

Date: March 7, 2024

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

From: Healthcare Quality

Re: Continuation of 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

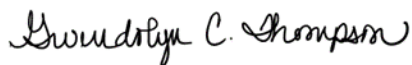
1. Pursuant to S.C. Code Sections 44-7-250 and -260(A)(1), the Department establishes and enforces minimum standards for the licensure, maintenance, and operation of hospitals to ensure the safe and appropriate treatment of persons served in this state. The Department proposes amending R.61-16, *Minimum 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.

8. At the Board's February 8, 2024 meeting, a public hearing for the proposed amendments was commenced and comments were received. The Board voted to keep open and extend the public hearing until the March 7, 2024 meeting, and to receive additional comments on the proposed amendments.

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.



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**

March 7, 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)

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***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 Infirmiry: 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 Infirmiry: 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 infirmiry 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.~~

402305. 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)(bc) 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	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 ~~4240.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 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 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 ~~du~~ly 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 their 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.~~

~~5. 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 Reports.

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.

~~AB. 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.

BC. 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 (100th) 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;~~

~~e. 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~~

~~e. 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 Outline of the maximum number of patients to be temporarily admitted;~~

e. 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 ~~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 e~~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.~~

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

~~GE. 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;
 - ~~16.~~ 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. Drugs taken during pregnancy, labor and delivery;
 8. Results of measurements of fetal maturity and well-being (e.g., lung maturity and ultrasonography);
 9. Duration of ruptured membranes and labor, including length of second stage;
 10. Method of delivery, including indications for operative or instrumental interference;
 11. 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.

B3. 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.

C4. 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.

D5. 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.

1202C. 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;~~

~~e. 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~~

~~e. 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. (H)

~~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 professional 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 Department's 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.~~

1208E. Central Supply. (I)

~~A₁. 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.

12091202. Surgery Optional Hospital Services. (II)

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.~~

1212B. 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.

1215H. Inpatient Dialysis Services. (H)

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

A1. 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.

B2. Renal Dialysis Service Equipment and Supplies

1a. Equipment and supplies shall include at least:

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

bii. Dialysis equipment appropriate for pediatric patients, if treated.

2b. 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

3c. 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. (H)

~~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. (H)

~~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. (H)

~~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. (H)

~~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.~~

1220I. Chemical and Substance Abuse Treatment Services. (H)

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.

A1. 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.

B2. 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.

A1. Organization: Pediatric services, if provided, shall be under the supervision of a registered nurse.

B2. 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.

C3. 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 ~~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 Bbeds must beare placed with at least three feet apartof clearance on three sides of the bed.~~

C. ~~The Facility shall ensure Aat least one private room shall beis 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 ~~Aeach~~ nurses' station ~~shall~~ serves not 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 Aat least one soiled utility room per main/central nurses' station shall beis 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 Aat least one clean utility room per main/central nurses' station shall beis provided, which contains a counter with hand washing 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 Designation	Temperature		Relative Humidity	
	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
<p>Comment:</p> <p>Cardiovascular Services</p> <p>HCA Healthcare's South Atlantic Division hospitals were surprised that the Department chose not to 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.</p> <p>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.</p> <p>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. <i>See</i> 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. <i>See</i> Section 1202.K.</p>	
Name	Section
SCHA	General
<p>Comment:</p>	

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
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Tidelands Health	General
<p data-bbox="186 237 326 264">Comment:</p> <p data-bbox="186 270 505 300"><i>Cardiac Catheterization</i></p> <p data-bbox="186 306 1406 489">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.</p> <p data-bbox="186 527 1406 632">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.</p> <p data-bbox="186 674 1406 814">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.</p> <p data-bbox="186 856 1406 1182">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.</p> <p data-bbox="186 1224 1406 1365">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.</p> <p data-bbox="186 1407 1406 1547">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.</p> <p data-bbox="186 1589 480 1619">Department Response:</p> <p data-bbox="186 1625 1406 1873">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. <i>See</i> 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</p>	

nationally accredited organization and, under certain circumstances, to have written transfer protocols. *See* Section 1202.K.

Regarding Tideland's 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 Tideland's 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
<p>Comment:</p> <p><u>NICU Designations</u></p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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</p>	

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 travel 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. In 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
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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, nonpartisan, 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 Tideland's 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 Tideland's 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. (H)

~~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 discarded, 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: March 7, 2024

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

From: Healthcare Quality

Re: Continuation of 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.

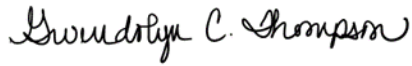
II. Facts

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.

8. At the Board's February 8, 2024 meeting, a public hearing for the proposed amendments was commenced and comments were received. The Board voted to keep open and extend the public hearing until the March 7, 2024 meeting, and to receive additional comments on the proposed amendments.

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***

March 7, 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.

BC. 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.

CD. 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).

DE. Advanced Practice Registered Nurse. An individual who has official recognition as such by the S.C. State Board of Nursing.

EF. 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).

FG. Anesthesiologist's Assistant. An individual currently licensed as such by the S.C. Board of Medical Examiners.

GH. Anesthesiologist. A physician who has completed a residency in anesthesiology.

HI. 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.

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.

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.

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.

P. Consultation. A visit by Department representatives who will provide information to the licensee in order to facilitate compliance with these regulations.

Q. Dentist. An individual currently licensed by the S.C. Board of Dentistry to practice dentistry.

R. Department. The S.C. Department of Health and Environmental Control (DHEC).

S. Direct Care Staff Member. An individual who provides care, treatment, surgery, and/or services, or performs procedures for a patient.

T. Endoscopy. Visual inspection of any cavity of the body by means of an endoscope.

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.

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.

SY. 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.

FBB. Inspection. A visit by Department representative(s) for the purpose of determining compliance with this regulation.

UCC. 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.

VDD. Initial License. A license granted to a new facility.

WEE. 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.

XFF. 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.

YGG. License. A certificate issued by the Department to an Ambulatory Surgical Facility to provide care, treatment, procedures, surgery, and/or services.

ZHH. Licensed Nurse. An individual currently licensed by the S.C. State Board of Nursing as a registered nurse or licensed practical nurse.

~~AAII~~. 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.

~~BBJJ~~. 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.

~~CCKK~~. 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.

~~DDLL~~. 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.

~~EEQQ~~. 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.

~~FFPP~~. Pharmacist. An individual currently registered as such by the S.C. Board of Pharmacy.

~~GGQQ~~. Physical Examination. An examination of a patient by a physician or physician assistant that addresses those issues identified in Section 802 of this regulation.

~~HHRR~~. Physician. An individual currently licensed as such by the S.C. Board of Medical Examiners.

~~HSS~~. Physician Assistant. An individual currently licensed as such by the S.C. Board of Medical Examiners.

~~HTT~~. Podiatrist. An individual currently licensed as such by the S.C. Board of Podiatry Examiners.

~~KKUU~~. 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.

~~LLVV~~. Procedure Room. A room where procedures not requiring general anesthesia can be safely performed.

~~MMWW~~. 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.

~~NNXX~~. Recovery Area. An area used for the recovery of patients.

~~OOYY~~. 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.

~~PPZZ~~. 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.

~~QQAAA~~. Revocation of License. An action by the Department to cancel or annul a license by recalling, withdrawing, or rescinding its authority to operate.

~~RRBBB~~. Same Day. A period of time not to exceed twenty-four (24) hours after admission.

~~SSCCC~~. Staff Member. An adult who is a compensated employee of the facility on either a full or part-time basis.

~~TTDDD~~. 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.

~~UUEEE~~. Surgical Suite. An area that includes one or more operating rooms and a recovery area.

~~VVFFF~~. 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.

~~WWGGG~~. 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.

<u>Initial/Relocation Inspection Fee</u>	<u>Calculated - \$350 + \$45 per operating, endoscopy, and procedure room</u>
<u>Initial/Relocation Follow-Up Fee</u>	<u>Calculated - \$200 + \$45 per operating, endoscopy, and procedure room</u>
<u>Routine Inspection Fee</u>	<u>Calculated - \$350 + \$45 per operating, endoscopy, and procedure room</u>
<u>Routine Follow-Up Fee</u>	<u>Calculated - \$350 + \$45 per operating, endoscopy, and procedure room</u>
<u>Unit Increase or Service Modification Fee</u>	<u>Calculated - \$200 + \$45 per operating, endoscopy, and procedure room</u>
<u>Unit Increase of Service Modification Follow-Up Fee</u>	<u>Calculated - \$200 + \$45 per operating, endoscopy, and procedure room</u>

G. Construction Fees. The Facility shall pay the following inspection fees during the construction phase of the project.

<u>Construction Inspection Fees</u>	
<u>Plan Inspection</u>	
<u>Total Project Cost</u>	<u>Fee</u>
<u>< \$10,001</u>	<u>\$750</u>
<u>\$10,001 - \$100,000</u>	<u>\$1,500</u>
<u>\$100,001 - \$500,000</u>	<u>\$2,000</u>
<u>> \$500,000</u>	<u>\$2,500 plus \$100 for each additional \$100,000 in project costs</u>
<u>Site Inspection</u>	<u>\$500</u>

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 Ppolicies 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.

505506. 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.

506507. 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.

507508. 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.

508509. 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 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.

BC. 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.

808809. 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.*, glutaraldehyde, 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.

SECTION 1700

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
<p>Comment:</p> <p>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.</p> <p>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. <i>See</i> Section 601.B.</p>	
Name	Section
Tidelands Health	General
<p>Comment:</p> <p>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.</p> <p>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.</p>	
Name	Section
SCHA	General
<p>Comment:</p> <p><u>Cardiovascular Services</u></p> <p>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.</p>	

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 Tideland’s 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 Tideland’s 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 Tideland's 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 Tideland's 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 Tideland's 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 Tideland's 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
<p>Comment:</p> <p>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.</p> <p>Here is the CMS discussion from the Final rule dated 9/30/2019:</p> <p>[Final Rule Language Omitted]</p> <p>We recommend that the transfer language be removed:</p> <p>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.</p> <p>Department Response: Partially adopt. Department staff have proposed providing an exception where facilities have attempted to obtain a transfer agreement, but are unsuccessful. <i>See</i> 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. <i>See</i> 42 C.F.R. § 416.41.</p>	
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
SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

March 7, 2024

- () ACTION/DECISION
(X) INFORMATION

- I. TITLE:** Healthcare Quality Administrative and Consent Orders.
- II. SUBJECT:** Healthcare Quality Administrative Orders and Consent Orders for the period of January 1, 2024, through January 31, 2024.
- III. FACTS:** For the period of January 1, 2024, through January 31, 2024, Healthcare Quality reports five Consent Orders totaling \$56,200 in assessed monetary penalties.

Bureau	Facility, Service, Provider, or Equipment Type	Administrative Orders	Consent Orders	Assessed Penalties	Required Payment
Community Care	Community Residential Care Facilities	0	4	\$55,900	\$55,900
Healthcare Systems and Services	Hospice Programs	0	1	\$300	\$300
TOTAL			5	\$56,200	\$56,200

Submitted By:

Gwendolyn C. Thompson

Gwen C. Thompson
Deputy Director
Healthcare Quality

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

March 7, 2024

Bureau of Community Care

Facility Type	Total Number of Licensed Facilities	Total Number of Licensed Beds
Community Residential Care Facilities (CRCFs)	460	22,222

1. Pacifica Skylyn LLC d/b/a Pacifica Senior Living Skylyn – Spartanburg County – 169 licensed beds

Investigation and Violations: From April 11, 2023, to September 11, 2023, the Department visited Pacifica Senior Living Skylyn (the Facility) multiple times to conduct various types of inspections and investigations that it does of all licensed CRCFs. As a result of those visits, Department staff observed and cited the following violations of Regulation 61-84:

- The Facility failed to implement its policies and procedures regarding resident care, rights, and operation of the Facility.
- The Facility failed to submit written reports of its investigations to the Department within five days of the incidents and/or accidents.
- The Facility failed to coordinate a resident’s medical care as ordered by a physician.
- The Facility failed to render care in accordance with a physician’s orders for administering medications.
- The Facility failed to maintain fire protection and suppression systems in accordance with the codes adopted by the SC Building Code Council and the SC Fire Marshall.
- The Facility failed to ensure all equipment and building components were in good repair and operating condition, and in compliance with the International Fire Code.
- The Facility failed to ensure it was clean and free from vermin and offensive odors.
- The Facility failed to ensure each specific interior area of the Facility was clean.
- The Facility failed to submit to the Department for review and approval plans for additions and/or alterations for the renovations being conducted on the second and third floors.
- The Facility failed to maintain halls, corridors, and other means of egress from the building free of obstructions.
- The Facility failed to maintain documentation of the annual HVAC system inspection.
- The Facility failed to maintain a temperature between 72 and 78 degrees in resident areas.

Enforcement: The Department notified the Facility that an enforcement action was being considered. The Department and the Facility met and agreed to resolve this matter through a Consent Order, which was executed on January 4, 2024. The Facility agreed to the assessment of a \$40,900 monetary penalty. The Facility has paid the penalty.

Remedial Action: The Facility also agreed to schedule and attend a compliance assistance meeting. The Facility had its compliance assistance meeting.

Prior Orders: In March 2022, the Facility executed a consent order for various regulatory violations. Pursuant to that consent order, the Facility agreed to a \$14,000 monetary penalty, with \$10,000 being paid and \$4,000 being held in abeyance.

2. Cunningham-Waters Construction Company Inc. d/b/a Patriot Living of Florence – Florence County – 80 licensed beds

Investigation and Violations: From May 2, 2023, to September 11, 2023, the Department visited Patriot Living of Florence (the Facility) multiple times to conduct various types of inspections and investigations that it does of all licensed CRCFs. As a result of those visits, Department staff observed and cited the following violations of Regulation 61-84:

- The Facility failed to review and/or revise residents' individual care plans at least semi-annually.
- The Facility failed to have a resident's physician-ordered medication available for administration.
- The Facility failed to record the administration of medications by initialing the medication administration records as medications were administered.
- The Facility failed to maintain records of controlled substances in sufficient detail to enable an accurate reconciliation.
- The Facility failed to ensure all equipment and building components were in good repair and operating condition, and in compliance with the International Fire Code.
- The Facility failed to ensure it was clean and free from vermin and offensive odors.
- The Facility failed to ensure each specific interior area was clean.
- The Facility failed to ensure window treatments in the bathroom and resident rooms were arranged in a manner to provide privacy.

Enforcement: The Department notified the Facility that an enforcement action was being considered. The Department and the Facility met and agreed to resolve this matter through a Consent Order, which was executed on January 24, 2024. The Facility agreed to the assessment of a \$5,000 monetary penalty, which will be paid through two installments of \$2,500.

Remedial Action: The Facility also agreed to schedule and attend a compliance assistance meeting. The Facility has scheduled its compliance assistance meeting. Further, the Facility agreed to complete the necessary repairs and understands to notify and coordinate with the Department's Division of Health Facilities Construction, as required by applicable laws.

Prior Orders: None in the past five years.

3. Cunningham-Waters Construction Company Inc. d/b/a Patriot Living of Hartsville – Darlington County – 60 licensed beds

Investigation and Violations: From May 11, 2023, to September 13, 2023, the Department visited Patriot Living of Hartsville (the Facility) multiple times to conduct various types of inspections and investigations that it does of all licensed CRCFs. As a result of those visits, Department staff observed and cited the following violations of Regulation 61-84:

- The Facility failed to record the administration of medications by initialing the medication administration records as medications were administered.
- The Facility failed to maintain its kitchen and food preparation in compliance with *Retail Food Establishment*, Regulation 61-25.

- The Facility failed to ensure all equipment and building components were in good repair and operating condition, and in compliance with the International Fire Code.
- The Facility failed to ensure it was clean and free from vermin and offensive odors.
- The Facility failed to ensure each specific interior area was clean.
- The Facility failed to ensure plumbing fixtures accessible to residents were supplied with water that is controlled to a temperature of at least 100 degrees F and not to exceed 120 degrees F.

Enforcement: The Department notified the Facility that an enforcement action was being considered. The Department and the Facility met and agreed to resolve this matter through a Consent Order, which was executed on January 24, 2024. The Facility agreed to the assessment of a \$5,000 monetary penalty, which will be paid through two installments of \$2,500.

Remedial Action: The Facility also agreed to schedule and attend a compliance assistance meeting. The Facility has scheduled its compliance assistance meeting. Further, the Facility agreed to complete the necessary repairs and understands to notify and coordinate with the Department's Division of Health Facilities Construction, as required by applicable laws.

Prior Orders: None in the past five years.

4. Cunningham-Waters Construction Company Inc. d/b/a Patriot Living of Sumter – Sumter County – 60 licensed beds

Investigation and Violations: From May 4, 2023, to September 12, 2023, the Department visited Patriot Living of Sumter (the Facility) multiple times to conduct various types of inspections and investigations that it does of all licensed CRCFs. As a result of those visits, Department staff observed and cited the following violations of Regulation 61-84:

- The Facility failed to employ a licensed CRCF administrator.
- The Facility failed to notify the Department via telephone or email within 72 hours of the departure of its administrator.
- The Facility failed to render care to residents in accordance with orders of the physicians or authorized healthcare providers.
- The Facility failed to have residents' physician-ordered medications available for administration.
- The Facility failed to record the administration of medications by initialing the medication administration records as medications were administered.
- The Facility failed to maintain records of a controlled substance in sufficient detail to enable an accurate reconciliation.
- The Facility failed to ensure that the current weeks' menus included any substitutions or changes made.
- The Facility failed to ensure all equipment and building components were in good repair and operating condition, and in compliance with the International Fire Code.
- The Facility failed to ensure it was clean and free from vermin and offensive odors.
- The Facility failed to ensure plumbing fixtures accessible to residents were supplied with water that is controlled to a temperature of at least 100 degrees F and not to exceed 120 degrees F.
- The Facility failed to maintain documentation of annual HVAC system inspections conducted by certified and/or licensed technicians.
- The Facility failed to maintain a temperature between 72 and 78 degrees in resident areas.

Enforcement: The Department notified the Facility that an enforcement action was being considered. The Department and the Facility met and agreed to resolve this matter through a Consent Order, which was

executed on January 24, 2024. The Facility agreed to the assessment of a \$5,000 monetary penalty, which will be paid through two installments of \$2,500.

Remedial Action: The Facility also agreed to schedule and attend a compliance assistance meeting. The Facility has scheduled its compliance assistance meeting. Further, the Facility agreed to complete the necessary repairs and understands to notify and coordinate with the Department's Division of Health Facilities Construction, as required by applicable laws.

Prior Orders: None in the past five years.

Bureau of Healthcare Systems and Services

Provider Type	Total Number of Licensed Hearing Aid Specialists
Hospice Programs	100

1. Wren Hospice, LLC d/b/a Wren Hospice – Greenville County

Investigation and Violations: The Program failed to submit a timely renewal application and licensing fees by the license expiration date.

Enforcement: The Department and the Program decided to resolve the matter through a Consent Order. The Program paid the \$300 monetary penalty.

Remedial Action: none

Prior Orders: None in the past 5 years.

SUMMARY SHEET
BOARD OF HEALTH AND ENVIRONMENTAL CONTROL
March 7, 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 January 1, 2024, through January 31, 2024.
3. **FACTS:** For the reporting period of January 1, 2024, through January 31, 2024, the Office of Environmental Affairs issued sixty-five (65) Consent Orders with total assessed civil penalties in the amount of two hundred thirty-two thousand, one hundred forty dollars (\$232,140.00). Also, five (5) Administrative Orders with total assessed civil penalties in the amount of forty-one thousand, eight hundred forty-three dollars (\$41,843.00) were reported during this period.

Bureau and Program Area	Administrative Orders	Assessed Penalties	Consent Orders	Assessed Penalties
Land and Waste Management				
UST Program	3	\$37,803.00	2	\$8,500.00
Solid Waste	0	0	0	0
Hazardous Waste	0	0	3	\$37,500.00
Mining	0	0	0	0
Radiological Health	0	0	0	0
SUBTOTAL	3	\$37,803.00	5	\$46,000.00
Water				
Recreational Water	2	\$4,040.00	33	\$35,240.00
Drinking Water	0	0	7	\$3,400.00
Water Pollution	0	0	8	\$57,000.00
SUBTOTAL	2	\$4,040.00	48	\$95,640.00
Air Quality				
SUBTOTAL	0	0	3	\$78,500.00
Environmental Health Services				
Onsite Wastewater	0	0	7	\$4,000.00
SUBTOTAL	0	0	7	\$4,000.00
OCRM				
SUBTOTAL	0	0	2	\$8,000.00
TOTAL	5	\$41,843.00	65	\$232,140.00

Submitted by:

Myra C. Reece
Myra C. Reece
Director of Environmental Affairs

**ENVIRONMENTAL AFFAIRS ENFORCEMENT REPORT
BOARD OF HEALTH AND ENVIRONMENTAL CONTROL
March 7, 2024**

BUREAU OF LAND AND WASTE MANAGEMENT

Underground Storage Tank Enforcement

- 1) Order Type and Number: Administrative Order 23-0047-UST
 Order Date: January 3, 2024
 Individual/Entity: **Jerry W. Page**
 Facility: Pages Service Center
 Location: Highway 9
 Lake View, SC 29563
 Mailing Address: P.O. Box 661
 Lake View, SC 29563
 County: Dillon
 Previous Orders: None
 Permit/ID Number: 17227
 Violations Cited: The State Underground Petroleum
 Environmental Response Bank Act of 1988 (SUPERB Act), S.C. code Ann. § 44-
 2-10 et seq. (2018); and South Carolina Underground Storage Tank Control
 Regulation, 7 S.C. Code Ann., Regs. 61-92, 280.65 (2012 & Supp. 2022).

Summary: Jerry W. Page (Individual/Entity) owned underground storage tanks (USTs) in Dillon County, South Carolina. Based on a routine file review conducted on September 27, 2023, the Department issued a Notice of Alleged Violation. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to determine the full extent of a release in accordance with a schedule established by the Department.

Action: The Individual/Entity is required to: submit either a Quality Assurance Project Plan Contractor Addendum or a Site-Specific Work Plan (SSWP) for groundwater sampling by February 19, 2024; and within sixty (60) days of the Department's approval of the SSWP, a completed Initial Groundwater Assessment. The Department has assessed a total civil penalty in the amount of six thousand, eight hundred three dollars (\$6,803.00). The Individual/Entity shall pay a civil penalty in the amount of six thousand, eight hundred three dollars (**\$6,803.00**) by February 19, 2024.

Update: None

- 2) Order Type and Number: Administrative Order 23-0125-UST
 Order Date: January 10, 2024
 Individual/Entity: **Sai Ram SC, LLC**
 Facility: EZ Trip 3
 Location: 4623 Savannah Highway

Mailing Address: North, SC 29112
114 McSwain Drive
West Columbia, SC 29169

County: Orangeburg

Previous Orders: None

Permit/ID Number: 10631

Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. code Ann. § 44-2-10 et seq.; and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs 61-92, 280.93(a) (2012 & Supp 2022).

Summary: Sai Ram SC, LLC (Individual/Entity) owned underground storage tanks (USTs) in Orangeburg County, South Carolina. On June 7, 2022, a release was confirmed. On May 2, 2023, the Department conducted a file review of the Facility and issued a Notice of Alleged Violation. The Individual/Entity violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to demonstrate financial responsibility for an UST system.

Action: The Individual/Entity shall: submit a completed Certificate of Financial Responsibility form and evidence of financial assurance as directed by the Department by March 15, 2024. The Department has assessed a total penalty in the amount of twenty-eight thousand dollars (\$28,000.00). The Individual/Entity shall pay a civil penalty in the amount of twenty-eight thousand dollars (**\$28,000.00**) by March 15, 2024.

Update: None.

3) Order Type and Number: Administrative Order 23-02-UST

Order Date: January 17, 2024

Individual/Entity: Terrel Sanders

Facility: Sanders Automotive & Paint

Location: 700 West Libert Street
Marion, South Carolina 29571

Mailing Address: Same

County: Marion

Previous Orders: None

Permit/ID Number: 16717

Violations Cited: The South Carolina Pollution Control Act (PCA), S.C. code Ann. § 48-1-50(6), (20), and (21).

Summary: Terrel Sanders (Individual/Entity) owns a former bulk gas plant in Marion County, South Carolina. On February 11, 2022, the Department conducted a file review of the site and sent a letter requesting the submission of a Site-Specific Work Plan (SSWP) for a Tier II Assessment to be conducted at the Site. The Individual/Entity violated the PCA, as follows: failed to conduct studies, investigations, and research with respect to pollution abatement, control or prevention; failed to conduct investigations of conditions in the air or waters of the State to determine whether or not standards are being contravened and the origin of materials which are causing the pollution condition; and failed to establish the cause, extent and origin of damages from waste including damages to the fish, waterfowl, and other aquatic animals and public property which result from the discharge of waste to the waters of the State.

Action: The Individual/Entity is required to submit a SSWP for a Tier II Assessment report by March 25, 2024. The Department has assessed a total civil penalty in the amount of three thousand dollars (\$3,000.00). The Individual/Entity shall pay a civil penalty in the amount of three thousand dollars (**\$3,000.00**) by March 25, 2024.

Update: None

- 4) Order Type and Number: Consent Order 23-0119-UST
Order Date: January 2, 2024
Individual/Entity: **Mike Morrow**
Facility: Hilda Grocery and Meat
Location: 31 Broughton Avenue
Hilda, SC 29813
Mailing Address: 658 Morrow Drive
Blackville, SC 29817
County: Barnwell
Previous Orders: None
Permit/ID Number: 00868
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. code Ann. § 44-2-10 et seq. and § 44-2-60(A)(2018); and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs 61-92, 280.34(c), 280.36(a)(1)(i)&(ii), and 280.242(b)(3)&(4) (2012 & Supp 2022).

Summary: Mike Morrow (Individual/Entity) owns an underground storage tank (UST) in Barnwell County, South Carolina. The Department conducted a routine compliance inspection and issued a Notice of Alleged Violation on March 30, 2023. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to provide records to the Department upon request; failed to conduct monthly and annual walkthrough inspections; and failed to validate that monthly requirements had been performed and physically visit each assigned facility at least once a quarter.

Action: The Individual/Entity is required to: submit proof a Class A/B Operator/Walkthrough Inspection Log has been initiated and is being properly maintained by February 16, 2024. The Department has assessed a total civil penalty in the amount of one thousand, three hundred dollars (\$1,300.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand, three hundred dollars (**\$1,300.00**) by February 16, 2024.

Update: None

- 5) Order Type and Number: Consent Order 23-0297-UST
Order Date: January 19, 2024
Individual/Entity: **AM-PM Convenience Stores, Inc.**
Facility: Gaspro – Trenton
Location: 1 Pinehouse Road
Trenton, SC 29847
Mailing Address: 110-A Harlem Grovetown Road
Grovetown, GA 30813

County: Edgefield
Previous Orders: None
Permit/ID Number: 10804
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. code Ann. § 44-2-10 et seq. (2018); and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs 61-92, 280.10(d) (2012 & Supp 2020).

Summary: AM-PM Convenience Stores, Inc. (Individual/Entity) owns underground storage tanks (USTs) in Edgefield County, South Carolina. The Department conducted a routine compliance inspection on October 10, 2023, and issued a Notice of Alleged Violation. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: introduced product into an unregistered or unpermitted UST.

Action: The Individual/Entity corrected all violations prior to issuance of the Order. The Department has assessed a total penalty in the amount of seven thousand, two hundred dollars (\$7,200.00). The Individual/Entity shall pay a civil penalty in the amount of seven thousand, two hundred dollars (**\$7,200.00**) by March 4, 2024.

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

Hazardous Waste Enforcement

6) Order Type and Number: Consent Order 24-01-HW
Order Date: January 19, 2023
Individual/Entity: **Safety Kleen Systems, Inc.**
Facility: Safety Kleen Systems, Inc.
Location: 2818 Old Woodruff Road
Greer, SC 29304
Mailing Address: Same
County: Spartanburg
Previous Orders: None
Permit/ID Number: SCD 981 031 040
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: Safety Kleen Systems, Inc. (Individual/Entity) operates a commercial hazardous waste management facility offering solvent collection and reclamation services to customers who are primarily engaged in automotive repair, industrial maintenance, and dry-cleaning activities at their facility in Spartanburg County, South Carolina. The Department conducted an inspection at the facility on June 22, 2023. The Individual/Entity has violated the South Carolina Hazardous Waste Management Act and the Hazardous Waste Management Regulations, as follows: failed to design, construct, maintain, and operate the facility in a manner to minimize the possibility of a fire, explosion, or any unplanned sudden or non-sudden release of hazardous waste constituents to air, soil, or surface water which could threaten human health or the

environment; failed to keep all containers holding hazardous waste closed during storage, except when it is necessary to add or remove waste; failed to mark or label containers with: the words “Hazardous Waste,” an indication of the hazards of the contents, and the date upon which each period of accumulation begins clearly visible for inspection on each container; failed to design, install, or operate the secondary containment system in accordance to the detailed design plans and descriptions contained in the approved Permit which states secondary containment for all tanks will be maintained free of cracks and gaps to prevent migration of releases to soil, ground, or groundwater; failed to follow the general inspection requirements and failed to remedy any deterioration or malfunction discovered by an inspection; failed to comply with the manifest requirements; failed to comply with the quarterly reporting requirements; failed to conduct and maintain training documents and records at the facility; failed to include in the contingency plan: a street map of the facility in relation to surrounding businesses, schools, and residential areas to understand how best to get to the facility and also evacuate citizens and workers, and the identification of on-site notification systems; failed to ensure the containment system has sufficient capacity to contain 10% of the volume of the containers or the volume of the largest container, whichever is greater; and failed to ensure that the capacity, which includes all wastes stored in that building did not exceed 6,912 gallons for container storage in the West Warehouse.

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 eighteen thousand, five hundred dollars (\$18,500.00). The Individual/Entity shall pay a civil penalty in the amount of eighteen thousand, five hundred dollars (**\$18,500.00**) by February 18, 2023.

Update: The Individual/Entity has paid the civil penalty and the Order is closed.

7) Order Type and Number: Consent Order 23-36-HW
Order Date: January 25, 2024
Individual/Entity: **Volvo Car USA LLC**
Facility: Volvo Car USA LLC
Location: 1801 Volvo Car Drive
Ridgeville, SC 29472
Mailing Address: Same
County: Berkeley
Previous Orders: None
Permit/ID Number: SCR 000 784 249
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: Volvo Car USA LLC (Individual/Entity) is a car manufacturer located in Berkeley County, South Carolina. The Department conducted an inspection at the facility on June 12, 2023, and issued a Notice of Alleged Violation on August 10, 2023. The Individual/Entity has violated the South Carolina Hazardous Waste Management Act and the Hazardous Waste Management Regulations as follows: failed to ensure central accumulation and satellite accumulation containers were marked or labeled with an indication of the hazards of the contents; failed to make an accurate waste determination; failed to demonstrate the length of time that a universal waste has been accumulated from

the date it becomes a waste or is received; failed to ensure universal waste is accumulated for no greater than one (1) year; failed to at least weekly inspect central accumulation areas; failed to comply with the standards of subpart M of this part, Preparedness, Prevention and Emergency Procedures for Large Quantity Generators; failed to review, and immediately amend, if necessary, whenever the list of emergency coordinators changes; failed to list names and emergency telephone numbers of all persons qualified to act as emergency coordinator, and keep the list up to date; failed to include an evacuation plan for generator personnel where there is a possibility that evacuation could be necessary; and failed to submit a copy of the contingency plan and all revisions to all local emergency responders.

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 ten thousand dollars (\$10,000.00). The Individual/Entity is required to pay a civil penalty in the amount of ten thousand dollars (**\$10,000.00**) by February 26, 2024.

Update: None

8) Order Type and Number: Consent Order 24-03-HW
Order Date: January 25, 2024
Individual/Entity: **Medline Industries, LP**
Facility: Medline Industries, LP
Location: 308 Church Street
Honea Path, SC 29654
Mailing Address: Same
County: Anderson
Previous Orders: None
Permit/ID Number: SCD 039 135 801
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: Medline Industries, LP (Individual/Entity) manufactures liquid polyisoprene for use in medical gloves and a variety of healthcare products at their facility located in Anderson County, South Carolina. The Department conducted an inspection at the facility on July 26, 2023, and issued a Notice of Alleged Violation on October 23, 2023. The Individual/Entity has violated the South Carolina Hazardous Waste Management Act and the Hazardous Waste Management Regulations as follows: failed to mark or label its containers with the words “Hazardous Waste” and an indication of the hazards of the contents; 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 keep a copy of each manifest signed, onsite for three (3) years or until a signed copy from the designated facility which received the waste is received; failed to submit an Exception Report to the Department when they had not received a copy of the manifest with the handwritten signature of the owner or operator of the designated facility within forty-five (45) days of the date the waste was accepted by the initial transporter; failed to retain onsite a copy of all notices, certifications, waste analysis data, and other documentation produced pursuant to this section for at least three (3) years from the date that the waste that is the subject of such documentation was last sent to onsite or offsite treatment, storage, or disposal; failed to, at least weekly, inspect the central accumulation

areas and look for leaking containers and for deterioration of containers caused by corrosion or other factors; failed to describe in the Contingency Plan, the arrangements agreed to with the local police departments, fire departments, other emergency response teams, emergency response contractors, equipment suppliers, and local hospitals; failed to submit a copy of the contingency plan and all revisions and a quick reference guide of the contingency plan to all local emergency responders or the Local Emergency Planning Committee; and failed to maintain a written job description for each position at the facility.

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 nine thousand dollars (\$9,000.00). The Individual/Entity shall pay a civil penalty in the amount of nine thousand dollars (**\$9,000.00**) by February 24, 2024.

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

BUREAU OF WATER

Recreational Waters Enforcement

- 9) Order Type and Number: Administrative Order 23-141-RW
 Order Date: November 2, 2023
 Individual/Entity: **Mariners Watch Homeowners
Association, d.b.a. Mariners Watch**
 Facility: Mariners Watch
 Location: 1514 North Waccamaw Drive
 Murrells Inlet, SC 29576
 Mailing Address: 633 Red Fox Road
 Camden, SC 29020
 County: Horry
 Previous Orders: None
 Permit/ID Number: 26-H68-1
 Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Mariners Watch Homeowners Association, d.b.a. Mariners Watch (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool. On April 27, 2023, June 26, 2023, and August 2, 2023, the pool was inspected, and a violation was issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a skimmer was missing a weir; a gate did not self-close and latch; the pool rules sign was not legible and was not completely filled out; the pool operator of record information was not posted to the public; 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 two thousand forty dollars (\$2,040.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand forty dollars (**\$2,040.00**).

Update: The civil penalty has been paid and the Administrative Order is closed.

- 10) Order Type and Number: Administrative Order 23-122-RW
Order Date: January 7, 2024
Individual/Entity: **Bluffton Investment, LLC**
Facility: Comfort Suites
Location: 23 Towne Drive
Bluffton, SC 29910
Mailing Address: Same
County: Beaufort
Previous Orders: 21-217-RW (\$680.00)
Permit/ID Number: 07-1064B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Bluffton Investment, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Beaufort County, South Carolina. On June 5, 2023, and July 20, 2023, the pool was inspected, and a violation was 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 and was not tight and secure; the waterline tiles were dirty; the pool furniture was not at least four feet from the edge of the pool; the deck was uneven with sharp edges; the foot rinse shower was not operating properly; a drinking water fountain was not within fifty feet of the pool; there were non-pool related items stored in the equipment room; 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; the shepherd's crook was attached to a telescoping pole and was not clear of obstructions; the "No Lifeguard On Duty-Swim At Your Own Risk" signs were obstructed; and the bound and numbered log book was not maintained on a daily basis.

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

Update: The Administrative Order is being settled through the issuance of a Consent Order.

