1804. Live Animals.
1805. Laundry and Linens.
1806. Waste Management.
1807. Water Requirements.
SECTION 1900. DESIGN, CONSTRUCTION, REPAIRS, ALTERATIONS, AND ~~CONSTRUCTION~~ADDITIONS
1901. General.
1902. Codes and Standards.
1903. Submission of Plans.
1904. Construction ~~Inspections~~Permits.
1905. Patient Rooms.

SECTION 100
DEFINITIONS

101. Definitions.

For the purpose of these Standards, the following definitions shall apply:

A. Administrator: The individual designated by the governing body or owner who is in charge of and responsible for the administration of the facility.

B. Annual (Annually): A time period that requires an activity to be performed at least every twelve to thirteen (12 to 13) months.

C. Contact Investigation: Procedures that occur when a case of infectious TB is identified, including finding persons (contacts) exposed to the case, testing and evaluation of contacts to identify Latent TB Infection (LTBI) or TB disease, and treatment of these persons, as indicated.

D. Department: The South Carolina Department of Health and Environmental Control.

E. Facility: Hospitals and institutional general infirmaries licensed by the Department, shall be defined and classified as follows:

1. General Hospital: A facility with an organized medical staff to maintain and operate organized facilities and services to accommodate two or more nonrelated persons for the diagnosis, treatment and care of such persons overnight and provides medical and surgical care of acute illness, injury or infirmity and must provide on-campus emergency services; that may provide obstetrical care~~,~~; and in which all diagnoses, treatment or care are administered by or performed under the direction of persons currently licensed to practice medicine, surgery, or osteopathy in the State of S.C.

2. Specialized Hospital: A facility which has an organized medical staff, maintains and operates organized facilities and services to accommodate two or more nonrelated persons for the diagnosis, treatment and/or care of such persons overnight and which provides a specialized service for one type of care~~, such as, maternity, orthopedics, pediatrics, E.E.N.T., psychiatry, etc.~~ and must provide on-campus emergency services; and in which all diagnoses, treatment or care are under the direction of persons currently licensed to practice medicine, surgery, osteopathy in the State of S.C.

3. Institutional General Infirmary: A facility which is established within the jurisdiction of a larger nonmedical institution and which maintains and operates organized facilities and services to accommodate two or more nonrelated students, residents or inmates with illness, injury or infirmity for a period exceeding 24 hours for the diagnosis, treatment and care of such persons and which provides medical, surgical and professional nursing care, and in which all diagnoses, treatment and care are performed under the direction of persons currently licensed to practice medicine and surgery in the State of S.C.

4. Long Term Acute Care Hospital (LTACH): A general hospital which has been classified and certified as a long term acute care hospital designed to provide extended medical and rehabilitative care for patients who are clinically complex and have acute or chronic conditions. In a LTACH patients have an average length of stay of 25 days or more.

5. Critical Access Hospital (CAH): A general hospital designated by the state as such through the Medicare Rural Hospital Flexibility Program, in accordance with 42CFR485 Subpart F.

~~6. Privately-Owned Educational Institutional Infirmary: These facilities may be established within the jurisdiction of a larger nonmedical institution which maintains and operates organized facilities and services to accommodate two or more nonrelated students, faculty, and staff with illness, injury, or infirmity for a period exceeding twenty-four hours for the diagnosis, treatment, and care of such persons and which provides medical, surgical, and professional nursing care, and in which all diagnoses, treatment, and care are performed under the direction of persons currently licensed to practice medicine and surgery in South Carolina. However, privately-owned education infirmaries also may care for patients who are not students, faculty, or staff when the privately-owned education infirmary has agreed to provide such care to this class or patients prior to January 1, 2007 pursuant to 44-7-261.~~

F. Designee: A physician, dentist, osteopath, podiatrist, physician's assistant, or advanced practice registered nurse who has staff privileges, selected by a prescriber to sign verbal orders for medication or treatment in the prescriber's absence.

G. Dietitian: An individual who is registered by the Commission on Dietetic Registration and currently licensed as a dietitian by the South Carolina Department of Labor, Licensing and Regulation.

H. Existing Facility: A facility which was in operation and/or one which began the construction or renovation of a building, for the purpose of operating the facility, prior to the adoption of these standards. The licensing standards governing new facilities apply if and when an existing facility is not continuously operated and licensed under these Standards.

I. Health Assessment: An evaluation of the health status of a staff member or volunteer by a physician, other legally authorized healthcare provider, or registered nurse, pursuant to written standing orders and/or protocol approved by a physician's signature.

J. Licensee: The individual, corporation, organization, or public entity that has been issued a license to provide care, treatment, and services at a facility and with whom rests the ultimate responsibility for compliance with this regulation.

K. Live Birth: The complete expulsion or extraction from its mother of a product of human conception, irrespective of the duration of pregnancy, which after such expulsion or extraction, breathes or shows any other evidence of life such as beating of the heart, pulsation of the umbilical cord, or definite movement of the voluntary muscles, whether or not the umbilical cord has been cut or the placenta is attached.

Heartbeats are to be distinguished from transient cardiac contractions and respirations are to be distinguished from fleeting respiratory efforts or gasps.

L. License: A certificate issued by the Department to the licensee that authorizes the operation of a hospital or institutional general infirmary.

M. Legally Authorized Healthcare Provider: An individual authorized by law and currently licensed in South Carolina to provide specific medical treatments, care, or services to staff members and/or patients, e.g., advanced practice registered nurses, physician assistants.

N. New Facility: A facility which began operation and/or one which began construction or renovation of a building for the purpose of operating the facility after the adoption of these standards.

O. Nurse: A registered nurse, licensed practical nurse, or vocational nurse as those terms are defined by each party state's practice laws.

P. Patient: Any individual who is receiving treatment or services at the facility.

Q. Quarterly: A time period that requires an activity to be performed at least four (4) times a year within intervals ranging from eighty-one to ninety-nine (81 to 99) days.

R. External Medical Surge: Providing medical care services in an area outside of the licensed inpatient hospital building(s). For purposes of External Medical Surge, these locations are called Alternate Care Sites.

S. Internal Medical Surge: An emergency situation when a facility needs to set up and utilize beds beyond its licensed bed capacity in an area within the licensed inpatient facility building(s).

T. Inpatient Dialysis: Dialysis which, because of medical necessity, is furnished to an End-Stage Renal Disease (ESRD) patient on a temporary inpatient basis in a hospital.

U. Emergency Care: The treatment which is usually and customarily available at the respective hospital and that must be provided immediately to sustain a person's life, to prevent serious permanent disfigurement or loss or impairment of the function of a bodily member or organ, or to provide for the care of a woman in active labor and the infant.

SECTION 200
LICENSE REQUIREMENTS AND FEES

201. License Requirements.

A. No person, private or public organization, political subdivision, or governmental agency shall establish, operate, maintain, or represent itself (advertise or market) as a hospital or institutional general infirmary in South Carolina without first obtaining a license from the Department. Admission of patients or the provision of care, treatment, and/or services to patients prior to the effective date of licensure is a violation of S.C. Code Ann. Section 44 7 260(A) (1976, as amended). (I)

B. A license shall be effective for a period of time specified by the Department.

C. A new facility, or one that has not been continuously licensed under these or prior standards, shall not admit patients until permission is granted by the Department.

D. Hospitals that provide services to patients requiring skilled nursing care must maintain a separate license for the areas where the services are provided.

E. Upon receipt of a written request from the hospital authorities to the Department requesting such certification, any general hospital having a current license to operate may be certified as a suitable facility for the performance of abortions. A hospital shall comply with Chapter 41 of Title 44 of the S.C. Code of Laws. (I)

F. Applicants for a license shall file application under oath on a form and frequency specified by the Department. An application shall be signed/authenticated by the owner, if an individual or partnership; or in the case of a corporation, by two of its officers; or in the case of a governmental unit, by the head of the governmental department having jurisdiction over it. The application shall set forth the full name and address of the facility for which the license is sought and of the owner in case his address is different from that of the facility; the names of persons in control thereof and such additional information as the Department may require, including affirmative evidence of ability to comply with reasonable standards, rules and regulations as may be lawfully prescribed. No proposed hospital shall be named nor may an existing hospital have its name changed to the same or similar name as a hospital licensed in the State. Applicants shall make payment of all outstanding fees (initial licensure fees, annual licensure fees, inspection fees, construction fees, etc.) prior to the Department's issuance of a license.

G. Licensing Fees. The initial and annual license fee shall be ten dollars ($10.00) per licensed bed. ~~Annual license fees must also include any outstanding inspection fees. Such fees shall be made payable by check or credit card to the Department~~All fees are non-refundable, and shall be made payable to the Department via a secured portal or specific website.

H. A facility shall request issue of an amended license, by application to the Department prior to any of the following circumstances:

1. Change of ownership by purchase or lease;

2. Change of facility's name;

3. Addition ~~or replacement~~ of beds (an inspection will be required prior to issuance of license);

4. Deletion of beds; ~~or~~

5. Reallocation of types of beds as shown on license~~.~~; or

6. Relocation of a facility.

202. ~~Exceptions~~Variance to Licensing Standards.

~~The Department reserves the right to make exceptions to these standards where it is determined that the health and welfare of the community requires the services of the facility. When an "exception" applies to an existing facility, it will continue to meet the standards in effect at the time it was licensed.~~A variance is an alternative method that ensures the equivalent level of compliance with the standards in this regulation. The Facility may request a variance to this regulation in a format as determined by the Department. Variances shall be considered on a case by case basis by the Department. The Department may revoke issued variances as determined to be appropriate by the Department.

SECTION 300
ENFORCING REGULATIONS AND ENFORCEMENT ACTIONS

301. General.

The Department shall utilize inspections, investigations, consultations, and other pertinent documentation regarding a proposed or licensed facility in order to enforce this regulation.

302. Inspections and Investigations.

A. An inspection shall be conducted prior to initial licensing. Inspections shall be conducted as deemed appropriate by the Department. (I)

B. All facilities, proposed facilities, or unlicensed facilities are subject to inspection or investigation at any time without prior notice by individuals authorized by South Carolina Code of Laws. (II)

C. Individuals authorized by the Department shall be granted access to all properties and areas, objects, and records. If photocopies are made for the Department inspector, they shall be used only for purposes of enforcement of regulations and confidentiality shall be maintained except to verify individuals in enforcement action proceedings. Physical area of inspections shall be determined by the extent to which there is potential impact or effect upon patients as determined by the inspector. (I)

D. A facility or proposed facility found noncompliant with the standards of this regulation shall submit an acceptable plan of correction to the Department that shall be signed by the administrator and returned by the date specified on the report of inspection or investigation. The written plan of correction shall describe: (II)

1. The actions taken to correct each cited deficiency;

2. The actions taken to prevent recurrences (actual and similar); and

3. The actual or expected completion dates of those actions.

E. Reports of inspections or investigations conducted by the Department, including the response(s) by the facility or proposed facility, shall be provided to the public upon written request with the redaction of the names of those persons in the report as provided by S.C. Code Ann. Sections 44-7-310 and 44-7-315 (1976, as amended).

F. In accordance with S.C. Code Section 44 7 270, the Department may charge a fee for inspections. The fee for initial and biennial routine inspections shall be four hundred fifty dollars ($450.00) plus ten dollars ($10.00) per licensed bed. The fee for initial unit increase or service modification is two hundred fifty dollars ($250.00) plus ten dollars ($10.00) per licensed bed. The fee for follow up inspections shall be two hundred fifty dollars ($250.00) plus ten dollars ($10.00) per licensed bed.

303. Compliance.

A. A license shall not be issued until the licensee has demonstrated to the Department that the proposed facility is in compliance with the licensing standards. In the event a licensee who already has a facility or activity licensed by the Department makes application for another facility or activity or increase in licensed capacity, the currently licensed facility or activity shall be in substantial compliance with the applicable standards prior to the Department issuing a license to the proposed facility or activity or an

amended license to the existing facility. Facilities shall comply with applicable State, Federal, and local laws, codes, and regulations. (II)

B. The license is considered property of the Department and may not be duplicated in such a manner that it cannot be distinguished from the original. (II)

C. Any additions or renovations to an existing facility shall be approved by the Department prior to occupancy.

~~*SECTION 400*~~
~~*ENFORCEMENT ACTIONS*~~

~~401. General.~~304. Enforcement Actions

~~A.~~When the Department determines that a licensee, proposed licensee, or an unlicensed facility owner is in violation of statutory provisions, rules, or regulations relating to the operation of a facility, the Department, upon proper notice to the licensee, may impose a monetary penalty and/or deny, suspend, revoke, or refuse to issue or renew a license.

~~B.Food service permits may be revoked or suspended for violations in accordance with DHEC Regulation 61-25.~~

~~402~~305. Violation Classifications.

Violations of standards in this regulation are classified as follows:

A. Class I violations are those that the Department determines to present an imminent danger to the health and safety of the persons in the facility or a substantial probability that death or serious physical harm could result there from. A physical condition or one (1) or more practices, means, methods or operations in use in a facility may constitute such a violation. The condition or practice constituting a Class I violation shall be abated or eliminated immediately unless a fixed period of time, as stipulated by the Department, is required for correction. When a specific time is designated for correction, each day such violation exists after expiration of the time established by the Department shall be considered a subsequent violation.

B. Class II violations are those, other than Class I violations, that the Department determines to have a negative impact on the health and safety of persons in the facility. The citation of a Class II violation may specify the time within which the violation is required to be corrected. When a specific time is designated for correction, each day such violation exists after expiration of the time established by the Department shall be considered a subsequent violation.

C. Class III violations are those that are not classified as Class I or II in these regulations or those that are against the best practices as interpreted by the Department. The citation of a Class III violation may specify the time within which the violation is required to be corrected. When a specific time is designated for correction, each day such violation exists after expiration of the time established by the Department shall be considered a subsequent violation.

D. Violations of §44-7-320(A)(1)(~~b~~c) ~~and (A)(1)(d)~~ of the South Carolina Code of Laws of 1976, as amended, are considered Class I violations.

E. The notations, "(I)" or "(II)" placed within sections of this regulation, indicate those standards are considered Class I or II violations, respectively, if they are not met. Standards not so annotated are considered Class III violations.

F. In arriving at a decision to take enforcement action, the Department will consider the following factors: the number and classification of violations, including repeat violations; specific conditions and their impact or potential impact on health and safety of the patients; efforts by the facility to correct cited violations; behavior of the licensee that would reflect negatively on the licensee's character, such as illegal or illicit activities; overall conditions of the facility; history of compliance; any other pertinent conditions that may be applicable to statutes and regulations.

G. When a decision is made to impose monetary penalties, the Department may invoke S.C. Code Ann. Section 44-7-320(C) (1976, as amended), to determine the dollar amount or may utilize the following schedule as a guide to determine the dollar amount:

Frequency of Violation of Standard within a 24-month period	**MONETARY PENALTY RANGES**		
	Class I	**Class II**	**Class III**
1st	$ 200-1000	$ 100-500	$ 100
2nd	500-2000	200-1000	100-500
3rd	1000-5000	500-2000	200-1000
4th	5000	1000-5000	500-2000
5th	5000	5000	1000-5000
6th and more	5000	5000	5000

H. In addition to or in lieu of any action taken by the Department affecting the license of any hospital, when it is established that any officer, employee, or member of the hospital medical staff has recklessly violated the provisions of Section ~~1210.A.5~~1201.D.1, the Department may require the hospital to pay a civil penalty of up to ten thousand dollars pursuant to 44-7-260(E).

I. Any Department decision involving the issuance, denial, renewal, suspension, or revocation of a license and/or the imposition of monetary penalties where an enforcement action order has been issued may be appealed by an affected person with standing pursuant to applicable law, including S.C. Code Title 44, Chapter 1; and Title 1, Chapter 23.

SECTION 400
POLICIES AND PROCEDURES

401. General. (II)

A. The Facility shall maintain and adhere to written policies and procedures addressing the manner in which the requirements of this regulation shall be met. The Facility shall develop, implement, and enforce policies and procedures. The Facility shall be in full compliance with the policies and procedures. (II)

B. The Facility shall establish a time period for review of all policies and procedures, and such reviews shall be documented and signed by the Chief Executive Officer (or his/her designee(s)). All policies and procedures shall be accessible to Facility staff, printed or electronically, at all times.

402. Quality of Care. (II)

The Facility shall develop, implement, and maintain an effective, ongoing, facility-wide, data-driven quality assessment and performance improvement program. The Facility's governing body shall ensure that the program reflects the complexity of the Facility's organization and services; involves all Facility departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors.

403. Security. (II)

In order to ensure the safety and well-being of all patients, staff, and visitors, the Facility's governing body (or its designee) shall conduct an annual risk assessment to identify potential areas or situations that may cause harm or where an incident may occur. Based upon the findings of that assessment, the Facility's governing body (or its designee) shall develop and implement a plan to provide for the appropriate level of security necessary.

SECTION 500
STAFF AND TRAINING

501. General.

Every facility shall be organized, equipped, staffed and administered in order that adequate care may be provided for each person admitted.

502. Control. (II)

~~A.The governing body, or the owner, or the person or persons designated by the owner as the governing authority shall be the supreme authority in the hospital responsible for the management control of the hospital and appointment of the medical staff. The governing body will work with the senior managers and leaders of the organized medical staff to annually evaluate the hospital's performance in relation to its mission, vision, and goals.~~ The Facility shall have a governing body which is effective in carrying out its responsibilities for the conduct of the Facility. In the absence of an organized governing body, the Facility shall maintain written documentation that identifies the individual or individuals that are legally responsible for the conduct of the Facility's operations.

~~B.The governing body is ultimately accountable for the safety of patients and staff and the quality of care, treatment, and services provided.~~

~~C.A written set of bylaws for operation of the hospital shall be developed by the governing authority. Committees as determined by the needs and services of the hospital shall be provided. The medical staff shall be accountable to the governing authority for the clinical and scientific work of the hospital.~~

503. Chief Executive Officer.

The Facility shall appoint a Chief Executive Officer (CEO) ~~shall be the administrator of the facility and be selected by the governing body or owner and shall have charge of and be~~who is responsible for the administration of the facility ~~in~~and all its branches and departments~~ and shall see that the bylaws and amendments thereto are complied with~~. The Facility shall notify the Department of ~~A~~any change in the ~~position of the~~ Chief Executive Officer ~~shall be reported immediately by the governing body or owner to the Department~~ in writing within twenty-four (24) hours and shall provide the Department the name of the

newly-appointed, interim CEO, or other person who is in charge of and responsible for administration of the facility, and the effective date of the appointment.

504. Medical Staff Appointment. (II)

A. The ~~hospital~~Facility shall have a medical staff organized in accordance with the facility's by-laws and accountable to the governing body including, but not limited to the quality of professional services provided by individuals with clinical privileges. Prior to a physician's initial appointment and periodic reappointment, the governing body shall assure itself that the physician is qualified and competent to practice in ~~his~~their profession. This organized group shall, with the approval of the hospital governing body, adopt bylaws, rules and regulations to govern its operation as an organized medical staff. ~~Hospital~~Facility bylaws shall contain renewal procedures, authority to limit or terminate staff privileges, and appeal procedures. A hospital is prohibited from using economic criteria unrelated to quality of care or professional competency in determining an individual's qualifications for initial or continuing hospital medical staff membership or privileges. (II)

B. To be eligible for membership on a staff an applicant must be licensed to practice in his profession in the State of South Carolina competent in his respective field, worthy in character and in matters of professional ethics, and meet the requirements of the hospital's bylaws. Medical staff membership must be limited to doctors of medicine or osteopathy by the State Board of Medical Examiners, dentists licensed to practice dentistry by the State Board of Dentistry and podiatrists licensed to practice podiatry by the State Board of Podiatry Examiners. No individual is automatically entitled to membership on the medical staff or to the exercise of any clinical privilege merely because he is licensed to practice in any state, because he is a member of any professional organization, because he is certified by any clinical examining board, or because he has clinical privileges or staff membership at another ~~hospital~~Facility without meeting the criteria for membership established by the governing body of the respective ~~hospital~~Facility.

C. The medical staff, either as a whole or on a department or clinical service basis, shall meet at a frequency as determined by the ~~facilities~~Facility's policies and procedures to review and analyze their clinical experience. Written minutes of such meetings shall be recorded and filed. There shall be mechanisms in place for monitoring and evaluation of the quality of patient care services, for improving services, and for evaluation of the effectiveness of improvement efforts.

D. The governing body may establish categories for membership in the medical staff. These categories for membership shall be identified and defined in the medical staff by-laws, rules, or regulations.

E. In hospitals maintaining organized departments or services, ~~such as medicine, surgery, obstetrics, pediatrics, orthopedics, etc.,~~ the medical staff shall elect periodically a chief of staff and staff members to be the responsible heads or chiefs for each department or service, subject to the approval of the governing body. Minutes of all department or service meetings shall be recorded and filed.

F. In compliance with such rules for professional services of resident physicians as the medical staff prescribes, the medical staff shall supervise resident physicians in the diagnosis and treatment of all patients and in the performance of any other professional duties and shall recommend them for approval or disapproval to the governing body and chief executive officer. (II)

G. All persons admitted to any facility covered by these Standards must be under the care of a person ~~duly~~ licensed to practice medicine, dentistry or osteopathy. Patients of podiatrists and dentists who are members of the medical staff of a ~~hospital~~Facility must be co-admitted by a doctor of medicine or osteopathy who is a member of the medical staff of the ~~hospital~~Facility who shall be responsible for the

general medical care of the patient. Oral surgeons who have successfully completed a postgraduate program in oral surgery accredited by a nationally recognized accredited body approved by the U.S. Department of Education may admit patients without the requirement of co-admission if permitted by the bylaws of the ~~hospital~~Facility and medical staff. (I)

H. All ~~hospitals~~Facilities shall have a licensed physician available on call at all times. (I)

505. Nursing Services. (II)

A. Nursing Services shall be organized and staffed at all times to provide safe, appropriate, and individualized care to each patient. The authority, responsibility and function of all patient care providers shall be clearly defined by written ~~hospital~~Facility policy and position descriptions.

B. The ~~hospital~~Facility must have an organized nursing service that provides 24-hour nursing services. ~~The nursing services must be furnished or supervised by a registered nurse.~~ This service must be ~~a well organized service of the hospital and~~ under the direction of a Chief Nursing Officer (CNO), who is a ~~single~~ registered nurse. A registered ~~professional~~ nurse shall be designated in writing to act in the ~~ir~~ absence of the CNO. ~~Nurses must be currently licensed in the state of South Carolina.~~

C. There shall be a sufficient number of duly licensed registered nurses on duty at all times provide nursing care to meet the needs of the patient population for all areas where nursing care is provided. A registered nurse must be on duty at all times.

D. ~~Other~~Facility personnel ~~shall~~may be employed to assist the registered nurse in providing nursing care. Licensed practical nurses and all other workers who are employed by a facility in nursing services shall be assigned based on their education, training, and competency.

E. All personnel who render nursing care services in the ~~hospital~~Facility shall be under the supervision of nursing leadership and shall be subject to all policies and procedures of the facility.

F. All nurses employed in a nursing role in a facility shall be currently licensed to practice in South Carolina or pursuant to the Nurse Licensure Compact.

~~G. A procedure manual that is in accordance with current accepted practices must be readily available to the nursing personnel.~~

506. Employees. (II)

A. The Chief Executive Officer shall designate an individual to conduct Human Resources Management within the organization. That individual, and other individuals as needed, shall have responsibility for hiring, personnel management, compensation and benefits, and maintenance of accurate and complete personnel records.

B. The facility shall develop and make available to the employee a written job description for each type of job in the facility. Each job description shall include a written description of the education, experience, license, certification, or other qualifications required for the position.

C. ~~The licensee shall maintain either personnel records or a data base in accordance with all appropriate state and federal laws.~~ The Facility personnel records shall contain, at a minimum, the following:

1. For clinical personnel, information sufficient to verify the employee's qualifications for the job for which that individual is employed. That information includes, but is not limited to: employee's education, professional certification or licensure status, other training, experience and indication of clinical competence.

2. For nursing personnel, the information shall also include either a copy of the employee's South Carolina nursing license or a multi-state compact license. Applicants shall be hired only after obtaining verification of their license from the South Carolina Board of Nursing or verification of their multi-state license from the appropriate state Board.

3. For non-clinical personnel, information regarding the employee's education, training, experience and professional competence sufficient to verify the employee's qualifications for the job for which that individual is employed. Such information shall be kept current.

4. Current information relative to periodic work performance and/or competences evaluations.

53. Records of pre-employment health assessment as described in Section 602. screenings and of subsequent health services rendered to the employees as are necessary to determine that all facility employees are physically able to perform the essential duties of their positions.

D. The facility shall develop, establish and maintain personnel policies and practices which support sound patient care. The policies shall be in writing and made available to all employees. The policies shall be reviewed periodically but no less than annually and the date of the most recent review shall be indicated on the written policies. A procedure shall be established for notifying employees of changes in the established personnel policies. The Facility must have a written procedure to ensure that nursing personnel, for whom licensure is required, have valid and current licensure.

507. Job Orientation and In-Service Training.

A. Orientation of all new personnel shall be structured to educate them about the organization and environment of the facility, the employees' specific duties and responsibilities, and patients' needs. Each employee shall be familiar with the facility's emergency disaster plans. The hospital must ensure annual training of employees regarding emergency management, including surge policies and procedures and events that would indicate a need to implement surge policies and procedures. This requirement for job orientation may be accomplished through any combination of in-person or online sessions, completion of modules, videos, or other types of training approaches.

B. In-service training programs shall be planned and provided for all personnel to ensure and maintain their understanding of their duties and responsibilities. Records shall be maintained to reflect program content and individuals attending. This requirement for in-service training may be accomplished through any combination of in-person or online sessions, completion of modules, videos, or other types of training approaches.

C. Either as a component of orientation or in a separate session, all new employees who will have contact with patients or who will handle or potentially handle blood, body fluids or tissue must receive general education regarding infection prevention and control within the hospital.

D. Each employee shall be familiar with the Facility's emergency disaster plan and fire response plans. The hospital must ensure at orientation and annually thereafter that employees receive training regarding emergency management, including surge policies and procedures and events that would indicate a need to implement surge policies and procedures, and fire response.

~~**508. Plans and Training for Fires and Other Internal Emergencies. (II)**~~

~~A.Each facility shall develop, in coordination with its supporting fire department and/or disaster preparedness agency, suitable written plans for actions to be taken in the event of fire and other emergencies. All employees shall be made familiar with these plans and instructed as to required actions.~~

~~B.Each employee shall receive instructions covering fire protection training.~~

~~C.A fire drill shall be conducted for each shift at least quarterly. Records of drills shall be maintained to report the date, time, shift and a description and evaluation of the drill.~~

~~D.Drills shall be designed and conducted to:~~

~~1. Assure that all personnel are capable of performing assigned tasks or duties;~~

~~2. Assure that all personnel know the location, use and how to operate firefighting equipment;~~

~~3. Assure that all personnel are thoroughly familiar with the fire plan; and~~

~~4. Evaluate the effectiveness of plans and personnel.~~

SECTION 600
EMPLOYEE HEALTH (II)

601. Employee Health Program.

A hospital shall provide an employee health program to support a safe, healthy workplace by providing timely and quality health assessments, prevention services and if needed, intervention strategies. In order to minimize the possibility of contamination and transfer of infection, the employee health program shall include the establishment of policies and monitoring procedures to ensure that all employees are free from communicable infections and open skin lesions.

602. New Employees.

A. To ensure that every person accepted for employment is medically capable of performing the required job duties, a new employee shall be required to satisfactorily pass a health assessment conducted prior to direct patient contact by one of the following:

1. Medical Doctor or Doctor of Osteopathy;

2. Physician Assistant;

3. Nurse Practitioner; or

4. Registered nurse, pursuant to standing orders approved by a physician as required by hospital policy by the physician. The standing orders must be reviewed annually, with a copy maintained at the facility.

B. The health assessment must ensure that all potential hospital employees are evaluated for conditions related to infectious diseases that may have an impact on patient care, the employee, or other healthcare

workers. Based upon recommendations of the CDC's Advisory Committee on Immunization Practices (ACIP) for immunization of healthcare personnel, as listed in the CDC Guideline for infection control in healthcare personnel (1998) and as amended, this evaluation must include:

1. Medical history, including immunization status and assessment for conditions that may predispose the person to acquiring or transmitting communicable diseases;

2. Tuberculosis screening, which is performed in a manner prescribed in the CDC and the Department's most current tuberculosis guidelines; and

3. Serologic screening for vaccine-preventable diseases, as deemed appropriate by the hospital.

C. The hospital must provide evidence of education of employees about influenza vaccination and must offer the influenza vaccine to these persons.

D. Employee health programs must provide evidence of ongoing review and monitoring of both CDC and the Department recommendations and updates and methods for revising the programs as needed.

603. Employee Records.

A. All employee health records, including any medical history, shall be retained in a separate and confidential file in Employee Health. Access to these records will be permitted only to those authorized through hospital policy.

B. The hospital shall have policies and procedures for the maintenance and destruction of employee health records after employment has been terminated.

604. Volunteer Workers. (II)

A. All volunteer workers who handle food or provide patient care shall have a physical examination prior to their initial food handling or patient care activity. If a volunteer worker's patient care responsibility is limited to only administering vaccinations, then the facility does not need to have a physical examination of that volunteer worker.

B. For patient care volunteers, the tuberculin testing and treatment program described in Section 602.B also applies.

SECTION 700
REPORTING (II)

701. ~~Fire Report.~~

~~The Department shall be notified immediately regarding any fire, regardless of size or damage that occurs in the facility, and followed by a complete written report to include fire department reports, if any, to be submitted within a time period determined by the facility, but not to exceed 7 business days.~~

~~702. Accident and/or~~ Incident Report<u>s</u>.

A. The Facility shall document every incident, and include an incident review, investigation, and evaluation as well as corrective action taken, if any. The Facility shall retain all documented incidents

reported pursuant to this section for three (3) years following the incident. For the first year following discharge, these records shall be kept on site and readily available at that Facility.

~~A~~B. ~~A record of each accident and/or~~The Facility shall report the following types of incidents ~~occurring in the facility, including serious medication errors and adverse drug reactions, shall be retained~~to the Department and the patient's responsible party, sponsor, or emergency contact within twenty-four (24) hours or by the next regular business day from when the facility had reasonable cause to believe an incident occurred. The Facility shall notify the Department via the Department's electronic reporting system or as otherwise determined by the Department. ~~Incidents resulting in death or serious injury shall be reported, in writing, to the Department within 10 days of the occurrence. Information included in a facilities' report that is acquired from a peer review committee shall maintain its privilege pursuant to S.C. Code of Laws Sections 40-71-20, 44-30-60, and 44-7-315. However, the duty of hospitals to report serious accidents and incidents is not affected by any privilege or confidentiality.~~ The following incidents~~, including but not limited to those stated,~~ shall be reported:

1. ~~Suicides.~~

~~2. Wrong site surgery.~~

~~3. Medication errors resulting in death or serious injury.~~

~~4. Major fractures or head injuries resulting from falls or other events.~~

~~5. Patient death or serious injury resulting from being in a restraint.~~

~~6. Criminal events and assaults.~~

~~7. Transfusion errors.~~

~~8. Neonatal injuries.~~

~~9. Maternal deaths or injuries.~~

~~10. Elopement events.~~

~~11. Anesthesia-related events resulting in death or serious injury.~~

~~12. Ventilator errors resulting in death or serious injury.~~

~~13. Infant abductions.~~ Surgical or Invasive Procedure Events.

a. Surgery or other invasive procedure performed on the wrong site;

b. Surgery or other invasive procedure performed on the wrong patient;

c. Wrong surgical or other invasive procedure performed on a patient;

d. Unintended retention of a foreign object in a patient after surgery or other invasive procedure; and

e. Intraoperative or immediately postoperative/postprocedure death in an American Society of Anesthesiologists (ASA) Class 1 patient.

2. Product or Device Events.

a. Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the healthcare setting.

b. Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used or functions other than as intended; and

c. Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a healthcare setting.

3. Patient Protection Events.

a. Discharge or release of a patient of any age, who is unable to make decisions, to other than an authorized person;

b. Patient death or serious injury associated with patient elopement (disappearance); and

c. Patient suicide, attempted suicide, or self-harm that results in serious injury, while being cared for in a healthcare setting.

4. Care Management Events.

a. Patient death or serious injury associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration);

b. Patient death or serious injury associated with unsafe administration of blood products;

c. Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting;

d. Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy;

e. Patient death or serious injury associated with a fall while being cared for in a healthcare setting;

f. Any Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission/presentation to a healthcare setting;

g. Artificial insemination with the wrong donor sperm or wrong egg;

h. Patient death or serious injury resulting from the irretrievable loss of an irreplaceable biological specimen; and

i. Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results.

5. Environmental Events.

a. Patient or staff death or serious injury associated with an electric shock in the course of a patient care process in a healthcare setting;

b. Any incident in which systems designated for oxygen or other gas to be delivered to a patient contains no gas, the wrong gas, or are contaminated by toxic substances;

c. Patient or staff death or serious injury associated with a burn incurred from any source in the course of a patient care process in a healthcare setting; and

d. Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in a healthcare setting.

6. Radiologic Events.

a. Death or serious injury of a patient or staff associated with the introduction of a metallic object into the MRI area.

7. Potential Criminal Events.

a. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider;

b. Abduction of a patient of any age;

c. Sexual abuse/assault on a patient or staff member within or on the grounds of a healthcare setting; and

d. Death or serious injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a healthcare setting.

~~B~~C. The Facility shall submit a separate written investigation report within seven (7) business days from when the facility had reasonable cause to believe an incident occurred via the Department's electronic reporting system or as otherwise determined by the Department. Reports submitted to the Department shall contain at a minimum: facility name, patient age and sex, date of incident, location, witness names, extent and type of injury and how treated, *e.g.*, hospitalization, identified cause of incident, internal investigation results if cause unknown, identity of other agencies notified of incident and the date of the report.

702. Loss of Essential Services.

Should a facility experience a loss of an essential service such as cooling, potable water, or electrical power, the facility shall notify the Department by email to HQEP@dhec.sc.gov or other email address prescribed by the Department after ensuring the safety of the patients, but not to exceed twenty-four (24) hours from the loss of service.

703. Facility Closure.

A. Prior to the permanent closure of a facility, the Department shall be notified in writing of the intent to close and the effective closure date. Within 10 days of the closure, the facility shall notify the

Department of the provisions for the maintenance of the records, the identification of displaced patients, the relocated site, and the dates and amounts of patient refunds. On the date of closure, the license shall be returned to Department.

B. In instances where a facility temporarily closes, the Department shall be given written notice within a reasonable time in advance of closure. At a minimum this notification shall include, but not be limited to: the reason for the temporary closure, the location where the patients have been/will be transferred, the manner in which the records are being stored, and the anticipated date for reopening. The Department shall consider, upon appropriate review, the necessity of inspecting and determining the applicability of current construction standards of the facility prior to its reopening. If the facility is closed for a period longer than one year, and there is a desire to re-open, the facility shall ~~re-apply to the Department for licensure and shall~~ be subject to all licensing requirements ~~at the time of that application,~~prior to reopening, including construction-related requirements for a new facility.

704. Zero Census.

In instances when there have been no patients in a facility for any reason for a period of ninety (90) calendar days or more, the ~~f~~Facility shall notify the Department in writing that there have been no admissions, no later than the hundredth (100^{th}) day following the date of departure of the last active patient. At the time of that notification, the Department shall consider, upon appropriate review of the situation, the necessity of inspecting the ~~f~~Facility prior to any new and/or re-admissions to the ~~f~~Facility. If the ~~f~~Facility has no patients for a period longer than one year, and there is a desire to admit a patient, the ~~f~~Facility ~~shall re-apply to the Department for licensure and~~ shall be subject to all licensing requirements ~~at the time of that application~~ prior to admission of a patient, including construction-related requirements for a new facility.

705. Joint Annual Report.

~~The Department requires each health care facility to annually complete a questionnaire named~~The Facility shall submit a "Joint Annual Report" ~~and return this report within the time period~~ as specified ~~in the report's accompanying cover letter~~ by the Department.

706. Hospital Infections Disclosure Act (HIDA) & Reporting Requirements. (I)

~~A hospital~~The Facility ~~is required to~~shall collect data and submit reports to the Department on hospital acquired infection rates and methods and adequacy of selected infection control process ~~to be in compliance with~~pursuant to S.C. Code of Laws Sections 44-7-2410 through 44-7-2460. ~~Hospitals are also required to report methods and adequacy of selected infection control processes. The Department will notify hospitals annually about the current HIDA reporting requirements and the methods for submitting those reports to the Department.~~

SECTION 800
REQUIREMENTS OF THE LEWIS BLACKMAN ACT (I)

801. Compliance.

In order to be in compliance with The Lewis Blackman Hospital Patient Safety Act, hospitals are required to:

A. Identify all clinical staff, clinical trainees, medical students, interns, and resident physicians as such with identification badges that include their names, their departments, and their job or trainee titles.

B. Institute a procedure whereby a patient may request that a nurse call his or her attending physician regarding the patient's personal medical care.

C. If the patient is able to communicate with and desires to call his or her attending physician or designee, upon the patient's request, the nurse must provide the patient with the telephone number and assist the patient in placing the call.

D. Provide a mechanism, available at all times, and the method for accessing it, through which a patient may access prompt assistance for the resolution of the patient's personal medical care concerns.

E. Establish procedures for the implementation of the mechanism providing for initiation of contact with administrative or supervisory clinical staff who shall promptly assess the urgent patient care concern and cause the patient care concern to be addressed.

F. Provide to each patient prior to, or at the time of the patient's admission to the hospital for inpatient care or outpatient surgery, written information describing the general role of clinical trainees, medical students, interns, and resident physicians in patient care.

SECTION 900
~~DISASTER MANAGEMENT(II)~~ EMERGENCY PREPAREDNESS

901. ~~Emergency Evacuation~~ All-Hazards Emergency Operations Plan. (II)

A. All facilities shall develop, implement, and maintain~~by contact and consultation with their county emergency preparedness agency,~~ a ~~suitable~~ written all-hazards emergency operations plan for actions to be taken in the event of a disaster and/or emergency evacuation. ~~In the event of mass casualties, the facility shall provide resources as available.~~ Additionally, in instances where there are applications for increases in licensed bed capacity~~,~~ or a change in ownership, the emergency ~~evacuation~~ plan shall be updated to reflect the proposed new total licensed bed capacity and/or change in ownership. The Facility shall review the plan ~~shall be updated, as appropriate,~~at least annually~~, or as needed~~.

B. ~~Each facility shall maintain a means of communication with their local emergency management agency that is capable of transmitting information and/or data during periods when normal communication systems are inoperable. The facility shall also maintain a back-up system. Both systems shall be exercised periodically.~~The all-hazards emergency operations plan shall include, but not be limited to:

1. A sheltering plan to include:

a. Name, address, and phone number of the sheltering facility(ies) to which patients will be relocated during a disaster; and

b. A letter of agreement signed by an authorized representative of each sheltering facility, which shall include: the number of relocated patients that can be accommodated; sleeping, feeding, and medication plans for the relocated patients; and provisions for accommodating relocated staff members. The letter shall be updated with the sheltering facility at least every three (3) years and whenever significant changes occur. For those facilities located in Beaufort, Berkeley, Charleston, Colleton, Dorchester, Georgetown, Horry, and Jasper counties, at least one (1) sheltering facility shall be located in a county other than these counties.

2. A transportation plan, to include letter of agreement signed by an authorized representative with each entity for relocating patients, which addresses:

a. The relocation needs of the patients and staff contingent upon the type of disaster/emergency confronted;

b. Procedures for providing appropriate medical support, food, water and medications during relocation based on the needs and number of the patients; and

c. Estimated time to accomplish the relocation during normal conditions.

3. A staffing plan for the relocated patients, to include:

a. How care will be provided to the relocated patients, including facility staff members that will accompany patients who are relocated;

b. Prearranged transportation arrangements to ensure staff members are relocated to the sheltering facility; and

c. Co-signed statement by an authorized representative of the sheltering facility if staffing, bedding, or medical supplies that are to be provided by the sheltering facility.

C. ~~Each facility shall operate under an incident command system that is in compliance with FEMA's National Incident Management System (NIMS), and the Hospital Incident Command System (HICS).~~ The Facility shall maintain written acknowledgement from the local county emergency management agency of such agency's receipt of the Facility's all-hazards emergency operations plan.

D. ~~Annually, prior to June 1st of each year, each facility shall validate/provide the Department the information required by the Department's Critical Data Sheet (CDS) Information system. Hospital data provided to the CDS system will assist the Department, during times of disaster and emergencies, determine the appropriateness of evacuation or shelter in place. The disaster/emergency evacuation plan shall include, but not be limited to:~~

~~1. A sheltering plan to include:~~

~~a. Name, address and phone number of the sheltering facility(ies) to which the patients will be relocated during a disaster; and~~

~~b. A letter of agreement signed by an authorized representative of each sheltering facility which shall include: the number of relocated patients that can be accommodated; sleeping, feeding, and medication plans for the relocated patients; and provisions for accommodating relocated staff members. The letter shall be updated with the sheltering facility at least every three (3) years and whenever significant changes occur. For those facilities located in Beaufort, Charleston, Colleton, Horry, Jasper, and Georgetown counties, at least one (1) sheltering facility shall be located in a county other than these counties.~~

~~2. A transportation plan, to include agreements with entities for relocating patients, which addresses:~~

~~a. The relocation needs of the patients and staff contingent upon the type of disaster/emergency confronted;~~

~~b. Procedures for providing appropriate medical support, food, water and medications during relocation based on the needs and number of the patients;~~

~~c. Estimated time to accomplish the relocation during normal conditions; and~~

~~d. Primary and secondary routes to be taken to the sheltering facility.~~

~~3. A staffing plan for the relocated patients, to include:~~

~~a. How care will be provided to the relocated patients, including facility staff members that will accompany patients who are relocated;~~

~~b. Prearranged transportation arrangements to ensure staff members are relocated to the sheltering facility; and~~

~~c. Co-signed statement by an authorized representative of the sheltering facility if staffing, bedding, or medical supplies are to be provided by the sheltering facility.~~ Facilities annually, prior to June 1st of each year, shall:

1. Validate/provide the information required by the Department's Critical Data Sheet (CDS); and

2. Submit a shelter-in-place plan in a format determined by the Department, if the Facility may seek to shelter-in-place during an emergency evacuation.

E. Within 30 days prior to the renewal of its license, ~~Each~~the facility shall ~~validate/~~provide ~~the Department~~ the information required for the Department's Emergency Evacuation Plan Summary ~~in Section 901.D. no less than annually~~. Submission of this information will be in a format determined by the Department.

F. Each Facility shall maintain a means of primary and secondary communication with their local county emergency management agency that is capable of transmitting information and/or data during periods when normal communication systems are inoperable. The Facility shall also maintain a back-up system. Both systems shall be tested periodically.

902. Internal Medical Surge.

A. ~~It is the responsibility of the facility to know what areas are within the licensed inpatient building(s). If a hospital needs to set up and utilize beds in an area outside of the licensed inpatient hospital building(s), it must follow Section 903 of this regulation.~~

~~B.~~ A facility desiring to activate internal medical surge and temporarily admit patients in excess of licensed bed capacity due to an emergency shall provide written notification to the Department upon prescribed forms that include the following information ~~should do the following~~:

1. ~~Request that the Department concur that an~~A description of the emergency situation ~~exists.~~;

2. ~~During the call to the Department, facility should be prepared to:~~

~~a. Describe the emergency situation;~~

~~b.~~ An ~~O~~outline of the maximum number of patients to be ~~temporarily~~ admitted;

~~c. Provide an anticipated date for discharge of the temporary patients; and~~

~~d. Describe how and where the temporary patients will be housed.~~

3. ~~Patients temporarily admitted during the emergency situation will not be required to undergo tuberculin screening or submit to an admission history and physical examination.~~An anticipated date of discharge of the patients; and

4. ~~The facility must notify the Department when the patient census has returned to, or moves below, normal bed capacity by discharge or transfer to licensed beds~~A description of how and where the patients will be housed.

B. The Facility must notify the Department in writing when the Facility has deactivated its internal medical surge and its patient census has returned to within the Facility's licensed bed capacity.

C. If the event occurs after normal business hours, the Department must be contacted promptly during the next business day.

D. Other issues, such as staffing for the care of the temporary patients, physicians' orders, additional food for the temporary patients and handling of medications, ~~should~~shall be resolved ahead of time by memorandum of agreements, internal policies and procedures, and emergency planning documents.

903. External Medical Surge.

A. Some emergency situations might overwhelm a ~~hospital's~~Facility's plans for Internal Medical Surge or render the licensed inpatient hospital building(s) unusable. In such situations, a ~~hospital~~Facility may activate External Medical Surge and operate an Alternate Care Site (ACS) under the authority of its license during an emergency situation such as a mass casualty event or ~~f~~Facility evacuation. To activate an ACS, the Facility's census must be projected to surge beyond its planned Internal Medical Surge capacity or the Facility's main building, or a portion of the building, must be rendered unusable.

B. If a ~~hospital~~Facility desires to be approved to operate an ACS, the ~~hospital~~Facility ~~must contact the Department for current requirements and guidance in planning~~ shall~~.~~:

1. ~~In order to facilitate activation of an ACS, hospitals are advised to~~ ~~c~~Conduct an assessment of the proposed ACS location utilizing the Department's Alternate Care Site Preliminary Assessment Form. ~~The Department will not authorize activation of an ACS until the hospital has provided assessment information.~~ Every ACS shall be planned, designed, and equipped to provide adequate accommodations for the care, safety, and treatment of each patient. Buildings selected for ACS should comply with the local building codes and ordinances applicable to the buildings' original intended use. It is the ~~hospital's~~Facility's responsibility to use the assessment process to assure that an ACS building is in compliance with local codes and has the structural soundness and capacity to provide patient treatment contemplated by the ~~hospital~~Facility.

2. ~~The Social Security Act contains a provision that allows an emergency waiver of the Emergency Medical Treatment and Active Labor Act (EMTALA) requirements that hospitals accept certain patients until stabilized. See 42 U.S.C. Section 1320b-5. In order for South Carolina hospitals with an ACS to qualify for these waiver provisions, hospitals should provide documentation from the DHEC Regional Public Health Preparedness Director that the ACS location can be identified as an alternative location for~~

~~the direction or relocation of individuals to receive medical screenings under a State emergency and pandemic preparedness plans.~~

~~3.~~ Once a location has been identified, the Department will meet with ~~hospital~~Facility staff to discuss the details of the ACS. When appropriate, the Department will send ~~the requesting hospital a letter confirming~~written confirmation that the location has been ~~identified~~approved for future use as an ACS. The location will retain its status as an ACS unless modifications are made to the site. Modifications that might affect the use of an ACS include, but are not limited to, renovations, construction, demolition, or change of ownership. Any modifications to the site should be reported in writing to the Department. ~~Because changes to a site could affect its use as an ACS, hospitals are encouraged to construe the term "modifications" broadly.~~

C. ~~Alternate Care Sites can only be operated during emergency situations and activation must be coordinated with the Department. To activate an ACS, the hospital's census must be projected to surge beyond its Internal Medical Surge capacity or the hospital's main building, or a portion of the building, must be rendered unusable.~~

~~D. A facility desiring to activate External Medical Surge and activate an~~Prior to activating an Alternate Care Site~~, due to an emergency situation~~the Facility shall do the following:

1. ~~Request that the Department concur that an emergency situation does exist.~~Have prior approval of the ACS from the Department as described in Section 903.B; and

2. ~~As part of the activation process, the hospital shall be prepared to~~Provide the following information to the Department:

a. Describe the emergency situation;

b. Explain why activating Internal Medical Surge will not address the situation;

c. Identify the ACS;

d. Outline the maximum number of patients to be treated at the ACS; and

e. Provide an anticipated date for discontinuance of the ACS.

~~E. Immediately following activation with the Department, the hospital~~Facility ~~shall notify the DHEC Regional Emergency Point of Contact for possible coordination of activities under State emergency, pandemic preparedness, or mass casualty response plans.~~

~~F~~D. After the emergency situation is over, the ~~hospital~~Facility must notify the Department in writing when the ACS is ~~closed~~being deactivated.

~~G~~E. Other issues such as staffing, food service, equipment requirements, medication management, medical records, and physicians' orders ~~should~~shall be resolved ~~ahead of time~~prior to activation by memorandum of agreements, internal policies and procedures, and emergency planning documents.

904. Emergency Call Data. (I)

Emergency call information shall be immediately available to personnel ~~in charge~~ on each unit when needed. Emergency call data shall include at least the following information:

A. Non emergency telephone numbers of fire and police departments;

B. Name, address, and telephone number of all personnel to be called in case of fire or emergency;

C. Name, address, and telephone number of physician on call;

D. Name, address, and telephone number of supervisory personnel when on call; and

E. Address and telephone number of a poison control center.

~~**905. Security.**~~

~~In order to assure the safety and well-being of all patients, staff, and visitors, the administration shall conduct an annual risk assessment to identify potential areas or situations that may cause harm or where an incident may occur. Based upon the findings of that assessment, the administration shall develop and implement a plan to provide for the appropriate level of security necessary.~~

SECTION 1000
ACCOMMODATIONS FOR PATIENTS (II)

1001. Maximum Number of Beds.

A. No facility shall have set up or in use at any time more beds than the number stated on the face of the license except in cases of justified emergencies. The following categories of beds are not chargeable to the licensed number:

1. Labor room;

2. Newborn nursery;

3. Recovery room;

4. Emergency room treatment;

5. Classroom use only.

B. Neonatal special care beds will be shown on the face of the license in addition to the licensed bed capacity.

C. The Facility shall have the capability to set up the number of beds stated on the face of its license.

1002. Location of Beds.

A. In semi-private and multi-bed rooms there shall be curtains or other means of providing privacy that completely shield the patient.

B. Beds, gurneys, recliners, chairs or other similar furniture shall not be placed in corridors, solaria or other locations not designed as patient room areas except in cases of justified emergencies.

SECTION 1100

MEDICAL RECORDS (II)

1101. Physician's Responsibility.

It shall be the responsibility of each physician to complete and authenticate the medical record within a stipulated time after discharge, not to exceed 30 days after discharge.

1102. Organization.

The responsibility for supervision, filing, indexing, maintenance and storage of medical records shall be assigned to a responsible employee of the hospital who has had training in this field.

1103. Indexing.

Medical records shall be properly indexed, organized, filed and ready for access by members of the staff.

1104. Ownership.

Medical records of patients are the property of the organization and must not be released from the hospital's authority or control except by court order.

1105. Contents.

A. Each entry in the medical records must be legible, dated, timed and signed/authenticated by the clinician or designee that created the entry. A medical record must be created for all patients admitted to the hospital and newborns delivered in the hospital. Initials will be accepted provided such initials can be readily identified within the medical record. A minimum medical record shall include the following information:

1. An admission record must be prepared for each patient and must contain the following information, when obtainable: Name; address, including county; ~~occupation;~~ age; date of birth; sex; marital status; religion; race and ethnicity;~~county of birth; father's name; mother's maiden name; husband's or wife's name; dates of military service;~~ health insurance number; provisional diagnosis; case number; days of care; social security number; ~~the name of the person providing information;~~ name~~, address~~ and telephone number of person or persons to be notified in the event of emergency; name ~~and address~~ of referring physician; name ~~and address and telephone number~~ of attending physician; date and hour of admission;

2. History and physical within 48 hours after admission;

3. Provisional or working diagnosis;

4. Pre-operative diagnosis;

5. Plan of care;

6. Complete surgical record, if any, including technique of operation and findings, statement of tissue and organs removed and post-operative diagnosis;

7. Report of anesthesia;

8. Nurses' notes;

9. Progress notes;

10. Gross pathological findings and microscopic, if applicable;

11. Vital signs and other measurements appropriate to patient;

12. Medication Administration Record or similar document for recording of medications, treatments and other pertinent data. This record shall be signed/authenticated after each medication administered or treatment is rendered;

13. Final diagnosis and discharge summary, including date and time of discharge;

14. ~~Date and time of discharge summary;~~

~~15.~~ In case of death, cause and autopsy findings, if autopsy is performed, unless the death becomes subject to review by the coroner's office, and;

1~~6~~5. Special examinations, if any, e.g., consultations, clinical laboratory, x-ray and other examinations.