- 11) Order Type and Number: Consent Order 24-001-RW
Order Date: January 2, 2024
Individual/Entity: **Burriss Properties, LLC**
Facility: MUV Fitness
Location: 619 North Lake Drive
Lexington, SC 29072
Mailing Address: Same
County: Lexington
Previous Orders: None
Permit/ID Number: 32-1072B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Burriss Properties, 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 April 5, 2023, and September 26, 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 obstructed by rug on the pool deck; the pool walls had holes in the plaster; the pool floor was dirty and delaminated; the waterline tiles were dirty; there was standing water on the pool deck; the pool furniture was not at least four feet from the edge of the pool; there was debris in the skimmer baskets; skimmer baskets were floating; a skimmer was missing a weir; the step edge tile stripe was not within one inch of the step edge; returns were missing covers; a light in the pool wall was out of its niche; a gate did not self-close and latch; the shepherd's crook was not mounted in its designated location and was not easily accessible; the pool rules sign was not completely filled out; and the flow meter was not operating.

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

Update: The civil penalty has been paid and the Consent Order is closed.

12) <u>Order Type and Number:</u>	Consent Order 24-002-RW
<u>Order Date:</u>	January 2, 2024
<u>Individual/Entity:</u>	Cardinal Crossing Apartments, LLC
<u>Facility:</u>	Cardinal Apartments
<u>Location:</u>	4615 Forest Drive Columbia, SC 29206
<u>Mailing Address:</u>	320 Broad Street, Suite 600 Charleston, SC 29401
<u>County:</u>	Richland
<u>Previous Orders:</u>	22-121-RW (\$680.00)
<u>Permit/ID Number:</u>	40-1185B
<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-51(J)

Summary: Cardinal Crossing Apartments, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Richland County, South Carolina. The Department conducted inspections on June 26, 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: frost proof tiles were missing on the pool wall; the deck was uneven with sharp edges; the water level was too low; the foot rinse shower was not operating properly; 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; the facility address was not on record with 911 dispatch; the bound and numbered log book was not maintained a minimum of three times per week by the pool operator of record; and readings were not recorded daily and the cyanuric acid level was not recorded weekly 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 one thousand three hundred sixty dollars (\$1,360.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand three hundred sixty dollars (**\$1,360.00**).

Update: The civil penalty has been paid and the Consent Order is closed.

- 13) Order Type and Number: Consent Order 24-003-RW
Order Date: January 5, 2024
Individual/Entity: **Pralax, LLC**
Facility: Quality Inn & Suites
Location: 328 West Main Street
Lexington, SC 29072
Mailing Address: Same
County: Lexington
Previous Orders: None
Permit/ID Number: 32-130-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Pralax, 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 17, 2023, and August 25, 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; the universal “no diving” tiles were not non-slip finished; the water level was too low; the main drain valve was partially closed; there was no six-inch air gap in the backwash pit; the pool equipment room was not locked; the flow meter was not operating properly; the chlorine level was not within the acceptable range of water quality standards; the facility address was not posted at the emergency notification device; the pool was not approved for night swimming; 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 24-004-RW
Order Date: January 5, 2024
Individual/Entity: **Kismet Rock Hill, LLC**
Facility: Holiday Inn – Rock Hill
Location: 503 Galleria Boulevard
Rock Hill, SC 29730
Mailing Address: Same
County: York
Previous Orders: 22-010-RW (\$2,040.00)
Permit/ID Number: 46-1105B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Kismet Rock Hill, 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 March 31, 2023, 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 water level was too low; the flow meter was not operating properly; the chlorine level was not within the acceptable range of water quality standards; the log book was not properly bound or numbered on the first inspection; the bound and numbered log book was not maintained on a daily basis on the second inspection; 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 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.

15) <u>Order Type and Number:</u>	Consent Order 24-005-RW
<u>Order Date:</u>	January 5, 2024
<u>Individual/Entity:</u>	Homes of Polo Homeowners Association, Inc.
<u>Facility:</u>	Homes of Polo
<u>Location:</u>	101 Hounds Court South Columbia, SC 29223
<u>Mailing Address:</u>	Same
<u>County:</u>	Richland
<u>Previous Orders:</u>	None
<u>Permit/ID Number:</u>	40-210-1
<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-51(J)

Summary: Homes of Polo 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 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: the pool walls were dirty; a skimmer was missing a weir; the bathrooms were not accessible; a gate did not self-close and latch; waterline tiles were dirty; an equalizer line cover was missing; the backwash discharge was not approved; a light in the pool wall was out of its niche; 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.

16) <u>Order Type and Number:</u>	Consent Order 24-006-RW
<u>Order Date:</u>	January 5, 2024
<u>Individual/Entity:</u>	HAMR Borrower 3, LLC
<u>Facility:</u>	Austin Woods Apartments

Location: 7648 Garners Ferry Road
Columbia, SC 29209
Mailing Address: 88 University Place, 11th Floor
New York, NY 10003
County: Richland
Previous Orders: None
Permit/ID Number: 40-083-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: HAMR Borrower 3, 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 6, 2023, and September 15, 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 universal “No Diving” tiles on the pool deck were missing; the deck depth marker tiles at the waterline were missing; the deck depth marker tiles were not non-slip finished; a ladder was missing bumpers; the waterline tiles and the pool floor were dirty; there was standing water on the deck; the water level was too high on the first inspection and was too low on the third inspection; skimmers were missing weirs; there was debris in the skimmer baskets; the bathrooms were dirty and did not have toilet paper, soap, or paper towels/hand dryers; only one bathroom was available to the public; the drinking water fountain and foot rinse shower were not operating properly; non-pool related items were stored in the equipment room; the chlorine and pH levels were not within the acceptable range of water quality standards; the bound and numbered log book was not maintained on a daily basis; the disinfection equipment was not connected properly on the first inspection; and there was a leak in the disinfection equipment tubing 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.

17) Order Type and Number: Consent Order 24-007-RW
Order Date: January 5, 2024
Individual/Entity: **Laxmimaya, Inc.**
Facility: Comfort Inn Greenville-Haywood Mall
Location: 246 Congaree Road
Greenville, SC 29607
Mailing Address: Same
County: Greenville
Previous Orders: None
Permit/ID Number: 23-289-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Laxmimaya, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Greenville County, South Carolina. The Department conducted inspections on July 6, 2023, and September 26, 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 deck marker tiles were broken; the pH level was not within the acceptable range of water quality standards; the shepherd's crook was missing a bolt, and the handle was not the approved length; the pool rules sign was not completely filled out; 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.

18) <u>Order Type and Number:</u>	Consent Order 24-008-RW
<u>Order Date:</u>	January 5, 2024
<u>Individual/Entity:</u>	Triangle Palisades of Blythewood I, LLC
<u>Facility:</u>	Palisades of Blythewood Phase I
<u>Location:</u>	2051 Blythewood Crossing Lane Blythewood, SC 29016
<u>Mailing Address:</u>	Same
<u>County:</u>	Richland
<u>Previous Orders:</u>	None
<u>Permit/ID Number:</u>	40-1088B
<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-51(J)

Summary: Triangle Palisades of Blythewood I, 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 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 floor was dirty; a skimmer was missing a weir; the flow meter was missing; a gate did not self-close and latch; the life ring was deteriorated; the pool rules sign was not clearly displayed and 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 maintained on a daily basis; the cyanuric acid level was not checked weekly; there was debris in the skimmer baskets; and the bathrooms did not have paper towels or a hand dryer.

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) <u>Order Type and Number:</u>	Consent Order 24-009-RW
<u>Order Date:</u>	January 5, 2024
<u>Individual/Entity:</u>	Triangle Palisades of Blythewood II, LLC
<u>Facility:</u>	Palisades of Blythewood Phase II

Location: 2051 Blythewood Crossing Lane
Blythewood, SC 29016
Mailing Address: Same
County: Richland
Previous Orders: None
Permit/ID Number: 40-1136B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Triangle Palisades of Blythewood II, 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 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; a skimmer was missing a weir; skimmer baskets were floating; the flow meter was not operating; a gate did not self-close and latch; the chlorine level was not within the acceptable range of water quality standards; 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 checked weekly; the emergency notification device was not operational; the pool rules sign was not completely filled out; and the current pool operator of record information was not posted to the public.

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

Update: The civil penalty has been paid and the Consent Order is closed.

20) Order Type and Number: Consent Order 24-010-RW
Order Date: January 8, 2024
Individual/Entity: **Lexington Hotel Associates, LLC**
Facility: Wingate Inn
Location: 108 Saluda Point Court
Lexington, SC 29072
Mailing Address: 1 Surrey Court
Columbia, SC 29212
County: Lexington
Previous Orders: None
Permit/ID Number: 32-1068B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Lexington Hotel Associates, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a public swimming pool located in Lexington County, South Carolina. The Department conducted inspections on July 19, 2023, and September 15, 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 walls were dirty; skimmers were missing weirs; there was no backflow prevention for the backwash waste line; a gate did not self-close and latch; a section of the perimeter fence had openings greater than four inches; the chlorine level

was not within the acceptable range of water quality standards; the pool was not approved for night swimming; the cyanuric acid level was not recorded on a weekly basis in the bound and numbered log book; and the disinfection equipment was leaking.

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

Update: The civil penalty has been paid and the Consent Order is closed.

21) Order Type and Number: Consent Order 24-011-RW
Order Date: January 8, 2024
Individual/Entity: **Legends Luxe, LLC**
Facility: Legends at Lake Murray
Location: 1200 Meredith Drive
Columbia, SC 29212
Mailing Address: 380 Union Street
Springfield, MA 1089
County: Lexington
Previous Orders: None
Permit/ID Number: 32-167-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Legends Luxe, 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 11, 2023, and August 17, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: tiles on the pool wall were missing; there was debris in the skimmer baskets; skimmers were missing weirs; the foot rinse shower was not operating properly; the pool equipment room was not accessible; the flow meter was missing; the emergency notification device was not operational; there was no pool rules sign; there were no “No Lifeguard On Duty – Swim At Your Own Risk” signs posted; the current pool operator of record information was not posted to the public; the bound and numbered log book was not maintained on a daily basis and was not maintained a minimum of three times per week by the pool operator of record on the first inspection; and the bound and numbered log book was not available for review 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.

22) Order Type and Number: Consent Order 24-012-RW
Order Date: January 10, 2024
Individual/Entity: **Madison Park Homeowners Association, Inc.**

Facility: Madison Park
Location: 109 Avensong Drive
Columbia, SC 29072
Mailing Address: 4910 Trenholm Road, Suite C
Columbia, SC 29206
County: Lexington
Previous Orders: None
Permit/ID Number: 32-1117B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Madison Park 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 17, 2023, and September 12, 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 waterline tiles were dirty; there was debris in the skimmer baskets; the foot rinse shower was not operating properly; the lock box was open; the chlorine level was not within the acceptable range of water quality standards; there was no life ring; the pool rules sign was not completely filled out; the pool was not approved for night swimming; the current pool operator of record information was not posted to the public; the bound and numbered log book was not maintained on a daily basis; the cyanuric acid level was not recorded on a weekly basis in the bound and numbered log book; 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.

23) Order Type and Number: Consent Order 24-013-RW
Order Date: January 10, 2024
Individual/Entity: **Wellesley Community Association, Inc.**
Facility: Wellesley
Location: 200 Tolbert Court
Lexington, SC 29072
Mailing Address: 1630 Military Cutoff Road, Suite 212
Wilmington, NC 28403
County: Lexington
Previous Orders: None
Permit/ID Number: 32-1070B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Wellesley Community 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 17, 2023, and September 15, 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 was not attached to the pool wall on the first inspection; the lifeline

floats were not properly spaced on the second inspection; a ladder was missing a rung; the pool deck was not clear of hazards and was uneven with sharp edges; there was debris in the skimmer baskets; a skimmer was missing a weir; the bathrooms did not have paper towels or a hand dryer; a return inlet was missing a cover; there were non-pool related items stored in the equipment room; the flow meter was not operating properly; a gate did not self-close and latch; the chlorine level was not within the acceptable range of water quality standards; the pool rules sign 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 maintained on a daily basis; the cyanuric acid level was not recorded on a weekly basis in the bound and numbered log book; the disinfection equipment was not in operable condition; 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.

24) <u>Order Type and Number:</u>	Consent Order 24-014-RW
<u>Order Date:</u>	January 10, 2024
<u>Individual/Entity:</u>	CBSP Community Association, Inc.
<u>Facility:</u>	Sterling Ponds Amenity Center
<u>Location:</u>	8 Middleknight Court Blythewood, SC 29016
<u>Mailing Address:</u>	1612 Military Cutoff Road, Suite 108 Wilmington, NC 28403
<u>County:</u>	Richland
<u>Previous Orders:</u>	None
<u>Permit/ID Number:</u>	40-1166B
<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-51(J)

Summary: CBSP Community 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 27, 2023, and August 14, 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; skimmers were missing weirs; there was debris in the skimmer baskets; the drinking water fountain was not operating properly; non-pool related items were stored in the equipment room; the flow meter was not operating; a light in the pool wall was out of its niche; a section of the perimeter fence had openings greater than four inches; the chlorine level was not within the acceptable range of water quality standards; the life ring rope was too short; and the facility address posted at the emergency notification device did not match the address provided by emergency dispatch personnel.

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.

25) Order Type and Number: Consent Order 24-015-RW
Order Date: January 11, 2024
Individual/Entity: **Continental 361 Fund, LLC**
Facility: Springs at Laurens Road
Location: Laurens Road
Greenville, SC 29607
Mailing Address: West 134 N8675 Executive Parkway
Menomonee Falls, WI 530501
County: Greenville
Previous Orders: None
Permit/ID Number: 32-1068B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Continental 361 Fund, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a public swimming pool located in Greenville County, South Carolina. The Department conducted inspections on July 11, 2023, and September 25, 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 was algae on the pool floor; the drinking water fountain was not operating properly; the chlorine level was not within the acceptable range of water quality standards; the pool rules sign was not completely filled out; only one “Shallow Water – No Diving Allowed” sign was posted; the “No Lifeguard On Duty – Swim At Your Own Risk” signs posted did not have the correct wording; and the log book was not properly bound and numbered.

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

Update: The civil penalty has been paid and the Consent Order is closed.

26) Order Type and Number: Consent Order 24-016-RW
Order Date: January 16, 2024
Individual/Entity: **Woodside Farm Homeowners Association, Inc.**
Facility: Woodside Farm
Location: 100 Scarlet Oak Way
Lexington, SC 29072
Mailing Address: 4910 Trenholm Road, Suite C
Columbia, SC 29206
County: Lexington
Previous Orders: None
Permit/ID Numbers: 32-1047B; 29-1046C
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Woodside Farm Homeowners Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool and a kiddie

pool located in Lexington County, South Carolina. The Department conducted inspections on July 19, 2023, and September 15, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: some of the frost-proof tiles were missing and some were broken; the deck was uneven with sharp edges; the water level was too high; the bathrooms did not have paper towels or hand dryers; the deck was not clear of hazards; the equipment room was not locked; there was no flow meter; the fill spout was not stainless steel or equivalent; non-pool related items were stored in the equipment room; a main drain grate valve was partially closed; there was no cover for one of the pool equalizer lines; 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 life ring was deteriorated; the pool rules sign was not legible; the pool rules sign had hours of operation listed after sunset and the pools were not approved for night swimming; the current pool operator of record information was not posted to the public; the bound and numbered log book was not maintained on a daily basis; and the automatic controller was not operating properly.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of one thousand three hundred sixty dollars (\$1,360.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand three hundred sixty dollars **(\$1,360.00)**.

Update: The civil penalty has been paid and the Consent Order is closed.

27) <u>Order Type and Number:</u>	Consent Order 24-017-RW
<u>Order Date:</u>	January 16, 2024
<u>Individual/Entity:</u>	Hammock Bay Owners' Association, Inc.
<u>Facility:</u>	Hammock Bay
<u>Location:</u>	115 Grand Palm Circle Lexington, SC 29072
<u>Mailing Address:</u>	1722 Main Street, Suite 150 Columbia, SC 29201
<u>County:</u>	Lexington
<u>Previous Orders:</u>	None
<u>Permit/ID Number:</u>	32-1064D
<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-51(J)

Summary: Hammock Bay Owners' Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a spa located in Lexington County, South Carolina. The Department conducted inspections on July 10, 2023, and September 5, 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 water level was too low; backflow prevention devices were missing; the flow meter was not in the correct location; the flow meter was not operating; the chlorine and pH levels were not within the acceptable range of water quality standards; the spa temperature was not monitored or recorded; the current pool operator of record information was not posted to the public; the bound and numbered log book 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; there were chlorine sticks in the skimmer baskets; and the disinfection equipment, automatic controller, and chemical feeders were not operating.

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

Update: The civil penalty has been paid and the Consent Order is closed.

28) <u>Order Type and Number:</u>	Consent Order 24-018-RW
<u>Order Date:</u>	January 16, 2024
<u>Individual/Entity:</u>	DLH Polo Commons, LLC
<u>Facility:</u>	Polo Commons Apartments
<u>Location:</u>	811 Polo Road Columbia, SC 29223
<u>Mailing Address:</u>	Same
<u>County:</u>	Richland
<u>Previous Orders:</u>	None
<u>Permit/ID Number:</u>	40-425-1
<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-51(J)

Summary: DLH Polo Commons, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Richland County, South Carolina. The Department conducted inspections on June 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: ladders were not tight and secure and were missing bumpers and rungs; the waterline tiles were dirty; the pool furniture was not at least four feet from the edge of the pool; the deck was uneven with sharp edges; there was standing water on the deck; deck drains were broken; skimmer baskets were floating; skimmer lids were cracked; there was debris in the skimmer baskets; the bathrooms did not have toilet paper, paper towels, or hand dryers; the drinking water fountain and foot rinse shower were not operating properly; the equipment room was not locked; non-pool related items were stored in the equipment room; a vacuum was operating inside the pool while the pool was open to the public; the flow meter was not operating; air was coming out of the returns; one of the returns did not have a cover; the gate did not self-close and latch; the chlorine and pH levels were not within the acceptable range of water quality standards; the main drain grates were not visible due to cloudy water; the life ring did not have a permanently attached grab rope; the pool rules sign was not completely filled out and did not have all the required rules; there were no “Shallow Water – No Diving Allowed” signs posted; only one “No Lifeguard On Duty - Swim At Your Own Risk” sign was posted and the sign posted did not have the correct wording and the letters were not the appropriate size; the current pool operator of record information was not posted to the public and the facility could not produce current valid documentation of pool operator certification; the bound and numbered log book was not available for review on the first inspection; 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.

29) Order Type and Number: Consent Order 24-019-RW
Order Date: January 16, 2024
Individual/Entity: **Planters Station Owners Association, Inc.**
Facility: Planters Station
Location: 4105 Mineral Springs Road
Lexington, SC 29072
Mailing Address: Same
County: Lexington
Previous Orders: None
Permit/ID Number: 32-132-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Planters Station 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 July 19, 2023, and September 14, 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 non-slip tread inserts; the plaster on the pool floor was discolored; the deck was not clear of hazards and was uneven with sharp edges; the bathrooms were not accessible; the drinking water fountain and foot rinse shower were not operating properly; the gate did not self-close and latch; the chlorine level was not within the acceptable range of water quality standards; the cyanuric acid level was above the water quality standards acceptable limit; the main drain grates were missing screws; the life ring was deteriorated; the shepherd's crook was not properly mounted in its designated location; the pool rules sign was not completely filled out; and there was a leak in the recirculation and filtration system.

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.

30) Order Type and Number: Consent Order 24-020-RW
Order Date: January 16, 2024
Individual/Entity: **Timberland Place Homeowners Association, Inc.**
Facility: Timberland Place
Location: 131 Timbermill Drive
Lexington, SC 29073
Mailing Address: 508 Hampton Street, Suite 200
Columbia, SC 29201
County: Lexington
Previous Orders: None
Permit/ID Number: 32-1022C
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Timberland Place Homeowners Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a kiddie pool located in Lexington County, South Carolina. The Department conducted inspections on May 30, 2023, July 11, 2023, and August 29, 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 was algae on the pool walls; the pool furniture was not at least four feet from the edge of the pool; the deck was uneven with sharp edges; the water level was too low; the bathrooms were not accessible; the pool equipment and chemical storage rooms were not accessible on the second inspection; the chemicals were not stored in the chemical storage room on the third inspection; the flow meter was not operating properly; 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 bound and numbered log book was not available for review on the second inspection, and the cyanuric acid level was not recorded on a weekly basis in the bound and numbered log book on the third inspection.

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

Update: The civil penalty has been paid and the Consent Order is closed.

31) <u>Order Type and Number:</u>	Consent Order 24-021-RW
<u>Order Date:</u>	January 16, 2024
<u>Individual/Entity:</u>	Ayaan Hospitality, LLC
<u>Facility:</u>	Best Western Plus
<u>Location:</u>	601 Columbia Avenue Lexington, SC 29072
<u>Mailing Address:</u>	Same
<u>County:</u>	Lexington
<u>Previous Orders:</u>	None
<u>Permit/ID Number:</u>	32-186-1
<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-51(J)

Summary: Ayaan 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 20, 2023, and September 26, 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 plaster on the pool floor was discolored; the waterline tiles were dirty; the drinking water fountain was not operating properly; there were non-pool related items stored in the equipment room; the flow meter was not operating properly; the cyanuric acid level was above the water quality standards acceptable limit; the life ring was deteriorated on the first inspection, and the life ring was not United States Coast Guard approved on the second inspection; the cyanuric acid level was not recorded on a weekly basis in the bound and numbered log book; 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.

32) Order Type and Number: Consent Order 24-022-RW
Order Date: January 17, 2024
Individual/Entity: **OM Arihant, LLC**
Facility: Quality Inn
Location: 1391 East Main Street
Duncan, SC 29334
Mailing Address: Same
County: Spartanburg
Previous Orders: None
Permit/ID Number: 42-137-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: OM Arihant, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a public swimming pool located in Spartanburg County, South Carolina. The Department conducted inspections on July 17, 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: there was debris in the skimmer baskets; skimmers were missing baskets; a section of the perimeter fence was damaged; only one “No Lifeguard On Duty – Swim At Your Own Risk” sign was posted; 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.

33) Order Type and Number: Consent Order 24-023-RW
Order Date: January 17, 2024
Individual/Entity: **Edward Rose Development Company, LLC**
Facility: Killian Lakes
Location: 9559 Farrow Road
Columbia, SC 29203
Mailing Address: 38525 Woodward Avenue
Bloomfield Hills, MI 48304
County: Richland
Previous Orders: None
Permit/ID Number: 40-1129B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Edward Rose Development Company, 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 28, 2023, and August 14, 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 plaster on the pool floor was deteriorated; skimmers were missing weirs; the bathrooms were dirty; the bathrooms did not have paper towels or soap on the first inspection; the bathrooms did not have soap on the second inspection; a gate did not self-close and latch; the life ring was not United States Coast Guard approved; the emergency notification device was not operational; only one “No Lifeguard On Duty-Swim At Your Own Risk” sign was posted and the sign posted did not have the correct wording; the current pool operator of record information was not posted to the public; 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.

34) <u>Order Type and Number:</u>	Consent Order 24-024-RW
<u>Order Date:</u>	January 19, 2024
<u>Individual/Entity:</u>	Lauren Ridge Apts, LLC
<u>Facility:</u>	Lauren Ridge Apartments, LLC
<u>Location:</u>	500 Carlen Avenue Lexington, SC 29072
<u>Mailing Address:</u>	Same
<u>County:</u>	Lexington
<u>Previous Orders:</u>	None
<u>Permit/ID Number:</u>	32-1075B
<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-51(J)

Summary: Lauren Ridge Apts., 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 11, 2023, and August 29, 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 on the deck were broken; a ladder was missing bumpers, rungs, and non-slip tread inserts; the deck was uneven with sharp edges; a skimmer was missing a weir; the pool equipment room was not locked; the flow meter was not operating properly; a gate did not self-close and latch; a section of the perimeter fence had openings greater than four inches; the pH level was not within the acceptable range of water quality standards; the pool was not approved for night swimming; and the pool equipment was leaking.

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

Update: The civil penalty has been paid and the Consent Order is closed.

35) Order Type and Number: Consent Order 24-025-RW
Order Date: January 19, 2024
Individual/Entity: **The Village at Hilton Homeowners Association, Inc.**
Facility: Village at Hilton
Location: 205 Lake Hilton Drive
Chapin, SC 29036
Mailing Address: 298 Hilton Village Drive
Chapin, SC 29036
County: Richland
Previous Orders: None
Permit/ID Number: 40-1016B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: The Village at Hilton 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 July 20, 2023, and September 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 bumpers; frost proof tiles were missing on the pool wall; the water level was too high; the bathrooms did not have paper towels or hand dryers; there was no flow meter; the fill spout was not stainless steel or equivalent; a gate did not self-close and latch; the main drains were missing screws; the life ring was deteriorated; only one “Shallow Water – No Diving Allowed” sign was posted; 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 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.

36) Order Type and Number: Consent Order 24-027-RW
Order Date: January 22, 2024
Individual/Entity: **DLH The Shores, LLC**
Facility: Shores at Elders Pond
Location: 4515 Hard Scrabble Road
Columbia, SC 29223
Mailing Address: 4500 Hard Scrabble Road
Columbia, SC 29229
County: Richland
Previous Orders: 21-208-RW (\$680.00)
Permit/ID Number: 40-1027B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: DLH The Shores, 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 7, 2023, and July 21, 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 non-slip tread inserts; there were broken tiles on the pool wall; skimmers were missing weirs; skimmer baskets were floating; the bathrooms were not accessible; the gate was propped open; the chlorine and pH levels were not within the acceptable range of water quality standards; the life ring was deteriorated and did not have a permanently attached rope; the life ring rope was too short; the pool rules sign was not completely filled out; only one “No Lifeguard On Duty – Swim At Your Own Risk” sign was posted and the letters were not the appropriate size; and the automatic controller was not approved by the Department.

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.

37) <u>Order Type and Number:</u>	Consent Order 24-026-RW
<u>Order Date:</u>	January 23, 2024
<u>Individual/Entity:</u>	Ft. Jackson Hotel Partners, LLC
<u>Facility:</u>	Home 2 Suites
<u>Location:</u>	7340 Garners Ferry Road Columbia, SC 29209
<u>Mailing Address:</u>	Same
<u>County:</u>	Richland
<u>Previous Orders:</u>	22-143-RW (\$680.00)
<u>Permit/ID Number:</u>	40-1187B
<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-51(J)

Summary: Ft. Jackson Hotel Partners, 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 19, 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 skimmer was missing a weir; 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 was deteriorated; the pool rules sign did not have accurate locations for the lifesaving equipment and the emergency notification device; the pool was not approved for night swimming; the bound and numbered log book was not maintained on a daily basis and was not maintained a minimum of three times per week by the pool operator of record; the cyanuric acid level was not checked weekly; the disinfection equipment was not operating properly; the recirculation and filtration system was not operating properly; the water level was too low; chemicals were stored outside of the chemical storage room; a light in the pool wall was out of its niche; 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 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.

38) Order Type and Number: Consent Order 24-028-RW
Order Date: January 30, 2024
Individual/Entity: **Blythewood Inn, LLC**
Facility: Holiday Inn Express
Location: 120 Creech Road
Blythewood, SC 29016
Mailing Address: Same
County: Richland
Previous Orders: None
Permit/ID Number: 40-421-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Blythewood Inn, 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 27, 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 non-slip tread inserts; the pool walls were dirty; there was debris in the skimmer baskets; skimmers were missing weirs; the water level was too low; the drinking water fountain was not operating properly; the flow meter was not operating; the bound and numbered log book was not maintained on a daily basis; the cyanuric acid level was not recorded weekly in the bound and numbered log book; the disinfection equipment was not operating properly; and the recirculation and filtration system was not operating properly.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of 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.

39) Order Type and Number: Consent Order 24-029-RW
Order Date: January 30, 2024
Individual/Entity: **Welcome Group, LLC**
Facility: Hampton Inn
Location: 1094 Chris Circle
West Columbia, SC 29169
Mailing Address: Same
County: Lexington
Previous Orders: 21-196-RW (\$680.00)
Permit/ID Number: 32-104-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Welcome Group, 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 19, 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 bumpers; there was debris in the skimmer baskets; the drinking water fountain and foot rinse shower were not operating properly; the required backflow prevention devices were missing; there was no flow meter; the fill spout was not stainless steel or equivalent; the pH level was not within the acceptable range of water quality standards; the facility address posted at the emergency notification device did not match the address provided by emergency dispatch personnel; the pool rules sign did not have all the required rules; there were no “Shallow Water – No Diving Allowed” signs posted on the first inspection; only one “Shallow Water – No Diving Allowed” sign was posted on the second inspection; the “No Lifeguard On Duty – Swim At Your Own Risk” signs posted did not have the correct wording; the current pool operator of record information was not posted to the public; 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; there were chlorine sticks in the skimmer baskets; and the disinfection equipment 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.

40) <u>Order Type and Number:</u>	Consent Order 24-030-RW
<u>Order Date:</u>	January 30, 2024
<u>Individual/Entity:</u>	SN Riverside, LLC
<u>Facility:</u>	Alight Columbia
<u>Location:</u>	800 Alexander Road Cayce, SC 29033
<u>Mailing Address:</u>	Same
<u>County:</u>	Lexington
<u>Previous Orders:</u>	None
<u>Permit/ID Number:</u>	32-163-1
<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-51(J)

Summary: SN Riverside, 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 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: deck depth marker tiles were broken; the pool floor was dirty; frost-proof tiles were missing; skimmers were missing weirs; skimmer baskets were broken and floating; skimmer baskets were not the appropriate size; the water level was too low; there was debris in the skimmer baskets; there was no drinking water fountain; the foot rinse shower was not operating properly; the required backflow prevention devices were missing; there was no flow meter; the gates did not self-close and latch; the chlorine and pH levels were not within the acceptable range of water quality standards; the main drain grates were not visible due to cloudy water; the shepherd’s crook was missing a bolt and was not permanently attached to the handle; the pool rules sign was not completely filled out; there were no “Shallow

Water – No Diving Allowed” signs posted; only one “No Lifeguard On Duty - Swim At Your Own Risk” sign was posted and the sign posted did not have the correct wording; 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 on the first inspection; 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; 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.

41)	<u>Order Type and Number:</u>	Consent Order 24-031-RW
	<u>Order Date:</u>	January 31, 2024
	<u>Individual/Entity:</u>	Ashton Woods, L.P.
	<u>Facility:</u>	Ashton Woods
	<u>Location:</u>	4001 Pelham Road Greer, SC 29605
	<u>Mailing Address:</u>	Same
	<u>County:</u>	Greenville
	<u>Previous Orders:</u>	None
	<u>Permit/ID Number:</u>	23-219-1
	<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-51(J)

Summary: Ashton Woods, L.P. (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 3, 2023, and September 22, 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 walls were dirty; the chlorine level was not within the acceptable range of water quality standards; the bound and numbered log book was not maintained on a daily basis; 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.

42)	<u>Order Type and Number:</u>	Consent Order 24-032-RW
	<u>Order Date:</u>	January 31, 2024
	<u>Individual/Entity:</u>	AA Holding Company, LLC
	<u>Facility:</u>	Rivers Edge Retreat
	<u>Location:</u>	1019 Garden Valley Lane

	Columbia, SC 29210
<u>Mailing Address:</u>	Same
<u>County:</u>	Lexington
<u>Previous Orders:</u>	22-125-RW (\$680.00)
<u>Permit/ID Number:</u>	32-033-1
<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-51(J)

Summary: AA Holding Company, 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 5, 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 ladder was not tight and secure; a ladder was missing rungs; the pool floor was dirty; the plaster on the pool floor was deteriorated; tiles were missing on the pool floor; a skimmer lid was not the appropriate size; there was debris in the skimmer baskets; a skimmer was missing a weir; a skimmer basket was floating; the bathrooms did not have toilet paper, paper towels, or hand dryers; the foot rinse shower was not operating properly on the first inspection; there was no foot rinse shower on the second inspection; the drinking water fountain was not operating properly; the flow meter was missing, the fill spout was not stainless steel or equivalent; the pool equipment room was not locked; current Vac-Alert certification was missing on the first inspection; invalid Vac-Alert certification was posted in the pool equipment room on the second inspection; a section of the perimeter fence was broken; the pool entry door did not self-close and latch on the first inspection; a gate did not self-close and latch and the entry gate was propped open on the second inspection; the life ring did not have a permanently attached rope; the pool rules sign was not completely filled out on the first inspection; there was no pool rules sign posted on the second inspection; only one "Shallow Water – No Diving Allowed" sign was posted; only one "No Lifeguard On Duty – Swim At Your Own Risk" sign was posted; the current pool operator of record information was not posted to the public; the bound and numbered log book was not available for review; there were chlorine sticks in the skimmer baskets; the disinfection equipment was not operating; and the recirculation and filtration system was not operating.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of one thousand two hundred dollars (\$1,200.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand two hundred dollars (**\$1,200.00**).

Update: The civil penalty has been paid and the Consent Order is closed.

43)	<u>Order Type and Number:</u>	Consent Order 24-033-RW
	<u>Order Date:</u>	January 30, 2024
	<u>Individual/Entity:</u>	KTAD RE Holdings, LLC
	<u>Facility:</u>	KTAD
	<u>Location:</u>	407 9 th Avenue South Myrtle Beach, SC 29577
	<u>Mailing Address:</u>	1005 Sea Mountain Highway North Myrtle Beach, SC 29582
	<u>County:</u>	Horry
	<u>Previous Orders:</u>	21-115-RW (\$1,360.00)
	<u>Permit/ID Number:</u>	26-1956D

Violations Cited:

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

Summary: KTAD RE Holdings, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a spa located in Horry County, South Carolina. The Department conducted inspections on July 10, 2023, July 26, 2023, and October 13, 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 pool equipment room was not accessible; the chemical storage room was not accessible; the gate did not self-close and latch; the chlorine and pH levels were not within the acceptable range of water quality standards; there was no spa rules sign posted; only one “No Lifeguard On Duty – Swim At Your Own Risk” sign was posted; 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 four thousand eight hundred dollars (\$4,800.00). The Individual/Entity shall pay a civil penalty in the amount of four thousand eight hundred dollars (**\$4,800.00**).

Update: The civil penalty has been paid and the Consent Order is closed.

Drinking Water Enforcement

44)	<u>Order Type and Number:</u>	Consent Order 24-001-DW
	<u>Order Date:</u>	January 4, 2024
	<u>Individual/Entity:</u>	The Wade Corporation
	<u>Facility:</u>	Cottages on Sandalwood Road
	<u>Location:</u>	Sandalwood Road Leesville, SC 29070
	<u>Mailing Address:</u>	615 Knox Abbot Drive Cayce, SC 29033
	<u>County:</u>	Saluda
	<u>Previous Orders:</u>	None
	<u>Permit/ID Number:</u>	4174002
	<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-58.7

Summary: The Wade Corporation (Individual/Entity) owns and is responsible for the proper operation and maintenance of a public water system (PWS) located in Saluda County, South Carolina. The Department conducted an inspection of the PWS on July 21, 2023, and it was rated unsatisfactory for failure to properly operate and maintain. The Individual/Entity has violated the State Primary Drinking Water Regulation as follows: Well 1 and Well 2 had not been permitted by the Department as public supply wells; Well 1 and Well 2 did not have a concrete pad, the sanitary seals were in disrepair, and the wellhead piping and storage tanks were in disrepair; Well 2 did not have an approvable well house that could be locked; the PWS has tested present for total coliform on multiple occasions; and complete, up-to-date written programs and procedures for the operation and maintenance of the PWS were not provided for Department review.

Action: The Individual/Entity is required to: provide for a South Carolina professional engineer to complete an evaluation of the PWS and a corrective action plan

(CAP) with a schedule and submit the evaluation, CAP, and schedule to the Department for review and approval by April 3, 2024; and submit written programs and procedures for the operation and maintenance of the PWS within thirty days of the date of the completion of the CAP. The Department has assessed a total civil penalty in the amount of four thousand dollars (\$4,000.00). The Individual/Entity shall pay a **stipulated penalty** in the amount of four thousand dollars (**\$4,000.00**) should any requirement of the Order not be met.

Update: None

45) Order Type and Number: Consent Order 24-002-DW
Order Date: January 4, 2024
Individual/Entity: **Williamsburg County Water & Sewer Authority**
Facility: Williamsburg County Water & Sewer Authority
Location: 130 West Main Street
Kingstree, SC 29556
Mailing Address: P.O. Box 1124
Kingstree, SC 29556
County: Williamsburg
Previous Orders: None
Permit/ID Number: 4510007
Violations Cited: S.C. Code Ann. Regs. 61-58.17.K(1)

Summary: Williamsburg County Water & Sewer Authority (Individual/Entity) owns and is responsible for the proper operation and maintenance of a public water system (PWS) located in Williamsburg County, South Carolina. On November 2, 2023, a violation was issued as a result of review of monitoring records. The Individual/Entity has violated the State Primary Drinking Water Regulation as follows: the PWS tested present for total coliform and E. coli, which resulted in a violation of the maximum contaminant level for E. coli.

Action: The Individual/Entity is required to: submit a written program and records for detecting and repairing leaks at the PWS and an investigative report and a corrective action plan with a schedule to address the causes of the total coliform and E. coli present results at the PWS by February 4, 2024. The Department has assessed a total civil penalty in the amount of four thousand dollars (\$4,000.00). The Individual/Entity shall pay a **stipulated penalty** in the amount of four thousand dollars (**\$4,000.00**) should any requirement of the Order not be met.

Update: The Individual/Entity submitted a written leak detection and repair program and a corrective action plan which were approved by the Department.

46) Order Type and Number: Consent Order 24-003-DW
Order Date: January 10, 2024
Individual/Entity: **Russell Powell, Individually and d.b.a. Brazells MHP**
Facility: Brazells MHP
Location: 1120 Lower Richland Boulevard

Mailing Address: Hopkins, SC 29061
2206 South Partridge Circle
Hopkins, SC 29061
County: Richland
Previous Orders: None
Permit/ID Number: 4060060
Violations Cited: S.C. Code Ann. Regs. 61-58.17.K(1)

Summary: Russell Powell, Individually and d.b.a. Brazells MHP (Individual/Entity) owns and is responsible for the proper operation and maintenance of a public water system (PWS) located in Richland County, South Carolina. On November 17, 2023, a violation was issued as a result of review of monitoring records. The Individual/Entity has violated the State Primary Drinking Water Regulation as follows: the PWS tested present for total coliform and E. coli, which resulted in a violation of the maximum contaminant level for E. coli.

Action: The Individual/Entity is required to: submit an investigative report and a corrective action plan with a schedule to address the causes of the total coliform and E. coli present results at the PWS by February 10, 2024. The Department has assessed a total civil penalty in the amount of four thousand dollars (\$4,000.00). The Individual/Entity shall pay a **stipulated penalty** in the amount of four thousand dollars (**\$4,000.00**) should any requirement of the Order not be met.

Update: The Individual/Entity submitted an investigative report and a corrective action plan with a schedule which were approved by the Department.

47) Order Type and Number: Consent Order 24-004-DW
Order Date: January 11, 2024
Individual/Entity: **Daniel Morgan Water District**
Facility: Daniel Morgan Water District
Location: 3329 Chesnee Highway
Gaffney, SC 29341
Mailing Address: P.O. Box 116
Chesnee, SC 29323
County: Cherokee
Previous Orders: None
Permit/ID Number: 1120001
Violations Cited: S.C. Code Ann. Regs. 61-58.5.P(2)(b)

Summary: Daniel Morgan Water District (Individual/Entity) owns and is responsible for the proper operation and maintenance of a public water system (PWS) located in Cherokee County, South Carolina. On November 8, 2023, a violation was issued as a result of review of monitoring records. The Individual/Entity has violated the State Primary Drinking Water Regulation as follows: the PWS exceeded the maximum contaminant level (MCL) for haloacetic acids five (HAA5).

Action: The Individual/Entity is required to: submit to the Department a corrective action plan with a schedule to address the MCL violations by April 10, 2024. The Department has assessed a total civil penalty in the amount of eight thousand dollars (\$8,000.00). The Individual/Entity shall pay a **stipulated penalty** in the amount of eight thousand dollars (**\$8,000.00**) should any requirement of the Order not be met.

Update: None

48) Order Type and Number: Consent Order 24-005-DW
Order Date: January 17, 2024
Individual/Entity: **City of Pickens**
Facility: City of Pickens
Location: 219 Pendelton Street
Pickens, SC 29671
Mailing Address: Same
County: Pickens
Previous Orders: None
Permit/ID Number: 3910001
Violations Cited: S.C. Code Ann. Regs. 61-58.5.P(2)(b)

Summary: The City of Pickens (Individual/Entity) owns and is responsible for the proper operation and maintenance of a public water system (PWS) located in Pickens County, South Carolina. On November 8, 2023, a violation was issued as a result of review of monitoring records. The Individual/Entity has violated the State Primary Drinking Water Regulation as follows: the PWS exceeded the maximum contaminant level (MCL) for haloacetic acids five (HAA5).

Action: The Individual/Entity is required to: submit to the Department a corrective action plan with a schedule to address the MCL violation by April 16, 2024. The Department has assessed a total civil penalty in the amount of four thousand dollars (\$4,000.00). The Individual/Entity shall pay a **stipulated penalty** in the amount of four thousand dollars (**\$4,000.00**) should any requirement of the Order not be met.

Update: None

49) Order Type and Number: Consent Order 24-007-DW
Order Date: January 24, 2024
Individual/Entity: **Town of Cheraw**
Facility: Town of Cheraw
Location: 200 Market Street
Cheraw, SC 29520
Mailing Address: P.O. Box 219
Cheraw, SC 29520
County: Chesterfield
Previous Orders: None
Permit/ID Number: 1310001
Violations Cited: S.C. Code Ann. Regs. 61-58.5.P(2)(b)

Summary: The Town of Cheraw (Individual/Entity) owns and is responsible for the proper operation and maintenance of a public water system (PWS) located in Chesterfield County, South Carolina. On November 8, 2023, and November 29, 2023, a violation was issued as a result of review of monitoring records. The Individual/Entity has violated the State Primary Drinking Water Regulation as follows: the PWS exceeded the maximum contaminant level (MCL) for total trihalomethanes.

Action: The Individual/Entity is required to: submit to the Department a corrective action plan with a schedule to address the MCL violation by April 23, 2024. 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 **stipulated penalty** in the amount of eight thousand dollars (**\$8,000.00**) should any requirement of the Order not be met.

Update: None

50) Order Type and Number: Consent Order 24-006-DW
Order Date: January 25, 2024
Individual/Entity: **Meansville-Riley Road Water Company, Inc.**
Facility: Hully Bridge Road
Location: Hully Bridge Road
Mailing Address: P.O. Box 823
Union, SC 29379
County: Union
Previous Orders: None
Permit/ID Number: 4420001
Violations Cited: S.C. Code Ann. Regs. 61-58.1.B

Summary: Meansville-Riley Road Water Company, Inc. (Individual/Entity) owns and is responsible for obtaining from the Department the proper permitting for the construction of public water supply mains and the associated appurtenances (PWS) to serve one residential lot and two non-residential lots located on Hully Bridge Road in Union County, South Carolina. On November 21, 2023, the Department issued a Notice of Enforcement Conference to the Individual/Entity for failure to obtain a permit to construct a PWS. The Individual/Entity has violated the State Primary Drinking Water Regulation as follows: failed to obtain a permit to construct from the Department prior to the construction of a PWS.

Action: The Individual/Entity is required to: complete the construction in accordance with the permit and contact the Department to request an inspection to obtain written approval to operate. The Department has assessed a total civil penalty in the amount of three thousand four hundred dollars (\$3,400.00). The Individual/Entity shall pay a civil penalty in the amount of three thousand four hundred dollars (**\$3,400.00**).

Update: The Individual/Entity obtained the required permit to construct, completed the construction in accordance with the permit, and obtained written approval to operate. The civil penalty has been paid and the Consent Order is closed.

Water Pollution Enforcement

51) Order Type and Number: Consent Order 24-001-W
Order Date: January 2, 2024
Individual/Entity: **SC Pet Food Solutions, LLC**
Facility: SC Pet Food Solutions, LLC
Location: 1299 Duncan Road
Ward, SC 29166

Mailing Address: Same
County: Saluda
Previous Orders: 20-029-W (\$3,780.00)
Permit/ID Number: ND0089419
Violations Cited: Pollution Control Act, S.C. Code Ann. § 48-1-110(a) and (d) and the Water Pollution Control Permits Regulation S.C. Code Ann. Regs. 61-9.505.41(a), (e)(1) and (p)

Summary: SC Pet Food Solutions, LLC (Individual/Entity) owns and is responsible for a poultry protein conversion facility and an onsite wastewater treatment facility located in Saluda County, South Carolina. The Department conducted an Environmental Complaint Evaluation (ECE) and observed multiple discharges and unauthorized discharge pipes at numerous stormwater basins and ponds. The Individual/Entity has violated the Pollution Control Act and the Water Pollution Control Permits Regulation, as follows: failed to comply with permit conditions related to the construction and operation of systems of treatment and control (and related appurtenances) and allowed runoff of waste outside the permitted area.

Action: The Individual/Entity is required to: submit a corrective action plan and a schedule for implementation and reporting for the corrective actions taken and planned to address the violations identified by the ECE; and implement monitoring of treated wastewater at the chlorine contact chamber and spray field wet well to demonstrate the effectiveness of the treatment system. The Department has assessed a total civil penalty in the amount of twenty thousand dollars (\$20,000.00). The Individual/Entity shall pay a civil penalty in the amount of twenty thousand dollars (**\$20,000.00**) by February 1, 2024.

Update: None

52) Order Type and Number: Consent Order 24-003-W
Order Date: January 4, 2024
Individual/Entity: **Kiawah River Utility Company**
Facility: Kiawah River Utility Company Wastewater Treatment Facility
Location: Intersection of Mullet Rd and Bonneau Rd
Charleston, SC
Mailing Address: 320 Broad Street, Suite 600
Charleston, SC 29401
County: Charleston
Previous Orders: 23-039-W (\$4,000.00)
Permit/ID Number: ND0088897
Violations Cited: Pollution Control Act, S.C Code Ann § 48-1-110 (d) and the Water Pollution Control Permits, S.C. Code Ann Regs. 61-9.122.41 (a).

Summary: Kiawah River Utility Company (Individual/Entity) owns and is responsible for the proper operation and maintenance of a wastewater treatment facility (WWTF) located in Charleston County, South Carolina. On August 24, 2023, a Notice of Violation was issued as a result of violations of the permitted discharge limits for total suspended solids (TSS) as reported 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 discharge limits for TSS.

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 by February 4, 2024; 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 four thousand dollars (\$4,000.00). The Individual/Entity shall pay a civil penalty in the amount of four thousand dollars **(\$4,000.00)** by February 4, 2024.

Update: The civil penalty has been paid.

53) Order Type and Number: Consent Order 24-004-W
Order Date: January 4, 2024
Individual/Entity: **Town of Calhoun Falls**
Facility: Sawney Creek Wastewater Treatment Facility
Location: 125 Walnut Street
Calhoun Falls, SC 29628
Mailing Address: P.O. Box 246
Calhoun Falls, SC 29628
County: Abbeville
Previous Orders: 19-015-W (\$980.00), 19-062-W (\$280.00)
Permit/ID Number: SC0025721
Violations Cited: Pollution Control Act, S.C Code Ann § 48-1-110 (d) and the Water Pollution Control Permits, S.C. Code Ann Regs. 61-9.122.41 (a).

Summary: The Town of Calhoun Falls (Individual/Entity) owns and is responsible for the proper operation and maintenance of a wastewater treatment facility (WWTF) located in Abbeville County, South Carolina. On May 30, 2023, a Notice of Violation was issued as a result of violations of the permitted discharge limits for ammonia nitrogen (ammonia) as reported 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 discharge limits for ammonia.

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 by February 4, 2024; 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 eight thousand dollars (\$8,000.00). The Individual/Entity shall pay a civil penalty in the amount of eight thousand dollars **(\$8,000.00)** by February 4, 2024.

Updates: None

54) Order Type and Number: Consent Order 24-005-W
Order Date: January 4, 2024
Individual/Entity: **Town of Calhoun Falls**
Facility: Sawney Creek Wastewater Treatment Facility
Location: 125 Walnut Street
Calhoun Falls, SC 29628
Mailing Address: P.O. Box 246
Calhoun Falls, SC 29628
County: Abbeville
Previous Orders: 19-015-W (\$980.00), 19-062-W (\$280.00)
Permit/ID Number: NPDES Permit SC0025721
Violations Cited: Pollution Control Act, S.C Code Ann § 48-1-110 (d) and Water Pollution Control Permits, S.C. Code Ann Regs. 61-9.122.41 (a).

Summary: The Town of Calhoun Falls (Individual/Entity) owns and is responsible for the proper operation and maintenance of a wastewater treatment facility (WWTF) located in Abbeville County, South Carolina. On January 26, 2023, a Notice of Violation was issued as a result of an unsatisfactory Compliance Sampling Inspection. The Individual/Entity has violated the Pollution Control Act and the Water Pollution Control Permits Regulation as follows: failed to maintain and operate the WWTF in accordance with the Permit.

Action: The Individual/Entity is required to: submit a notarized document by April 1, 2024 certifying a valid individual listed as responsible official in ePermitting, an operational bar screen as required by the Permit, properly operational mechanical aerators, an operational high wet well alarm system, documentation of the last backflow device inspection, a schedule for manhole inspections, and an Operation and Maintenance manual that includes an emergency operation plan for the pump station. The Department has assessed a total civil penalty in the amount of four thousand dollars (\$4,000.00). The Individual/Entity shall pay a civil penalty in the amount of four thousand dollars (**\$4,000.00**) by February 4, 2024.

Update: None

55) Order Type and Number: Consent Order 24-006-W
Order Date: January 4, 2024
Individual/Entity: **WestRock CP LLC**
Facility: WestRock CP LLC
Location: 7320 Mill Road
Florence, SC 29506
Mailing Address: Same
County: Florence County
Previous Orders: None
Permit/ID Number: SC0000876
Violations Cited: Pollution Control Act, S.C Code Ann § 48-1-110 (d) and Water Pollution Control Permits, S.C. Code Ann Regs. 61-9.122.41 (a)

Summary: WestRock CP, LLC (Individual/Entity) is responsible for the proper operation and maintenance of a wastewater treatment facility (WWTF) located in Florence County, South Carolina. On January 30, 2023, a Notice of Violation was issued as a result of violations of the permitted discharge limits for fecal coliform (fecal) as reported 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 discharge limits for fecal.

Action: The Individual/Entity is required to: complete a six (6) event compliance confirmation period upon completion of corrective actions. The Department has assessed a total civil penalty in the amount of four thousand dollars (\$4,000.00). The Individual/Entity shall pay a civil penalty in the amount of four thousand dollars (**\$4,000.00**) by February 4, 2024.

Update: The civil penalty has been paid and the six-month compliance confirmation period has been completed. The Order is closed.

56) Order Type and Number: Consent Order 24-002-W
Order Date: January 5, 2023
Individual/Entity: **Bucksport Water System Inc**
Facility: Bucksport Water System Pauley Swamp Well Ros
Location: Pee Dee Hwy and Pauley Swamp Rd. Conway, SC 29527
Mailing Address: 2809 4th Ave Conway, SC 29527
County: Horry
Previous Orders: None
Permit/ID Number: SCG646075
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. 61-9.122.21(d)

Summary: Bucksport Water System, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a wastewater treatment facility (WWTF) in Horry County, South Carolina. On September 15, 2023, a Notice of Violation was issued for reported violations of the permitted effluent limits for Acute Toxicity (ATOX) on discharge monitoring reports submitted to the Department for the January-December 2021 and January-December 2022 annual monitoring periods. The Individual/Entity has violated the Pollution Control Act and the Water Pollution Control Permits Regulation as follows: failure to comply with the permitted effluent discharge limits for ATOX.

Action: The Individual/Entity is required to: submit a written notification of planned completion date for all corrective actions necessary to resolve the effluent violations by February 2, 2024; 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 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 February 2, 2024.

Updates: The civil penalty has been paid.

57) Order Type and Number: Consent Order 24-008-W
Order Date: January 26, 2023
Individual/Entity: **South Carolina Water Utilities-PUI, Inc.**
Facility: Spears Creek Wastewater Treatment Facility
Location: One third (1/3) mile West-North-West of Highway Church Road bridge at the end of Brazzell Lane, about three (3) miles south of the Town of Elgin, SC 29045
Mailing Address: 1710 Woodcreek Farms Rd
Elgin, SC 29045
County: Kershaw
Previous Orders: 19-037-W (\$12,000.00)
Permit/ID Number: SC0043451
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. 61-9.122.21(d)

Summary: South Carolina Water Utilities-PUI, Inc. F/K/A Palmetto Utilities Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a wastewater treatment facility (WWTF) in Kershaw County, South Carolina. On May 31, 2023, a Notice of Violation was issued for reported violations of the permitted effluent limits for biochemical oxygen demand (BOD), ammonia-nitrogen (Ammonia), total suspended solids (TSS), ultimate oxygen demand (UOD), and Escherichia coliform (E. coli) on discharge monitoring reports submitted to the Department for the March 2023 and July 2023 monthly monitoring periods. The Individual/Entity has violated the Pollution Control Act, and the Water Pollution Control Permits Regulation as follows: failure to comply with the permitted effluent discharge limits for BOD, Ammonia, TSS, UOD, and E. coli.

Action: The Individual/Entity is required to: submit a written notification of planned completion date for all corrective actions necessary to resolve the effluent violations by February 25, 2024, 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 eleven thousand dollars (\$11,000.00). The Individual/Entity shall pay a civil penalty in the amount of eleven thousand dollars (**\$11,000.00**) by February 25, 2024.

Update: None

58) Order Type and Number: Consent Order 24-010-W
Order Date: January 31, 2024
Individual/Entity: **Dewees Utility Corporation**

Facility: Dewees Island Reverse Osmosis Wastewater Treatment Facility
Location: 273 Old House Lane
Dewees Island, SC 29451
Mailing Address: Same
County: Charleston
Previous Orders: None
Permit/ID Number: SC0046817
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. 61-9.122.21(d) and 61-9.122.41(a)

Summary: Dewees Utility Corporation (Individual/Entity) owns and is responsible for the Dewees Island Reverse Osmosis wastewater treatment facility (WWTF) located in Charleston County, South Carolina. A Notice of Violation was issued for failure to submit to the Department a timely permit renewal application. The Individual/Entity has violated the Pollution Control Act and the Water Pollution Control Permits Regulation, as follows: failed to submit a new application at least one hundred eighty (180) days before the expiration date of the Permit.

Action: The Individual/Entity is required to: continue to operate in accordance with the Permit until a new permit is issued, and within fifteen (15) days of execution submit an administratively complete permit renewal application for review. The Department has assessed a total civil penalty in the amount of one thousand dollars (\$1,000.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand dollars (**\$1,000.00**) by March 1, 2024.

Update: None

BUREAU OF AIR QUALITY

59) Order Type and Number: Consent Order 24-001-A
Order Date: January 4, 2024
Individual/Entity: **JW Aluminum Company**
Facility: JW Aluminum Company
Location: 435 Mount Holly Road
Goose Creek, SC 29445
Mailing Address: Same
County: Berkeley County
Previous Orders: 18-039-A
Permit/ID Number: 0420-0033
Violations Cited: S.C. Code Ann. Regs. 61-62.1, Section II,
Permit Requirements

Summary: JW Aluminum Company (Individual/Entity) manufactures aluminum coil and sheets at its facility located in Berkeley County, South Carolina. The Department received source test results from tests conducted by the Individual/Entity. The Individual/Entity has violated South Carolina Air Pollution Control Regulations, as follows: failed to limit particulate matter (“PM”) and and PM_{2.5} emissions for Secondary Aluminum Processing Unit 2 to 0.47 lb/hr, volatile organic compound emissions for

Secondary Aluminum Processing Unit 2 to 0.82 lb/hr, and PM, PM₁₀, and PM_{2.5} emissions for Secondary Aluminum Processing Unit 1 to 0.47 lb/hr, and failed to record pressure drop readings for the mist eliminator on 58 occasions during the reporting period of July 1, 2022, through June 30, 2023.

Action: The Individual/Entity is required to: comply with all terms and conditions of the current Title V Permit. The Department has assessed a total civil penalty in the amount of twenty-eight thousand five hundred dollars (\$28,500.00). The Individual/Entity shall pay a penalty of twenty-eight thousand five hundred dollars (**\$28,500.00**) by February 4, 2024.

Update: The Individual/Entity performed a retest and the results demonstrated compliance for both Secondary Aluminum Processing Units. Additionally, the Individual/Entity has paid the civil penalty.

60) Order Type and Number: Consent Order 24-003-A
Order Date: January 17, 2024
Individual/Entity: **ChromaScape, LLC**
Facility: N/A
Location: 105 Wood Street
Greenville, SC 29611
Mailing Address: Same
County: Greenville
Previous Orders: 13-015-A
Permit/ID Number: SOP-1200-0154
Violations Cited: S.C. Code Ann. Regs. 61-62.1 (Supp. 2022)
Section II, *Permit Requirements*

Summary: ChromaScape, LLC (Individual/Entity) manufactures dyestuffs for various industries in Greenville County, South Carolina. On June 26, 2023, the Department received a construction permit application to operate an existing 15,000 lb capacity mixer (“D1”) that was installed in 2014. The Individual/Entity has violated South Carolina Air Pollution Control Regulations, as follows: failed to obtain a construction permit from the Department prior to the commencement of construction of D1.

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 dollars (\$7,000.00). The Individual/Entity shall pay a penalty of seven thousand dollars (**\$7,000.00**) .

Update: The Individual/Entity has paid the civil penalty

61) Order Type and Number: Consent Order 24-004-A
Order Date: January 30, 2024
Individual/Entity: **Carolina Allserv, LLC, d/b/a Carolina Pallets & Recycling**
Facility: Carolina Pallets & Recycling
Location: 645 State Road S-4-317
Belton, SC 29627

Mailing Address: P.O. Box 843
Simpsonville, SC 29681
County: Anderson
Previous Orders: 22-016-A
Permit/ID Number: TV-0200-0284
Violations Cited: 40 CFR Part 60 and S.C. Code Ann. Regs. 61-62.60, Subpart III, S.C Code Ann. Regs. 61-62.5, Standard No. 3, S.C. Code Ann. Regs. 61.62.1, Section IV *Source Test*, S.C. Code Ann. Regs. 61-62.1 Section II, *Permit Requirements*, and Consent Order 22-016-A

Summary: Carolina Allserv, LLC, doing business as Carolina Pallets & Recycling (Individual/Entity), operates a pallet manufacturing operation at its facility located in Anderson County, South Carolina. On November 3, 2022, the Individual/Entity conducted a source test on the air curtain incinerator (ACI) for opacity emissions. On December 5, 2022, the Department received the source test report from Carolina Pallets. On August 29 and October 12, 2023, the Department conducted an investigation at the Individual/Entity. The Individual/Entity has violated US EPA and South Carolina Air Pollution Control Regulations, as follows: failed to submit a site-specific test plan nor notify the Department at least two (2) weeks prior to the date of the test and failed to conduct the source test within sixty (60) days of the execution of Consent Order 22-016-A; failed to limit opacity to 20% in accordance with Standard 3; failed to operate a strain gauge on the incinerator stacking rakes as required by the Permit; failed to include all of the required information in the operator training program and submit it to the Department for approval; and failed to operate and maintain the 78.4 hp diesel engine (Engine) according to the manufacturer's emissions-related written instructions.

Action: The Individual/Entity is required to: comply with all terms and conditions of the Title V Operating Permit; henceforth perform maintenance on the Engine at a minimum of every 500 hours as specified by the manufacturer; comply with all emissions limits in accordance with Standard 3; submit to the Department the incinerator operator training program, including all required information in accordance with Standard 3, to the Department for approval no later than February 14, 2024, Conduct an annual source test on the ACI no later than March 31, 2024, and annually thereafter, and install and operate strain gauges on each stacking rake used to load the incinerator no later than February 29, 2024. The Department has assessed a civil penalty in the amount of forty-three thousand dollars (\$43,000.00). The Individual/Entity shall pay a penalty of forty-three thousand dollars (**\$43,000.00**), by February 29, 2024.

Update: On April 27, 2023, the Department received a test report for a Department-approved source test conducted by Carolina Pallets on the ACI on March 31, 2023. The results indicated compliance with the applicable regulations as determined in Consent Order 22-016-A.

BUREAU OF ENVIRONMENTAL HEALTH SERVICES

On-Site Wastewater Enforcement

62) Order Type and Number: Consent Order 23-097-OSWW
Order Date: January 4, 2024

<u>Individual/Entity:</u>	Seth Parkkonen, DBA Ashmore Homes
<u>Facility:</u>	Seth Parkkonen, DBA Ashmore Homes
<u>Location:</u>	186 Sherwood Drive Wellford, SC 29385
<u>Mailing Address:</u>	841 Ben Johnson Road Inman, SC 29349
<u>County:</u>	Spartanburg
<u>Previous Orders:</u>	None
<u>Permit Number:</u>	None
<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-56

Summary: Seth Parkkonen, DBA Ashmore Homes, (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 the OSWW system was mostly covered, and the maximum depth specified on the Permit to Construct had been exceeded. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that all systems for which the licensee is responsible are constructed, repaired, and cleaned in accordance with S.C. Regulation 61-56 and permits issued by the Department; and failed to leave the OSWW system uncovered until the scheduled Final Inspection.

Action: The Individual/Entity is required to cease and desist covering OSWW systems before the scheduled Final Inspection; and installing OSWW systems outside the parameters 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.

63) <u>Order Type and Number:</u>	Consent Order 23-101-OSWW
<u>Order Date:</u>	January 4, 2024
<u>Individual/Entity:</u>	Aaron Karon, DBA Trinity Brothers Construction
<u>Facility:</u>	Aaron Karon, DBA Trinity Brothers Construction
<u>Location:</u>	Lot 14 Dogwood Trails Campobello, SC 29322
<u>Mailing Address:</u>	502 Clearwater Road Landrum, SC 29356
<u>County:</u>	Spartanburg
<u>Previous Orders:</u>	None
<u>Permit Number:</u>	None
<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-56

Summary: Aaron Karon, DBA Trinity Brothers Construction, (Individual/Entity) installed an OSWW system on property located in Spartanburg County, South Carolina. The Department conducted a Final Inspection on September 13, 2023, and observed that over half of the OSWW system was covered. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to

wait the required thirty (30) minutes after the scheduled Final Inspection time before covering the OSWW system.

Action: The Individual/Entity is required to cease and desist covering the OSWW system until thirty (30) minutes after the 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.

64)	<u>Order Type and Number:</u>	Consent Order 23-102-OSWW
	<u>Order Date:</u>	January 11, 2024
	<u>Individual/Entity:</u>	Cody Williams, DBA Williams Plumbing
	<u>Facility:</u>	Cody Williams, DBA Williams Plumbing
	<u>Location:</u>	301 Green River Road Gaffney, SC 29341
	<u>Mailing Address:</u>	911 Corn Mill Road Cowpens, SC 29330
	<u>County:</u>	Cherokee
	<u>Previous Orders:</u>	None
	<u>Permit Number:</u>	None
	<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-56

Summary: Cody Williams, DBA Williams Plumbing, (Individual/Entity) installed an OSWW system on property located in Cherokee County, South Carolina. The Department attempted to conduct a Final Inspection on August 16, 2023, but the OSWW system was covered. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to wait to cover the OSWW system until thirty (30) minutes after the scheduled Final Inspection.

Action: The Individual/Entity is required to cease and desist covering the OSWW system until at least thirty (30) minutes after the 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**) by February 11, 2024.

Update: On February 27, 2024, the Department issued a payment Demand Letter to the Individual/Entity.

65)	<u>Order Type and Number:</u>	Consent Order 23-106-OSWW
	<u>Order Date:</u>	January 19, 2024
	<u>Individual/Entity:</u>	Dalford Wilson, DBA Wilson Septic Tank Service
	<u>Facility:</u>	Dalford Wilson, DBA Wilson Septic Tank Service
	<u>Location:</u>	Shrivers Green Road Ridgeway, SC 29130
	<u>Mailing Address:</u>	4740 Great Falls Highway

	Great Falls, SC 29055
<u>County:</u>	Kershaw
<u>Previous Orders:</u>	20-029-OSWW
<u>Permit Number:</u>	None
<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-56

Summary: Dalford Wilson, DBA Wilson Septic Tank Service, (Individual/Entity) installed an OSWW system on property located in Kershaw County, South Carolina. The Department conducted an investigation on September 28, 2023, and determined that the Individual/Entity had not scheduled a Final Inspection with the Department. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to schedule a Final Inspection for a newly installed OSWW system.

Action: The Individual/Entity is required to cease and desist installing OSWW systems without scheduling a Final Inspection with the Department. 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.

66) <u>Order Type and Number:</u>	Consent Order 23-109-OSWW
<u>Order Date:</u>	January 19, 2024
<u>Individual/Entity:</u>	Lloyd Cobb, DBA Cobb Construction, LLC
<u>Facility:</u>	Lloyd Cobb, DBA Cobb Construction, LLC
<u>Location:</u>	270 Green River Road Cowpens, SC 29330
<u>Mailing Address:</u>	P.O. Box 1687 Gaffney, SC 29342
<u>County:</u>	Spartanburg
<u>Previous Orders:</u>	21-042-OSWW, 21-076-OSWW
<u>Permit Number:</u>	None
<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-56

Summary: Lloyd Cobb, DBA Cobb Construction, LLC, (Individual/Entity) installed an OSWW system on property located in Spartanburg County, South Carolina. The Department conducted a review of documents submitted by the Individual/Entity and determined the system was installed outside the area specified on the Permit to Construct. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to install the OSWW system as specified by the Permit to Construct and the regulation.

Action: The Individual/Entity is required to cease and desist installing OSWW systems outside the parameters of the Permit to Construct and the regulation. 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.

67) Order Type and Number: Consent Order 23-092-OSWW
Order Date: January 26, 2024
Individual/Entity: **Kenneth Cooper**
Facility: Kenneth Cooper
Location: 2527 Triple Crown Boulevard
Florence, SC 29506
Mailing Address: 3624 E. National Cemetery Road
Florence, SC 29506
County: Florence
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: Kenneth Cooper (Individual/Entity) installed an OSWW system on property located in Florence County, South Carolina. The Department conducted an investigation on July 28, 2023, and determined that the Individual/Entity was not licensed by the Department to install OSWW systems. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: engaged in the business of constructing and repairing onsite sewage treatment systems without first applying for, receiving, and subsequently maintaining a valid license to conduct such activities as required by the Department.

Action: The Individual/Entity is required to cease and desist installing OSWW systems without first applying for, receiving, and maintaining a Department issued license for those activities. 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**) by February 26, 2024.

Update: None.

68) Order Type and Number: Consent Order 23-107-OSWW
Order Date: January 29, 2024
Individual/Entity: **Greg West, DBA J Alan Companies**
Facility: Greg West, DBA J Alan Companies
Location: 351 Terra Plains Drive
Greer, SC 29651
Mailing Address: 3808 North Highway 14
Greer, SC 29651
County: Spartanburg
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: Greg West, DBA J Alan Companies, (Individual/Entity) installed an OSWW system on property located in Spartanburg County, South Carolina. The Department conducted a review of documents that were submitted for the site on September 21, 2023, and determined the system was installed outside the area specified

on the Permit to Construct. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to install the OSWW system as specified by the Permit to Construct and the regulation.

Action: The Individual/Entity is required to cease and desist installing OSWW systems outside the parameters of the Permit to Construct and the regulation. The Department has assessed a total civil penalty in the amount of one thousand dollars (\$1,000.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand dollars **(\$1,000.00)**.

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

OFFICE OF OCEAN & COASTAL RESOURCE MANAGEMENT

69) Order Type and Number: Consent Order AF-0000295
Order Date: January 3, 2024
Individual/Entity: **Michael and Laura Schulte**
Location: 1301 Debordieu Boulevard
Georgetown, SC 29440 (Site)
Mailing Address: 2526 Red Fox Trail
Charlotte, NC 28211
County: Georgetown
Previous Orders: None
Permit/ID Number: N/A
Violations Cited: S.C. Code Ann. §48-39-130(A) and (C) and S.C. Code Ann. Regs. 30-2(B); S.C. Code Ann. §48-39-130(D)(1)(a) and S.C. Code Ann. Regs. 30-15(H)(2); S.C. Code Ann. Regs. 30-15(H)(3)(d); S.C. Code Ann. Regs. 30-15(H)(3)(g); S.C. Code Ann. Regs. 30-15(H)(3)(h); S.C. Code Ann. Regs 30-13(L)(3)(a-c) and S.C. Code Ann. Regs 30-15(H)(5).

Summary: Michael and Laura Schulte (Individual/Entity) are the current owners of certain property, located in Georgetown County, abutting the Atlantic Ocean. An inspection at the Site was conducted on September 23, 2020, and a Notice of Alleged Violation/Admission Letter was issued on December 11, 2020. The Individual/Entity violated the S.C. Coastal Tidelands and Wetlands Act and Coastal Division Regulations by installing sandbags, fabric wrap, and additional non-beach compatible fill materials seaward of the setback line and in the beach/dune system critical area at the Site without authorization from the Department.

Action: The Individual/Entity is required to: provide the Department with a financially binding commitment in the amount of \$5,173.00 to cover the cost of the removal of the sandbags by February 17, 2024; and provide evidence of a restrictive covenant recorded in the Register of Deeds Office of Georgetown County that gives clear notice of the study at the Site and the requirements of the Order. The Department has assessed a total civil penalty in the amount of four thousand dollars (\$4,000.00). The Individual/Entity shall pay a civil penalty in the amount of four thousand dollars **(\$4,000.00)** by February 2, 2024.

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

- 70) Order Type and Number: Consent Order AF-0000296
Order Date: January 18, 2024
Individual/Entity: **Price and Carolyn Sloan**
Location: 1425 Debordieu Boulevard
Georgetown, SC 29440 (Site)
Mailing Address: Same
County: Georgetown
Previous Orders: None
Permit/ID Number: N/A
Violations Cited: S.C. Code Ann. §48-39-130(A) and (C) and S.C. Code Ann. Regs. 30-2(B); S.C. Code Ann. §48-39-130(D)(1)(a) and S.C. Code Ann. Regs. 30-15(H)(2); S.C. Code Ann. Regs. 30-15(H)(3)(d); S.C. Code Ann. Regs. 30-15(H)(3)(g); S.C. Code Ann. Regs. 30-15(H)(3)(h); S.C. Code Ann. Regs 30-13(L)(3)(a-c) and S.C. Code Ann. Regs 30-15(H)(5).

Summary: Price and Carolyn Sloan (Individual/Entity) are the current owners of certain property, located in Georgetown County, abutting the Atlantic Ocean. An inspection at the Site was conducted on September 23, 2020, and a Notice of Alleged Violation/Admission Letter was issued on December 11, 2020. The Individual/Entity violated the S.C. Coastal Tidelands and Wetlands Act and Coastal Division Regulations by installing sandbags, fabric wrap, and additional non-beach compatible fill materials seaward of the setback line and in the beach/dune system critical area at the Site without authorization from the Department.

Action: The Individual/Entity is required to: provide the Department with a financially binding commitment in the amount of \$2,478.00 to cover the cost of the removal of the sandbags by March 3, 2024; and provide evidence of a restrictive covenant recorded in the Register of Deeds Office of Georgetown County that gives clear notice of the study at the Site and the requirements of the Order. The Department has assessed a total civil penalty in the amount of four thousand dollars (\$4,000.00). The Individual/Entity shall pay a civil penalty in the amount of four thousand dollars (**\$4,000.00**) by February 17, 2024.

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

* 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

March 7, 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 January 1, 2024, through January 31, 2024.
- III. FACTS:** For the period of January 1, 2024, through January 31, 2024, Health Promotion and Services reports 0 Administrative Orders and 37 Consent Orders totaling \$44,450.00 in assessed civil penalties.