B. Contingent upon the availability of pertinent information in the perinatal records of the mother, newborn records should include the following:

1. History of hereditary conditions in mother's and/or father's family;

2. First day of the last menstrual period (L.M.P.) and estimated day of confinement (E.D.C.);

3. Mother's blood group and RH type - evidence of sensitization and/or immunization (such as, administration of anti-D hyperimmune globulin);

4. Serological test including dates performed for syphilis, HIV, Rubella, and Hepatitis B, results of any other tests performed during pregnancy (e.g., Group B Strep, Chlamydia, Gonorrhea, Herpes);

5. ~~Number, duration and outcome of previous pregnancies, with dates;~~

~~6.~~ Maternal disease (e.g., diabetes, hypertension, pre-eclampsia, infections);

~~7~~6. Drugs taken during pregnancy, labor and delivery;

~~8~~7. Results of measurements of fetal maturity and well-being (e.g., lung maturity and ultrasonography);

~~9~~8. Duration of ruptured membranes and labor, including length of second stage;

~~10~~9. Method of delivery, including indications for operative or instrumental interference;

~~11~~10. Complications of labor and delivery (e.g., hemorrhage or evidence of fetal distress), including a representative strip of the fetal ECG if recorded;

~~12~~11. Description of placenta at delivery, including number of umbilical vessels;

~~13~~12. Estimated amount and description of amniotic fluid;

~~14~~13. Apgar scores at one and five minutes of age. Description of resuscitations, if required, detailed description of abnormalities and problems occurring from birth until transfer to the special nursery or the referral facility;

~~15~~14. Results and date specimen was collected for neonatal testing to detect inborn metabolic errors and hemoglobinopathies, including PKU, hypothyroidism and various other metabolic disorders. Exception: Parents may object because of religious grounds only, and in writing using a form promulgated by the Department; and

~~16~~15. Results and dates of pulse oximetry screening and/or follow up of evaluation for critical congenital heart defects.

Exception: Parents may object only in writing to the screening for reason pertaining to religious beliefs.

C. When restraints are utilized, there must be an order to include length of time to be used and signed/ authenticated by the legally authorized healthcare provider approving use of restraint or seclusion either at the time they are applied to a patient, or in case of emergency, within 24 hours after they have been applied. Each procedure manual shall contain information and instructions on the specific types of safety precautions that may or may not be used.

1106. Orders for Medication and Treatment.

All medical records shall contain the necessary consent forms for the treatment provided, along with orders for medication and treatment, signed/authenticated and dated by the prescriber or his designee. All orders, including verbal orders, shall be properly recorded in the medical record, dated and signed/authenticated by the prescriber within 30 days.

1107. Storage.

A. Provisions shall be made by the hospital for the storage of medical records in an environment which will prevent unauthorized access and deterioration. The records shall be treated as confidential and shall not be disposed of before 10 years. Records may be destroyed after 10 years provided that:

1. Records of minors must be retained until after the expiration of the period of election following achievement of majority as prescribed by statute; and

2. The hospital retains a register, either electronic or paper based.

B. Facilities that store records in a format other than paper, such as, but not limited to, microfilm, before 10 years have expired must include the entire record.

C. In the event of change of ownership, all medical records shall be transferred to the new owners.

D. Prior to the closing of a hospital for any reason, the facility shall arrange for preservation of records to ensure compliance with these regulations. The facility shall notify the Department, in writing, describing these arrangements.

1108. Information to be Provided to Other Health Care Providers.

In order to contribute to the continuity of quality of care, procedures must be established and implemented to provide discharge summaries and/or other appropriate information to health care providers to whom patients are discharged, transferred or referred.

1109. Maintenance and Disposal.

Records shall be maintained and disposed of as specified in Section 1107.

1110. Access to Medical Records.

Only authorized personnel should have access to medical records and a hospital shall have policies and procedures to assure that a patient's protected health information is private. The patient shall have access to his/her clinical records within a reasonable timeframe and a hospital shall have a process in place to facilitate that access if requested.

SECTION 1200
PATIENT CARE AND SERVICES

1201. ~~Medications.~~ Basic Facility Functions. (I)

A. Pharmaceutical Services.

~~A. Drugs and biologicals must be prepared and administered in accordance with the orders of the legally authorized healthcare provider(s) responsible for the patient's care as specified under the hospital's governing body as it pertains to the care of the patient. All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with approved medical staff policies and procedures.~~The Facility must have pharmaceutical services that meet the needs of the patients. The Facility must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the Facility's organized pharmaceutical service.

1. Pharmacy management and administration. The pharmacy or drug storage area must be administered in accordance with accepted professional principles.

a. A full-time, part-time, or consulting pharmacist must be responsible for developing, supervising, and coordinating all the activities of the pharmacy services.

b. The pharmaceutical service must have an adequate number of personnel to ensure quality pharmaceutical services, including emergency services.

c. Current and accurate records must be kept of the receipt and disposition of all drugs.

2. Delivery of services. In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and State law.

a. All compounding, packaging, and dispensing of drugs and biologicals must be under the supervision of a pharmacist and performed consistent with State and Federal laws.

b. All drugs and biologicals must be kept in a secure area and locked when appropriate.

c. Drugs listed in Schedules II, III, IV, and V of the State and Federal controlled substances laws must be kept locked within a secure area.

d. Only authorized personnel may have access to locked areas.

e. Outdated, discontinued, mislabeled, or otherwise unusable drugs and biologicals shall not be available for patient use and shall be returned to the pharmacy for proper disposition in accordance with good pharmaceutical practice and facility policy.

f. Multi-dose vials shall be labeled with the date and time when opened or the date and time the vial should expire, as defined by facility policy and/or manufacture guidelines, whichever timeframe is shorter.

g. When a pharmacist is not available, drugs and biologicals must be removed from the pharmacy or storage area only by personnel designated in the policies of the medical staff and pharmaceutical service, in accordance with Federal and State law.

h. Drugs and biologicals not specifically prescribed as to time or number of doses must automatically be stopped after a reasonable time that is predetermined by the medical staff.

i. Drug administration errors, adverse drug reactions, and incompatibilities must be immediately reported to the attending physician and, if appropriate, to the hospital's quality assessment and performance improvement program.

j. Abuses and losses of controlled substances must be reported, in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.

k. Information relating to drug interactions and information of drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration must be available to the professional staff.

~~B~~3. Student nurses may only administer medications under the direct supervision of a registered nurse who is the student's instructor and/or preceptor. The medical record must be signed/authenticated by both parties.

~~C~~4. Self-administration of medications by patients may be permitted only when specifically ordered by the legally authorized healthcare provider in writing and the medications have been reviewed by a Registered Pharmacist prior to administration.

~~D~~5. Medication variances and adverse drug reactions shall be reported immediately to the prescriber, supervising nurse and pharmacist, and recorded in the patient's medical record.

B. Radiological Services.

The Facility must maintain, or have available, diagnostic radiologic services. If therapeutic services are also provided, the therapeutic services and diagnostic services must meet professionally approved standards for safety and personnel qualifications.

1. The Facility must maintain, or have available, radiologic services according to needs of the patients.

2. The radiologic services, particularly ionizing radiology procedures, must be free from hazards for patients and personnel.

a. Proper safety precautions must be maintained against radiation hazards. This includes adequate shielding for patients, personnel, and facilities, as well as appropriate storage, use, and disposal of radioactive materials.

b. Periodic inspection of equipment must be made and hazards identified must be promptly corrected.

c. Radiation workers must be checked periodically, by the use of exposure meters or badge tests, for amount of radiation exposure.

d. Radiologic services must be provided only on the order of practitioners with clinical privileges or, consistent with State law, of other practitioners authorized by the medical staff and the governing body to order the services.

3. Personnel must adhere to the following:

a. A qualified full-time, part-time, or consulting radiologist must supervise the ionizing radiology services. For purposes of this section, a radiologist is a doctor of medicine or osteopathy who is qualified by education and experience in radiology.

b. Only personnel designated as qualified by the medical staff may use the radiologic equipment and administer procedures.

4. Records of radiologic services must be maintained.

a. The radiologist or other practitioner who performs radiology services must sign reports of his or her interpretations.

b. The Facility must maintain the following for at least 5 years:

i. Copies of reports and printouts.

ii. Films, scans, and other image records, as appropriate.

~~1202~~C. Laboratory Services. ~~(H)~~

~~A.Organization:~~

~~1. The hospital must have laboratory services available, either on site or through a contractual agreement with a certified laboratory, whose services are provided in accordance with Clinical Laboratory Improvement Amendments (CLIA) requirements and possess a current CLIA certificate.~~

2. The laboratory shall be under the supervision of a laboratory director with training in clinical laboratory procedures.

3. Laboratory personnel shall be qualified by education, training and experience for the type of services rendered.

B. The laboratory shall:

1. Have appropriate and sufficient equipment, instruments, reagents, materials and supplies for the type and volume of testing performed.

2. Ensure the quality of testing through monitoring of analytical performance, quality control, proficiency testing and quality improvement activities and as defined by CLIA regulations.

3. Include safety procedures, engineering controls and personal protective equipment readily available, maintained, inspected and utilized to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.

4. Include records and materials maintained and stored under conditions that ensure proper preservation.

5. Include a procedure manual for the complete collections and handling instructions for all laboratory specimens, and there must be documentation of an annual review.

6. Perform proficiency testing and have written procedures sufficient for the extent and complexity of testing performed in the laboratory.

7. Have a clearly defined policy and procedure outlining ongoing monitoring of analytical performance, including:

a. Number and frequency of controls,

b. Tolerance limits and,

c. Corrective actions based on quality control data.

8. The following clinical laboratory services must be available twenty-four (24) hours a day:

a. Chromosome analysis;

b. Viral Culture; and

c. Emergency laboratory services must be available either on-site or via contractual agreement twenty-four (24) hours per day, seven (7) days a week.

C. The laboratory must be constructed, arranged and maintained to ensure adequate and safe space, ventilation and utilities necessary for all phases of the testing and to minimize contamination.

D. The governing body shall approve the pathologist or physician as physician-in-charge or Medical Director of blood bank and transfusion services.

~~E. Hospitals which provide procurement, storage and transfusion of blood shall have acceptable facilities, including a refrigerator, for whole blood. The temperature shall be maintained at 2 to 6 degrees C. or 36 to 43 degrees F., and no foods may be kept in this refrigerator. Standards of the American Association of Blood Banks, as outlined in the most current edition of Standards for a Blood Transfusion Service, will be used as a guide for licensing purposes.~~

~~F. Records shall be kept on file indicating the receipt and disposition of all blood handled. Care shall be taken to ascertain that blood administered has not exceeded its expiration date, and meets all criteria for safe administration.~~

~~G. The facility shall make arrangements to secure on short notice all necessary supplies of blood, typed, and crossmatched as required, for emergencies.~~

The Facility must maintain, or have available, adequate laboratory services to meet the needs of its patients. The Facility must ensure that all laboratory services are provided in accordance with Clinical Laboratory Improvement Act (CLIA) requirements.

1. The Facility must have laboratory services available, either directly or through a contractual agreement with a CLIA-certified laboratory.

2. Emergency laboratory services must be available 24 hours a day.

3. A written description of services provided must be available to the medical staff.

4. The laboratory must make provision for proper receipt and reporting of tissue specimens.

5. The medical staff and a pathologist must determine which tissue specimens require a macroscopic (gross) examination and which require both macroscopic and microscopic examinations.

6. The Facility must maintain:

a. Records of the source and disposition of all units of blood and blood components for at least 10 years from the date of disposition in a manner that permits prompt retrieval; and

b. A fully funded plan to transfer these records to another Facility or other entity if such Facility ceases operation for any reason.

D. Emergency Services.

1. No person, regardless of his ability to pay or county of residence, may be denied emergency care if a member of the admitting hospital's medical staff or, in the case of a transfer, a member of the accepting hospital's medical staff determines that the person is in need of emergency care.

2. Hospitals that do not offer Obstetrical services shall have readily available in the emergency department a precipitous delivery kit, to include at a minimum: bulb suction syringe, cord clamp, scissors, sterile towels, and emergency telephone numbers for the appropriate Regional Perinatal Center.

3. If the care required for any patient is not available at the hospital, arrangements must be made for transfer to a more appropriate hospital. Prior to the transfer of a patient to another hospital, the receiving hospital shall be notified of the impending transfer.

4. On its initial and renewal licensure applications, each hospital shall classify itself to indicate its capability in providing emergency care. Such classification will be for the hospital's on-campus emergency service and, if applicable, its off-campus emergency service. General Hospitals shall be classified as a Type I, II, or III. Specialized Hospitals shall be classified as a Type I, II, III, or IV. Off-campus emergency services may be the same Type as or a lower-level Type than the hospital's on-campus emergency service (*e.g.*, if a hospital's on-campus emergency service is a Type II, the off-campus emergency service may not be a Type I).

a. Type I means a hospital that offers comprehensive emergency care 24 hours per day, with at least one physician experienced in emergency care on duty in the emergency care area. There is in-hospital physician coverage by members of the medical staff or by senior-level residents for at least medical, surgical, orthopedic, obstetric/gynecologic, pediatric, and anesthesia services. Other specialty consultation is available within approximately 30 minutes.

b. Type II means a hospital that offers emergency care 24 hours per day, with at least one physician experienced in emergency care on duty in the emergency care area. Specialty consultation is available within 30 minutes by members of the medical staff or senior-level residents. The hospital's scope of services includes in-house capabilities for managing physical and related emotion problems, with provision for patient transfer to another organization when needed.

c. Type III means a hospital that offers emergency care 24 hours per day, with at least one physician available to the emergency care area within 30 minutes through a medical staff call roster. Specialty consultation is available by request of the attending medical staff member or by transfer to a designated hospital where definitive care can be provided.

d. Type IV means a hospital that offers reasonable care in determining whether an emergency exists, renders lifesaving first aid, and makes appropriate referral to the nearest organization that is capable of providing needed services. Type IV Hospitals do not represent or hold themselves out to the public as offering emergency care 24 hours per day. The mechanism for providing physician coverage at all times is defined by the medical staff.

5. A hospital licensed in South Carolina may open and operate freestanding emergency services within a 35-mile radius of its hospital campus. This freestanding emergency service shall be an extension of the existing hospital's on-campus emergency service.

6. For Types I, II, and III, the emergency service entrance shall be separated from the main entrance, well-marked and illuminated, easily accessible from the street and sufficiently covered or enclosed to protect ambulance patients from the elements during the unloading process.

7. For Types I, II, and III, the hospital shall post rosters designating medical staff members on duty or on call for primary coverage and specialty consultation in the emergency care area.

8. For Type IV, hospitals shall provide physician and registered nurse coverage 24 hours per day. Nursing and other allied health professionals shall be readily available in the hospital. Staff may have collateral duties elsewhere in the hospital, but must be able to respond when needed without adversely affecting patient care or treatment elsewhere in the hospital. Type IV hospitals shall have trained staff to screen patients, staff, and visitors, to render lifesaving first aid, and transfer to an appropriately licensed facility.

9. Diversion Status – Inability to Deliver Emergency Services.

a. Types I, II, and III hospitals shall develop and implement a diversion policy which describes the process of handling those times when the hospital must temporarily divert ambulances from transporting patients requiring emergency services to the hospital. The policy must include the following: when diversion is authorized to be called; who is authorized to call and discontinue diversion; efforts the hospital will make to minimize the usage of diversion; and how diversion will be monitored and evaluated.

b. Types I, II, and III hospitals shall notify local ambulance providers and/or other appropriate parties when the hospital is temporarily unable to deliver emergency services and is declaring itself on diversion.

10. As part of its quality assessment and performance improvement program, a hospital with a Type I, II, or III emergency service shall on at least an annual basis evaluate its emergency service staffing utilizing appropriate emergency services metrics, which may include door to doctor times, patients leaving without being seen, boarding hours, lengths of stay, and patient experience. The hospital must document the findings and recommendations of its evaluation and, when appropriate, implement measures to improve its emergency services staffing.

~~**1203. Radiology. (II)**~~

~~A.Imaging services shall be under the supervision of a full-time radiologist, consulting radiologist, or a physician experienced in the particular imaging modality and the physician in charge must have the credentials required by facility policies.~~

~~B.Activities of the imaging service may include radio-therapy.~~

~~C.All imaging equipment shall be operated by personnel trained in the use of imaging equipment and knowledgeable of all applicable safety precautions required by the Department. Copies of additional regulations are available from the Department.~~

~~D.A written, signed/authenticated report on each x-ray or diagnostic image and therapy treatment shall be made a part of the patient's record; copies of the report shall be readily accessible in the imaging department. Each request for x-ray or diagnostic image examination shall include a concise statement of the reason for the examination.~~

~~E.The length of time that an x-ray image shall be kept on file shall be determined by the individual hospital. For its own protection, every hospital should consult with its legal counsel before selling or disposing of film.~~

~~F.Patients and employees shall be provided protection from radiation in accordance with current practices outlined by the Department.~~

~~G.Ultrasound and echocardiogram services shall be available within one hour on a twenty four (24) hour basis.~~

~~**1204. Pharmacy Services. (I)**~~

~~A.The pharmaceutical service shall be directed by a registered pharmacist either on a full or part-time basis. The pharmacist directing the pharmaceutical services is responsible to the administration of the~~

hospital for developing, supervising and coordinating all of the activities of the pharmacy department, which should include, but are not limited to, the following:

1. Dispensing medications in such form that will minimize additional preparation before administering to the patient.

2. Monitoring all medication orders to ensure that clinically significant chemical and therapeutic incompatibilities within the patient's drug regimens are reported to the prescribing physician.

3. Providing education programs for the facility's personnel and counseling patients regarding their medications, including their safe use.

4. Providing a method by which medications can be obtained during the absence of a pharmacist in the facility in such a manner that will minimize the potential for medication error and assure control and accountability of any drugs. A pharmacist shall be available on an on-call basis at all times.

5. Assisting in the formulation of prof/essional policies regarding the evaluation, appraisal, selection, procurement, storage, distribution, use, and safety procedures relating to drugs in the facility.

6. Monthly review of drugs and drug records in all locations in which drugs are stored, including, but not limited to, nursing stations, emergency rooms, outpatient departments, operating suites, emergency kits, etc.

B.Each institutional pharmacy shall be directed by a pharmacist, herein after referred to as the pharmacist-in-charge, who is licensed to engage in the practice of pharmacy in this state.

C.The pharmacist-in-charge must be assisted by a sufficient number of licensed pharmacists and registered pharmacy technicians as may be required to competently and safely provide pharmacy services.

D.The pharmacist-in-charge shall maintain and file with the Board of Pharmacy on a form provided by the board, a current list of all pharmacy technicians assisting in the provision of pharmacy services.

1205. Drug Distribution and Control.

The pharmaceutical service shall have written policies and procedures for control and accountability, drug distribution, and assurance of quality of all drugs and biological products throughout the hospital. The pharmacist-in-charge shall provide the current license for the institutional pharmacy from the SC Board of Pharmacy, the individual's professional license, and the professional licenses of all personnel working within the pharmacy upon request of the Departments inspectors. The pharmacist-in-charge of an institutional pharmacy shall establish written policies and procedures to provide for access to drugs by the medical staff whenever a licensed pharmacist is not physically present in an institutional facility by use of night cabinets and/or by access to the pharmacy. A licensed pharmacist must be on call at all times.

A.A record of the stock and distribution of all controlled substances in Schedule II shall be maintained in such a manner that the disposition of any particular item may be readily traced. All such records shall be maintained in compliance with the requirements of the Federal and State Controlled Substances Acts.

B.Records for investigational drugs shall be maintained in the pharmacy in compliance with the Federal Food and Cosmetic Act Regulations.

1206. Physical Facilities and Storage.

~~A.Drug storage on the nursing units shall be reviewed monthly by the pharmacist or a properly trained individual designated by the pharmacist; a record of each review shall be maintained. All floor stocks shall be properly controlled. Medications requiring refrigeration shall be kept in a secured refrigerator used exclusively for medications, or in a secured manner in which medications are separated from other items kept in a refrigerator (e.g. Lock Box). Refrigerators shall be provided with a thermometer accurate to plus or minus 2 degrees F. Documentation of appropriate temperature control is required by manual or electronic means.~~

~~B.Pharmacy practice shall be governed by the SC Board of Pharmacy Practice Act as detailed in the S.C. Code of Laws. If services are provided at more than one location, each location must be permitted by the SC Board of Pharmacy.~~

~~C.Only personnel approved by the hospital administrator or his/her designees shall have access to the pharmacy.~~

~~D.Emergency boxes, kits or (crash) carts shall be sealed and, when not in actual use, stored either in a secured area or under visual control from the nurses' station. The contents of these containers shall be approved by the appropriate committee of the facility. An inventory list of the contents shall be maintained in or on the container.~~

~~1207. Labeling of Medications. (I)~~

~~A.Any medication administered to inpatients shall be identified with its name and strength labeled on the container in which it is provided or on each single unit package. The labeling of medications administered to inpatients shall be in compliance with applicable Federal, State, and local laws and regulations. The labeling information may also be available through electronic means.~~

~~B.Labeling of drugs dispensed to outpatients shall be in compliance with applicable federal, state, and local laws and regulations .~~

~~C.Outdated or discontinued medications shall be returned to the pharmacy for proper disposition in accordance with good pharmaceutical practice and facility policy. Medications that have been subjected to contamination shall not be redispensed.~~

~~D.Unused medications may be turned over to the patient for whom prescribed on discharge only on the written order of the attending physician. Such medications must be returned to the pharmacy to be labeled in accordance with Section 1207.A before release.~~

~~E.~~Medical staff in conjunction with the pharmacist in charge shall establish policy and procedure when certain medications not specifically prescribed as to time or number of doses will be automatically stopped after a time limit set by the medical staff.

~~F.~~Multi-dose vials shall be labeled with the date and time when opened.

~~G.~~Up-to-date reference materials shall be readily available.

~~1208~~E. Central Supply.~~(I)~~

~~A~~1. The department head shall be qualified for the position by education, training and experience as determined by the ~~hospital~~Facility policies and procedures. (II)

~~B~~2. The number of supervisory and other personnel shall be related to the scope of the services provided. (II)

~~C~~3. There shall be written policies and procedures for the decontamination and sterilization activities performed in central supply and elsewhere in the ~~hospital~~Facility. These policies and procedures shall ~~relate, but are not limited to~~address the following:

~~1~~a. The use of sterilization process monitors, including temperature and pressure recordings, and the use and frequency of appropriate chemical indicator and bacteriological spore tests for all sterilizers.

~~2~~b. Designation of the shelf life for each hospital-wrapped and hospital-sterilized medical item and, to the maximum degree possible, for each commercially prepared item, by a specific expiration date that sets a limit on the number of days an item will be considered safe for use. When possible, load control numbers shall be used to designate the sterilization equipment used for each item, including the sterilization date and cycle.

~~D~~4. A recognized method of checking sterilizer performance shall be used. A chemical indicator of some type should be included in the largest package of each load. Biological indicators (live bacterial spores) should be included in all steam and hot air sterilizers at least once per week or more often depending upon the degree of sterilizer usage. Gas sterilizers should employ such indicators on at least a weekly basis and preferably on a daily basis. Further, the gas sterilization of implants, prosthetic devices, etc., should be accompanied by a biological monitor in each load. Monthly checks shall be made to ensure the above, and a written report retained.

~~E~~5. Adequate precautions shall be taken to ensure that sterile supplies and equipment are not mixed with unsterile material. Suitable space shall be provided for keeping equipment and supplies in a clean, convenient and orderly manner.

~~F~~6. All packaged supplies and containers for solutions, drugs, medicated supplies, etc., shall be labeled so as to remain plainly legible before and after sterilization. Labels shall include at least the expiration date of the contents.

~~G~~7. Outdated medical supplies, solutions, etc., shall be returned to central supply for resterilization or disposal.

~~1209~~1202. ~~Surgery~~ Optional Hospital Services. (~~I~~I)

A. Surgical Services.

~~A.The surgical service shall be under the supervision of a member of the active staff of physicians.~~

~~B.The operating rooms must be supervised by a registered nurse or a doctor of medicine or osteopathy.~~

~~C.Licensed practical nurses (LPNs) and surgical technologists (operating room technicians) may serve as "scrub nurses" under the supervision of a registered nurse.~~

~~D.Qualified registered nurses may perform circulating duties in the operating room. In accordance with applicable State laws and approved medical staff policies and procedures, LPNs and surgical technologists may assist in circulatory duties under the supervision of a qualified registered nurse.~~

~~E. Surgical privileges must be delineated for all practitioners performing surgery in accordance with the competencies of each practitioner. The surgical service must maintain a roster of practitioners specifying the surgical privileges of each practitioner.~~

~~F. Hospitals providing surgery should have available consulting physicians to address additional patient needs.~~

If the hospital provides surgical services, the services must be well organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered, the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.

1. The organization of the surgical services must be appropriate to the scope of the services offered.

a. The operating rooms must be supervised by an experienced registered nurse or a doctor of medicine or osteopathy.

b. Licensed practical nurses (LPNs) and surgical technologists (operating room technicians) may serve as "scrub nurses" under the supervision of a registered nurse.

c. Qualified registered nurses may perform circulating duties in the operating room. In accordance with applicable State laws and approved medical staff policies and procedures, LPNs and surgical technologists may assist in circulatory duties under the supervision of a qualified registered nurse who is immediately available to respond to emergencies.

d. Surgical privileges must be delineated for all practitioners performing surgery in accordance with the competencies of each practitioner. The surgical service must maintain a roster of practitioners specifying the surgical privileges of each practitioner.

2. Surgical services must be consistent with needs and resources. Policies governing surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care.

a. Prior to surgery or a procedure requiring anesthesia services and except in the case of emergencies:

i. A medical history and physical examination must be completed and documented no more than 30 days before or 24 hours after admission or registration, and except as provided under Section 1202.A.2.a.iii.

ii. An updated examination of the patient, including any changes in the patient's condition, must be completed and documented within 24 hours after admission or registration when the medical history and physical examination are completed within 30 days before admission or registration, and except as provided under Section 1202.A.2.a.iii.

iii. An assessment of the patient must be completed and documented after registration (in lieu of the requirements of Section 1202.A.2.a.i and -ii) when the patient is receiving specific outpatient surgical or procedural services and when the medical staff has chosen to develop and maintain a policy that identifies specific patients as not requiring a comprehensive medical history and physical examination, or any update to it, prior to specific outpatient surgical or procedural services.

b. A properly executed informed consent form for the operation must be in the patient's chart before surgery, except in emergencies.

c. The following equipment must be available to the operating room suites: call-in-system, cardiac monitor, resuscitator, defibrillator, aspirator, and tracheotomy set.

d. There must be adequate provisions for immediate post-operative care.

e. The operating room register must be complete and up-to-date.

f. An operative report describing techniques, findings, and tissues removed or altered must be written or dictated immediately following surgery and signed by the surgeon.

g. Hospitals shall provide surgical equipment and instruments in good repair and free of potentially harmful microorganisms to assure safe and aseptic treatment. Any indication of contamination shall be immediately called to the attention of the nursing supervisor or the physician in charge of the service.

~~**1210. Facilities.**~~

~~The operating rooms shall be separated from non-sterile areas and shall be located so as not to be used as a passageway between, or subject to contamination from, other parts of the hospital.~~

~~**1211. Equipment. (I)**~~

~~A.Hospitals shall provide surgical equipment and instruments in good repair and free of potentially harmful microorganisms to assure safe and aseptic treatment. Any indication of contamination shall be immediately called to the attention of the nursing supervisor and the physician in charge of the service.~~

~~B.Life support and medical gas equipment shall be readily available and functional.~~

~~1212~~B. Anesthesia Services.~~ (I)~~

~~A. Anesthesia shall be administered according to the South Carolina Code of Laws and the South Carolina Code of State Regulations by:~~

~~1. A qualified anesthesiologist;~~

~~2. A doctor of medicine or osteopathy other than an anesthesiologist;~~

~~3. A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law;~~

~~4. A certified registered nurse anesthetist (CRNA), as defined in S.C. Code Ann. Section 40-33-20(20), is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed; or~~

~~5. An anesthesiologist's assistant, as defined in S.C. Code Ann. Section 40-47-1210(2), who is under the supervision of an anesthesiologist who is immediately available if needed.~~

~~B. The organization of anesthesia services must be appropriate to the scope of the services offered.~~

~~C. Operations under a general anesthetic shall not be performed nor a general anesthetic given until the patient has had a physical examination except in emergency situations. The results of these examinations shall be entered in the patient's record. The history and physical must be readily available in the patient medical record.~~

~~D. Anesthesia apparatus shall be equipped with a device to measure the oxygen concentration of the gas being inhaled by the patient. The device shall emit an audible and/or visual alarm should the proportion of oxygen fall below a safe level.~~

If the hospital furnishes anesthesia services, those services must be provided in a well-organized manner under the direction of a qualified doctor of medicine or osteopathy. The service is responsible for all anesthesia administered in the hospital.

1. The organization of anesthesia services must be appropriate to the scope of the services offered. Anesthesia must be administered only by:

a. A qualified anesthesiologist;

b. A doctor of medicine or osteopathy (other than an anesthesiologist);

c. A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law;

d. A certified registered nurse anesthetist (CRNA) practicing in accordance with the Nurse Practice Act; or

e. An anesthesiologist's assistant, who is under the supervision of an anesthesiologist who is immediately available if needed.

2. Anesthesia services must be consistent with needs and resources. Policies on anesthesia procedures must include the delineation of preanesthesia and postanesthesia responsibilities. The policies must ensure that the following are provided for each patient:

a. A preanesthesia evaluation completed and documented by an individual qualified to administer anesthesia performed within 48 hours prior to surgery or a procedure requiring anesthesia services.

b. An intraoperative anesthesia record.

c. A postanesthesia evaluation completed and documented by an individual qualified to administer anesthesia no later than 48 hours after surgery or a procedure requiring anesthesia services. The postanesthesia evaluation for anesthesia recovery must be completed in accordance with State law and with hospital policies and procedures that have been approved by the medical staff and that reflect current standards of anesthesia care.

C. Nuclear Medicine Services.

If the hospital provides nuclear medicine services, those services must meet the needs of the patients in accordance with acceptable standards of practice.

1. The organization of the nuclear medicine service must be appropriate to the scope and complexity of the services offered.

a. There must be a director who is a doctor of medicine or osteopathy qualified in nuclear medicine.

b. The qualifications, training, functions, and responsibilities of nuclear medicine personnel must be specified by the service director and approved by the medical staff.

2. Radioactive materials must be prepared, labeled, used, transported, stored, and disposed of in accordance with acceptable standards of practice.

a. In-house preparation of radiopharmaceuticals is by, or under the supervision of, an appropriately trained registered pharmacist or a doctor of medicine or osteopathy.

b. There is proper storage and disposal of radioactive material.

c. If laboratory tests are performed in the nuclear medicine service, the service must meet the applicable requirement for laboratory services.

3. Equipment and supplies must be appropriate for the types of nuclear medicine services offered and must be maintained for safe and efficient performance. The equipment must be:

a. Maintained in safe operating condition; and

b. Inspected, tested, and calibrated at least annually by qualified personnel.

4. The hospital must maintain signed and dated reports of nuclear medicine interpretations, consultations, and procedures.

a. The hospital must maintain copies of nuclear medicine reports for at least 5 years.

b. The practitioner approved by the medical staff to interpret diagnostic procedures must sign and date the interpretation of these tests.

c. The hospital must maintain records of the receipt and disposition of radiopharmaceuticals.

d. Nuclear medicine services must be ordered only by a practitioner whose scope of Federal or State licensure and whose defined staff privileges allow such referrals.

~~1213.~~ D. Outpatient Services.~~ (H)~~

~~A.If the hospital provides outpatient services, the services must meet the needs of the patients in accordance with acceptable standards of practice. Outpatient services must be appropriately organized and integrated with inpatient services. The hospital must assign one or more individuals to be responsible for outpatient services and have appropriate professional and nonprofessional personnel available.~~

~~B.If the hospital provides outpatient services, complete records shall be kept on all outpatients and shall be completed immediately after treatment is rendered. These records shall contain sufficient identification data, a description of what was done and/or prescribed for the patient and must be signed or authenticated by the attending physician. When a patient is admitted as an inpatient, all of his outpatient records shall be made a part of his permanent medical record. Records of patients are the property of the facility and must not be taken from the hospital property except by court order. These records shall be maintained and disposed of as specified in Section 1107.~~

~~C. Outpatient Services shall be in a location that is easily accessible for all patients and shall have easy access to all necessary hospital services.~~

If the hospital provides outpatient services, the services must meet the needs of the patients in accordance with acceptable standards of practice.

1. Outpatient services must be appropriately organized and integrated with inpatient services.

2. The hospital must:

a. Assign one or more individuals to be responsible for outpatient services.

b. Have appropriate professional and nonprofessional personnel available where outpatient services are offered, based on the scope and complexity of outpatient services.

3. Outpatient services must be ordered by a practitioner who meets the following conditions:

a. Is responsible for the care of the patient.

b. Is licensed in the State where he or she provides care to the patient.

c. Is acting within his or her scope of practice under State law.

d. Is authorized in accordance with State law and policies adopted by the medical staff, and approved by the governing body, to order the applicable outpatient services. This applies to the following:

i. All practitioners who are appointed to the hospital's medical staff and who have been granted privileges to order the applicable outpatient services.

ii. All practitioners not appointed to the medical staff, but who satisfy the above criteria for authorization by the medical staff and the hospital for ordering the applicable outpatient services for their patients.

~~1214. Emergency Services. (I)~~

~~A.No person, regardless of his ability to pay or county of residence, may be denied emergency care if a member of the admitting hospital's medical staff or, in the case of a transfer, a member of the accepting hospital's medical staff determines that the person is in need of emergency care.~~

~~1. If a patient presents in labor, she should be delivered in the hospital to which she has come if appropriate delivery facilities exist, If she is a "high risk" patient or an adverse outcome is expected for the baby if delivered there, e.g., less than 34 weeks gestation, she should be transported to a hospital with appropriate capabilities unless delivery is imminent or unless the hospital has such capabilities.~~

~~2. Hospitals that do not offer Obstetrical services shall have readily available in the emergency department a precipitous delivery kit, to include at a minimum: bulb suction syringe, cord clamp, scissors, sterile towels, and emergency telephone numbers for the appropriate Regional Perinatal Center.~~

~~3. If the care required for any patient is not available at the facility, arrangements must be made for transfer to a more appropriate facility. Prior to the transfer of a patient to another hospital, the receiving hospital shall be notified of the impending transfer.~~

~~4. In addition to or in lieu of any action taken by the Department affecting the license of any hospital, when it is established that any officer, employee, or member of the hospital medical staff has negligently violated the provisions of this section, the Department may require the hospital to pay a civil penalty of up to ten thousand dollars pursuant to S.C. Code Ann. Section 44-7-260(E) (1976, as amended).~~

~~B. Each hospital shall provide emergency services which include life saving procedures when life is in jeopardy. Policies and procedures governing the acceptance and care of emergency patients shall be established. An appropriate record shall be maintained on each person who presents for emergency services.~~

~~1. Equipment and services shall be provided to render emergency resuscitative and life support procedures pending transfer of the critically ill or injured to other hospitals. A minimum capacity shall be established and equipment provided to perform stabilization procedures.~~

~~2. Basic services, such as radiology or routine laboratory services shall be maintained and personnel available for call.~~

~~3. A licensed physician shall be available and on call at all times. A registered nurse and ancillary personnel trained in emergency procedures shall be on duty within the hospital who are available 24 hours a day subject to call to assist in providing emergency services.~~

~~C.A poison control chart shall be readily available in the emergency room with communications access to a Poison Control Center for consultation.~~

~~D. The emergency service entrance shall be separated from the main entrance, well marked and illuminated, easily accessible from the street and sufficiently covered or enclosed to protect ambulance patients from the elements during the unloading process.~~

~~E. Space for stretchers and wheelchairs should be accessible to the facility and the facility should have the appropriate equipment to transport patients. Stretchers should be sufficiently sturdy to serve as examining tables.~~

~~F. In those instances wherein a specific hospital has been designated to provide emergency services for a political or other subdivision through mutual planning efforts of all the hospitals located in this subdivision, or otherwise determined, such designation obviates the necessity for the remaining hospitals to provide general emergency services.~~

E. Rehabilitation Services.

If the hospital provides rehabilitation, physical therapy, occupational therapy, audiology, or speech pathology services, the services must be organized and staffed to ensure the health and safety of patients.

1. The organization of the service must be appropriate to the scope of the services offered.

a. The director of the services must have the necessary knowledge, experience, and capabilities to properly supervise and administer the services.

b. Physical therapy, occupational therapy, speech-language pathology or audiology services, if provided, must be provided by qualified physical therapists, physical therapist assistants, occupational therapists, occupational therapy assistants, speech-language pathologists, or audiologists.

2. Services must only be provided under the orders of a qualified and licensed practitioner who is responsible for the care of the patient, acting within his or her scope of practice under State law, and who is authorized by the hospital's medical staff to order the services in accordance with hospital policies and procedures and State laws.

a. All rehabilitation services orders must be documented in the patient's medical record.

b. The provision of care and the personnel qualifications must be in accordance with national acceptable standards of practice.

F. Psychiatric Services.

If the hospital provides psychiatric services, the services must be organized and staffed to ensure the health and safety of patients.

1. A physician, preferably a board-certified psychiatrist, shall be designated as physician-in-charge (or chief) of the psychiatric service. A designated physician who is experienced in the practice of psychiatry should be on call at all times.

2. A registered nurse who has had at least two years of training and/or experience in psychiatric nursing shall be responsible for the nursing care of psychiatric patients. At least one registered nurse shall be on duty in each nursing unit at all times.

3. Each patient must receive a psychiatric evaluation that must:

a. Be completed within 60 hours of admission;

b. Include a medical history;

c. Contain a record of mental status;

d. Note the onset of illness and the circumstances leading to admission;

e. Describe attitudes and behavior;

f. Estimate intellectual functioning, memory functioning, and orientation; and

g. Include an inventory of the patient's assets in descriptive, not interpretative, fashion.

4. Treatment plan:

a. Each patient must have an individual comprehensive treatment plan that must be based on an inventory of the patient's strengths and disabilities. The written plan must include:

i. A substantiated diagnosis;

ii. Short-term and long-range goals;

iii. The specific treatment modalities utilized;

iv. The responsibilities of each member of the treatment team; and

v. Adequate documentation to justify the diagnosis and the treatment and rehabilitation activities carried out.

b. The treatment received by the patient must be documented in such a way to assure that all active therapeutic efforts are included.

5. Progress notes for the patient must be documented, in accordance with applicable State scope-of-practice laws and hospital policies, by the following qualified practitioners: Doctor(s) of medicine or osteopathy, or other licensed practitioner(s), who is responsible for the care of the patient; nurse(s) and social worker(s) (or social service staff) involved in the care of the patient; and, when appropriate, others significantly involved in the patient's active treatment modalities. The frequency of progress notes is determined by the condition of the patient but must be recorded at least weekly for the first 2 months and at least once a month thereafter and must contain recommendations for revisions in the treatment plan as indicated, as well as precise assessment of the patient's progress in accordance with the original or revised treatment plan.

6. The record of each patient who has been discharged must have a discharge summary that includes a recapitulation of the patient's hospitalization and recommendations from appropriate services concerning follow-up or aftercare as well as a brief summary of the patient's condition on discharge.

G. Respiratory Care Services.

If the hospital provides respiratory care services, the services must be organized and staffed to ensure the health and safety of patients.

1. The organization of the respiratory care services must be appropriate to the scope and complexity of the services offered.

a. There must be a director of respiratory care services who is a doctor of medicine or osteopathy with the knowledge, experience, and capabilities to supervise and administer the service properly. The director may serve on either a full-time or part-time basis.

b. There must be adequate numbers of respiratory therapists, respiratory therapy technicians, and other personnel who meet the qualifications specified by the medical staff, consistent with State law.

2. Services must be delivered in accordance with medical staff directives.

a. Personnel qualified to perform specific procedures and the amount of supervision required for personnel to carry out specific procedures must be designated in writing.

b. If blood gases or other laboratory tests are performed in the respiratory care unit, the unit must meet the applicable requirements for laboratory services.

c. Services must only be provided under the orders of a qualified and licensed practitioner who is responsible for the care of the patient, acting within his or her scope of practice under State law, and who

is authorized by the hospital's medical staff to order the services in accordance with hospital policies and procedures and State laws.

d. All respiratory care services orders must be documented in the patient's medical record.

~~1215~~H. Inpatient Dialysis Services. ~~(I)~~

If the hospital provides inpatient dialysis services, the services must be organized and staffed to ensure the health and safety of patients.

~~A~~1. Written policies and procedures shall be developed and maintained by the service provider responsible for the service in consultation with other appropriate health professionals and the administration. Procedures shall be approved by the administration and medical staff where such is appropriate.

~~B~~2. Renal Dialysis Service Equipment and Supplies

~~1~~a. Equipment and supplies shall include at least:

~~a~~i. A dialysis machine or equivalent (with appropriate monitoring equipment) for each bed or station.

~~b~~ii. Dialysis equipment appropriate for pediatric patients, if treated.

~~2~~b. Water used for dialysis purposes shall be analyzed for bacteriological quality at least monthly and chemical quality at least quarterly and treated as necessary to maintain a continuous water supply that is biologically and chemically compatible with acceptable dialysis techniques. Water used to prepare a dialysate shall not contain concentrations of elements or organisms in excess of those specified below:

ELEMENTS	LIMIT IN MILLIGRAMS PER LITER
Aluminum	.01
Arsenic	.005
Barium	.100
Cadmium	.001
Calcium	2.0
Chloramines (Tested Daily)	.001
Chlorine (Tested Daily)	.500
Chromium	.014
Copper	.100
Fluorides	.200
Lead	.005
Magnesium	4.0
Mercury	.0002
Nitrates (Nitrogen)	2.0
Potassium	8.0
Selenium	.090
Silver	.005
Sodium	70.0
Sulfates	100.0

ELEMENTS	LIMIT IN MILLIGRAMS PER LITER
Zinc	.100
Bacteria	200 colonies per milliliter

~~3~~c. A written preventive maintenance program for all equipment used in dialysis and related procedures including, but not limited to, all patient monitoring equipment, isolated electrical systems, conductive flooring, patient ground systems, and medical gas systems shall be developed and implemented. This equipment shall be checked and/or tested at such intervals to ensure proper operation and a state of good repair. After repairs and/or alterations are made to any equipment or system, the equipment or system shall be thoroughly tested for proper operation before returning it to service. Records shall be maintained on each piece of equipment to indicate its history of testing and maintenance.

~~**1216. Dental Surgery. (II)**~~

~~In a hospital providing dental services, the services shall be performed by a qualified practitioner of dentistry who shall be a member of the medical staff.~~

~~**1217. Physical Therapy. (II)**~~

~~If offered as a service of the hospital, physical therapy shall be on orders of a physician and administered by or under supervision of a registered physical therapist. Adequate space and equipment shall be provided.~~

~~**1218. Occupational Therapy. (II)**~~

~~If offered as a service of the hospital, occupational therapy shall be on orders of a physician and administered by or under supervision of an occupational therapist. Adequate space and equipment shall be provided.~~

~~**1219. Psychiatric Services. (II)**~~

~~A.A physician, preferably a board-certified psychiatrist, should be designated as physician-in-charge (or chief) of the psychiatric service. A designated physician who is experienced in the practice of psychiatry should be on call at all times.~~

~~B.A registered nurse who has had at least two years training and/or experience in psychiatric nursing shall be responsible for the nursing care of psychiatric patients. At least one registered nurse shall be on duty in each nursing unit at all times.~~

~~1220~~I. Chemical and Substance Abuse Treatment Services. ~~(II)~~

If the hospital provides chemical and substance abuse treatment services, the services must be organized and staffed to ensure the health and safety of patients.

~~A~~1. A physician, who is experienced in the treatment of chemical and substance abuse, shall be designated as physician-in-charge of this service. Such a physician shall also be on call at all times.

~~B~~2. A registered nurse who has had at least two years training and/or experience in chemical and substance abuse care shall be responsible for the nursing care of this service. At least one registered nurse shall be on duty in each nursing unit at all times who has demonstrable training in chemical and substance abuse treatment. Relevant content of this training shall include physical and psychological assessment,

psychopharmacology, basic counseling and intervention techniques, and the role of self-help groups in the recovery process. The training may be received through on-the-job training, specialized workshops, or classroom experience.

~~1221~~J. Pediatrics~~.~~ Services.~~ (H)~~

If the hospital provides pediatric services, the services must be organized and staffed to ensure the health and safety of patients.

~~A~~1. Organization: Pediatric services, if provided, shall be under the supervision of a registered nurse.

~~B~~2. Facilities: Pediatric services shall have separate facilities for the care of children. Facilities and procedures shall be provided for isolation of children having contagious infections or communicable diseases.

~~C~~3. Pediatric Nursery: Pediatric nurseries shall provide at least 40 square feet per bassinet or 80 square feet per crib.

K. Cardiovascular Care Services.

A. Prior to establishing or offering any cardiac catheterization or cardiac surgery services, the hospital must have applied for and be in the process of obtaining accreditation for such services from the American College of Cardiologists, Accreditation for Cardiovascular Excellence, or other nationally recognized accrediting organization approved by the Department. To continue offering such services, a hospital must obtain such accreditation within two years from application unless otherwise approved by the Department. Hospitals must maintain documentation evidencing their application for accreditation and accreditation for such services. If a hospital is denied accreditation or has its accreditation revoked, the hospital must immediately notify the Department in writing, cease offering such services, and cannot resume offering such services for a period of five years from the date of denial or revocation.

B. Hospitals that offer cardiac catheterization services without onsite cardiac surgery shall have written protocols ensuring immediate, efficient, and safe transfer of patients to the nearest hospital with onsite cardiac surgery in the case of an emergency.

SECTION 1300
PERINATAL SERVICES

1301. Newborn Hearing Screening.

A. A facility that averages greater than 100 deliveries a year shall conduct a hearing screening on each newborn prior to discharge. In addition, the facility shall provide educational information about the screening procedure, the importance of the screening and the importance of having a complete audiobiological evaluation after discharge if the need is indicated.

B. If a facility averages fewer than 100 deliveries a year, a hearing screening is not required for each newborn, but the facility shall give the parents of each newborn educational information concerning the hearing screening procedure and the importance of having the screening procedure after discharge.

C. Each facility required to conduct newborn hearing screening shall regularly report the results of the screening to the Department in the required format.

1302. Shaking infant video & infant CPR information for parents and caregivers of newborn infants and adoptive parents.

A. A facility shall provide to the parents of each newborn baby delivered in the facility a video presentation on the dangers associated with shaking infants and young children. The facility shall also make available information on the importance of parents and caregivers learning infant CPR.

B. The facility shall request that the maternity patient, the father, or the primary caregiver view the video. Those persons whom the facility requests to view the video shall sign a document prescribed by the Department of Health and Environmental Control stating that they have been offered an opportunity to view the video.

C. The facility shall only use a video approved by the Director, or his/her designee, of the Department of Health and Environmental Control.

1303. Providing a Safe Haven for Abandoned Babies.

Facilities and outpatient facilities shall:

A. Accept temporary physical custody of an infant not more than sixty (60) days old who is voluntarily left by a person who does not express an intent to return for the infant and the circumstances create a reasonable belief that a person does not intend to return for the infant.

B. Be in full compliance with EMTALA rules and regulations and perform any act necessary to protect the physical health or safety of the infant.

C. Offer the person information concerning the legal effect of leaving the infant by delivering to the person the information brochure supplied by the state DSS. Ask the person to identify any parent other than the person leaving the infant. Attempt to obtain from the person information concerning the infant's background and medical history as specified in the forms provided by DSS and appropriate forms available from facility files.

D. Using the DSS form, an attempt must be made to get information concerning use of controlled substances by the infant's mother and other pertinent health information which might determine medical care required by the infant.

E. If the person does not wish to provide or is unable to provide the information to the facility, the person must be offered the DSS form with a prepaid envelope supplied to the facility by DSS.

F. No later than the close of the first business day, after the date on which the facility takes possession of the infant, the facility must notify DSS that it has taken temporary physical custody of the infant. DSS will have legal custody of the infant upon receipt of this notice and DSS will assume physical custody no later than 24 hours after receiving notice that the infant is ready for discharge.

1304. Paternity – In-Hospital Voluntary Paternity Acknowledgement Program.

A. In accordance with 45 CFR 303, a hospital that provides obstetrical services at a minimum must provide to both the mother and alleged father:

1. Written materials about paternity establishment.

2. Forms as provided by the Department necessary to voluntarily acknowledge.

3. Notice, both orally and in writing of the alternatives to the legal consequences of, and the rights and responsibilities of acknowledging paternity, and

4. The opportunity to speak with staff, either by telephone or in person, who are trained to clarify information and answer questions about paternity establishment.

B. Hospital must forward completed voluntary acknowledgement forms, or copies to the Department Division of Vital Records.

1305. Perinatal Organization.

A. Each hospital providing perinatal services shall request designation as a Level I, II, III, or IV perinatal hospital, or regional perinatal center (RPC) by letter to the Department. Initially, a hospital shall demonstrate capability to comply with requirements of a particular designation by submitting to the Department documentation pertaining to the request for desired designation. For licensure renewals, along with maintaining compliance with the requirements of Section 1306, the hospital shall have birth weight-specific neonatal mortality data readily available for Department review relative to hospitals in the state of the same designation.

B. Each Level I, II, III, and IV hospital shall maintain and document a relationship with its designated RPC for consultation, transport and continuing education. All patients shall be transferred to the appropriate RPC when medically appropriate, if beds are available. This agreement/relationship shall include the ability to share data, as appropriate, related to these functions.

C. Labor and delivery shall occur in a hospital capable of meeting the expected needs of both the mother and the neonate. Ongoing risk assessment shall occur to determine the appropriate level of care.

1306. Designation of Inpatient Perinatal Care Services.

A. Basic Perinatal Center with Well Newborn Nursery (Level I). Level I hospitals shall provide services for normal uncomplicated pregnancies. Level I hospitals shall identify maternity patients requiring transfer to a facility providing the appropriate level of care for the fetus, consult with the RPC on such matters, and offer a basic level of newborn care to infants at low risk. Level I hospitals shall have personnel who provide care for physiologically stable infants born at or beyond 35 weeks of gestation and stabilize ill newborn infants born at less than 35 weeks of gestation until they can be transferred to a facility where the appropriate level of neonatal care is provided. Level I hospitals shall have personnel and equipment available to provide neonatal resuscitation at every delivery and to evaluate and provide routine postnatal care for healthy term newborn infants. Level I hospitals shall have the capability to begin an emergency cesarean delivery within an interval based on timing that best incorporates maternal and fetal risks and benefits. When it is anticipated or determined that these criteria will not be or have not been met, consultation and a plan of care shall be initiated and mutually agreed upon with the RPC and documented in the medical record, immediately after the patient is stabilized. Level I hospitals shall provide care of postpartum conditions and make provisions of accommodations and policies that allow families, including their other children, to be together in the hospital following birth. Appropriate anesthesia, radiology, and laboratory and blood bank services shall be available on a twenty-four (24) hour basis. Management shall include emergency resuscitation and/or stabilization for both maternal and neonatal patients in preparation for transfer/transport for more specialized services. Hospitals at this level shall not provide care or services which are designated only for higher level hospitals, except under unforeseen, emergent circumstances. In this situation, the Department shall be notified within 24 hours.

B. Specialty Perinatal Center with Special Care Nursery (Level II). In addition to complying with all requirements of Section 1306.A, Level II hospitals shall provide services for both normal and selected high-risk obstetrical and neonatal patients. Level II hospital care shall include management of neonates who are at least 32 weeks of gestation with an anticipated birth weight of at least 1500 grams and problems expected to resolve rapidly (neonates not in need of sub-specialty services on an urgent basis). Level II hospitals shall provide care for infants convalescing after intensive care. Level II hospital shall stabilize infants born before 32 weeks of gestation and weigh less than 1500 grams until transfer to a neonatal intensive care facility. Level II hospitals shall have experienced personnel capable of providing continuous positive pressure airway pressure or mechanical ventilation for a brief period (less than 24 hours) or both until the infant's condition improves or the infant can be transferred to a higher-level facility. Level II hospitals shall have equipment (e.g. portable x-ray equipment, blood gas laboratory) and personnel (e.g. physicians, specialized nurses, respiratory therapists, radiology technicians, and laboratory technicians) available at all times to provide ongoing care and address emergencies. Referral to a higher level of care should occur for all infants when needed, for medical or subspecialty intervention. Support personnel shall include respiratory therapists, radiology technicians, laboratory technicians, and a lactation consultant. A board-certified or board-eligible pediatrician shall be in the hospital or on site within 30 minutes, 24 hours a day. There shall be no limit on the duration of Nasopharyngeal Continuous Positive Airway Pressure (NCPAP) or Nasal Prong Continuous Positive Airway Pressure (NPCPAP) when cared for by a neonatologist. The provision of CPAP or mechanical ventilation beyond the immediate stabilization period requires the immediate availability of respiratory therapists with neonatal training (including intubation of premature infants), nursing support with training to identify and respond to complications of ventilation, and the immediate availability of personnel and equipment to evacuate a pneumothorax. Level II hospitals with a board certified or board eligible neonatologist having responsibilities limited to a single center and in house or within 30 minutes of the unit at all times may provide care for patients requiring mechanical ventilation for up to 24 hours. For shared neonatology coverage, a certified Neonatal Nurse Practitioner having responsibilities limited to a single center and in house may provide coverage for that center. Neonates requiring the initiation of mechanical ventilator support beyond 24 hours of age shall be referred to the RPC. Neonates shall not require high-frequency ventilation support. These hospitals shall manage no less than an average of 500 deliveries annually, calculated over the previous three years based on the individual hospital statistics. This calculation shall include the number of maternal transfers made prior to delivery to higher level perinatal hospitals. A Level II hospital shall not admit outborn neonates into its nursery without prior concurrence with the RPC. Level II units shall not transport neonates between hospitals. Hospitals at this level shall not provide care or services which are designated only for higher level hospitals, except under unforeseen, emergent circumstances. In this situation, the Department shall be notified within 24 hours.

C. Subspecialty Perinatal Center with Neonatal Intensive Care Unit (Level III). In addition to complying with all requirements of Sections 1306.A through 1306.B, Level III hospitals shall provide all aspects of perinatal care, including intensive care and a range of continuously available subspecialty consultation as recommended in the most recent edition of the *Guidelines for Perinatal Care* (GPC) by the American Academy of Pediatrics (AAP) and The American College of Obstetricians and Gynecologists. Level III hospitals shall provide care for mothers and infants at less than 32 weeks gestation, estimated fetal weight less than 1500 grams, and anticipated complex medical or surgical conditions for mother or infant that may require sub-specialty services. Level III hospitals shall also provide care for infants born at less than 32 weeks of gestation and weigh less than 1500 grams at birth or have actual or anticipated complex medical or surgical conditions regardless of gestational age. Level III hospital care shall include expertise in neonatology and maternal-fetal medicine. Level III neonatal intensive care units (NICUs) shall include continuously available personnel (neonatologists, neonatal nurses, and respiratory therapists) and equipment available to provide life support as long as needed. Level III facilities shall provide ongoing assisted ventilation for periods longer than 24 hours, which may

include conventional ventilation, high- frequency ventilation, and inhaled nitric oxide. Level III hospitals shall provide services and care for women and fetuses at high risk, both admitted and transferred to the facility. Level III hospitals shall have advanced respiratory support and physiologic monitoring equipment, laboratory and imaging facilities, nutrition and pharmacy support with pediatric expertise, social services, and pastoral care. Pediatric ophthalmology services and an organized program for the monitoring, treatment, and follow-up of retinopathy of prematurity shall also be readily available in Level III hospitals. Level III hospitals shall have the capability to perform advanced imaging with interpretation on an urgent basis, including computed tomography, magnetic resonance imaging, and echocardiography. Level III hospitals shall also have the capability to perform major surgery on site or at a closely related institution. A board-certified or board-eligible neonatologist shall be in the hospital or on site within 30 minutes, 24 hours a day. A board-certified maternal-fetal medicine specialist (perinatologist) shall be available for supervision and consultation, 24 hours a day. Perinatal consultation requirements may be met via telemedicine arrangements with a RPC. In addition to the Level II capabilities, Level III hospitals shall have the staffing and technical capability to manage high-risk obstetric and complex neonatal patients, including neonates requiring prolonged ventilatory support, surgical intervention, or 24-hour availability of multispecialty management. Hospitals with Level III designation shall manage no less than an average of 1500 deliveries annually, calculated over the previous three years, and at least an average of 100 neonate admissions who weigh less than 1500 grams each, require ventilatory support for over twenty-four (24) hours, or require surgery based on individual hospital statistics. This calculation shall include the number of maternal transfers made prior to delivery to higher level perinatal hospitals. The NICU budget shall include support for outcomes measurement, including data collection and membership in a multi-institutional collaborative quality improvement data base. Level III hospitals shall collect data to assess outcomes within their facility and to compare with other hospitals within their level. Hospitals at this level shall not provide additional care or services designated only for RPC's, or perform neonatal transport, except under unforeseen, emergent circumstances. In this situation, the Department shall be notified within 24 hours.

D. Regional Perinatal Center with Neonatal Intensive Care Units (Level III) (RPC). In addition to complying with all requirements of Sections 1306.A through 1306.C, the RPC shall provide consultative, outreach, and support services to Level I, II, and III hospitals in the region. The RPC shall manage no less than an average of 2000 deliveries annually, calculated over the previous three years. Personnel qualified to manage obstetric or neonatal emergencies shall be in-house. A board- certified maternal-fetal medicine specialist (perinatologist) shall be in the hospital or on site within 30 minutes for supervision and consultation, 24 hours a day. The RPC shall participate in residency programs for obstetrics, pediatrics, and/or family practice. Physician-to-physician consultation shall be available 24 hours a day for Level I, II, and III hospitals. Regional Perinatal Centers shall coordinate the development and implementation of professional continuing education to maintain competency and provide education to other facilities within the region, facilitate transport from the perinatal centers to the regional perinatal center and back transport when possible, and collect data on long-term outcomes to evaluate the effectiveness of delivery of perinatal care services and the efficacy of new therapies. The RPC shall provide a perinatal transport system that operates 24 hours a day, seven days a week, and return transports neonates to lower level perinatal hospitals when the neonates' condition and care requirements are within the capability of those hospitals.

E. Complex Neonatal Intensive Care Unit (Level IV). In addition to complying with all requirements of Sections 1306.A through 1306.C, Level IV hospitals shall include additional capabilities and considerable experience in the care of the most complex and critically ill newborn infants and have pediatric medical and surgical specialty consultants available 24 hours a day. Level IV hospitals shall have capability to perform surgical repair of complex congenital or acquired conditions (e.g. Congenital malformations that require cardiopulmonary bypass with or without extracorporeal membrane oxygenation). Level IV hospitals shall maintain a full range of pediatric medical subspecialists, pediatric surgical subspecialists,

and pediatric anesthesiologists at the facility. Not all Level IV hospitals need to act as regional centers. Regional organization of perinatal health care services requires that there be coordination in the development of specialized services, professional continuing education to maintain competency, facilitation of opportunities for transport and return transport, and collection of data on long-term outcomes to evaluate both the effectiveness of delivery of perinatal health care services and the safety and efficacy of new therapies. Level IV hospitals shall collect data to assess outcomes within their facility, and to compare with other hospitals within their level, if applicable.

1307. Personnel.

A. Detailed components of support services and medical, nursing and ancillary staffing for each level shall meet the recommendations outlined in the most recent edition of the *Guidelines for Perinatal Care*.

B. The following medical specialists and subspecialists shall have medical staff credentials and/or written consultative agreements as follows:

1. Level I shall include:

a. Membership: Physician designated as physician-in-charge of obstetric services, physician designated for supervision of newborn care, anesthesia personnel with credentials to administer obstetric anesthesia available within 30 minutes, 24-hours a day, one person capable of initiating neonatal resuscitation available at every delivery.

b. Consultation: Obstetrician, pediatrician, general surgeon.

2. Level II, in addition to Level I requirements, shall include:

a. Membership: General surgeon, pathologist, radiologist, obstetrician, pediatrician, and anesthesiologist;

b. Consultation: Maternal-fetal medicine specialist, neonatologist, and pediatric surgeon.

3. Level III and RPC, in addition to Level II requirements, shall include:

a. Membership: Maternal-fetal medicine specialist or effective consultation with Maternal- Fetal medicine specialist, (available 24 hours a day, 7 days a week) via telemedicine, obstetrician or radiologist with special interest and competence in maternal disease and its complications, pediatric radiologist, anesthesiologist with perinatal training and/or experience; pathologists with special competence in placental, fetal, and neonatal disease, and pediatric surgeon.

b. Urgent Consultation: Pediatric subspecialists including cardiology, neurology, hematology, genetics, endocrinology, nephrology, gastroenterology-nutrition, infectious diseases, pulmonology, immunology, pathology, metabolism and pharmacology. Pediatric surgical subspecialists, to include cardiovascular, neurosurgery, orthopedics, ophthalmology, urology and otolaryngology.

c. For Level III hospitals: Pediatric medical subspecialists, pediatric anesthesiologists, pediatric surgeons, and pediatric ophthalmologists may be at the site or at a closely related institution by prearranged consultative agreement. Prearranged consultative agreements can be performed using, for example, telemedicine technology, or telephone consultation, or both from a distant location.

4. Level IV, in addition to Level III requirements, shall include: Membership and on-site: Maternal-fetal medicine specialist, obstetrician or radiologist with special interest and competence in maternal disease and its complications, pediatric radiologist, anesthesiologist with perinatal training and/or experience; pathologists with special competence in placental, fetal, and neonatal disease, and pediatric surgeon.

1308. Neonatal Intensive Care Nurse Staffing.

Neonatal intensive care nurse staffing is required if any of the following conditions exist:

A. Any advanced support therapy, e.g., extracorporeal membrane oxygenation, nitric oxide, high frequency ventilation, peritoneal dialysis;

B. Acute pre- or post-operative surgical conditions, except for minor surgical procedures such as inguinal hernia repair;

C. Ventilator support (with the exception of do-not-resuscitate situations and chronic ventilator-dependent conditions);

D. Less than 32 weeks of gestation and less than 1500 grams on the first day of life;

E. Chest tubes required;

F. Cardio-pulmonary resuscitation required in the previous 24 hours;

G. Vital signs required every hour or more frequently;

H. Umbilical artery or vein catheterization or three or more intravenous sites required;

I. Pressor agent (excluding initial stabilization) or inotropic support required, e.g., dopamine (doses for renal perfusion maintenance excluded);

J. Complex diagnostic/assessment support required; or

K. Evidence of seizure activity/unstable neurologic status.

1309. General Facility and Care Requirements.

A. Environment, equipment, supplies, and procedures utilized in the care of perinatal patients shall meet the recommendations outlined in the most recent edition of the *Guidelines for Perinatal Care*. The environmental temperature in newborn care areas should be independently adjustable, as to maintain per the GPC.

B. Obstetrical Care: In each hospital providing obstetrical services, written policies and procedures shall be established and implemented through cooperative efforts of the medical and nursing staffs. These policies and procedures shall outline the process, providers, and methods of providing risk-appropriate care to the obstetrical patient, and shall include, but not be limited to:

1. Admission criteria and documentation;

2. Preterm labor;

3. Maternal transfer to another hospital;

4. Induction and augmentation;

5. Analgesia and anesthesia;

6. Labor process;

7. Capability to perform cesarean delivery within 30 minutes of the decision to do so;

8. Immediate neonatal care/resuscitation;

9. Recovery room care; and

10. Postpartum care.

1310. Neonatal Care.

Specific policies and procedures for the care of the neonate shall follow the recommendations outlined in the most recent edition of the GPC.

1311. Neonatal Resuscitation.

A. Personnel, equipment, supplies, and medications as recommended by the most recent edition of the American Heart Association and AAP *Textbook of Neonatal Resuscitation* shall be readily available in every hospital providing perinatal services.

B. In order to meet the potential need for resuscitation of every neonate, at least one person who has a current provider-designation, as defined by completion of the AAP Neonatal Resuscitation Program, shall be on site.

C. Personnel trained and qualified to perform neonatal resuscitation must be immediately available and not responding from an area removed from the delivery or nursery area.

D. Equipment, supplies, and medications for neonatal resuscitation must be immediately available to the delivery and nursery areas at all times.

1312. Inter-hospital Care of the Perinatal Patient (Transport).

A. Each hospital providing perinatal services shall establish and implement a written plan which outlines the process, providers, and methods of providing risk-appropriate stabilization and transport of any high-risk perinatal patient requiring specialized services. This plan shall be updated in conjunction with the designated RPC on an annual basis, and shall include, but not be limited to, procedures outlining:

1. Communication between referring hospitals and the RPC, transport teams and medical control, and perinatal providers and families;

2. Indications for both acute phase and return transport between perinatal hospitals, to include essential contact persons and telephone numbers for referral and transport; and

3. A list of all medical record copies and additional materials to accompany each patient in transport.

B. Equipment, supplies, and procedures used in preparation and support of transport of maternal patients shall be based upon the most recent edition of the GPC. Equipment, supplies, and procedures used in the transport of a neonate shall be based upon the most recent edition of the AAP *Guidelines for Air and Ground Transport of Neonatal and Pediatric Patients*.

1313. Evaluation of Perinatal Care.

A. Review of maternal and neonate mortality and morbidity shall be conducted at least every three months by the medical staff or designated committee, regardless of the size or designation of the perinatal service. A perinatal mortality and morbidity review committee composed of representatives from the pediatric, obstetrical, and nursing staffs, with additional participation from other professionals, depending upon the cases to be reviewed, shall be established at all perinatal centers.

B. In all perinatal centers, selected case reviews shall include, but not be limited to:

1. Analysis of total perinatal mortality with identification of deaths attributable to various categories of complication;

2. Analysis of perinatal morbidity and related factors.

C. Level I and II hospitals shall review all live births or fetal/neonatal deaths in which the neonate weighed at least 350 grams and less than 1500 grams, utilizing the Department's *Very Low Birthweight Self-monitoring Tool*. Each completed self-monitoring DHEC form shall be retained by the facility and a copy made available to the Department as specified in the self-monitoring tool.

D. Each event shall be evaluated for potential opportunities for intervention with the intervention and follow-up described, if applicable. Written minutes of committee meetings shall be maintained and made available to the Department for review.

E. Each Level I, II, and III perinatal center shall annually review and document the findings from these case reviews with its designated RPC. Minutes of these meetings shall be maintained and made available to the Department for review.

SECTION 1400
VITAL STATISTICS

1401. General.

Hospitals must comply fully with the Regulations of the Department relating to vital statistics.

1402. Birth Certificates.

A. For inpatient newborns a licensee shall be responsible for filing a birth certificate for all live births occurring in the licensed facility (see ~~DHEC~~ Regulation 61-19 for definition of live birth). The record should be filed as prescribed within five (5) days of delivery per ~~DHEC~~ Regulation 61-19.

B. A licensee shall be responsible for filing a birth certificate for outpatient newborns brought to the emergency room when a live birth was delivered either at home or en route to the hospital. If the live birth

is delivered by a licensed midwife or other practitioner, the licensee shall not be responsible for filing a birth certificate.

1403. Death Certificates.

Filing of a death certificate shall be in accordance with ~~DHEC~~ Regulation 61-19 and the S.C. Code of Laws.

SECTION 1500
FOOD AND NUTRITION SERVICE (II)

1501. Approval.

All facilities that prepare food on-site shall be approved by the Department, and shall be regulated, inspected, and graded pursuant to ~~DHEC~~ Regulation 61-25.

1502. Services.

All facilities shall provide food and nutrition services to meet the daily nutritional and dietary needs of patients in accordance with written policies and procedures.

1503. Management.

The nutrition services shall be under the direction of a dietitian or qualified food and nutrition manager/director who has a written agreement for consultation services by a dietitian. These services shall be organized with established lines of accountability and clearly defined job assignments. A qualified food and nutrition manager/director shall be a person who:

A. Is a graduate of a dietetic technician training program approved by the American Dietetic Association; or

B. Is a graduate of a course of study meeting the requirements of the American Dietetic Association and approved by the Department; or

C. Is certified by the Certifying Board for Dietary Managers of the Dietary Managers Association and maintains that credential; or

D. Has at least three (3) years of training and experience in meal service supervision and management in military service equivalent in content to the programs described in paragraph A, B, or C above.

1504. Personnel.

A. Dietary services shall be organized with established lines of accountability and clearly defined job assignments for those engaged in food preparation and serving. There shall be trained staff members/volunteers to supervise the preparation and serving of the proper diet to the patients including having sufficient knowledge of food values in order to make appropriate substitutions when necessary.

B. The qualified food and nutrition manager/director shall be responsible for supervising food and nutrition service personnel, the preparation and serving of the food, and the maintenance of proper records. When the qualified food and nutrition service manager/director is not on duty, a responsible person shall be assigned to assume their job responsibilities.

C. Work assignments and duty schedules shall be posted and kept current.

D. No person, infected with or a carrier of a communicable disease, or while having boils, open or infected skin lesions, or an acute respiratory infection, shall work in any area of food preparation and service.

E. Employees shall wear clean garments, maintain a high degree of cleanliness, and conform to hygienic practices while on duty. Individuals engaged in the preparation and service of food shall wear clean hair restraints, e.g., hair nets, hair wraps, hats, that will properly restrain all hair of the face and head and prevent contamination of food and food contact surfaces. They shall wash their hands thoroughly in an approved hand washing lavatory before starting work, after visiting the bathroom and as often as may be necessary to remove soil and contamination.

1505. Diets.

Diets shall be prepared in conformance with orders of a physician or, if permitted by the facility's policies, a dietitian. A current diet manual shall be readily available to attending physicians, food and nutrition service personnel, nursing personnel, and dietitians.

A. Diets shall be prescribed, dated and signed or authenticated by the physician or dietitian.

B. Facilities with patients in need of special or therapeutic diets shall provide for such diets.

C. Notations shall be made in the medical record of diet served, counseling or instructions given, as identified by patient and/or nutritional assessment and patient's tolerance of the diet.

D. Diets shall be planned, written, prepared and served with consultation from a dietitian.

E. Persons responsible for diets shall have sufficient knowledge of food values in order to make substitutions when necessary. All substitutions made on the master menu shall be documented.

F. Nothing in this regulation shall be read or interpreted to prohibit a facility's policies from allowing a dietitian to:

1. Order or prescribe patient diets, including therapeutic diets;

2. Order laboratory tests to monitor the effectiveness of dietary plans and orders; and/or

3. Make subsequent modifications to patient diets based on the results of laboratory tests.

1506. Planning of Menus and Food Supplies.

A. Menus shall be planned and written at least two weeks in advance and dated as served. The current week's menus, including routine and special diets and any substitutions or changes made, shall be posted in one or more conspicuous places in the Food and Nutrition Services area.

B. Records of menus as served shall be filed and maintained for at least 30 days.

C. Food supplies shall be adequate to meet menu and emergency plan requirements.

D. Records of food and supplies purchased shall be kept on file.

1507. Preparation and Serving of Food.

A. Food shall be prepared by methods that conserve the nutritive value, flavor and appearance. The food shall be palatable, properly prepared, and sufficient in quantity and quality to meet the nutritional needs of the patients.

B. A file of tested recipes, adjusted to appropriate yield, shall correspond to items on the posted menus.

C. Food shall be served with special attention given to preparation and prompt serving in order to maintain correct food temperatures in accordance with ~~DHEC~~ Regulation 61-25 and to meet individual needs.

D. Food and Nutrition service personnel will have the responsibility of accompanying the food cart to the patient care area when necessary to complete tray assembly. Facilities with automated food distribution systems in operation are not required to have dietary personnel accompanying the cart. Each facility shall designate who will be responsible for distribution of trays, feeding of patients, and collection of soiled trays.

1508. Dietary and Food Sanitation.

A. Sanitary conditions shall be maintained in all aspects of the storage, preparation and distribution of food.

B. The facility shall be in compliance with local health codes and ~~DHEC~~ Regulation 61-25.

C. Written procedures for cleaning, disinfecting and sanitizing all equipment and work areas shall be developed and followed.

D. Written reports of inspections by state and local health authorities shall be kept on file in the facility with notations made of actions taken by the facility to comply with recommendations.

E. Drugs shall not be stored in the food and nutrition services area or any refrigerator or storage area utilized by the food and nutrition services area.

F. All walk-in refrigerators and freezers must be equipped with opening devices which will permit opening of the door from the inside at all times.

1509. Meal Service.

A minimum of three nutritionally balanced meals in each 24-hour period shall be offered for each patient unless otherwise directed by the patient's physician. Not more than 14 hours shall elapse between the serving of the evening meal and breakfast. As an exception, there may be up to 16 hours between the scheduled serving of the evening meal and breakfast the following day if approved by the patient's attending physician and the patient, and if a nourishing snack is provided after the evening meal.

1510. Ice and Drinking Water.

Ice and water that meets the approval of the Department shall be available and precautions shall be taken to prevent contamination. Ice delivered to patient areas in bulk shall be in nonporous, easily cleanable

covered containers. The ice scoop shall be stored in a sanitary manner with the handle at no time coming in contact with the ice. Clean, sanitary drinking water shall be available and accessible in adequate amounts at all times.

SECTION 1600
MAINTENANCE (II)

An institutional structure, its component parts, facilities, and all equipment shall be kept in good repair and operating condition.

SECTION 1700
HOUSEKEEPING AND REFUSE DISPOSAL (II)

1701. Housekeeping.

A. A facility shall be kept neat and clean. Accumulated waste material must be removed daily or more often if necessary. There must be frequent cleaning of floors, walls, ceilings, woodwork, windows and premises. There must be an effective rodent and insect control program for the facility to prevent infestation. Bath and toilet facilities must be maintained in a clean and sanitary condition at all times. Dry dusting and dry sweeping are prohibited.

B. Upon discharge or transfer of a patient, all bedside equipment shall be cleansed and disinfected. Bed linen shall be removed and mattresses turned; if damaged, replaced. Beds shall be made with fresh linens to maintain them in a clean and sanitary condition for each patient.

C. Employee locker rooms shall be maintained in a clean and sanitary condition.

D. Janitor closets, floors, walls, sinks, mops, mop buckets, and all equipment shall be cleaned daily or more often as needed. A supervisory hospital employee shall make frequent inspections to assure compliance.

E. All storage spaces shall be kept clean, orderly and free of trash, papers, old cloths and empty boxes. In areas provided with a sprinkler system, a minimum vertical distance of 18 inches shall be maintained between the top of stored items and the sprinkler heads.

1702. Refuse Disposal.

A. All garbage and refuse storage shall be in accordance with ~~DHEC~~ Regulation 61-25.

B. All contaminated dressings, pathological, and/or similar waste shall be properly disposed of in accordance with ~~DHEC~~ Regulation 61-105.

C. All radioactive waste shall be disposed of by a method in accordance with ~~DHEC~~ Regulation 61-63.

D. All outside areas, grounds and/or adjacent buildings on the premises shall be maintained neat and clean.

SECTION 1800
INFECTION CONTROL (I)

1801. General.

A. The hospital shall provide a safe and healthy environment that minimizes infection exposure and risk to patients, employees, health care workers, volunteers and visitors. The hospital shall implement and maintain a written, effective, organized, active, hospital-wide program for the surveillance, prevention, control, and investigation of infections, infectious agents and communicable diseases, with the goal of implementing best practices and continuously reducing infections. The infection prevention and control program must be implemented in a manner that minimizes the risk of health care associated infections. The hospital must designate a qualified employee as the hospital's Infection Practitioner, whose function is to administer the infection prevention and control program. The Infection Practitioner must be provided with the resources and assistance necessary to carry out the activities of the infection prevention and control program. Each hospital must assess the time requirement needed for surveillance and infection prevention activities at each of its locations and provide sufficient staffing to meet the organization's assessed needs.

B. Hospital policies and procedures for infection prevention and control shall comply with Federal and State laws and regulations and shall reference guidelines, including but not limited to, the following:

1. Bloodborne Pathogens Standard of the Occupational Safety and Health Act (OSHA) of 1970; 29 CFR 1910 Occupational Safety and Health Standards with emphasis on compliance with 29 CFR 1910-1030 (Bloodborne Pathogens);

2. The Center for Disease Control and Prevention's (CDC) Immunization of Health-Care Workers: Recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Hospital Infection Control Practices Advisory Committee (HICPIC);

3. CDC's Guideline for Hand Hygiene in Health-Care Settings and/or the World Health Organization's Moments of Hand Hygiene Guidelines;

4. CDC's Guidelines for Environmental Infection Control in Health-Care Facilities;

5. CDC's Guideline for Disinfection and Sterilization in Healthcare Facilities;

6. CDC's Guidelines for the Management of Multidrug-Resistant Organisms In Healthcare Settings;

7. ~~DHEC~~ Regulation 61-105;

8. CDC's Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings; and

9. CDC's Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005.

C. The hospital must comply with and demonstrate compliance with this regulation as well as their own policies and procedures.

1802. Infection Control Training.

A. The hospital shall require annual education regarding infection prevention and control for all employees, students, and volunteers who have contact with patients or who handle or potentially handle blood, body fluids, or tissue. If any of these persons work or perform tasks at more than one hospital, the hospital may accept infection prevention and control education received at another hospital or at an

in-person or online seminar to meet this requirement, but only if the education is reported to and documented by the hospital.

B. Infection prevention and control education requirements may be met through in-person or online training, or completion of modules, videos or other training materials designed to convey such education.

C. In addition to general infection prevention education provided during initial orientation, each employee, student, and volunteer who has contact with patients or who handles or potentially handles blood, body fluids or tissue, shall receive infection prevention and control education specific to his/her job classification and work activities to inform him/her about the infection prevention and control policies and procedures of his/her position. Infection prevention and control training should be targeted to the functions of different categories of employees.

1803. Patient/Public Education and Disclosure.

Prior to or upon admission to the hospital as an inpatient or for outpatient surgery, the hospital must provide to patients materials designed to educate the patient and his/her responsible party about the prevention of healthcare associated infections and the public availability of healthcare associated infection reports through the Hospital Infections Disclosure Act, S.C. Code Ann. Section 44-7-2410, et. seq. The hospital must document provision of this information to the patient or responsible party. The hospital is not required to provide the information to the patient or responsible party if he or she is unable or unwilling to receive the information or if there is no responsible party.

1804. Live Animals.

Service animals~~, therapy animals, and personal pets~~ may be permitted in the facility in accordance with the Americans with Disability Act and other applicable state or federal statutes or regulations ~~for strictly limited visitation pursuant to strict hospital policies; however, no non-human primates may be allowed in the hospital. Each hospital must have appropriate policies which require at a minimum that the animal is free of fleas, ticks, and intestinal parasites, has been screened by a veterinarian within the past twelve (12) months prior to entering the facility, has received all required inoculations, is clean and well-groomed, and presents no apparent threat to the health and safety of patients, visitors, employees or others. All animals must be supervised by persons who know the animal and its behavior and can control the animal~~.

1805. Laundry and Linens.

A. Linen includes surgical clothing. An adequate supply of clean, sanitary linen shall be available at all times.

B. The hospital shall have a clean linen storage area and a separate soiled linen storage area. These storage areas shall be used solely for their intended purposes. The soiled linen storage area shall have mechanical ventilation to the outside.

C. In order to prevent contamination of clean linen by dust or other airborne particles or organisms, linen shall be stored and transported in a sanitary manner, i.e., enclosed and covered. Clean linen shall be stored in a dedicated cart, closet, or cabinet which is covered and dedicated only for the use of clean linen. Non-linen items shall not be stored in the same cart as clean linen. Clean non-linen items may be stored in the same closet or cabinet as clean linen, but shall not be stored on the same shelf.

D. The hospital shall have policies addressing the storage, handling, distribution, collection, and reprocessing of linen for the hospital. If the hospital uses an off-site laundry, the hospital must ensure

through contract that the linen is handled and cleaned properly to institutional standards. The hospital will assure that laundry services whether operated by the hospital or contracted will exercise necessary precautions to render all linen to be safe for reuse.

E. The hospital shall have policies for collecting, transporting, and storing all soiled linen. Soiled linen shall be kept in closed or covered containers while being collected, transported or stored and shall be stored separately from clean linen and patient areas. These containers shall be cleaned and disinfected weekly at a minimum and immediately if visibly soiled. Hospitals operating laundries within the buildings accommodating patients shall provide proper insulation to prevent transmission of noises to patient areas. The laundry shall be well ventilated and the general air movement shall be from the cleanest areas to the most contaminated areas.

F. All used linen must be handled as if it is infectious. Used linen shall be placed in durable bags which, by color or terminology, identify the contents as contaminated and must be transported in these closed bags to the soiled linen holding area or laundry. All linen from patients with infectious or communicable diseases shall be placed in durable bags identified "contaminated" and transported in these closed bags to the soiled linen holding area or laundry.

G. Soiled linen shall be neither sorted nor rinsed in patient rooms.

H. Laundry operations shall not be carried out in patient rooms or where food is prepared, served, or stored.

I. Soiled linen area floors shall be cleaned daily. The area shall be cleaned and disinfected weekly at a minimum and more frequently if necessary to control odors and bacteria.

J. If linen chutes are used, the linen shall be enclosed in durable bags, identified, by color or terminology, as contaminated, before placing in the chute. Chutes shall be cleaned monthly.

K. Personnel must wear appropriate protective attire in accordance with the hospitals policies and procedures. Personnel must wash their hands thoroughly after handling soiled linen.

1806. Waste Management.

A. The hospital shall be able to demonstrate that it has a comprehensive waste management program for identification, collection, handling, and management, of all medical waste, including nonhazardous and hazardous pharmaceutical waste.

B. The hospital shall provide for a regular review of its policies and procedures to assure compliance of its waste management practices in comparison with federal EPA and state regulatory requirements.

C. Accumulated waste, including all contaminated sharps, dressings, and/or similar infectious waste, shall be disposed of in compliance with the following standards: Bloodborne Pathogens Standard of the Occupational Safety and Health Act (OSHA) of 1970; related regulations at 29 CFR 1910; the Department's *Guidelines for Prevention and Control of Antibiotic Resistant Organisms in Health Care Settings*; ~~DHEC~~ Regulation 61-105, and other applicable federal, state and local laws and regulations.

D. The hospital shall inform personnel involved in the handling and disposal of potentially infectious waste of health and safety hazards, and ensure that they are trained in appropriate handling and disposal methods.

E. The hospital shall have policies for the use and disposal of sharps. The hospital shall use sharps containers capable of maintaining their impermeability after waste treatment to avoid subsequent physical injuries during final disposal. Disposable syringes with needles, including sterile sharps that are being discarded, scalpel blades, and other sharp items must be placed into puncture-resistant containers located as close as practical to the point of use.

F. Regulated medical wastes awaiting treatment shall be stored in a properly ventilated area inaccessible to vermin. Waste containers that prevent development of noxious odors must be used. If treatment options are not available at the site where the medical waste is generated, the hospital must ensure transport of the regulated medical wastes in closed, impervious containers to the on- site treatment location or to another facility for treatment as appropriate. Regulated medical wastes must be treated by using a method (e.g., steam sterilization, incineration, interment, or an alternative treatment technology) in accordance with local, state and federal laws and regulations.

1807. Water Requirements.

A. The hospital shall establish written policies and procedures to prevent waterborne microbial contamination within the water distribution system.

B. The hospital shall ensure the practice of hand hygiene to prevent the hand transfer of pathogens, and the use of barrier precautions (e.g. gloves) in accordance with established guidelines.

C. The hospital shall eliminate contaminated water or fluid from environmental reservoirs (e.g. in equipment or solutions) wherever possible.

D. The hospital shall not place decorative fountains and fish tanks in patient-care areas. If decorative fountains are used in separate public areas, the hospital shall ensure that they are disinfected in accordance with manufacturer's instructions and safely maintained.

E. The hospital plumbing fixtures which require hot water and which are accessible to patients shall be supplied with water which thermostatically controlled to a temperature of at least 100 degrees F. (37.8 degrees C) and not exceeding 125 degrees F. (51.7 degrees C.) at the fixture.

F. The hospital shall have a written plan to respond to disruptions in water supply. The plan must include a contingency plan to estimate water demands for the entire facility in advance of significant water disruptions (i.e., those expected to result in extensive and heavy microbial or chemical contamination of the potable water), sewage intrusion, or flooding.

G. When a significant water disruption or an emergency occurs, the hospital shall:

1. Adhere to any advisory to boil water issued by the municipal water utility;

2. Alert patients, families, employees, volunteers, students and visitors not to consume water from drinking fountains, ice, or drinks made from municipal tap water, while the advisory is in effect, unless the water has been disinfected;

3. After the advisory is lifted, run faucets and drinking fountains at full flow for greater than 5 minutes, or use high-temperature water flushing or chlorination;

4. All ice and drinks that may have been contaminated must be disposed and storage containers cleaned; and

5. Decontaminate the hot water system as necessary after a disruption in service or a cross-connection with sewer lines has occurred.

H. The hospital shall adhere to Association for the Advancement of Medical Instrumentation (AAMI) standards for quality assurance performance of devices and equipment used to treat, store and distribute water in hemodialysis units and for the preparation of concentrates and dialysate.

I. The hospital shall follow appropriate recommendations to prevent cross connection and other sources of contamination of ice for human consumption, and to prevent contamination of hydrotherapy equipment and medical equipment connected to water systems (e.g. automated endoscope reprocessors).

J. The hospital shall maintain and implement policies and procedures addressing the management of failure of waste water systems.

SECTION 1900
DESIGN, CONSTRUCTION, REPAIRS, ALTERATIONS, AND ~~CONSTRUCTION~~ADDITIONS

1901. General. (II)

~~Every facility~~ The Facility shall be planned, designed, and equipped to provide ~~adequate facilities~~ for and promote the care, safety, and ~~treatment~~well-being of each patient. The Facility design shall be such that all patients shall have access to required services.

1902. Codes and Standards. (II)

~~The design and construction specifications for hospitals shall conform to the most current nationally accepted standards for hospital design set forth in the International Building Code (IBC); International Fire Codes (IFC); International Plumbing Codes (IPC); International Mechanical Codes (IMC); National Fire Protection Association (NFPA) codes – NFPA 10 – Standard for Portable Fire Extinguishers, NFPA 11 – Standard for Low-, Medium-, and High-Expansion Foam, NFPA 12 – Standard on Carbon Dioxide Extinguishing Systems, NFPA 12A – Standard on Halon 1301 Fire Extinguishing Systems, NFPA 13 – Standard for the Installation of Sprinkler Systems, NFPA 13R – Standard for the Installation of Sprinkler Systems in Low-Rise Residential Occupancies, NFPA 14 – Standard for the Installation of Standpipe and Hose Systems, NFPA 15 – Standard for Water Spray Fixed Systems for Fire Protection, NFPA 16 – Standard for the Installation of Foam-Water Sprinkler and Foam-Water Spray Systems, NFPA 17 – Standard for Dry Chemical Extinguishing Systems, NFPA 17A – Standard for Wet Chemical Extinguishing Systems, NFPA 18 – Standard on Wetting Agents, NFPA 20 – Standard for the Installation of Stationary Pumps for Fire Protection, NFPA 22 – Standard for Water Tanks for Private Fire Protection, NFPA 24 – Standard for the Installation of Private Fire Service Mains and Their Appurtenances, NFPA 25 – Standard for the Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems, NFPA 30 – Flammable and Combustible Liquids Code, NFPA 30A – Code for Motor Fuel Dispensing Facilities and Repair Garages, NFPA 52 – Vehicular Gaseous Fuel Systems Code, NFPA 54 – National Fuel Gas Code, NFPA 58 – Liquefied Petroleum Gas Code, NFPA 59 – Utility LP-Gas Plant Code, NFPA 70 – National Electrical Code®, NFPA 72 – National Fire Alarm and Signaling Code, NFPA 96 – Standard for Ventilation Control and Fire Protection of Commercial Cooking Operations, NFPA 99 – Health Care Facilities Code, NFPA 101 – Life Safety Code®, and NFPA 110 – Standard for Emergency and Standby Power Systems; International Code Council (ICC) American National Standards I (ANSI) A117.1 – Accessibility Codes; the *Guidelines for Design and Construction of Health Care Facilities* as published by the Facility Guidelines Institute (FGI); and International Existing Building Code (IEBC).~~

A. Facility design and construction shall comply with provisions of the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal. Further, the design and construction shall comply with the provisions of the Facility Guidelines Institute's (FGI) *Guidelines for Design and Construction of Hospitals* and *Guidelines for Design and Construction of Outpatient Facilities*. When conflict exists for compliance with the FGI *Guidelines* and officially adopted codes or this regulation, the Facility shall comply with the strictest provision.

B. Unless specifically required otherwise by the Department, all facilities shall comply with the codes and regulations applicable at the time of final plan approval by the Department.

1903. Submission of Plans. (II)

A. ~~When construction is contemplated either for new buildings, additions or major alterations or replacement to existing buildings, buildings being licensed for the first time, buildings changing license type, or facilities increasing occupant load/licensed capacity, plans and specifications shall be submitted to the Department for review. Final plans and specifications shall be prepared by an architect and/or engineer registered in South Carolina and shall bear their seals and signatures. Architectural plans shall also bear the seal of a South Carolina registered architectural corporation. These submissions shall be made in at least three stages: schematic, design development, and final. All plans shall be drawn to scale with the title, stage of submission and date shown thereon. Any construction changes from the approved documents shall be approved by the Department. Construction work shall not commence until a plan approval has been received from the Department. During construction the owner shall employ a registered architect and/or engineer for supervision and inspections. The Department shall conduct periodic inspections throughout each project.~~Plans and specifications shall be prepared by an architect and/or engineer registered in South Carolina. Unless directed otherwise by the Department, the architect and/or engineer shall submit plans at the schematic, design development, and final stages. All plans shall be drawn to scale. Any construction changes from the approved documents shall be approved by the Department. Construction work shall not commence until a plan approval has been received from the Department. During construction, the Facility shall employ a registered architect and/or engineer for construction administration. Upon approval of the Department, construction administration may be performed by an entity other than the architect. The Department shall conduct periodic inspections throughout each project.

B. ~~When alterations are contemplated that are new construction, or projects with changes to the physical plant of a licensed facility which has an effect on: the function, use or accessibility of an area; structural integrity; active and passive fire safety systems (including kitchen equipment such as exhaust hoods or equipment required to be under the said hood); door, wall and ceiling system assemblies; exit corridors; Increase the occupant load/licensed capacity; and projects pertaining to any life safety systems, require preliminary drawings and specifications, accompanied by a narrative completely describing the proposed work, shall be submitted to the Department Cosmetic changes utilizing paint, wall covering, floor covering, etc., that are required to have a flame spread rating or other safety criteria shall be documented with copies of the documentation and certifications, kept on file at the facility and made available to the Department.~~ Plans and specifications shall be submitted to the Department for a project that has an effect on:

1. The function of a space;

2. The accessibility to or of an area;

3. The structural integrity of the facility;

4. The active and/or passive fire safety systems (including kitchen equipment such as exhaust hoods or equipment required to be under an exhaust hood);

5. Doors;

6. Walls;

7. Ceiling system assemblies;

8. Exit corridors;

9. Life safety systems; or

10. Increases the occupant load or licensed capacity of the facility.

C. The Facility shall submit ~~A~~all subsequent addenda, change orders, field orders, and documents altering the Department's review ~~must be submitted~~. Any substantial deviation from the accepted documents shall require written notification, review, and approval from the Department.

D. The licensee shall pay the following inspection fees during the construction phase of the project. The plan inspection fee is based on the total estimated cost of the project whether new construction, an addition, or a renovation. The fees are detailed in the table below.

Construction Inspection Fees	
Plan Inspection	
Total Project Cost	**Fee**
< $10,001.00	$750
$10,001 $100,000-	$1,500
$100,001 - $500,000	$2,000
> $500,000	$2,500 plus $100 for each additional $100,000 in project cost
Site Inspection	
50% Inspection	$500
80% Inspection	$500
100% Inspection	$500

E. Cosmetic changes utilizing paint, wall covering, floor covering, etc., that are required to have a flame-spread rating, smoke development, or other safety criteria shall be documented with copies of the documentation and certifications kept on file at the facility and made available to the Department.

F. Any construction work which violates codes or standards will be required to be brought into compliance.

1904. Construction ~~Inspections~~Permits. (II)

~~Construction work which violates codes or standards will be required to be brought into compliance. All projects~~The Facility shall obtain all required permits (i.e., zoning and building) from the locality having jurisdiction for all projects. Construction without proper permitting shall not be inspected by Department.

1905. Patient Rooms.

A. ~~Cubicle curtains with built in curtain tracks shall be provided in all multiple bed rooms which will shield each patient completely. Curtains will be flameproof.~~ The Facility shall ensure that all curtains are flame proof (including cubicle curtains).

B. The Facility shall ensure patient ~~B~~beds ~~must be~~are placed with at least three feet ~~apart~~of clearance on three sides of the bed.

C. The Facility shall ensure ~~A~~at least one private room ~~shall be~~is provided in each nursing unit for purposes of medical isolation, incompatibility, personality conflicts, etc.

1906. Signal System. (II)

A signal system shall be provided for each patient. The system shall consist of a call button for each bed, bath, toilet and treatment/examination room; a light at or over each patient room door visible from the corridor; a control panel in utility rooms, treatment/examination rooms, medication rooms, nurses' lounges and floor kitchens. Indicators and control panels shall employ both an audible and visual signal.

1907. Nurses Station.

The ~~Hospital~~ Facility shall ensure ~~A~~each nurses' station ~~shall~~ serves no~~t~~ more than forty-four (44) beds, unless additional services and facilities are provided. In order for a nurses' station to be permitted to serve more than forty-four (44) beds, the Facility shall provide the Department, in writing, justification ~~must be furnished~~ showing how the additional beds served will not adversely affect the ~~health~~ care provided to each patient.

1908. Utility Rooms.

A. Soiled Utility Room~~:~~. The Facility shall ensure ~~A~~at least one soiled utility room per main/central nurses' station ~~shall be~~is provided, which contains a clinical sink, work counter, hand wash sink, waste receptacle, and soiled linen receptacle. This requirement is not applicable to satellite/remote nurses' stations.

B. Clean Utility Room. The Facility shall ensure ~~A~~at least one clean utility room per main/central nurses' station ~~shall be~~is provided, which contains a counter with hand wash~~ing~~ sink, ~~and~~ space for the storage, and space assembly of supplies for nursing procedures. If the Facility provides individually sealed, one-time-use packaged items for patient care, a hand wash sink is not required. This requirement is not applicable to satellite/remote nurses' stations.

~~Exception: Item B above does not apply to facilities licensed prior to May 1968.~~

C. Nourishment Room. The Facility shall ensure there is at least one nourishment room per main/central nurses' station which contains a counter with hand wash sink, refrigerator, ice machine, space for storage, and space for the assembly of packaged food and drink for patient use. This requirement is not applicable to satellite/remote nurses' stations.

~~**1909. Temperature and Humidity. (II)**~~

~~A.Minimum design temperature of 75 degrees F. (23.9 degrees C.) at winter design conditions and 81 degrees F. maximum summer design conditions shall be provided for all occupied areas not listed below. The systems shall be designed to provide the following temperatures and humidities in the areas noted:~~

~~Area~~	~~Temperature~~		~~Relative Humidity~~	
~~Designation~~	~~F~~	~~C~~	~~Minimum~~	~~Maximum~~
~~Operating Room~~	~~68-75~~	~~20.0-24.0~~	~~20~~	~~60~~
~~Recovery Rooms~~	~~75~~	~~23.9~~	~~30~~	~~60~~
~~Intensive Care Units~~	~~75-80~~	~~23.9-26.7~~	~~30~~	~~60~~

~~B.Perinatal design temperature and humidity shall follow the current edition of *Guidelines for Perinatal Care.*~~

SECTION 2000
FIRE PROTECTION, PREVENTION AND LIFE SAFETY (I)

2001. Alarms.

A. A partial, manual, automatic, supervised fire alarm system shall be provided. The system shall be arranged to transmit an alarm automatically to a third party by an approved method. The alarm system shall notify by audible and visual alarm all areas and floors of the building. The alarm system shall shut down central recirculating systems and outside air units that serve the area(s) of alarm origination as a minimum.

B. There must be a fire alarm pull station in or near each nurses station.

C. All fire, smoke, heat, sprinkler flow, or manual fire alarming devices or systems must be connected to the main fire alarm system and trigger the system when they are activated.

2002. Emergency Generator Service.

A. Facilities shall provide certification that construction and installation of emergency generator service complies with requirements of all adopted State, Federal, or local codes, ordinances, and regulations.

B. An emergency generator shall be provided to deliver emergency electrical service during interruption of the normal electrical service and shall be provided to the distribution system as follows:

1. Exit lights and exit directional signs;

2. Exit access corridor lighting;

3. Lighting of means of egress and staff work areas;

4. Fire detection and alarm systems;

5. In patient care areas;

6. Signal system;

7. Equipment necessary for maintaining telephone service;

8. Elevator service that will reach every patient floor when rooms are located on other than the ground floor;

9. Fire pump;

10. Equipment for heating patient rooms;

11. Public restrooms;

12. Essential mechanical equipment rooms;

13. Battery-operated lighting and a receptacle in the vicinity of the emergency generator;

14. Alarm systems, water flow alarm devices, and alarms required for medical gas systems;

15. Patient records when solely electronically based.

2003. Fire Reports. (II)

The Facility shall immediately notify the Department by email to firewatch@dhec.sc.gov or other email address prescribed by the Department regarding any fire, regardless of size or damage that occurs in the facility, and followed by a complete written report to include fire department reports, if any, to be submitted within a time period determined by the facility, but not to exceed 7 business days.

2004. Fire Safety. (II)

The facility shall comply with the provisions of the codes officially adopted by the South Carolina Building Codes Council, and the South Carolina State Fire Marshal.

2005. Plans and Training for Fires. (II)

A. Each facility shall develop, in coordination with its supporting fire department and/or disaster preparedness agency, suitable written plans for actions to be taken in the event of fires. All employees shall be made familiar with these plans and instructed as to required actions.

B. Each employee shall receive fire protection training.

C. A fire drill shall be conducted for each shift at least quarterly. Records of drills shall be maintained to report the date, time, shift and a description and evaluation of the drill.

D. Drills shall be designed and conducted to:

1. Assure that all personnel are capable of performing assigned tasks or duties;

2. Assure that all personnel know the location, use and how to operate firefighting equipment;

3. Assure that all personnel are thoroughly familiar with the fire plan; and

4. Evaluate the effectiveness of plans and personnel.

2006. Tests and Inspections. (II)

The Facility shall maintain and test all fire protection and suppression systems in accordance with the provisions of the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal applicable to the Facility.

2007. Gases.

The Facility shall take safety precautions against fire and other hazards when oxygen is dispensed, administered, or stored. "No Smoking" signs shall be posted conspicuously, and cylinders shall be properly secured in place.

2008. Furnishings and Equipment. (II)

A. The Facility shall maintain the physical plant free of fire hazards or impediments to fire prevention.

B. The Facility shall not permit portable electric or unvented fuel heaters.

C. The Facility shall require all wastebaskets, window dressings, portable partitions, cubicle curtains, mattresses, and pillows to be noncombustible, inherently flame-resistant, or treated or maintained flame-resistant.

SECTION 2100
PREVENTIVE MAINTENANCE OF LIFE SUPPORT EQUIPMENT

A written preventive maintenance program for all life support equipment including, but not limited to, all patient monitoring equipment, isolated electrical systems, conductive flooring, patient grounding systems, and medical gas systems shall be developed and implemented. This equipment shall be checked and/or tested at such intervals to ~~insure~~ensure proper operation and a state of good repair. After repairs and/or alterations are made to any equipment or system, the equipment or system shall be thoroughly tested for proper operation before returning it to service. Records shall be maintained on each piece of life support equipment to indicate its history of testing and maintenance.

~~***SECTION 2200***~~
~~***GENERAL***~~

~~Conditions which have not been covered in these regulations shall be handled in accordance with the best practices as interpreted by the Department.~~

Fiscal Impact Statement:

Implementation of this regulation will not require additional resources. There is no anticipated additional cost by the Department or state government due to any requirements of this regulation.

Statement of Need and Reasonableness:

DESCRIPTION OF REGULATION: 61-16, *Minimum Standards for Licensing Hospitals and Institutional General Infirmaries*

Purpose: The Department proposes amending R.61-16 to ensure alignment with current state laws and to update and revise definitions, license requirements and fees, staff and training, reporting, disaster management, accommodation for patients, patient care and services, design and construction, fire protection, prevention, and life safety, and policies and procedures.

Legal Authority: 1976 Code Section(s) 44-7-110 through 44-7-340

Plan for Implementation: The amendments will take legal effect upon General Assembly approval and 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 AND EXPECTED BENEFITS:

The amendments are necessary to incorporate changes in state law as well as changes to current practices and standards. The amendments incorporated consistency with statutory requirements, to update and revise definitions, license requirements and fees, staff and training, reporting, disaster management, accommodations for patients, patient care and services, design and construction, fire protection, prevention and life safety, and policies and procedures. Many of the proposed amendments align the licensing standards with the Federal Regulation for coverage with Medicare (see 42 C.F.R. Part 482), which are applicable to a substantial amount of existing facilities. Finally, the proposed amendments relating to fees update the manner and method of fees such that there are more convenient and efficient transactions with the Department.

DETERMINATION OF COSTS AND BENEFITS:

Implementation of these proposed amendments will not require additional resources. There is no anticipated additional cost to the Department or state government due to any inherent requirements of these proposed amendments. There are no anticipated additional costs to the regulated community.

UNCERTAINTIES OF ESTIMATES:

There are no uncertainties associated with the estimations beyond those normally inherent in estimating future costs and benefits.

EFFECT ON ENVIRONMENT AND PUBLIC HEALTH:

The proposed amendments will have no effect on the environment of this State. These regulations contribute to the Department's function of protecting public welfare and promoting safety and wellbeing for patients receiving care and treatment from hospital facilities and institutional general infirmaries.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED:

There is no anticipated detrimental effect on the environment. If the proposed revisions are not implemented, the regulation will be maintained in its current form; the benefits of the proposed amendments herein will not be realized.

Statement of Rationale:

Here below is the Statement of Rationale pursuant to S.C. Code Section 1-23-110(A)(3)(h):

These revised regulations are updated to ensure alignment with current state laws and to update and revise definitions, license requirements and fees, staff and training, reporting, disaster management, accommodations for patients, patient care and services, design and construction, fire protection, prevention and life safety, and policies and procedures.