Permit Type	Administrative Orders	Consent Orders	Assessed Civil Penalties
Retail Food Establishments	0	37	\$44,450.00

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

March 7, 2024

CONSENT ORDERS (37)

PENALTY TOTALS:

ADMINISTRATIVE ORDERS- \$0

CONSENT ORDERS- \$44,450.00

CONSENT ORDERS – FOOD PROTECTION

1)	<u>Order Type and Number:</u>	Consent Order 23-378-FOOD
	<u>Order Date:</u>	January 5, 2024
	<u>Individual/Entity:</u>	Kingsman
	<u>Facility:</u>	Kingsman
	<u>Location:</u>	936 Axtell Drive Cayce, SC 29033
	<u>Mailing Address:</u>	Same
	<u>County:</u>	Lexington
	<u>Previous Orders:</u>	None
	<u>Permit Number:</u>	32-206-06094

Summary: The Department conducted inspections on August 16, 2023, August 24, 2023, October 12, 2023, October 19, 2023, and October 25, 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; 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 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 one thousand seven hundred dollars (\$1,700.00). The Individual/Entity shall pay a civil penalty in the amount of one

thousand seven hundred dollars (\$1,700.00). The Individual/Entity has met all requirements of the Order. This Order has been closed.

- 2) Order Type and Number: Consent Order 23-354-FOOD
 Order Date: January 9, 2024
 Individual/Entity: Paris and Potter Management Corporation
 Facility: KFC of Surfside
 Location: 504 Highway 17 North
 Surfside, SC 29575
 Mailing Address: 430 Ramsey Street, Suite 106
 Fayetteville, NC 28302
 County: Horry
 Previous Orders: 22-36-FOOD (\$800.00)
 Permit Number: 26-206-10192

Summary: The Department conducted inspections on February 23, 2023, August 15, 2023, August 25, 2023, and September 25, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: 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; failed to ensure floors, floor coverings, walls, wall coverings, and ceilings were designed, constructed, and installed so they are smooth and easily cleanable; and failed to clean the physical facilities as often as necessary to keep them clean.

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 (22-36-FOOD) was issued when the Individual/Entity violated the South Carolina Retail Food Establishment Regulation by failing to ensure that equipment is maintained in a state of repair and condition that meets the regulation requirements (C).

- 3) Order Type and Number: Consent Order 23-393-FOOD

Order Date: January 16, 2024
Individual/Entity: The Quarterdeck
Facility: The Quarterdeck
Location: 5905 South Kings Highway
Myrtle Beach, SC 29575
Mailing Address: Same
County: Horry
Previous Orders: None
Permit Number: 26-206-11407

Summary: The Department conducted inspections on August 11, 2023, March 1, 2023, March 10, 2023, and October 23, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to provide individual disposable towels at each hand washing sink or group of adjacent handwashing sinks; and failed to ensure that an air gap between the water supply inlet and the flood level rim of the plumbing fixture, equipment, or nonfood equipment was at least twice the diameter of the water supply inlet and not be less than one (1) inch.

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.

4) Order Type and Number: Consent Order 23-410-FOOD
Order Date: January 16, 2024
Individual/Entity: Bojangles 751
Facility: Bojangles 751
Location: 104 Loyola Drive
Surfside, SC 29588
Mailing Address: P. O. Box 773
Conway, SC 29526
County: Horry
Previous Orders: None
Permit Number: 26-206-14473

Summary: The Department conducted inspections on September 12, 2022, March 21, 2023, and October 31, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that when time without temperature control is used as a public health control, foods with expired time labels, unmarked containers or packages, shall be discarded.

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.

5) <u>Order Type and Number:</u>	Consent Order 23-396-FOOD
<u>Order Date:</u>	January 16, 2024
<u>Individual/Entity:</u>	Lobster House Seafood
<u>Facility:</u>	Lobster House Seafood
<u>Location:</u>	5301 South Kings Highway Myrtle Beach, SC 29575
<u>Mailing Address:</u>	Same
<u>County:</u>	Horry
<u>Previous Orders:</u>	23-101-FOOD (\$400.00); and 23-154-FOOD (\$800.00)
<u>Permit Number:</u>	26-206-13657

Summary: The Department conducted inspections on April 26, 2023, and October 24, 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 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 five hundred

dollars (\$1,500.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand five hundred dollars (\$1,500.00). No update at this time.

Previous Orders: The previous consent order (23-101-FOOD) was issued when the Individual/Entity violated the South Carolina Retail Food Establishment Regulation by failing to maintain the premises free of insects, rodents, and other pests (PF). The previous Consent Order (23-154-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).

6) <u>Order Type and Number:</u>	Consent Order 23-406-FOOD
<u>Order Date:</u>	January 16, 2024
<u>Individual/Entity:</u>	Flip Flops Bar & Grill
<u>Facility:</u>	Flip Flops Bar & Grill
<u>Location:</u>	9619 Shore Drive Myrtle Beach, SC 29572
<u>Mailing Address:</u>	9023 Fort Mill Way Myrtle Beach, SC 29579
<u>County:</u>	Horry
<u>Previous Orders:</u>	22-189-FOOD (\$1,600.00)
<u>Permit Number:</u>	26-206-14045

Summary: The Department conducted inspections on September 19, 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 two thousand dollars (\$2,000.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand dollars (\$2,000.00). No update at this time.

Previous Orders: The previous Consent Order (22-189-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).

7) Order Type and Number: Consent Order 23-449-FOOD
Order Date: January 16, 2024
Individual/Entity: Tasty Spot
Facility: Tasty Spot
Location: 2017 Doetrail
 Dillon, SC 29536
Mailing Address: Same
County: Florence
Previous Orders: None
Permit Number: N/A

Summary: The Department conducted inspections on October 5, 2023, and November 20, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: providing 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). No update at this time.

8) Order Type and Number: Consent Order 23-399-FOOD
Order Date: January 16, 2024
Individual/Entity: Carolina Calabash
Facility: Carolina Calabash
Location: 700 Church Street
 Conway, SC 29526
Mailing Address: 501 44th Avenue North, D-5
 Myrtle Beach, SC 29577
County: Horry
Previous Orders: None
Permit Number: 26-206-14231

Summary: The Department conducted inspections on October 14, 2022, February 24, 2023, October 19, 2023, and October 27, 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 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 two thousand one hundred dollars (\$2,100.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand one hundred dollars (\$2,100.00). The Department has entered into a payment plan with the Individual/Entity for the civil penalty.

- 9) Order Type and Number: Consent Order 23-404-FOOD
 Order Date: January 22, 2024
 Individual/Entity: Barnacle Bills
 Facility: Barnacle Bills
 Location: 3522 Highway 17 Business
 Murrells Inlet, SC 29576
 Mailing Address: 1125 Dickpond Road
 Myrtle Beach, SC 29575
 County: Georgetown
 Previous Orders: None
 Permit Number: 22-206-06581

Summary: The Department conducted inspections on December 29, 2022, September 27, 2023, and October 6, 2023. Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to keep shellstock tags or labels attached to the container in which the shellstock are received, until the container is empty.

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.

- 10) Order Type and Number: Consent Order 23-417-FOOD
 Order Date: January 22, 2024
 Individual/Entity: Hardee's Sumter #3
 Facility: Hardee's Sumter #3
 Location: 493 North Guignard Drive
 Sumter, SC 29150
 Mailing Address: 755 South Fourth Street
 Hartsville, SC 29550
 County: Sumter
 Previous Orders: None
 Permit Number: 43-206-00182

Summary: The Department conducted inspections on October 3, 2023, October 12, 2023, and October 18, 2023. Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to keep equipment food contact surfaces and utensils clean to sight and touch.

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

- 11) Order Type and Number: Consent Order 23-450-FOOD
 Order Date: January 22, 2024
 Individual/Entity: Farmhaus
 Facility: Farmhaus
 Location: 604 Coleman Boulevard
 Mount Pleasant, SC 29464
 Mailing Address: Same
 County: Charleston
 Previous Orders: None
 Permit Number: 10-206-14134

Summary: The Department conducted an inspection on November 22, 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 Individual/Entity has met all requirements of the Order. This Order has been closed.

12)	<u>Order Type and Number:</u>	Consent Order 23-467-FOOD
	<u>Order Date:</u>	January 22, 2024
	<u>Individual/Entity:</u>	Jasper's Frosty Dog Cafe
	<u>Facility:</u>	Jasper's Frosty Dog Café
	<u>Location:</u>	8 North Forest Beach Drive Hilton Head Island, SC 29928
	<u>Mailing Address:</u>	11331 NW 18 th Street Fort Lauderdale, FL 33323
	<u>County:</u>	Beaufort
	<u>Previous Orders:</u>	23-409-FOOD (\$800.00)
	<u>Permit Number:</u>	07-206-09598

Summary: The Department conducted inspections on April 18, 2023, October 6, 2023, and December 7, 2023. Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain the premises free of insects, rodents, and other pests.

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

Previous Orders: The previous Consent Order (23-409-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 store poisonous or toxic materials so that they cannot contaminate food equipment, utensils, linens, and single-service and single-use articles (P).

- 13) Order Type and Number: Consent Order 23-452-FOOD
 Order Date: January 22, 2024
 Individual/Entity: Nagoya Japanese Grill
 Facility: Nagoya Japanese Grill
 Location: 1354 North Fraser Street
 Georgetown, SC 29440

 Mailing Address: Same
 County: Georgetown
 Previous Orders: None
 Permit Number: 22-206-06299

Summary: The Department conducted inspections on February 22, 2023, June 26, 2023, and October 24, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to store foods in a manner to prevent cross contamination.

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.

- 14) Order Type and Number: Consent Order 23-469-FOOD
 Order Date: January 22, 2024
 Individual/Entity: Hardee's St. Matthews 3177-6070
 Facility: Hardee's St. Matthews 3177-6070
 Location: 401 South Harry Raysor
 St. Matthews, SC 29135

 Mailing Address: 755 South 4th Street
 Hartsville, SC 29550

 County: Calhoun
 Previous Orders: None
 Permit Number: 09-206-00064

Summary: The Department conducted inspections on November 30, 2023, December 7, 2023, and December 12, 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.

15)	<u>Order Type and Number:</u>	Consent Order 23-416-FOOD
	<u>Order Date:</u>	January 22, 2024
	<u>Individual/Entity:</u>	Turbeville IGA #17 Deli
	<u>Facility:</u>	Turbeville IGA #17 Deli
	<u>Location:</u>	5262 Turbeville Highway Turbeville, SC 29162
	<u>Mailing Address:</u>	P. O. Box 205 Turbeville, SC 29162
	<u>County:</u>	Clarendon
	<u>Previous Orders:</u>	None
	<u>Permit Number:</u>	14-206-00603

Summary: The Department conducted inspections on October 9, 2023, October 19, 2023, and October 27, 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.

16) Order Type and Number: Consent Order 23-468-FOOD
 Order Date: January 22, 2024
 Individual/Entity: Golden Pantry
 Facility: Golden Pantry
 Location: 7006 Capital Way
 Springfield, SC 29146

 Mailing Address: Same
 County: Orangeburg
 Previous Orders: None
 Permit Number: 38-206-02460

Summary: The Department conducted inspections on February 6, 2023, February 16, 2023, and December 7, 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.

17) Order Type and Number: Consent Order 23-448-FOOD
 Order Date: January 22, 2024
 Individual/Entity: Mr. Crab
 Facility: Mr. Crab
 Location: 506 Highway 17 North
 North Myrtle Beach, SC 29582

 Mailing Address: Same
 County: Horry
 Previous Orders: None
 Permit Number: 26-206-14268

Summary: The Department conducted inspections on February 24, 2023, July 21, 2023, and November 17, 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.

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| 18) | <u>Order Type and Number:</u> | Consent Order 23-409-FOOD |
| | <u>Order Date:</u> | January 22, 2024 |
| | <u>Individual/Entity:</u> | Jasper's Frosty Dog Cafe |
| | <u>Facility:</u> | Jasper's Frosty Dog Café |
| | <u>Location:</u> | 8 North Forest Beach Drive
Hilton Head Island, SC 29928 |
| | <u>Mailing Address:</u> | 11331 NW 18 th Street
Fort Lauderdale, FL 33323 |
| | <u>County:</u> | Beaufort |
| | <u>Previous Orders:</u> | None |
| | <u>Permit Number:</u> | 07-206-09598 |

Summary: The Department conducted inspections on April 18, 2023, October 6, 2023, and October 16, 2023. 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 store poisonous or toxic materials so that they cannot contaminate food equipment, utensils, linens, and single-service and single-use articles.

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

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| 19) | <u>Order Type and Number:</u> | Consent Order 23-323-FOOD |
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Order Date: January 22, 2024
Individual/Entity: Alyses
Facility: Alyses
Location: 1040 Highway 17 Business South
Surfside Beach, SC 29575
Mailing Address: 108 Old Towne Way, Unit 1
Myrtle Beach, SC 29588
County: Horry
Previous Orders: None
Permit Number: 26-206-14181

Summary: The Department conducted inspections on July 8, 2022, January 6, 2023, and August 24, 2023. 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). No update at this time.

20) Order Type and Number: Consent Order 23-392-FOOD
Order Date: January 22, 2024
Individual/Entity: Old Bull and Bush
Facility: Old Bull and Bush
Location: 4700 Highway 17 Bypass
Myrtle Beach, SC 29588
Mailing Address: 1745 D Low Country Place
Myrtle Beach, SC 29577
County: Horry
Previous Orders: None
Permit Number: 26-206-14344

Summary: The Department conducted inspections on March 20, 2023, March 30, 2023, and October 16, 2023. 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). No update at this time.

21)	<u>Order Type and Number:</u>	Consent Order 23-416-FOOD
	<u>Order Date:</u>	January 22, 2024
	<u>Individual/Entity:</u>	7 Up Mart
	<u>Facility:</u>	7 Up Mart
	<u>Location:</u>	10297 Scott Avenue Manning, SC 29102
	<u>Mailing Address:</u>	Same
	<u>County:</u>	Clarendon
	<u>Previous Orders:</u>	None
	<u>Permit Number:</u>	14-206-00664

Summary: The Department conducted inspections on September 28, 2023, October 6, 2023, October 13, 2023, and October 20, 2023. 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; and failed to provide a test kit or other device that accurately measures the concentration of MG/L of sanitizing solutions.

Action: The Individual/Entity is required to operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25. The Department has assessed a total civil penalty in the amount of 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)	<u>Order Type and Number:</u>	Consent Order 23-419-FOOD
	<u>Order Date:</u>	January 22, 2024
	<u>Individual/Entity:</u>	Dumpling & Seafood Restaurant
	<u>Facility:</u>	Dumpling & Seafood Restaurant
	<u>Location:</u>	9650 North Kings Highway Myrtle Beach, SC 29572

Mailing Address: Same
County: Horry
Previous Orders: 23-259-FOOD (\$800.00)
Permit Number: 26-206-14785

Summary: The Department conducted an inspection on October 24, 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 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 (23-259-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).

23) Order Type and Number: Consent Order 23-447-FOOD
Order Date: January 22, 2024
Individual/Entity: 2 Gingers
Facility: 2 Gingers
Location: 245 Bush River Road
Columbia, SC 29210
Mailing Address: Same
County: Richland
Previous Orders: 22-63-FOOD (\$1,500.00);
23-317-FOOD (\$4,500.00); and
23-381-FOOD (\$2,500.00)
Permit Number: 40-206-07493

Summary: The Department conducted inspections on August 7, 2023, October 5, 2023, and November 30, 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; 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 was safe, unadulterated, and honestly presented.

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 (22-63-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). The previous Consent Order (23-317-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); by failing to maintain the premises free of insects, rodents, and other pests (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 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 (P). The previous Consent Order (23-381-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); by failing to maintain the premises free of insects, rodents, and other pests (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); by failing to ensure that physical facilities were maintained in good repair (C); and by failing to ensure that restricted use pesticides specified in 7-202.12 (C) met the requirements specified in 40 CFR 152, Subpart I, Classification of Pesticides (P).

24) Order Type and Number: Consent Order 23-428-FOOD
 Order Date: January 22, 2024
 Individual/Entity: Popeyes of Myrtle Beach
 Facility: Popeyes of Myrtle Beach
 Location: 5910 South Kings Highway
 Myrtle Beach, SC 29575

 Mailing Address: 15235 Paulo Place
 Waterford, VA 20197

 County: Horry
 Previous Orders: 23-27-FOOD (\$1,600.00); and
 23-137-FOOD (\$1,000.00)

 Permit Number: 26-206-14489

Summary: The Department conducted inspections on May 16, 2023, November 1, 2023, November 9, 2023, and November 17, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure food employees kept their fingernails trimmed, filed, and maintained so the edges and surfaces are cleaned and not rough; 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 one thousand five hundred dollars (\$1,500.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand five hundred dollars (\$1,500.00). No update at this time.

Previous Orders: The previous Consent Order (23-27-FOOD) was issued when the Individual/Entity violated the South Carolina Retail Food Establishment Regulation by failing to ensure written procedures were in place and made available to the Department when the facility uses time as a public health control (P); by failing to ensure floors, floor coverings, walls, wall coverings, and ceilings were designed, constructed, and installed so they are smooth and easily cleanable (C); and by failing to ensure that physical facilities were maintained in good repair (C). The previous Consent Order (23-137-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).

25) Order Type and Number: Consent Order 23-453-FOOD

Order Date: January 22, 2024
Individual/Entity: Loris IGA Deli #19
Facility: Loris IGA Deli #19
Location: 3030 Broad Street
Loris, SC 29569
Mailing Address: P. O. Box 1629
Lake City, SC 29560
County: Horry
Previous Orders: None
Permit Number: 26-206-08753

Summary: The Department conducted inspections on June 13, 2023, November 1, 2023, November 9, 2023, and November 20, 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 was safe, unadulterated, and honestly presented.

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.

26) Order Type and Number: Consent Order 23-414-FOOD
Order Date: January 22, 2024
Individual/Entity: 7-Eleven #36848J
Facility: 7-Eleven #36848J
Location: 3498 East River Street
Anderson, SC 29621
Mailing Address: P. O. Box 139044
Dallas, TX 75313
County: Anderson
Previous Orders: None
Permit Number: 04-206-04914

Summary: The Department conducted inspections on September 28, 2023, October 5, 2023, October 10, 2023, and October 16, 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 was safe, unadulterated, and honestly presented; 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 that when time without temperature control is used as a public health control, foods with expired time labels, unmarked containers or packages, shall be discarded.

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 eight hundred dollars (\$1,800.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand eight hundred dollars (\$1,800.00). The Individual/Entity has met all requirements of the Order. This Order has been closed.

27)	<u>Order Type and Number:</u>	Consent Order 23-470-FOOD
	<u>Order Date:</u>	January 22, 2024
	<u>Individual/Entity:</u>	China Garden
	<u>Facility:</u>	China Garden
	<u>Location:</u>	481 By-Pass 72 NW, Suite 101 Greenwood, SC 29649
	<u>Mailing Address:</u>	Same
	<u>County:</u>	Greenwood
	<u>Previous Orders:</u>	23-95-FOOD (\$500.00)
	<u>Permit Number:</u>	24-206-02013

Summary: The Department conducted inspections on March 15, 2023, March 27, 2023, November 16, 2023, and November 20, 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 was safe, unadulterated, and honestly presented.

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 (23-95-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.

28) Order Type and Number: Consent Order 23-436-FOOD
 Order Date: January 22, 2024
 Individual/Entity: KFC
 Facility: KFC
 Location: 1425 Sandifer Boulevard
 Seneca, SC 29678
 Mailing Address: 904 Montague Avenue
 Greenwood, SC 29649
 County: Oconee
 Previous Orders: None
 Permit Number: 37-206-01197

Summary: The Department conducted inspections on September 2, 2023, October 4, 2023, October 12, 2023, October 18, 2023, October 23, 2023, and November 1, 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 three thousand two hundred dollars (\$3,200.00). The Individual/Entity shall pay a civil penalty in the amount of three thousand two hundred dollars (\$3,200.00). The Individual/Entity has met all requirements of the Order. This Order has been closed.

29) Order Type and Number: Consent Order 23-381-FOOD
 Order Date: January 23, 2024
 Individual/Entity: Hemang Bhavsar
 Facility: 2 Gingers
 Location: 245 Bush River Road

	Columbia, SC 29210
<u>Mailing Address:</u>	Same
<u>County:</u>	Richland
<u>Previous Orders:</u>	22-63-FOOD (\$1,500.00); and 23-317-FOOD (\$4,500.00)
<u>Permit Number:</u>	40-206-07493

Summary: The Department conducted inspections on August 7, 2023, August 17, 2023, August 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 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; failed to maintain the premises free of insects, rodents, and other pests; 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 physical facilities were maintained in good repair; and failed to ensure that restricted use pesticides specified in 7-202.12 (C) met the requirements specified in 40 CFR 152, Subpart I, Classification of Pesticides.

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 (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). The previous Consent Order (23-317-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); by failing to maintain the premises free of insects, rodents, and other pests (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 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 (P).

30) Order Type and Number: Consent Order 23-435-FOOD
 Order Date: January 23, 2024
 Individual/Entity: Team Carolinas Inc.
 Facility: Domino's Pizza
 Location: 199 Southport Road
 Spartanburg, SC 29302
 Mailing Address: 122 Avalon Drive, Suite G
 Salisbury, NC 28146

 County: Spartanburg
 Previous Orders: None
 Permit Number: 42-206-06496

Summary: The Department conducted inspections on February 15, 2023, October 25, 2023, November 2, 2023, November 9, 2023, November 1, 2023, and November 27, 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 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.

31) Order Type and Number: Consent Order 23-456-FOOD
 Order Date: January 24, 2024
 Individual/Entity: Pizza Hyena
 Facility: Pizza Hyena
 Location: 13 South Ocean Boulevard
 Surfside Beach, SC 29575

 Mailing Address: P. O. Box 70328

Myrtle Beach, SC 29572
County: Horry
Previous Orders: 23-48-FOOD (\$1,600.00); and
23-246-FOOD (\$1,000.00)
Permit Number: 26-206-13908

Summary: The Department conducted an inspection on November 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 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 Orders (23-48-FOOD) and (23-246-FOOD) were 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).

32) Order Type and Number: Consent Order 23-309-FOOD
Order Date: January 24, 2024
Individual/Entity: The Clubhouse
Facility: The Clubhouse
Location: 77 Highway 17
North Myrtle Beach, SC 29582
Mailing Address: Same
County: Horry
Previous Orders: 22-311-FOOD (\$400.00)
Permit Number: 26-206-14584

Summary: The Department conducted inspections on February 24, 2023, August 7, 2023, and August 17, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain the proper sanitization concentration in a chemical sanitizer used in a manual or mechanical operation during contact times.

Action: The Individual/Entity is required to operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25. The Department has assessed a total civil penalty in the amount of 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 Department has entered into a payment plan with the Individual/Entity for the civil penalty.

Previous Orders: The previous Consent Order (22-311-FOOD) was issued when the Individual/Entity violated the South Carolina Retail Food Establishment Regulation by failing to maintain the premises free of insects, rodents, and other pests (PF).

33)	<u>Order Type and Number:</u>	Consent Order 23-401-FOOD
	<u>Order Date:</u>	January 22, 2024
	<u>Individual/Entity:</u>	China Buffet
	<u>Facility:</u>	China Buffet
	<u>Location:</u>	1105 Church Street Conway, SC 29526
	<u>Mailing Address:</u>	Same
	<u>County:</u>	Horry
	<u>Previous Orders:</u>	22-52-FOOD (\$3,250.00); 22-130-FOOD (\$1,000.00); and 22-224-FOOD (\$1,000.00)
	<u>Permit Number:</u>	26-206-11146

Summary: The Department conducted inspections on August 2, 2023, September 20, 2023, and September 29, 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 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.

Previous Orders: The previous Consent Order (22-52-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 food was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling (P); failing to maintain the proper sanitization

concentration in a chemical sanitizer used in a manual or mechanical operation during contact times (P); 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 failing to ensure written procedures were in place and made available to the Department when the facility uses time as a public health control (P). The previous Consent Orders (22-130-FOOD) and (22-224-FOOD) were issued when the Individual/Entity violated the South Carolina Retail Food Establishment Regulation by failing to ensure written procedures were in place and made available to the Department when the facility uses time as a public health control (P).

34)	<u>Order Type and Number:</u>	Consent Order 24-03-FOOD
	<u>Order Date:</u>	January 24, 2024
	<u>Individual/Entity:</u>	Sakura Hibachi, LLC
	<u>Facility:</u>	Sakura Hibachi, LLLC
	<u>Location:</u>	220 East Greer Street Honea Path, SC 29654
	<u>Mailing Address:</u>	Same
	<u>County:</u>	Anderson
	<u>Previous Orders:</u>	None
	<u>Permit Number:</u>	04-206-04224

Summary: The Department conducted inspections on November 6, 2023, November 8, 2023, November 15, 2023, November 22, 2023, and November 30, 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 four hundred dollars (\$2,400.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand four hundred dollars (\$2,400.00). The Individual/Entity has met all requirements of the Order. This Order has been closed.

35)	<u>Order Type and Number:</u>	Consent Order 23-462-FOOD
	<u>Order Date:</u>	January 24, 2024
	<u>Individual/Entity:</u>	Falafel King

Facility: Falafel King
Location: 2020 Gervais Street
Columbia, SC 29204
Mailing Address: Same
County: Richland
Previous Orders: None
Permit Number: 40-206-09499

Summary: The Department conducted inspections on November 7, 2023, December 8, 2023, and December 14, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to store foods in a manner to prevent cross contamination; 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 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.

36) Order Type and Number: Consent Order 23-424-FOOD
Order Date: January 24, 2024
Individual/Entity: Power Trac 2
Facility: Power Trac 2
Location: 21 N. Greenwood Avenue Extension
Ware Shoals, SC 29692
Mailing Address: P. O. Box 40
Piedmont, SC 29673
County: Greenwood
Previous Orders: None
Permit Number: 01-206-00993

Summary: The Department conducted inspections on October 17, 2023, October 24, 2023, and November 9, 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.

37) Order Type and Number: Consent Order 23-368-FOOD
 Order Date: January 25, 2024
 Individual/Entity: Ken Patel
 Facility: Corner Cupboard #8
 Location: 162 South Main Street
 Society Hill, SC 29593

 Mailing Address: Same
 County: Darlington
 Previous Orders: None
 Permit Number: 16-206-03012

Summary: The Department conducted inspections on October 20, 2021, August 16, 2022, July 3, 2023, July 13, 2023, July 18, 2023, and August 18, 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; and failed to store foods in a manner to prevent cross contamination.

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 four hundred dollars (\$1,400.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand four hundred dollars (\$1,400.00). The Individual/Entity has paid the civil penalty; however, correction of the violation has not been verified.

BOARD OF HEALTH AND ENVIRONMENTAL CONTROL
SUMMARY SHEET
March 7, 2024

[x] ACTION/DECISION
[] INFORMATION

- I. TITLE:** Request for approval of the Draft 2024 South Carolina Health Plan.
- II. SUBJECT:** Presentation of the Draft 2024 South Carolina Health Plan for final Board approval.
- III. FACT:** The Draft 2024 South Carolina Health Plan (“Draft Plan” or “SHP”) has been developed with the advice of the South Carolina Health Planning Committee (Committee). On May 16, 2023, the Governor signed into law Act 20. Act 20 partially repeals the Certificate of Need program. The Draft Plan reflects those changes due to Act 20. On November 24, 2023, the Department opened the Draft Plan for public comment. During the open comment period the Department held four regional public hearings for the solicitation of comments. On December 27, 2023, at 5:00 PM the Department closed the comment period. On January 17, 2023, the Committee was provided an updated Draft Plan with updates from the comment period and voted to adopt the changes. On February 14, 2024, the Committee reconvened and voted to move a final version of the SHP to the Board for approval.
- IV. ANALYSIS:** The Committee recommends the Board adopt the attached Draft 2024 South Carolina Health Plan. Proposed changes to sections of the Plan are set forth below and organized by SHP chapter.

Chapter 1. Introduction.

Corrections to reflect Act 20. Updated the current South Carolina Health Planning Committee Members list.

Chapter 2. Inventory Regions and Service Areas.

Corrections to reflect Act 20.

Chapter 3. ~~General Hospitals~~Nursing Homes.

Organized to move Nursing Homes to Chapter 3 and to move General Hospitals to Chapter 5.

Chapter 4. ~~Psychiatric Services~~Home Health Agencies.

Organized to move Home Health Agencies to Chapter 4 and to move Psychiatric Services to Chapter 5. Changed Standards to allow an applicant to submit one Certificate of Need (CON) application for the number of counties proposed to serve. Organized the Home Health Agency chart by region and county.

~~Chapter 5. Rehabilitation Facilities~~Hospitals.

Organized to consolidate Chapter 3, General Hospitals; Chapter 4, Psychiatric Services; Chapter 5, Rehabilitation; and Chapter 6, Inpatient Treatment Facilities to move to Chapter 5, Hospitals. Changed the psychiatric bed methodology from a service area to a statewide need and the occupancy rate to 50%. Effective January 1, 2027, CON is repealed for all hospital projects.

~~Chapter 6. Alcohol and Drug Abuse Facilities.~~

Deleted to reflect Act 20. Inpatient Treatment Facilities moved to Chapter 5, Hospitals, to consolidate Hospital chapters.

~~Chapter 7. Residential Treatment Facilities (RTF) for Children and Adults~~

Deleted to reflect Act 20.

~~Chapter 8. Cardiovascular Care.~~

Deleted to reflect Act 20.

~~Chapter 9. Radiation Oncology.~~

Deleted to reflect Act 20.

~~Chapter 10. Outpatient Facilities~~

Deleted to reflect Act 20.

~~Chapter 11. Long Term Care Facilities and Services.~~

Deleted to reflect Act 20. Nursing Homes moved to Chapter 3. Home Health Agencies moved to Chapter 4.

Glossary.

Updated the Glossary section to reflect what is in the State Health Plan

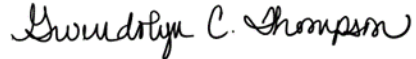
V. RECOMMENDATION:

The State Health Planning Committee recommends that the Board approve the Draft 2024 South Carolina Health Plan for use in the Certificate of Need Program, and that all applications received after the effective date of the Plan be reviewed under this Plan.

VI. ATTACHMENTS:

1. Draft 2024 South Carolina Health Plan
2. Strikethrough version of Draft 2024 South Carolina Health Plan

Approved by:



Gwen C. Thompson,
Deputy Director, Healthcare Quality

DRAFT
2024 SOUTH
CAROLINA
HEALTH PLAN



SOUTH CAROLINA HEALTH PLANNING COMMITTEE

<u>MEMBER</u>	<u>REPRESENTING</u>	<u>EXPIRATION</u>
Anne Summer	1st District, Business	6/30/2024
Gokul Gondi, MD	2nd District Health Care, Provider	6/30/2025
McKenzie Speed	3rd District	6/30/2026
Sonya Younger	4th District, Health Care, Consumer	6/30/2026
Kurt E. Moore	5th District, Admin of LTC Facility	6/30/2018
Elbert R. Malone	6th District	6/30/2025
Tim Holland	7th District	6/30/2024
Bradley W. Moorehouse	Admin of licensed For Profit Nursing Home	6/30/2016
Henry Well	Consumer	6/30/2027
Whitney Wright	Consumer	6/30/2027
Roger Hall, Esq.	Consumer Affairs (Ex-Officio)	
Robert R. Morgan Jr., MD	Board of Health and Environmental Control	
Sarah C. Harrell	Health Care Financier, Business	6/30/2025

South Carolina Health Planning Committee
Department of Health & Environmental
Control Certificate of Need Program
2600 Bull Street
Columbia, SC 29201
coninfo@dhec.gov
Phone: (803) 545-
4200

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CHAPTER 1

INTRODUCTION

SOUTH CAROLINA HEALTH PLAN

The South Carolina Code of Laws requires the Department of Health and Environmental Control ("Department") to prepare a South Carolina Health Plan ("Plan"), with the advice of the Health Planning Committee, for use in the administration of the Certificate of Need Program. See [§44-7-180\(8\)](#).

CERTIFICATE OF NEED

Certificate of Need (CON) must be obtained from the Department before undertaking certain health care related projects. Specifically, a person or nursing home is required to obtain a CON prior to undertaking: the construction or other establishment of a new nursing home; a change in the existing bed complement of a nursing home through the addition of one or more beds or change in the classification of licensure of one or more beds; and other projects enumerated in statute. See [§ 44-7-160\(A\)](#). A home health agency shall obtain a CON before licensure. See [§ 44-69-75\(A\)](#). Finally, a person or health care facility is required to obtain a CON prior to undertaking: the construction or other establishment of a hospital; and a change in the existing bed complement of a hospital through the addition of one or more beds or change in the classification of licensure of one or more beds. See [§ 44-7-160\(B\)](#). Effective January 1, 2027, the CON requirements for hospitals are repealed. See [§ 44-7-160\(C\)](#).

HEALTH PLANNING COMMITTEE

The Health Planning Committee advises the Department in the drafting of the South Carolina Health Plan. It is comprised of fourteen members, twelve of whom are appointed by the Governor, which must include at least one member from each congressional district. One member is appointed by the chairman of the Department's Board, and by virtue of their office, the final member is either the South Carolina Consumer Advocate or their designee. Health care consumers, health care financiers (including business and insurance), and health care providers (which must include at least one administrator of a for-profit nursing home) are represented. The Health Planning Committee reviews the South Carolina Health Plan and submits it to the Board of Health and Environmental Control for final revision and adoption. See [§ 44-7-180](#).

STATUTORY REQUIREMENTS

In accordance with [§ 44-7-180\(8\)](#), this Plan contains (1) an *inventory* of existing and CON

approved health care facilities, beds, specified health services and equipment; (2) *projections of need* for additional health care facilities, beds, specified health services, and equipment; (3) *standards for distribution* of health care facilities, beds, specified health services, and equipment ("Certificate of Need Standards"); and (4) a general statement as to the *project review criteria* considered to be the most important in evaluating Certificate of Need applications for each type of facility, service and equipment. Effective May 16, 2023, Act No. 20 substantially revised Certificate of Need requirements. As a result, inventories, projections of need, and standards for many health care facilities, services, and equipment no longer requiring Certificate of Need have been removed from the 2023 update to the South Carolina Health Plan.

(1) INVENTORY

[Chapter 2](#) of this Plan identifies the inventory regions and service areas used in the administration of the Certificate of Need Program. Health care facilities, specified health services, beds and equipment are inventoried where applicable.

(2) PROJECTIONS OF NEED

Chapters 3 through 5 of this Plan discuss the need for additional health care facilities, beds, specified health services and equipment in the State. While the methodologies used to determine these needs vary depending on the type of healthcare facility, bed, specified health service, or equipment, a determination of projected need is calculated for most areas addressed by the Plan.

(3) CERTIFICATE OF NEED STANDARDS

In consultation with the Health Planning Committee, the Department formulated these standards to guide health providers throughout the State. Inclusion of these standards in the application process is designed to give applicants notice of its requirements and to elicit from them a commitment to incorporate these standards into both their applications and finished projects.

(4) PROJECT REVIEW CRITERIA

A general statement has been added to most sections of the Plan setting forth the Project Review Criteria considered to be the most important in reviewing Certificate of Need applications for each type of health care facility, bed, specified health service, and equipment. The staff may reorder the relative importance of the Project Review Criteria no more than one (1) time. The staff's reordering of the relative importance of the Project Review Criteria does not extend the review period. These criteria can be found in [Regulation 61-15](#). Where appropriate, the Plan contains a finding as to whether the benefits of improved accessibility to each such type of facility, service

and equipment may outweigh the adverse effects caused by the duplication of any existing facility, service or equipment.