ATTACHMENT B

SUMMARY OF PUBLIC COMMENTS AND DEPARTMENT RESPONSES

R.61-16, *Minimum Standards for Licensing Hospitals and Institutional General Infirmaries*

As of December 27, 2023, close of the Notice of Proposed Regulation comment period:

Name	Section
HCA Healthcare	General

Comment:

Cardiovascular Services

HCA Healthcare's South Atlantic Division hospitals were surprised that the Department chose not adopt any of the recommendations that it or the SCHA made with respect to cardiovascular services in HCA's August 28, 2023 letter concerning "Public Comments on Regulation 61-16". Specifically, the SCHA and the HCA South Atlantic hospitals asked the Department to include certain standards relative to cardiac catheterization that were included in the South Carolina Health Plan, and to consider language from the state of Florida's licensing regulations with respect to cardiovascular care. Both SCHA and HCA South Atlantic hospitals strongly urge the department to require that cardiac catheterization services, especially interventional catheterization services, remain hospital-based, given the dire consequences if the patient were to experience complications in an outpatient setting.

With respect to open heart surgical services, the SCHA and HCA South Atlantic hospitals recommend incorporating the AHA/ACC/SCAI standards and the current Health Plan definitions, scope of services and standards set forth on pp. 75 - 80 into the licensure regulations. However, with respect to volume requirements for both cardiac catheterization and open-heart procedures, compliance with thresholds should be reviewed on a retrospective basis given the repeal of CON review for these services.

Department Response: Partially adopt. Department staff are hesitant to promulgate regulations reinstating Certificate of Need (CON) standards/criteria for offering cardiovascular care health services as doing so could be inconsistent with the General Assembly's intent in repealing CON for such services. *See* 2023 Act No. 20. However, we recognize both the need to ensure safe cardiovascular care procedures in hospitals and the correlation between volume and outcomes for these services. Accordingly, Department staff propose requiring hospitals offering such services to be accredited by a nationally accredited organization and, under certain circumstances, to have written transfer protocols. *See* Section 1202.K.

Name	Section
SCHA	General

Comment:

Cardiovascular Services

Since May 25, 2023, South Carolina has been without a regulatory scheme to ensure the quality and safety of cardiovascular care. Prior to that date, South Carolina's Certificate of Need ("CON") laws required applicants wishing to provide cardiac catheterizations and open-heart surgery in South Carolina to meet certain quality standards.

Implementing rigorous standards for cardiovascular services in hospital licensure is critical to maintaining safe cardiac care in South Carolina. The 2020 South Carolina Health Plan ("State Health Plan") provides the appropriate standards for the regulation of cardiac care in South Carolina hospitals. See Chapter 8, pp. 65-81. These standards have been thoroughly vetted by various health care policy-making authorities and are familiar to South Carolina's regulated community. SCHA suggests DHEC incorporate the following language into Regulation 61-16 for hospital-based cardiac catheterization and open-heart surgery.

Cardiac Catheterization

SCHA recommends adopting the definitions for cardiac catheterizations contained on pages 65–66 of the State Health Plan. Additionally, SCHA would recommend DHEC incorporate the cardiac catheterization "Scope of Services" section from the State Health Plan into Regulation 61-16. State Health Plan pp. 66-67.

The State Health Plan also contains a set of standards for cardiac catheterization volumes. The higher the volume, the better the care. These standards are set by the American Heart Association, American College of Cardiology, and Society for Cardiovascular Angiography and Interventions ("SCAI").

In the absence of CON, projecting volume standards is no longer necessary. The standards, however, are still an excellent method for evaluating cardiac catheterization programs. SCHA urges DHEC to incorporate those same volume standards into Regulation 61-16 for the evaluation of catheterization procedures and catheterization labs.

The State Health Plan includes specific numbers for various catheterization procedures (e.g., 200 minimum diagnostic catheterizations procedures annually). SCHA suggests DHEC omit the specific numbers and instead refer only to the applicable standards published by the American Heart Association, American College of Cardiology, and SCAI. Doing so prevents a scenario where volumes change but the regulatory process is too slow to adapt. The following language from the State of Florida could serve as a model.

All licensed hospitals that establish adult diagnostic cardiac catheterization laboratory services under section 408.0361, F.S., shall operate in compliance with the most recent guidelines of the American College of Cardiology/American Heart Association regarding the operation of diagnostic cardiac catheterization laboratories. Hospitals are considered to be in compliance with American College of Cardiology/American Heart Association guidelines when they adhere to standards regarding staffing, physician training and experience, operating procedures, equipment, physical plant, and patient selection criteria to ensure patient quality and safety.

See Fla. Admin. Code Ann. R. 59A-3.246.

In addition, SCHA requests that certain cardiac catheterization procedures and catheterization labs remain hospital-based. Specifically, those are percutaneous coronary interventions ("PCIs") and comprehensive catheterization laboratories. According to the American College of Cardiology/American Heart Association/SCAI standards, these services and facilities are best provided and located in hospitals for patient safety reasons. SCHA proposes the same standards apply in Regulation 61-16.

Open Heart Surgery
SCHA makes a similar recommendation for open heart surgery. DHEC should adopt the State Health Plan definitions and scope of services for open heart surgery. State Health Plan pp 75-77. DHEC should also incorporate the applicable standards published by American Heart Association/American College of Cardiology/SCAI for open heart surgery and include all of the standards contained in the State Health Plan on pages 77-80. Just as with cardiac catheterization, however, DHEC should convert the standards from projections to retrospective volume reviews for the service year.

Additional Cardiovascular Care Regulation Needed
We have also included reference to these standards in our comments to Regulation 61-91. Unfortunately, placing standards in Regulation 61-16 alone will not guarantee quality of care for all patients in South Carolina. Without CON, physicians can perform cardiovascular services in ambulatory surgery centers and possibly other locations. SCHA strongly encourages the Department to include the same cardiovascular care standards in 61-16 and 61-91.

Finally, SCHA would encourage DHEC to work with the South Carolina Board of Medical Examiners to modify the office-based surgery rules to include regulation of cardiovascular procedures as well.

Department Response:
Partially adopt. Department staff are hesitant to promulgate regulations reinstating CON standards/criteria for offering health services as doing so could be inconsistent with the General Assembly's intent in repealing CON for such services. *See* 2023 Act No. 20. However, we recognize both the need to ensure safe cardiovascular care procedures in hospitals and the correlation between volume and outcomes for these services. Accordingly, Department staff propose requiring hospitals offering such services to be accredited by a nationally accredited organization and, under certain circumstances, to have written transfer protocols. *See* Section 1202.K.

Regarding SCHA's comment regarding cardiovascular care being performed in non-hospital settings, the Department's authority is limited to establishing standards for the facilities that it licenses and regulates. With that being said, Department staff address the performance of PCIs and establishment of catheterization labs in ASFs in the ASF notice of final regulation (NFR) and comment chart.

Name	Section

Tidelands Health	General

Comment:

Cardiac Catheterization

Given the unique risks associated with cardiac procedures, including catheterization, it is critically important that providers and facilities meet specific competencies and comply with best practices, including minimum procedure volumes. These standards should apply to hospitals, ASFs, mobile providers and others offering cardiac care and be included in the regulations applying to each type of facility.

To that end, Tidelands Health recommends adoption in 61-16 of the cardiac catheterization definitions contained on pages 65-66 of the State Health Plan, as well as the Scope of Services on pages 66-67 of the State Health Plan.

As a general guide for updates and additions to 61-16 related to cardiac catheterization labs, we would recommend using the standards jointly set by the American Heart Association, American College of Cardiology and Society for Cardiovascular Angiography and Interventions ("SCAI") through the SCAI Expert Consensus Statement on Best Practices.

Of particular note, Tidelands Health would recommend DHEC incorporate the applicable catheterization volume standards from the SCAI Expert Consensus Statement on Best Practices into Regulation 61-16. Rather than refer to specific numbers as currently reflected in the State Health Plan, Tidelands Health suggests DHEC instead refer to the applicable standards published as part of the current version of SCAI's Statement on Best Practices and its successors. Doing so prevents a scenario where standards change but the regulatory process is too slow to adapt. As part of the licensure application, new providers should be required to demonstrate a reasonable expectation that they will be able to meet volume standards once operational. Going forward, they should be held to the standards to maintain licensure.

We believe it is important to limit percutaneous coronary interventions ("PCIs") and comprehensive catheterization laboratories to acute care hospitals, which the American College of Cardiology/American Heart Association/SCAI agree are best provided in hospitals for patient safety reasons.

Also for patient safety reasons, we would recommend that any hospitals without cardiac surgery capabilities be required to have documented transfer protocols and agreements with at least one hospital that offers cardiac surgery. In case of complications, timely access to a cardiac surgery program can be crucial.

Department Response:

Partially adopt suggestions regarding inclusion of licensing standards for cardiac catheterization. As noted, Department staff are hesitant to promulgate regulations reinstating CON standards/criteria for offering health services as doing so could be inconsistent with the General Assembly's intent in repealing CON for such services. *See* 2023 Act No. 20. However, we recognize both the need to ensure safe cardiovascular care procedures in hospitals and the correlation between volume and outcomes for these services. Accordingly, Department staff propose requiring hospitals offering such services to be accredited by a

nationally accredited organization and, under certain circumstances, to have written transfer protocols. *See* Section 1202.K.

Regarding Tidelands' comment that PCIs and catheterization labs should only be in acute care hospitals, the Department's authority is limited to establishing standards for the facilities that it licenses and regulates. With that being said, Department staff address the performance of PCIs and establishment of catheterization labs in ASFs in the ASF NFR and comment chart.

Partially adopt Tidelands' comment to require hospitals without cardiac surgery capabilities to have transfer protocols and agreements with at least one hospital that offers cardiac surgery. Department staff propose requiring hospitals offering cardiac catheterization services without onsite cardiac surgery to have written protocols to transfer to the nearest hospital with onsite cardiac surgery. *See* Section 1202.K.

Name	Section
MUSC	General

Comment:

Cardiovascular Care

MUSC generally supports the S.C. Hospital Association's proposal to codify certain CON standards for cardiovascular care contained in the 2020 South Carolina Health Plan in Regulation 61-16. MUSC agrees with SCHA that this approach most appropriately maintains the clinical and quality standards currently governing cardiac catheterization services and open heart surgery.

MUSC further generally supports SCHA's request for DHEC to evaluate its licensing regulations to ensure that certain cardiac catheterization procedures can be performed safely in a non-hospital setting. MUSC strongly agrees that DHEC must review and amend Regulation 61-91 to incorporate rigorous cardiac catheterization standards in its ASC licensing regulation. With respect to Regulation 61-108 (Licensing Standards for Freestanding and Mobile Technology), MUSC notes that according to DHEC's website, there are no providers or facilities currently licensed under this regulation; therefore, MUSC recommends that DHEC repeal Regulation 61-108 in its entirety.

Finally, there is a relatively small number of pediatric patients in need of open heart surgery in South Carolina, and such care must be provided in centralized, high-volume settings to maximize the specialized resources needed for such care and to maintain the highest level of quality for these critically ill patients. MUSC proposes that, in addition to the general 2020 Health Plan CON standards applicable to pediatric cardiovascular care, DHEC incorporate into Regulation 61-16 the requirement that a pediatric open heart surgery program can only be licensed and operated in a hospital that is licensed as a Level IV neonatal intensive care unit (NICU).

Department Response:

Partially adopt. Department staff are hesitant to promulgate regulations reinstating CON standards/criteria for offering health services as doing so could be inconsistent with the General Assembly's intent in repealing CON for such services. *See* 2023 Act No. 20.

However, we recognize both the need to ensure safe cardiovascular care procedures in hospitals and the correlation between volume and outcomes for these services. Accordingly, Department staff propose requiring hospitals offering such services to be accredited by a nationally accredited organization and, under certain circumstances, to have written transfer protocols. *See* Section 1202.K.

Regarding MUSC's comment regarding cardiac catheterization procedures being performed in non-hospital settings, the Department's authority is limited to establishing standards for the facilities that it licenses and regulates. With that being said, Department staff address the performance cardiac procedures in ASFs in the ASF NFR and comment chart.

Not adopt MUSC's comments regarding adoption of the State Health Plan CON standards applicable to pediatric open heart surgery and require that such procedures be performed in only hospitals that are designated as a Level IV NICU. As noted above, Department staff have proposed requiring accreditation for hospitals offering certain cardiovascular care services.

Name	Section
MUSC	General

Comment:

Burn Units

MUSC proposes that DHEC take this opportunity to expressly require, as a condition of hospital licensure, that any hospital operating a burn unit must meet the following minimum requirements:

(i) the unit may only be operated on the main hospital campus

(ii) the hospital must comply with the most recent published "Guidelines for the Operation of Burn Centers," in Resources for Optimal Care of the Injured Patient, by the Committee on Trauma, American College of Surgeons that include the following elements:

a. Staffing
b. Physician training and experience
c. Operating procedures
d. Equipment
e. Physical plan
f. Patient selection criteria

(iii) the unit must achieve American Burn Association accreditation within 5 years; failure to achieve accreditation will result in immediate revocation of that component of hospital's license to operate a designated burn unit

Department Response: Not adopt. At this time, Department staff determined the addition of standards specific to burn units is unnecessary to ensure the safe and adequate treatment of persons served in South Carolina hospitals.

Name	Section
MUSC	General

Comment:

Transplant Programs

Transplant surgery is one of the highest and most complex levels of care that a hospital provides, requiring a comprehensive programmatic system and network of integrated specialists and sub-specialists. The bulk of the medical literature firmly supports the correlation between high volume programs and better outcomes, i.e., decreased mortality and morbidity. MUSC has dedicated significant resources to its organ transplantation program, which most recently expanded from its home base of Charleston to MUSC Health Lancaster Medical Center to provide greater access to transplant care for patients from across the state and beyond. The results of such dedicated resources include excellent surgical outcomes, concentration of clinical expertise, development of a multi-disciplinary approach to patient care, and maintenance of a highly specialized program for the smallest of pediatric transplant surgery patients.

MUSC strongly believes that DHEC must take this opportunity to license organ-specific transplantation programs and incorporate certain volume requirements for hospitals to achieve and maintain in order to offer these services to their patients. MUSC has looked to other states for guidance on this issue, such as Florida which has established specific staffing, equipment, support services, and volume requirements for organ transplantation programs. After careful evaluation and consideration of requirements already imposed by the United Network for Organ Sharing (UNOS) and CMS, MUSC proposes that DHEC establish program volume requirements for licensure. Because volume requirements should be uniquely tailored to the overall state population and geographic distribution of the limited number of patients in need of organ transplantation, it makes sense to establish minimum volume requirements at the state level.

MUSC proposes that as a condition of initial licensure, a hospital's transplantation program must be certified by CMS and UNOS within eighteen months of opening. In addition, MUSC proposes the following minimum volume requirements for organ transplantation programs:

Organ Type	Year 1	Year 2	Year 3+
Heart	10	20	30
Kidney	15	30	50
Liver	15	30	50
Lung	6	10	15

MUSC strongly recommends that DHEC actively engage in post-licensure enforcement of the above initial licensure requirements, as well as volume requirements, such that a hospital's failure to achieve and maintain these levels of care over an extended period of time will result in the hospital's surrender or DHEC's revocation of the hospital's license to operate that service. MUSC proposes that DHEC's enforcement approach balance factors that may be beyond the hospital's control against the need for hospitals to maintain volumes essential to sustain consistent quality of care.

Department Response: At this time, Department staff determined the addition of standards specific to transplant services is unnecessary to ensure the safe and adequate treatment for persons served in South Carolina hospitals.

Name	Section
MUSC	General

Comment:

NICU Designations

MUSC appreciates DHEC's communication during the October 25, 2023 Stakeholder Engagement Meeting that it intends to take more time, and in a different regulatory amendment cycle, to carefully study and consider input from the regulated community and community-based advocates for high-quality perinatal care to assess the need for revisions to South Carolina's perinatal licensing standards. MUSC further is committed to dedicating resources to any and all workgroups or other bodies formed to assist DHEC in this effort. However, to the extent that others in the regulated community continue to advocate for DHEC to make revisions now, MUSC reiterates its comments submitted in response to the July 28, 2023 Notice of Drafting, which are restated below.

As DHEC is well aware, some South Carolina hospitals have engaged in a decades-long campaign to lower South Carolina's threshold requirements for establishing and operating a Level III neonatal intensive care unit (NICU) in order to operate small, Level III NICU programs. While this campaign has taken many forms over the years – CON litigation, attempted revisions to Regulation 61-16, proposed legislation, revisions to the South Carolina Health Plan standards – MUSC and the regulated perinatal community in South Carolina have vigorously opposed these efforts, and DHEC and the General Assembly have rejected them, because they would result in the dismantling of South Carolina's system of perinatal regionalization. Throughout this ongoing campaign, hundreds if not thousands of pages of materials containing clinical and statistical analyses have been submitted to DHEC in various forms and contexts, and the unavoidable conclusion every time is **there is no new medical literature that would support a dilution of South Carolina's system of perinatal regionalization**.

As DHEC is well aware through both its Bureau of Maternal and Child Health and Bureau of Health Facilities Licensing, for approximately 3 decades, DHEC's hospital licensing requirements reflect this State's endorsement of a regionalized system of perinatal care. This system is designed to concentrate neonatal intensive care of South Carolina's smallest, most gravely ill, and fragile premature babies in a relatively small number of NICUs in our Regional Perinatal Centers. South Carolina regionalizes NICU care because concentrating the care of the relatively small number of premature babies we have in the State in a small number of NICUs allows these NICUs to have higher volumes. We strive for higher volumes in our NICUs because higher volumes help NICU providers (physicians, nurses, and other staff) develop and maintain proficiency. We want higher-volume NICUs with proficient providers because these NICUs have better outcomes. The important corollary here is we do not want lower-volume NICUs with less-proficient providers these NICUs expose premature babies to an increased risks of disability and death.

The national perinatal standards issued by the March of Dimes ("Toward Improving the Outcome of Pregnancy") and the guidelines issued by the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists support regionalized NICU care. DHEC's Healthy Mothers Healthy Babies Plan supports regionalized NICU care. This DHEC

Plan recognizes that perinatal regionalization decreases the risk of neonatal death. This DHEC plan recognizes that NICUs that care for higher volumes of premature babies have on average lower mortality rates than NICUs with low volumes. And this DHEC plan commends our State's system of perinatal regionalization built by DHEC with legislative support.

As set forth above and in separate letters from MUSC's clinical leaders, South Carolina's rationale for maintaining strong perinatal regionalization remains clinically sound. In light of CON repeal, it is even more critically important to ensure that DHEC's licensing regulations preserve this system. Thus, DHEC must maintain an apolitical, clinically driven, and forward-looking approach that rejects the sacrifice of good outcomes and clinical quality in the name of increased "competition." This is because hospitals advocating for a reduction in Level III NICU licensing requirements have made it clear that although they want the benefits of being licensed as a Level III NICU – i.e., increased market share – they do not want to shoulder all of the obligations and burdens.1 This is not the approach that MUSC Health historically has taken. For example, since opening hospitals with Level II programs outside of Perinatal Region V, MUSC Health has fully supported and respected regionalization by consulting with and transferring patients to our hospital's applicable Regional Perinatal Center. In other areas of care where medical advancement supported relaxation of requirements for hospitals to provide certain services, such as Percutaneous Coronary Intervention without open heart backup, MUSC endorsed such revisions to PCI standards even though it did not financially benefit MUSC Health to do so.

MUSC requests that DHEC carefully review and consider the various letters and materials submitted by our clinical leaders in response to the July 28, 2023, Notice of Drafting.

Department Response: Acknowledged.

Name	Section
Prisma	101 and 1201.D

Comment:
SECTION 101. DEFINITIONS / SECTION 1202.D. EMERGENCY SERVICES: As amended, Section 101 of Regulation 61- 16 revises the definitions of "General Hospital" and "Specialized Hospital" to require both to provide on-campus emergency services, and Section 1202.D establishes numerous criteria related to the provision of emergency services and requires that every hospital classify itself, based upon its capability of providing emergency services, on its initial and renewal licensing applications. In that regard, Specialized Hospitals must be classified as either Type I, II, III, or IV, as defined in Section 1202.D.4. Specialized Hospitals have never been required to provide on-campus emergency services, and the proposed amendments far exceed Specialized Hospitals' federal EMTALA obligations without providing any patient benefit or improving access to care.

Pursuant to Section 1202.D.4, Type IV hospitals do "not represent or hold themselves out to the public as offering emergency care 24 hours per day;" yet, the requirements for operating a Type IV hospital essentially equate to the operation of a full-service emergency department ("ED"). As drafted, Type IV hospitals, *inter alia*,

- shall have trained staff to **triage emergency care** for each patient, staff and visitor, to

stabilize the presenting condition, and transfer to an appropriately licensed facility. Type TV hospitals must have **an emergency area which includes a treatment room, storage for supplies and equipment, provisions for reception and control of patients, convenient patient toilet room, and communication hookup and access to a poison control center.**

Presumably, Specialized Hospitals would generally be classified as Type IV.

Specialized Hospitals, subject to EMTALA, are required to screen for emergency conditions, stabilize patients with an emergent condition, and transfer those patients to an appropriate facility. Specialized Hospitals must also accept emergency transfers pursuant to their respective capacity to treat the patient, but federal regulations do not require a Specialized Hospital to maintain what is essentially a mini-ED. In reality, patients in need of emergency care are unlikely to present to a Specialized Hospital for treatment, particularly when the Specialized Hospital does not provide the necessary services and does not hold itself out as providing emergency care. Stated differently, a person with chest pain is unlikely to come to a psychiatric hospital for care, and no emergency medical service will transport them there. In the event a cardiac patient does present to a psychiatric hospital, the hospital will no doubt do everything in its capability to care for that patient pending transfer to an appropriate facility.

The proposed amendments are unnecessary, will substantially increase costs to providers, and will create confusion regarding what is specifically required to meet the conditions imposed,1 but they will do nothing to improve access to patient care. There simply is no reason to require a Specialized Hospital to expend resources to meet unnecessary regulatory requirements to do something it would already do - i.e., take all necessary action to meet the needs of any individual in crisis (whether patient, staff, or visitor) to the best of its ability. For these reasons, Prisma recommends the Department (i) delete the requirement that Specialized Hospitals provide on-campus emergency services in Section 101.E.2, (ii) delete the requirement that Specialized Hospitals be classified by Type in Section 1202.D.4, and (iii) clarify that Specialized Hospitals are not subject to the requirements of a Type TV hospital set forth in Section 1202.D.8.

Department Response: Not adopt proposed deletions/partially adopt amendments to clarify. The statutory definition of "hospital", which is inclusive of both general and specialized hospitals, requires that they "must provide on-campus emergency services." *See* S.C. Code Ann. § 44-7-130(17). Thus, Department staff are unable to delete the requirement that specialized hospitals provide on-campus emergency services. State statute clarifies that no persons may be denied emergency care if a member of the admitting hospital's medical staff or, in the case of a transfer, a member of the accepting hospital's medical staff determined that person is in need of emergency care. *Id.* § 44-7-260(E). Emergency care is further defined as "treatment which is usually and customarily available at the respective hospital and that must be provided immediately to sustain a person's life, to prevent serious permanent disfigurement, or loss or impairment of the function of a bodily member or organ, or to provide for the care of a woman in active labor if the hospital is so equipped and, if the hospital is not so equipped, to provide necessary treatment to allow the woman to trave l to a more appropriate facility without undue risk of serious harm." *Id.*

Prisma contends the proposed amendments are unnecessary, will increase costs, and will create confusion. To the contrary, Department staff have proposed the amendments to clarify and provide certainty. Prisma's contention that specialized hospitals will need to create and maintain mini-EDs is misplaced. If the amendments are approved, Department staff anticipate specialized hospitals will generally classify themselves as Type IV which means they offer reasonable care in determining whether an emergency exists, renders lifesaving first aid, and make appropriate referral to the nearest organization that is capable of providing needed services. *See* R.61-16 § 1201.D.4.d. However, to reduce any confusion or any needed clarification regarding Type IV emergency services, Department staff have proposed amending Section 1201.D.4.d to address Prisma's concerns about staff trained to "triage" and for having an "emergency area." The proposed amendment instead requires having staff trained to screen patients, staff, and visitors, to render lifesaving first aid, and transfer to an appropriate facility. Further, Department staff propose removing the requirement to have an "emergency area."

Name	Section
SCHA	101.E

Comment:
SCHA requests that DHEC add the following definition to this section: "acute hospital care at home shall mean acute-level hospital care to treat a subset of diagnoses that respond safely and effectively to home-based acute care, utilizing technology to provide continuous remote patient monitoring and connectivity to the patient and developing in-home services to ensure the same level of care in the home as in a traditional hospital stay as well as patient safety. Acute hospital care at home must be provided by a hospital licensed pursuant to this regulation to eligible patients who have provided consent to such care, utilizing a multidisciplinary team to deliver the care."

Several hospitals in South Carolina implemented or began to implement hospital at home programs authorized by the United States Centers for Medicare and Medicaid Services ("CMS") during the pandemic. Under the Governor's public health declaration, DHEC allowed hospitals to pursue hospital at home care but upon the expiration of that declaration South Carolina hospitals were unable to continue pursuing hospital at home programs. Studies of hospital at home programs have shown demonstrated benefits in patient outcomes. One such study published in the Annals of Internal Medicine in 2020 showed a significant reduction in readmissions and a marked increase in a patient's physical activity. Other studies have shown a thirty-eight percent lower six-month mortality rate amongst hospital at home patients when compared to hospitalized patients. Attached as Appendix A are several articles highlighting other benefits of hospital at home for patients.

SCHA hopes including a definition for hospital at home care in the licensing regulation will allow those hospitals interested in pursuing such programs the opportunity to do so.

Department Response: Not adopt. The Department lacks statutory authority to license and regulate acute hospital care at home. If a hospital intends to provide this service, it would not be provided under its hospital license. Department staff are monitoring S.858, which would grant the Department authority to regulate and would require promulgation of regulations

addressing the provision of acute hospital care at home care.

Name	Section
Prisma	202

Comment:
SECTION 202. VARIANCE TO LICENSING STANDARDS: As amended, Section 202 strikes the Department's discretion to approve exceptions to the licensing requirements and inserts language to allow the Department to approve variances. Prisma has several concerns related to this proposed amendment.

First, Regulation 61-16 currently allows the Department to grant an exception to a licensing standard if the Department determines that "the health and welfare of the community requires the services of the facility." As amended, there is no articulated standard by which the Department will analyze variance requests. The amended language defines a variance as "an alternative method that ensures the equivalent level of compliance with the standards in the regulations," but arguably there could be many situations in which there is no "equivalent" alternative but the proposed alternative would still allow the hospital to provide services while maintaining patient safety. ln fact, there are likely a number of hospitals currently operating under a licensing exception that would not be considered to meet an "equivalent level of compliance," and many of those facilities likely have been providing services safely for many years.

Also, the amended language provides that "[t]he Department may review issued variances as determined to be appropriate." Currently, Section 202 provides that "[w]hen an 'exception' applies to an existing facility, it will continue to meet the standards in effect at the time it was licensed," but the proposed amendment deletes this language. As amended, will hospitals currently operating under a licensing exception have to request a variance, and if so, what standard would the hospital be required to demonstrate for approval? The fact that the Department could revoke an approved variance at any time, in its sole discretion, is deeply concerning, as providers need to be able to rely upon government approvals once granted. Revocation of variances could have catastrophic effects on providers. At best, a provider might be required to make substantial capital improvements that would otherwise be unnecessary and do nothing to improve patient safety. At worst, a provider might be required to cancel services or close facilities altogether. which could adversely impact access to care, particularly in rural areas.

For these reasons, Prisma requests the Department keep Section 202 of Regulation 61-16 as written, without amendment, or alternatively, clarify that hospitals currently in operation may continue to operate, as is, without requesting or receiving a variance unless the scope of services offered materially changes. In any event, the Department's focus with regard to exceptions/variances should remain on the health and welfare of the community served.

Department Response: Not adopt. Department staff propose amending this section in an effort to have uniformity across the Healthcare Quality regulations with respect to exceptions or variances. The proposed amendment will not otherwise have an impact on currently approved exceptions. The proposed amendment does have a standard by which Department staff will

review variance requests – *i.e.,* whether the alternative method ensures an equivalent level of compliance with regulatory standards. In other words, if the proposed amendment is approved, Department staff will evaluate whether a hospital requesting a variance to a particular regulatory standard has accounted for the health or safety purposes of that standard in some other equivalent manner.

Name	Section
Prisma	401.B

Comment:
SECTION 401.B. POLICIES AND PROCEDURES IN GENERAL: As amended, Section 401.B requires the Chief Executive Officer ("CEO") to review and sign all policies and procedures. This requirement is unnecessary and does not reflect typical, hospital administrative procedures. Typically, any number of hospital vice presidents or administrative officers may be responsible for approving different policies and procedures based upon their respective areas of expertise. For example, many hospital policies involve clinical, patient care. These policies are typically approved by a Chief Nursing Officer ("'CNO'") or other administrative official with a clinical background. Many CEOs lack the requisite knowledge and experience to meaningfully review policies addressing clinical matters. Furthermore, requiring CEOs to approve every hospital policy and procedure would be unduly burdensome and would not be an efficient and effective use of their time or talents. For these reasons, Prisma recommends the Department delete this requirement from Section 401.B.

Department Response: Partially adopt. Department staff propose allowing CEO delegation of review of policies and procedures to his/her designee(s). *See* Section 401.B.

Name	Section
Tidelands Health	401.B

Comment:
Given the volume of policies employed by hospitals, it would be overly burdensome to have each policy review signed by the Chief Executive Officer. As such, we would suggest simply requiring that policy reviews be completed and documented.

Department Response: Partially adopt. Department staff propose allowing CEO delegation of review of policies and procedures to his/her designee(s). *See* Section 401.B.

Name	Section
Prisma	503

Comment:
SECTION 503. CHIEF EXECUTIVE OFFICER: As amended. Section 503 requires a hospital to notify the Department, in writing, within 24 hours, if there has been a change of CEO, to include the name of the new or interim CEO. Prisma recommends the time frame for reporting this information be extended, as the appointment of a new CEO, including an interim or acting CEO, can take time, and a CEO's departure should not immediately impact a hospital's day-to-day operations. A hospital should presumably be able to continue operations under the direction of the Chief Operating Officer or other administrative official in the short-term; thus, there should be no need to emergency report a change in the CEO.

Department Response: Not adopt. Upon a change in leadership, Department staff need to know immediately, but not less than 24 hours, of changes in the person ultimately responsible for the operations of a facility. To clarify, Department staff propose amending to clarify that this person may not be the "newly-appointed or interim CEO", but may be some other person who is responsible for administration of the facility. *See* Section 503.

Name	Section
Prisma	505.B

Comment:
SECTION 505.B. NURSING SERVICES: As amended, Section 505.B requires that a registered nurse be designated, in writing, to act in the absence of the CNO; however, the regulation does not clarify whether this applies to any time the CNO is not in the facility or only when the CNO's employment has been terminated. Prisma recommends the Department clarify this requirement.

Department Response: The regulation requires designation of a registered nurse to act in the absence of the CNO. When and how this person would act is ultimately up to the facility; however, the intent of the provision is to require facility's to designate an registered nurse to act in the CNO's absence, whether that involves resignation or termination of the CNO, the CNO not being present in the facility, or other scenarios. Notably, other than reference to the title "Chief Nursing Officer," this is a not new regulatory provision.

Name	Section
SCHA	604.A

Comment:
This regulation requires volunteer workers in hospital to receive a physical examination prior to providing any patient care activity. SCHA proposes amending this regulation to eliminate the physical exam requirement for volunteers if the volunteer's only patient care activity is providing vaccinations.

Administering vaccines has a relatively low physical impact on the vaccinator, and COVID-19 illuminated the severe constraints of a pandemic on the health care workforce. Given the importance of getting volunteers in the field quickly, SCHA respectfully requests this regulation be amended to remove the physical examination requirement for volunteers who only assist with vaccine administration. Additionally, SCHA would request DHEC consider a suspension of the volunteer physical requirement in its entirety during either a declared public health emergency or a declared state of emergency in South Carolina. Doing so would make it easier to bring volunteers in to assist South Carolinians in need.

Department Response: Adopt comment regarding elimination of the physical examination requirement for volunteers only providing vaccinations. *See* Section 604.A.

Further, the Department will consider suspension of the physical examination requirement in its entirety should there be a declared public health emergency or a declared state of emergency.

Name	Section

Prisma	701

Comment:
SECTION 701. INCIDENT REPORTS: As amended. Section 701 reduces the time a facility must make an initial incident report from 10 days to within 24 hours of the incident and increases the list of conditions for which facilities must submit mandatory reports. Prisma has several significant concerns related to this proposed amendment.

First, the proposed reduction of time for making an initial incident report from 10 days to 24 hours is unduly burdensome and poses unreasonable requirements. This is particularly true in an acute care setting where the departments responsible for the internal management of regulatory reporting do not work seven days per week. Staff report any event they believe to deviate from the standard of care, but not every event witnessed by staff requires an agency report. It takes time for management to review and investigate events to determine whether a report is required and, if so, to which agency. Thus, even if the involved departments were staffed 24 hours a day, seven days week at regulated facilities, the 24-hour deadline for completing initial report is an untenable timeline.

Additionally, the proposed expanded list of conditions requiring mandatory reports within 24 hours makes compliance for large healthcare systems unduly burdensome and the Department's enforcement impracticable. For example, reporting stage 3, 4, or unstageable pressure ulcers within a 24-hour period of development imposes a significant burden upon healthcare providers. As the largest healthcare system in the State of South Carolina, Prisma Health is uniquely situated to speak to this burden with objective data. Based upon anecdotal information that Prisma was submitting a significantly higher number of incident reports than other facilities in its markets, Prisma submitted a FOIA request to the Department in 2023 for the number of reports submitted by similar facilities within each of its markets for a six-month period of time. Prisma was informed through communications with its colleagues in the hospital community that although Prisma was voluntarily reporting stage 3, 4, or unstageable pressure ulcers, which are considered a "never event" by the National Quality Forum (“"NQF"), other facilities were not. Consequently, Prisma was submitting roughly 10 times the number of incident reports as other facilities in its markets. Thus, Prisma has firsthand knowledge of the burden created by requiring hospitals to report stage 3, 4, and unstageable ulcers, particularly within a 24-hour period. Prisma is very concerned about the practical impact mandating these reports will have for all providers and for the Department, as the volume of reports the Department will receive will no doubt increase dramatically.

Inasmuch as the proposed amended reporting requirements appear to mirror the "Never Events" identified by the NQF, Prisma questions whether this amendment creates an unnecessary governmental mandate for providers who are already self-regulating in pursuit of the highest standards of patient safety. The NQF is a not-for-profit, nonpa1tisan, membership-based organization that works to improve healthcare outcomes, safety, equity, and affordability and is a proud affiliate of The Joint Commission. If institutions, such as Prisma, are already complying with NQF standards, is it necessary for the government to impose additional regulatory burdens? If the potential impact in reports received is a tenfold increase (or more), since the proposed amendments include many reporting obligations in addition to pressure ulcers, does the Department have adequate staff and other resources required to

manage the deluge and what is the anticipated impact in enforcement activity?

Prisma respectfully submits that the proposed amendments to the reporting requirements are unnecessary, unduly burdensome, unrealistic, and unlikely to lead to an improvement in patient safety; however, they are very likely to substantially increase administrative burdens for providers and the Department. For these reasons, Prisma recommends the Department reconsider the amendments to Section 701.

Department Response: Partially adopt. Department staff propose requiring the initial report within 24 hours or by the next regular business day from when the facility had reasonable cause to believe an incident occurred. *See* Section 701.B.

Further, Department staff propose requiring the investigative report within seven (7) business days from when the facility had reasonable cause to believe an incident occurred. *See* Section 701.C.

Department staff appreciate Prisma's concerns about the potential impacts of this change. However, based upon other feedback and commentary, the proposed SREs provide clarity when compared to the current reportable incidents. Furthermore, many hospitals already report these incidents and, accordingly, there will not be additional burdens in making such reports to the Department.

Name	Section
Tidelands	701.B

Comment:
First, please accept our appreciation for aligning the list of reportable items with NQF standards, which will help clear up confusion within the hospital community. However, we have concerns about the proposed new reporting timelines included in this section, which represent a major change from current regulation.

First, we would encourage all reporting timelines to begin when the facility becomes aware of an incident because, in some cases, a facility may not learn of an incident until several days afterward, such as when a patient returns for further treatment (e.g., bowel perforation, anastomosis failure, infection). Timelines should also be defined by "working" days rather than calendar days.

The proposed change to a 24-hour initial report followed by a 5-day written investigative report for all incidents is duplicative, and the timelines represent a major departure from current regulation, which requires a single report within 10 days. These changes will place significant new burden on hospitals across the state.

To balance this concern with the department's interest in disclosure and prompt reporting, we would suggest:

- Requiring notification of the patient, responsible party, sponsor, or emergency contact within 24 hours of the facility becoming aware of the event. A new field(s) could be added to the DHEC online reporting form where facilities could be required to confirm

this report took place.
- Requiring investigative reports be submitted to the Department within 7 working days.

Department Response:
Partially adopt Tidelands' suggestion that the reporting timeline to begin when the facility becomes aware of the incident. Department staff propose the timeline to begin when the facility had reasonable cause to believe an incident occurred. *See* Sections 701.B and 701.C.

Partially adopt Tidelands' suggestions regarding the timeframes for submitting reports to the Department. Department staff propose requiring the initial report within 24 hours or by the next regular business day from when the facility had reasonable cause to believe an incident occurred. *See id.* Further, Department staff propose requiring the investigative report within seven (7) business days from when the facility had reasonable cause to believe an incident occurred. *See id.*

Name	Section
SCHA	702

Comment:
SCHA appreciates DHEC providing more clarity on the reporting requirements contained in this section.

In our original comments we asked if the incident reporting applied to patients or if it applied to staff and visitors as well. In reading the current draft we assume that it is only patients based on the wording "The facility shall retain all documented incidents reported pursuant to this section for six (6) years after the Patient involved is discharged."

We also ask that the time for reporting continue to be 10 days or, at a minimum, 5 business days.

Department Response: To SCHA's comment regarding incident reporting applying to patients, generally the reportable incidents, as proposed, concern patient events; however, reportable incidents may be staff events. Accordingly, Department staff propose clarifying Section 701.A to delete the language that could possibly imply that incident reports only apply to patients. *See* Section 701.A.

Partially adopt the suggestions regarding the timeframes for submitting reports to the Department. Department staff propose requiring the initial report within 24 hours or by the next regular business day from when the facility had reasonable cause to believe an incident occurred. Further, Department staff propose requiring the investigative report within seven (7) business days from when the facility had reasonable cause to believe an incident occurred. *See* Sections 701.B and 701.C.

Name	Section
SCHA	900

Comment:
Every hospital in South Carolina is a signatory to the statewide Mutual Aid Agreement ("MAA"). It reflects the basic tenets of a cooperative and coordinated response plan and sharing of resources in the event of an emergency. The MAA is a primary component of most hospitals' disaster preparedness plan. Given the uniform use of the MAA statewide, SCHA believes reference to the MAA should be incorporated into § 900 and a hospital's participation in the MAA should be considered satisfaction of the requirements contained in § 901.

Department Response: Not adopt. The MAA, as currently drafted, does not meet all of the regulatory requirements for the all-hazards emergency operations plan. While the MAA does address sheltering facilities, it does not address a facility's plans for transportation of relocated patients and staffing for those relocated patients. Should the MAA be updated/amended to sufficiently address all components of the proposed Section 901, then Department staff would consider a hospital's participation in the MAA as satisfaction of the requirements of Section 901.

Name	Section
Tidelands Health	901

Comment:
Instead of listing the shelters where patients "will" be relocated during a disaster, Tidelands Health suggests modifying 901(B)(1)(a) to require hospitals to document the sheltering facilities with which the hospital has an agreement to shelter patients as required in 901(B)(1)(b).

Rather than requiring "letters of agreement" in Sections § 901 (B)(1)(b) and (B)(2), Tidelands Health would suggest modifying this language to simply require one or more "agreements" that address the requirements outlined in these parts of the regulation. This would be consistent with the approach taken by other states, such as Georgia, and is intended to create a path by which the statewide Mutual Aid Agreement ("MAA"), if drafted in a way satisfactory to the Agency, could satisfy § 901 (B)(1) and (B)(2). The goal would be to achieve the safety aims of the Agency while reducing duplicative work that hospitals otherwise have been required to perform.

Department Response: Not adopt. The MAA, as currently drafted, does not meet all of the regulatory requirements for the all-hazards emergency operations plan. While the MAA does address sheltering facilities, it does not address a facility's plans for transportation of relocated patients and staffing for those relocated patients. Should the MAA be updated/amended to sufficiently address all components of the proposed Section 901, then Department staff would consider a hospital's participation in the MAA as satisfaction of the requirements of Section 901.

Name	Section
MUSC	1002

Comment:
MUSC supports the proposals submitted by SCHA to ensure that our hospitals can meet the needs of our patients.

Department Response: Not adopt. The MAA, as currently drafted, does not meet all of the regulatory requirements for the all-hazards emergency operations plan. While the MAA does address sheltering facilities, it does not address a facility's plans for transportation of relocated patients and staffing for those relocated patients. Should the MAA be updated/amended to sufficiently address all components of the proposed Section 901, then Department staff would consider a hospital's participation in the MAA as satisfaction of the requirements of Section 901.

Name	Section
SCHA	1002.B

Comment:
Section 1002(B) limits bed placement to areas designed as patient room areas "except in cases of justified emergencies." SCHA understands there are also fire code limitations related to hallway beds that are beyond the scope of this regulation but ultimately, hospitals would like more flexibility to determine when it is appropriate to place patients in hallway beds. To that end, SCHA is offering two suggestions to address the hallway bed issue. We are hopeful the Department will consider them and other possible strategies during this regulatory review process.

One method for addressing hallway beds would be to allow hospitals to classify some areas, like emergency departments, as "suites" instead of individual rooms off a corridor. This concept is more fully described in NFPA 101 Life Safety Code used by the Joint Commission. The suite concept promotes free movement of caregivers with easy access to patients, equipment, and supplies. Providing for suite classification in Regulation 61-16 might be one method for alleviating the hallway bed issue.

Another concept to explore would be expanding the definition of "justified emergency." As all South Carolina hospitals have seen throughout the last two years, emergency departments and hospital beds can fill up quickly. Even in non-pandemic times emergency departments can quickly become overcrowded or have several high acuity cases that demand the attention of many caregivers working in the ED. Perhaps DHEC in partnership with hospitals could develop a formula that accounts for the acuity of patients being seen in the ED, the number of patients being waiting to be seen, and the average wait times for those patients in the waiting area. Once the formula exceeds a certain threshold, then the hospital can begin to treat some patients in hallway beds. As long as a hospital was operating at or above that threshold, then treatment of hallway beds would qualify as a justified emergency.

Ultimately, South Carolina's hospitals and health systems, SCHA, and DHEC all want the best possible health outcomes for our citizens. Hallway beds are a complex problem that deserves continued discussion and analysis. SCHA is hopeful these suggestions are a starting point to resolve this issue.

Department Response: Not adopt. Regarding the proposed suite method, Department staff acknowledge that International Building Code and the International Fire Code allow for design and construction of care suites. Hospitals are able to construct such suites or reconfigure its' existing spaces to become suites in accordance with applicable codes. As noted, despite the regulatory language, the International Fire Code has specific requirements concerning corridors/hallways including the requirement that the minimum width or required capacity of corridors must be unobstructed with certain exceptions.

Regarding redefining "justified emergency," Department staff are unable to devise a formula that would address the hallway bed issue.

Department staff remain committed to finding a reasonable solution that allow hospitals to operate effectively while best providing for the health, safety, welfare, and privacy of patients in hospitals.

Name	Section
Prisma	1105

Comment:
SECTION 1105. CONTENTS: As amended, Section 1105 requires certain demographic information to be maintained within a patient's medical record. Prisma proposes the Department revise Section 1105.1 to require hospitals to also record a patient's race and ethnicity. Race and ethnicity are vital information for determining compliance with health equity initiatives, and Prisma believes that federal and state regulatory agencies will increasingly require providers to demonstrate compliance with existing, and future, health equity laws. Requiring hospitals to track this information now will improve providers' and the State's ability to access and report this information, as needed, in the future.

Department Response: Adopt. *See* Section 1105.A.1.

Name	Section
Prisma	1201.B.3.a

Comment:
SECTION 1201.B.3.A. RADIOLOGICAL SERVICES: As amended, Section 1201.B, governing radiological services (currently Section 1203), requires that "[a] qualified full-time. part-time, or consulting radiologist must supervise the ionizing radiology services and must interpret only those tests that are determined by the medical staff to require a radiologist's specialized knowledge. . . ." This would require a hospital's medical staff (presumably through its Medical Executive Committee) to determine all the types or tests that could be interpreted by a radiologist (e.g., orthopedic imaging. nuclear cardiology), even though radiologists may routinely read those same types of tests now without medical staff approval. The reasoning behind this requirement is unclear, and it arguably impinges upon a hospital's medical staff oversight and physician scope of practice. For these reasons, Prisma recommends deleting Section 1201.B.3.a.

Department Response: Partially adopt. The language contained in the NPR comes directly from the Medicare Conditions of Participation (CoPs). *See* 42 C.F.R. 482.26(c)(1). In the

State Operations Manual, CMS provides the following guidance on this CoP: "For diagnostic radiologic services using ionizing radiation, policies and procedures must, in addition to the requirements addressed in other portions of the radiologic services condition of participation, identify which types of radiologic tests require interpretation by a radiologist, as opposed to another type of practitioner holding privileges; the hospital's medical staff must approve this policy." Nonetheless, Department staff understand Prisma's confusion over the NPR language. For that reason, Department staff propose deleting the following language from Section 1201.B.3.a – "and must interpret only those radiologic tests that are determined by the medical staff to require a radiologist's specialized knowledge." *See* Section 1201.B.3.a.

Name	Section
MUSC	1200.D.4

Comment:

Freestanding Emergency Departments

MUSC supports the proposal by SCHA that DHEC make it clear that only South Carolina hospitals licensed under Regulation 61-16 can open and operate freestanding emergency departments in South Carolina.

With respect to the location of any licensed FSED, MUSC proposes that DHEC permit a South Carolina licensed hospital to establish a FSED in a location consistent with CMS requirements set forth in 42 C.F.R. §413.65(e)(3), which include a location within 35 miles of the hospital's main campus.

In addition, MUSC proposes the following revision to the proposed Section 1200(D)(4) as follows:

> 4. On its initial and renewal licensure applications, each hospital shall classify itself to indicate its capability in providing emergency care. Such classification will be for the hospital's on-campus emergency service and, if applicable, its off-campus emergency service, which off-campus emergency service may be the same Type as or a lower-level Type than the on-campus emergency service. General Hospitals shall be classified as a Type I, II, or III. Specialized Hospitals shall be classified as a Type I, II, III, or IV.

MUSC further requests that DHEC clarify that no hospital may extend and provide care under its trauma, stroke, or burn unit designations in its freestanding emergency department.

Department Response: Acknowledge MUSC's comments regarding making it clear that only South Carolina hospitals can open and operate FSEDs in South Carolina and allowing establishment of FSEDs in a location consistent with CMS's requirements, which includes a location within 35 miles of the hospital's campus. As proposed in the NPR, Section 1201.D.5 states, "A hospital licensed in South Carolina may open and operate freestanding emergency services within a 35-mile radius of its hospital campus. This freestanding emergency service shall be an extension of the existing hospital's on-campus emergency service."

Partially adopt MUSC's suggestion regarding the classification of off-campus emergency services in relation to the on-campus emergency services. Department staff propose slightly

different wording than MUSC's suggested language, but establishes the suggested substantive requirement. *See* Section 1201.D.4.

Not adopt MUSC's suggested prohibition of hospital's extending/providing care under other designations in a freestanding emergency service. Department staff at this time determined this suggestion is unnecessary.

Name	Section
JoLee Gudmundson on behalf of the SC Association of Nurse Anesthetists	1201.D and 1202.B

Comment:

COMMENT: "1201.D. Emergency services" would add a new requirement for hospitals to classify themselves by levels (Type I – IV) according to the capability to provide emergency care. For Type I hospitals, this appears to include a new requirement for in-hospital physician or senior-level resident coverage for anesthesia services (and other areas), as follows this is problematic for any CRNA-only facilities in the state that could not meet this restrictive new requirement, specifically rural facilities.

D. Emergency Services.

1. No person, regardless of his ability to pay or county of residence, may be denied emergency care if a member of the admitting hospital's medical staff or, in the case of a transfer, a member of the accepting hospital's medical staff determines that the person is in need of emergency care.

2. Hospitals that do not offer Obstetrical services shall have readily available in the emergency department a precipitous delivery kit, to include at a minimum: bulb suction syringe, cord clamp, scissors, sterile towels, and emergency telephone numbers for the appropriate Regional Perinatal Center.

3. If the care required for any patient is not available at the hospital, arrangements must be made for transfer to a more appropriate hospital. Prior to the transfer of a patient to another hospital, the receiving hospital shall be notified of the impending transfer.

4. On its initial and renewal licensure applications, each hospital shall classify itself to indicate its capability in providing emergency care. Such classification will be for the hospital's on - campus emergency service and, if applicable, its off - campus emergency service. General Hospitals shall be classified as a Type I, II, or III. Specialized Hospitals shall be classified as a Type I, II, III, or IV.

a. Type I means a hospital that offers comprehensive emergency care 24 hours per day, with at least one physician experienced in emergency care on duty in the emergency care area. There is in - hospital physician coverage by members of the medical staff or by senior - level residents for at least medical, surgical, orthopedic, obstetric/gynecologic, pediatric, and anesthesia services (**anesthesia services to also include: an individual qualified to administer anesthesia).** Other specialty consultation is available within approximately 30 minutes.

b. Type II means a hospital that offers emergency care 24 hours per day, with at least one physician experienced in emergency care on duty in the emergency care area. Specialty consultation is available within 30 minutes by members of the medical staff or senior - level residents. The hospital's scope of services includes in - house

capabilities for managing physical and related emotion problems, with provision for patient transfer to another organization when needed.

c. Type III means a hospital that offers emergency care 24 hours per day, with at least one physician available to the emergency care area within 30 minutes through a medical staff call roster. Specialty consultation is available by request of the attending medical staff member or by transfer to a designated hospital where definitive care can be provided.

d. Type IV means a hospital that offers reasonable care in determining whether an emergency exists, renders lifesaving first aid, and makes appropriate referral to the nearest organization that is capable of providing needed services. Type IV Hospitals do not represent or hold themselves out to the public as offering emergency care 24 hours per day. The mechanism for providing physician coverage at all times is defined by the medical staff.

. . . .

COMMENT: Paragraph (d) would align the regulation with the CRNA practice act and would keep the regulation current as to the practice requirements for CRNAs.

~~1212~~ B. Anesthesia Services. ~~(I)~~

~~A. Anesthesia shall be administered according to the South Carolina Code of Laws and the South Carolina Code of State Regulations by:~~

~~1. A qualified anesthesiologist;~~

~~2. A doctor of medicine or osteopathy other than an anesthesiologist;~~

~~3. A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law;~~

~~4. A certified registered nurse anesthetist (CRNA), as defined in S.C. Code Ann. Section 40 - 33 - 20(20), is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed; or~~

~~5. An anesthesiologist's assistant, as defined in S.C. Code Ann. Section 40 - 47 - 1210(2), who is under the supervision of an anesthesiologist who is immediately available if needed.~~

~~B. The organization of anesthesia services must be appropriate to the scope of the services offered.~~

~~C. Operations under a general anesthetic shall not be performed nor a general anesthetic given until the patient has had a physical examination except in emergency situations. The results of these examinations shall be entered in the patient's record. The history and physical must be readily available in the patient medical record.~~

~~D. Anesthesia apparatus shall be equipped with a device to measure the oxygen concentration of the gas being inhaled by the patient. The device shall emit an audible and/or visual alarm should the proportion of oxygen fall below a safe level.~~

If the hospital furnishes anesthesia services, those services must be provided in a well - organized manner under the direction of a qualified doctor of medicine or osteopathy. The service is responsible for all anesthesia administered in the hospital.

1 . The organization of anesthesia services must be appropriate to the scope of the services offered. Anesthesia must be administered only by:

a. A qualified anesthesiologist;
b. A doctor of medicine or osteopathy (other than an anesthesiologist);
c. A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law;
d. A certified registered nurse anesthetist (CRNA) is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed; **), as defined in S.C. Code Ann. Section 40 - 33 - 20(19)or[1]**
e. An anesthesiologist's assistant, who is under the supervision of an anesthesiologist who is immediately available if needed.

2. Anesthesia services must be consistent with needs and resources. Policies on anesthesia procedures must include the delineation of preanesthesia and postanesthesia responsibilities. The policies must ensure that the following are provided for each patient:

a. A preanesthesia evaluation completed and documented by an individual qualified to administer anesthesia performed within 48 hours prior to surgery or a procedure requiring anesthesia services.
b. An intraoperative anesthesia record.
c. A postanesthesia evaluation completed and documented by an individual qualified to administer anesthesia no later than 48 hours after surgery or a procedure requiring anesthesia services. The postanesthesia evaluation for anesthesia recovery must be completed in accordance with State law and with hospital policies and procedures that have been approved by the medical staff and that reflect current standards of anesthesia care.

[1] (19) "Certified Registered Nurse Anesthetist" or "CRNA" means an advanced practice registered nurse who:
(a) has successfully completed an advanced, organized formal CRNA education program at a minimum of the master's level accredited by the national accrediting organization of this specialty area and that is recognized by the board;
(b) is certified by a board approved national certifying organization; and
(c) demonstrates advanced knowledge and skill in the delivery of anesthesia services.

A CRNA must practice in accordance with approved written guidelines developed under supervision of a licensed physician or dentist or approved by the medical staff within the facility where practice privileges have been granted.

Department Response: Not adopt the proposed addition to the Section 1201.D.4.a's description of Type I emergency services, which requires in-hospital physician coverage by members of the medical staff or by senior-level residents for anesthesia services, to allow CRNA-coverage. Type I emergency services are the most comprehensive level of emergency services. Hospitals unable to have in-hospital physician coverage for anesthesia services, such as the CRNA-only facilities, would be unable to classify themselves as a Type I. However, such facilities would not necessarily be precluded from classifying themselves as the other types of emergency services. *See* Sections 1201.D.4.b through -d.

Partially adopt the proposed amendment to Section 1202.B.1.d regarding anesthesia being administered only by certain professionals. Department staff propose amending this section to clarify CRNAs are allowed to administer anesthesia in accordance with the Nurse Practice Act. *See* Section 1202.B.1.d.

Name	Section
Sonny Kinney, Jr.	1202.D

Comment:
1. Pursuant to S.C. Code Sections 44-7-250 and -260(A)(1), the Department establishes and enforces minimum standards for licensure, maintenance, and operation of hospitals, to* ensure the safe and appropriate treatment of persons served in this state*.

1202 D. Emergency Services
4. a.-d.
Reference to Physician

Current regulations for Type I, II, III, and IV hospitals only require at a minimum one physician experienced in emergency care or a number of physicians to be determined by the medical staff.

To "ensure the safe treatment of the persons served in this state", emergency rooms should be required to staff additional physicians based on times of operation, weekends, and holidays. This should be based on historical occupancy as recorded by each individual hospital and quality measures they use, such as time from admission to ER, until time of contact by a physician.

With this being said, based on my experiences, "Minimum Standards" do not "ensure the safe treatment of persons served in this state" and should be corrected to improve the quality of care in our hospital Emergency Rooms.

Department Response: Partially Adopt. Department staff propose adding Section 1201.D.10 which will require hospitals with Type I, II, and III emergency services to periodically evaluate its emergency service staffing utilizing emergency service metrics, document its findings and recommendations, and implement measures to staffing, when appropriate. *See* Section 1201.D.10.

Name	Section
Prisma	1801.B.3

Comment:
SECTION 1801.B.3. INFECTION CONTROL IN GENERAL: Prisma recommends that the Department revise Section 1801.B.3 to recognize the World Health Organization's Moments of Hand Hygiene Guidelines in addition to the CDC's Guideline for Hand Hygiene in Health-Care Settings.

Department Response: Adopt. *See* Section 1801.B.3.

Name	Section
Tidelands	1804

Comment:
We would suggest aligning this section of the regulation with Americans with Disability Act standards, which permit very limited inquiry into service dogs. For example, under ADA, hospitals cannot inquire as to the health status of a service animal or ask for evidence of screening within the past 12 months as required by this section of the regulation.

Department Response: Adopt. *See* Section 1804.

Name	Section
HCA Healthcare	1806.E

Comment:
Regulation 61-16 Section 1806 Waste Management. Section (E)
HCA South Atlantic's hospitals would request the following changes to the **language** in Section E:

> *"The hospital shall have policies for the use and disposal of sharps. The hospital shall use sharps containers capable of maintaining their impermeability after waste treatment to avoid subsequent physical injuries during final disposal. Disposable syringes with needles, including sterile sharps that are being discorded, scalpel blades, and other sharp items must be placed into puncture- resistant containers located as close as practical to the point of use. For the* ***purposes of this section,*** **empty** ***Intact medicine vials are not defined as sharps."***

Recently, DHEC has enforced different interpretations about the definition for sharps related to empty intact vials. DHEC is currently considering empty intact vials **as a** "potential sharp" and therefore empty intact vials are considered as infectious waste. Not only is this interpretation financially taxing, it also creates added burden on employees. Under this interpretation, sharp containers have to be emptied more frequently throughout the day as the vials fill the sharps containers significantly faster than their intended products.

After a national search, we have confirmed that our neighboring states in the Southeast, such as North Carolina, Georgia, Florida and Tennessee, do not interpret empty intact vials as potential sharps requiring them to be treated as infectious waste.

Department Response: Not adopt. In interpreting and enforcing R.61-16, Department staff have deferred to other relevant regulations including R.61-105, Infectious Waste Management,

which defines “sharps” as “any discarded article that may cause punctures or cuts, including but not limited to: needles, syringes, Pasteur pipettes, lancets, broken glass or other broken materials, and scalpel blades.”

Name	Section
HCA Healthcare	1002.B

Comment:

Regulation 61-16 Section 1002 Locations of Beds (B)

HCA South Atlantic's hospitals agree with SCHA on the following recommendations pertaining to the location of beds.

Section 1002(B) limits bed placement to areas designed as patient room areas except in cases of justified emergencies." HCA South Atlantic's hospitals understand there are also fire code limitations related to hallway beds that are beyond the scope of this regulation but ultimately, hospitals would like more flexibility to determine when it Is appropriate to place patients in hallway beds. To that end, SCHA is offering two suggestions to address the hallway bed Issue. HCA South Atlantic's hospitals are hopeful the Department will consider them and other possible strategies during this regulatory review process.

One method for addressing hallway beds would be to allow hospitals to classify some areas, like emergency departments, as "suites" instead of individual rooms off a corridor. This concept is more fully described in NFPA 101 Life Safety Code used by the Joint Commission. The suite concept promotes free movement of caregivers with easy access to patients, equipment, and supplies. Providing for suite classification in Regulation 61-16 might be one method for alleviating the hallway bed issue.

Another concept to explore would be expanding the definition of "justified emergency." As all South Carolina hospitals have seen throughout the last two years, emergency departments and hospital beds can fill up quickly. Even in non-pandemic times, emergency departments can quickly become overcrowded or have several high acuity cases that demand the attention of many caregivers working in the ED. Perhaps DHEC in partnership with hospitals could develop a formula that accounts for the acuity of patients being seen in the ED, the number of patients being waiting to be seen, and the average wait times for those patients in the waiting area. Once the formula exceeds a certain threshold, then the hospital can begin to treat some patients in hallway beds. As long as a hospital was operating at or above that threshold, then treatment of hallway beds would Qualify as a justified emergency.

Ultimately, South Carolina's hospitals and health systems, SCHA, and DHEC all want to best possible health outcome for our citizens. Hallway beds are a complex problem that deserves continued discussion and analysis.

Department Response: Not adopt. Regarding the proposed suite method, Department staff acknowledge that International Building Code and the International Fire Code allow for design and construction of care suites. Hospitals are able to construct such suites or reconfigure its’ existing spaces to become suites in accordance with applicable codes. As noted, despite the regulatory language, the International Fire Code has specific requirements concerning

corridors/hallways including the requirement that the minimum width or required capacity of corridors must be unobstructed with certain exceptions.

Regarding redefining “justified emergency,” Department staff are unable to devise a formula that would address the hallway bed issue.

Department staff remain committed to finding a reasonable solution that allow hospitals to operate effectively while best providing for the health, safety, welfare, and privacy of patients in hospitals.

Name	Section
Prisma	1908

Comment:
SECTION 1908. UTILITY ROOMS: As amended. Section 1908 does not align with the Facility Guidelines Institution ("·FGI") 2022 Guidelines for Design and Construction ("Guidelines"'). Currently, the FGI requires providers to conduct an infection control risk assessment to determine the provider's needs based on actual workflow. As drafted, Section 1908 could create a redundancy in soiled, clean, and nourishment workrooms when there are central and satellite nursing stations serving one patient population. For example remote nursing stations can provide a work area for clinical staff in proximity to the patient. but every remote nursing station does not necessarily require a separate clean utility room. As written, hospitals may be required to have multiple, unnecessary rooms. which would increase construction costs and inhibit optimum floor plan design.

For these reasons, Prisma recommends the Department strike the language in Section 1908 in its entirety and replace it with language requiring hospitals to comply with the most recent version of the FGI Guidelines. Alternatively, the Department could amend Section 1908 to allow the use of an infection control risk assessment to be performed to determine if soiled and clean utility rooms and nourishment rooms can be shared when multiple nursing stations serve the same patient population.

Department Response: Partially adopt. Department staff propose clarifying that the utility room requirements are required per main/central nurses’ stations, but not satellite/remote nurses’ stations. *See* Section 1908.

Date: February 8, 2024

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

From: Healthcare Quality

Re: Public Hearing for Notice of Final Regulation Amending R.61-91, *Standards for Licensing Ambulatory Surgical Facilities*, Document No. 5264

I. Introduction

Healthcare Quality proposes the attached Notice of Final Regulation amending R.61-91, *Standards for Licensing Ambulatory Surgical Facilities*. Legal authority resides in S.C. Code Sections 44-7-250 and 44-7-260(A)(4), which requires the Department of Health and Environmental Control ("Department") to establish and enforce the minimum standards for licensure, maintenance, and operation of ambulatory surgical facilities to ensure the safe and appropriate treatment of persons served in this state. The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments.

II. Facts

1. In accordance with 2023 Act No. 20 (S.164), the Department proposes amending R.61-91 to promulgation regulations concerning the provision of uncompensated indigent/charity care required pursuant to S.C. Code Section 44-7-266(C), including related definitions, licensure requirements, reporting requirements, and enforcement. Additionally, the Department proposes amending the regulation to address the required quality of care, services, and treatment provided by facilities and to prescribe the manner and method of fee payments.

2. The Department had a Notice of Drafting published in the August 25, 2023 *State Register*. The Department received public comments from eight parties by September 25, 2023, the close of the public comment period.

3. Department staff conducted a virtual stakeholder meeting on September 13, 2023, to receive comments on the proposed amendments. No comments were offered during this meeting.

4. Appropriate Department staff conducted an internal review of the proposed amendments on October 17, 2023.

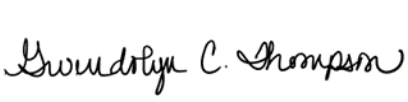
5. Upon receiving approval during the November 9, 2023 Board meeting, Healthcare Quality had a Notice of Proposed Regulation published in the November 24, 2023 *State Register*. The Department received public comments from seven parties by December 27, 2023, close of the public comment period. Attachment B presents a summary of these public comments received and Department responses.

6. Department staff conducted a second set of virtual stakeholder meetings on December 11, 2023, and February 6, 2024, to discuss the proposed amendments and to receive comments on the proposed amendments.

7. After consideration of all timely received comments, staff has made substantive changes to the regulatory text of the Notice of Proposed Regulation approved by the Board in the November 9, 2023, Board meeting and published in the November 24, 2023 *State Register*. Descriptions of the changes appear in Attachment B, Summary of Public Comments and Department Responses.

III. Request for Approval

Healthcare Quality respectfully requests the Board to find need and reasonableness of the attached proposed amendment of R.61-91, *Standards for Licensing Ambulatory Surgical Facilities*, for submission to the General Assembly.



Gwen C. Thompson
Deputy Director
Healthcare Quality

Kristen Juarez Kollu
Director, Medical Services Division
Bureau of Healthcare Systems and Services
Healthcare Quality

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

ATTACHMENT A

STATE REGISTER NOTICE OF FINAL REGULATION
FOR R.61-91, *Standards for Licensing Ambulatory Surgical Facilities*

February 8, 2024

Document No. 5264
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Sections 44-7-110 through 44-7-394

61-91. Standards for Licensing Ambulatory Surgical Facilities.

Synopsis:

Pursuant to S.C. Code Sections 44-7-250 and 44-7-260(A)(4), the Department establishes and enforces the minimum standards for the licensure, maintenance, and operation of ambulatory surgical facilities to ensure the safe and appropriate treatment of persons served in this state. In accordance with 2023 Act No. 20 (S.164), the Department proposes amending R.61-91 to promulgate regulations concerning the provision of uncompensated indigent/charity care required pursuant to S.C. Code Section 44-7-266(B) and -(C), including related definitions, licensure requirements, reporting requirements, and enforcement. Additionally, the Department proposes amending the regulation to address the required quality of care, services, and treatment provided by facilities and to prescribe the manner and method of fee payments. The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments.

The Department had a Notice of Drafting published in the August 25, 2023, South Carolina State Register.

Section-by-Section Discussion of Proposed Amendments:

Section	Type of Change	Purpose
101	Reorganization	Recodification of definitions due to additions of new definition.
101.B, 101.J, 101.M, 101.N, 101.W, 101.X, 101.Z, 101.AA, 101.MM, 101.NN, 101.HHH, 101.III, 101.JJJ	Addition	Added definitions for clarity.
103.G	Addition	Added requirement to make payment of fees before the Department's issuance of a license.
103.H	Revision	Revised for clarification.
103.N.1 and 103.N.2	Addition	Language added in accordance with ACT 20.
202.F and 202.G	Addition	Inspection and Construction fees added for clarification.
401.A and 402.B	Revision	Revised to clarify requirements for policies and procedures, the time period for reviewing

Section	Type of Change	Purpose
		policies and procedures, and their accessibility to staff.
503	Addition	The governing body section added to address quality of care, services and treatment provided by facilities.
504, 505, 506, 507, 508, and 509	Reorganization	Recodification of section due to addition of section 503.
601.B	Revision	Revised to add some of the NQF Serious Reportable Events as reportable incidents.
801.D	Addition	Added a new section for transfer agreements including an exception for when a facility is unable to secure such an agreement.
804.B	Addition	Added to be consistent with federal regulation and to address quality of care.
807.A and -B	Revision	Revised to add provisions regarding the offering of cardiovascular care services.
808 and 809	Reorganization	Recodified due to the addition of 807.
804.C	Reorganization	Recodified due to the addition of 804.B.
901.A	Deletion	Deletion of incorrect reference to SC Code.
1201.A	Addition	Added emergency equipment requirements.
1201.B	Deletion	Deleted subsection.
1504.E	Addition	Added requirement concerning collection, transportation, and storage of contaminated equipment.
1601.C	Addition	Added requirements concerning governing body involvement with the quality improvement program to be consistent with federal regulations and to address quality of care.
2006.E	Revision	Revised the minimum toilet fixture requirement.

Instructions:

Print the regulation as shown below. All other items remain unchanged.

~~Indicates Matter Stricken~~

Indicates New Matter

Text:

61-91. Standards for Licensing Ambulatory Surgical Facilities.

Statutory Authority: 1976 Code Sections 44-7-110 through 44-7-394

SECTION 100

DEFINITIONS, REFERENCES, AND LICENSE REQUIREMENTS

101. Definitions.

For the purpose of these standards, the following definitions shall apply:

A. Administrator. The individual designated by the facility licensee to have the authority and responsibility to manage the facility.

B. Adjusted Gross Revenue. Total Gross Revenue minus Medicaid and Medicare contractual adjustments only and bad debt.

~~B~~C. Administering Medication. The direct application of a single dose or multi-dose of medication to the body of a patient by injection, ingestion, or any other means.

~~C~~D. Advance Directive. A written statement such as a living will, a durable power of attorney for health care, or a do-not-resuscitate order relating to the provision of health care when the individual is incapacitated. The exercise by a patient of self-determination that encompasses making choices regarding life-sustaining treatment (including resuscitative services).

~~D~~E. Advanced Practice Registered Nurse. An individual who has official recognition as such by the S.C. State Board of Nursing.

~~E~~F. Ambulatory Surgical Facility. A facility organized and administered for the purpose of performing surgical procedures and/or endoscopy for which patients are scheduled to arrive, receive surgery, and be discharged on the same day.

1. The owner or operator shall make the facility available to other providers who comprise an organized professional staff, *i.e.*, an open medical staff (see Section 101.BB).

2. This definition does not apply to any facility used as an office or clinic for the private practice of licensed healthcare professionals (see Section 101.JJ).

~~F~~G. Anesthesiologist's Assistant. An individual currently licensed as such by the S.C. Board of Medical Examiners.

~~G~~H. Anesthesiologist. A physician who has completed a residency in anesthesiology.

~~H~~I. Anesthetic Agent. Any drug or combination of drugs administered parenterally or inhaled with the purpose of creating conscious or deep sedation.

J. Bad Debt. The amount a party has an obligation to pay, but that is considered uncollectible. Bad debt represents the portion of a patient's account not expected to be collected from the patient or other responsible party (the patient's portion). The patient's portion of a bill should not be categorized as bad debt for medically indigent patients. Bad debt must be differentiated from charity services. Patient charges otherwise eligible for classification as charity care should only be treated as bad debt if all conditions of your facility's charity care criteria are not met.

~~I~~K. Certified Nursing Assistant. A person whose duties are assigned by a licensed nurse and who has successfully completed a state-approved training program or course with a curriculum prescribed by the South Carolina Department of Health and Human Services, holds a certificate of training from that program or course and is listed on the South Carolina Registry of Certified Nurse Aides.

~~J~~L. Certified Registered Nurse Anesthetist. A registered nurse who is authorized to practice as a certified registered nurse anesthetist by the S. C. State Board of Nursing.

M. Charity Care. Any unpaid charges for services to patients as defined in S.C. Code Ann. Section 44-6-5(5). Only the portion of a patient's account that meets the facility's charity care criteria is recognized as charity.

N. Contractual Adjustments. Any charges that are not paid by third-party payers and cannot be billed to the patient pursuant to contractual agreements. Contractual adjustments for Medicare, Medicaid and other payers should be captured separately.

~~K~~O. Controlled Substance. A medication or other substance included in Schedule I, II, III, IV, and V of the Federal Controlled Substances Act and the S.C. Controlled Substances Act.

~~L~~P. Consultation. A visit by Department representatives who will provide information to the licensee in order to facilitate compliance with these regulations.

~~M~~Q. Dentist. An individual currently licensed by the S.C. Board of Dentistry to practice dentistry.

~~N~~R. Department. The S.C. Department of Health and Environmental Control (DHEC).

~~O~~S. Direct Care Staff Member. An individual who provides care, treatment, surgery, and/or services, or performs procedures for a patient.

~~P~~T. Endoscopy. Visual inspection of any cavity of the body by means of an endoscope.

~~Q~~U. Existing Facility. A facility that was in operation and/or one that began the construction or renovation of a building, for the purpose of operating the facility, prior to the promulgation of this regulation. The licensing standards governing new facilities apply if and when an existing facility is not continuously operated and licensed under this regulation.

~~R~~V. Facility. An ambulatory surgical facility licensed by the Department.

W. Gross Indigent and Charity Care Patient Charges. The total uncompensated charges for patients who qualify as indigent or charity under the relevant definitions.

X. Gross Patient Revenue. Includes charges generated by all patients at full-established rates before provisions for contractual and other adjustments are applied. Include any revenue forgone for provision of care for indigent/charity patients at full-established rates.

~~S~~Y. Health Assessment. An evaluation of the health status of a staff member or volunteer by a physician, physician assistant, or advanced practice registered nurse, or by a registered nurse, pursuant to standing orders approved by a physician, as evidenced by the physician's signature in accordance with facility policy.

Z. Indigent and Charity Care Write-Offs. Unpaid charges for indigent and charity care cases should be related only to the provision of ambulatory surgical facility services that are licensed and regulated by the Department. Unpaid charges from other lines of business should not be included.

AA. Indigent Care. Any unpaid charges for services to medically indigent patients as defined in S.C. Code Ann. Section 44-6-5(5). Unpaid charges for patients who were eligible for Medicare, Medicaid, Third Party, or patients provided other free care are not included in Indigent Care.

~~T~~BB. Inspection. A visit by Department representative(s) for the purpose of determining compliance with this regulation.

~~U~~CC. Investigation. A visit by Department representative(s) to a licensed or unlicensed entity for the purpose of determining the validity of allegations received by the Department relating to this regulation.

~~V~~DD. Initial License. A license granted to a new facility.

~~W~~EE. Legally Authorized Healthcare Provider. An individual authorized by law and currently licensed in S.C. to provide specific medical care, treatment, procedures, surgery, and/or services to patients. Examples of individuals who may be authorized by law to provide the aforementioned care, treatment, procedures, surgery, and/or services may include, but are not limited to, advanced practice registered nurses, and physician assistants.

~~X~~FF. Legend Drug.

1. A drug required by federal law to be labeled with any of the following statements prior to being dispensed or delivered:

a. "Caution: Federal law prohibits dispensing without prescription";

b. "Rx only."

2. A drug required by federal or state law to be dispensed pursuant to a prescription drug order or restricted to use by practitioners only;

3. Any drug products designated by the S.C. Board of Pharmacy to be a public health threat; or

4. Any prescribed compounded prescription within the meaning of the Pharmacy Act.

~~Y~~GG. License. A certificate issued by the Department to an Ambulatory Surgical Facility to provide care, treatment, procedures, surgery, and/or services.

~~Z~~HH. Licensed Nurse. An individual currently licensed by the S.C. State Board of Nursing as a registered nurse or licensed practical nurse.

~~AA~~II. Licensee. The individual, corporation, organization, or public entity that has received a license to provide care, treatment, procedures, surgery, and/or services at a facility and with whom rests the ultimate responsibility for compliance with this regulation.

~~BB~~JJ. New Facility. All buildings or portions of buildings, new and existing, that are:

1. Being licensed for the first time;

2. Providing a different service that requires a change in the type of license;

3. Being licensed after the previous licensee's license has been revoked, suspended, or after the previous licensee has voluntarily surrendered the license and the facility has not continuously operated.

~~CC~~KK. Open Medical Staff. Members of the medical staff, which includes physicians, dentists, or podiatrists, of an ambulatory surgical facility, that have individually submitted application to the facility, and subsequently been approved to perform surgery/procedures in accordance with criteria established by the facility for approving qualified applicants.

~~DD~~LL. Operating Room. A room in which surgery is performed.

MM. Other Free Care. Other uncompensated care provided as a result of employee discounts, administrative adjustments, courtesy discounts, small bill write-offs, or other similar write-offs not based on a patient's inability to pay. Should not include amounts properly classified as "contractual adjustments."

NN. Other Revenue. Other revenues or gains are derived from services other than providing services to patients. This may include revenues shared with the facility from another organizational entity.

~~EE~~OO. Nonlegend Medication. A medication that may be sold without a prescription and that is labeled for use by the consumer in accordance with the requirements of the laws of this State and the Federal government.

~~FF~~PP. Pharmacist. An individual currently registered as such by the S.C. Board of Pharmacy.

~~GG~~QQ. Physical Examination. An examination of a patient by a physician or physician assistant that addresses those issues identified in Section 802 of this regulation.

~~HH~~RR. Physician. An individual currently licensed as such by the S.C. Board of Medical Examiners.

~~II~~SS. Physician Assistant. An individual currently licensed as such by the S.C. Board of Medical Examiners.

~~JJ~~TT. Podiatrist. An individual currently licensed as such by the S.C. Board of Podiatry Examiners.

~~KK~~UU. Private Practice. An individually-licensed physician or group of licensed physicians who practice together at a certain location/address in a legally-constituted professional corporation, association, or partnership; patient encounters in the office or clinic are for the purpose of diagnosis and treatment, and not limited primarily to the performance of surgery and related care, treatment, procedures, and/or services.

~~LL~~VV. Procedure Room. A room where procedures not requiring general anesthesia can be safely performed.

~~MM~~WW. Quality Improvement Program. The process used by a facility to examine its methods and practices of providing care, treatment, procedures, surgery, and/or services, identify the ways to improve its performance, and take actions that result in higher quality of care, treatment, procedures, surgery, and/or services for the facility's patients.

~~NN~~XX. Recovery Area. An area used for the recovery of patients.

~~OO~~YY. Repeat Violation. The recurrence of a violation cited under the same section of the regulation within a 36-month period. The time-period determinant of repeat violation status is not interrupted by ownership changes.

~~PP~~ZZ. Responsible Party. A person who is authorized by law to make decisions on behalf of a patient, including, but not limited to, a court-appointed guardian or conservator, or person with a health care power of attorney or other durable power of attorney.

~~QQ~~AAA. Revocation of License. An action by the Department to cancel or annul a license by recalling, withdrawing, or rescinding its authority to operate.

~~RR~~BBB. Same Day. A period of time not to exceed twenty-four (24) hours after admission.

~~SS~~CCC. Staff Member. An adult who is a compensated employee of the facility on either a full or part-time basis.

~~TT~~DDD. Surgery. Treatment of conditions by operative means involving incision, whether with a scalpel or a laser, followed by removal or repair of an organ or other tissue.

~~UU~~EEE. Surgical Suite. An area that includes one or more operating rooms and a recovery area.

~~VV~~FFF. Surgical Technologist. An individual who meets one of the requirements listed in 1976 Code Section 44-7-380(B)(1)(a) – (d) to practice surgical technology in South Carolina.

~~WW~~GGG. Suspension of License. An action by the Department requiring a facility to cease operation for a period of time or to require a facility to cease admitting patients until such time as the Department rescinds that restriction.

HHH. Total Expenses. The sum of resources consumed in fulfillment of a facility's ongoing major or central operations. Expenses may result from current expenditures, incurring obligations to make future expenditures, or consuming resources obtained from previous expenditures. Expenses related to activities shared with entities other than the ambulatory surgical facility should be allocated between the entities. The expense component not allocated to the ambulatory surgical facility should not be included in the report. Appropriate matching of revenues and expenses excluded from the report should be made. Do not include bad debt as a total expense, but as a deduction from revenue.

III. Total Gross Revenue. The total revenue for the facility from all patient revenue and from other revenues or gains derived from services other than providing services to patients.

JJJ. Total Indigent and Charity Compensation. Funds provided by all public and private sources that are earmarked as compensation to offset uncompensated charges from indigent or charity care cases.

102. References.

The following publications/standards are referenced in this regulation:

A. Departmental:

1. R.61-4, *Controlled Substances*;

2. R.61-12, *Standards for Licensing Abortion Clinics*;

3. R.61-16, *Standards for Licensing Hospitals and Institutional General Infirmaries*;

4. R.61-20, *Communicable Diseases*;

5. R.61-25, *Retail Food Establishments*;

6. R.61-58, *State Primary Drinking Water Regulations*;

7. R.61-63, *Title A, Rules and Regulations for Radioactive Materials*;

8. R.61-64, *X-Rays, (Title B)*;

9. R.61-67, *Standards for Wastewater Facility Construction*;

10. R.61-105, *Infectious Waste Management Regulations*;

11. Guidelines for Prevention and Control of Antibiotic Resistant Organisms in Health Care Settings.

B. Non-Departmental:

1. American Association of Blood Banks;

2. American National Standards Institute (ANSI);

3. American Society of Heating, Refrigeration, and Air Conditioning Engineers (ASHRAE);

4. Bloodborne Pathogens Standards, Occupational Safety and Health Act (OSHA) of 1970;

5. Civil Rights Act of 1964;

6. Centers for Disease Control and Prevention (CDC);

7. International Building Code (IBC);

8. National Fire Protection Association (NFPA);

103. License Requirements (II).

A. License. No person, private or public organization, political subdivision, or governmental agency shall establish, operate, maintain, or represent itself (advertise/market) as an ambulatory surgical facility in S.C. without first obtaining a license from the Department. No such party shall provide care, treatment,

procedures, surgery, and/or services to patients prior to the effective date of licensure. Upon the Department's determination that such party provides care, treatment, procedures, surgery, and/or services without a Department-issued license, the party shall cease operation immediately and ensure safety, health, and well-being of the patients. Current or previous violations of the S.C. Code and/or Department regulations may jeopardize the issuance of a license or licensing of another facility or addition to an existing facility owned or operated by the violating licensee. (I)

B. Compliance. An initial license shall not be issued to a proposed facility that has not been previously and continuously licensed under Department regulations until the licensee has demonstrated to the Department that the proposed facility is in substantial compliance with the licensing standards. In the event a licensee who already has a facility/activity licensed by the Department makes application for another facility or increase in licensed capacity, the currently licensed facility/activity shall be in substantial compliance with the applicable standards prior to the Department issuing a license to the proposed facility or an amended license to the existing facility. A copy of the licensing standards shall be maintained at the facility and accessible to all staff members. Facilities shall comply with applicable local, state, and federal laws, codes, and regulations.

C. Compliance with Structural Standards. Facilities possessing a license issued prior to January 1, 2016 are considered in compliance with Section 1703 without modification of its licensed structure.

D. Licensed Capacity. No facility that has been licensed for a set number of operating rooms or procedure rooms shall exceed that number of operating or procedure rooms or establish new care, treatment, procedures, surgery, and/or services without first obtaining authorization from the Department. (I)

E. Issuance and Terms of License.

1. A license is issued by the Department and shall be posted in a conspicuous place in a public area within the facility.

2. The issuance of a license does not guarantee adequacy of individual care, treatment, procedures, surgery, and/or services, personal safety, fire safety, or the well-being of any patient or occupant of a facility.

3. A license is not assignable or transferable and is subject to revocation at any time by the Department for the licensee's failure to comply with the laws and regulations of this State.

4. A license shall be effective for a specified facility, at a specific location(s), for a specified period following the date of issue as determined by the Department. A license shall remain in effect until the Department notifies the licensee of a change in that status.

5. Facilities owned by the same entity but not located on the same adjoining or contiguous property shall be separately licensed. Roads or local streets, except limited access, *e.g.*, interstate highways, shall not be considered as dividing otherwise adjoining or contiguous property.

6. Separate licenses are not required, but may be issued, for separate buildings on the same or adjoining grounds where a single level or type of care is provided.

7. Multiple types of facilities on the same premises shall be licensed separately even though owned by the same entity.

8. A facility shall provide only the care, treatment, procedures, surgery, and/or services of which it is capable and equipped to provide, and has been authorized by the Department to provide pursuant to the definition in Section 101.E of this regulation.

9. Abortions shall not be performed in an ambulatory surgical facility unless it is also licensed as an abortion clinic pursuant to R.61-12.

F. Facility Name. No proposed facility shall be named nor shall any existing facility have its name changed to the same or similar name as any other facility licensed in S.C. The Department shall determine if names are similar. If the facility is part of a "chain operation" it shall then have the geographic area in which it is located as part of its name.

G. Application. Applicants for a license shall submit to the Department a completed application on a form prescribed and furnished by the Department prior to initial licensing and periodically thereafter at intervals determined by the Department. The application includes the applicant's oath, assuring that the contents of the application are accurate and true, and that the applicant will comply with this regulation. The application shall be signed by the owner(s) if an individual or partnership; in the case of a corporation, by two of its officers; or in the case of a governmental unit, by the head of the governmental department having jurisdiction. The application shall set forth the full name and address of the facility for which the license is sought and of the owner in the event his or her address is different from that of the facility, and the names of the persons in control of the facility. The Department may require additional information, including affirmative evidence of the applicant's ability to comply with these regulations. Corporations or partnerships shall be registered with the S.C. Office of the Secretary of State. Applicants shall make payment of all outstanding fees (initial licensure fees, annual licensure fees, inspection fees, construction fees, etc.) prior to the Department's issuance of a license.

H. Fees. The initial and annual license fee shall be $150.00 per operating/procedure room or $600.00, whichever is greater. ~~Such fee shall be made payable by check or money order to the Department and is not refundable. The Department may charge a fee for plan reviews, construction inspections and licensing inspections.~~ All fees are non-refundable and shall be made payable to the Department via a secured portal or specific website.

I. Late Fee. Failure to submit a renewal application after the license expiration date may result in a late fee of 25% of the licensing fee amount, in addition to the licensing fee. Continual failure to submit completed and accurate renewal applications and/or fees by the time-period specified by the Department may result in an enforcement action.

J. License Renewal. To renew a license, an applicant shall file an application with the Department and pay a license fee. If the license renewal is delayed due to enforcement action, the renewal license shall be issued only when the matter has been resolved satisfactorily by the Department or when the adjudicatory process is completed, whichever is applicable. If an application is denied, a portion of the fee shall be refunded based upon the remaining months of the licensure year.

K. Change of License.

1. A facility shall request issuance of an amended license by application to the Department prior to any of the following circumstances:

a. Change of ownership;

b. Reallocation of types of operating or procedure rooms as shown on the license;

c. Change of facility location from one geographic site to another;

d. The addition or replacement of a surgical suite or any part thereof, or the deletion of operating or procedure rooms.

2. Changes in facility name or address (as notified by the post office) shall be accomplished by application or by letter from the licensee.

L. An ambulatory surgical facility license shall not be required for, nor shall such a license be issued to:

1. Facilities operated by the federal government;

2. Ambulatory surgical services or procedures provided in licensed hospitals (such services remain within the purview of R.61-16);

3. Private practices (see Section 101.JJ).

M. Exceptions to Licensing Standards. The Department has the authority to make exceptions to these standards where it is determined that the health, safety, and well-being of the patients are not compromised, and provided the standard is not specifically required by statute.

N. Indigent/Charity Care. Any Facility established or constructed after May 16, 2023, and which did not require a Certificate of Need, must provide indigent charity care as described below in Section 103.N.2 after it has been in operation for two calendar years:

1. Annual Reports: After being in operation for two calendar years, a Facility subject to Section 103.N shall submit annual reports in a form prescribed by the Department and located on the Department's website. Further, a Facility subject to Section 103.N shall submit the annual reports by a deadline set by the Department and indicated on the Department's website. The annual reports shall include, but not be limited to the following information:

a. Gross patient revenue;

b. Medicare contractual adjustments;

c. Medicaid contractual adjustments;

d. Other contractual adjustments;

e. Bad debt;

f. Indigent care gross charges;

g. Indigent care compensation;

h. Charity care gross charges;

i. Charity care compensation;

j. Other free care;

k. Other revenue; and

l. Total expenses.

2. Indigent/Charity Care requirements:

a. If the Facility provides care to Medicaid beneficiaries, it must provide uncompensated indigent/charity care to the underinsured or medically indigent in an amount equal to or greater than 2% of its adjusted gross revenue; or

b. If the Facility does not provide care to Medicaid beneficiaries, it must provide uncompensated indigent/charity care to the underinsured or medically indigent in an amount equal to or greater than 3% of its adjusted gross revenue.

c. Noncompliance with Section 103.N.2.a or -b shall result in a monetary penalty in the amount of the difference between the services which the Facility is required to provide and the amount it actually provided.

SECTION 200

ENFORCING REGULATIONS

201. General.

The Department shall utilize inspections, investigations, consultations, and other pertinent documentation regarding a proposed or licensed facility in order to enforce this regulation.

202. Inspections/Investigations.

A. An inspection shall be conducted prior to initial licensing of a facility and subsequent inspections conducted as deemed appropriate by the Department. Other regulatory-related inspections may be considered in determining the appropriateness of Department inspections, e.g., Joint Commission on Accreditation of Health Care Organizations (JCAHO), Accreditation Association for Ambulatory Health Care (AAAHC), American Osteopathic Association (AOA), American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF) inspections.

B. All facilities are subject to inspection or investigation at any time without prior notice by individuals authorized by the Department.

C. Individuals authorized by the Department shall be granted access to all properties and areas, objects, and records, and have the authority to require the facility to make photocopies of those documents required in the course of inspections or investigations. Photocopies shall be used for purposes of enforcement of regulations and confidentiality shall be maintained except to verify the identity of individuals in enforcement action proceedings. (II)

D. A facility found noncompliant with the standards of this regulation shall submit an acceptable written plan of correction to the Department that shall be signed by the administrator and returned by the date specified on the report of inspection or investigation. The written plan of correction shall describe: (II)

1. The actions taken to correct each cited deficiency;

2. The actions taken to prevent recurrences (actual and similar);

3. The actual or expected completion dates of those actions.

E. Reports of inspections or investigations conducted by the Department, including the facility response, shall be made available upon written request with the redaction of the names of those individuals in the report as provided by § 44-7-310 and 315 of the S.C. Code Ann. (2002).

F. Inspection Fees. The Facility shall pay the inspection fee for initial, relocation, routine inspection, and routine follow-up. The Facility shall pay a fee for unit increase of service modification or follow-up.

Initial/Relocation Inspection Fee	Calculated - $350 + $45 per operating, endoscopy, and procedure room
Initial/Relocation Follow-Up Fee	Calculated - $200 + $45 per operating, endoscopy, and procedure room
Routine Inspection Fee	Calculated - $350 + $45 per operating, endoscopy, and procedure room
Routine Follow-Up Fee	Calculated - $350 + $45 per operating, endoscopy, and procedure room
Unit Increase or Service Modification Fee	Calculated - $200 + $45 per operating, endoscopy, and procedure room
Unit Increase of Service Modification Follow-Up Fee	Calculated - $200 + $45 per operating, endoscopy, and procedure room

G. Construction Fees. The Facility shall pay the following inspection fees during the construction phase of the project.

Construction Inspection Fees	
Plan Inspection	
Total Project Cost	Fee
< $10,001	$750
$10,001 -$100,000	$1,500
$100,001 - $500,00	$2,000
> $500,000	$2,500 plus $100 for each additional $100,000 in project costs
Site Inspection	$500

SECTION 300

ENFORCEMENT ACTIONS

301. General.

When the Department determines that a facility is in violation of any statutory provision, rule, or regulation relating to the operation or maintenance of such facility, the Department, upon proper notice to the licensee, may impose a mandatory penalty and/or deny, suspend, and/or revoke its license.

302. Violation Classifications.

Violations of standards in this regulation are classified as follows:

A. Class I violations are those that the Department determines to present an imminent danger to the health, safety, or well-being of the persons in the facility or a substantial probability that death or serious physical harm could result therefrom. A physical condition or one or more practices, means, methods or operations in use in a facility may constitute such a violation. The condition or practice constituting a Class I violation shall be abated or eliminated immediately unless a fixed period of time, as stipulated by the Department, is required for correction. Each day such violation exists after expiration of this time established by the Department may be considered a subsequent violation.

B. Class II violations are those, other than Class I violations, that the Department determines to have a negative impact on the health, safety, or well-being of persons in the facility. The citation of a Class II violation may specify the time within which the violation is required to be corrected. Each day such violation exists after expiration of this time may be considered a subsequent violation.

C. Class III violations are those that are not classified as Class I or II in these regulations or those that are against the best practices as interpreted by the Department. The citation of a Class III violation may specify the time within which the violation is required to be corrected. Each day such violation exists after expiration of this time may be considered a subsequent violation.

D. The notations "(I)" or "(II)", placed within sections of this regulation, indicate that those standards are considered Class I or II violations, if they are not met, respectively. Standards not so annotated are considered Class III violations.

E. In arriving at a decision to take enforcement actions, the Department shall consider the following factors: specific conditions and their impact or potential impact on health, safety, or well-being of the patients; efforts by the facility to correct cited violations; behavior of the licensee that reflects negatively on the licensee's character, such as illegal or illicit activities; overall conditions; history of compliance; and any other pertinent factors that may be applicable to current statutes and regulations.

F. When a decision is made to impose monetary penalties, the following schedule shall be used as a guide to determine the dollar amount:

Frequency of violation of standard within a 36-month period:

MONETARY PENALTY RANGES

FREQUENCY	CLASS I	CLASS II	CLASS III
1st	$ 500 - 1,500	$ 300 - 800	$ 100 - 300
2nd	1,000 - 3,000	500 - 1,500	300 - 800
3rd	2,000 - 5,000	1,000 - 3,000	500 - 1,500
4th	5,000	2,000 - 5,000	1,000 - 3,000
5th	7,500	5,000	2,000 - 5,000
6th	10,000	7,500	5,000

G. Any enforcement action taken by the Department may be appealed in a manner pursuant to the Administrative Procedures Act, 1976 Code Section 1-23-310, et seq.

SECTION 400

POLICIES AND PROCEDURES

401. General (II).

A. The Facility shall maintain and adhere to ~~P~~policies and procedures addressing each section of this regulation regarding care, treatment, procedures, surgery, and/or services, patient rights, and the operation of the facility ~~shall be developed and implemented, and revised as required in order to accurately reflect actual facility operation~~. The policies and procedures shall follow current accepted standards of medical and surgical practice to ensure services are provided in a manner which protects the health and safety of patients. The Facility shall be in full compliance with the policies and procedures. ~~The licensee shall establish a time period for review of all policies and procedures. These policies and procedures shall be accessible in each facility at all times, either by hard copy or electronically.~~

B. ~~Policies and procedures shall describe the means by which the facility shall assure that the standards described in this regulation that the licensee has agreed to meet, as confirmed by signature on the application for licensing, will be met (see Section 1601.B).~~ The Facility shall establish a time period for review, not to exceed two (2) years, of all policies and procedures, and such reviews shall be documented. The Facility shall ensure all policies and procedures are accessible to staff at all times, either by hard copy or electronically.

SECTION 500

STAFF

501. General (II).

A. A facility shall be fully staffed in sufficient numbers and training as required by this Section at all times a patient is in the facility or the facility is open to accept patients, in order to:

1. Effectively meet the needs and condition of the patients, to include the demands of effective emergency on-site action that might arise;

2. Properly operate equipment in accordance with the equipment manufacturer's recommendations;

3. Adhere to current professional organizational standards;

4. Comply with all local, state, and federal laws.

B. The facility shall provide additional staff members if the Department determines that the facility staff on duty is inadequate to provide appropriate care, treatment, procedures, surgery, and/or services to the patients of a facility.

C. All staff members shall be assigned duties and responsibilities in accordance with the individual's capability that shall be in writing and be reviewed on an annual basis by the staff member and supervisor.

D. There shall be accurate current information maintained regarding all staff members of the facility, to include at least an address, phone number, and health and personal/work/training background. For those staff members who are licensed/certified, a copy of the license/certificate shall be available for review.

E. Direct care staff members of the facility shall not have a prior conviction or have pled no contest (nolo contendere) within the last 10 years for child or adult abuse, neglect, exploitation, or mistreatment,

or for sexual assault or assault with a deadly weapon. Facilities may take certain considerations into account regarding criminal records when making hiring decisions, i.e., discretion may be exercised regarding convictions/nolo contendere pleas occurring more than 10 years ago and may determine that an applicant, who would otherwise be disqualified, could be hired. (I)

F. A staff member shall not have an active dependency on a psychoactive substance(s) that would impair his or her ability to perform assigned duties. (I)

502. Administrator (II).

A. The facility shall have an administrator who shall be capable of meeting the responsibilities of operating the facility to ensure that it is in compliance with these regulations, and shall demonstrate adequate knowledge of these regulations. An administrator appointed subsequent to the promulgation of this regulation shall be a registered nurse or shall have a baccalaureate or associate degree with at least three years experience in a health-related field within the past five years.

B. A staff member shall be designated, by name or position, in writing, to act in the absence of the administrator.

503. Control (I).

The Facility must have a governing body designated in writing by the licensee that assumes full responsibility for determining, implementing, and monitoring policies governing the Facility's total operations. The governing body has oversight and accountability for the quality improvement program, and ensures that Facility policies and programs are administered so as to provide quality health care in a safe environment.

~~503~~504. Medical Director (II).

A. There shall be a medical director of the facility who is a physician.

B. The administrator and medical director may be the same individual.

~~504~~505. Medical Staff (I).

A. Physicians, dentists, and podiatrists performing surgery and/or procedures shall be appropriately licensed to perform these functions as well as adequately trained in any special requirements that are necessary to perform such surgery/procedures, including being board certified or board eligible.

B. Privileges for each physician, dentist, and podiatrist performing surgery/procedures shall be in accordance with criteria that the facility has established and approved.

C. There shall be a roster of medical staff having surgery, procedures, and anesthesia privileges at the facility, specifying the privileges and limitations of each and a current listing of all types of surgery and/or procedures offered by the facility.

D. A physician shall be physically present or available within 30 minutes until all patients have departed the premises.

E. There shall be at least one physician on staff who has admitting privileges at one or more hospitals.

~~505~~506. Nursing Staff (I).

A. An adequate number of licensed nurses shall be on duty to meet the total nursing needs of patients.

B. At least one registered nurse shall be on duty whenever patients are present in the facility.

C. Nursing staff shall be assigned to duties consistent with their scope of practice as determined through their licensure and educational preparation.

~~506~~507. Advanced Cardiac Life Support (I).

A. An individual who possesses a valid Advanced Cardiac Life Support credential shall be on duty in the facility whenever patients are present in the facility.

B. An individual who possesses a valid Pediatric Advanced Life Support credential shall be on duty in the facility whenever pediatric patients are present in the facility.

~~507~~508. Inservice Training (II).

A. Training for the tasks each staff member performs shall be conducted in order to provide the care, treatment, procedures, surgery, and/or services delineated in Sections 501.A and 800.

B. The following training shall be provided to staff members by appropriate resources, e.g., licensed or registered persons, video tapes, books, *etc.*, to all staff members in context with their job duties and responsibilities, prior to patient contact and at a frequency determined by the facility, but at least annually:

1. Cause, effect, transmission, prevention, and elimination of infections, to include management and care of persons with contagious and/or communicable disease, *e.g.*, hepatitis, tuberculosis, HIV infection;

2. OSHA standards regarding bloodborne pathogens;

3. Confidentiality of patient information and records and the protection of patient rights;

4. Emergency procedures and disaster preparedness within 24 hours of their first day on the job in the facility (see Section 1200).

5. Fire response training within 24 hours of their first day on the job in the facility (see Section 1303);

6. Aseptic techniques such as handwashing and scrubbing practices, proper gowning and masking, dressing care techniques, disinfecting and sterilizing techniques, and the handling and storage of equipment and supplies.

C. All licensed nurses shall possess a valid cardio-pulmonary resuscitation (CPR) certificate within three months from the first day on the job in the facility; a staff member with a valid CPR certificate shall be on duty whenever patients are present in the facility.

D. All newly-hired staff members shall be oriented to acquaint them with the facility organization and physical plant, specific duties and responsibilities of staff members, and patients' needs.

~~508~~509. Health Status (I).

A. All staff members who have contact with patients shall have, within 12 months prior to initial patient contact, a health assessment as defined in Section 101.R.

B. The health assessment shall include a tuberculin skin test as described in Sections 1505 and 1506.

C. If a staff member is working at multiple facilities operated by the same licensee, copies of records for tuberculin skin testing and the pre-employment health assessment shall be acceptable at each facility. (II)

SECTION 600

REPORTING

601. Accidents/Incidents (II).

A. The licensee shall report a record of each accident and/or incident occurring at the facility to the Department within five (5) days of occurrence. Reports submitted to the Department shall contain only: facility name, license number, type of accident/incident, date of accident/incident occurred, number of patients directly injured or affected, patient medical record identification number, patient age and sex, number of staff directly injured or affected, number of visitors directly injured or affected, witness(es) name(s), identified cause of accident/incident, internal investigation results if cause unknown, a brief description of the accident/incident including location where occurred, and treatment of injuries. The report retained by the facility, in addition to the minimum reported to the Department, shall contain: names of patient(s), staff, and/or visitor(s), the injuries and treatment associated with each patient, staff, and/or visitor. Records of all accidents and incidents shall be retained by the facility for ten (10) years after the patient stops receiving services at the facility.

B. The licensee shall report each accident and/or incident resulting in unexpected death or serious injury to the next of kin or party responsible for each affected individual at the earliest practicable hour, not exceeding twenty-four (24) hours. The licensee shall notify the Department immediately, not to exceed twenty-four (24) hours, via telephone, email or facsimile. The licensee shall submit a report of the licensee's investigation of the accident and/or incident to the Department within five (5) days. Accidents and/or incidents requiring reporting include, but are not limited to,:

1. ~~Abuse, Neglect or Exploitation (Confirmed);~~

~~2. Abuse, Neglect or Exploitation (Suspected);~~

~~3. Criminal event against patient;~~

~~4. Death;~~

~~5. Fall resulting in fracture of bone or joint;~~

~~6. Hospitalization as a result of accident/incident;~~

~~7. Medication E~~error ~~with adverse reaction;~~

~~8. Procedures on wrong person;~~

~~9. Procedures on wrong site;~~

~~10. Severe burn;~~

~~11. Severe hematoma;~~

~~12. Severe laceration;~~

~~13. Attempted suicide; or~~

~~14. Anesthesia apparatus malfunction.~~Surgical or Invasive Procedure Events

a. Surgery or other invasive procedure performed on the wrong site;

b. Surgery or other invasive procedure performed on the wrong patient;

c. Wrong surgical or other invasive procedure performed on a patient;

d. Unintended retention of a foreign object in a patient after surgery or other invasive procedure; and

e. Intraoperative or immediately/postprocedure death.

2. Product or Device Events

a. Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the Facility;

b. Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used or functions other than as intended; and

c. Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in the Facility.

3. Patient Protection Events

a. Discharge or release of a patient of any age, who is unable to make decisions, to other than an authorized person;

b. Patient death or serious injury associated with patient elopement; and

c. Patient suicide, attempted suicide, or self-harm that results in serious injury while being cared for in the Facility.

4. Care Management Events

a. Patient death or serious injury associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration);

b. Patient death or serious injury associated with unsafe administration of blood products;

c. Patient death or serious injury associated with a fall while being cared for in the Facility;

d. Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results.

5. Environmental Events

a. Patient or staff death or serious injury associated with an electric shock in the course of a patient care process in the Facility;

b. Any incident in which systems designated for oxygen or other gas to be delivered to a patient contains no gas, the wrong gas, or are contaminated by toxic substances;

c. Patient or staff death or serious injury associated with a burn incurred from any source in the course of a patient care process in the Facility; and

d. Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in the Facility.

6. Potential Criminal Events

a. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider;

b. Abduction of any patient of any age;

c. Sexual abuse/assault on a patient or staff member within or on the grounds of the Facility; and

d. Death or serious injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of the Facility.

602. Fire/Disasters (II).

A. The Department shall be notified immediately via telephone, email or facsimile regarding any fire in the facility, and followed by a complete written report, to include fire department reports, if any, to be submitted within a time-period determined by the facility, but not to exceed seventy-two (72) hours from the occurrence of the fire.