DISCLAIMERS

- (1) The hyperlinks provided throughout this Plan were checked for accuracy immediately prior to publication. Due to factors outside our control, we cannot guarantee the links will not expire or otherwise become unavailable after publication. Should you be unable to access the hyperlinked information, please feel free to request the information from the Certificate of Need Program via e-mail (coninfo@dhec.sc.gov).
- (2) The population data set forth in this Plan was received from the South Carolina Revenue and Fiscal Affairs Office in October of 2022. The material includes population projections that are subject to the following conditions:

These projections offer only one scenario of future population change using the most current data available. They are intended to demonstrate a likely scenario if future events unfold in a manner that reflects previous trends observed within each group. The model cannot account for unprecedented events that may significantly alter an area's demographic composition in the future. The possible events include large factory openings or closings, changes in technology, public health crises, environmental events, changes in the economy or other conditions that could affect birth rates, death rates, or domestic and international migration. This means that population projections are likely to be more accurate in the immediate future than in distant years into the future.

CHAPTER 2

INVENTORY REGIONS AND SERVICE AREAS

INVENTORY REGIONS

This Plan has adopted the [Department's regions](#) for the purpose of inventorying [Health Care Facilities](#) and [Health Services](#) as designated and enumerated below:

<u>Region</u>	<u>Counties</u>
I - Upstate	Abbeville, Anderson, Cherokee, Greenville, Greenwood, Laurens, McCormick, Oconee, Pickens, Spartanburg, and Union
II - Midlands	Aiken, Barnwell, Chester, Edgefield, Fairfield, Kershaw, Lancaster, Lexington, Newberry, Richland, Saluda and York
III- Pee Dee	Chesterfield, Clarendon, Darlington, Dillon, Florence, Georgetown, Horry, Lee, Marion, Marlboro, Sumter and Williamsburg
IV- Lowcountry	Allendale, Bamberg, Beaufort, Berkeley, Calhoun, Charleston, Colleton, Dorchester, Hampton, Jasper and Orangeburg

NEED FOR HEALTH CARE FACILITIES AND BEDS

This Plan calculates the need for certain Health Care Facilities and Health Services throughout South Carolina based on certain formulae and criteria set forth in detail in this Plan. For example:

- The need for hospital beds is based on the utilization of individual facilities.
- The need for acute psychiatric beds, alcohol and drug abuse beds, and comprehensive rehabilitation beds is based on various service areas and utilization methodologies specified in this Plan.
- The need for long-term care and skilled nursing beds is projected by county.

SERVICE AREAS

In addition to inventory regions, this Plan designates service areas for certain Health Care Facilities and Health Services. These service areas may be comprised of one or more counties. Service areas may cross the inventory regions identified above. The need for a service is analyzed by assessment of existing resources and need in the relevant service area, along with other factors set forth in this Plan, applicable statutes and regulations.

BED TRANSFER BETWEEN AFFILIATED FACILITIES

Given the ever-changing nature of the health care delivery system, affiliated facilities may want to transfer or exchange licensed beds in order to better meet an identified need. [Affiliated facilities](#) are two or more nursing homes or hospitals, whether owned, leased, or who have a formal legal relationship with a central organization and whose relationship has been established for reasons other than for transferring beds. In certain instances such a transfer or exchange of beds could be accomplished in a cost-effective manner and result in a more efficient allocation of health care resources. *A Certificate of Need is required to transfer or exchange beds.* To evaluate a proposal for the transfer or exchange of beds reviewed under the Certificate of Need program, the following criteria must be applied to it:

1. A transfer or exchange of beds may be approved only if there is no overall increase in the number or amount of such beds.
2. A transfer or exchange initiated under this Chapter may only occur within the service area(s) established in this Plan.
3. The facility receiving the beds must demonstrate the need for the additional capacity based on historical and/or projected utilization patterns.
4. The applicants must explain the impact of transferring the beds on the health care delivery system of the county and/or service area from which it is to be taken; any negative impact must be detailed, along with the perceived benefits of the proposal.
5. The facility giving up beds may not use the loss of such beds as justification for a subsequent request to establish or re-establish such beds.
6. A written contract or agreement between the governing bodies of the affiliated facilities approving the transfer or exchange of beds must be included in the Certificate of Need application.
7. Each facility giving up beds must acknowledge in writing that this exchange is permanent; any further transfers would be subject to this same process.

ESTIMATED STATE CIVILIAN POPULATION

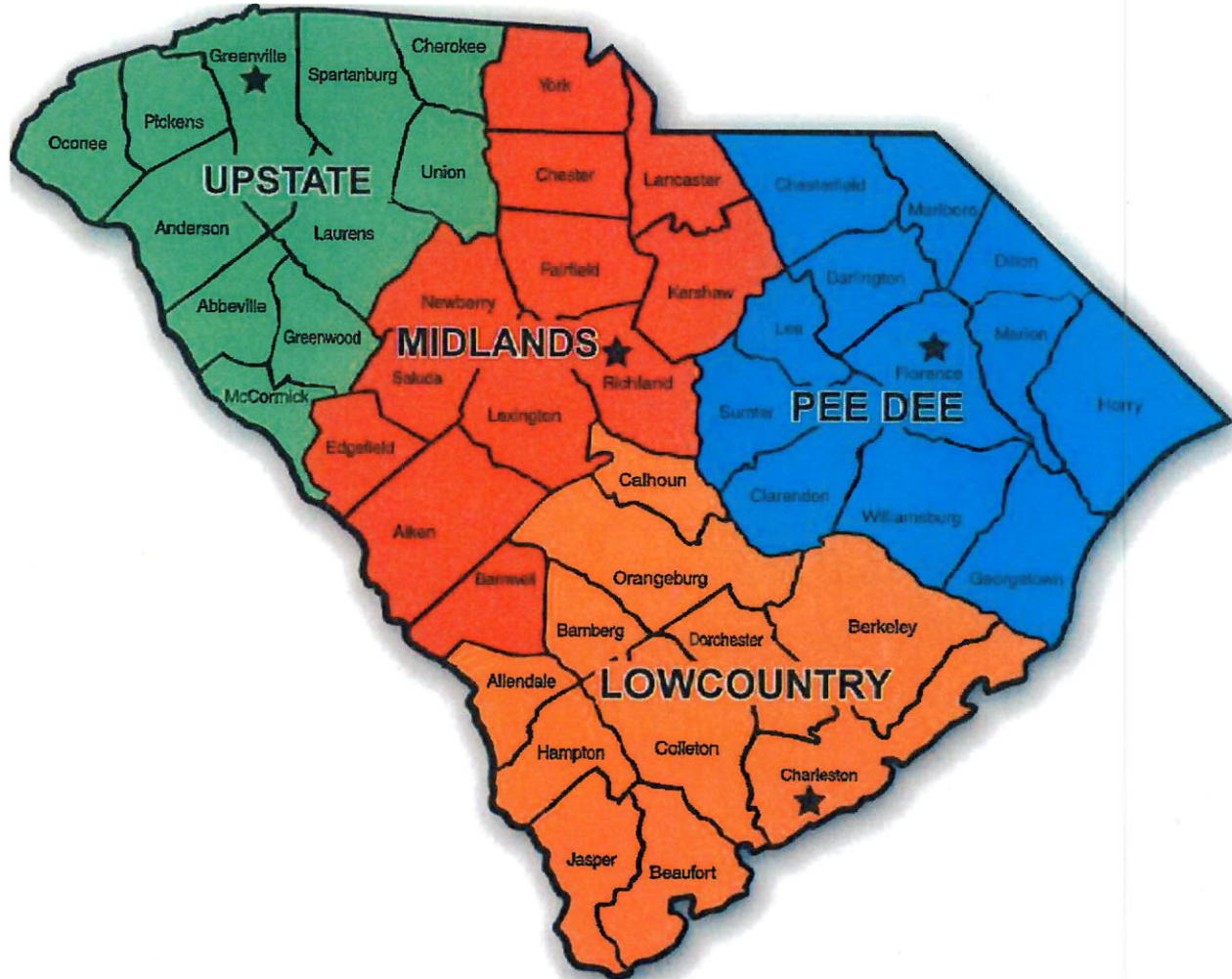
Where these projections were required for calculations, this Plan has been developed using the estimated civilian population of 5,177,874 for 2021 and projected population of 5,460,568 for 2027. All population data (county, planning area, and statewide) were provided by the South Carolina Revenue and Fiscal Affairs Office, Health and Demographics Section, in October 2022.

INVENTORY DATES

Only those facilities reviewed under the Certificate of Need program are included in the inventory. The cut-off date for inclusion of information in this Plan was December 31, 2022. Inventory and utilization data set forth in this Plan is derived from the 2021 Joint Annual Reports (JARs). The period of time in which the individual data was collected is set forth by the reporting entity in its individual JAR submission.

DHEC REGIONS MAP

(Chapter 2)



CHAPTER 3

NURSING HOMES

NURSING HOMES

Nursing homes provide inpatient care for convalescent or chronic disease residents who require nursing care and related medical services. This care is performed under the general direction of persons licensed to practice medicine, surgery, or osteopathy in the State. Facilities furnishing primarily domiciliary care are not included. The licensing list of nursing homes also denotes the facilities that have Alzheimer's units. For more specific detail about nursing homes, refer to [Regulation 61-17](#) (*Standards for Licensing Nursing Homes*).

Since the vast majority of patients utilizing nursing homes are 65 years of age or older, only this segment of the population is used in the need calculations. County bed needs are projected through 2027. A two-year projection is used because nursing homes can be constructed and become operational in two years.

CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

1. Based on observations of methodologies from other states operating a Certificate of Need regime, and recognizing that potential reliance on long-term skilled nursing services increases with age, bed need is calculated on a county basis using the following ratios:
 - a) 10 beds/1,000 population aged 65-74; and
 - b) 58 beds/1,000 population aged 75 and over
2. For each county, these needs are calculated separately. The individual age-group needs are then added together, and the existing bed count subtracted from that total to determine the deficit or surplus of beds.
3. When a county shows surplus beds, additional beds will not be approved, except to allow an individual nursing home to add some additional beds in order to make more economical nursing units. These additions are envisioned as small increments in order to increase the efficiency of the nursing home. This exception for additional beds will not be approved if it results in a three-bed ward. A nursing home may add up to 16 additional beds per nursing unit to create either 44 or 60 bed nursing units, regardless of the projected bed need for the county. The nursing home must document how these additional beds will make a more economical unit(s).

4. Some Institutional Nursing Homes are dually licensed, with some beds restricted to residents of the retirement community and the remaining beds available to the general public. The beds restricted to residents of the retirement community are not eligible to be certified for Medicare or Medicaid. Should such a facility have restricted beds that are inadvertently certified, the facility will be allowed to apply for a Certificate of Need to convert these beds to general nursing home beds, regardless of the projected bed need for that county.

The Nursing Home Inventory and Bed Need Chart are located at the end of this Chapter.

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

The following project review criteria are considered the most important in evaluating Certificate of Need applications for these beds or facilities:

1. Community Need Documentation;
2. Distribution (accessibility);
3. Staff Resources; and
4. Record of the Applicant.

Because nursing homes are located within approximately 30 minutes travel time for the majority of the residents of the State and at least one nursing home is located in every county, no justification exists for approving additional nursing homes or beds that are not indicated as needed in this Plan. The major accessibility problem is caused by the lack of Medicaid funding since the Medicaid Program pays for approximately 65% of all nursing home residents. This Plan projects the need for nursing home beds by county. The benefits of improved accessibility will be equally weighed with the adverse effects of duplication in evaluating Certificate of Need applications for this service.

MEDICAID NURSING HOME PERMITS

The Medicaid Nursing Home Permit Act, formerly known as the Nursing Home Licensing Act of 1987, sets forth a regulatory scheme whereby Medicaid nursing home permits and Medicaid patient days are allocated in South Carolina. A long-term care facility (nursing home) must obtain a Medicaid nursing home permit from the Department in order to serve Medicaid patients. A Medicaid patient is a person who is eligible for Medicaid (Title XIX) sponsored long-term care services. In the annual appropriations act, the South Carolina General Assembly establishes the maximum number of Medicaid patient days the Department is authorized to issue. A Medicaid patient day is a day of nursing home care for which the holder of a Medicaid nursing home permit can receive Medicaid reimbursement. The South Carolina Department of Health and Human Services provides the number of Medicaid patient days available to the Department within thirty (30) days after the effective date of the annual appropriations act.

The Medicaid Patient Days and Medicaid Beds Requested & Authorized Chart is located at the end of this Chapter.

INSTITUTIONAL NURSING HOME (RETIREMENT COMMUNITY NURSING HOME)

An institutional nursing home means a nursing facility {established within the jurisdiction of a larger non-medical institution) that maintains and operates organized facilities and services to accommodate only residents of the institution. These facilities provide necessary services for retirement communities as established by church, fraternal, or other organizations. Such beds must serve only the residents of the housing complex and either be developed after the housing has been established or be developed as a part of a total housing construction program that has documented that the entire complex is one inseparable project.

CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

To be considered under this special bed category, the following criteria must be met:

1. The nursing home must be a part of and located on the campus of the retirement community.
2. It must restrict admissions to campus residents.
3. The facility may not participate in the Medicaid program.

There is no projection of need for this bed category. The applicant must demonstrate that the proposed number of beds is justified and that the facility meets the above qualifications. If approved by the Department, such a facility would be licensed as an "Institutional Nursing Home" and the beds generated by such a project will be placed in the statewide inventory at the end of this Chapter. These beds are not counted against the projected need of the county where the facility is located. For established retirement communities, a generally accepted ratio of nursing home beds to retirement beds is 1:4.

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

The following project review criteria are considered the most important in evaluating Certificate of Need applications for these beds or facilities:

1. Community Need Documentation;
2. Acceptability; and

3. Record of the Applicant.

Because Institutional Nursing Home Beds are used solely by the residents of the retirement community, there is no justification for approving this type of nursing home unless the need can be documented by the retirement center. The benefits of improved accessibility will be equally weighed with the adverse effects of duplication in evaluating Certificate of Need applications for these beds or facilities.

SWING-BEDS

A Certificate of Need is not required to participate in the Swing Bed Program in South Carolina; however, the hospital must obtain Medicare certification.

The Social Security Act (Section 1883(a)(1) . [42 U.S.C. 1395tt]) permits certain small, rural hospitals to enter into a swing bed agreement, under which the hospital can use its beds to provide either acute or Skilled Nursing Facility (SNF) care, as needed. The hospital must be located in a rural area and have fewer than 100 beds.

Medicare Part A covers the services furnished in a swing bed hospital under the SNF Prospective Payment System (PPS). The PPS classifies residents into one of 44 categories for payment purposes. To qualify for SNF-level services, a beneficiary is required to receive acute care as a hospital inpatient for a stay of at least three consecutive days, although it does not have to be from the same hospital as the swing bed. Typical medical criteria include daily physical, occupational and/or speech therapy, IV or nutritional therapy, complex wound treatment, pain management, palliative care, and end-of-life care.

The Swing-Bed Participants Chart is located at the end of this Chapter.

**LONG-TERM CARE INVENTORY
(Chapter 3)**

Region I	# Beds
Abbeville	
Abbeville Nursing Home	94
Anderson	
Brookdale Anderson	44
Condor Health - Anderson 1	181
Iva Post Acute 2	60
Linley Post Acute 3	88
NHC HealthCare Anderson	290
Richard M. Campbell Veterans Nursing Home	220
Piedmont Post Acute 4	88
Cherokee	
Blue Ridge in Brookview House	132
Peachtree Centre 5	151
Greenville	
Arboretum at the Woodlands	30
Brushy Creek Post Acute	144
Carlyle Senior Care of Fountian Inn	60
Gables on Pelham Skilled Nursing and Rehab 6	45
Greenville Post Acute	132
Greer Post Acute 7	133
Linville Courts at the Cascades Verdae	44
Magnolia Manor - Greenville	99
NHC HealthCare Greenville	176
NHC HealthCare Mauldin	180
Patewood Post Acute 8	120
Promedica Skilled Nursing and Rehabilitation Greenville East 9	132
Promedica Skilled Nursing and Rehabilitation Greenville West 10	125
River Falls Post Acute 11	44
Rolling Green Village Health Care Facility	74
Simpsonville Post Acute 12	132
Southpointe Healthcare and Rehabilitation	120
West Village Post Acute 13	132
Greenwood	
Greenwood Transitional Rehabilitation Unit	12
Magnolia Manor - Greenwood	88
NHC HealthCare Greenwood	152
Wesley Commons Health and Rehabilitation Center	80

LONG-TERM CARE INVENTORY
(Chapter 3)

Laurens

Martha Franks Baptist Retirement Community	88
NHC HealthCare Clinton	131
NHC HealthCare Laurens	176
Presbyterian Communities of SC - Clinton (48 institutional beds)	64

McCormick

McCormick Rehabilitation and Healthcare Center	120
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Oconee

Prisma Health Lila Doyle	120
Seneca Health and Rehabilitation Center	132

Pickens

Capstone Rehabilitation and Healthcare Center	60
Clemson Area Retirement Center - Health Care Center	68
Easley Place 14	60
Fleetwood Rehabilitation and Healthcare Center	103
Manna Rehabilitation and Healthcare Center	130
Presbyterian Communities of South Carolina - Foothills	44
PruittHealth - Pickens	44

Spartanburg

Golden Age Operations	44
Inman Operations	40
Lake Emory Post Acute Care	88
Magnolia Manor - Inman	176
Magnolia Manor - Spartanburg	95
Mountainview Nursing Home	132
Physical Rehabilitation & Wellness Center of Spartanburg	120
Rosecrest Rehabilitation and Healthcare	75
Skylyn Nursing and Rehabilitation Center	44
Spartanburg Hospital for Restorative Care SNF	25
Summit Hills Skilled Nursing Facility	33
Valley Falls Terrace	88
White Oak at North Grove	132
White Oak Estates	88
White Oak Manor Spartanburg 15	100
Woodruff Manor	88

Union

Ellen Sagar Nursing Center	113
Promedica Skilled Nursing and Rehabilitation - Union	88

**LONG-TERM CARE INVENTORY
(Chapter 3)**

Region II

Aiken	
Anchor Post Acute 16	120
Carlyle Senior Care of Aiken	86
NHC HealthCare North Augusta	192
Place at Pepper Hill	125
PruittHealth - Aiken	176
PruittHealth - North Augusta	132
Barnwell	
Blackville Healthcare and Rehab	85
PruittHealth - Barnwell	44
Williston Healthcare and Rehab	44
Chester	
MUSC Health Chester Nursing Center	80
Edgefield	
Edgefield Post Acute 17	120
Fairfield	
PruittHealth - Ridgeway	150
Ridgeway Manor Healthcare Center	112
Kershaw	
KershawHealth Karesh Long Term Care 18	132
Springdale Healthcare Center	148
Lancaster	
Lancaster Health and Rehabilitation	142
MUSC Health Lancaster Nursing Center	14
White Oak Manor Lancaster	132
Lexington	
Brian Center of Nursing Care - St. Andrews	108
Heritage at Lowman Rehabilitation & Healthcare	176
Laurel Crest Retirement Community 19	12
Lexington Medical Center Extended Care	388
Millennium Post Acute Rehabilitation	132
NHC HealthCare Lexington	170
Opus Post Acute Rehabilitation	98
Presbyterian Communities of South Carolina - Columbia 20	44
Retreat at Wellmore of Lexington	60
South Carolina Episcopal Home at Still Hope	70
Newberry	
JF Hawkins Nursing Home	118
White Oak Manor Newberry	146

**LONG-TERM CARE INVENTORY
(Chapter 3)**

Richland

CM Tucker Jr. Nursing Center Fewell & Stone Pavilions	252
CM Tucker Jr. Nursing Center Roddey Pavilion	308
Life Care Center of Columbia	179
Midlands Health & Rehabilitation Center	88
NHC HealthCare Parklane	180
Promedica Skilled Nursing and Rehabilitation - Columbia 21	132
PruittHealth - Blythewood	120
PruittHealth - Columbia	150
Rice Estate Rehabilitation and Healthcare	80
Sedgewood Manor Health Care Center	38
White Oak Manor Columbia	120
Wildewood Downs Nursing and Rehabilitation Center	80

Saluda

Saluda Nursing Center	176
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York

Lodge at Wellmore	60
Magnolia Manor - Rock Hill	106
PruittHealth Rock Hill	132
Rock Hill Post Acute Care Center	99
Westminster Health and Rehabilitation Center	66
White Oak Manor York	109
White Oak of Rock Hill	141
Willow Brook Court at Park Pointe Village	40

Region III

Chesterfield

Cheraw Healthcare	120
Rehab Center of Cheraw	104

Clarendon

Lake Marion Nursing Facility	88
Windsor Manor Nursing Home 22	88

Darlington

Betha Baptist Health Care Center 23	88
Medford Nursing Center	88
Morrell Nursing Center	154
Oakhaven Nursing Center	88

**LONG-TERM CARE INVENTORY
(Chapter 3)**

Dillon

Carlyle Senior Care of Fork	111
PruittHealth Dillon	84

Florence

Carlyle Senior Care of Florence	88
Commander Nursing Center	163
Faith Healthcare Center	104
Heritage Home of Florence	132
Honorage Nursing Center	88
Lake City-Scranton Healthcare Center	88
Methodist Manor Healthcare Center	32
Presbyterian Communities of South Carolina - Florence	44
Southland Health Care Center	88

Georgetown

Blue Ridge in Georgetown	84
Lakes at Litchfield Skilled Nursing Center	24
Prince George Healthcare Center	148

Horry

Angel Oak Nursing and Rehabilitation Center 24	88
Brightwater Skilled Nursing Center	67
Compass Post Acute Rehabilitation	95
Conway Manor	190
Loris Rehab and Nursing Center	88
Myrtle Beach Manor	60
NHC HealthCare Garden City	148
PruittHealth Conway at Conway Medical Center	88

Lee

McCoy Memorial Nursing Center	120
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Marion

MUSC Health Mullins Nursing Center	92
Senior Care of Marion	95

Marlboro

Dundee Manor	110
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Sumter

Blue Ridge of Sumter	96
Covenant Place Nursing Center (16 institutional beds)	44
NHC HealthCare Sumter	138
Sumter East Health and Rehabilitation Center	176

Williamsburg

Carlyle Senior Care of Kingstree	96
Dr. Ronald E McNair Nursing and Rehabilitation Center	88

LONG-TERM CARE INVENTORY
(Chapter 3)

Region IV

Allendale

John Edward Harter Nursing Center 44

Bamberg

Pruitthealth - Bamberg 88

Beaufort

Bayview Manor 170

Broad Creek Care Center Skilled Nursing 25

Fraser Health Care 33

Life Care Center of Hilton Head 88

NHC HealthCare Bluffton 120

Preston Health Center 77

Sprenger Healthcare of Bluffton 60

Sprenger Healthcare of Port Royal 65

Berkeley

Viviant Healthcare of Hanahan **25** 135

Lake Moultrie Nursing Home 88

PruittHealth - Moncks Corner 132

Retreat at Wellmore of Daniel Island 60

Calhoun

Calhoun Convalescent Center 120

Charleston*

Bishop Gadsden Episcopal Health Care Center **26** 100

Franke Health Care Center 44

Viviant Healthcare of Charleston **27** 125

Johns Island Post Acute 132

Kempton of Charleston **28** 23

Life Care Center of Charleston 148

Mount Pleasant Manor 132

NHC HealthCare Charleston 132

Riverside Health and Rehab 160

Sandpiper Rehab & Nursing 176

Shem Creek Nursing and Rehab 40

White Oak Manor Charleston, Inc. 176

Colleton

Pruitthealth - Walterboro 132

Veterans Victory House 220

**LONG-TERM CARE INVENTORY
(Chapter 3)**

Dorchester

Hallmark Healthcare Center	88
Oakbrook Health and Rehabilitation Center	88
Presbyterian Communities of South Carolina-Summerville	88
St. George Healthcare Center	88

Hampton

PruittHealth Estill	104
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Jasper

Ridgeland Nursing Center	88
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Orangeburg

Edisto Post Acute	113
Jolley Acres Healthcare Center	60
The Oaks Healthcare 29	122
PruittHealth - Orangeburg	88

Statewide Total

20,670

- 1** Formerly known as Ellenburg Nursing Center.
- 2** Formerly known as Iva Rehabilitation and Healthcare Center.
- 3** Formerly known as Linley Park Rehabilitation and Healthcare.
- 4** Formerly known as Southern Oaks Rehabilitation and Healthcare Center.
- 5** CON SC-20-28 issued on 7-15-2020 for the conversion of 40 assisted living beds to skilled nursing beds for a total of 151 skilled nursing beds.
- 6** Formerly known as Brookdale Greenville.
- 7** Formerly known as Greer Rehabilitation and Healthcare Center.
- 8** Formerly known as Patewood Rehabilitation and Healthcare Center.
- 9** Formerly known as Heartland Care Center - Greenville East.
- 10** Formerly known as Heartland Care Center - Greenville West.
- 11** Formerly known as River Falls Rehabilitation and Healthcare Center.
- 12** Formerly known as Simpsonville Rehabilitation and Healthcare Center.
- 13** Formerly known as Poinsett Rehabilitation and Healthcare Center.
- 14** Formerly known as Brookdale Easley.
- 15** CON SC-21-20 issued on 5/18/2021 for the construction of a new 65,000 sf nursing home for the replacement of the current White Oak Manor - Spartanburg Home and add the addition of 40 skilled nursing beds for a total of 100 skilled nursing beds.
- 16** Formerly known as Anchor Rehabilitation and Healthcare Center of Aiken.

LONG-TERM CARE INVENTORY
(Chapter 3)

17 Formerly known as Ridge Rehabilitation and Healthcare Center.

18 CON SC-20-39 issued on 9/16/2020 for the construction of a 87,690 sf facility for the replacement of the current facility and the addition of 36 skilled nursing beds for a total of 132 skilled nursing beds.

19 CON SC-19-103 issued September 12, 2019 for conversion of 12 Institutional Nursing beds to 12 Non-Institutional Nursing beds at a total project cost of \$50,000.

20 CON SC-20-15 issued 5/15/2020 for renovations with no additional bed count.

21 Formerly known as Heartland of Columbia Rehabilitation & Nursing Center.

22 CON SC-19-117 issued 12/10/2019 for the construction for the replacement of the current facility and the addition of 24 skilled nursing beds for a total of 88 skilled nursing beds.

23 CON SC-19-15 issued February 12, 2019 for construction of a 44,804 sf building for the replacement of an existing 88-bed skilled nursing facility, with no increase in beds.

24 Formerly known as Grand Strand Rehab and Nursing Center.

25 Formerly known as Heartland of West Ashley Rehabilitation & Nursing Center.

26 CON SC-19-23 issued April 10, 2019 for construction of a new health care facility that will offer a 100 bed health care center, which includes an additional 50 skilled nursing beds.

27 Formerly known as Heartland of West Ashley Rehabilitation & Nursing Center.

28 CON SC-21-72 issued November 16, 2021 for the construction for the establishment of a 23-bed skilled nursing facility at a total project cost of \$7,703,284; facility licensed March 3, 2022.

29 Formerly known as Methodist Oaks.

* Savannah Grace at the Palms of Mt. Pleasant closed on 2/25/2022. Forty-eight (48) beds removed from inventory.

*North Charleston Post Acute 12/21/2017 decision granting approval for the construction of a new 70 bed skilled nursing facility was under appeal. Applicant withdrew the application prior to court decision. Facility has been removed from inventory.

**LONG-TERM CARE BED NEED
(Chapter 3)**

Regions	2024 Population (Thousands) Age 65-74 Years	Bed Need (Pop x 10)	2024 Population (Thousands) Age 75+ Years	Bed Need (Pop x 58)	Existing Beds	Total # Beds to be Added
Region I						
Abbeville	3.35	34	2.71	157	94	97
Anderson	23.66	237	18.41	1,068	971	334
Cherokee	6.24	62	4.64	269	283	48
Greenville	58.54	585	43.75	2,538	1,937	1,186
Greenwood	8.10	81	6.92	401	332	150
Laurens 1	8.07	81	5.99	347	411	17
McCormick	2.01	20	1.72	100	120	0
Oconee	12.47	125	9.15	530	252	403
Pickens	13.56	136	10.95	635	509	262
Spartanburg	34.90	349	25.90	1,502	1,368	483
Union	3.50	35	2.52	146	201	(20)
Region I Total	174.41	1,744	132.65	7,694	6,478	2,960
Region II						
Aiken	22.57	226	17.50	1,015	831	410
Barnwell	2.49	25	1.87	108	173	(40)
Chester	3.83	38	2.80	163	80	121
Edgefield	3.40	34	2.79	162	120	76
Fairfield	3.48	35	2.32	135	262	(93)
Kershaw	8.53	85	6.21	360	280	166
Lancaster	14.33	143	12.79	742	288	597
Lexington	34.36	344	24.91	1,445	1,258	530
Newberry	4.85	49	3.77	219	264	3
Richland	39.01	390	26.77	1,553	1,727	216
Saluda	2.50	25	2.21	128	176	(23)
York	31.42	314	21.23	1,231	753	793
Region II Total	170.78	1,708	125.18	7,260	6,212	2,756
Region III						
Chesterfield	5.46	55	4.19	243	224	74
Clarendon	5.02	50	4.08	237	176	111
Darlington	8.02	80	6.17	358	418	20
Dillon	3.32	33	2.35	137	195	(25)
Florence	15.28	153	11.50	667	827	(7)
Georgetown	12.05	121	9.37	543	256	408
Horry	77.96	780	47.12	2,733	824	2,689
Lee	2.04	20	1.49	86	120	(13)
Marion	3.86	39	2.88	167	187	18
Marlboro	3.00	30	2.25	131	110	51
Sumter 2	11.47	115	8.61	499	438	176
Williamsburg	4.00	40	3.12	181	184	37
Region III Total	151.49	1,515	103.13	5,981	3,959	3,537
Region IV						
Allendale	1.04	10	0.83	48	44	14
Bamberg	1.82	18	1.53	89	88	19
Beaufort	35.45	354	30.44	1,766	638	1,482
Berkeley	25.61	256	17.50	1,015	415	856
Calhoun	2.08	21	1.76	102	120	3
Charleston	50.41	504	35.35	2,050	1,388	1,166
Colleton	4.86	49	3.43	199	352	(104)
Dorchester	17.72	177	12.21	708	352	533
Hampton	2.20	22	1.75	101	104	19
Jasper	5.83	58	3.53	205	88	175
Orangeburg	10.43	104	8.53	495	383	216
Region IV Total	157.44	1,574	116.86	6,778	3,972	4,380
Statewide Totals	654.13	6,541	478	27,714	20,621	13,634

1 48 institutional beds at Presbyterian Communities of SC - Clinton are not included in Laurens County inventory.
2 16 institutional beds at Covenant Place Nursing Center are not included in Sumter County inventory.

Medicaid Patient Days and Medicaid Beds Requested and Authorized:

Year	# Days Requested	Beds	# Days Authorized	Beds	# Days Difference
1988-1989	3,032,839	8,309	2,971,811	8,142	61,028
1989-1990	3,644,248	9,984	3,644,248	9,984	0
1990-1991	3,709,814	10,163	3,659,965	10,028	49,849
1991-1992	3,856,833	10,567	3,659,965	10,028	196,868
1992-1993	3,976,576	10,895	3,806,382	10,429	170,194
1993-1994	4,012,359	10,993	3,856,382	10,566	155,977
1994-1995	4,023,690	11,024	3,892,882	10,665	130,808
1995-1996	3,969,681	10,876	3,892,882	10,665	76,799
1996-1997	4,072,519	11,158	4,002,382	10,965	70,137
1997-1998	4,119,753	11,287	4,097,282	11,225	22,471
1998-1999	4,265,182	11,685	4,265,182	11,685	0
1999-2000	4,367,134	11,965	4,341,832	11,895	25,302
2000-2001	4,420,522	12,111	4,378,332	11,995	42,190
2001-2002	4,473,170	12,255	4,275,998	11,715	197,172
2002-2003	4,340,158	11,891	4,205,553	11,522	134,605
2003-2004	4,304,160	11,792	4,205,553	11,522	98,607
2004-2005	4,294,977	11,767	4,205,553	11,522	89,424
2005-2006	4,291,812	11,758	4,205,553	11,522	86,259
2006-2007	4,283,209	11,735	4,205,553	11,522	77,656
2007-2008	4,263,785	11,682	4,205,553	11,522	58,232
2008-2009	4,231,047	11,592	4,205,553	11,522	25,494
2009-2010	4,215,522	11,549	4,205,553	11,522	9,969
2010-2011	4,217,584	11,555	4,205,553	11,522	12,031
2011-2012	4,250,190	11,644	3,771,878	10,333	478,312
2012-2013	4,268,032	11,693	3,815,921	10,455	452,111
2013-2014	4,132,731	11,323	3,815,921	10,455	316,810
2014-2015	4,094,917	11,219	3,815,921	10,455	278,996
2015-2016	4,112,740	11,268	3,815,921	10,455	296,819
2016-2017	4,006,470	10,977	3,815,921	10,455	190,549
2017-2018	4,020,582	11,015	3,815,921	10,455	204,661
2018-2019	4,114,439	11,272	3,864,665	10,588	249,774
2019-2020	4,259,602	11,670	3,864,665	10,588	394,937
2020-2021	4,259,602	11,670	0 ¹	0	4,452,015
2021-2022	4,190,765	11,482	3,864,665	10,588	326,100
2022-2023	4,259,602	11,670	3,864,665	10,588	394,937

¹ No new Medicaid Permits were issued for 2020-2021 in light of Executive Order 2020-11.

SWING-BED PARTICIPANTS*
(Chapter 3)

FACILITY	TOTAL BEDS	SWING BEDS	2021 ADMISSIONS	2021 PT DAYS	ADC
Abbeville Area Medical Center	25	25	101	1,115	3.05
Allendale County Hospital 1	25	25	NR	NR	#VALUE!
McLeod Health Cheraw	59	49	27	418	1.15
Edgefield County Healthcare 2	14	14	83	1,698	4.65
Hampton Regional Medical Center	32	10	10	246	0.67
McLeod Health Clarendon	81	18	26	308	0.84
McLeod Health Medial Center Dillon	79	40	27	205	
MUSC Health Marion Medical Center	124	10	0	0	0.00
McLeod Medical Center - Darlington 3	23	0	0	0	0.00
Newberry County Memorial Hospital	90	20	15	119	0.33
Union Medical Center	85	0	0	0	--
Williamsburg Regional Hospital	25	10	26	492	1.35

* E-19-02 issued for the permanent closure of Fairfield Memorial Hospital effective December 2018. Fairfield Memorial removed from inventory.

1 No 2021 JAR completed

2 Formerly Edgefield County Hospital.

3 Facility issued license for decrease in general beds from 49 to 0 and a decrease in swing beds from 24 to 0. Effective 02/02/2021, facility is only licensed for 23 psychiatric beds.

CHAPTER 4

HOME HEALTH AGENCIES

HOME HEALTH

[Home Health Agencies](#)

Home Health Agency means a public, nonprofit, or proprietary organization, whether owned or operated by one or more persons or legal entities, which furnishes or offers to furnish home health services. Home health services means those items and services furnished to an individual by a home health agency, or by others under arrangement with the home health agency, on a visiting basis and except for (d) below, in a place of temporary or permanent residence used as the individual's home as follows:

Part-time or intermittent skilled nursing care as ordered by a physician or an Advanced Practice Registered Nurse (APRN) or Physician Assistant (PA) and provided by or under the supervision of a registered nurse and at least one other therapeutic service listed below: (a) physical, occupational, or speech therapy; (b) medical social services, home health aide services, and other therapeutic services; (c) medical supplies as indicated in the treatment plan and the use of medical appliances, to include durable medical equipment and (d) any of the above items and services provided on an outpatient basis under arrangements made by the home health agency with a hospital, nursing home or rehabilitation center and the furnishing of which involves the use of equipment of such a nature that the items/services cannot readily be made available to the individual in his/her home, or which are furnished at one of the above facilities while the patient is there to receive such items or services. Transportation of the individual in connection with any such items or services is not included. For more specific details about home health agencies, refer to Regulation 61-77 (*Standards for Licensing Home Health Agencies*).

CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

1. An applicant must propose home health services to cover the geographic area of an entire county and agree to serve residents throughout the entire county.
2. An application is required for the counties identified by the applicant in which services are to be provided.
3. A new home health agency or expansion of an existing home health agency

may be approved if an applicant can demonstrate it will serve 50 or more patients projected to be in need in non-rural counties, or 25 or more patients projected to be in need in rural counties, through evidence that may include, but would not be limited to, the following:

- a. Letters of support that identify need for additional home health services from physicians and other referral sources.
 - b. Evidence of underutilization of home health services.
 - c. Evidence of limited scope home health agency service including skilled nursing, physical therapy, occupational therapy, speech therapy, home health aides, and medical social workers.
 - d. Evidence of the denial or delay in the provision of home health services, including but not limited to long waiting lists or delays which exceed industry standards.
 - e. Evidence that one or more existing home health agencies has failed to meet the minimum patient service requirements set forth in Standard 8 of this section of the Plan within two years of the initiation of patient services after receiving a home health license.
4. For the purposes of this Section, a rural county shall mean a county with a population of less than 50,000, according to the most recent projections of the South Carolina Revenue and Fiscal Affairs office as of the time the current Plan was adopted.
 5. All home health agency services (Skilled Nursing, Physical Therapy, Occupational Therapy, Speech Therapy, Home Health Aide, and Medical Social Worker) should be available within a county. If there is no hospital in a county and the existing licensed home health agencies between them do not provide all of the services identified above, this may be cited as potential justification for the approval of an additional agency that intends to offer these services.
 6. Specialty home health providers are exempt from the need calculation applicable to full-service home health agencies, but are otherwise subject to Certificate of Need.
 7. The applicant should have a track record that demonstrates a commitment to quality services. There should be no history of prosecution, consent order,

abandonment of patients in other business operations, or loss of license. However, any consent orders or loss of licenses related to licenses that were obtained from the Department between July 1, 2013 and May 22, 2014 without a Certificate of Need shall not be grounds for denial of a Certificate of Need application pursuant to this Section. The applicant must provide a list of all licensed home health agencies it operates and the state(s) where it operates them.

8. The applicant must document that it can serve at least 25 patients annually in each rural county for which it is licensed and 50 patients annually in each non-rural county for which it is licensed within two years of initiation of services. The applicant must assure the Department that, should it fail to reach this threshold number two years after initiation of services in a county, it will voluntarily relinquish its license for that county.
9. Nothing in this Section is intended to restrict the ability of the Department to approve more than one new Home Health Agency in a county at any given time.

The Home Health Agency Inventory Chart is located at the end of this Chapter.

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

The following project review criteria, as outlined in Chapter 8 of [Regulation 61-15](#), are considered to be the most important in reviewing Certificate of Need applications for this service:

1. Community Need Documentation;
2. Distribution (Accessibility); and
3. Medically Underserved Groups.

The benefits of improved accessibility outweigh the adverse effects caused by the duplication of any existing service.

Pediatric Home Health Agencies

Due to the limited number of home health providers available to treat children 18 years or younger, an exception to the above criteria may be made for a Certificate of Need for a Home Health Agency restricted to providing intermittent home health skilled nursing services to patients 18 years or younger. The license for the agency will be restricted to serving children

18 years or younger and will ensure access to necessary and appropriate intermittent home health skilled nursing services to these patients. Any such approved agency will not be counted in the county inventories for need projection purposes.

CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

1. An application is required for the counties identified by the applicant in which specialized service to pediatric patients are to be provided.
2. The applicant must document that there is an unmet need for this service in the county of application, and the agency will limit such services to the pediatric population 18 years or younger.
3. The applicant must document the full range of services that they intend to provide to pediatric patients.

Continuing Care Retirement Community Home Health Agencies

A licensed continuing care retirement community that also incorporates a skilled nursing facility may provide home health services and *does not require Certificate of Need review provided:*

- a. The continuing care retirement furnishes or offers to furnish home health services only to residents who reside in living units provided by the continuing care retirement community pursuant to a continuing care contract;
- b. The continuing care retirement community maintains a current license and meets the applicable home health agency licensing standards; and
- c. Residents of the continuing care retirement community may choose to obtain home health services from other licensed home health agencies.

Staff from other areas of the continuing care retirement community may deliver the home health services, but at no time may staffing levels in any area of the continuing care retirement community fall below minimum licensing standards or impair the services provided. If the continuing care retirement community includes charges for home health services in its base contract, it is prohibited from billing additional fees for those services. Continuing care retirement communities certified for Medicare or Medicaid, or both, must comply with government reimbursement requirements concerning charges for home health services. The continuing care retirement

community shall not bill in excess of its costs. These costs will be determined on non-facility-based Medicare and/or Medicaid standards.

HOME HEALTH AGENCY INVENTORY

Region I

Facility by County

Abbeville County

ADVANCED NURSING SOLUTIONS **5**
AMEDISYS HOME HEALTH OF CLINTON
CENTERWELL HOME HEALTH-ANDERSON **7**
HEALTH RELATED HOME CARE
HOMECARE OF HOSPICECARE OF THE PIEDMONT **8**
HOME HEALTH SERVICES OF SELF REGIONAL HEALTHCARE
INTERIM HEALTHCARE OF THE UPSTATE
INTRAMED PLUS (Limited to home infusion nursing services) **12**
MEDICAL SERVICES OF AMERICA HOME HEALTH
NHC HOMECARE-GREENWOOD
OPTUM WOMEN'S AND CHILDREN'S HEALTH LLC (Obstetric Patients Only) **13**
PALMETTO INFUSION SERVICES (Limited to Home Infusion Nursing Services)
PRISMA HEALTH HOME HEALTH-UPSTATE **14**
PRUITTHEALTH @ HOME - COLUMBIA

Anderson County

ADVANCED NURSING SOLUTIONS **1**
AMEDISYS HOME HEALTH OF CLINTON
ANMED HEALTH HOME HEALTH AGENCY
BAYADA HOME HEALTH CARE-GREENVILLE
BIOSCRIP INFUSION SERVICES (May Serve Pediatric Patients Only) **26**
CENTERWELL HOME HEALTH-ANDERSON **7**
CENTERWELL HOME HEALTH-GREENVILLE **15**
HEALTH RELATED HOME CARE
INTERIM HEALTHCARE OF THE UPSTATE
INTRAMED PLUS (Limited to home infusion nursing services) **12**
MEDICAL SERVICES OF AMERICA HOME HEALTH
NHC HOMECARE-LAURENS
OPTUM WOMEN'S AND CHILDREN'S HEALTH LLC (Obstetric Patients Only) **13**
PALMETTO INFUSION SERVICES (Limited to Home Infusion Nursing Services)
PRISMA HEALTH HOME HEALTH-UPSTATE
PROVIDENCE CARE AT HOME
PRUITTHEALTH @ HOME - COLUMBIA
ST FRANCIS HOSPITAL HOME CARE
WELL CARE HOME HEALTH OF THE UPSTATE

Cherokee County

ADVANCED NURSING SOLUTIONS **5**
AMEDISYS HOME HEALTH OF CLINTON
BIOSCRIP INFUSION SERVICES (May Serve Pediatric Patients Only) **26**
CENTERWELL HOME HEALTH-ANDERSON **7**
CENTERWELL HOME HEALTH-GREENVILLE **15**
CENTERWELL HOME HEALTH-UPSTATE **16**
INTERIM HEALTHCARE OF THE UPSTATE

INTRAMED PLUS (Limited to home infusion nursing services) **12**
MEDICAL SERVICES OF AMERICA HOME HEALTH
NEIGHBORS CARE HOME HEALTH AGENCY AN AMEDISYS COMPANY
OPTUM WOMEN'S AND CHILDREN'S HEALTH LLC (Obstetric Patients Only) **13**
PALMETTO INFUSION SERVICES (Limited to Home Infusion Nursing Services)
PROVIDENCE CARE AT HOME
PRUITTHEALTH @ HOME - COLUMBIA
SPARTANBURG MEDICAL CENTER HOME HEALTH
WELL CARE HOME HEALTH OF THE UPSTATE

Greenville County

ADVANCED NURSING SOLUTIONS **1**
AMEDISYS HOME HEALTH OF CLINTON
BAYADA HOME HEALTH CARE-GREENVILLE
BIOSCRIP INFUSION SERVICES (May Serve Pediatric Patients Only) **26**
BRIGHTSTAR OF SPARTANBURG
CENTERWELL HOME HEALTH-ANDERSON **7**
CENTERWELL HOME HEALTH-GREENVILLE **15**
HEALTH RELATED HOME CARE
INTERIM HEALTHCARE OF THE UPSTATE
INTRAMED PLUS (Limited to home infusion nursing services) **12**
MEDICAL SERVICES OF AMERICA HOME HEALTH
NHC HOMECARE-LAURENS
OPTUM WOMEN'S AND CHILDREN'S HEALTH LLC (Obstetric Patients Only) **13**
PALMETTO INFUSION SERVICES (Limited to Home Infusion Nursing Services)
PRISMA HEALTH HOME HEALTH-UPSTATE
PROVIDENCE CARE AT HOME
PRUITTHEALTH @ HOME - COLUMBIA
ROLLING GREEN VILLAGE HOME HEALTH AGENCY (Serving continuing care retirement
community at Rolling Green Village residents only)
SPARTANBURG MEDICAL CENTER HOME HEALTH
ST FRANCIS HOSPITAL HOME CARE
WELL CARE HOME HEALTH OF THE UPSTATE

Greenwood County

ADVANCED NURSING SOLUTIONS **4**
AMEDISYS HOME HEALTH OF CLINTON
CENTERWELL HOME HEALTH-ANDERSON **7**
HEALTH RELATED HOME CARE
HOMECARE OF HOSPICECARE OF THE PIEDMONT **8**
HOME HEALTH SERVICES OF SELF REGIONAL HEALTHCARE
INTRAMED PLUS (Limited to home infusion nursing services) **12**
MEDICAL SERVICES OF AMERICA HOME HEALTH
NHC HOMECARE-GREENWOOD
OPTUM WOMEN'S AND CHILDREN'S HEALTH LLC (Obstetric Patients Only) **13**
PALMETTO INFUSION SERVICES (Limited to Home Infusion Nursing Services)
PRISMA HEALTH HOME HEALTH-UPSTATE
PRUITTHEALTH @ HOME - COLUMBIA
WESLEY COMMONS HOME HEALTH CARE (Serving Campus Residents Only)

Laurens County

ADVANCED NURSING SOLUTIONS **2**
AMEDISYS HOME HEALTH OF CLINTON
BIOSCRIP INFUSION SERVICES (May Serve Pediatric Patients Only) **26**
CENTERWELL HOME HEALTH-ANDERSON **7**
CENTERWELL HOME HEALTH-GREENVILLE **15**
HEALTH RELATED HOME CARE
HOMECARE OF HOSPICECARE OF THE PIEDMONT **8**
HOME HEALTH SERVICES OF SELF REGIONAL HEALTHCARE
INTERIM HEALTHCARE OF THE UPSTATE
INTRAMED PLUS (Limited to home infusion nursing services) **12**
MEDICAL SERVICES OF AMERICA HOME HEALTH
NHC HOMECARE-LAURENS
OPTUM WOMEN'S AND CHILDREN'S HEALTH LLC (Obstetric Patients Only) **13**
PALMETTO INFUSION SERVICES (Limited to Home Infusion Nursing Services)
PRESBYTERIAN COMMUNITIES OF SC HOME HEALTH AGENCY (Serving Continuing Care Retirement Community Campuses Only)
PRISMA HEALTH HOME HEALTH-UPSTATE **14**
PROVIDENCE CARE AT HOME
PRUITTHEALTH @ HOME - COLUMBIA
WELL CARE HOME HEALTH OF THE UPSTATE

McCormick County

ADVANCED NURSING SOLUTIONS **4**
AMEDISYS HOME HEALTH OF LEXINGTON
CENTERWELL HOME HEALTH-ANDERSON **7**
HEALTH RELATED HOME CARE
HOMECARE OF HOSPICECARE OF THE PIEDMONT **8**
HOME HEALTH SERVICES OF SELF REGIONAL HEALTHCARE
INTRAMED PLUS (Limited to home infusion nursing services) **12**
MEDICAL SERVICES OF AMERICA HOME HEALTH
NHC HOMECARE-GREENWOOD
OPTUM WOMEN'S AND CHILDREN'S HEALTH LLC (Obstetric Patients Only) **13**
PALMETTO INFUSION SERVICES (Limited to Home Infusion Nursing Services)
PRUITTHEALTH @ HOME - LOW COUNTRY

Oconee County

ADVANCED NURSING SOLUTIONS **2**
AMEDISYS HOME HEALTH OF CLINTON
BIOSCRIP INFUSION SERVICES (May Serve Pediatric Patients Only) **26**
BRIGHTSTAR CARE OF PIEDMONT/EASLEY **17**
CENTERWELL HOME HEALTH-ANDERSON **7**
CENTERWELL HOME HEALTH-GREENVILLE **15**
INTERIM HEALTHCARE OF THE UPSTATE **16**
INTRAMED PLUS (Limited to home infusion nursing services) **12**
MEDICAL SERVICES OF AMERICA HOME HEALTH
NHC HOMECARE-LAURENS
OPTUM WOMEN'S AND CHILDREN'S HEALTH LLC (Obstetric Patients Only) **13**
PALMETTO INFUSION SERVICES (Limited to Home Infusion Nursing Services)

PRISMA HEALTH HOME HEALTH-UPSTATE
PRUITTHEALTH @ HOME - COLUMBIA
WELL CARE HOME HEALTH OF THE UPSTATE

Pickens County

ADVANCED NURSING SOLUTIONS **3**
AMEDISYS HOME HEALTH OF CLINTON
ANMED HEALTH HOME HEALTH AGENCY
BIOSCRIP INFUSION SERVICES (May Serve Pediatric Patients Only) **26**
BRIGHTSTAR CARE OF PIEDMONT/EASLEY **17**
CENTERWELL HOME HEALTH-ANDERSON **7**
CENTERWELL HOME HEALTH-GREENVILLE **15**
INTERIM HEALTHCARE OF THE UPSTATE
INTRAMED PLUS (Limited to home infusion nursing services) **12**
MEDICAL SERVICES OF AMERICA HOME HEALTH
NHC HOMECARE-LAURENS
OPTUM WOMEN'S AND CHILDREN'S HEALTH LLC (Obstetric Patients Only) **13**
PALMETTO INFUSION SERVICES (Limited to Home Infusion Nursing Services)
PRESBYTERIAN COMMUNITIES OF SC HOME HEALTH AGENCY (Serving Continuing Care
Retirement Community Campuses Only)
PRISMA HEALTH HOME HEALTH-UPSTATE
PROVIDENCE CARE AT HOME
PRUITTHEALTH @ HOME - COLUMBIA
ST FRANCIS HOSPITAL HOME CARE
WELL CARE HOME HEALTH OF THE UPSTATE

Spartanburg County

ADVANCED NURSING SOLUTIONS **2**
AMEDISYS HOME HEALTH OF CLINTON
BAYADA HOME HEALTH CARE-GREENVILLE **15**
BIOSCRIP INFUSION SERVICES (May Serve Pediatric Patients Only)
BRIGHTSTAR OF SPARTANBURG
CENTERWELL HOME HEALTH-ANDERSON **7**
CENTERWELL HOME HEALTH-GREENVILLE **15**
INTERIM HEALTHCARE OF THE UPSTATE
INTRAMED PLUS (Limited to home infusion nursing services) **12**
MEDICAL SERVICES OF AMERICA HOME HEALTH
NHC HOMECARE-LAURENS
OPTUM WOMEN'S AND CHILDREN'S HEALTH LLC (Obstetric Patients Only) **13**
PALMETTO INFUSION SERVICES (Limited to Home Infusion Nursing Services)
PRISMA HEALTH HOME HEALTH-UPSTATE **14**
PROVIDENCE CARE AT HOME
PRUITTHEALTH @ HOME - COLUMBIA
SPARTANBURG MEDICAL CENTER HOME HEALTH
ST FRANCIS HOSPITAL HOME CARE
WELL CARE HOME HEALTH OF THE UPSTATE

Union County

ADVANCED NURSING SOLUTIONS **2**
AMEDISYS HOME HEALTH OF CLINTON

BIOSCRIP INFUSION SERVICES (May Serve Pediatric Patients Only) **26**
INTERIM HEALTHCARE OF THE UPSTATE
INTRAMED PLUS (Limited to home infusion nursing services) **12**
MEDICAL SERVICES OF AMERICA HOME HEALTH
NHC HOMECARE-PIEDMONT
OPTUM WOMEN'S AND CHILDREN'S HEALTH LLC (Obstetric Patients Only) **13**
PALMETTO INFUSION SERVICES (Limited to Home Infusion Nursing Services)
PRUITTHEALTH @ HOME - COLUMBIA
SPARTANBURG MEDICAL CENTER HOME HEALTH
WELL CARE HOME HEALTH OF THE UPSTATE

Region II

Facility by County

Aiken County

ADVANCED NURSING SOLUTIONS **6**
AMEDISYS HOME HEALTH OF LEXINGTON
CENTERWELL HOME HEALTH-MIDLANDS **18**
ENHABIT HOME HEALTH AIKEN **19**
INTRAMED PLUS (Limited to home infusion nursing services) **12**
MEDICAL SERVICES OF AMERICA HOME HEALTH
NHC HOMECARE-AIKEN
OPTUM WOMEN'S AND CHILDREN'S HEALTH LLC (Obstetric Patients Only) **13**
PALMETTO INFUSION SERVICES (Limited to Home Infusion Nursing Services)
PRUITTHEALTH @ HOME - LOW COUNTRY
TRINITY HOME HEALTH OF AIKEN
UNIVERSITY HOME HEALTH SERVICES **20**
WELL CARE HOME HEALTH OF THE MIDLANDS

Barnwell County

ADVANCED NURSING SOLUTIONS **6**
AMEDISYS HOME HEALTH OF LEXINGTON
CENTERWELL HOME HEALTH-MIDLANDS **18**
INTRAMED PLUS (Limited to home infusion nursing services) **12**
MEDICAL SERVICES OF AMERICA HOME HEALTH
NHC HOMECARE-AIKEN
OPTUM WOMEN'S AND CHILDREN'S HEALTH LLC (Obstetric Patients Only) **13**
PALMETTO INFUSION SERVICES (Limited to Home Infusion Nursing Services)
PRUITTHEALTH @ HOME - LOW COUNTRY
TRINITY HOME HEALTH OF AIKEN
VNA OF GREATER BAMBERG **21**

Chester County

ADVANCED NURSING SOLUTIONS **3**
BAYADA HOME HEALTH CARE-ROCK HILL **24**
BIOSCRIP INFUSION SERVICES **26**
CENTERWELL HOME HEALTH-MIDLANDS **18**
CENTERWELL HOME HEALTH-UPSTATE **16**

HOME CARE OF LANCASTER
INTERIM HEALTHCARE OF ROCK HILL
INTRAMED PLUS (Limited to home infusion nursing services) **12**
MEDICAL SERVICES OF AMERICA HOME HEALTH
NEIGHBORS CARE HOME HEALTH AGENCY AN AMEDISYS COMPANY
NHC HOMECARE-PIEDMONT **25**
OPTUM WOMEN'S AND CHILDREN'S HEALTH LLC (Obstetric Patients Only) **13**
PALMETTO INFUSION SERVICES (Limited to Home Infusion Nursing Services)
PHC HOME HEALTHCARE
PROVIDENCE CARE AT HOME
PROVIDENCE HOME HEALTH, LLC **27**
PRUITTHEALTH @ HOME - COLUMBIA
WELL CARE HOME HEALTH OF THE UPSTATE

Edgefield County

ADVANCED NURSING SOLUTIONS **6**
AMEDISYS HOME HEALTH OF LEXINGTON
CENTERWELL HOME HEALTH-MIDLANDS **18**
HEALTH RELATED HOME CARE
HOME HEALTH SERVICES OF SELF REGIONAL HEALTHCARE
INTRAMED PLUS (Limited to home infusion nursing services) **12**
MEDICAL SERVICES OF AMERICA HOME HEALTH
NHC HOMECARE-AIKEN
OPTUM WOMEN'S AND CHILDREN'S HEALTH LLC (Obstetric Patients Only) **13**
PALMETTO INFUSION SERVICES (Limited to Home Infusion Nursing Services)
PRUITTHEALTH @ HOME - LOW COUNTRY
TRINITY HOME HEALTH OF AIKEN
UNIVERSITY HOME HEALTH SERVICES **20**

Fairfield County

ADVANCED NURSING SOLUTIONS **6**
AMEDISYS HOME HEALTH OF CAMDEN
CENTERWELL HOME HEALTH-MIDLANDS **18**
INTRAMED PLUS (Limited to home infusion nursing services) **12**
MEDICAL SERVICES OF AMERICA HOME HEALTH
NHC HOMECARE-MIDLANDS
OPTUM WOMEN'S AND CHILDREN'S HEALTH LLC (Obstetric Patients Only) **13**
PALMETTO INFUSION SERVICES (Limited to Home Infusion Nursing Services)
PRECIOUS JEWELS MEDICAL AND HEALTH SERVICES, LLC **22**
PRUITTHEALTH @ HOME - COLUMBIA
WELL CARE HOME HEALTH OF THE MIDLANDS

Kershaw County

ADVANCED NURSING SOLUTIONS **2**
AMEDISYS HOME HEALTH OF CAMDEN
CENTERWELL HOME HEALTH **23**
HOME CARE OF LANCASTER
INTRAMED PLUS (Limited to home infusion nursing services) **12**
MEDICAL SERVICES OF AMERICA HOME HEALTH
MUSC HEALTH AT HOME KERSHAW **28**

NHC HOMECARE-MIDLANDS

OPTUM WOMEN'S AND CHILDREN'S HEALTH LLC (Obstetric Patients Only) **13**

PALMETTO INFUSION SERVICES (Limited to Home Infusion Nursing Services)

PRUITTHEALTH @ HOME - COLUMBIA

REANIMATIONS HOME HEALTH AGENCY **29**

WELL CARE HOME HEALTH OF THE MIDLANDS

Lancaster County

ADVANCED HOME HEALTH **31**

ADVANCED NURSING SOLUTIONS **3**

ATRIUM HEALTH AT HOME YORK (Previously HEALTHY @ HOME)

BAYADA HOME HEALTH CARE-ROCK HILL

BIOSCRIP INFUSION SERVICES **26**

BRIGHTSTAR CARE

CENTERWELL HOME HEALTH-MIDLANDS **18**

HOME CARE OF LANCASTER

INTERIM HEALTHCARE OF ROCK HILL

INTRAMED PLUS (Limited to home infusion nursing services) **12**

MEDICAL SERVICES OF AMERICA HOME HEALTH

NEIGHBORS CARE HOME HEALTH AGENCY AN AMEDISYS COMPANY

NHC HOMECARE-PIEDMONT **25**

OPTUM WOMEN'S AND CHILDREN'S HEALTH LLC (Obstetric Patients Only) **13**

PALMETTO INFUSION SERVICES (Limited to Home Infusion Nursing Services)

PHC HOME HEALTHCARE

PROVIDENCE CARE AT HOME

PRUITTHEALTH @ HOME - COLUMBIA

REANIMATIONS HOME HEALTH AGENCY **29**

WELL CARE HOME HEALTH OF THE UPSTATE

Lexington County

ADVANCED NURSING SOLUTIONS **1**

AMEDISYS HOME HEALTH OF CAMDEN

AMEDISYS HOME HEALTH OF LEXINGTON

BAYADA HOME HEALTH CARE-GREENVILLE

BIOSCRIP INFUSION SERVICES **26**

CENTERWELL HOME HEALTH **23**

CENTERWELL HOME HEALTH-MIDLANDS **18**

ENHABIT HOME HEALTH AIKEN **19**

INTERIM HEALTHCARE OF THE UPSTATE **10**

INTRAMED PLUS (Limited to home infusion nursing services) **12**

LAUREL CREST HOME HEALTH (May Serve Retirement Community Only)

MEDICAL SERVICES OF AMERICA HOME HEALTH

NHC HOMECARE-MIDLANDS

OPTUM WOMEN'S AND CHILDREN'S HEALTH LLC (Obstetric Patients Only) **13**

PALMETTO INFUSION SERVICES (Limited to Home Infusion Nursing Services)

PRESBYTERIAN COMMUNITIES OF SC HOME HEALTH AGENCY (Serving Continuing Care Retirement Community Campuses Only)

PRISMA HEALTH HOME HEALTH

PRUITTHEALTH @ HOME - COLUMBIA

STILL HOPES HOME HEALTH (Serving Campus Residents Only)

WELL CARE HOME HEALTH OF THE MIDLANDS

Newberry County

ADVANCED NURSING SOLUTIONS **6**

AMEDISYS HOME HEALTH OF CAMDEN

AMEDISYS HOME HEALTH OF LEXINGTON

BIOSCRIP INFUSION SERVICES **26**

CENTERWELL HOME HEALTH-MIDLANDS **18**

HEALTH RELATED HOME CARE

HOME HEALTH SERVICES OF SELF REGIONAL HEALTHCARE

INTERIM HEALTHCARE OF THE UPSTATE **9**

INTRAMED PLUS (Limited to home infusion nursing services) **12**

MEDICAL SERVICES OF AMERICA HOME HEALTH

NHC HOMECARE-GREENWOOD

OPTUM WOMEN'S AND CHILDREN'S HEALTH LLC (Obstetric Patients Only) **13**

PALMETTO INFUSION SERVICES (Limited to Home Infusion Nursing Services)

PRISMA HEALTH HOME HEALTH-UPSTATE **14**

PRUITTHEALTH @ HOME - COLUMBIA

WELL CARE HOME HEALTH OF THE MIDLANDS

Richland County

ADVANCED NURSING SOLUTIONS **1**

AMEDISYS HOME HEALTH OF CAMDEN

AMEDISYS HOME HEALTH OF LEXINGTON

BAYADA HOME HEALTH CARE-GREENVILLE

BIOSCRIP INFUSION SERVICES **26**

CENTERWELL HOME HEALTH-MIDLANDS **18**

FIRST PRIORITY HOME HEALTH CARE

INTERIM HEALTHCARE OF THE UPSTATE **10**

INTRAMED PLUS (Limited to home infusion nursing services) **12**

MEDICAL SERVICES OF AMERICA HOME HEALTH

NHC HOMECARE-MIDLANDS

OPTUM WOMEN'S AND CHILDREN'S HEALTH LLC (Obstetric Patients Only) **13**

PALMETTO INFUSION SERVICES (Limited to Home Infusion Nursing Services)

PRESBYTERIAN COMMUNITIES OF SC HOME HEALTH AGENCY (Serving Continuing Care Retirement Community Campuses Only) **30**

PRISMA HEALTH HOME HEALTH

PROVIDENCE HOME HEALTH

PRUITTHEALTH @ HOME - COLUMBIA

WELL CARE HOME HEALTH OF THE MIDLANDS

Saluda County

ADVANCED NURSING SOLUTIONS **5**

AMEDISYS HOME HEALTH OF LEXINGTON

CENTERWELL HOME HEALTH-MIDLANDS **18**

HEALTH RELATED HOME CARE

HOMECARE OF HOSPICECARE OF THE PIEDMONT (Terminally Ill Patients Only) **8**

HOME HEALTH SERVICES OF SELF REGIONAL HEALTHCARE

INTRAMED PLUS (Limited to home infusion nursing services) **12**

MEDICAL SERVICES OF AMERICA HOME HEALTH
NHC HOMECARE-GREENWOOD
OPTUM WOMEN'S AND CHILDREN'S HEALTH LLC (Obstetric Patients Only) **13**
PALMETTO INFUSION SERVICES (Limited to Home Infusion Nursing Services)
PRUITTHEALTH @ HOME - LOW COUNTRY
WELL CARE HOME HEALTH OF THE MIDLANDS

York County

ADVANCED HOME HEALTH **31**
ADVANCED NURSING SOLUTIONS **3**
ATRIUM HEALTH AT HOME YORK (Previously HEALTHY @ HOME) **32**
BAYADA HOME HEALTH CARE-ROCK HILL
BIOSCRIP INFUSION SERVICES **26**
BRIGHTSTAR CARE
CENTERWELL HOME HEALTH-MIDLANDS **18**
CENTERWELL HOME HEALTH-UPSTATE **16**
EXCEL HOME CARE **33**
HOME CARE OF LANCASTER
INTERIM HEALTHCARE OF ROCK HILL
INTRAMED PLUS (Limited to home infusion nursing services) **12**
MEDICAL SERVICES OF AMERICA HOME HEALTH
NEIGHBORS CARE HOME HEALTH AGENCY AN AMEDISYS COMPANY
NHC HOMECARE-PIEDMONT **25**
OPTUM WOMEN'S AND CHILDREN'S HEALTH LLC (Obstetric Patients Only) **13**
PALMETTO INFUSION SERVICES (Limited to Home Infusion Nursing Services)
PHC HOME HEALTHCARE
PROVIDENCE CARE AT HOME
PRUITTHEALTH @ HOME - COLUMBIA
WELL CARE HOME HEALTH OF THE UPSTATE
WESTMINSTER TOWERS HOME HEALTH (Serving Campus Residents Only)

Region III

Facility by County

Chesterfield County

ADVANCED NURSING SOLUTIONS **3**
AMEDYSIS HOME HEALTH OF CONWAY **35**
CENTERWELL HOME HEALTH-PEE DEE **34**
CHESTERFIELD VISITING NURSES SERVICE
INTRAMED PLUS (Limited to home infusion nursing services) **12**
MCLEOD HOME HEALTH
MEDICAL SERVICES OF AMERICA - COASTAL
NHC HOMECARE-DARLINGTON **48**
OPTUM WOMEN'S AND CHILDREN'S HEALTH LLC (Obstetric Patients Only) **13**
PALMETTO INFUSION SERVICES (Limited to Home Infusion Nursing Services)
PRUITTHEALTH @ HOME - FLORENCE

Clarendon County

ADVANCED NURSING SOLUTIONS **2**
AMEDISYS HOME HEALTH CARE
CENTERWELL HOME HEALTH-PEE DEE **34**
COASTAL HEALTH LLC
INTRAMED PLUS (Limited to home infusion nursing services) **12**
INTREPID USA HEALTHCARE SERVICES
MCLEOD HOME HEALTH
MEDICAL SERVICES OF AMERICA HOME HEALTH
NHC HOMECARE-LOW COUNTRY
OPTUM WOMEN'S AND CHILDREN'S HEALTH LLC (Obstetric Patients Only) **13**
PALMETTO INFUSION SERVICES (Limited to Home Infusion Nursing Services)
PRISMA HEALTH TUOMEY HOME HEALTH
PRUITTHEALTH @ HOME - FLORENCE
WELL CARE HOME HEALTH OF THE MIDLANDS

Darlington County

ADVANCED NURSING SOLUTIONS **2**
AMEDISYS HOME HEALTH OF CAMDEN
AMEDISYS HOME HEALTH OF CONWAY
BETHEA HOME HEALTH (May Serve Retirement Community Only)
CAROLINAS HOME HEALTH
CENTERWELL HOME HEALTH-PEE DEE **34**
CHESTERFIELD VISITING NURSES SERVICE
INTRAMED PLUS (Limited to home infusion nursing services) **12**
MCLEOD HOME HEALTH
MEDICAL SERVICES OF AMERICA - COASTAL
NHC HOMECARE-DARLINGTON **48**
OPTUM WOMEN'S AND CHILDREN'S HEALTH LLC (Obstetric Patients Only) **13**
PALMETTO INFUSION SERVICES (Limited to Home Infusion Nursing Services)
PRUITTHEALTH @ HOME - FLORENCE
WELL CARE HOME HEALTH OF THE MIDLANDS

Dillon County

ADVANCED NURSING SOLUTIONS **2**
AMEDISYS HOME HEALTH OF CONWAY
CAROLINAS HOME HEALTH
CENTERWELL HOME HEALTH-PEE DEE **34**
COASTAL HEALTH LLC
FLORENCE VISITING NURSES SERVICE
INTRAMED PLUS (Limited to home infusion nursing services) **12**
MCLEOD HOME HEALTH
MEDICAL SERVICES OF AMERICA - COASTAL
NHC HOMECARE-MURRELLS INLET
OPTUM WOMEN'S AND CHILDREN'S HEALTH LLC (Obstetric Patients Only) **13**
PALMETTO INFUSION SERVICES (Limited to Home Infusion Nursing Services)
PRUITTHEALTH @ HOME - FLORENCE
WELL CARE HOME HEALTH OF THE MIDLANDS

Florence County

ADVANCED NURSING SOLUTIONS **6**

AMEDISYS HOME HEALTH CARE
BAYADA HOME HEALTH CARE-GREENVILLE
CAROLINAS HOME HEALTH
CENTERWELL HOME HEALTH-PEE DEE **34**
COASTAL HEALTH LLC
FLORENCE VISITING NURSES SERVICE
INTRAMED PLUS (Limited to home infusion nursing services) **12**
MCLEOD HOME HEALTH
MEDICAL SERVICES OF AMERICA - COASTAL
METHODIST MANOR HOME HEALTH (May Serve Retirement Community Only)
MUSC HEALTH AT HOME BY BAYADA - CONWAY **36**
NHC HOMECARE-DARLINGTON **48**
OPTUM WOMEN'S AND CHILDREN'S HEALTH LLC (Obstetric Patients Only) **13**
PALMETTO INFUSION SERVICES (Limited to Home Infusion Nursing Services)
PRESBYTERIAN COMMUNITIES OF SC HOME HEALTH AGENCY (Serving Continuing Care Retirement Community Campuses Only)
PRUITTHEALTH @ HOME - FLORENCE
WELL CARE HOME HEALTH OF THE MIDLANDS

Georgetown County

ADVANCED NURSING SOLUTIONS **5**
AMEDISYS HOME HEALTH CARE
AMEDISYS HOME HEALTH OF GEORGETOWN
CENTERWELL HOME HEALTH-COASTAL **37**
CENTERWELL HOME HEALTH-PEE DEE **34**
INTRAMED PLUS (Limited to home infusion nursing services) **12**
INTREPID USA HEALTHCARE SERVICES
LIBERTY HOME CARE-MYRTLE BEACH
MEDICAL SERVICES OF AMERICA - COASTAL
MUSC HEALTH AT HOME BY BAYADA - CONWAY
NHC HOMECARE-MURRELLS INLET
OPTUM WOMEN'S AND CHILDREN'S HEALTH LLC (Obstetric Patients Only) **13**
PALMETTO INFUSION SERVICES (Limited to Home Infusion Nursing Services)
PRUITTHEALTH @ HOME - FLORENCE
WELL CARE HOME HEALTH OF THE LOWCOUNTRY

Horry County

ADVANCED NURSING SOLUTIONS **1**
AMEDISYS HOME HEALTH OF CONWAY
AMEDISYS HOME HEALTH OF MYRTLE BEACH
CENTERWELL HOME HEALTH-COASTAL **37**
CENTERWELL HOME HEALTH-PEE DEE **34**
INTRAMED PLUS (Limited to home infusion nursing services) **12**
LIBERTY HOME CARE-MYRTLE BEACH
MCLEOD HOME HEALTH
MEDICAL SERVICES OF AMERICA - COASTAL
MUSC HEALTH AT HOME BY BAYADA - CONWAY
NHC HOMECARE-MURRELLS INLET
OPTUM WOMEN'S AND CHILDREN'S HEALTH LLC (Obstetric Patients Only) **13**

PALMETTO INFUSION SERVICES (Limited to Home Infusion Nursing Services)
PRUITTHEALTH @ HOME - FLORENCE
WELL CARE HOME HEALTH OF THE LOWCOUNTRY

Lee County

ADVANCED NURSING SOLUTIONS **5**
AMEDISYS HOME HEALTH OF LEXINGTON
CENTERWELL HOME HEALTH-PEE DEE **34**
FLORENCE VISITING NURSES SERVICE
INTRAMED PLUS (Limited to home infusion nursing services) **12**
MCLEOD HOME HEALTH
MEDICAL SERVICES OF AMERICA HOME HEALTH
NHC HOMECARE-DARLINGTON **48**
OPTUM WOMEN'S AND CHILDREN'S HEALTH LLC (Obstetric Patients Only) **13**
PALMETTO INFUSION SERVICES (Limited to Home Infusion Nursing Services)
PRISMA HEALTH TUOMEY HOME HEALTH
PRUITTHEALTH @ HOME - FLORENCE
WELL CARE HOME HEALTH OF THE MIDLANDS