B. Any natural disaster that requires displacement of the patients or jeopardizes or potentially jeopardizes the safety of the patients, shall be reported to the Department via telephone, email or facsimile immediately, with a complete written report submitted within a time-period as determined by the facility, but not to exceed seventy-two (72) hours.

C. Where a required fire protection system is out of service, the facility shall notify the fire department and the fire code official immediately, and where required by the fire code official, the building shall either be evacuated or the facility shall provide an approved fire watch for all occupants left unprotected by the shut down until the fire protection system has been returned to service, as applicable to Division of Health Facilities Construction (DHFC) Guidelines Manual.

603. Communicable Diseases (I).

All cases of diseases that are required to be reported to the appropriate county health department shall be accomplished in accordance with R.61-20.

604. Administrator Change.

The Department shall be notified in writing by the licensee within 10 days of any change in administrator. The notice shall include at a minimum the name of the newly-appointed individual, documented qualifications as required by Section 502, and the effective date of the appointment.

605. Joint Annual Report.

Facilities shall complete and return a "Joint Annual Report" to the Department's Planning and Certificate of Need Division within the time-period specified by that division.

606. Accounting of Controlled Substances (I).

Any facility registered with the Department's Bureau of Drug Control and the federal Drug Enforcement Agency shall report any theft or loss of controlled substances to local law enforcement and to the Bureau of Drug Control within three working days of the discovery of the loss/theft. Any facility permitted by the S.C. Board of Pharmacy shall report the loss or theft of drugs or devices within three working days of the discovery of the loss/theft.

607. Facility Closure.

A. Prior to the permanent closure of a facility, the Department shall be notified in writing of the intent to close and the effective closure date. Within 10 days of the closure, the facility shall notify the Department of the provisions for the maintenance of the records. On the date of closure, the current original license shall be returned to the Department.

B. In instances where a facility temporarily closes, the Department shall be given written notice within a reasonable time in advance of closure. At a minimum this notification shall include, but not be limited to: the reason for the temporary closure, the manner in which the records are being stored, and the anticipated date for reopening. The Department shall consider, upon appropriate review, the necessity of inspecting and determining the applicability of current construction standards to the facility prior to its reopening. If the facility is closed for a period longer than one year, and there is a desire to re-open, the facility shall re-apply to the Department and shall be subject to all licensing requirements at the time of that application, including construction-related requirements for a new facility.

608. Zero Census.

In instances when there have been no patients in a facility for any reason, for a period of 90 days or more, the facility shall notify the Department in writing no later than the 100th day following the date of the last procedure/surgery performed. At the time of that notification, the Department shall consider, upon appropriate review of the situation, the necessity of inspecting the facility prior to any new and/or re-admissions to the facility. The facility shall still apply and pay the licensing fee to keep the license active despite being at zero census or temporarily closed. If the facility has no patients for a period longer than one year, and there is a desire to re-open, the facility shall re-apply to the Department and shall be subject to all licensing requirements at the time of that application, including construction-related requirements for a new facility.

SECTION 700

PATIENT RECORDS

701. Content (II).

A. The facility shall initiate and maintain an organized record for each patient. The record shall contain: sufficient documented information to identify the patient; the person responsible for each patient; the description of the diagnosis and the care, treatment, procedures, surgery, and/or services provided, to include the course of action taken and results; and the response and reaction to the care, treatment, procedures, surgery, and/or services provided. All entries shall be indelibly written, authenticated by the author, and dated.

B. Specific entries/documentation shall include at a minimum:

1. Consultations by physicians or other legally authorized healthcare providers;

2. Physical examination report, including pertinent medical history;

3. Orders and recommendations for all care, treatment, procedures, surgery, and/or services from physicians or other legally authorized healthcare providers, completed prior to, or at the time of patient arrival at the facility, and subsequently, as warranted;

4. Care, treatment, procedures, surgery, and/or services provided;

5. Record of administration of each dose of medication;

6. Medications administered and procedures followed if an error is made;

7. Special procedures and preventive measures performed, *e.g.*, isolation for symptoms of tuberculosis;

8. Notes of observation during recovery, to include vital signs pre- and post-operative;

9. Discharge summary, including condition at discharge or transfer, instructions for self-care and instructions for obtaining postoperative emergency care;

10. Special information, *e.g.*, allergies, *etc*. Documentation regarding organ donation shall be included in the record at the patient's request;

11. Signed informed consent;

12. If applicable, anesthesia records of pertinent preoperative and postoperative reports including pre-anesthesia evaluation, type of anesthesia, technique and dosage used, and post-anesthesia follow-up note;

13. Operative report (dictated or written into the record after surgery/procedure) to include at least:

a. Description of findings;

b. Techniques utilized to perform procedure/surgery;

c. Specimens removed, if applicable;

d. Primary surgeon and assistants.

14. Reports of all laboratory, radiological, and diagnostic procedures along with tests performed and the results appropriately authenticated.

C. Except as required by law, patient records may contain written and interpretative findings and reports of diagnostic studies, tests, and procedures, *e.g.*, interpretations of imaging technology and video tapes without the medium itself.

702. Authentication.

A. Each document generated by a user shall be separately authenticated.

B. Written signatures or initials and electronic signatures or computer-generated signature codes are acceptable as authentication.

C. In order for a facility to employ electronic signatures or computer-generated signature codes for authentication purposes, staff shall be identified who are authorized to authenticate patient records utilizing electronic or computer-generated signatures.

1. At a minimum, the facility shall provide authentication safeguards to ensure confidentiality, including, but not limited to, the following:

a. Each user shall be assigned a unique identifier that is generated through a confidential code;

b. The facility shall certify in writing that each identifier is kept strictly confidential. This certification shall include a user's commitment to terminate his or her use of an assigned identifier if it is found that the identifier has been misused, meaning that the user has allowed another person(s) to use his or her personally-assigned identifier, or that the identifier has otherwise been inappropriately utilized;

c. The user shall certify in writing that he or she is the only person with access to the identifier and the only person authorized to use the signature code.

2. The authentication system shall include a verification process to insure that the content of authenticated entries is accurate. The verification process shall include, at a minimum, the following provisions:

a. Blanks, gaps, obvious contradictory statements, or other documentation that require the attention of the authorized user shall be considered authenticated until reviewed and corrected by the user and a revised report issued;

b. Opportunity shall be provided for the user to verify that the document is accurate and that the signature has been properly recorded.

3. A user may terminate authorization for use of electronic or computer-generated signature upon written notice to the individual responsible for the maintenance of patient records.

D. The use of rubber stamp signature is acceptable under the following conditions:

1. The individual whose signature the rubber stamp represents shall be the only individual who has possession of and utilizes the stamp;

2. The individual places in the administrative offices of the facility a signed statement indicating that he or she is the only individual who has possession of and shall utilize the stamp;

3. Rubber stamp signatures are not permitted on orders for medications listed as "controlled substances" pursuant to R.61-4.

703. Record Maintenance.

A. The licensee shall provide accommodations, space, supplies, and equipment adequate for the protection, security, and storage of patient records.

B. When a patient is transferred to an emergency facility, a transfer summary to include, at a minimum, the diagnosis and medication administration record, shall accompany the patient to the receiving facility at the time of transfer or forwarded immediately after the transfer. Documentation of the information forwarded shall be maintained in the facility's patient record. (I)

C. The patient record is confidential. Records containing protected or confidential health information shall be made available only to individuals granted access to that information, in accordance with state and federal laws. The facility shall have a written policy designating the persons allowed to access confidential patient information. (II)

D. Records generated by organizations or individuals contracted by the facility for care, treatment, procedures, surgery, and/or services shall be maintained by the facility that has admitted the patient. Appropriate information shall be provided to assure continuity of care.

E. The facility shall determine the medium in which information is stored. The information shall be readily retrievable and accessible by facility staff, as needed, and for regulatory compliance inspections.

F. Upon discharge of a patient, the record shall be completed within 60 days and filed in an inactive/closed file maintained by the licensee. Prior to the closing of a facility for any reason, the licensee shall arrange for preservation of records to ensure compliance with these regulations and other applicable law. The licensee shall notify the Department, in writing, describing these arrangements and the location of the records.

G. Records of patients shall be maintained for at least six years following the discharge of the patient. Other documents required by the regulation, *e.g.*, fire drills, shall be retained at least 12 months or until the next Department inspection, whichever is longer.

H. Patient records are the property of the facility; the original record shall not be removed without court order. (II)

SECTION 800

CARE/TREATMENT/PROCEDURES/SURGERY/SERVICES

801. General (I).

A. Care, treatment, procedures, surgery, and/or services shall be provided, given, or performed effectively and safely in accordance with orders from physicians or other legally authorized healthcare providers, and precautions shall be taken for patients with special conditions, *e.g.*, pacemakers, pregnancy, Alzheimer's disease, etc., and/or for those who may be susceptible to deleterious effects as a result of the treatment.

B. The facility shall comply with all current federal, state, and local laws and regulations related to patient care, treatment, procedures, surgery, and/or services, and protection.

C. When a facility engages a source other than the facility to provide services normally provided by the facility, *e.g.*, staffing, training, food service, maintenance, housekeeping, there shall be a written agreement with the source that describes how and when the services are to be provided, the exact services to be provided, and a statement that these services are to be provided by qualified individuals. The source shall comply with this regulation in regard to patient care, treatment, procedures, surgery, and/or services, confidentiality, and rights. (II)

D. The Facility shall have a written transfer agreement with one (1) or more hospitals that provides reasonable assurance that transfer of patients will be made between the hospital and the facility. The transfer agreement shall be dated and signed by authorized officials who are a party to the agreement. The agreement shall be updated following a change of Administrator; the agreement shall be updated following changes in licensee or at any other time as deemed advisable to maintain or further improve continuity of care.

Exception: A facility which has attempted, but has been unable to secure such an agreement shall maintain documentation of its efforts, and shall provide the local hospitals written notice of its hours of operation and patient population.

802. Physical Examination (I).

A. A preoperative history and physical examination, pertaining to the procedure to be performed, shall be completed by a physician or legally authorized healthcare provider no earlier than 14 days prior to surgery/procedure, or 30 days prior to surgery/procedure with the condition that, on the day of surgery/procedure, the physician or legally authorized healthcare provider documents no notable changes in the original history and physical examination. If notable changes are discovered at that time, a history and physical examination shall be completed. A discharge summary from a health care facility that includes a history and physical examination may be acceptable as the preoperative history and physical examination, provided the summary is within the time requirements of this section, and is reviewed by the physician or legally authorized healthcare provider performing the surgery/procedure.

B. If a patient or potential patient has a communicable disease, a physician or other legally authorized healthcare provider shall insure that the facility has the capability to provide adequate care and prevent the spread of the disease, and that the staff members are adequately trained and qualified to manage the patient, or transfer the patient to an appropriate facility, if necessary.

803. Surgical Services.

If surgical services are provided, a current listing of all types of surgical services offered by the facility shall be available.

804. Anesthesia Services (I).

A. Anesthesia shall be administered only by:

1. An anesthesiologist;

2. A physician, other than an anesthesiologist, or dentist, or podiatrist who is qualified to administer anesthesia pursuant to the S.C. Code of Laws;

3. A certified registered nurse anesthetist; or

4. An anesthesiologist's assistant.

B. Immediately before surgery:

1. A physician must examine the patient to evaluate the risk of the procedure to be performed; and

2. A physician, certified registered nurse anesthetist, or anesthesiologist's assistant must examine the patient to evaluate the risk of anesthesia.

~~B~~C. After the administration of a general anesthetic, a patient shall be attended by a physician until the patient may be safely placed under post-operative/procedure supervision by the nursing staff who shall then attend the patient until he or she has regained full consciousness, or until the effects of the anesthetic have sufficiently subsided for the patient to be able to summon aid when needed.

805. Laboratory Services (II).

A. Each facility shall provide or make arrangements for obtaining laboratory services required in connection with the surgery/procedure to be performed.

B. Should the facility conduct tests that involve human specimens by utilizing any laboratory equipment such as finger-stick glucose, hemoglobin, monitoring devices, *etc.*, for the purpose of providing information for the diagnosis, prevention, or treatment of disease or impairment, or assessment of health, the facility shall obtain a Certificate of Waiver from the Clinical Laboratories Improvement Amendments (CLIA) Program through the Department's CLIA Program.

C. Laboratory supplies shall not be expired.

D. A pathologist shall examine all surgical specimens except for those types of specimens that the medical staff has determined and documented do not require examination.

806. Radiology Services (II).

A. Each facility shall have the capability of providing or obtaining diagnostic radiology services in connection with the surgery/procedure to be performed.

B. Those facilities where radiological equipment and materials are used shall be in compliance with R.61-63 and R.61-64.

807. Cardiovascular Care Services.

A. Prior to establishing or offering invasive cardiac procedures, including cardiac catheterization services, a facility must have applied for and be in the process of obtaining accreditation for such services from the American College of Cardiologists, Accreditation for Cardiovascular Excellence, or other

nationally recognized accrediting organization approved by the Department. To continue providing such services, a facility must obtain such accreditation within two years from application unless otherwise approved by the Department. Facilities must maintain documentation evidencing their application for accreditation and accreditation for such services. If a facility is denied accreditation or has its accreditation revoked, the facility must immediately notify the Department in writing, cease offering such services, and cannot resume offering such services for a period of five years from the date of denial or revocation.

B. Facilities that offer cardiac catheterization services shall have written protocols ensuring immediate, efficient, and safe transfer of patients to the nearest hospital with onsite cardiac surgery in the case of an emergency.

808. Adverse Conditions (I).

Patients in whom any adverse condition exists or in whom a complication is known or suspected to have occurred during or after the performance of the operative procedure shall remain in the facility until the condition/complication is eliminated, as determined by the physician, and the patient is stabilized. Patients requiring care for periods in excess of those set forth in Section 101.RR shall be transferred to a hospital.

~~808~~809. Patient Instruction (I).

Written instructions shall be issued to all patients upon discharge and shall include, at a minimum, the following:

A. Signs and symptoms of possible complications;

B. Telephone number of the facility or the attending physician or other knowledgeable professional staff member from the facility should any complication occur or question arise;

C. An emergency telephone number should any complication occur. It shall be the responsibility of the attending physician to arrange for needed care;

D. Limitations regarding activities, foods, *etc.*;

E. Date for follow-up or return visit, if applicable.

SECTION 900

RIGHTS AND ASSURANCES

901. General (II).

A. The facility shall comply with all current federal, state, and local laws and regulations concerning patient care, treatment, procedures, surgery, and/or services, patient rights and protections, and privacy and disclosure requirements~~, *e.g.*, § 44-81-10, *et seq.*, S.C. Code Ann. (2002)~~.

B. The facility shall comply with all relevant federal, state, and local laws and regulations concerning discrimination, *e.g.*, Title VII, Section 601 of the Civil Rights Act of 1964, and insure that there is no discrimination with regard to source of payment in the recruitment, location of patient, acceptance or provision of services to patients or potential patients, provided that payment offered is not less than the cost of providing services.

C. The facility shall develop and post in a conspicuous place in a public area of the facility a grievance/complaint procedure to be exercised on behalf of the patients that includes the address and phone number of the Department and a provision prohibiting retaliation should the grievance right be exercised.

D. Care, treatment, procedures, surgery, and/or services provided by the facility, and the charges for such, shall be delineated in writing. Patients shall be made aware of such charges and services, as verified by the signature of the patient or responsible party.

E. Patients shall be permitted to use the telephone and allowed privacy when making calls.

F. Adequate safeguards shall be provided for protection and storage of patients' personal belongings.

G. Patient rights shall be guaranteed, prominently displayed, and the facility shall inform the patient of these rights, to include, at a minimum:

1. The care, treatment, procedures, surgery, and/or services to be provided;

2. Informed consent for care, treatment, procedures, surgery, and/or services;

3. Respect for the patient's property;

4. Freedom from mental and physical abuse and exploitation;

5. Privacy while being treated and while receiving care;

6. Respect and dignity in receiving care, treatment, procedures, surgery, and/or services;

7. Refusal of treatment. The patient shall be informed of the consequences of refusal of treatment, and the reason shall be reported to the physician and documented in the patient record;

8. Refusal of experimental treatment and drugs. The patient's written consent for participation in research shall be obtained and retained in his or her patient record;

9. Confidentiality and privacy of records. Written consent by the patient shall be obtained prior to release of information except to persons authorized by law. If the patient is mentally incompetent, written consent is required from the patient's responsible party. The facility shall establish policies to govern access and duplication of the patient's record.

H. Except in emergencies, documentation regarding informed consent shall be properly executed prior to surgery/procedure.

SECTION 1000

MEDICATION MANAGEMENT

1001. General (I).

A. Medications, including controlled substances, medical supplies, intravenous solutions, and those items necessary for the rendering of first aid shall be properly managed in accordance with local, state, and federal laws and regulations, to include the securing, storing, and administering of medications, medical

supplies, first aid supplies, biologicals and their disposal when discontinued or expired, or at discharge, death, or transfer of a patient.

B. Non-legend medications that can be obtained without a prescription may be retained and labeled as stock in the facility for administration as ordered by a physician or other legally authorized healthcare provider.

C. If controlled substances are to be used, a controlled substances registration from the Department's Bureau of Drug Control and a controlled substance registration from the federal Drug Enforcement Administration (DEA) shall be obtained. The registration(s) shall be displayed in a conspicuous location within the facility.

D. Each facility shall maintain, upon the advice and written approval of the Medical Director or consultant pharmacist, an emergency kit/cart of lifesaving medicines and equipment for the use of physicians or other legally authorized healthcare providers in treating the emergency needs of patients.

1. The kit/cart shall be sealed and stored in such a manner as to prevent unauthorized access and to ensure a proper environment for preservation of the medications within, but in such a manner as to allow immediate access.

2. The exterior of each emergency medication kit/cart shall have displayed the following information:

a. "For Emergency Use Only";

b. Name, address, and telephone number of the consultant pharmacist.

3. Whenever the kit/cart is opened, it shall be restocked and resealed within a reasonable time to prevent risk of harm to a patient.

4. Medications used from the kit/cart shall be replaced pursuant to orders from a physician or other legally authorized healthcare provider according to facility policy.

5. Contents of each section of the kit/cart shall be listed and maintained on or in the kit/cart, and shall correspond to the list. Documentation of monthly checks of expiration dates of medications and supplies is to be retained by the facility for a period of two years or until the Department's next inspection, whichever is longer.

E. Medications shall not be expired.

F. Applicable reference materials published within the previous year shall be available at the facility in order to provide staff members with adequate information concerning medications.

1002. Medication Orders (I).

A. Medications, to include oxygen, shall be administered in the facility to patients only upon orders of a physician or other legally authorized healthcare provider.

B. All orders (including verbal) shall be received only by licensed nurses or authorized healthcare providers, and shall be authenticated and dated by a physician or other legally authorized healthcare provider pursuant to the facility's policies and procedures, but no later than 72 hours after the order is given. Verbal orders received shall include the time of receipt of the order, description of the order, and

identification of the physician or other legally authorized healthcare provider and the individual receiving the order.

C. Medications and medical supplies ordered for a specific patient shall not be provided to or administered to any other patient.

1003. Administering Medication (I).

A. Each medication dose administered shall be properly recorded in the patient's record as the medication is administered. The medication administration record shall include the name of the medication, dosage, mode of administration, date, time, and the signature of the individual administering the medication. Initials may be utilized when recording administration, provided identification of the individual's initials is located within the record.

B. Expired medications shall not be administered to patients.

1004. Pharmacy Services (I).

Facilities that maintain stocks of legend medications and biologicals for patient use within the facility shall obtain and maintain from the S.C. Board of Pharmacy a valid, current, nondispensing drug outlet permit, displayed in a conspicuous location in the facility, and have a consultant pharmacist on-call during facility operating hours.

1005. Medication Containers (I).

Medications for each patient shall be dispensed from their original container(s), to include unit dose systems. There shall be no transferring between containers or opening blister packs to remove medications for destruction or adding new medications for administration, except by direction of a pharmacist.

1006. Medication Storage (I).

A. Medications shall be stored under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, safety and security. Medications shall be stored in accordance with manufacturer's directions and in accordance with all applicable state and federal laws and regulations.

B. Medications shall be properly stored and safeguarded to prevent access by unauthorized persons. Expired or discontinued medications shall not be stored with current medications. Storage areas shall be of sufficient size for clean and orderly storage, and shall be locked when not under direct observation by a licensed healthcare provider. Storage areas shall not be located near sources of heat, humidity, or other hazards that may negatively impact medication effectiveness or shelf-life.

C. Medications requiring refrigeration shall be stored in a refrigerator at the temperature established by the U. S. Pharmacopeia (36 - 46 degrees F.). Food and drinks shall not be stored in the same refrigerator in which medications and biologicals are stored. Blood and blood products may be stored in the same refrigerator with medications and biologicals if stored in a separate compartment from the medications and biologicals.

D. Medications shall be stored:

1. Separately from poisonous substances, blood, or body fluids;

2. In a manner that provides for separation between oral and topical medications;

3. Separately from food.

E. Records shall be maintained of all stock controlled substances that indicate an accounting of all items received and/or administered in such a manner that the disposition of each dose of any particular item may be readily traced. Records shall be maintained for a minimum of two years or until the next inspection by the Department, whichever is longer.

F. Review of medication storage areas shall be conducted by the consultant pharmacist or his or her designee on at least a monthly basis. Records of such reviews shall be retained by the facility for at least two years or until the Department's next inspection, whichever is longer.

1007. Disposition of Medications (I).

A. Medications shall not be retained in stock after the expiration date on the label and no contaminated or deteriorated medications shall be maintained. Expired, damaged, or deteriorated medications and biologicals shall be disposed of in the following manner:

1. When noncontrolled legend medications are destroyed, the following shall be documented: date of destruction, medication name, strength, quantity, mode of destruction, and the names of the individual performing the destruction and a witness. (This shall not be applicable to partial unused doses of medications.) The medications may also be disposed of by returning them to the dispensing pharmacy and obtaining a receipt from the pharmacy.

2. The destruction of controlled substances shall be accomplished pursuant to the requirements of R.61-4.

B. Destruction records shall be retained by the facility for at least two years or until the Department's next inspection, whichever is longer.

SECTION 1100

MEAL SERVICE

1101. General (II).

A. All facilities that prepare food on-site shall be approved by the Department, and shall be regulated, inspected, and graded pursuant to R.61-25.

B. When meals or snacks are catered to a facility, such meals shall be obtained from a food service establishment graded by the Department, pursuant to R.61-25, and there shall be a written executed contract with the food service establishment.

1102. Food Storage (II).

A. All food items shall be stored at a minimum of six inches above the floor on clean surfaces and in such a manner as to be protected from splash and other contamination.

B. Food stored in the refrigerator or freezer shall be covered, labeled, and dated. Prepared food shall not be stored in the refrigerator for more than 72 hours.

1103. Food Equipment and Utensils (II).

The equipment and utensils utilized, and the cleaning, sanitizing, and storage of such shall be in accordance with R.61-25.

1104. Ice and Drinking Water (II).

A. Ice from a water system that is in accordance with R.61-58, shall be available and precautions taken to prevent contamination. The ice scoop shall be stored in a sanitary manner outside of the ice container.

B. Potable drinking water shall be available and accessible to patients at all times.

C. The use of common drinking cups shall be prohibited.

D. Ice delivered to patient areas in bulk shall be in nonporous, covered containers that shall be cleaned after each use.

1105. Equipment (II).

A. Liquid or powder soap in dispensers and sanitary paper towels shall be available at each food service handwash lavatory.

B. The facility shall include a separate handwash sink, convenient to serving, food preparation, and dishwashing areas.

C. All walk-in refrigerators and freezers shall be equipped with opening devices that will permit opening of the door from the inside at all times. (I)

1106. Refuse Storage and Disposal (II).

Refuse storage and disposal shall be in accordance with R.61-25.

SECTION 1200

EMERGENCY PROCEDURES/DISASTER PREPAREDNESS

1201. Emergency Services (I).

A. Appropriate equipment and services shall be provided to render emergency resuscitative and life-support procedures pending transfer to a hospital. The emergency equipment must meet the following requirements:

1. Be immediately available for use during emergency situations;

2. Be appropriate for the facility's patient population; and

3. Be maintained by appropriate personnel in accordance with manufacturer's instructions.

~~B. The facility shall have the capability of obtaining blood and blood products to meet emergency situations.~~

1202. Disaster Preparedness (II).

A facility that participates in a community disaster plan shall establish plans, based on its capabilities, to meet its responsibilities for providing emergency care.

1203. Emergency Call Numbers (I).

Although the facility may have access to "911," emergency call data shall be immediately available and shall include, at a minimum, the telephone numbers of fire and police departments, ambulance service, and the Poison Control Center. Other emergency call information shall be available, to include the names, addresses, and telephone numbers of staff members to be notified in case of emergency.

1204. Continuity of Essential Services (II).

There shall be a written plan to be implemented to assure the continuation of essential patient support services for reasons such as power outage, water shortage, or in the event of the absence of any portion of the staff resulting from inclement weather or other causes.

SECTION 1300

FIRE PREVENTION

1301. Arrangements for Fire Department Response/Protection (I).

A. Each facility shall develop, in coordination with its supporting fire department and/or disaster preparedness agency, suitable written plans for actions to be taken in the event of fire, *i.e.*, fire plan and evacuation plan.

B. Facilities located outside a service area or range of a public fire department shall arrange for the nearest fire department to respond in case of fire by written agreement with that fire department. A copy of the agreement shall be kept on file in the facility.

1302. Tests and Inspections (I).

A. Fire protection and suppression systems shall be maintained and tested in accordance with NFPA 10, 13, 14, 15, 25, 70, 72, and 96.

B. Fire alarm systems shall be maintained in a safe, operable condition in accordance with NFPA 70 and 99 and shall be inspected at least annually.

1303. Fire Response Training (I).

A. Each staff member shall receive training within 24 hours of his or her first day of employment in the facility and at least annually thereafter, addressing at a minimum, the following:

1. Fire plan;

2. Reporting a fire;

3. Use of the fire alarm system, if applicable;

4. Location and use of fire-fighting equipment;

5. Methods of fire containment; and

6. Specific responsibilities, tasks, or duties of each staff member.

B. A plan for the evacuation of patients, staff members, and visitors, to include evacuation routes and procedures in case of fire or other emergencies, shall be established and posted in conspicuous public areas throughout the facility.

1304. Fire Drills (I).

A. An unannounced fire drill shall be conducted at least quarterly for all shifts. Each staff member shall participate in a fire drill at least once each year. Records of drills shall be maintained at the facility, indicating the date, time, shift, description and evaluation of the drill, and the names of staff members directly involved in responding to the drill. If fire drill requirements are mandated by statute or regulation, the provisions of the statute or regulation shall be complied with and shall supersede the requirements of this section.

B. Drills shall be designed and conducted in consideration of and reflecting the content of the fire response training described in Section 1303 above.

SECTION 1400

MAINTENANCE

1401. General (II).

A. The structure, including its component parts and equipment, shall be properly maintained to perform the functions for which it is designed.

B. The facility shall keep its component parts and all equipment in good repair and operating condition and documented.

1402. Equipment (II).

A. Equipment used in the provision of care, treatment, procedures, surgery, and/or services shall meet appropriate specifications and calibrations and shall be monitored and operated in accordance with the manufacturer's guidelines and with local, State, and Federal laws.

B. If utilized, all equipment for the administration of anesthesia shall be readily available, clean or sterile, and operating properly.

1. Anesthesia apparatus shall be equipped with a device to measure the oxygen component of the gas being inhaled by the patient. The device shall emit audible and visual alarms should the proportion of oxygen fall below a safe level. (I)

2. Inspections shall be made prior to each use of the anesthesia equipment, as well as a record of all service and repair performed on all anesthesia machines, vaporizers, and ventilators, shall be maintained and retained for a minimum of two years or until the next Department's inspection, whichever is longer.

1403. Preventive Maintenance of Life Support Equipment (II).

A. A written preventive maintenance program shall be developed and implemented for all life support equipment, to include, but not be limited to:

1. Patient monitoring equipment;

2. Isolated electrical systems;

3. Patient ground systems; and

4. Medical gas systems.

B. This equipment shall be calibrated, if applicable, and/or tested at periodic intervals, but not less than annually, to insure proper operation. After repairs and/or alterations are made to any equipment or system, thorough testing for proper operation shall be accomplished prior to returning it to service. (I)

C. Records shall be maintained on all life support equipment to indicate its history of testing and maintenance.

SECTION 1500

INFECTION CONTROL AND ENVIRONMENT

1501. Staff Practices (I).

Staff and volunteer practices shall promote conditions that prevent the spread of infectious, contagious, or communicable diseases and provide for the proper disposal of toxic and hazardous substances. These preventive measures and practices shall be in compliance with applicable guidelines of the Bloodborne Pathogens Standard of the Occupational Safety and Health Act (OSHA) of 1970; the Centers for Disease Control and Prevention (CDC) Immunization of Health-Care Workers: Recommendations of the Advisory Committee on Immunization Practices and the Hospital Infection Control Practices Advisory Committee; the Department's *Guidelines For Prevention and Control of Antibiotic Resistant Organisms in Health Care Settings*, and R.61-105; and other applicable federal, state, and local laws and regulations.

1502. Vaccinations (I).

A. Hepatitis B.

1. All direct care staff who perform tasks involving contact with blood, blood-contaminated body fluids, other body fluids, or sharps shall have the hepatitis B vaccination series unless the vaccine is contraindicated or an individual is offered the series and declines. In either case the decision shall be documented.

2. Each staff member who elects vaccination shall have completed the initial dose of the three-dose series within 30 days of employment.

B. Influenza. All direct care staff shall have an annual influenza vaccination unless contraindicated or offered and declined. In either case the decision shall be documented.

C. MMR and Varicella. All direct care staff shall have been vaccinated or have evidence of immunity for measles, rubella, and varicella prior to patient contact unless contraindicated or offered and declined. In either case the decision shall be documented. Immunity to mumps is recommended.

1503. Live Animals.

Live animals shall not be permitted in facilities.

EXCEPTION: This standard does not apply to patrol dogs accompanying security or police officers, guide dogs, or other service animals accompanying individuals with disabilities.

1504. Sterilization Procedures (I).

A. Sterilizing equipment of appropriate type shall be available and of adequate capacity to properly sterilize instruments and operating room materials as well as laboratory equipment and supplies. The sterilizing equipment shall have approved control and safety features. The accuracy of instrumentation and equipment shall be tested at least quarterly; periodic calibration and/or preventive maintenance shall be provided as necessary and a history of testing and service maintained.

B. The dates of sterilization and expiration shall be marked on all supplies sterilized in the facility.

EXCEPTION: Facilities may utilize "event-related" methodologies for determining sterile integrity in lieu of "time-related" methods provided there is an established policy and procedure.

C. The facility shall provide for appropriate storage and distribution of sterile supplies and equipment pursuant to facility policies and procedures.

D. Cleaning and disinfection, as needed, of equipment used and/or maintained in each area, appropriate to the area and the equipment's purpose or use, shall be accomplished. A recognized method of monitoring disinfectant performance shall be employed. Disinfectants, *e.g.*, glutraldehyde, Cidex, Sporox, hydrogen peroxide, shall be tested and maintained according to manufacturer's instructions and shall include, at a minimum, a record of readings/testings and change dates of the disinfectant solution.

E. Collection, transportation, and storage of contaminated or used equipment must be performed in a safe manner and in accordance with approved policies and procedures of the Facility.

1505. Tuberculosis Risk Assessment (I).

A. All facilities shall conduct an annual tuberculosis risk assessment in accordance with CDC guidelines (See Section 102.B.6) to determine the appropriateness and frequency of tuberculosis screening and other tuberculosis related measures to be taken.

B. The risk classification, *i.e.*, low risk, medium risk, shall be used as part of the risk assessment to determine the need for an ongoing TB screening program for staff and patients and the frequency of screening. A risk classification shall be determined for the entire facility. In certain settings, *e.g.*, healthcare organizations that encompass multiple sites or types of services, specific areas defined by geography, functional units, patient population, job type, or location within the setting may have separate risk classifications.

1506. Staff Tuberculosis Screening (I).

A. Tuberculosis Status. Prior to date of hire or initial patient contact, the tuberculosis status of direct care staff shall be determined in the following manner in accordance with the applicable risk classification:

B. Low Risk:

1. Baseline two-step Tuberculin Skin Test (TST) or a single Blood Assay for *Mycobacterium tuberculosis* (BAMT): All staff (within three (3) months prior to contact with patients) unless there is a documented TST or a BAMT result during the previous twelve (12) months. If a newly employed staff has had a documented negative TST or a BAMT result within the previous twelve (12) months, a single TST (or the single BAMT) can be administered to serve as the baseline.

2. Periodic TST or BAMT is not required.

3. Post-exposure TST or a BAMT for staff upon unprotected exposure to *M. tuberculosis*: Perform a contact investigation when unprotected exposure is identified.

Administer one (1) TST or a BAMT as soon as possible to all staff who have had unprotected exposure to an infectious TB case/suspect. If the TST or the BAMT result is negative, administer another TST or a BAMT eight to ten (8-10) weeks after that exposure to *M. tuberculosis* ended.

C. Medium Risk:

1. Baseline two-step TST or a single BAMT: All staff (within three (3) months prior to contact with patients) unless there is a documented TST or a BAMT result during the previous twelve (12) months. If a newly employed staff has had a documented negative TST or a BAMT result within the previous twelve (12) months, a single TST (or the single BAMT) can be administered to serve as the baseline.

2. Periodic testing (with TST or BAMT): Annually, of all staff who have risk of TB exposure and who have previous documented negative results. Instead of participating in periodic testing, staff with documented TB infection (positive TST or BAMT) shall receive a symptom screen annually. This screen shall be accomplished by educating the staff about symptoms of TB disease (including the staff and/or direct care volunteers responses), documenting the questioning of the staff about the presence of symptoms of TB disease, and instructing the staff to report any such symptoms immediately to the administrator or director of nursing. Treatment for latent TB infection (LTBI) shall be considered in accordance with CDC and Department guidelines and, if recommended, treatment completion shall be encouraged.

3. Post-exposure TST or a BAMT for staff upon unprotected exposure to *M. tuberculosis*: Perform a contact investigation when unprotected exposure is identified. Administer one (1) TST or a BAMT as soon as possible to all staff who have had unprotected exposure to an infectious TB case/suspect. If the TST or the BAMT result is negative, administer another TST or a BAMT eight to ten (8-10) weeks after that exposure to *M. tuberculosis* ended.

D. Baseline Positive or Newly Positive Test Result:

1. Staff with a baseline positive or newly positive test result for *M. tuberculosis* infection (*i.e.*, TST or BAMT) or documentation of treatment for latent TB infection (LTBI) or TB disease or signs or symptoms of tuberculosis, *e.g.*, cough, weight loss, night sweats, fever, shall have a chest radiograph performed immediately to exclude TB disease (or evaluate an interpretable copy taken within the previous three (3) months). These staff members will be evaluated for the need for treatment of TB disease or latent TB infection (LTBI) and will be encouraged to follow the recommendations made by a physician with TB expertise (*i.e.*, the Department's TB Control program).

2. Staff who are known or suspected to have TB disease shall be excluded from work, required to undergo evaluation by a physician or legally authorized healthcare provider, and permitted to return to work only with approval by the Department TB Control program. Repeat chest radiographs are not required unless symptoms or signs of TB diseases develop or unless recommended by a physician or legally authorized healthcare provider.

1507. Housekeeping (II).

The facility and its grounds shall be uncluttered, clean, and free of vermin and offensive odors.

A. Interior housekeeping shall at a minimum include:

1. Cleaning each specific area of the facility (dry sweeping and dusting shall be prohibited in restricted areas as identified in facility policies and procedures);

2. Cleaning of operating/procedure rooms in accordance with established written procedures after each operation/procedure.

B. Exterior housekeeping shall at a minimum include:

1. Cleaning of all exterior areas, *e.g.*, porches and ramps, and removal of safety impediments such as snow and ice;

2. Keeping facility grounds free of weeds, rubbish, overgrown landscaping, and other potential breeding sources for vermin.

1508. Infectious Waste (I).

Accumulated waste, including all contaminated sharps, dressings, and/or similar infectious waste, shall be disposed of in a manner compliant with OSHA Bloodborne Pathogens Standard, the Department's Guidelines For Prevention and Control of Antibiotic Resistant Organisms in Health Care Settings, and R.61-105.

1509. Clean/Soiled Linen and Surgical Clothing (II).

A. A supply of clean, sanitary linen/surgical clothing shall be available at all times. In order to prevent the contamination of clean linen/surgical clothing by dust or other airborne particles or organisms, it shall be stored and transported in a sanitary manner, *i.e.*, enclosed and covered. Linen/Surgical clothing storage rooms shall be used only for the storage of linen/surgical clothing. Clean linen/Surgical clothing shall not be stored with other items.

B. Soiled linen/Surgical clothing.

1. Provisions shall be made for collecting, transporting, and storing soiled linen and surgical clothing;

2. Soiled linen/Surgical clothing shall be kept in enclosed/covered containers.

SECTION 1600

QUALITY IMPROVEMENT PROGRAM

1601. General (II).

A. There shall be a written, implemented quality improvement program that provides effective self-assessment and implementation of changes designed to improve the care, treatment, procedures, surgery, and/or services provided by the facility.

B. The quality improvement program, at a minimum, shall:

1. Establish desired outcomes and the criteria by which policy and procedure effectiveness is systematically, objectively, and regularly accomplished at a frequency as determined by the facility to ensure that policies and procedures and this regulation are met, but not less than every three months;

2. Identify, evaluate, and determine the causes of any deviation from the desired outcomes;

3. Identify the action taken to correct deviations and prevent future deviation, and the person(s) responsible for implementation of these actions;

4. Establish ways to measure the quality of patient care and staff performance as well as the degree to which the policies and procedures are followed;

5. Analyze the necessity of care, treatment, procedures, surgery, and/or services rendered;

6. Analyze the effectiveness of the fire plan;

7. Analyze all serious incidents and accidents, to include all patient deaths and significant medication errors;

8. Analyze any other unusual occurrences that threaten the health, safety, or well-being of the patients;

9. At least every three months, review an established percentage of patient records to verify the accuracy and integrity of the system, and take corrective action as needed;

10. Establish a systematic method of obtaining feedback from patients and other interested persons, *e.g.*, family members and peer organizations, as expressed by the level of satisfaction with care, treatment, procedures, surgery, and/or services received.

C. The governing body must ensure the quality improvement program:

1. Is defined, implemented, and maintained by the Facility;

2. Addresses the Facility's priorities and that all improvements are evaluated for effectiveness;

3. Specifies data collection methods, frequency, and details;

4. Clearly establishes its expectations for safety; and

5. Adequately allocates sufficient staff, time, information systems, and training to implement the quality improvement program.

DESIGN AND CONSTRUCTION

1701. General (II).

A facility shall be planned, designed, and equipped to provide and promote the health, safety, and well-being of each patient.

1702. Local and State Codes and Standards (II).

Buildings shall comply with pertinent local and state laws, codes, ordinances, and standards with reference to design and construction. No facility shall be licensed unless the Department has assurance that responsible local officials (zoning and building) have approved the facility for code compliance.

1703. Applicable Code Editions (II).

A. Facility design and construction shall comply with provisions of the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal applicable to ambulatory surgical facilities.

B. Unless specifically required otherwise by the Department, all facilities shall comply with the construction codes and construction regulations applicable at the time its license was issued.

C. Any facility that closes, has its license revoked, or surrenders its license, and applies for re-licensure at the same site, shall be considered a new building and shall meet the current codes, regulations, and requirements for the building and its essential equipment and systems in effect at the time of application for re-licensing.

1704. Submission of Plans and Specifications.

A. Plans and specifications shall be submitted to the Department for review and approval for new construction, additions or alterations to existing buildings, replacement of major equipment, buildings being licensed for the first time, buildings changing license type, and for facilities increasing occupant load or licensed capacity. Final plans and specifications shall be prepared by an architect and/or engineer registered in South Carolina and shall bear their seals and signatures. Architectural plans shall also bear the seal of a South Carolina registered architectural corporation. Unless directed otherwise by the Department, submit plans at the schematic, design development, and final stages. All plans shall be drawn to scale with the title, stage of submission and date shown thereon. Any construction changes from the approved documents shall be approved by the Department. Construction work shall not commence until a plan approval has been received from the Department. During construction the owner shall employ a registered architect and/or engineer for observation and inspections. Upon approval of the Department, construction administration may be performed by an entity other than the architect. The Department shall conduct periodic inspections throughout each project.

B. Plans and specifications shall be submitted to the Department for review and approval for projects that have an effect on:

1. The function of a space;

2. The accessibility to or of an area;

3. The structural integrity of the facility;

4. The active and/or passive fire safety systems (including kitchen equipment such as exhaust hoods or equipment required to be under an exhaust hood);

5. Doors;

6. Walls;

7. Ceiling system assemblies;

8. Exit corridors;

9. Life safety systems; or

10. That increases the occupant load or licensed capacity of the facility.

C. All subsequent addenda, change orders, field orders, and documents altering the Department review must be submitted. Any substantial deviation from the accepted documents shall require written notification, review and re-approval from the Department.

D. Cosmetic changes utilizing paint, wall covering, floor covering, etc., that are required to have a flame-spread rating or other safety criteria shall be documented with copies of the documentation and certifications kept on file at the facility and made available to the Department.

E. Any construction work which violates codes or standards will be required to be brought into compliance. All projects shall obtain all required permits from the locality having jurisdiction. Construction without proper permitting shall not be inspected by Department.

1705. Construction Inspections.

All projects shall obtain all required permits from the locality having jurisdiction. Construction without proper permitting shall not be inspected by Department.

SECTION 1800

FIRE PROTECTION EQUIPMENT AND SYSTEMS

1801. Fire Alarms (I).

A. A facility shall include a partial, manual, automatic, supervised fire alarm system. The system shall be arranged to transmit an alarm automatically to a third party by an approved method. The alarm system shall notify by audible and visual alarm all areas and floors of the building. The alarm system shall shut down central recirculating systems and outside air units that serve the area(s) of alarm origination as a minimum.

B. There must be a fire alarm pull station at each required exit and in or near each nurses station.

C. All fire, smoke, heat, sprinkler flow, or manual fire alarming devices or systems must be connected to the main fire alarm system and trigger the system when they are activated.

1802. Gases (I).

Safety precautions shall be taken against fire and other hazards when oxygen is dispensed, administered, or stored. “No Smoking” signs shall be posted conspicuously inside the facility and on oxygen cylinders. All cylinders shall be properly secured in place.

SECTION 1900

ELECTRICAL

1901. Signal System.

A. All facilities shall have a signal system consisting of a call button for each bed, bath, toilet and treatment/examination room. A light shall be at or over each patient room door visible from the corridor. There shall be an audio-visual master station in a location continuously monitored by staff.

B. Activation of signal system shall be by pull cord or electronic device. Pull cord shall hang to a maximum of four (4) inches above finished floor.

1902. Emergency Generator Service (I).

A. With concurrence of the local authority having jurisdiction, facilities shall have an emergency generator with a ten (10) second startup and six (6) hour run time based on the maximum load rating of the generator. As a minimum, emergency power shall be provided for but not limited to:

1. Emergency and Exit lighting;

2. Lighting for staff work areas;

3. All lighting and power at patient care areas;

4. Fire alarm telephone and signal systems;

5. At least one (1) elevator where required;

6. Fire pump and associated equipment;

7. Public toilet rooms;

8. All HVAC equipment serving patient areas; and

9. All patient life safety equipment;

EXCEPTION: In endoscopy facilities, an emergency power supply system is not required.

B. An Uninterruptible Power System (UPS) is not acceptable as an alternative to the generator system.

C. In the event of natural disaster or electrical power failure, no new surgery/procedures shall commence, and surgery/procedures in progress shall be concluded as soon as possible.

SECTION 2000

PHYSICAL PLANT

2001. Surgical Suite(s).

The size and design of the surgical suite(s) shall be in accordance with individual programs and this regulation. The following basic elements, designed to ensure no flow of through traffic, shall be incorporated in all facilities:

A. Operating/Procedure Room(s).

1. The number shall depend on the projected caseload and types of procedures to be performed. Rooms shall have adequate space to accommodate necessary equipment and staff.

2. Each operating room shall have a minimum clear area of 180 square feet exclusive of fixed and movable cabinets and shelves. The minimum width shall be 12 feet.

3. Each procedure room shall have a minimum clear area of 140 square feet exclusive of fixed and movable cabinets and shelves. The minimum width shall be 10 feet.

4. Additional clear area may be required as described in the narrative program to accommodate special functions in one or more of these rooms.

5. The facility shall include an emergency communication system connecting with the surgical suite work station.

B. Surgery/Procedure and Recovery Equipment and Supplies

1. Each operating/procedure room shall be completely equipped and supplied for the types of procedures to be performed. (I)

2. The center's medical staff and governing body shall develop policies and procedures to specify the types of emergency equipment required for use in the Ambulatory Surgical Facility's operating room(s). The equipment must meet the following requirements: (I)

(a) Be immediately available for use during emergency situations;

(b) Be appropriate for the facility's patient population; and

(c) Be maintained by appropriate personnel.

C. Surgical/Procedure Service Areas. The facility shall include the following:

1. A work station located to permit visual surveillance of persons entering the surgical/procedure areas and the recovery area;

2. Sterilizing equipment with autoclave(s) conveniently located to serve all operating rooms;

EXCEPTION: Sterilizing equipment is not required in endoscopy facilities; however, a high-level disinfection of equipment is required in such facilities.

3. A medication distribution station provided for storage and preparation of medication to be administered to patients;

4. Scrub facilities provided near the entrance to each operating room. Scrub facilities with foot or knee controls shall be arranged to minimize any incidental splatter on nearby staff or supply carts. At a minimum, the facility shall include the following:

a. Scrub sink with knee, elbow, or foot controls;

b. Soap dispenser.

EXCEPTION: For endoscopy facilities, in lieu of scrub facilities, there shall be a handwash sink in each procedure room that is equipped with valves that can be operated without the use of hands.

5. A soiled workroom for the exclusive use of the surgical suite staff. The soiled workroom shall contain a clinical sink or equivalent flushing type fixture, waste receptacle, and covered soiled receptacle, unless there is a separate soiled linen storage room;

EXCEPTION: In endoscopy facilities, a designated soiled work area will suffice in lieu of a soiled workroom.

6. A clean workroom when clean materials are assembled within the surgical suite prior to use. The workroom shall contain a work counter, a sink equipped for handwashing and space for clean and sterile supplies;

EXCEPTION: In endoscopy facilities, a designated clean work area will suffice in lieu of a clean workroom.

7. An area for cleaning, testing, and storing anesthesia equipment in accordance with accepted principles of aseptic technique.

EXCEPTION: An anesthesia area is not required in endoscopy facilities.

8. Staff change areas that shall contain adequate dressing space for changing of scrubs and shall contain lockers, showers, toilets, lavatories, and receptacles and facilities for the appropriate disposition of soiled scrubs; these areas shall be arranged to allow a restricted traffic pattern of authorized staff from outside the surgical suite to change into appropriate attire and enter the surgical suite;

EXCEPTION: Showers and areas for donning of scrub suits and boots are not required in endoscopy facilities.

9. Provisions for emergency eye-washing.

D. Recovery Area. The facility shall include the following:

1. An area for recovery of patients;

2. Handwashing facilities, secured medication storage space, clerical work space, and sufficient storage space for supplies and equipment;

3. At least four feet between beds or stretchers (two feet if next to a wall) and adequate space at the foot of the bed or stretcher as needed for work and staff circulation;

4. Partitions, walls and/or cubicle curtains (on built-in tracks) to afford visual privacy for each patient;

5. Recovery beds or reclining type of vinyl upholstered chairs or recovery stretchers;

6. Equipment for oxygen, resuscitation, and suction.

2002. Soiled Utility Room.

Facilities shall have at least one soiled utility room per floor containing a clinical sink, work counter, waste receptacle and soiled linen receptacle.

2003. Clean Utility Room.

Facilities shall have at least one clean utility room per floor containing a counter with handwashing sink and space for the storage and assembly of supplies for nursing procedures.

2004. Corridors (II).

A. Minimum public corridor width shall be five feet.

B. There shall be at least one corridor that is no less than eight feet clear width between doors from the recovery area and/or operating/procedure rooms and an exit door. In a one-story building or on the ground floor of a multi-story building, if there is less than eight feet clear width, the corridors shall be so arranged as to allow a stretcher to exit from the recovery area or operating rooms directly into the corridor without turning and move to the required exit without having to make a turn. Minimum width shall be five feet.

C. The location of items such as drinking fountains, telephone booths, vending machines, and portable equipment shall not restrict corridor traffic or reduce the required corridor width. (II)

2005. Handrails/Guardrails (II).

The facility shall have handrails on at least one side of each corridor/hallway, and on all stairways, ramps, and porches with two or more steps. Ends of all installed handrails shall return to the wall.

2006. Restrooms (II).

A. There shall be an appropriate number of restrooms in the facility, to accommodate patients, staff, and visitors.

B. The restrooms shall be accessible during all operating hours of the facility.

C. A restroom(s) shall be equipped with at least one toilet fixture, toilet paper installed in a holder, a lavatory supplied with hot and cold running water, liquid or granulated soap, single-use disposable paper towels or electric air dryer, and a covered waste receptacle.

D. The waiting/lobby area must have at least one restroom.

E. The facility shall have toilet fixtures in restrooms for patient use in ample number, located within or adjacent to the recovery area. The minimum requirement is one toilet fixture for every ~~surgical and procedure room~~eight pre-operative and post-operative beds.

F. All toilet fixtures used by patients shall have approved grab bars securely fastened in a usable fashion.

G. Privacy shall be provided at toilet fixtures and urinals.

2007. Janitor's Closets.

A. The facility shall include at least one (1) lockable janitor's closet throughout the facility.

B. Each shall contain a floor receptor or service sink and storage space for housekeeping equipment and supplies, *e.g.*, mops.

2008. Storage Areas.

A. Adequate general storage areas shall be provided for patient and staff/volunteer belongings, equipment, and supplies as well as clean linen, soiled linen, wheelchairs, and general supplies and equipment.

B. Soiled linen shall be stored in an enclosed room. This room may also be the soiled workroom.

C. Storage buildings on the premises shall meet the requirements of the current building code regarding distance from the licensed building. Storage in buildings other than on the facility premises shall be secure and accessible. An appropriate controlled environment shall be provided if necessary for storage of items requiring such an environment.

D. Supplies/Equipment shall not be stored directly on the floor. Supplies/Equipment susceptible to water damage/contamination shall not be stored under sinks or other areas with a propensity for water leakage.

E. Chemicals indicated as harmful on the product label, cleaning materials, and supplies shall be safely stored in cabinets or well-lighted closets/rooms.

2009. Elevators (II).

Elevators shall be inspected and tested upon installation, prior to first use, and annually thereafter by a certified elevator inspector.

2010. Telephone Service.

At least one land-line telephone shall be available on each floor of the facility for use by patients and/or visitors for their private, discretionary use; pay phones for this purpose are acceptable

2011. Location.

A. Transportation. The facility shall be served by roads that are passable at all times and are adequate for the volume of expected traffic.

B. Parking. The facility shall have a parking area to reasonably satisfy the needs of patients, staff members, and visitors.

C. Access to firefighting equipment. Facilities shall maintain adequate access to and around the building(s) for firefighting equipment. (I)

2012. Incinerators (I).

If the facility has an incinerator, it shall conform to the requirements of the Department.

2013. Furnishings/Equipment (I).

A. The facility shall maintain the physical plant free of fire hazards and impediments to fire prevention.

B. No portable electric or unvented fuel heaters shall be permitted in the facility except as permitted by the State Fire Marshal Regulations.

C. Wastebaskets, window dressings, portable partitions, cubicle curtains, mattresses, and pillows shall be noncombustible, inherently flame-resistant, or treated or maintained flame-resistant in accordance with the applicable code in Section 1700.

2014. Water Requirements.

A. The facility shall establish written policies and procedures to prevent waterborne microbial contamination within the water distribution system.

B. The facility shall ensure the practice of hand hygiene to prevent the hand transfer of pathogens, and the use of barrier precautions (e.g. gloves) in accordance with established guidelines.

C. The facility shall eliminate contaminated water or fluid from environmental reservoirs (e.g. in equipment or solutions) wherever possible.

D. The facility shall not place decorative fountains and fish tanks in patient-care areas. If decorative fountains are used in separate public areas, the facility shall ensure they are disinfected in accordance with manufacturer's instructions and safely maintained.

E. The facility plumbing fixtures that require hot water and are accessible to patients shall be supplied with water which thermostatically controlled to a temperature of at least 100 degrees F. (37.8 degrees C) and not exceeding 125 degrees F. (51.7 degrees C.) at the fixture.

F. The facility shall have a written plan to respond to disruptions in water supply. The plan must include a contingency plan to estimate water demands for the entire facility in advance of significant water disruptions (i.e., those expected to result in extensive and heavy microbial or chemical contamination of the potable water), sewage intrusion, or flooding.

G. When a significant water disruption or an emergency occurs, the facility shall:

1. Adhere to any advisory to boil water issued by the municipal water utility;

2. Alert patients, families, employees, volunteers, students and visitors not to consume water from drinking fountains, ice, or drinks made from municipal tap water, while the advisory is in effect, unless the water has been disinfected;

3. After the advisory is lifted, run faucets and drinking fountains at full flow for greater than 5 minutes, or use high-temperature water flushing or chlorination;

4. All ice and drinks that may have been contaminated must be disposed and storage containers cleaned; and

5. Decontaminate the hot water system as necessary after a disruption in service or a cross-connection with sewer lines has occurred.

H. The facility shall follow appropriate recommendations to prevent cross connection and other sources of contamination of ice for human consumption and to prevent contamination of hydrotherapy equipment and medical equipment connected to water systems (e.g. automated endoscope reprocessors).

I. The facility shall maintain and implement policies and procedures addressing the management of failure of waste water systems.

J. Patient and staff handwashing lavatories and showers, if any, shall include hot and cold water at all times.

2015. Panelboards (II).

The directory shall be labeled to conform to the actual room designations. Clear access of stored materials shall be maintained to the panel. The panelboard directory shall be labeled to conform to the actual room numbers or designations.

2016. Lighting.

A.Spaces occupied by persons, machinery, equipment within buildings, approaches to buildings, and parking lots shall be lighted. (II)

B.The facility shall have adequate artificial light to include sufficient illumination for reading, observation, and activities.

2017. Heating, Ventilation, and Air Conditioning (HVAC) (II).

A. The HVAC system shall be inspected at least once a year by a certified/licensed technician.

B. No HVAC supply or return grill shall be installed within three feet of a smoke detector. (I)

C. Intake air ducts shall be filtered and maintained to prevent the entrance of dust, dirt, and other contaminating materials.

D. Each bath/restroom shall have either operable windows or have approved mechanical ventilation.

SECTION 2100

SEVERABILITY

2101. General.

In the event that any portion of these regulations is construed by a court of competent jurisdiction to be invalid, or otherwise unenforceable, such determination shall in no manner affect the remaining portions of these regulations, and they shall remain in effect as if such invalid portions were not originally a part of these regulations.

SECTION 2200

GENERAL

2201. General.

Conditions that have not been addressed in these regulations shall be managed in accordance with the best practices as interpreted by the Department.

Fiscal Impact Statement:

Implementation of this regulation will not require additional resources. There is no anticipated additional cost by the Department or state government due to any requirements of this regulation.

Statement of Need and Reasonableness:

DESCRIPTION OF REGULATION: 61-91, *Standards for Licensing Ambulatory Surgical Facilities*

Purpose: The Department proposes promulgating provisions concerning uncompensated indigent/charity requirements set forth in S.C. Code Section 44-7-266(C). See 2023 Act No. 20 (S.164). The Department is further proposing amendments related to quality of care, services and treatment provided by ambulatory surgical facilities and the manner and method of fee payments.

Legal Authority: 1976 Code Section(s) 44-7-110 through 44-7-340

Plan for Implementation: The amendments will take legal effect upon General Assembly approval and 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 AND EXPECTED BENEFITS:

The proposed amendments are required to implement newly enacted statutory requirements concerning uncompensated indigent/charity care set forth in S.C. Code Section 44-7-266(C). Further, the proposed amendments will further provide for the quality of care, services, and treatment offered and provided at ambulatory surgical facilities in this State. Many of the proposed amendments relating to quality of care are consistent with the conditions of coverage set forth in Federal Regulation for participation in the Medicare (*see* 42 C.F.R Part 416), which are applicable to a substantial amount of existing facilities. Finally, the proposed amendments relating to fees update the manner and method of fees such that there are more convenient and efficient transactions with the Department.

DETERMINATION OF COSTS AND BENEFITS:

Implementation of these proposed amendments will not require additional resources. There is no anticipated additional cost to the Department or state government due to any inherent requirements of these proposed amendments. There are no anticipated additional costs to the regulated community.

UNCERTAINTIES OF ESTIMATES:

There are no uncertainties associated with the estimations beyond those normally inherent in estimating future costs and benefits.

EFFECT ON ENVIRONMENT AND PUBLIC HEALTH:

The proposed amendments will have no effect on the environment of this State. These regulations contribute to the Department's function of protecting public welfare and promoting safety and wellbeing for patients receiving care and treatment from hospital facilities and institutional general infirmaries.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED:

There is no anticipated detrimental effect on the environment. If the proposed revisions are not implemented, the regulation will be maintained in its current form; the benefits of the proposed amendments herein will not be realized.

Statement of Rationale:

Here below is the Statement of Rationale pursuant to S.C. Code Section 1-23-110(A)(3)(h):

These revised regulations are updated to implement new statutory requirements concerning uncompensated indigent/charity care, and to ensure the safety and wellbeing of patients of ambulatory surgical facilities.

ATTACHMENT B

SUMMARY OF PUBLIC COMMENTS AND DEPARTMENT RESPONSES

R.61-91, *Standards for Licensing Ambulatory Surgical Facilities*

As of December 27, 2023, close of the Notice of Proposed Regulation comment period:

Name	Section
Dr. Robert R. Morgan, Jr.	General
Comment: As it relates to the reporting of various outcomes in Ambulatory Surgical Facilities, I suggest referencing the same requirements for inpatient facilities to seek consistency in the items reported. One example I used in the Board meeting was surgical site infections (SSIs). In the present proposal for amending 61-91, I believe the list of reporting requirements for ASFs is significantly shorter than it is for inpatient facilities. In the interest of patient care, quality outcomes, and full transparency, I respectfully suggest aligning those reporting outcomes as much as possible where appropriate. Department Response: Adopt. Department staff propose amending Section 601.B to incorporate the National Quality Forum's (NQF) list of serious reportable events that are reasonably applicable to ambulatory surgery facilities. *See* Section 601.B.	
Name	Section
Tidelands Health	General
Comment: We believe it is important to limit percutaneous coronary interventions (PCIs) and comprehensive catheterization laboratories to acute care hospitals, which the American College of Cardiology/American Heart Association/SCAI agree are best provided in hospitals for patient safety reasons. Department Response: Not adopt. With advances and improvements in technology, standards of care, etc., which improve quality of care, and the cost savings to patients associated with having procedures performed in facilities, Department staff are reluctant to prohibit facilities from performing PCIs. Notably, CMS has approved reimbursement for PCIs in the ASF setting.	
Name	Section
SCHA	General
Comment: **<u>Cardiovascular Services</u>** Since May 25, 2023, South Carolina has been without a regulatory scheme to ensure the quality and safety of cardiovascular care. Prior to that date, South Carolina's Certificate of Need ("CON") laws required applicants wishing to provide cardiac catheterizations and open-heart surgery in South Carolina to meet certain quality standards.	

Implementing rigorous standards for cardiovascular services in hospital licensure is critical to maintaining safe cardiac care in South Carolina. The *2020 South Carolina Health Plan* ("State Health Plan") provides the appropriate standards for the regulation of cardiac care in South Carolina hospitals. *See* Chapter 8, pp. 65-81. These standards have been thoroughly vetted by various health care policy-making authorities and are familiar to South Carolina's regulated community. SCHA suggests DHEC incorporate the following language into Regulation 61-16 for hospital-based cardiac catheterization and open-heart surgery.

Cardiac Catheterization
SCHA recommends adopting the definitions for cardiac catheterizations contained on pages 65–66 of the State Health Plan. Additionally, SCHA would recommend DHEC incorporate the cardiac catheterization "Scope of Services" section from the State Health Plan into Regulation 61-16. State Health Plan pp. 66-67.

The State Health Plan also contains a set of standards for cardiac catheterization volumes. The higher the volume, the better the care. These standards are set by the American Heart Association, American College of Cardiology, and Society for Cardiovascular Angiography and Interventions ("SCAI").

In the absence of CON, projecting volume standards is no longer necessary. The standards, however, are still an excellent method for evaluating cardiac catheterization programs. SCHA urges DHEC to incorporate those same volume standards into Regulation 61-16 for the evaluation of catheterization procedures and catheterization labs.

The State Health Plan includes specific numbers for various catheterization procedures (e.g., 200 minimum diagnostic catheterizations procedures annually). SCHA suggests DHEC omit the specific numbers and instead refer only to the applicable standards published by the American Heart Association, American College of Cardiology, and SCAI. Doing so prevents a scenario where volumes change but the regulatory process is too slow to adapt. The following language from the State of Florida could serve as a model.

All licensed hospitals that establish adult diagnostic cardiac catheterization laboratory services under section 408.0361, F.S., shall operate in compliance with the most recent guidelines of the American College of Cardiology/American Heart Association regarding the operation of diagnostic cardiac catheterization laboratories. Hospitals are considered to be in compliance with American College of Cardiology/American Heart Association guidelines when they adhere to standards regarding staffing, physician training and experience, operating procedures, equipment, physical plant, and patient selection criteria to ensure patient quality and safety.

See Fla. Admin. Code Ann. R. 59A-3.246.

In addition, SCHA requests that certain cardiac catheterization procedures and catheterization labs remain hospital-based. Specifically, those are percutaneous coronary interventions ("PCIs") and comprehensive catheterization laboratories. According to the American College of Cardiology/American Heart Association/SCAI standards, these services and facilities are best

provided and located in hospitals for patient safety reasons. SCHA proposes the same standards apply in Regulation 61-16.

Open Heart Surgery
SCHA makes a similar recommendation for open heart surgery. DHEC should adopt the State Health Plan definitions and scope of services for open heart surgery. *State Health Plan* pp 75-77. DHEC should also incorporate the applicable standards published by American Heart Association/American College of Cardiology/SCAI for open heart surgery and include all of the standards contained in the State Health Plan on pages 77-80. Just as with cardiac catheterization, however, DHEC should convert the standards from projections to retrospective volume reviews for the service year.

Additional Cardiovascular Care Regulation Needed
We have also included reference to these standards in our comments to Regulation 61-91. Unfortunately, placing standards in Regulation 61-16 alone will not guarantee quality of care for all patients in South Carolina. Without CON, physicians can perform cardiovascular services in ambulatory surgery centers and possibly other locations. SCHA strongly encourages the Department to include the same cardiovascular care standards in 61-16 and 61-91.

Finally, SCHA would encourage DHEC to work with the South Carolina Board of Medical Examiners to modify the office-based surgery rules to include regulation of cardiovascular procedures as well.

Department Response: Partially adopt. Department staff are hesitant to promulgate regulations reinstating Certificate of Need ("CON") standards/criteria for offering cardiovascular care health services as doing so could be inconsistent with the General Assembly's intent in repealing CON for such services. *See* 2023 Act No. 20. However, we recognize both the need to ensure safe cardiovascular care procedures in ASFs and the correlation between volume and outcomes for these services. Accordingly, Department staff propose requiring facilities offering such services to be accredited by a nationally accredited organization and to have written protocols for transfer of patients to the nearest hospital with onsite cardiac surgery. *See* Section 807.

Name	Section
MUSC	General

Comment:
Cardiovascular Care
Consistent with the S.C. Hospital Association's proposal to codify the CON standards for cardiovascular care contained in the 2020 South Carolina Health Plan in hospital licensing regulations, which MUSC supports, such standards should also be codified, where applicable, in Regulation 61-91 to ensure that certain cardiac catheterization procedures can be performed safely in a non-hospital setting. MUSC strongly believes that if DHEC elects to allow certain cardiac procedures to be performed in an ASC, DHEC must amend Regulation 61-91 to incorporate rigorous cardiac catheterization standards in its ASC licensing regulation, which will most appropriately maintain the clinical and quality standards currently governing cardiac catheterization services.

Specifically, MUSC proposes that, in addition to the applicable CON standards in the 2020 Health Plan, DHEC require that an ASC seeking licensure to perform certain cardiac catheterization procedures is owned, in whole or in part, by a hospital licensed under Regulation 61-16. For non-hospital-owned ASC's, DHEC may grant licensure only if all acute care hospitals which offer cardiac catheterization services and/or PCI services, located within a thirty (30) minute automobile travel time of the proposed ASC, provide a written letter of support to DHEC.

Department Response: Partially adopt. As noted above, Department staff are hesitant to promulgate regulations reinstating CON standards/criteria for offering health services as doing so could be inconsistent with the General Assembly's intent in repealing CON for such services. *See* 2023 Act No. 20. However, we recognize both the need to ensure safe cardiovascular care procedures in ASFs and the correlation between volume and outcomes for these services. Accordingly, Department staff propose requiring facilities offering such services to be accredited by a nationally accredited organization and to have written protocols for transfer of patients to the nearest hospital with onsite cardiac surgery. *See* Section 807.

Department staff decline to adopt MUSC's suggestion regarding non-hospital-owned ASFs needing a letter of support from all hospitals within a 30 minute travel time of the ASF. At this time, Department staff finds such a requirement is not necessary for ensuring safe and adequate treatment of persons in ASFs.

Name	Section
SCHA	General

Comment:

Quality, Safety, and Reporting

SCHA believes that DHEC should require ASFs to obtain and maintain certification by the Joint Commission or other accrediting agency that has obtained deemed status from CMS. This standard should apply to any new ASF and a reasonable timeframe should be established for existing ASFs to comply. This standard already applies to hospital-based outpatient surgery and would establish a baseline for quality clinical care and ensure ASFs physical plant, infection control, fire prevention, etc. remain consistent with standards as they evolve.

Department Response: Not adopt. At this time, Department staff have determined accreditation by a third party organization for all facilities is unnecessary as a licensure requirement for ensuring safe and adequate treatment of persons served in South Carolina.

Name	Section
SCHA	General

Comment:
Transfer Agreements
We are pleased to see the inclusion of a required transfer agreement and protocol included in the regulation and encourage DHEC to include this in the final regulation.

Department Response: Acknowledged/Partially Adopted. Based upon another comment regarding transfer agreements (Section 801.D), Department staff have proposed providing an exception where facilities have attempted to obtain a transfer agreement, but are unsuccessful. For such facilities, there shall be documentation of the facilities' efforts to obtain an agreement, and the facilities shall provide the hospitals written notice of their hours of operation and patient population. This proposal encourages facilities and hospitals to enter into transfer agreements; however, it provides an alternative method of compliance for when such agreements are not achievable. Further, this proposal is consistent with the CMS conditions for coverage. *See* 42 C.F.R. § 416.41.

Name	Section
Self Regional Healthcare	General

Comment:
Self Regional Healthcare is pleased to see the inclusion of a required transfer agreement and protocol included in the proposed regulation and encourage DHEC to include this in the final regulation.

Department Response: Acknowledged/Partially Adopted. Based upon another comment regarding transfer agreements (Section 801.D), Department staff have proposed providing an exception where facilities have attempted to obtain a transfer agreement, but are unsuccessful. For such facilities, there shall be documentation of the facilities' efforts to obtain an agreement, and the facilities shall provide the hospitals written notice of their hours of operation and patient population. This proposal encourages facilities and hospitals to enter into transfer agreements; however, it provides an alternative method of compliance for when such agreements are not achievable. Further, this proposal is consistent with the CMS conditions for coverage. *See* 42 C.F.R. § 416.41.

Name	Section
Tidelands Health	103

Comment:
Additional clarity is needed within the regulation to specify the types of procedures that may be performed within an ASF.

We would suggest:

- Amending 103(E)(8) to clarify the procedures permitted within an ASF to be those that can reasonably be expected to require four hours or less of operating time and require four hours or less of directly supervised recovery. Permitted procedures should include, but not be limited to, procedures listed on the Centers for Medicare and Medicaid Services 2022 Ambulatory Surgical Center Covered Procedures List and its successors. Pennsylvania offers language that could serve as a model (See: 28 Pa. Code § 551.21).
- The four-hour time limits should not be exceeded except in situations where additional time could not have been anticipated prior to surgery.

- We would suggest the regulation specify that ASFs are not to perform procedures that are emergency or life-threatening in nature unless no hospital is available for the procedure and the need for surgery could not be anticipated.
- Additional consideration is needed within the regulation related to pediatric care. For quality and safety reasons, we would suggest new standards that would:
    - Prohibit ASFs from treating children ages 1 year or younger.
    - For all other children under 18, if the treatment sought can reasonably be expected to require more than one hour of general anesthesia, ASFs should be required to consult (or at least document attempts to consult) with the child's primary care provider to validate the medical appropriateness of an ASF for the treatment. This will help limit the risk of complications to the child and advance continuity of care. In situations where consultation is not obtained, the ASF should retain record explaining the reason consultation could not take place.
    - Like hospitals, ASFs that perform procedures on children should be required to have the specialized equipment and personnel/training needed to safely care for children.
- **It's important that ASFs be held to the same quality, safety and reporting standards as hospitals that perform outpatient surgery**. We strongly encourage DHEC to require ASFs to obtain and maintain certification by The Joint Commission or other accrediting agency that has obtained "deemed status" from CMS. This standard should apply immediately to new ASFs; the agency may want to consider granting existing ASFs a reasonable timeframe to comply with the new standards. Implementing this standard, which already applies to hospital outpatient surgery, would not only help establish a quality baseline for quality of day-to-day clinical care, but would also ensure ASFs physical plant, infection control, fire prevention, etc. remain consistent with modern standards as they evolve.

Department Response: Not adopt Tidelands' suggestion regarding amending Section 103.E.8 to limit the number of hours for surgeries at facilities and the number of hours for recovery, with an exception. Department staff have determined the existing and proposed provisions relating to care, treatment, and services reasonably ensure the safe and adequate treatment of persons served in ASFs. Moreover, our statutory definition of ASF explains such facilities are "for the purpose of performing surgical procedures for which patients are scheduled to arrive, receive surgery, and be discharged ***on the same day***." S.C. Code Ann. § 44-7-130(2) (emphasis added); *see also* R.61-91 § 101.RR (defining "Same Day" as "A period of time not to exceed twenty-four (24) hours after admission."). Additionally, Department staff have proposed provisions to ensure ASFs only perform appropriate surgeries on appropriate patients. *See, e.g.,* proposed Section 804.

Not adopt Tidelands' suggestion to limit procedures to those listed on the CMS 2022 ASC Covered Procedures List and successors. Department staff are unable to determine why or how limiting facilities to performing only those procedures reimbursed by Medicare relates to

establishment of basic standards for the licensure, maintenance, and operation of ASFs and services to ensure the safe and adequate treatment of persons in South Carolina.

Not adopt Tidelands' suggestion to prohibit ASFs from performing procedures that are emergencies or life-threatening in nature unless no hospital is available for the procedure and the need for surgery could not be anticipated. Department staff are unaware of any existing facilities performing emergency surgeries/procedures. Instead, surgeries/procedures performed at ASFs are generally elective and scheduled. Moreover, the suggested prohibition may cause administration issues for Department staff and result in confusion from the regulated community.

Not adopt Tidelands' suggestion to place limitations/prohibitions related to facilities' care of pediatric patients. At this time, Department staff have determined the existing and proposed provisions relating to care, treatment, and services reasonably ensure the safe and adequate treatment of pediatric patients served in ASFs. Notably, ASFs currently are required to have consultations by physicians and physical examinations, including medical histories, in patients' records. *See* Section 701.B.1. and -2. Moreover, Department staff have proposed requiring an individual with a valid pediatric advanced life support credential to be on duty whenever pediatric patients are present. *See* Section 507.B. Finally, Department staff have proposed requiring facilities have emergency equipment that is appropriate for the facility's patient population. *See* Section 1201.A.2.

Not adopt Tidelands' suggestion to require all facilities maintain certification by the Joint Commission or other accrediting agencies that have obtained "deemed status." At this time, Department staff have determined Facility accreditation by a third party organization is unnecessary as a licensure requirement for ensuring safe and adequate treatment of persons served in South Carolina.

Name	Section
MUSC	300

Comment:
MUSC further strongly recommends that DHEC actively engage in post-licensure enforcement of the ASC licensure requirements that it adopts, such that an ASC's failure to achieve and maintain these standards will result in the ASC's surrender or DHEC's revocation of the ASC's license for a significant period of time. In addition to existing ASC licensure standards, DHEC's enforcement priorities further should include cardiac catheterization volume requirements, transfer agreement requirements, and the indigent/charity care requirements set forth in Act No. 20 (now in S.C. Code § 44-7-266(C)).

Department Response: Acknowledged comments regarding enforcement of facility licensure requirements.

Name	Section
Tidelands Health	505

Comment:
We support inclusion of the provision requiring providers performing surgery to be board certified or board eligible and would encourage DHEC to retain this provision in the final regulation.

In case of complications at an ASF that require transfer to a hospital, the physician who performed the procedure at the ASF should be required to admit and continue attending to the patient in the receiving hospital until the patient is stabilized. This is an important quality and safety standard to help ensure continuity of care and the best possible outcome for the patient.

We would suggest requiring all physicians who perform surgical procedures at an ASF have admitting privileges at any hospitals with which the ASF maintains a transfer agreement.

Department Response: Acknowledge comment about inclusion of requiring providers be board certified or board eligible.

Not adopt Tidelands' suggestion that the physician performing a procedure at the facility be required to admit and continue attending to the patient in the receiving hospital. Department staff note that there are existing provisions ensuring continuity of care. *See, e.g.,* Sections 504.E (requiring at least one physician on staff to have admitting privileges at one or more hospitals) and 703.B (requiring a transfer summary when a patient is transferred to an emergency facility). Moreover, under normal circumstances, Department staff would anticipate that facilities would transfer their patients to hospital emergency departments for receipt of emergency care.

Name	Section
Tidelands Health	601

Comment:
We would suggest several enhancements, as italicized below, to strengthen this section and provide additional clarity on the accidents/incidents that should be reported to DHEC.
6. Hospitalization as a result of accident/incident during service;
7. Medication error resulting in any patient harm;
8. Procedures on wrong person; wrong site; wrong procedure; wrong implant
9. ~~Procedures on wrong site;~~
10. Severe burn;
11. Severe hematoma;
12. Severe laceration;
13. Attempted suicide;
14. Anesthesia apparatus malfunction resulting in any level of patient harm; or
15. *Identification of any condition or disease listed on the 2023 South Carolina List of Reportable Conditions and its successors.*

Department Response: Not adopt. As noted, Department staff proposed amending Section 601.B to incorporate the National Quality Forum's (NQF) list of serious reportable events applicable to ambulatory surgery facilities. Further, Section 603 states, "All cases of diseases that are required to be reported to the appropriate county health department shall be accomplished in accordance with R.61-20."

Name	Section
Peter Lohrengel, SC Ambulatory Surgery Center Association	801.D

Comment:

In regards to new paragraph D, we disagree. CMS issued revisions to the Conditions for Coverage in 2019 under the Burden Reduction Act which eliminated the requirement that ASCs must have a written transfer agreement with a hospital. In place of the transfer agreement, CMS mandated that ASCs must report by written notice its hours of operation and patient population served.

Here is the CMS discussion from the Final rule dated 9/30/2019:

[Final Rule Language Omitted]

We recommend that the transfer language be removed: . . . .

We believe that there is no benefit to South Carolina patients having the state regulation exceed the standard set by CMS. Written transfer agreements have long been a source of confusion and may form a barrier to entry into the South Carolina healthcare marketplace in direct opposition to the goals of the Legislature in CON repeal. ASCs transfer very few patients (many none at all) to hospitals due to the nature of the surgeries performed and the patient population served. The CMS notice has been developed after extensive public comment and provides the hospital with more than adequate notice to plan for and be equipped to receive the few ASC patients who might present or be transferred to the emergency room. SCASCA is not aware of any concerns that have arisen since the CMS change was implemented.

Department Response: Partially adopt. Department staff have proposed providing an exception where facilities have attempted to obtain a transfer agreement, but are unsuccessful. *See* Section 801.D. For such facilities, there shall be documentation of the facilities' efforts to obtain an agreement, and the facilities shall provide the hospitals their hours of operation and patient population. This proposal encourages facilities and hospitals to enter into transfer agreements; however, provides an alternative method of compliance for when such agreements are not achievable. Further, this proposal is generally consistent with the CMS conditions for coverage. *See* 42 C.F.R. § 416.41.

Name	Section
Tidelands Health	801.D

Comment:
We support the required transfer agreement and protocol included in the regulation and encourage DHEC to include this in the final regulation. These types of agreements are commonplace in state regulations across the country, particularly in states such as SC that allow a broader – and more high risk - range of services be performed in the ASF setting.

Department Response: Acknowledged/Partially Adopt. In light of another comment regarding this section, Department staff have proposed providing an exception where facilities have attempted to obtain a transfer agreement, but are unsuccessful. *See* Section 801.D. For such facilities, there shall be documentation of the facilities' efforts to obtain an agreement, and the facilities shall provide the hospitals their hours of operation and patient population. This proposal encourages facilities and hospitals to enter into transfer agreements; however, provides an alternative method of compliance for when such agreements are not achievable. Further, this proposal is generally consistent with the CMS conditions for coverage. *See* 42 C.F.R. § 416.41.

Name	Section
Prisma Health	801.D

Comment:
As amended, Section 801.D of Regulation 61-91 requires an ambulatory surgical facility ("ASF") to have a written transfer agreement with one or more hospitals, which must be updated upon a change in the licensee or the ASF administrator or as otherwise required to maintain or improve continuity of care. Prisma strongly supports the Department's decision to include this language. Maintaining robust relationships with hospitals is vital to ensuring patient safety in the event transfer of care is required. Prisma encourages the Department to maintain this licensing requirement.

Department Response: Acknowledged/Partially Adopt. In light of another comment regarding this section, Department staff have proposed providing an exception where facilities have attempted to obtain a transfer agreement, but are unsuccessful. *See* Section 801.D. For such facilities, there shall be documentation of the facilities' efforts to obtain an agreement, and the facilities shall provide the hospitals their hours of operation and patient population. This proposal encourages facilities and hospitals to enter into transfer agreements; however, provides an alternative method of compliance for when such agreements are not achievable. Further, this proposal is generally consistent with the CMS conditions for coverage. *See* 42 C.F.R. § 416.41.

Name	Section
Prisma Health	804.B.1

Comment:
As amended, Section 804, governing anesthesia services, requires a physician to "examine the patient to evaluate the risk of the procedure to be performed" immediately prior to surgery. Prisma respectfully asks the Department provided clarification on this requirement. Physicians routinely examine patients and evaluate the risks of any procedure to be performed, and physicians continuously assess a patient's condition pre-operatively, during the procedure, and post-operatively. Thus, the reason for the Department's inclusion of this language is unclear; therefore, Prisma requests clarification regarding this licensing requirement.

Department Response: Not adopt. The proposed amendment to Section 804 that requires a physician to "examine the patient to evaluate the risk of the procedure to be performed" is taken from the CMS Conditions for Coverage for ASFs. *See* 42 C.F.R. § 416.42(a)(1)(ii). The reason for inclusion is to require such examination for purposes of state licensure. Clarification of what this entails is explained at the CMS State Operations Manual Appendix L at Q-0061 and may include incorporation of the American Society of Anesthesiologists Physical Status Classification for predicting morbidity and mortality in surgical patients and the risk of the procedure for patients.

Name	Section
Tidelands Health	807

Comment:
In alignment with the above, this provision should be amended to reflect that in case of transfer to a hospital due to complications, the physician who performed the procedure at the ASF should be required to *admit and continue attending to the patient in the receiving hospital until the patient is stabilized*.

Department Response: Not adopt. Department staff have determined the existing and proposed provisions relating to continuity of care reasonably ensure the safe and adequate treatment of patients served in ASFs. *See, e.g.,* Sections 504.E (requiring at least one physician n staff to have admitting privileges at one or more hospitals) and 703.B (requiring a transfer summary when a patient is transferred to an emergency facility). Moreover, under normal circumstances, it would be anticipated that ASFs would transfer their patients to hospital emergency departments for receipt of emergency care.

Name	Section
Peter Lohrengel, SC Ambulatory Surgery Center Association	1201.B

Comment:
Secondly, we would like to bring a difficult element of the existing regulation to the Department's attention and ask that it be fully redacted. This is the requirement at 1201 B. requiring that all facilities in the state have an agreement to be able to obtain blood and blood products in the event of an emergency.

This requirement is extremely burdensome of the resources of both ASCs and Blood Banks and provides no patient benefit whatsoever. The nature of the procedures performed in ASCs do not lead to extensive blood loss nor require transfusion. For any emergency that might occur which involved damage to a large blood pathway the medical standard calls for pressuring the wound and transferring the patient to an emergency room.

In order to properly comply with 1201(I) B an ASC would have to either:

A. Delay emergency transport while it waits for blood to be transported from the blood bank to the ASC- further endangering the patient; or
B. Hold a minimum of both O type bloods (+ or -) at the facility. In this case, RBCs are only good for 35-42 days. This would mean that ASCs across the state would be wasting all blood on hand every 5-6 weeks…for no beneficial reason and while our state continues to face a perennial blood shortage.

We recommend that this language be removed:

~~B. The facility shall have the capability of obtaining blood and blood products to meet emergency situations.~~

Department Response: Adopt. Department staff propose deleting Section 1201.B.

SUMMARY SHEET
BOARD OF HEALTH AND ENVIRONMENTAL CONTROL
February 8, 2024

_____ 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 December 1, 2023, through December 31, 2023.

3. **FACTS:** For the reporting period of December 1, 2023, through December 31, 2023, the Office of Environmental Affairs issued thirty-four (34) Consent Orders with total assessed civil penalties in the amount of one hundred sixty-three thousand, six hundred five dollars ($163,605.00). Also, three (3) Administrative Orders with total assessed civil penalties in the amount of zero dollars ($0.00) were reported during this period.

Bureau and Program Area	Administrative Orders	Assessed Penalties	Consent Orders	Assessed Penalties
Land and Waste Management				
UST Program	0	0	1	$500.00
Solid Waste	0	0	0	0
Hazardous Waste	0	0	2	$15,800.00
Mining	0	0	0	0
Radiological Health	0	0	0	0
SUBTOTAL	**0**	**0**	**3**	**$16,300.00**
Water				
Recreational Water	0	0	21	$22,080.00
Drinking Water	0	0	0	0
Water Pollution	0	0	3	$17,600.00
SUBTOTAL	**0**	**0**	**24**	**$39,680.00**
Air Quality				
SUBTOTAL	**0**	**0**	**5**	**$106,625.00**
Environmental Health Services				
Onsite Wastewater	3	0	2	$1,000.00
SUBTOTAL	**3**	**0**	**2**	**$1,000.00**
OCRM				
SUBTOTAL	**0**	**0**	**0**	**0**
TOTAL	3	**0**	**34**	**$163,605.00**

Submitted by:

Myra C. Reece
Director of Environmental Affairs

ENVIRONMENTAL AFFAIRS ENFORCEMENT REPORT
BOARD OF HEALTH AND ENVIRONMENTAL CONTROL
February 8, 2024

BUREAU OF LAND AND WASTE MANAGEMENT

Underground Storage Tank Enforcement

1) Order Type and Number: Consent Order 23-0208-UST
Order Date: December 14, 2023
Individual/Entity: **Mitul Patel**
Facility: Harry's Store
Location: 355 Patterson Mill Road
Barnwell, SC 29812
Mailing Address: 2118 Jackson Street
Barnwell, SC 29812
County: Barnwell
Previous Orders: None
Permit/ID Number: 00887
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. code Ann. § 44-2-10 et seq. and § 44-2-10(A) (2018); and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs 61-92, 280.21a), 280.31(a), 280.70(c), and 280.93(a) (2012 & Supp 2022).

Summary: Mitul Patel (Individual/Entity) owns underground storage tanks (USTs) in Barnwell County, South Carolina. On June 28, 2023, the Department conducted a file review of the Facility and issued a Transfer of Ownership-New Owner 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 abandon a permanently closed UST system after twelve (12) months; and failed to pay annual tank registration fees (ATRFs) and associated late fees.

Action: The Individual/Entity is required to submit: a completed Tank and Sludge Disposal form for the permanent closure of the USTs at the Facility by January 28, 2024; within forty-five days (45) of the Department's approval of the Tank and Sludge Disposal form, permanently close the USTs; within sixty (60) days after the USTs have been permanently closed, submit a UST Closure and Assessment Report to the Department; and submit payment of ATRFs and associated late fees, in the amount of nine thousand, four hundred thirty-eight dollars ($9,438.00), for fiscal years 2011 through 2023, in accordance with a promissory note. The Department has assessed a total civil penalty in the amount of nineteen thousand, seven hundred dollars ($19,700.00). The Individual/Entity shall pay a civil penalty in the amount of five hundred dollars **($500.00)** and pay a **suspended penalty** in the amount of nineteen thousand two hundred dollars **($19,200.00)** should any requirement of the Order not be met.

Update: The Individual/Entity has paid the civil penalty and submitted the Tank

and Sludge Disposal Form.

Hazardous Waste Enforcement

2) Order Type and Number: Consent Order 23-34-HW
Order Date: December 14, 2023
Individual/Entity: **AmbioPharm, Inc.**
Facility: AmbioPharm, Inc.
Location: 1024 Dittman Court
North Augusta, SC
Mailing Address: Same
County: Aiken
Previous Orders: None
Permit/ID Number: SCR 000 769 414
Violations Cited: The South Carolina Hazardous Waste Management Act**,** S.C. Code Ann. §§ 44-56-10 et seq. (2018) and the South Carolina Hazardous Waste Management Regulation, 6 and 7 S.C. Code Ann. Regs. 61-79 (2012 and Supp. 2021).

Summary: AmbioPharm, Inc. (Individual/Entity) is a peptide manufacturing facility located in Aiken County, South Carolina. The Department conducted an inspection at the facility on April 5, 2023, and issued a Notice of Alleged Violation on June 29, 2023. The Individual/Entity has violated the South Carolina Hazardous Waste Management Act and the Hazardous Waste Management Regulations as follows: failed to make an accurate waste determination; failed to ensure satellite accumulation area storage containers remain closed; failed to mark or label satellite accumulation area containers with the words "Hazardous Waste" and an indication of the hazards of the contents; failed to ensure central accumulation area storage containers remain closed; failed to inspect weekly central accumulation areas; failed to mark or label central accumulation area containers with the words "Hazardous Waste" and the date upon which each period of accumulation began; failed to attempt to make arrangements with the local emergency responders; and failed to ensure all employees were thoroughly familiar with proper waste handling and emergency procedures.

Action: The Individual/Entity corrected the violations prior to the issuance of the Order. The Department has assessed a total civil penalty in the amount of eight thousand dollars ($8,000.00). The Individual/Entity is required to pay a civil penalty in the amount of eight thousand dollars **($8,000.00)**.

Update: The Individual/Entity paid the civil penalty. The order is closed.

3) Order Type and Number: Consent Order 23-35-HW
Order Date: December 14, 2023
Individual/Entity: **William Jennings Bryan Dorn VA Medical Center**
Facility: Wiliams Jennings Bryan Dorn VA Medical Center
Location: 6439 Garners Ferry Road
Columbia, SC 29209

Mailing Address: Same
County: Richland
Previous Orders: None
Permit/ID Number: SC4 360 090 001
Violations Cited: The South Carolina Hazardous Waste Management Act**,** S.C. Code Ann. §§ 44-56-10 et seq. (2018), and the South Carolina Hazardous Waste Management Regulation, 6 and 7 S.C. Code Ann. Regs. 61-79 (2012 and Supp. 2021).

Summary: The William Jennings Bryan Dorn VA Medical Center (Individual/Entity) provides comprehensive inpatient and outpatient medical, mental health, surgical, and long-term care services for veterans at its facility in Richland County, South Carolina. The Department conducted an inspection at the facility on July 21, 2023. The Individual/Entity has violated the South Carolina Hazardous Waste Management Act and the Hazardous Waste Management Regulations as follows: accumulated non-creditable hazardous waste pharmaceuticals on site for greater than one (1) year; failed to mark or label Satellite Accumulation Area containers with the words "Hazardous Waste," and an indication of the hazards of the contents; failed to ensure that during the treatment, storage, or disposal of ignitable or reactive wastes, and the mixture or commingling of incompatible waste and other materials, to conduct these activities so they do not: Generate extreme heat or pressure, fire or explosions, or violent reactions, produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health or the environment, produce uncontrolled flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions, damage the structural integrity of the device or facility containing the waste, or through other like means threaten human health or the environment; failed to ensure that each lamp or a container or package in which such lamps are contained is labeled with the words "Universal Waste – Lamp(s)," or "Waste Lamp(s)," or "Used Lamp(s)"; failed to clearly label universal waste batteries (i.e., each battery), or a container in which the batteries are contained with the words "Universal Waste -Battery(ies)," or "Waste Battery(ies)," or "Used Battery(ies)"; failed to demonstrate the length of time that the universal waste had been accumulated from the date it becomes a waste or is received; failed to maintain records documenting the arrangements with the local fire department.

Action: The Individual/Entity corrected the violations prior to the issuance of the Order. The Department has assessed a total civil penalty in the amount of seven thousand, eight hundred dollars ($7,800.00). The Individual/Entity shall pay a civil penalty in the amount of seven thousand, eight hundred dollars **($7,800.00)**.

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

BUREAU OF WATER

Recreational Waters Enforcement

4) Order Type and Number: Consent Order 23-172-RW
Order Date: December 1, 2023
Individual/Entity: **Bridge WF SC Reserve River Walk, LLC**

Facility:	Reserve at Riverwalk Apartments
Location:	4501 Bentley Drive Columbia, SC 29210
Mailing Address:	Same
County:	Richland
Previous Orders:	22-202-RW ($680.00)
Permit/ID Number:	40-325-1
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Bridge WF SC Reserve River Walk, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Richland County, South Carolina. The Department conducted inspections on June 22, 2023, and August 1, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a ladder was missing bumpers; a ladder was missing rungs; a ladder was missing non-slip tread inserts; the pool floor was dirty; the pool walls were dirty; a skimmer lid was cracked; the chlorine level was not within the acceptable range of water quality standards; the life ring was not United States Coast Guard approved; there was algae on the pool walls; there was debris in the skimmer baskets; the bathrooms were not accessible; the fill spout was broken; there was a pool vacuum operating in the pool at the time of the inspection; the gate did not self-close and latch; there were openings in the fence greater than four inches; and the bound and numbered log book was not available for review.

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

Update: The civil penalty has been paid and the Consent Order is closed.

5)

Order Type and Number:	Consent Order 23-173-RW
Order Date:	December 1, 2023
Individual/Entity:	**The Commons at Arcadia Homeowners Association, Inc.**
Facility:	Commons at Arcadia
Location:	203 Cross Creek Lane Columbia, SC 29223
Mailing Address:	1216 Pickens Street Columbia, SC 29201
County:	Richland
Previous Orders:	None
Permit/ID Number:	40-168-1
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: The Commons at Arcadia Homeowners Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Richland County, South Carolina. The Department conducted inspections on June 15, 2023, and July 28, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the lifeline floats were not properly spaced on the first inspection;

the lifeline was not in serviceable condition on the second inspection; a ladder was missing a non-slip tread insert; the pool floor was dirty; the pool furniture was not at least four feet from the edge of the pool; a skimmer was missing a weir; the water level was too high; the pool equipment room was not locked; a gate did not self-close and latch; the chlorine level was not within the acceptable range of water quality standards; and the bound and numbered log book was not maintained on a daily basis.

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

Update: The civil penalty has been paid and the Consent Order is closed.

6)

Order Type and Number:	Consent Order 23-174-RW
Order Date:	December 4, 2023
Individual/Entity:	**Shree Ganesh Hospitality, LLC**
Facility:	Sleep Inn
Location:	1002 Monterey Drive Aiken, SC 29803
Mailing Address:	Same
County:	Aiken
Previous Orders:	None
Permit/ID Number:	02-109-1
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Shree Ganesh Hospitality, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Aiken County, South Carolina. The Department conducted inspections on June 26, 2023, and August 11, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a ladder was missing bumpers; the pool floor was dirty; there was debris in the skimmer baskets; the pool equipment room was not locked; the life ring was deteriorated and did not have a permanently attached rope; the pool rules sign was not legible or completely filled out; and the bound and numbered log book was not maintained on a daily basis.

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

Update: The civil penalty has been paid and the Consent Order is closed.

7)

Order Type and Number:	Consent Order 23-176-RW
Order Date:	December 4, 2023
Individual/Entity:	**Abney Hill Estates Property Owners Association, Inc.**
Facility:	Abney Hills Subdivision
Location:	Abney Estates Drive Blythewood, SC 29016

Mailing Address:	4910 Trenholm Road, Suite C Columbia, SC 29206
County:	Richland
Previous Orders:	None
Permit/ID Number:	40-1186B
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Abney Hill Estates Property Owners Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Richland County, South Carolina. The Department conducted inspections on June 26, 2023, and August 9, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a ladder was missing bumpers; the pool furniture was not at least four feet from the edge of the pool; the deck was chipped; skimmers were missing weirs; the chlorine level was not within the acceptable range of water quality standards; the closure time listed on the pool rules sign was too late and the pool is not approved for night swimming; the bound and numbered log book was not maintained on a daily basis; and the emergency notification device was not operational.

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

Update: The civil penalty has been paid and the Consent Order is closed.

8)

Order Type and Number:	Consent Order 23-177-RW
Order Date:	December 7, 2023
Individual/Entity:	**Bretagne Homeowners' Association, Inc.**
Facility:	Bretagne
Location:	1070 Regions Boulevard Indian Land, SC 29707
Mailing Address:	2245 Lorie Valley Drive Indian Land, SC 29707
County:	Lancaster
Previous Orders:	21-213-RW ($2,040.00)
Permit/ID Number:	29-1062C
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Bretagne Homeowners' Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a kiddie pool located in Lancaster County, South Carolina. The Department conducted inspections on June 6, 2023, July 13, 2023, and August 2, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the chlorine and pH levels were not within the acceptable range of water quality standards; and the bound and numbered 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 three thousand three hundred sixty dollars

($3,360.00). The Individual/Entity shall pay a civil penalty in the amount of three thousand three hundred sixty dollars **($3,360.00)**.

Update: The civil penalty has been paid and the Consent Order is closed.

9) Order Type and Number: Consent Order 23-175-RW
Order Date: December 11, 2023
Individual/Entity: **Ginkgo Woodcreek, LLC**
Facility: Woodcreek Farm Apartments
Location: 751 Jacob Mill Pond Road
Elgin, SC 29045
Mailing Address: 200 South College Street, Suite 200
Charlotte, NC 28202
County: Richalnd
Previous Orders: None
Permit/ID Number: 40-1036B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Ginkgo Woodcreek, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Richland County, South Carolina. The Department conducted inspections on June 23, 2023, and August 4, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a ladder was missing bumpers; the pool floor was dirty; there was standing water on the pool deck; the water level was too high; skimmers were missing weirs; there was only one bathroom; the drinking water fountain was not operating properly; a light in the pool wall was out of its niche; a return cover was missing; the skimmer valve was partially closed; there were chemicals that were not being stored in the chemical storage room; there was no backflow prevention for the backwash; the step edge stripe was missing tiles; the gate did not self-close and latch; the chlorine level was not within the acceptable range of water quality standards; the pool rules sign did not have all of the required rules; the closure time listed on the pool rules sign was too late and the pool is not approved for night swimming; and the current pool operator of record information was not posted to the public.

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

Update: The civil penalty has been paid and the Consent Order is closed.

10) Order Type and Number: Consent Order 23-178-RW
Order Date: December 11, 2023
Individual/Entity: **Sunrise Hospitality, LLC**
Facility: Days Inn Lexington
Location: 1015 South Lake Drive
Lexington, SC 29073
Mailing Address: Same
County: Lexington

Previous Orders: None
Permit/ID Number: 32-184-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Sunrise Hospitality, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Lexington County, South Carolina. The Department conducted inspections on July 7, 2023, and August 3, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: there were no universal "no diving" tiles; the water level was too low; the foot rinse shower was not operating properly; the drinking water fountain was missing; a light in the pool wall was out of its niche; a gate did not self-close and latch; the chlorine and pH levels were not within the acceptable range of water quality standards; the life ring did not have a permanently attached rope; the pool rules sign posted was not completely filled out; the current pool operator of record information was not posted to the public; the bound and numbered log book was not available for review on the first inspection; and the bound and numbered log book was not maintained on a daily basis, and the cyanuric acid level was not recorded on a weekly basis in the bound and numbered log book on the second inspection.

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

Update: The civil penalty has been paid and the Consent Order is closed.

11) Order Type and Number: Consent Order 23-179-RW
Order Date: December 11, 2023
Individual/Entity: **TPG CTC USC, LLC**
Facility: College Town on the River Apartments
Location: 500 Alexander Road
West Columbia, SC 29169
Mailing Address: P.O. Box 222
Southeastern, PA 19399
County: Lexington
Previous Orders: None
Permit/ID Number: 32-1055B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: TPG CTC USC, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Lexington County, South Carolina. The Department conducted inspections on June 15, 2023, and August 3, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the frost proof tiles were broken on the first inspection, and were missing on the second inspection; the pool furniture was not at least four feet from the edge of the pool; the water level was too high on the first inspection, and too low on the second inspection; a skimmer was missing a weir; the bathrooms were dirty; a gate did not self-close and latch; the chlorine level was not within the acceptable range of water quality standards; a main drain grate was missing a bolt; the shepherd's crook was not properly mounted in

its designated location and was not clear of obstructions; the shepherd's crook handle was attached to a telescoping pole; only one "No Lifeguard On Duty – Swim At Your Own Risk" sign was posted; the bound and numbered log book was not maintained on a daily basis and was not maintained a minimum of three times per week by the pool operator of record; the cyanuric acid level was not recorded on a weekly basis in the bound and numbered log book; the disinfection equipment was not operating properly and was leaking; and there were chlorine sticks in the skimmer baskets.

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

Update: The civil penalty has been paid and the Consent Order is closed.

12)

Order Type and Number:	Consent Order 23-180-RW
Order Date:	December 11, 2023
Individual/Entity:	**C & M Hospitality Group - SC, LLC**
Facility:	Best Western Airport Inn
Location:	5009 Pelham Road Greenville, SC 29615
Mailing Address:	Same
County:	Greenville
Previous Orders:	None
Permit/ID Number:	23-264-1
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: C & M Hospitality Group - SC, 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 5, 2023, and August 7, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the lifeline floats were not properly spaced; the transition line was not present; the chlorine and pH levels were not within the acceptable range of water quality standards; and the bound and numbered log book was not available for Department review**.**

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

Update: The civil penalty has been paid and the Consent Order is closed.

13)

Order Type and Number:	Consent Order 23-181-RW
Order Date:	December 11, 2023
Individual/Entity:	**The Gates at Williams-Brice Condominium Association**
Facility:	The Gates at Williams Brice
Location:	1085 Shop Road Columbia, SC 29201

Mailing Address:	1216 Pickens Street Columbia, SC 29201
County:	Richland
Previous Orders:	None
Permit/ID Number:	40-1065B
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: The Gates at Williams-Brice Condominium Association (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Richland County, South Carolina. The Department conducted inspections on June 29, 2023, and August 8, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: there were broken depth marker tiles on the pool deck; the pool deck was uneven and had sharp edges; skimmers were missing weirs; there was only one bathroom; the drinking water fountain was not operating; the gate did not self-close and latch; the chlorine level was not within the acceptable range of water quality standards; the shepherd's crook was not located in the designated location; the pool rules sign did not have a location for the lifesaving equipment; the letters on one of the "Shallow Water – No Diving Allowed" signs posted were not the appropriate size; the letters on one of the "No Lifeguard On Duty – Swim At Your Own Risk" signs posted were not the appropriate size; the current pool operator of record information was not posted to the public; and the bound and numbered log book was not maintained on a daily basis.

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

Update: The civil penalty has been paid and the Consent Order is closed.

14)

Order Type and Number:	Consent Order 23-182-RW
Order Date:	December 14, 2023
Individual/Entity:	**MHH Myrtle Beach Holdings, LLC**
Facility:	Hampton Inn Resort
Location:	1801 S Ocean Boulevard Myrtle Beach, SC 29577
Mailing Address:	Same
County:	Horry
Previous Orders:	None
Permit/ID Number:	26-Q95-1 & 26-1778D
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: MHH Myrtle Beach Holdings, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a kiddie pool and a spa located in Horry County, South Carolina. The Department conducted inspections on June 14, 2023, July 20, 2023, and November 8, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: skimmers were missing weirs; the bound and numbered log book was not maintained on a daily basis; frost proof tiles were broken on the spa wall; the plaster on the kiddie pool floor was deteriorated; and the chlorine level was not within the acceptable range of water quality standards.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of two thousand seven hundred twenty dollars ($2,720.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand seven hundred twenty dollars **($2,720.00)**.

Update: The civil penalty has been paid and the Consent Order is closed.

15)

Order Type and Number:	Consent Order 23-183-RW
Order Date:	December 15, 2023
Individual/Entity:	**Wildewood Community Partners Group, Inc.**
Facility:	The Wildewood Club
Location:	90 Mallett Hill Road Columbia, SC 29223
Mailing Address:	Same
County:	Richland
Previous Orders:	None
Permit/ID Number:	40-1200C
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Wildewood Community Partners Group, 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 conducted inspections on June 21, 2023, and August 8, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a gate did not self-close and latch; the facility address posted at the emergency notification device was incorrect and was not weather resistant; the chlorine level was not within the acceptable range of water quality standards; the disinfection equipment was not operating properly; the automatic controller was not operating on the first inspection; and the automatic controller was not operating properly on the second inspection.

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

Update: The civil penalty has been paid and the Consent Order is closed.

16)

Order Type and Number:	Consent Order 23-184-RW
Order Date:	December 15, 2023
Individual/Entity:	**TREAP The Row at the Stadium Owner, LLC**
Facility:	The Row at the Stadium
Location:	1105 Shop Road Columbia, SC 29201
Mailing Address:	Same
County:	Richland
Previous Orders:	22-105-RW ($680.00)
Permit/ID Number:	40-1188B

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

Summary: TREAP The Row at the Stadium Owner, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Richland County, South Carolina. The Department conducted inspections on June 29, 2023, and August 8, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the pool floor was dirty; a skimmer was missing a weir; the foot rinse shower was not operating properly; the pool equipment room was not locked; the pool hours posted were not approved because the pool is not approved for night swimming; there were chlorine pucks in the skimmer baskets; the pool floor was dirty; there was algae on the pool walls; the chlorine level was not within the acceptable range of water quality standards; the cyanuric acid level was not checked weekly; and the bound and numbered log book was not maintained on a daily basis.

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

Update: The civil penalty has been paid and the Consent Order is closed.