Marion County

ADVANCED NURSING SOLUTIONS **6**
AMEDISYS HOME HEALTH OF CONWAY
CAROLINAS HOME HEALTH
CENTERWELL HOME HEALTH-PEE DEE **35**
COASTAL HEALTH LLC
FLORENCE VISITING NURSES SERVICE
INTRAMED PLUS (Limited to home infusion nursing services) **12**
MCLEOD HOME HEALTH
MEDICAL SERVICES OF AMERICA - COASTAL
MUSC HEALTH AT HOME BY BAYADA - CONWAY **36**
NHC HOMECARE-MURRELLS INLET
OPTUM WOMEN'S AND CHILDREN'S HEALTH LLC (Obstetric Patients Only) **13**
PALMETTO INFUSION SERVICES (Limited to Home Infusion Nursing Services)
PRUITTHEALTH @ HOME - FLORENCE
WELL CARE HOME HEALTH OF THE LOWCOUNTRY

Marlboro County

ADVANCED NURSING SOLUTIONS **6**
AMEDISYS HOME HEALTH OF CAMDEN
AMEDISYS HOME HEALTH OF CONWAY
CAROLINAS HOME HEALTH
CENTERWELL HOME HEALTH-PEE DEE **34**
CHESTERFIELD VISITING NURSES SERVICE
INTRAMED PLUS (Limited to home infusion nursing services) **12**
MCLEOD HOME HEALTH
MEDICAL SERVICES OF AMERICA - COASTAL
NHC HOMECARE-DARLINGTON **48**
OPTUM WOMEN'S AND CHILDREN'S HEALTH LLC (Obstetric Patients Only) **13**
PALMETTO INFUSION SERVICES (Limited to Home Infusion Nursing Services)
PRUITTHEALTH @ HOME - FLORENCE

Sumter County

ADVANCED NURSING SOLUTIONS **2**
AMEDISYS HOME HEALTH OF LEXINGTON
BAYADA HOME HEALTH CARE-GREENVILLE
CENTERWELL HOME HEALTH-PEE DEE **35**

COVENANT PLACE CCRC HOME HEALTH SERVICES (May Serve Retirement Community Only)
INTRAMED PLUS (Limited to home infusion nursing services) **12**
KINDRED AT HOME-PEE DEE
MCLEOD HOME HEALTH
MEDICAL SERVICES OF AMERICA HOME HEALTH
NHC HOMECARE-MIDLANDS
OPTUM WOMEN'S AND CHILDREN'S HEALTH LLC (Obstetric Patients Only) **13**
PALMETTO INFUSION SERVICES (Limited to Home Infusion Nursing Services)
PRISMA HEALTH TUOMEY HOME HEALTH
PROVIDENCE HOME HEALTH
PRUITTHEALTH @ HOME - COLUMBIA **38**
PRUITTHEALTH @ HOME - FLORENCE **39**
WELL CARE HOME HEALTH OF THE MIDLANDS

Williamsburg County

ADVANCED NURSING SOLUTIONS **6**
AMEDISYS HOME HEALTH CARE
AMEDISYS HOME HEALTH OF GEORGETOWN
CAROLINAS HOME HEALTH
CENTERWELL HOME HEALTH-COASTAL **37**
CENTERWELL HOME HEALTH-PEE DEE **34**
COASTAL HEALTH LLC
INTRAMED PLUS (Limited to home infusion nursing services) **12**
INTREPID USA HEALTHCARE SERVICES
MEDICAL SERVICES OF AMERICA - COASTAL
NHC HOMECARE-LOW COUNTRY
OPTUM WOMEN'S AND CHILDREN'S HEALTH LLC(Obstetric Patients Only) **13**
PALMETTO INFUSION SERVICES (Limited to Home Infusion Nursing Services)
PRUITTHEALTH @ HOME - FLORENCE
WELL CARE HOME HEALTH OF THE LOWCOUNTRY

Region IV

Facility by County

Allendale County

ADVANCED NURSING SOLUTIONS **6**
AMEDISYS HOME HEALTH OF BLUFFTON
AMEDISYS HOME HEALTH OF CHARLESTON EAST
CENTERWELL HOME HEALTH-LOW COUNTRY **40**
INTRAMED PLUS (Limited to home infusion nursing services) **12**
INTREPID USA HEALTHCARE SERVICES

MEDICAL SERVICES OF AMERICA HOME HEALTH
NHC HOMECARE-AIKEN
OPTUM WOMEN'S AND CHILDREN'S HEALTH LLC (Obstetric Patients Only) **13**
PALMETTO INFUSION SERVICES (Limited to Home Infusion Nursing Services)
PRUITTHEALTH @ HOME - LOW COUNTRY
VNA OF GREATER BAMBERG **21**

Bamberg County

ADVANCED NURSING SOLUTIONS **5**
AMEDISYS HOME HEALTH OF LEXINGTON
CENTERWELL HOME HEALTH-LOW COUNTRY **40**
GROVE PARK PHARMACY HOME CARE **41**
HOMECARE OF THE REGIONAL MEDICAL CENTER
INTRAMED PLUS (Limited to home infusion nursing services) **12**
INTREPID USA HEALTHCARE SERVICES
MEDICAL SERVICES OF AMERICA HOME HEALTH
NHC HOMECARE-LOW COUNTRY
OPTUM WOMEN'S AND CHILDREN'S HEALTH LLC (Obstetric Patients Only) **13**
PALMETTO INFUSION SERVICES (Limited to Home Infusion Nursing Services)
PRUITTHEALTH @ HOME - LOW COUNTRY
VNA OF GREATER BAMBERG **21**

Beaufort County

ADVANCED NURSING SOLUTIONS **2**
AMEDISYS HOME HEALTH OF BEAUFORT **42**
AMEDISYS HOME HEALTH OF BLUFFTON
BEAUFORT MEMORIAL HOME HEALTH CARE-AMEDISYS PARTNER **42**
BRIGHTSTAR CARE-BLUFFTON
CENTERWELL HOME HEALTH-LOW COUNTRY **40**
CYPRESS CLUB HOME HEALTH AGENCY (May Serve Retirement Community Only)
ENHABIT HOME HEALTH BLUFFTON **43**
INTERIM HEALTHCARE
INTERIM HEALTHCARE OF THE UPSTATE **11**
INTRAMED PLUS (Limited to home infusion nursing services) **12**
INTREPID USA HEALTHCARE SERVICES **44**
ISLAND HEALTH CARE
MEDICAL SERVICES OF AMERICA HOME HEALTH
MUSC HEALTH AT HOME BY BAYADA
NHC HOMECARE-BEAUFORT
OPTUM WOMEN'S AND CHILDREN'S HEALTH LLC (Obstetric Patients Only) **13**
PALLIATIVE CARE OF THE LOWCOUNTRY (Restricted to Terminally Ill Residents)
PALMETTO INFUSION SERVICES (Limited to Home Infusion Nursing Services)
PRUITTHEALTH @ HOME - LOW COUNTRY

SEABROOK WELLNESS AND HOME HEALTH CARE (Serving Retirement Campus Residents Only)
WELL CARE HOME HEALTH OF THE LOWCOUNTRY

Berkeley County

ADVANCED NURSING SOLUTIONS **2**
AMEDISYS HOME HEALTH OF CHARLESTON

AMEDISYS HOME HEALTH OF CHARLESTON EAST
CENTERWELL HOME HEALTH-LOW COUNTRY **40**
CONTINUUM PEDIATRIC NURSING
INTERIM HEALTHCARE
INTRAMED PLUS (Limited to home infusion nursing services) **12**
INTREPID USA HEALTHCARE SERVICES
KIDSCARE HOME HEALTH OF SOUTH CAROLINA **45**
MEDICAL SERVICES OF AMERICA - COASTAL
MUSC HEALTH AT HOME BY BAYADA-CHARLESTON
NHC HOMECARE-LOW COUNTRY
OPTUM WOMEN'S AND CHILDREN'S HEALTH LLC (Obstetric Patients Only) **13**
PALMETTO INFUSION SERVICES (Limited to Home Infusion Nursing Services)
PHC HOME HEALTH
PRESBYTERIAN COMMUNITIES OF SC HOME HEALTH AGENCY (Serving Continuing Care
Retirement Community Campuses Only)
PRUITTHEALTH @ HOME - LOW COUNTRY
ROPER-ST FRANCIS HOME HEALTH CARE
WELL CARE HOME HEALTH OF THE LOWCOUNTRY

Calhoun County

ADVANCED NURSING SOLUTIONS **5**
AMEDISYS HOME HEALTH OF CAMDEN
AMEDISYS HOME HEALTH OF LEXINGTON
CENTERWELL HOME HEALTH **23**
GROVE PARK PHARMACY HOME CARE **41**
HOMECARE OF THE REGIONAL MEDICAL CENTER
INTERIM HEALTHCARE OF THE UPSTATE **10**
INTRAMED PLUS (Limited to home infusion nursing services) **12**
INTREPID USA HEALTHCARE SERVICES
MEDICAL SERVICES OF AMERICA HOME HEALTH
NHC HOMECARE-MIDLANDS
OPTUM WOMEN'S AND CHILDREN'S HEALTH LLC (Obstetric Patients Only) **13**
PALMETTO INFUSION SERVICES (Limited to Home Infusion Nursing Services)
PRUITTHEALTH @ HOME - COLUMBIA
VNA OF GREATER BAMBERG
WELL CARE HOME HEALTH OF THE MIDLANDS

Charleston County

ADVANCED NURSING SOLUTIONS **1**
AMEDISYS HOME HEALTH OF CHARLESTON
AMEDISYS HOME HEALTH OF CHARLESTON EAST
BRIGHTSTAR CARE OF CHARLESTON
CENTERWELL HOME HEALTH-LOW COUNTRY **40**
CONTINUUM PEDIATRIC NURSING
INTERIM HEALTHCARE
INTRAMED PLUS (Limited to home infusion nursing services) **12**
INTREPID USA HEALTHCARE SERVICES
KIDSCARE HOME HEALTH OF SOUTH CAROLINA **45**
MEDICAL SERVICES OF AMERICA - COASTAL

MUSC HEALTH AT HOME BY BAYADA-CHARLESTON
NHC HOMECARE-LOW COUNTRY
OPTUM WOMEN'S AND CHILDREN'S HEALTH LLC (Obstetric Patients Only) 13
PALMETTO INFUSION SERVICES (Limited to Home Infusion Nursing Services)
PHC HOME HEALTH
PRUITTHEALTH @ HOME - LOW COUNTRY
ROPER-ST FRANCIS HOME HEALTH CARE
WELL CARE HOME HEALTH OF THE LOWCOUNTRY

Colleton County

ADVANCED NURSING SOLUTIONS 6
AMEDISYS HOME HEALTH OF CAMDEN
AMEDISYS HOME HEALTH OF CHARLESTON EAST
CENTERWELL HOME HEALTH-LOW COUNTRY 40
INTRAMED PLUS (Limited to home infusion nursing services) 12
INTREPID USA HEALTHCARE SERVICES
MEDICAL SERVICES OF AMERICA HOME HEALTH
MUSC HEALTH AT HOME BY BAYADA
NHC HOMECARE-BEAUFORT
OPTUM WOMEN'S AND CHILDREN'S HEALTH LLC (Obstetric Patients Only) 13
PALMETTO INFUSION SERVICES (Limited to Home Infusion Nursing Services)
PRUITTHEALTH @ HOME - LOW COUNTRY
VNA OF GREATER BAMBERG 21
WELL CARE HOME HEALTH OF THE LOWCOUNTRY

Dorchester County

ADVANCED NURSING SOLUTIONS 2
AMEDISYS HOME HEALTH OF CHARLESTON
AMEDISYS HOME HEALTH OF CHARLESTON EAST
CENTERWELL HOME HEALTH-LOWCOUNTRY 40
CONTINUUM PEDIATRIC NURSING
INTERIM HEALTHCARE
INTRAMED PLUS (Limited to home infusion nursing services) 12
INTREPID USA HEALTHCARE SERVICES
KIDSCARE HOME HEALTH OF SOUTH CAROLINA 45
MEDICAL SERVICES OF AMERICA HOME HEALTH
MUSC HEALTH AT HOME BY BAYADA-CHARLESTON
NHC HOMECARE-LOW COUNTRY
OPTUM WOMEN'S AND CHILDREN'S HEALTH LLC (Obstetric Patients Only) 13
PALMETTO INFUSION SERVICES (Limited to Home Infusion Nursing Services)
PHC HOME HEALTH
PRESBYTERIAN COMMUNITIES OF SC HOME HEALTH AGENCY (Serving Continuing Care
Retirement Community Campuses Only)
PRUITTHEALTH @ HOME - LOW COUNTRY
QUALITY OF LIFECARE, LLC 46
ROPER-ST FRANCIS HOME HEALTH CARE
WELL CARE HOME HEALTH OF THE LOWCOUNTRY

Hampton County

ADVANCED NURSING SOLUTIONS 5

AMEDISYS HOME HEALTH OF BLUFFTON
AMEDISYS HOME HEALTH OF CHARLESTON EAST
CENTERWELL HOME HEALTH-LOW COUNTRY **40**
INTERIM HEALTHCARE OF THE UPSTATE **11**
INTRAMED PLUS (Limited to home infusion nursing services) **12**
INTREPID USA HEALTHCARE SERVICES **44**
MEDICAL SERVICES OF AMERICA HOME HEALTH
NHC HOMECARE-BEAUFORT
OPTUM WOMEN'S AND CHILDREN'S HEALTH LLC (Obstetric Patients Only) **13**
PALMETTO INFUSION SERVICES (Limited to Home Infusion Nursing Services)
PRUITTHEALTH @ HOME - LOW COUNTRY
VNA OF GREATER BAMBERG **21**

Jasper County

ADVANCED NURSING SOLUTIONS **5**
AMEDISYS HOME HEALTH OF BEAUFORT **43**
AMEDISYS HOME HEALTH OF BLUFFTON
BEAUFORT MEMORIAL HOME HEALTH CARE-AMEDISYS PARTNER **43**
BRIGHTSTAR CARE-BLUFFTON
CENTERWELL HOME HEALTH-LOW COUNTRY **41**
ENHABIT HOME HEALTH BLUFFTON
INTERIM HEALTHCARE OF THE UPSTATE **11**
INTRAMED PLUS (Limited to home infusion nursing services) **12**
INTREPID USA HEALTHCARE SERVICES
ISLAND HEALTH CARE
MEDICAL SERVICES OF AMERICA HOME HEALTH
NHC HOMECARE-BEAUFORT
OPTUM WOMEN'S AND CHILDREN'S HEALTH LLC (Obstetric Patients Only) **13**
PALLIATIVE CARE OF THE LOWCOUNTRY (Restricted to Terminally Ill Residents)
PALMETTO INFUSION SERVICES (Limited to Home Infusion Nursing Services)
PRUITTHEALTH @ HOME - LOW COUNTRY

Orangeburg County

ADVANCED NURSING SOLUTIONS **5**
AMEDISYS HOME HEALTH OF CAMDEN
AMEDISYS HOME HEALTH OF LEXINGTON
CENTERWELL HOME HEALTH **23**
GROVE PARK PHARMACY HOME CARE **41**
HOMECARE OF THE REGIONAL MEDICAL CENTER
INTERIM HEALTHCARE OF THE UPSTATE **10**
INTRAMED PLUS (Limited to home infusion nursing services) **12**
INTREPID USA HEALTHCARE SERVICES
MEDICAL SERVICES OF AMERICA HOME HEALTH
MUSC HEALTH AT HOME BY BAYADA
NHC HOMECARE-AIKEN
OAKS HOME HEALTH (May Serve Campus Residents Only) **47**

OPTUM WOMEN'S AND CHILDREN'S HEALTH LLC (May Serve Obstetric Patients Only) **13**
PALMETTO INFUSION SERVICES (Limited to Home Infusion Nursing Services)

PRUITTHEALTH @ HOME - LOW COUNTRY
VNA OF GREATER BAMBERG 21
WELL CARE HOME HEALTH OF THE MIDLANDS

- 1 Advanced Nursing Solutions licensed 4/26/2021, CON issued 4/30/2021
- 2 Advanced Nursing Solutions licensed 7/28/2021, CON issued 9/15/2021
- 3 Advanced Nursing Solutions licensed 10/13/2021, CON issued 9/15/2021
- 4 Advanced Nursing Solutions licensed 12/10/2021, CON issued 12/7/2021
- 5 Advanced Nursing Solutions licensed 6/20/2022, CON issued 4/27/2022
- 6 Advanced Nursing Solutions licensed 09/22/2022, CON issued 6/23/2022
- 7 Effective 9/1/2022, name changed from Kindred at Home-Anderson to Centerwell Home Health-Anderson
- 8 Effective 7/14/2021, agency inactive
- 9 Interim Healthcare of the Upstate licensed 10/6/2021, CON issued 8/30/2021
- 10 Interim Healthcare of the Upstate licensed 11/8/2021, CON issued 11/1/2021
- 11 Interim Healthcare of the Upstate CON issued 9/15/2022; not licensed
- 12 Licensed 12/11/2020, CON issued 10/12/2020
- 13 Effective 3/15/2022, name changed from Optum Women's and Children's Health-Piedmont to Optum Women's and Children's Health, LLC
- 14 Prisma Health Home Health Agency CON issued 10/16/2020
- 15 Effective 9/1/2022, name changed from Kindred at Home-Greenville to Centerwell Home Health-Greenville
- 16 Effective 9/1/2022, name changed from Kindred at Home-Upstate to Centerwell Home Health-Upstate
- 17 CON issued 9/17/2021; agency closed as of 12/30/2022
- 18 Effective 9/1/2022, name changed from Kindred at Home-Midlands to Centerwell Home Health-Midlands
- 19 Effective 2/3/2022, name changed from Encompass Health Home Health Aiken to Enhabit Home Health Aiken
- 20 Effective 11/8/2021, name changed from University Home Health North Augusta to University Home Health Services
- 21 Effective 3/31/2022, agency closed
- 22 Effective 9/3/2021 agency licensed, CON issued 5/18/2021

- 23 Effective 10/7/2022, name changed from Kindred at Home to Centerwell Home Health
- 24 Effective 9/30/2020, agency licensed
- 25 Effective 7/15/2021, agency closed
- 26 Effective 10/18/2022 agency licensed, CON issued 10/4/2022
- 27 Chester County office no longer licensed
- 28 Effective 8/1/2021, name changed from KershawHealth Home Health to MUSC Health at Home Kershaw
- 29 Effective 4/8/2022 agency licensed, CON issued 8/30/2021
- 30 Effective 2/28/2020 exemption granted for closure of Richland County agency only

- 31 Effective 3/1/2020, name changed from Advanced Home Care to Advanced Home Health

- 32** Effective 4/1/2020 name changed from Healthy @ Home to Atrium Health at Home York
- 33** Effective 10/6/2021 agency licensed, CON issued 8/30/2021
- 34** Effective 10/7/2022, name changed from Kindred at Home-Pee Dee to Centerwell Home Health-Pee Dee
- 35** CON issued 8/17/2022; not licensed
- 36** Effective 4/6/2021 license issued for counties
- 37** Effective 9/1/2022, name changed from Kindred at Home-Coastal to Centerwell Home Health-Coastal
- 38** Effective 10/31/2022, county removed from license
- 39** Effective 10/31/2022, county added to license
- 40** Effective 9/1/2022, name changed from Kindred at Home-Low Country to Centerwell Home Health-Low Country
- 41** CON issued 9/15/2022; not licensed

- 42** Effective 9/7/2022, change in ownership completed and name changed from Amedisys Home Health of Beaufort to Beaufort Memorial Home Health Care-An Amedisys Partner
- 43** Effective 2/3/2022, name changed from Encompass Health Home Health Bluffton to Enhabit Home Health Bluffton
- 44** Effective 11/4/2021 agency licensed, CON issued 2/11/2021
- 45** Effective 5/11/2022 agency licensed, CON issued 12/3/2021
- 46** CON issued 8/17/2022; not licensed
- 47** Effective 1/31/2022, agency closed
- 48** CON issued 10/30/2017 and withdrawn on 4/13/2020

CHAPTER 5

HOSPITALS

GENERAL HOSPITALS

Hospital

Hospital means a facility that is organized and administered to provide overnight medical or surgical care or nursing care for an illness, injury, or infirmity and must provide on-campus emergency services; that may provide obstetrical care; and in which all diagnoses, treatment, or care is administered by or under the direction of persons currently licensed to practice medicine, surgery, or osteopathy.

Hospital may include a residential treatment facility for children, adolescents, or young adults in need of mental health treatment that is physically a part of a licensed psychiatric hospital. This definition does not include facilities that are licensed by the Department of Social Services. A residential treatment facility for children, adolescents, or young adults in need of mental health treatment that is physically part of a licensed psychiatric hospital is not required to provide on-campus emergency services.

Hospital Bed

A bed for an adult or child patient. Bassinets for the newborn in a maternity unit nursery, beds in labor rooms, recovery rooms, and other beds used exclusively for emergency purposes are not included in this definition.

Bed Capacity

For existing beds, capacity is considered bed space designated exclusively for inpatient care, including space originally designed or remodeled for inpatient beds, even though temporarily not used for such purposes. The number of beds counted in any patient room is the maximum number for which adequate square footage is provided, except that single beds in single rooms have been counted even if the room contained inadequate square footage.

Inventory and Bed Need

All licensed general hospitals, including Federal facilities, and CON-approved general hospitals are listed in the inventory. Patient days and admissions are as reported by the hospital in its Joint Annual Report (UAR). The number of patient days utilized for the general

hospital bed need calculations does not include days of care rendered in licensed psychiatric units, substance abuse units, or comprehensive rehabilitation units of hospitals. These days of care are shown in the corresponding inventories for each type of service. In addition, the days of care provided in Long-Term Care hospitals are not included in the general bed need calculations.

Total capacity by survey refers to a total designed capacity or maximum number of beds that may be accommodated as determined by an on-site survey. This capacity may exceed the number of beds actually set up and in use. It may also differ from the licensed capacity, which is based on State laws and regulations. Beds have been classified as conforming and nonconforming, according to standards of facility evaluation.

Variable Occupancy Rate

The General Acute Hospital bed need methodology uses the following variable occupancy rate factors:

- 0 - 174 bed hospitals → 65%
- 175 - 349 bed hospitals → 70%
- 350+ bed hospital → 75%

The population and associated utilization are broken down by age groups. The use rates and projected average daily census are made for the age cohorts of 0-17, 18-64, and 65 and over, in recognition that different population groups have different hospital utilization rates.

Where the term "hospital bed need" is used, these figures are based upon utilization data for the general acute hospitals. This term does not suggest that facilities cannot operate at higher occupancy rates than used in the calculations without adding additional beds.

Availability

The need for general hospital beds is determined through the consideration of current utilization and projected population growth with the goal of having beds available within approximately 30 minutes travel time for the majority of the residents of the State.

CERTIFICATE OF NEED PROJECTION AND STANDARDS

1. Calculations of hospital bed need are made for individual hospitals and for service areas.
2. For individual hospitals, the methodology for calculating bed need is as follows:
 - a. Determine the current facility use rate by dividing the 2021 patient days by the

2021 population in each of the three age cohorts.

- b. Multiply the current facility use rate for each age cohort by the projected population by age cohort and divide by 365 to obtain a projected average daily census (ADC) by age cohort.
 - c. Divide the sum of the age cohort projected ADC by the variable occupancy factor (.65/.70/.75) to determine the hospital's bed need.
 - d. The number of additional beds needed or excess beds for the hospital is obtained by subtracting the number of existing and approved beds from the hospital's bed need.
3. The methodology for calculating the statewide utilization bed need for a service area is as follows:
- a. Divide the statewide total patient days by 365 to determine the statewide average daily census.
 - b. Divide the statewide average daily census by the statewide occupancy factor (.75) to determine the total statewide bed need.
 - c. Divide the statewide bed need by the 2021 statewide population to generate a bed-per-population (BPP) multiplier.
 - d. For each service area, multiply the projected population by the BPP multiplier to determine the service area bed need, then subtract the total number of existing and approved beds to determine the statewide utilization bed need for the service area.
4. The bed need for each service area is the combined bed need for all individual hospitals in the service area. The bed need for service areas with no hospital, or for service areas in which no hospital has reported any utilization data on the most recent JAR, is the statewide utilization bed need.
5. If a service area indicates a surplus of beds, then no additional beds will be approved unless an individual hospital in the service area indicates a need for additional beds. Should an individual hospital indicate a need for additional beds, then a maximum of the actual projected bed need or up to 50 additional beds may be approved for that hospital to allow for the construction of an economical unit at either the existing hospital site or another site, if the existing hospital is relocating or has relocated in whole or in part to that site. The hospital requesting the addition must document the need for additional beds beyond those indicated as needed by the methodology

stated above, based on historical and projected utilization, as well as projected population growth or other factors demonstrating the need for the proposed beds. Additional beds will only be approved for the specific hospital indicating a need.

6. If there is a need for additional hospital beds in the service area, then any entity may apply to add these beds within the service area, and any entity may be awarded the Certificate of Need for these beds. If the number of beds needed is less than 50, then up to a total of 50 beds could be approved for any entity at any location within the service area. An applicant requesting additional beds beyond those indicated as needed by the methodology stated above must document the need for additional beds based on historical and projected utilization, projected population growth that has not been considered in this Plan or other factors demonstrating the need for the proposed beds. It is up to the applicant to document the need and the potential negative impact on the existing facilities.
7. A facility may apply to create a new additional hospital at a different site within the same service area through the transfer of existing licensed beds, the projected bed need for the facility, or a combination of both existing beds and projected bed need. The facility is not required to have a projected need for additional beds in order to create a new additional hospital. There is no required minimum number of beds in order to approve the CON application. The applicant must justify, through patient origin and other data, the need for a new hospital at the chosen site and the potential adverse impact a new hospital at the chosen site could have on the existing hospitals in the service area.
8. No additional general hospital will be approved unless it will provide:
 - a. A 24-hour emergency services department that meets the requirements of [Regulation 61-16](#):
 - b. Inpatient medical services to both surgical and non-surgical patients; and
 - c. Medical and surgical services on a daily basis within at least six of the major diagnostic categories as recognized by Centers for Medicare and Medicaid Services (CMS). Any applicant for a new hospital must provide a written commitment that the facility will accept Medicare and Medicaid patients and that unreimbursed services for indigent and charity patients are provided at a percentage that meets or exceeds other hospitals in the service area. The CMS Diagnostic Categories Chart is located at the end of this Chapter.
9. Due to the low utilization and the low capital cost of converting hospital-based nursing home, psychiatric, rehabilitation and/or substance abuse beds to general

acute care hospital beds, the following policies may apply:

- a. Hospitals that have licensed nursing home beds within the hospital may be allowed to convert nursing home beds to general acute care hospital beds only within the hospital, provided the hospital can document an actual need for additional general acute care beds. Need will be based on actual utilization, using current information. *A Certificate of Need is required for this conversion.*
 - b. Existing acute care hospitals that have inpatient psychiatric, rehabilitation, or substance abuse beds may be allowed to convert such beds to acute care hospital beds, regardless of the projected need for general acute care hospital beds. *A Certificate of Need is required for this conversion.*
10. In some areas of South Carolina, a considerable influx of tourists is not counted in the permanent population. If an individual hospital in these areas can document and demonstrate the need for additional beds due to non-resident (tourist) population and seasonal utilization fluctuations due to this population, then, based on further analysis, the Department may approve some additional beds at the existing hospital.
 11. Should the deletion of services at a federal facility result in an immediate impact on the utilization of a hospital, then the Department may approve a request for additional beds at the affected hospital. The affected hospital must document the increase in demand and explain why additional beds are needed to accommodate patients previously served at the federal facility.
 12. Changes in the delivery system due to health care reform have resulted in the consolidation of facilities and the establishment of provider networks. These consolidations and agreements may lead to situations where affiliated hospitals may wish to transfer beds between themselves in order to serve their patients in a more efficient manner. *A proposal to transfer or exchange hospital beds requires a Certificate of Need and must comply with the provisions outlined in Chapter 2, Transfer between Affiliated Facilities.*
 13. Factors to be considered regarding modernization of facilities include:
 - a. Functional arrangement of the facility as it relates to efficient handling of patients and related workloads.
 - b. The ability to update medical technology within the existing facility.
 - c. Existence of The Joint Commission (TJC) or other accreditation body

deficiencies or "grandfathered" licensure deficiencies.

- d. Cost efficiency of the existing physical facility versus facility revision, etc.
 - e. Private rooms are now considered the industry standard.
14. Each modernization proposal must be evaluated on the basis of merit, cost efficiency, and impact on health care delivery within the service area.

The Hospital Bed Need Chart is located at the end of this Chapter.

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

The following Project Review Criteria are considered to be the most important in evaluating Certificate of Need applications for this service:

1. Compliance with the Need Outlined in this Section of this Plan;
2. Community Need Documentation;
3. Distribution (Accessibility);
4. Acceptability;
5. Ability to Complete the Project; and
6. Adverse Effects on Other Facilities.

General hospital beds are typically located within approximately thirty (30) minutes travel time for the majority of the residents of the State. The benefits of improved accessibility will be equally weighed with the adverse effects of duplication in evaluating Certificate of Need applications for these beds.

LONG-TERM ACUTE CARE HOSPITALS

Long-Term Acute Care Hospitals (LTACHs) are hospitals with an average Medicare inpatient length of stay of greater than 25 days, including all covered and non-covered days of stay of Medicare patients. They provide treatment to patients with complex medical conditions, such as strokes, cardiac care, ventilator dependency, wound care and post-surgical care.

A LTACH may be either a freestanding facility or may occupy space in another hospital (“hospital-within-a-hospital”). Hospitals must meet additional federal criteria in order to qualify as a LTACH under the “hospital-within-a-hospital” model:

1. The new LTACH must have a governing body, which is separate from the governing body of the host hospital, and the new body cannot be under the control of the host hospital or any third entity that controls both hospitals.
2. The LTACH must have a separate Chief Executive Officer through whom all administrative authority flows, who is not employed by, or under contract with, the host hospital or any third entity that controls both hospitals.
3. The LTACH must have a separate Chief Medical Officer who reports directly to the governing body and is responsible for all medical staff activities. The Chief Medical Officer cannot be under contract with the host hospital or any third entity that controls both hospitals.
4. The LTACH must have a separate medical staff which reports directly to the governing body, and adopt bylaws governing medical care, including granting privileges to individual practitioners.

CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

1. An application for a LTACH must be in compliance with the relevant standards in [Regulation 61-16](#) (*Minimum Standards for Licensing Hospitals and Institutional General Infirmaries*).
2. Although LTACH beds are not considered to be a separate category for licensing purposes, they will be inventoried separately from general acute care hospital beds for planning purposes.

3. The utilization of LTACHs is not included in the bed need for general acute care hospital beds. No bed need will be calculated for LTACH beds. An applicant must document the need for LTACH beds based on the utilization of existing LTACH beds.
4. A hospital that has leased general beds to a LTACH shall be entitled to regain these beds once the lease is terminated. No entity other than the hospital (or its successor) that initially leased the general acute beds to the LTACH shall be entitled to the beds upon termination of the lease. *A Certificate of Need application is required:*
 - a. A hospital may be allowed to convert these former LTACH beds to general acute hospital beds regardless of the projected need for general acute beds;
 - b. A hospital may be allowed to convert these former LTACH beds to psychiatric, inpatient treatment facility, rehabilitation, or other specialty beds only if there is a bed need projected for this proposed other category of licensed beds.
5. A hospital which seeks to be designated as a LTACH, and has been awarded a CON for that purpose, must be certified as a LTACH by CMS within 24 months of accepting its first patient, or the CON issued to that hospital for that purpose shall be revoked. The entity that has had its CON revoked shall not have the authority to operate as a general acute care hospital.
6. A hospital that desires to be designated as a Pediatric LTACH must restrict admissions to patients under the age of 21 who require long-term medical care. Should the facility attempt to provide care that is inconsistent with this requirement or patient demand or other economic conditions require the facility to close, the Certificate of Need issued to that hospital for that purpose shall be revoked.

The Long-Term Acute Care Hospitals Chart is located at the end of this Chapter.

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

The following project review criteria are considered to be the most important in evaluating Certificate of Need applications for this service:

1. Compliance with the Need Outlined in this Section of this Plan;
2. Community Need Documentation;
3. Distribution (Accessibility); and

4. Record of the Applicant.

Long-Term Acute Care Hospital beds are located within approximately 60 minutes travel time for the majority of the residents of the State. The benefits of improved accessibility will be equally weighed with the adverse effects of duplication in evaluating Certificate of Need applications for these beds.

COMMUNITY PSYCHIATRIC BEDS

Inpatient psychiatric services are those services provided to patients who are admitted to institutions for the evaluation, diagnosis and treatment of mental, emotional or behavioral disorders. Services may be provided in either psychiatric units of general hospitals or freestanding psychiatric hospitals.

Special units for children, adolescents and geriatric patients have been developed throughout the State. If any additional beds are approved, they must come from the calculated psychiatric bed need in this Plan. These specialty psychiatric services should be identifiable units with sufficient space to have available areas for sleeping, dining, education, recreation, occupational therapy and offices of evaluation and therapy. The unit should be staffed with an appropriate multi-disciplinary care team of psychiatrists, psychologists, social workers, nurses, occupational therapists, recreational therapists, and psychiatric technicians. Other consultants should be available as needed.

The Psychiatric Programs Chart is located at the end of this Chapter.

CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

1. Need projections are calculated on a statewide basis to serve the needs of this population.
2. The applicant must document the need for the expansion of or the addition of psychiatric services based on the most current utilization data available. The existing resources must be considered, and documentation presented as to why these resources are not adequate to meet the needs of the community.
3. The methodology for calculating psychiatric bed need is as follows:
 - a. The statewide utilization rate for psychiatric beds will be used for each age cohort.
 - b. Multiply the applicable utilization rate by the projected population for the year 2027 for each age cohort (where such data is available) and divide by 365 to obtain a projected average daily census by age cohort.
 - c. Take the sum of average daily censuses by age cohort and divide by the target occupancy rate of 50% to determine the number of beds needed in the statewide.

- d. The number of additional beds needed or excess beds for the statewide is obtained by subtracting the number of existing beds from the bed need.

4 In the absence of a projected need for beds in a psychiatric service area, an existing facility can apply to add up to eight additional beds, given that it has achieved an occupancy rate of at least 70% as reported on the most recent Joint Annual Report (JAR") at the time the application is filed with the Department. Up to ten additional beds may be added in a facility which has achieved an occupancy rate of at least 90% as reported on the most recent JAR at the time the application is filed with the Department.

5 Priority should be given to excess general hospital beds that can be economically and cost effectively converted for use as a specialized psychiatric unit over the construction of new beds, if such beds will be accessible to the target population.

The Psychiatric Bed Need Chart is located at the end of this Chapter.

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

The following project review criteria are considered to be the most important in evaluating Certificate of Need applications for this service:

1. Community Need Documentation;
2. Distribution (Accessibility);
3. Record of the Applicant; and
4. Staff Resources.

Psychiatric beds are planned for and located within 60 minutes travel time for the majority of the residents of the State. In addition, current utilization and population growth are factored into the methodology for determining psychiatric bed need period. The benefits of improved accessibility will be equally weighed with the adverse effects of duplication in evaluating Certificate of Need applications for these services.

STATE MENTAL HEALTH FACILITIES

Psychiatric Hospital Beds

Department of Mental Health (DMH) operates a variety of psychiatric facilities. DMH has analyzed the patient population and plans to provide psychiatric services in the least restrictive environment, maintain patients in the community and keep hospitalization to a minimum. Since DMH cannot refuse any patient assigned to them by a court, renovation, replacement and expansion of the component programs should be allowed as long as the overall psychiatric hospital complement is maintained or reduced. As long as DMH does not add any additional beds over the 3,720 beds that were in existence on July 1, 1988, any changes in facility bed capacity would not require Certificate of Need review.