17)

Order Type and Number:	Consent Order 23-185-RW
Order Date:	December 19, 2023
Individual/Entity:	**Columbia Ft. Jackson, LLC**
Facility:	Candlewood Suites
Location:	921 Atlas Road Columbia, SC 29209
Mailing Address:	8632 Wilkinson Boulevard Charlotte, NC 28214
County:	Richland
Previous Orders:	22-149-RW ($680.00)
Permit/ID Number:	40-1086B
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Columbia Ft. Jackson, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Richland County, South Carolina. The Department conducted inspections on July 12, 2023, and August 10, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a handrail was not tight and secure; a ladder was missing non-slip tread inserts; the frost-proof tiles were missing; the drinking water fountain and foot rinse shower were not operating properly; non-pool related items were being stored in the equipment room; the required backflow prevention devices such as dual inline check valves were missing; the gate did not self-close and latch; the chlorine and pH levels were not within the acceptable range of water quality standards; the life ring did not have a permanently attached rope; the location of the lifesaving equipment and emergency phone was not current and up-to-date on the pool rules sign; only one “Shallow Water – No Diving Allowed” sign was posted; the current pool operator of record information was not posted to the public; the bound and numbered log book was not available for Department

review; the disinfection equipment was not in operable condition; and the recirculation and filtration system was not in operable condition.

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

Update: The civil penalty has been paid and the Consent Order is closed.

18) Order Type and Number: Consent Order 23-190-RW
Order Date: December 19, 2023
Individual/Entity: **Vintners Wood Homeowners' Association, Inc.**
Facility: Vintners Wood
Location: 518 River Falls Lane, Lexington, SC 29072
Mailing Address: Same
County: Lexington
Previous Orders: None
Permit/ID Number: 32-1091B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Vintners Wood Homeowners' Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Lexington County, South Carolina. The Department conducted inspections on July 6, 2023, and August 2, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a ladder was missing bumpers; the bathrooms did not have paper towels or soap; the foot rinse shower was not operating properly; the drinking water fountain was not operating properly; the pool equipment room and chemical storage room were not accessible; the chlorine and pH levels were not within the acceptable range of water quality standards; the pool rules sign was not completely filled out; the bound and numbered log book was not available for review; and the emergency notification device was not operational.

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

Update: The civil penalty has been paid and the Consent Order is closed.

19) Order Type and Number: Consent Order 23-191-RW
Order Date: December 20, 2023
Individual/Entity: **Plaza Place 2020, LLC**
Facility: Plaza Place Apartments
Location: 1300 Plaza Place Drive, North August, SC 29841
Mailing Address: 1969 Rutgers University Boulevard

	Lakewood, NJ 08701
County:	Aiken
Previous Orders:	None
Permit/ID Number:	02-051-1
Violations Cited:	S.C. Code Ann. Regs. 61-51.J.22

Summary: Plaza Place 2020, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Aiken County, South Carolina. The Department issued a Notice of Enforcement Conference on November 6, 2023, 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 March 19, 2024. The Individual/Entity will be required to properly fill in or remove the pool within sixty days of the date of written notification by the Department 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.

Update: On November 17, 2023, 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.

20)

Order Type and Number:	Consent Order 23-186-RW
Order Date:	December 27, 2023
Individual/Entity:	**Hampton Courts – Brandemere, LLC; Hampton Courts – Sabina, LLC; and Hampton Courts – Zarpuleo, LLC**
Facility:	Hampton Courts Apartments
Location:	501 Pelham Drive Columbia, SC 29209
Mailing Address:	7020 Fain Park Drive, Suite 5 Montgomery, AL 36117
County:	Richland
Previous Orders:	None
Permit/ID Number:	40-197-1
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Hampton Courts – Brandemere, LLC; Hampton Courts – Sabina, LLC; and Hampton Courts – Zarpuleo, LLC (Individual/Entity) own and are responsible for the proper operation and maintenance of a pool located in Richland County, South Carolina. The Department conducted inspections on July 5, 2023, and August 7, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the lifeline floats were not properly spaced; a ladder was missing bumpers; the pool floor was dirty; the pool furniture was not at least four feet from the edge of the pool; there was debris in the skimmer baskets; the water level was too low; skimmers were missing weirs; the

bathrooms were dirty and did not have toilet paper and soap; there was no drinking water fountain; the equipment room was not locked; the gate did not self-close and latch; the chlorine and pH levels were not within the acceptable range of water quality standards; the facility address was not posted at the emergency notification device; the locations provided for the emergency phone and life-saving equipment were not up-to-date on the pool rules sign; the letters on the "Shallow Water – No Diving Allowed" signs posted and on the "No Lifeguard On Duty – Swim At Your Own Risk" signs posted were not the appropriate size; the log book was not properly bound and numbered; the cyanuric acid level was not recorded on a weekly basis in the log book; the log book was not maintained on a daily basis; and the log book was not maintained a minimum of three times per week by the pool operator of record.

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

Update: The civil penalty has been paid and the Consent Order is closed.

21)

Order Type and Number:	Consent Order 23-187-RW
Order Date:	December 27, 2023
Individual/Entity:	**Shreeji Hospitality Investors, LLC**
Facility:	Fairfield Inn Rock Hill
Location:	578 Galleria Boulevard Rock Hill, SC 29730
Mailing Address:	6025 Blakeney Park Drive, Suite 125 Charlotte, NC 28277
County:	York
Previous Orders:	None
Permit/ID Number:	46-1164B
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Shreeji Hospitality Investors, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in York County, South Carolina. The Department conducted inspections on June 1, 2023, and July 3, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the flow meter was not operating; the chlorine and pH levels were not within the acceptable range of water quality standards; the cyanuric acid level was above the water quality standards acceptable limit; the pool rules sign did not have all the required rules; the current pool operator of record information was not posted to the public; the facility could not produce current valid documentation of pool operator certification; the log book was not properly bound and numbered on the first inspection; the bound and numbered log book was not maintained on a daily basis and was not maintained a minimum of three times per week by the pool operator of record; and the cyanuric acid level was not recorded on a weekly basis in the bound and numbered log book.

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

Update: The civil penalty has been paid and the Consent Order is closed.

22) Order Type and Number: Consent Order 23-188-RW
Order Date: December 27, 2023
Individual/Entity: **Shree Hari Hospitality Columbia, LLC**
Facility: Comfort Suites
Location: 1540 Daulton Drive
Columbia, SC 29223
Mailing Address: Same
County: Richland
Previous Orders: None
Permit/ID Number: 40-1090B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Shree Hari Hospitality Columbia, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Richland County, South Carolina. The Department conducted inspections on June 2, 2023, and July 18, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a ladder was missing rungs; the plaster on the pool floor was deteriorated; skimmers were missing weirs; the chlorine and pH levels were not within the acceptable range of water quality standards; the life ring was deteriorated on the first inspection; the life ring was not United States Coast Guard approved on the second inspection; the shepherd's crook handle was not the approved length; and the bound and numbered log book was not maintained on a daily basis.

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

Update: The civil penalty has been paid and the Consent Order is closed.

23) Order Type and Number: Consent Order 23-189-RW
Order Date: December 27, 2023
Individual/Entity: **Concord Mills Hotel Investments, LLC**
Facility: TownePlace Suites by Marriott
Location: 2135 Tabor Drive
Rock Hill, SC 29730
Mailing Address: Same
County: York
Previous Orders: None
Permit/ID Number: 46-1106B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Concord Mills Hotel Investments, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in York County, South Carolina. The Department conducted inspections on June 1, 2023, July 3, 2023, and August 1, 2023, and violations were issued for failure to properly operate and

maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the drinking water fountain was not operating; the flow meter was not operating; the chlorine level was not within the acceptable range of water quality standards; the pool rules sign did not have all of the required rules; the pool operator of record information was not posted to the public on the first inspection; the pool operator of record listed did not have a valid South Carolina certification and the facility could not produce current valid documentation on the second inspection; the log book was not properly bound and numbered on the first inspection; the bound and numbered log book was not maintained on the second inspection; and the bound and numbered log book was not available for review on the third inspection.

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)**.

Update: The civil penalty has been paid and the Consent Order is closed.

24)

Order Type and Number:	Consent Order 23-192-RW
Order Date:	December 28, 2023
Individual/Entity:	**Bridgepointe Owners Association, Inc.**
Facility:	Bridgepointe Condominiums
Location:	100 Sunset Boulevard West Columbia, SC 29169
Mailing Address:	Same
County:	Lexington
Previous Orders:	None
Permit/ID Number:	32-125-1
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Bridgepointe Owners Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Lexington County, South Carolina. The Department conducted inspections on June 15, 2023, and August 10, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: depth marker tiles were broken; there was debris in the skimmer baskets; the water level was too low; the pool equipment room and chemical storage room were not accessible; a gate did not self-close and latch; the life ring rope was deteriorated; the facility address was not posted at the emergency notification device; the pool rules sign included pool hours for night swimming and the pool is not approved for night swimming; the bound and numbered log book was not available for review; there was no drinking water fountain; there was no foot rinse shower; and the pH level was not within the acceptable range of water quality standards.

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

Update: The civil penalty has been paid and the Consent Order is closed.

Water Pollution Enforcement

25) Order Type and Number: Consent Order 23-056-W
Order Date: December 5, 2023
Individual/Entity: **DAK Americas LLC**
Facility: DAK Americas LLC
Location: 3350 Cypress Gardens Road
Moncks Corner, SC 29461
Mailing Address: Same
County: Berkeley County
Previous Orders: None
Permit/ID Number: NPDES Permit SC0026506
Violations Cited: Pollution Control Act, S.C Code Ann § 48-1-110 (d); Water Pollution Control Permits, S.C. Code Ann Regs. 61-9.122.41 (a)

Summary: DAK Americas, LLC (Individual/Entity) is responsible for the proper operation and maintenance of a wastewater treatment facility (WWTF) located in Berkeley County, South Carolina. On December 9, 2022, a Notice of Violation was issued as a result of violations of the permitted discharge limits for biochemical oxygen demand (BOD) ultimate oxygen demand (UOD) as 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 permitted effluent discharge limits for BOD and UOD.

Action: The Individual/Entity is required to: submit a written notification of the planned completion date for all corrective actions necessary to resolve the violations; conduct a six (6) 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 seven thousand dollars ($7,000.00). The Individual/Entity shall pay a civil penalty in the amount of seven thousand dollars **($7,000.00)**.

Update: The civil penalty has been paid and the planned notification of corrective actions has been submitted and retro dated; therefore, the compliance confirmation period has been completed. The Order is closed.

26) Order Type and Number: Consent Order 23-057-W
Order Date: December 5, 2023
Individual/Entity: **City of Belton**
Facility: Ducworth Wastewater Treatment Facility
Location: 1408 Highway 247
Belton, SC 29080
Mailing Address: P.O. Box 828
Belton, SC 29627
County: Anderson
Previous Orders: None
Permit/ID Number: SC0045896

Violations Cited: Pollution Control Act, S.C. Code Ann. § 48-1-110(d) and the Water Pollution Control Permits Regulation S.C. Code Ann. Regs. 61-9.122.41(a)

Summary: The City of Belton (Individual/Entity) owns and is responsible for the Ducworth wastewater treatment facility (WWTF) located in Anderson County, South Carolina. The Individual/Entity reported violations of ammonia-nitrogen (ammonia) and biochemical oxygen demand (BOD) on discharge monitoring reports submitted to the Department. The Individual/Entity has violated the Pollution Control Act and the Water Pollution Control Permits Regulation, as follows: failed to comply with the permitted effluent limitations for ammonia and BOD.

Action: The Individual/Entity is required to: submit written notification of the planned completion date for all corrective actions necessary to resolve the effluent violations by January 4, 2024; 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 five thousand, six hundred dollars ($5,600.00). The Individual/Entity shall pay a civil penalty in the amount of five thousand, six hundred dollars **($5,600.00)** by January 4, 2024.

Update: None.

27) Order Type and Number: Consent Order 23-058-W
Order Date: December 13, 2023
Individual/Entity: **Harbor Island Utilities, Inc.**
Facility: Harbor Island Utilities Wastewater Treatment Facility
Location: 2 Harbor Drive
Harbor Island, SC
Mailing Address: 31 Sora Rail Road
Kiawah Island, SC 29455
County: Beaufort
Previous Orders: 22-016-W ($3,500.00)
Permit/ID Number: ND0088013
Violations Cited: Pollution Control Act, S.C. Code Ann. § 48-1-110(d) and the Water Pollution Control Permits Regulation S.C. Code Ann Regs. 61-9.122.41(a)

Summary: South Carolina Water Utilities, Inc. (Individual/Entity) owns and is responsible for the Harbor Island Utilities, Inc. wastewater treatment facility (WWTF) located in Beaufort County, South Carolina. The Individual/Entity reported violations of total suspended solids (TSS) on discharge monitoring reports submitted to the Department. The Individual/Entity has violated the Pollution Control Act and the Water Pollution Control Permits Regulation, as follows: failed to comply with the permitted effluent limitations for TSS.

Action: The Individual/Entity is required to: submit written notification of the planned completion date for all corrective actions necessary to resolve the effluent violations by January 12, 2024; 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 five thousand dollars ($5,000.00). The Individual/Entity shall pay a civil penalty in the amount of five thousand dollars **($5,000.00)** by January 12, 2024.

Update: None.

BUREAU OF AIR QUALITY

28)

Order Type and Number:	Consent Order 23-031-A
Order Date:	December 5, 2023
Individual/Entity:	**Cochin Land LLC**
Facility:	N/A
Location:	731 Woodmont Circle Anderson, SC 29624
Mailing Address:	P.O. Box 114 Lilburn, GA 30048
County:	Anderson
Previous Orders:	None
Permit/ID Number:	N/A
Violations Cited:	S.C. Code Ann. Regs. 61-62.2 (Supp. 2022) *Prohibition of Open Burning*

Summary: Cochin Land LLC (Individual/Entity) owns property located in a residential neighborhood in Anderson County, South Carolina. On June 5, 2023, a Department inspector conducted an investigation in response to a complaint of open burning. The Individual/Entity has violated South Carolina Air Pollution Control Regulations, as follows: allowed to be burned materials other than those allowed by Section I of the Open Burning Regulations, specifically household garbage.

Action: The Individual/Entity is required to: cease all open burning except as permitted by the Regulations. The Department has assessed a total civil penalty in the amount of one thousand dollars ($1,000.00). The Individual/Entity shall pay a **suspended penalty** in the amount of one thousand dollars (**$1,000.00**) should any requirement of the Order not be met.

Update: None.

29)

Order Type and Number:	Consent Order 23-032-A
Order Date:	December 6, 2023
Individual/Entity:	**Guardian Industries LLC**
Facility:	Guardian Industries LLC
Location:	610 L&C Railway Distribution Park Richburg, SC 29729
Mailing Address:	Same
County:	Chester County
Previous Orders:	None

Permit/ID Number: 0640-0018
Violations Cited: U.S. EPA 40 CFR 70.5(a)(1)(iii), S.C. Code Ann. Regs. 61-62.70.5(a)(1)(iii), and S.C. Code Ann. Regs. 61-62.1, Section II, *Permit Requirements*

Summary: Guardian Industries LLC. (Individual/Entity) operates a flat and pattern glass manufacturing facility located in Chester County, South Carolina. On September 30, 2022, the Individual/Entity submitted a Title V Permit renewal request to the Department. The Title V Permit renewal request was due no later than June 30, 2022. The Individual/Entity has violated US EPA and South Carolina Air Pollution Control Regulations, as follows: failed to submit a timely Title V Permit renewal request to the Department.

Action: The Individual/Entity is required to: comply with all terms and conditions of the current Title V Permit, until such time as the Department issues a renewed Title V Permit. The Department has assessed a total civil penalty in the amount of seven thousand dollars ($7,000.00). The Individual/Entity shall pay a civil penalty in the amount of seven thousand dollars (**$7,000.00**) by January 6, 2024.

Update: None.

30) Order Type and Number: Consent Order 23-033-A
Order Date: December 29, 2023
Individual/Entity: **Takeuchi Manufacturing (US) Limited**
Facility: Takeuchi Manufacturing (US) Limited
Location: 1876 Moore-Duncan Highway
Moore, SC 29369
Mailing Address: Same
County: Spartanburg
Previous Orders: None
Permit/ID Number: CP-2060-0658
Violations Cited: S.C. Code Ann. Regs. 61-62.1, Section II
Permit Requirements

Summary: Takeuchi Manufacturing (US) Limited (Individual/Entity) is a manufacturing plant for compact truck loaders located in Spartanburg County, South Carolina. On February 10, 2023, the Department received a Conditional Major Operating Permit request. On July 17, 2023, the Department conducted a review of records in response to the Operating Permit request. The Individual/Entity has violated South Carolina Pollution Control Regulations, as follows: failed to apply for and obtain a construction permit prior to installing and operating sources of air pollution; failed to submit a timely written notification for the start of construction; failed to submit a timely written notification for initial start-up; failed to submit a timely request for a new or revised operating permit; failed to submit operational ranges for the shot blasting booth.

Action: The Individual/Entity is required to: comply with all terms and conditions of the Permit. The Department has assessed a total civil penalty in the amount of fourteen thousand, six hundred and twenty-five dollars ($14,625.00). The Individual/Entity shall pay a civil penalty in the amount of fourteen thousand, six hundred and twenty-five dollars **($14,625.00)** .

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

31) Order Type and Number: Consent Order 23-034-A
Order Date: December 29, 2023
Individual/Entity: **DAK Americas, LLC**
Facility: DAK Americas, LLC
Location: 3350 Cypress Gardens Road
Moncks Corner, SC 29461
Mailing Address: Same
County: Berkeley
Previous Orders: None
Permit/ID Number: 0420-0089
Violations Cited: US EPA 40 CFR 63 and S.C. Code Ann. Regs. 61-62.63 Subpart A, US EPA 40 CFR 70 and S.C. Code Ann. Regs. 61-62.70, and S.C. Code Ann. Regs 61-62.1, Section II, *Permit Requirements*.

Summary: DAK Americas (Individual/Entity) operates a polyethylene terephthalate plant, producing polyester fibers and pellets at its facility located in Berkeley County, South Carolina. The Department received a voluntary disclosure submission from the Individual/Entity. The Individual/Entity has violated US EPA and South Carolina Air Pollution Control Regulations, as follows: failed to operate and maintain an affected source, including associated air pollution control equipment and monitoring equipment, in a manner consistent with safety and good air pollution control practices by removing packing media from the scrubbers; failed to include all pollution control equipment in the Notice of Compliance Status ("NOCS"); failed to submit a revised NOCS following a change in operating status of the scrubbers following the removal of packing media; failed to identify and describe all air pollution control equipment and compliance monitoring devices or activities in the TV permit application; reported information which was inaccurate in a compliance certification stating that all information was true, accurate, and complete, in the TVACC; failed to obtain a construction permit from the Department prior to commencement of construction or document an exemption from construction permit requirements prior to constructing, altering, or adding to a source of air contaminants.

Action: The Individual/Entity is required to: discontinue all operations at the facility that require a Title V air permit (this does not include operation of the on-site wastewater treatment plant) and submit the appropriate Title V operating permit cancellation form to the Department.

Update: The Individual/Entity has submitted a permit cancellation request.

32) Order Type and Number: Consent Order 23-035-A
Order Date: December 29, 2023
Individual/Entity: **Argos Cement, LLC**
Facility: Argos Cement, LLC
Location: 463 Judge Street
Harleyville, SC 29448
Mailing Address: Same
County: Dorchester
Previous Orders: None

Permit/ID Number: 0900-0004
Violations Cited: S.C. Code Ann. Regs. 61-62.60, Subpart DDDD and S.C. Code Ann. Regs 61-62.1, Section II, *Permit Requirements*.

Summary: Argos Cement, LLC (Individual/Entity) operates a Portland cement manufacturing facility located in Dorchester County South Carolina. The Individual/Entity conducted multiple Department-approved performance tests for CO and lead emissions. Additionally, the Department received two Excess Emissions and Continuous Monitoring System Performance and Summary Report's. The Individual/Entity has violated US EPA and South Carolina Air Pollution Control Regulations, as follows: failed to limit CO emissions and lead emissions for the rotary kiln, Kiln coal mill (KCM), and Precalciner coal mill (PCM); failed to limit lead emissions for the rotary kiln, PCM, and clinker for the rotary kiln and PCM combined; failed to limit Hg emissions for a total of four days; failed to limit CO emissions and PM emissions; failed to limit Hg emissions for a total of eighty-seven days.

Action: The Individual/Entity is required to: henceforth, maintain compliance with all applicable emission limits specified in Subpart DDDD and the Title V Permit. The Department has assessed a total civil penalty in the amount of eighty-five thousand dollars ($85,000.00). The Individual/Entity shall pay a civil penalty in the amount of eighty-five thousand dollars (**$85,000.00**) by January 29, 2024.

Update: None.

BUREAU OF ENVIRONMENTAL HEALTH SERVICES

On-Site Wastewater Enforcement

33) Order Type and Number: Administrative Order 23-090-OSWW
Order Date: December 12, 2023
Individual/Entity: **Tarlisa Deangelo Dennis**
Facility: Tarlisa Deangelo Dennis
Location: 5210 McDaniel Road
Rembert, SC 29128
Mailing Address: Same
County: Sumter
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: Tarlisa Deangelo Dennis (Individual/Entity) owns property located in Sumter County, South Carolina. The Department conducted an investigation on June 26, 2023, and observed domestic wastewater discharging onto the surface of the ground. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that no septic tank effluent, domestic wastewater, or sewage was discharged to the surface of the ground without an appropriate permit from the Department.

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

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

34) Order Type and Number: Administrative Order 23-104-OSWW
Order Date: December 12, 2023
Individual/Entity: **Rena Dennison and Ezekiel Dennison**
Facility: Rena Dennison and Ezekiel Dennison
Location: 3571 East National Cemetery Road
Florence, SC 29506
Mailing Address: 1806 Butt Street
Georgetown, SC 29440
County: Florence
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: Rena Dennison and Ezekiel Dennison (Individual/Entity) owns property located in Florence County, South Carolina. The Department conducted an investigation on October 30, 2023, and observed domestic wastewater discharging onto the surface of the ground. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that no septic tank effluent, domestic wastewater, or sewage was discharged to the surface of the ground without an appropriate permit from the Department.

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

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

35) Order Type and Number: Administrative Order 23-105-OSWW
Order Date: December 12, 2023
Individual/Entity: **Rodney Smith and Candace Smith**
Facility: Rodney Smith and Candace Smith
Location: 301 South Lansdale Drive
Florence, SC 29506
Mailing Address: Same

County:	Florence
Previous Orders:	None
Permit Number:	None
Violations Cited:	S.C. Code Ann. Regs. 61-56

Summary: Rodney Smith and Candace Smith (Individual/Entity) owns property located in Florence County, South Carolina. The Department conducted an investigation on October 17, 2023, and observed domestic wastewater discharging onto the surface of the ground. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that no septic tank effluent, domestic wastewater, or sewage was discharged to the surface of the ground without an appropriate permit from the Department.

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

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

36)

Order Type and Number:	Consent Order 23-098-OSWW
Order Date:	December 1, 2023
Individual/Entity:	**Ronnie T. Gilbert, DBA AARMS of Boiling Springs**
Facility:	Ronnie T. Gilbert, DBA AARMS of Boiling Springs
Location:	140 Burchette Drive Chesnee, SC 29323
Mailing Address:	120 Riverdale Drive Chesnee, SC 29323
County:	Spartanburg
Previous Orders:	20-046-OSWW
Permit Number:	None
Violations Cited:	S.C. Code Ann. Regs. 61-56

Summary: Ronnie T. Gilbert, DBA AARMS of Boiling Springs (Individual/Entity) installed an OSWW system on property located in Spartanburg County, South Carolina. The Department conducted a Final Inspection on August 17, 2023, and observed that the OSWW system was covered before the time of the scheduled inspection. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to wait a full thirty (30) minutes from the time of a scheduled Final Inspection before covering any newly installed OSWW system.

Action: The Individual/Entity is required to cease and desist covering newly installed OSWW systems without waiting a full thirty (30) minutes from the time of a scheduled Final Inspection. The Department has assessed a total civil penalty in the

amount of five hundred dollars ($500.00). The Individual/Entity shall pay a civil penalty in the amount of five hundred dollars **($500.00)**.

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

37)

Order Type and Number:	Consent Order 23-103-OSWW
Order Date:	December 21, 2023
Individual/Entity:	**Trent Ivey, DBA Ivey Septic**
Facility:	Trent Ivey, DBA Ivey Septic
Location:	Pierce Cook Road Woodruff, SC 29388
Mailing Address:	412 Browns Creek Church Road Union, SC 29379
County:	Spartanburg
Previous Orders:	None
Permit Number:	None
Violations Cited:	S.C. Code Ann. Regs. 61-56

Summary: Trent Ivey, DBA Ivey Septic (Individual/Entity) installed an OSWW system on property located in Spartanburg County, South Carolina. The Department conducted a review of submitted documents on June 20, 2023, and determined the document was missing vital information, and the drainfield was installed outside the permitted area. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: installed portions of an OSWW system outside the specifications of the Permit to Construct.

Action: The Individual/Entity is required to cease and desist installing OSWW systems outside the specifications of the Permit to Construct. The Department has assessed a total civil penalty in the amount of five hundred dollars ($500.00). The Individual/Entity shall pay a civil penalty in the amount of five hundred dollars **($500.00)**.

Update: The Individual/Entity has met all requirements of the Order. 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

February 8, 2024

( ) ACTION/DECISION
(X) INFORMATION

I. **TITLE:** Health Promotion and Services Administrative and Consent Orders.

II. **SUBJECT:** Health Promotion and Services Administrative Orders and Consent Orders for the period of December 1, 2023, through December 31, 2023.

III. **FACTS:** For the period of December 1, 2023, through December 31, 2023, Health Promotion and Services reports 0 Administrative Orders and 27 Consent Orders totaling $33,550.00 in assessed civil penalties.

Permit Type	Administrative Orders	Consent Orders	Assessed Civil Penalties
Retail Food Establishments	0	27	$33,550.00

Submitted By:

Susan C. Best

Susan Best
Program Manager
Division of Food and Lead Risk Assessment

HEALTH PROMOTION AND SERVICES ENFORCEMENT REPORT
SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

February 8, 2024

CONSENT ORDERS (27)

1)	Order Type and Number:	Consent Order 23-375-FOOD
	Order Date:	December 1, 2023
	Individual/Entity:	Refuel Operating Company, LLC
	Facility:	Refuel #141
	Location:	711 Market Street Cheraw, SC 29520
	Mailing Address:	P. O. Box 20782 Charleston, SC 29413
	County:	Chesterfield
	Previous Orders:	None
	Permit Number:	13-206-01561

Summary: The Department conducted inspections on December 15, 2022, October 3, 2023, October 13, 2023, and October 23, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that at least one employee that has supervisory and management responsibility, the authority to direct and control food preparation and service, the ability to enforce employee health policies, and a frequent presence at the facility shall be a certified food protection manager who has shown proficiency of required information through passing a test that is part of an accredited program.

Action: The Individual/Entity is required to operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25. The Department has assessed a total civil penalty in the amount of four hundred dollars ($400.00). The Individual/Entity shall pay a civil penalty in the amount of four hundred dollars ($400.00). The Individual/Entity has paid the civil penalty; however, correction of the violation has not been verified

2)	Order Type and Number:	Consent Order 23-376-FOOD
	Order Date:	December 1, 2023
	Individual/Entity:	Refuel Operating Company, LLC

Facility:	Refuel #40
Location:	3370 Highway 601 North Pageland, SC 29728
Mailing Address:	P. O. Box 20782 Charleston, SC 29413
County:	Chesterfield
Previous Orders:	None
Permit Number:	13-206-01544

Summary: The Department conducted inspections on December 1, 2022, September 25, 2023, October 5, 2023, October 12, 2023, and October 20, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that at least one employee that has supervisory and management responsibility, the authority to direct and control food preparation and service, the ability to enforce employee health policies, and a frequent presence at the facility shall be a certified food protection manager who has shown proficiency of required information through passing a test that is part of an accredited program; and failed to ensure that at all times during operation, the person in charge shall be a certified food handler or a certified food protection manager who has shown proficiency of required information through passing a test that is part of an accredited program.

Action: The Individual/Entity is required to operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25. The Department has assessed a total civil penalty in the amount of six hundred dollars ($600.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred dollars ($600.00). The Individual/Entity has paid the civil penalty; however, correction of the violation has not been verified.

3)

Order Type and Number:	Consent Order 23-374-FOOD
Order Date:	December 1, 2023
Individual/Entity:	Refuel Operating Company, LLC
Facility:	Refuel #41
Location:	3567 Highway 601 North Pageland, SC 29728
Mailing Address:	P. O. Box 20782 Charleston, SC 29413

County: Chesterfield
Previous Orders: None
Permit Number: 13-206-01574

Summary: The Department conducted inspections on December 28, 2022, September 25, 2023, October 5, 2023, October 12, 2023, and October 20, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that at least one employee that has supervisory and management responsibility, the authority to direct and control food preparation and service, the ability to enforce employee health policies, and a frequent presence at the facility shall be a certified food protection manager who has shown proficiency of required information through passing a test that is part of an accredited program; and failed to ensure that at all times during operation, the person in charge shall be a certified food handler or a certified food protection manager who has shown proficiency of required information through passing a test that is part of an accredited program.

Action: The Individual/Entity is required to operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25. The Department has assessed a total civil penalty in the amount of six hundred dollars ($600.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred dollars ($600.00). The Individual/Entity has paid the civil penalty; however, correction of the violation has not been verified.

4) Order Type and Number: Consent Order 23-169-FOOD
Order Date: December 1, 2023
Individual/Entity: Karen Campbell
Facility: Tokyo Express
Location: 250 Highway 17 North
North Myrtle Beach, SC 29582
Mailing Address: 205 Utopia Court
Myrtle Beach, SC 29579
County: Horry
Previous Orders: 21-24-FOOD ($500.00); and
22-83-FOOD ($1,000.00)
Permit Number: 26-206-13707

Summary: The Department conducted inspections on November 28, 2022, March 10, 2023, March 16, 2023, and March 24, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that at least one employee that has supervisory and management responsibility, the authority to direct and control food preparation and service, the ability to enforce employee health policies, and a frequent presence at the facility shall be a certified food protection manager who has shown proficiency of required information through passing a test that is part of an accredited program.

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

Previous Orders: The previous consent order (21-24-FOOD) was issued when the Individual/Entity violated the South Carolina Retail Food Establishment Regulation by obscuring, covering, defacing, relocating, or removing the grade decal that was posted by the Department (CTG). The previous Consent Order (22-83-FOOD) was issued when the Individual/Entity violated the South Carolina Retail Food Establishment Regulation by failing to ensure that refrigerated, ready-to-eat, time/ temperature control for safety foods were discarded if the temperature and time combination exceeded seven (7) days or if the package was not properly date marked (P).

5)	Order Type and Number:	Consent Order 23-405-FOOD
	Order Date:	December 6, 2023
	Individual/Entity:	Chick-fil-A Surfside Chick-fil-A Surfside
	Facility:	
	Location:	2360 Dick Pond Road Myrtle Beach, SC 29575
	Mailing Address:	Same
	County:	Horry
	Previous Orders:	None
	Permit Number:	26-206-14327

Summary: The Department conducted inspections on April 14, 2023, April 20, 2023, and October 2, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain the premises free of insects, rodents, and other pests.

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

6)

Order Type and Number:	Consent Order 23-412-FOOD
Order Date:	December 6, 2023
Individual/Entity:	Belfair Grill Room
Facility:	Belfair Grill Room
Location:	16 Cottage Drive West Hilton Head, SC 29925
Mailing Address:	200 Belfair Oaks Boulevard Bluffton, SC 29910
County:	Beaufort
Previous Orders:	None
Permit Number:	07-206-02054

Summary: The Department conducted an inspection on November 9, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: obscured, covered, defaced, relocated, or removed the grade decal that was posted by the Department.

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

7) Order Type and Number: Consent Order 23-336-FOOD
Order Date: December 6, 2023
Individual/Entity: Sugrue's Pub and Eatery
Facility: Sugrue's Pub and Eatery
Location: 1200 Highway 17 South
North Myrtle Beach, SC 29582
Mailing Address: Same
County: Horry
Previous Orders: None
Permit Number: 26-206-14024

Summary: The Department conducted inspections on March 27, 2023, April 6, 2023, and September 15, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

Action: The Individual/Entity is required to operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25. The Department has assessed a total civil penalty in the amount of five hundred fifty dollars ($550.00). The Individual/Entity shall pay a civil penalty in the amount of five hundred fifty dollars ($550.00). No update at this time.

8) Order Type and Number: Consent Order 23-303-FOOD
Order Date: December 6, 2023
Individual/Entity: Little Pigs BBQ @ Surfside
Facility: Little Pigs BBQ @ Surfside
Location: 3901 Dick Pond Road, Suite C
Myrtle Beach, SC 29588
Mailing Address: Same
County: Horry
Previous Orders: None
Permit Number: 26-206-12094

Summary: The Department conducted inspections on February 15, 2023, February 24, 2023, and August 14, 2023. The Individual/Entity has violated the South Carolina Retail

Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

Action: The Individual/Entity is required to operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25. The Department has assessed a total civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred dollars ($800.00). No update at this time.

9)

Order Type and Number:	Consent Order 23-395-FOOD
Order Date:	December 6, 2023
Individual/Entity:	Marcos Pizza #8244
Facility:	Marcos Pizza #8244
Location:	2607 Highway 17, Suite C Garden City, SC 29576
Mailing Address:	930 Richland Street, Suite 200 Columbia, SC 29201
County:	Horry
Previous Orders:	None
Permit Number:	26-206-14324

Summary: The Department conducted inspections on April 5, 2023, October 18, 2023, and October 27, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure written procedures were in place and made available to the Department when the facility uses time as a public health control.

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

10) Order Type and Number: Consent Order 23-413-FOOD
Order Date: December 6, 2023
Individual/Entity: TGI Friday's #745
Facility: TGI Friday's #745
Location: 500 Highway 17 North
North Myrtle Beach, SC 29582
Mailing Address: 19111 North Dallas Parkway, Suite 165
Dallas, TX 75287
County: Horry
Previous Orders: 23-112-FOOD ($1,600.00); and
23-288-FOOD ($1,000.00)
Permit Number: 26-206-14483

Summary: The Department conducted an inspection on November 6, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

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

Previous Orders: The previous Consent Order (23-112-FOOD) was issued when the Individual/Entity violated the South Carolina Retail Food Establishment Regulation by failing to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling (P). The previous Consent Order (23-288-FOOD) was issued when the Individual/Entity violated the South Carolina Retail Food Establishment Regulation by failing to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling (P).

11) Order Type and Number: Consent Order 23-363-FOOD

Order Date:	December 6, 2023
Individual/Entity:	Scores Sports Bar
Facility:	Scores Sports Bar
Location:	3562 Highway 17 Bypass South Myrtle Beach, SC 29588
Mailing Address:	Same
County:	Horry
Previous Orders:	23-67-FOOD ($800.00)
Permit Number:	26-206-08459

Summary: The Department conducted inspections on September 21, 2023, and September 28, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

Action: The Individual/Entity is required to operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25. The Department has assessed a total civil penalty in the amount of two thousand dollars ($2,000.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand dollars ($2,000.00). The Individual/Entity has met all requirements of the Order. This Order has been closed.

Previous Orders: The previous Consent Order (23-67-FOOD) was issued when the Individual/Entity violated the South Carolina Retail Food Establishment Regulation by failing to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling (P); and by failing to ensure that refrigerated, ready-to-eat, time/temperature control for safety foods were discarded if the temperature and time combination exceeded seven (7) days or if the package was not properly date marked (P).

12)

Order Type and Number:	Consent Order 23-425-FOOD
Order Date:	December 7, 2023
Individual/Entity:	Piggly Wiggly #188 Deli
Facility:	Piggly Wiggly #188 Deli
Location:	800 North Greenwood Street Ware Shoals, SC 29692
Mailing Address:	Same

County:	Greenwood
Previous Orders:	None
Permit Number:	24-206-03044

Summary: The Department conducted inspections on October 17, 2023, October 24, 2023, and November 2, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

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

13)

Order Type and Number:	Consent Order 23-385-FOOD
Order Date:	December 7, 2023
Individual/Entity:	Super Favorita Market
Facility:	Super Favorita Market
Location:	611 East Cambridge Avenue Greenwood, SC 29646
Mailing Address:	Same
County:	Greenwood
Previous Orders:	None
Permit Number:	24-206-01997

Summary: The Department conducted inspections on August 22, 2023, August 25, 2023, September 5, 2023, September 13, 2023, September 22, 2023, and October 4, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain the premises free of insects, rodents, and other pests.

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

dollars ($1,600.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand six hundred dollars ($1,600.00). The Individual/Entity has met all requirements of the Order. This Order has been closed.

14)

Order Type and Number:	Consent Order 23-388-FOOD
Order Date:	December 14, 2023
Individual/Entity:	Buenavista Latin Café
Facility:	Buenavista Latin Café
Location:	322 Main Street Greenwood, SC 29646
Mailing Address:	Same
County:	Greenwood
Previous Orders:	None
Permit Number:	24-206-03142

Summary: The Department conducted an inspection on October 24, 2023. Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: obscured, covered, defaced, relocated, or removed the grade decal that was posted by the Department.

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

15)

Order Type and Number:	Consent Order 23-307-FOOD
Order Date:	December 14, 2023
Individual/Entity:	Baluinder Singh
Facility:	Sumter Stop
Location:	610 South Guignard Drive Sumter, SC 29150
Mailing Address:	Same
County:	Sumter

Previous Orders: None
Permit Number: 43-206-01163

Summary: The Department conducted inspections on May 23, 2023, August 9, 2023, August 17, 2023, and August 24, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that at least one employee that has supervisory and management responsibility, the authority to direct and control food preparation and service, the ability to enforce employee health policies, and a frequent presence at the facility shall be a certified food protection manager who has shown proficiency of required information through passing a test that is part of an accredited program; failed to ensure that at all times during operation, the person in charge shall be a certified food handler or a certified food protection manager who has shown proficiency of required information through passing a test that is part of an accredited program; failed to ensure that cleaned equipment and utensils, laundered linens, and single-use articles shall be stored in a clean, dry location; where they are not exposed to splash, dust, or other contamination; and at least 6 inches off the floor; and failed to keep food contact surfaces of cooking equipment and pans free of encrusted grease deposits and other soil accumulations and non-food contact surfaces clean and free of accumulation of dust, dirt, food residue, and other debris.

Action: The Individual/Entity is required to operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25. The Department has assessed a total civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred dollars ($800.00). No update at this time.

16) Order Type and Number: Consent Order 23-411-FOOD
Order Date: December 14, 2023
Individual/Entity: Carrabba's Italian Grill #9109
Facility: Carrabba's Italian Grill #9109
Location: 511 Courtfield Road
Murrells Inlet, SC 29576
Mailing Address: 2202 North West Shore Boulevard, 5th Floor
Tampa, FL 33607
County: Georgetown
Previous Orders: None
Permit Number: 22-206-05795

Summary: The Department conducted inspections on July 19, 2022, January 23, 2023, October 16, 2023, and October 26, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

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

17)

Order Type and Number:	Consent Order 23-372-FOOD
Order Date:	December 14, 2023
Individual/Entity:	Emily's Amish Oven
Facility:	Emily's Amish Oven
Location:	803 Bypass 25 NE Greenwood, SC 29646
Mailing Address:	Same
County:	Greenwood
Previous Orders:	23-267-FOOD ($4,800.00)
Permit Number:	24-206-03308

Summary: The Department conducted inspections on September 27, 2023, and October 4, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling; and failed to inform consumers of the significantly increased risk of consuming raw animal foods by way of a disclosure and reminder (using brochures, deli case or menu advisories, label statements, table tents, placards, or other effective written means).

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

($2,000.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand dollars ($2,000.00). The Department has entered into a payment plan with the Individual/ Entity for the civil penalty.

Previous Orders: The previous Consent Order (23-267-FOOD) was issued when the Individual/Entity violated the South Carolina Retail Food Establishment Regulation by failing to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling (P); by failing to ensure employees wash hands after engaging in activities that contaminate their hands (P); by failing to ensure that the handwashing sinks were accessible at all times (PF); by failing to store foods in a manner to prevent cross contamination (P); by failing to inform consumers of the significantly increased risk of consuming raw animal foods by way of a disclosure and reminder (using brochures, deli case or menu advisories, label statements, table tents, placards, or other effective written means) (PF); by failing to clearly and individually identify with the common name of the material, on all working containers used for storing poisonous or toxic materials such as cleaners and sanitizers taken from bulk supplies (PF); and by failing to provide a test kit or other device that accurately measures the concentration of MG/L of sanitizing solutions (PF).

18)

Order Type and Number:	Consent Order 23-360-FOOD
Order Date:	December 14, 2023
Individual/Entity:	Bonefish Grill LLC
Facility:	Bonefish Grill #0506
Location:	8703 Highway 17 Bypass Surfside Beach, SC 29582
Mailing Address:	2202 North West Shore Boulevard, 5th Floor Tampa, FL 33607
County:	Horry
Previous Orders:	23-26-FOOD ($800.00); and 23-208-FOOD ($1,000.00)
Permit Number:	26-206-10399

Summary: The Department conducted inspections on May 16, 2023, September 13, 2023, September 22, 2023, and October 2, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling; and

failed to keep food contact surfaces of cooking equipment and pans free of encrusted grease deposits and other soil accumulations and non-food contact surfaces clean and free of accumulation of dust, dirt, food residue, and other debris.

Action: The Individual/Entity is required to operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25. The Department has assessed a total civil penalty in the amount of two thousand two hundred fifty dollars ($2,250.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand two hundred fifty dollars ($2,250.00). The Individual/Entity has paid the civil penalty; however, correction of the violation has not been verified.

.

Previous Orders: The previous Consent Order (23-26-FOOD) was issued when the Individual/Entity violated the South Carolina Retail Food Establishment Regulation by failing to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling (P). The previous Consent Order (23-208-FOOD) was issued when the Individual/Entity violated the South Carolina Retail Food Establishment Regulation by failing to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling (P).

19)

Order Type and Number:	Consent Order 23-420-FOOD
Order Date:	December 14, 2023
Individual/Entity:	Ingles #239 Deli
Facility:	Ingles #239 Deli
Location:	1900 North Main Street Anderson, SC 29621
Mailing Address:	P. O. Box 6676 Asheville, NC 28816
County:	Anderson
Previous Orders:	23-379-FOOD ($1,600.00)
Permit Number:	04-206-02631

Summary: The Department conducted inspections on June 27, 2023, August 10, 2023, October 30, 2023, and November 6, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that the handwashing sinks were accessible at all times; failed to sanitize utensils and food contact surfaces of equipment before using, after cleaning; failed to ensure that time/temperature

control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling; failed to ensure that refrigerated, ready-to-eat, time/temperature control for safety foods were discarded if the temperature and time combination exceeded seven (7) days or if the package was not properly date marked; and failed to ensure written procedures were in place and made available to the Department when the facility uses time as a public health control.

Action: The Individual/Entity is required to operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25. The Department has assessed a total civil penalty in the amount of two thousand five hundred dollars ($2,500.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand five hundred dollars ($2,500.00). The Individual/Entity has met all requirements of the Order. This Order has been closed.

Previous Orders: The previous Consent Order (23-379-FOOD) was issued when the Individual/Entity violated the South Carolina Retail Food Establishment Regulation by failing to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling (P); by failing to sanitize utensils and food contact surfaces of equipment before using, after cleaning (P); by failing to ensure employees wash hands after engaging in activities that contaminate their hands (P); and by failing to keep equipment food contact surfaces and utensils clean to sight and touch (PF).

20)

Order Type and Number:	Consent Order 23-317-FOOD
Order Date:	December 14, 2023
Individual/Entity:	2 Gingers
Facility:	2 Gingers
Location:	245 Bush River Road Columbia, SC 29212
Mailing Address:	Same
County:	Richland
Previous Orders:	22-63-FOOD ($1,500.00)
Permit Number:	40-206-07493

Summary: The Department conducted inspections on July 28, 2023, August 7, 2023, August 9, 2023, August 17, 2023, August 25, 2023, and August 31, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as

follows: failed to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling; failed to maintain the premises free of insects, rodents, and other pests; and failed to ensure that the plumbing system was installed to preclude backflow of a solid, liquid, or gas contaminant into the water supply system at each point of use at the retail food establishment.

Action: The Individual/Entity is required to operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25. The Department has assessed a total civil penalty in the amount of four thousand five hundred dollars ($4,500.00). The Individual/Entity shall pay a civil penalty in the amount of four thousand five hundred dollars ($4,500.00). The Individual/Entity has met all requirements of the Order. This Order has been closed.

Previous Orders: The previous Consent Order (22-63-FOOD) was issued when the Individual/Entity violated the South Carolina Retail Food Establishment Regulation by failing to ensure that refrigerated, ready-to-eat, time/temperature control for safety foods were discarded if the temperature and time combination exceeded seven (7) days or if the package was not properly date marked (P); and by failing to maintain the premises free of insects, rodents, and other pests (PF).

21)

Order Type and Number:	Consent Order 23-391-FOOD
Order Date:	December 18, 2023
Individual/Entity:	Stoner's Pizza Joint
Facility:	Stoner's Pizza Joint
Location:	378 Columbiana Drive Columbia, SC 29212
Mailing Address:	502 Madison Oaks Drive Rincen, GA 31326
County:	Richland
Previous Orders:	None
Permit Number:	40-206-09062

Summary: The Department conducted inspections on October 16, 2023, October 24, 2023, and October 31, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F

and above, except during preparation, cooking, or cooling; and failed to ensure that food temperature measuring devices that are scaled only in Celsius or dually scaled in Celsius and Fahrenheit shall be accurate to plus or minus one (1) degrees C in the intended range of use; and food temperature measuring devices that are scaled only in Fahrenheit shall be accurate to plus or minus two (2) degrees F in the intended range of use.

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

22)

Order Type and Number:	Consent Order 23-352-FOOD
Order Date:	December 18, 2023
Individual/Entity:	Tropical Burger
Facility:	Tropical Burger
Location:	207 NE Main Street Easley, SC 29640
Mailing Address:	12 Staten Lane Taylors, SC 29687
County:	Pickens
Previous Orders:	22-85-FOOD ($500.00)
Permit Number:	39-206-02159

Summary: The Department conducted inspections on September 13, 2023, September 22, 2023, and September 29, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

Action: The Individual/Entity is required to operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25. The Department has assessed a total civil penalty in the amount of one thousand dollars ($1,000.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand dollars ($1,000.00). No update at this time.

Previous Orders: The previous Consent Order (22-85-FOOD) was issued when the Individual/Entity violated the South Carolina Retail Food Establishment Regulation by obscuring, covering, defacing, relocating, or removing the grade decal that was posted by the Department (CTG).

23)	Order Type and Number:	Consent Order 23-422-FOOD
	Order Date:	December 18, 2023
	Individual/Entity:	Deliteful Flavors
	Facility:	Deliteful Flavors
	Location:	104-A E Shockley Ferry Road Anderson, SC 29621
	Mailing Address:	165 Darlene Drive Belton, SC 29627
	County:	Anderson
	Previous Orders:	23-105-FOOD ($500.00); and 23-202-FOOD ($800.00)
	Permit Number:	04-206-04684

Summary: The Department conducted inspections on October 5, 2023, and November 8, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

Action: The Individual/Entity is required to operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25. The Department has assessed a total civil penalty in the amount of two thousand dollars ($2,000.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand dollars ($2,000.00). The Department has entered into a payment plan with the Individual/Entity for the civil penalty.

Previous Orders: The previous Consent Order (23-105-FOOD) was issued when the Individual/Entity violated the South Carolina Retail Food Establishment Regulation by obscuring, covering, defacing, relocating, or removing the grade decal that was posted by the Department (CTG). The previous Consent Order (23-202-FOOD) was issued when the Individual/Entity violated the South Carolina Retail Food Establishment Regulation by failing to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135

degrees F and above, except during preparation, cooking, or cooling (P).

24)

Order Type and Number:	Consent Order 23-434-FOOD
Order Date:	December 18, 2023
Individual/Entity:	Broke Leg BBQ
Facility:	Broke Leg BBQ
Location:	194 Evergreen Acres Road Pickens, SC 29671
Mailing Address:	Same
County:	Pickens
Previous Orders:	None
Permit Number:	Operating Without a Permit

Summary: The Department conducted investigations on October 27, 2023, and November 16, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: provided food to the public without a valid permit issued by the Department.

Action: The Individual/Entity is required to operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25. The Department has assessed a total civil penalty in the amount of two thousand dollars ($2,000.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand dollars ($2,000.00). The Department has entered into a payment plan with the Individual/ Entity for the civil penalty.

25)

Order Type and Number:	Consent Order 23-433-FOOD
Order Date:	December 20, 2023
Individual/Entity:	Broadway Bagels
Facility:	Broadway Bagels
Location:	2426 Hudson Road Greer, SC 29650
Mailing Address:	Same
County:	Greenville
Previous Orders:	None
Permit Number:	23-206-10882

Summary: The Department conducted inspections on June 7, 2022, January 5, 2023, and October 16, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that refrigerated, ready-to-eat, time/temperature control for safety foods were discarded if the temperature and time combination exceeded seven (7) days or if the package was not properly date marked.

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

26)

Order Type and Number:	Consent Order 23-421-FOOD
Order Date:	December 20, 2023
Individual/Entity:	Chipotle Mexican Grill #1820
Facility:	Chipotle Mexican Grill #1820
Location:	3556 Clemson Boulevard Anderson, SC 29621
Mailing Address:	P. O. Box 182566 Columbus, OH 43218
County:	Anderson
Previous Orders:	23-380-FOOD ($800.00)
Permit Number:	04-206-04005

Summary: The Department conducted inspections on October 9, 2023, October 14, 2023, and November 1, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to convey sewage to the point of disposal through an approved sanitary sewage system or other system, including use of sewage transport vehicles, waste retention tanks, pumps, pipes, hoses, and connections that are constructed, maintained, and operated according to law.

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

Previous Orders: The previous Consent Order (23-380-FOOD) was issued when the Individual/Entity violated the South Carolina Retail Food Establishment Regulation by failing to sanitize utensils and food contact surfaces of equipment before using, after cleaning (P).

27)

Order Type and Number:	Consent Order 23-347-FOOD
Order Date:	December 20, 2023
Individual/Entity:	Samantha's Mexican Restaurant
Facility:	Samantha's Mexican Restaurant
Location:	2518-B East North Street Greenville, SC 29615
Mailing Address:	Same
County:	Greenville
Previous Orders:	22-278-FOOD ($1,600.00)
Permit Number:	23-206-10624

Summary: The Department conducted inspections on November 29, 2021, October 19, 2022, and August 21, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to properly cool cooked time/temperature control for safety foods; failed to use effective methods to cool cooked time/temperature control for safety foods; failed to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling; and failed to ensure that refrigerated, ready-to-eat, time/temperature control for safety foods were discarded if the temperature and time combination exceeded seven (7) days or if the package was not properly date marked.

Action: The Individual/Entity is required to operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25. The Department has assessed a total civil penalty in the amount of one thousand two hundred fifty dollars ($1,250.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand two hundred fifty dollars ($1,250.00). The Individual/Entity has met all requirements of the Order. This Order has been closed.

Previous Orders: The previous Consent Order (22-278-FOOD) was issued when the Individual/Entity violated the South Carolina Retail Food Establishment Regulation by failing to properly cool cooked time/temperature control for safety foods (P); by failing to use effective methods to cool cooked time/temperature control for safety foods (PF); by failing to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling (P); and by failing to ensure that refrigerated, ready-to-eat, time/temperature control for safety foods were discarded if the temperature and time combination exceeded seven (7) days or if the package was not properly date marked (P).