INPATIENT TREATMENT FACILITIES (SUBSTANCE ABUSE BEDS)

An inpatient treatment facility is a short-term treatment service for persons who are in need of an organized intensive program of alcohol and/or drug rehabilitation, but who are without serious debilitating medical complications. These facilities may provide detoxification for their patients, as needed, in the inpatient treatment beds. These facilities are licensed either as a specialized hospital or as part of a hospital. For reference purposes only, these facilities are subject to compliance with Regulation 61-16.

The Inpatient Treatment Facilities Chart is located at the end of this Chapter.

CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

1. Need projections are calculated by service area.
2. The methodology for calculating inpatient treatment bed need is as follows:
 - a. For the service area, take the greater of the service area utilization rate or the statewide utilization rate for inpatient treatment beds by age cohort. The statewide utilization rate for each age cohort will be used for those service areas where no beds currently exist.

- b. Multiply the applicable utilization rate by the projected population for the year 2027 for each age cohort (where such data is available) and divide by 365 to obtain a projected average daily census by age cohort.
 - c. Take the sum of average daily censuses by age cohort and divide by the target occupancy rate of 75% to determine the number of beds needed in the service area.
 - d. The number of additional beds needed or excess beds for the service area is obtained by subtracting the number of existing beds from the bed need.
3. The significant prevalence of patients with mixed psychiatric/addictive etiologies presenting to hospitals with inpatient psychiatric beds, in the absence of a projected need statewide for inpatient treatment facility beds (substance abuse beds), a hospital or inpatient psychiatric facility without substance abuse beds may apply for a Certificate of Need to add up to eight (8) substance abuse beds if it can demonstrate need for the substance abuse beds at its facility, demonstrate an improvement in access to substance abuse beds statewide, and avoid materially adversely affecting existing inpatient treatment facilities.
 4. In the absence of a projected need in the service area, an existing inpatient treatment facility can apply to add up to eight additional inpatient treatment beds if it has achieved an occupancy rate of at least 70% as reported on its most recent Joint Annual Report ("JAR") at the time the application is filed with the Department.
 5. The establishment of a regional treatment center to serve more than a single service area may be proposed in order to improve access to care for patients in service areas that are not currently well served. Such a proposed center would be allowed to combine the bed need for separate, contiguous service areas, provided that each service area to be combined shows a positive bed need. The applicant must document with patient origin data the historical utilization of the residents in the service area that is to be combined, or why it is in the best interest of these residents for their projected bed need to be used to form a regional treatment facility.
 6. It is frequently impossible for a facility to totally predict or control short-term deviation in the number of patients with mixed psychiatric/addictive etiology. Therefore, in the case of facilities with licensed beds for both psychiatric and substance abuse treatment, 75% of licensed substance abuse beds may be utilized alternatively for the treatment of patients having diagnoses of both psychiatric and substance abuse disorders.

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

The following Project Review Criteria are considered to be the most important in evaluating Certificate of Need applications for this service.

1. Community Need Documentation
2. Distribution (Accessibility); and
3. Staff Resources

Services are accessible within 60 minutes travel time for the majority of residents of the state. The benefits of improved accessibility will be equally weighed with the adverse effects of duplication in evaluating Certificate of Need applications for this service.

The Inpatient Treatment Bed Need Chart is located at the end of this Chapter.

REHABILITATION FACILITIES (REHABILITATION BEDS)

A Rehabilitation Facility is operated for the primary purpose of providing comprehensive physical rehabilitation services through an intensive, coordinated team approach for patients with severe physical ailments. These facilities should be located where an extensive variety of professionals representing medical, psychological, social, and vocational rehabilitation evaluation and services are available. These beds are viewed as being comprehensive in nature and not limited only to a particular service or specialty. CMS identifies 13 specific conditions for which facilities must treat 60% of their patients ("the compliance threshold") in order to qualify for Medicare reimbursement. Certain comorbidities as specified in 42 CFR 412.29(b)(1) must be used to determine the compliance threshold.

Most general hospitals and other health care facilities offer physical rehabilitation services such as physical therapy, occupational therapy, speech therapy, or occupational therapy without the involvement of a formal interdisciplinary program. In addition, some hospitals have consolidated their rehabilitation services into a single unit to improve the coordination of care for acute patients in their facilities. These consolidations are intended to improve the quality of care for patients currently being treated in the facility and are not considered to be providing comprehensive physical rehabilitation services as defined in this section of the Plan.

The Rehabilitation Programs Chart is located at the end of this Chapter.

CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

1. The need for beds is calculated based on rehabilitation service areas.
2. The methodology takes the greater of the actual utilization of the facilities in the service area or the statewide average number of beds per 1,000 of the 65+ population cohort to project need.
3. In the absence of a projected need for beds in a rehabilitation facility service area, an existing facility can apply to add up to eight additional beds, given that it has achieved

an occupancy rate of at least 70% as reported on the most recent Joint Annual Report ("JAR") at the time the application is filed with the Department. Up to ten additional beds may be added in a facility which has achieved an occupancy rate of at least 90% as reported on the most recent JAR at the time the application is filed with the Department.

The Rehabilitation Bed Need Chart is located at the end of this Chapter.

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

The following project review criteria are considered to be the most important in evaluating Certificate of Need applications for this service:

1. Community Need Documentation;
2. Distribution (Accessibility); and
3. Ability to Complete the Project.

Rehabilitation facilities are now located throughout the state and are available within approximately 60 minutes' travel time for the majority of residents. Such facilities should be located where an extensive variety of health care professionals are available. The benefits of improved accessibility will be equally weighed with the adverse effects of duplication in evaluating Certificate of Need applications for this service.

Statewide Programs

The South Carolina Vocational Rehabilitation Center operates a 30-bed facility in West Columbia to serve the vocational training needs of the disabled.

CRITICAL ACCESS HOSPITALS (CAH)

The South Carolina Department of Health and Human Services administers programs through the Medicaid program to assist rural hospitals. One such program designates rural hospitals as Critical Access Hospitals (CAH) who are then eligible for more favorable Medicaid reimbursement methodology.

A CAH is intended to provide essential health services to rural communities. Converting a struggling rural hospital to a CAH can allow a community to maintain local health access that would otherwise be lost. CAHs are subject to review by the Independent Payment Advisory Board (IPAB), whereas other hospitals are not currently subject to IPAB review.

The impact of the Critical Access Hospital Program in South Carolina is a financial one, allowing cost-based reimbursement from Medicare for a facility choosing to participate. The designation as a CAH does not require a change in the licensing of an existing hospital. However, a hospital may be required to de-license a number of beds in order to meet the

25-bed requirement.

The designation of a hospital as a Critical Access Hospital *does not require Certificate of Need review* because it does not change the licensing category of the facility. However, an exemption from Certificate of Need review is required for a hospital to reduce its number of licensed beds in order to meet the criteria for a CAH. *Should a hospital later desire to revert to a general acute hospital, a Certificate of Need is required*, but the facility may be permitted to increase the number of licensed hospital beds up to the prior number of beds without regard or affect to the current bed need shown in the service area.

The Critical Access Hospitals Chart is located at the end of this Chapter.

PERINATAL SERVICES

PERINATAL REGIONS

The Perinatal Regions referred to in the Neonatal Services sections below are distinct from the Department's Regions defined in Chapter 2 of this Plan, and are identified by the name of its designated Regional Perinatal Center.

Perinatal Region

Counties

I- Prisma Health Greenville Memorial

Abbeville, Anderson, Edgefield, Greenville, Greenwood, Laurens, McCormick, Oconee, Pickens, Saluda

II- Spartanburg Regional

Cherokee, Chester, Spartanburg, Union

III- Prisma Health Richland

Aiken, Allendale, Bamberg, Barnwell, Calhoun, Clarendon, Fairfield, Kershaw, Lancaster, Lee, Lexington, Newberry, Orangeburg, Richland, Sumter, York

IV - Mcleod Regional

Chesterfield, Darlington, Dillon, Florence, Horry, Marion, Marlboro, Williamsburg

V - MUSC Medical

Beaufort, Berkeley, Charleston, Colleton, Dorchester, Hampton, Jasper, Georgetown

PERINATAL SERVICE LEVELS

Because the cost of high-risk obstetrical and neonatal services is so great, it is not desirable or cost-effective for all hospitals in the State to provide the higher levels of care. Over the years, a regionalized approach to perinatal care has been implemented in South Carolina to address the need for high quality, risk-appropriate, cost-effective perinatal health care. Regionalization provides a coordinated system of perinatal care for a well-defined population group. Each hospital providing perinatal services is designated by the Department's Bureau of Healthcare Systems and Services as a Level I, II, III, or IV Perinatal Hospital, or a Regional Perinatal Center (RPC). Each Level I, II, III and IV hospital maintains a relationship with its designated RPC for consultation, transport and continuing education. Patients are transferred to the appropriate RPC when medically appropriate, if beds are available. True regionalization for the optimization of perinatal care includes a stated goal of back-transporting infants when they no longer require the highest level of care. Convalescing infants benefit from a community-based program closer to home that promotes parent education and family bonding to facilitate a safe and timely discharge. In this way, quality care is provided to mothers and newborn infants, and specially trained perinatal personnel and intensive care facilities can be used efficiently and cost-effectively.

The complete descriptions of the five levels of perinatal services described briefly below are outlined in the Section of Regulation 61-16 entitled *Designation of Inpatient Perinatal Care Services*.

Basic Perinatal Center with Well Newborn Nursery (Level I). Level I hospitals provide services for normal uncomplicated pregnancies. A full list of the requirements for a Level I Basic Perinatal Center with Well Newborn Nursery can be found at Regulation 61-16, Section 1306.A.

Specialty Perinatal Center with Special Care Nursery (Level II). In addition to complying with the requirements of Regulation 61-16, Section 1306.A, Level II hospitals provide services for both normal and selected high-risk obstetrical and neonatal patients. A full list of the requirements for a Level II Specialty Perinatal Center can be found at Regulation 61-16, Section 1306.B.

Subspecialty Perinatal Center with Neonatal Intensive Care Unit (Level III). In addition to complying with the requirements of Regulation 61-16, Sections 1306.A and 1306.B, Level III hospitals 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. A full list of the requirements for a Level III Subspecialty Perinatal Center with Neonatal Intensive Care Unit can be found at Regulation 61-16, Section 1306.C. Neonatal transport may only be performed by Regional Perinatal Centers.

Regional Perinatal Center with Neonatal Intensive Care Unit (RPC). In addition to complying with the requirements of Regulation 61-16, Sections 1306.A through 1306.C, RPCs provide consultative, outreach, and support services to other hospitals in the region. A full list of the requirements for a Regional Perinatal Center can be found at Regulation 61-16, Section 1306.D. No more than one Regional Perinatal Center will be approved in each perinatal region.

Complex Neonatal Intensive Care Unit (Level IV). In addition to complying with the requirements of Regulation 61-16, 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. A full list of the requirements for a Complex Neonatal Intensive Care Unit can be found at Regulation 61-16, Section 1306.E. A Level IV hospital need not act as a Regional Perinatal Center (RPC).

The Perinatal-Capable Facilities Chart is located at the end of this Chapter.

NEONATAL SERVICES (NEONATAL INTENSIVE CARE BASSINETS)

Neonatal services are highly specialized and are only required by a very small percentage of infants. The need for these services is affected by the incidence of high-risk deliveries, the percentage of live births requiring neonatal services, and the average length of stay. The limited need for these services requires that they be planned for on a regional basis, fostering the location of these specialized units in hospitals that have the necessary staff, equipment, and consultative services and facilities. Referral networks facilitate the transfer of infants requiring this level of services from other facilities.

CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

1. The projected need for neonatal intensive care bassinets is calculated on a regional basis:
 - a. For each region take the average number of births from 2019-2021 and the average population of women age 15-44 for 2019-2021 to generate an average birth rate.
 - b. Multiply the average birth rate against the projected 2026 population of women age 15-44 to project the number of births in 2026.
 - c. Generate the projected number of intensive care bassinets needed in a region by applying a constant of 3.25 bassinets per 1,000 live births to the projected

birth rate and subtracting the existing bassinets from this total.

- d. Any Level 111, Level IV, or RPC neonatal unit may request additional intensive care bassinets beyond those indicated as needed by the methodology above. The Level 111, Level IV, or RPC neonatal unit requesting the addition must document the need for additional intensive care bassinets based on historical and projected utilization, projected population growth, routine swing of intermediate care bassinets into the intensive care setting, or other factors demonstrating the need for the proposed bassinets.
- e. In the absence of a projected need for Level III Intensive Care bassinets in a Perinatal Region as set forth in this Chapter, an existing Level II facility can be approved for a Certificate of Need to become a Subspecialty Perinatal Center and establish up to eight (8) neonatal intensive care bassinets (NICU beds), provided the applicant can demonstrate, during the 12 month period immediately prior to the month in which the CON application is submitted to the Department, a minimum of 1,500 births and 2,500 intermediate patient days at its facility.

2. Only Level III, Level IV, and RPC neonatal units have intensive care bassinets.

The Intensive and Intermediate Bassinets Chart, Utilization of Neonatal Special Care Units Chart and NICU Bed Need Chart are located at the end of this Chapter.

The addition of neonatal intermediate care bassinets does not require Certificate of Need review.

In some areas the number of intensive care bassinets should be increased. The intermediate care bassinets should be better utilized in Level II facilities so babies can be transferred back closer to their home community, potentially alleviating the high utilization of the current intensive/intermediate care bassinets in RPC facilities in some areas of the State. To improve the availability of the existing RPC neonatal intensive care bassinets, utilization of the back transport concept should be supported. This component of regionalized care involves the transfer of infants who no longer require neonatal intensive care to facilities with intermediate or continuing care bassinets appropriate to the individual baby's care needs. If more back transfers to the Level II facilities occurred, then some of the overcrowding problems of the existing RPC units would be alleviated.

It should be noted that some RPC, Level III, and Level IV facilities with intensive care bassinets may at times have intermediate type infants in intensive care bassinets and vice versa as the patient load changes within the unit. RPCs may use intermediate and intensive care bassinets interchangeably as the level of care required by the neonate varies.

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

The following criteria are considered the most important in evaluating Certificate of Need applications for neonatal intensive care bassinets:

1. Compliance with the Need Outlined in this Section of this Plan;
2. Distribution (Accessibility);
3. Record of the Applicant; and
4. Adverse Effects on Other Facilities.

Because neonatal services are planned and located regionally due to the small percentage of infants requiring neonatal services, this service is available within approximately 30 minutes travel time for the majority of the population. The benefits of improved accessibility will be equally weighed with the adverse effects of duplication in evaluating Certificate of Need applications for this service.

CMS MAJOR DIAGNOSTIC CATEGORIES (Chapter 5)

- MDC 1: Diseases and Disorders of the Nervous System
- MDC 2: Diseases and Disorders of the Eye
- MDC 3: Diseases and Disorders of the Ear, Nose, Mouth and Throat
- MDC 4: Diseases and Disorders of the Respiratory System
- MDC 5: Diseases and Disorders of the Circulatory System
- MDC 6: Diseases and Disorders of the Digestive System
- MDC 7: Diseases and Disorders of the Hepatobiliary System and Pancreas
- MDC 8: Diseases and Disorders of the Musculoskeletal System and Connective Tissue
- MDC 9: Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast
- MDC 10: Endocrine, Nutritional and Metabolic Diseases and Disorders
- MDC 11: Diseases and Disorders of the Kidney and Urinary Tract
- MDC 12: Diseases and Disorders of the Male Reproductive System
- MDC 13: Diseases and Disorders of the Female Reproductive System
- MDC 14: Pregnancy, Childbirth, and Puerperium
- MDC 15: Newborns and Other Neonates with Conditions Originating in the Perinatal Period
- MDC 16: Diseases and Disorders of the Blood, Blood Forming Organs, Immunological Disorders
- MDC 17: Myeloproliferative Diseases and Disorders, and Poorly Differentiated Neoplasm
- MDC 18: Infectious and Parasitic Diseases (Systemic or Unspecified Sites)
- MDC 19: Mental Diseases and Disorders
- MDC 20: Alcohol/Drug Use and Alcohol/Drug Induced Organic Mental Disorders
- MDC 21: Injuries, Poisonings and Toxic Effects of Drugs
- MDC 22: Burns
- MDC 23: Factors Influencing Health Status and Other Contacts with Health Services
- MDC 24: Multiple Significant Trauma
- MDC 25: Human Immunodeficiency Virus Infections

**GENERAL BED NEED*
(Chapter 5)**

Facility by Region and County	Age Cat	2021 Pop	2027 Pop	2021 Pt Days	Proj ADC	Var. Rate Factor	Bed Need	Licensed / Approved Beds	Staffed / Approved Beds	Add/ Excess Use	2021 % Occup. Rate	Statewide Bed Need	Add/ Excess State	Bed Need
Region I														
Abbeville Area Medical Center 1	<18	4,783	4,365			0								
	18-64	13,741	12,880			0								
	+65	5,546	5,938			0								
	TOTAL	24070	23183	0	0	65%	0	25	25	-25	0.00%			
Abbeville County Total							0	25	25	-25		39	14	-25
AnMed Health Medical Center 2	<18	46,404	47,781	34	0									
	18-64	121,758	127,403	36,207	104									
	+65	37,905	43,058	48,822	152									
	TOTAL	206,067	218,242	85,063	256	75%	342	495	274	-153	47.08%			
Anderson County Total							342	495	274	-153		0	-495	-153
Cherokee Medical Center	<18	12,856	12,200	0	0									
	18-64	33,505	32,561	2,263	6									
	+65	9,710	10,545	2,784	8									
	TOTAL	56,071	55,306	5,047	14	65%	21	125	80	-104	11.06%			
Cherokee County Total							21	125	80	-104		93	-32	-104
Prisma Health Greenville Memorial Hospital	<18	121,701	125,853	26,564	75									
	18-64	324,342	345,224	107,325	313									
	+65	88,040	105,542	67,852	223									
	TOTAL	534,083	576,619	201,741	611	75%	815	746	648	69	74.09%			
Prisma Health Greer Memorial Hospital	<18	121,701	125,853	118	0									
	18-64	324,342	345,224	10,788	31									
	+65	88,040	105,542	8,547	28									
	TOTAL	534,083	576,619	19,453	60	65%	93	82	70	11	64.99%			
Prisma Health Hillcrest Hospital	<18	121,701	125,853	6	0									
	18-64	324,342	345,224	4,198	12									
	+65	88,040	105,542	3,643	12									
	TOTAL	534,083	576,619	7,847	24	65%	38	43	43	-5	50.00%			
Prisma Health Patewood Hospital	<18	121,701	125,853	14	0									
	18-64	324,342	345,224	7,070	21									
	+65	88,040	105,542	563	2									
	TOTAL	534,083	576,619	7,647	23	65%	35	72	72	-37	29.10%			
Saint Francis - Downtown & Saint Francis - Millennium	<18	121,701	125,853	3	0									
	18-64	324,342	345,224	27,864	81									
	+65	88,040	105,542	38,937	128									
	TOTAL	534,083	576,619	66,804	209	70%	299	226	226	73	80.98%			
Saint Francis - Eastside	<18	121,701	125,853	27	0									
	18-64	324,342	345,224	11,548	34									
	+65	88,040	105,542	8,119	27									
	TOTAL	534,083	576,619	19,694	60	65%	93	93	93	0	58.02%			
Greenville County Total							1,373	1,262	1,152	111		966	-296	111
Self Regional Healthcare 1	<18	15,990	15,425	0	0									
	18-64	40,038	38,635	0	0									
	+65	13,210	14,272	0	0									
	TOTAL	69,238	68,332	58,277	158	70%	226	326	304	-100	48.98%			
Greenwood County Total							226	326	304	-100		115	-211	-100
Prisma Health Laurens County Hospital	<18	14,991	15,052	22	0									
	18-64	39,958	39,525	5,334	14									
	+65	12,788	14,176	7,391	22									
	TOTAL	67,737	68,753	12,747	37	65%	57	76	57	-19	45.95%			
Laurens County Total							57	76	57	-19		116	40	-19

GENERAL BED NEED*
(Chapter 5)

Facility by Region and County	Age Cat	2021 Pop	2027 Pop	2021 Pt Days	Proj ADC	Var. Rate Factor	Bed Need	Licensed / Approved Beds	Staffed / Approved Beds	Add/ Excess Use	2021 % Occup. Rate	Statewide Bed Need	Add/ Excess State	Bed Need
Prisma Health Oconee Memorial Hospital	<18	15,203	14,945	110	0									
	18-64	44,890	45,361	12,917	36									
	+65	19,046	21,670	17,732	55									
	TOTAL	79,139	81,976	30,759	91	65%	141	169	132	-28	49.86%			
Oconee County Total							141	169	132	-28		138	-31	-28
Prisma Health Baptist Easley Hospital	<18	28,148	30,808		0									
	18-64	82,888	89,292	8,323	25									
	+65	22,743	27,157	11,077	36									
	TOTAL	133,779	147,257	19,400	61	65%	94	109	89	-15	48.76%			
AnMed Health Cannon 1	<18	28,148	30,808		0									
	18-64	82,888	89,292		0									
	+65	22,743	27,157		0									
	TOTAL	133,779	147,257	2,753	8	65%	13	55	26	-42	13.71%			
Pickens County Total							107	164	115	-57		247	83	-57
Spartanburg Medical Center - Mary Black Campus	<18	78,189	86,009		0									
	18-64	203,027	228,145	12,760	39									
	+65	55,137	65,315	15,688	51									
	TOTAL	336,353	379,469	28,448	90	65%	139	174	119	-35	44.79%			
Spartanburg Medical Center	<18	78,189	86,009	2,058	6									
	18-64	203,027	228,145	80,062	246									
	+65	55,137	65,315	67,067	218									
	TOTAL	336,353	379,469	149,187	470	75%	628	484	456	144	84.45%			
Pelham Medical Center (Village Hospital)	<18	78,189	86,009		0									
	18-64	203,027	228,145	6,153	19									
	+65	55,137	65,315	7,074	23									
	TOTAL	336,353	379,469	13,227	42	65%	65	48	48	17	75.50%			
Spartanburg County Total							832	706	623	126		636	-70	126
Union Medical Center 1	<18	5,662	5,452		0									
	18-64	15,745	14,901	941	2									
	+65	5,624	5,936	959	3									
	TOTAL	27,031	26,289	1,900	5	65%	9	85	50	-76	6.12%			
Union County Total							9	85	50	-76		45	-40	-76
Region II														
Aiken Regional Medical Center 2	<18	35,969	35,170	305	1									
	18-64	98,893	97,545	19,379	52									
	+65	34,658	39,252	18,825	58									
	TOTAL	169,520	171,967	38,509	112	70%	160	197	197	-37	53.56%			
Aiken County Total							160	197	197	-37		289	92	-37
MUSC Health Chester Medical Center	<18	7,227	7,053	3	0									
	18-64	18,836	18,305	1,137	3									
	+65	6,167	6,549	1,498	4									
	TOTAL	32,230	31,907	2,638	7	65%	12	82	36	-70	8.81%			
Chester County Total							12	82	36	-70		54	-28	-70

GENERAL BED NEED*
(Chapter 5)

Facility by Region and County	Age Cat	2021 Pop	2027 Pop	2021 Pt Days	Proj ADC	Var. Rate Factor	Bed Need	Licensed / Approved Beds	Staffed / Approved Beds	Add/ Excess Use	2021 % Occup. Rate	Statewide Bed Need	Add/ Excess State	Bed Need
Edgefield County Healthcare	<18	4,391	3,901			0								
	18-64	15,871	14,511	57		0								
	+65	5,167	5,494	217		1								
	TOTAL	25,429	23,906	274	1	65%	2	25	25	-23	3.00%			
Edgefield County Total							2	25	25	-23		41	16	-23
Kershaw Health	<18	14,982	15,011	20		0								
	18-64	38,358	38,823	5,904		16								
	+65	12,532	13,951	7,611		23								
	TOTAL	65,872	67,785	13,535	38	65%	59	99	90	-40	37.46%			
Kershaw County Total							59	99	90	-40		114	15	-40
MUSC Health Lancaster Medical Center 3	<18	20,827	22,293	54		0								
	18-64	56,396	62,931	11,333		35								
	+65	21,529	26,166	13,399		45								
	TOTAL	98,752	111,390	24,786	77	70%	110	101	89	9	67.23%			
MUSC Health Indian Land Medical Center 3	<18	20,827	22,293	0		0								
	18-64	56,396	62,931	0		0								
	+65	21,529	26,166	0		0								
	TOTAL	98,752	111,390	0	0	65%	0	98	0	-98	0.00%			
Lancaster County Total							110	199	146	-89		187	-12	-89
Lexington Medical Center 4	<18	66,896	66,645	95		0								
	18-64	180,521	185,271	73,077		205								
	+65	49,806	58,597	71,959		232								
	TOTAL	297,223	310,513	145,131	438	75%	584	607	565	-23	65.51%			
Lexington County Total							584	607	565	-23		521	-86	-23
Newberry County Memorial Hospital	<18	8,291	8,114	16		0								
	18-64	21,648	20,913	2,851		8								
	+65	7,733	8,319	3,701		11								
	TOTAL	37,672	37,346	6,568	18	65%	29	90	54	-61	19.99%			
Newberry County Total							29	90	54	-61		63	-27	-61
Prisma Health Baptist Parkridge	<18	94,493	95,441	1,709		5								
	18-64	266,438	264,804	8,807		24								
	+65	57,160	67,009	7,278		23								
	TOTAL	418,091	427,254	17,794	52	65%	81	76	76	5	64.15%			
Prisma Health Baptist	<18	94,493	95,441	6,707		19								
	18-64	266,438	264,804	22,497		61								
	+65	57,160	67,009	16,644		53								
	TOTAL	418,091	427,254	45,848	133	70%	191	287	292	-96	43.77%			
Prisma Health Richland	<18	94,493	95,441	30,849		85								
	18-64	266,438	264,804	67,950		185								
	+65	57,160	67,009	53,202		171								
	TOTAL	418,091	427,254	152,001	441	75%	589	579	573	10	71.92%			
Providence Health	<18	94,493	95,441			0								
	18-64	266,438	264,804	10,518		29								
	+65	57,160	67,009	15,281		49								
	TOTAL	418,091	427,254	25,799	78	70%	112	258	173	-146	27.40%			
Providence Health - Northeast	<18	94,493	95,441			0								
	18-64	266,438	264,804	2,087		6								
	+65	57,160	67,009	2,315		7								
	TOTAL	418,091	427,254	4,402	13	65%	21	74	43	-53	16.30%			
Richland County Total							994	1,274	1,157	-280		716	-558	-280

GENERAL BED NEED*
(Chapter 5)

Facility by Region and County	Age Cat	2021 Pop	2027 Pop	2021 Pt Days	Proj ADC	Var. Rate Factor	Bed Need	Licensed / Approved Beds	Staffed / Approved Beds	Add/ Excess Use	2021 % Occup. Rate	Statewide Bed Need	Add/ Excess State	Bed Need
Piedmont Medical Center 5	<18	68,831	74,882	1,987	6									
	18-64	178,728	205,445	36,650	115									
	+65	43,519	55,067	32,688	113									
	TOTAL	291,078	335,394	71,325	235	70%	336	262	250	74	74.58%			
Fort Mill Medical Center 5	<18	68,831	74,882											
	18-64	178,728	205,445											
	+65	43,519	55,067											
	TOTAL	291,078	335,394	0	0	70%		100	64	-100	0			
York County Total							336	362	314	-34		562	200	-34
Region III														
McLeod Health Cheraw	<18	9,315	8,376	11	0									
	18-64	25,111	22,289	4,149	10									
	+65	8,253	8,489	4,926	14									
	TOTAL	42,679	39,154	9,086	24	65%	37	59	40	-22	42.19%			
Chesterfield County Total							37	59	40	-22		66	7	-22
McLeod Health Clarendon	<18	5,648	4,635	42	0									
	18-64	17,221	14,707	3,622	8									
	+65	7,640	7,665	4,202	12									
	TOTAL	30,509	27,007	7,866	20	65%	31	81	49	-50	26.61%			
Clarendon County Total							31	81	49	-50		46	-35	-50
Carolina Pines Regional Medical Center	<18	13,684	12,442	403	1									
	18-64	35,932	31,774	7,631	18									
	+65	12,302	12,203	6,790	18									
	TOTAL	61,918	56,419	14,824	38	65%	59	116	80	-57	35.01%			
McLeod Medical Center - Darlington 6	<18	13,684	12,442	0	0									
	18-64	35,932	31,774	6,947	17									
	+65	12,302	12,203	253	1									
	TOTAL	61,918	56,419	7,200	18	65%	28	0	0	28	40.26%			
Darlington County Total							87	116	80	-29		95	-21	-29
McLeod Medical Center Dillon	<18	6,961	6,091	124	0									
	18-64	15,970	13,867	5,419	13									
	+65	4,831	4,716	3,485	9									
	TOTAL	27,762	24,674	9,028	23	65%	35	79	34	-44	31.31%			
Dillon County Total							35	79	34	-44		42	-37	-44
MUSC Health Florence Medical Center	<18	31,701	29,863	14	0									
	18-64	80,427	77,053	24,710	65									
	+65	24,167	26,018	28,956	85									
	TOTAL	136,295	132,934	53,680	143	70%	205	310	310	-105	47.44%			
MUSC Health Florence Women's Pavilion	<18	31,701	29,863		0									
	18-64	80,427	77,053		0									
	+65	24,167	26,018		0									
	TOTAL	136,295	132,934	2,219	6	65%	10	20	0	-10	30.40%			
Lake City Community Hospital 7	<18	31,701	29,863	3	0									
	18-64	80,427	77,053	310	1									
	+65	24,167	26,018	345	1									
	TOTAL	136,295	132,934	658	2	65%	3	48	26	-45	3.76%			
McLeod Regional Medical Center of the Pee Dee	<18	31,701	29,863	2,696	7									
	18-64	80,427	77,053	68,165	179									
	+65	24,167	26,018	65,668	194									
	TOTAL	136,295	132,934	136,529	380	75%	507	517	440	-10	72.35%			
Florence County Total							725	895	776	-170		223	-672	-170
Tidelands Georgetown Memorial Hospital	<18	10,905	10,117	2	0									
	18-64	33,708	32,708	8,567	23									
	+65	19,136	22,455	10,094	32									
	TOTAL	63,749	65,280	18,663	55	65%	85	131	131	-46	39.03%			

GENERAL BED NEED*
(Chapter 5)

Facility by Region and County	Age Cat	2021 Pop	2027 Pop	2021 Pt Days	Proj ADC	Var. Rate Factor	Bed Need	Licensed / Approved Beds	Staffed / Approved Beds	Add/ Excess Use	2021 % Occup. Rate	Statewide Bed Need	Add/ Excess State	Bed Need
	+65	1,679	1,538	NR	0									
	TOTAL	7,745	6,355	0	0	65%	0	25	25	-25	0.00%			
Allendale County Total							0	25	25	-25		11	-14	-25

**GENERAL BED NEED*
(Chapter 5)**

Facility by Region and County	Age Cat	2021 Pop	2027 Pop	2021 Pt Days	Proj ADC	Var. Rate Factor	Bed Need	Licensed / Approved Beds	Staffed / Approved Beds	Add/ Excess Use	2021 % Occup. Rate	Statewide Bed Need	Add/ Excess State	Bed Need
Beaufort Memorial Hospital	<18	34,641	32,384	147	0									
	18-64	100,200	101,132	14,005	39									
	+65	54,196	63,237	16,358	52									
	TOTAL	189,037	196,753	30,510	91	65%	141	169	169	-28	49.46%			
Hilton Head Hospital	<18	34,641	32,384	8	0									
	18-64	100,200	101,132	6,992	19									
	+65	54,196	63,237	16,298	52									
	TOTAL	189,037	196,753	23,298	71	65%	110	93	93	17	68.63%			
South Of Broad Hospital 15	<18	34,641	32,384		0									
	18-64	100,200	101,132		0									
	+65	54,196	63,237		0									
	TOTAL	189,037	196,753	0	0	65%	0	20		-20				
Beaufort County Total							251	282	262	-31		330	48	-31
Roper St. Francis- Berkeley 16	<18	56,235	61,395	25	0									
	18-64	146,263	166,608	6,384	20									
	+65	34,975	45,848	4,487	16									
	TOTAL	237,473	273,851	10,896	36	65%	56	100	50	-44	29.85%			
MUHA Community Hospital 17	<18	56,235	61,395	0	0									
	18-64	146,263	166,608	0	0									
	+65	34,975	45,848	0	0									
	TOTAL	237,473	273,851	0	0	65%	0	128	128	-128	0.00%			
Berkeley County Total *							56	228	178	-172		459	231	231
Bon Secours - Saint Francis Xavier Hospital :	<18	80,988	79,488	76	0									
	18-64	259,628	265,300	19,068	53									
	+65	72,010	85,774	15,569	51									
	TOTAL	412,626	430,562	34,713	104	70%	150	190	149	-40	50.05%			
East Cooper Medical Center	<18	80,988	79,488	12	0									
	18-64	259,628	265,300	8,664	24									
	+65	72,010	85,774	7,114	23									
	TOTAL	412,626	430,562	15,790	48	65%	74	130	130	-56	33.28%			
Mount Pleasant Hospital	<18	80,988	79,488	0	0									
	18-64	259,628	265,300	4,489	13									
	+65	72,010	85,774	7,073	23									
	TOTAL	412,626	430,562	11,562	36	65%	55	85	73	-30	37.27%			
MUSC Medical Center	<18	80,988	79,488	29,405	79									
	18-64	259,628	265,300	108,319	303									
	+65	72,010	85,774	65,454	214									
	TOTAL	412,626	430,562	203,178	596	75%	795	685	656	110	81.26%			
Roper Hospital	<18	80,988	79,488	0	0									
	18-64	259,628	265,300	24,240	68									
	+65	72,010	85,774	34,677	113									
	TOTAL	412,626	430,562	58,917	181	70%	259	266	241	-7	60.68%			
Trident Medical Center	<18	80,988	79,488	65	0									
	18-64	259,628	265,300	34,904	98									
	+65	72,010	85,774	37,419	122									
	TOTAL	412,626	430,562	72,388	220	70%	315	282	273	33	70.33%			
Charleston County Total							1,648	1,638	1,522	10		722	-916	10

GENERAL BED NEED*
(Chapter 5)

Facility by Region and County	Age Cat	2021 Pop	2027 Pop	2021 Pt Days	Proj ADC	Var. Rate Factor	Bed Need	Licensed / Approved Beds	Staffed / Approved Beds	Add/ Excess Use	2021 % Occup. Rate	Statewide Bed Need	Add/ Excess State	Bed Need
Colleton Medical Center	<18	8,751	9,067	577		2								
	18-64	22,000	22,011	6,352		17								
	+65	7,996	8,829	7,593		23								
	TOTAL	38,747	39,907	14,522	41	65%	64	116	112	-52	34.30%			
Colleton County Total							64	116	112	-52		67	-49	-52
Summerville Medical Center 19	<18	38,629	38,412	4,020		11								
	18-64	100,412	104,469	22,632		65								
	+65	24,591	30,297	9,905		33								
	TOTAL	163,632	173,178	36,557	109	65%	168	174	124	-6	57.56%			
Dorchester County Total							168	174	124	-6		291	117	-6
Hampton Regional Medical Center	<18	3,983	3,672	0		0								
	18-64	10,526	9,085	1,106		3								
	+65	3,749	3,995	2,160		6								
	TOTAL	18,258	16,752	3,266	9	65%	14	32	14	-18	27.96%			
Hampton County Total							14	32	14	-18		29	-3	-18
Coastal Carolina Hospital (Formerly - Coastal Carolina Medical Center)	<18	5,493	5,116	15		0								
	18-64	17,284	16,947	4,705		13								
	+65	6,645	9,458	4,859		19								
	TOTAL	29,422	31,521	9,579	32	65%	49	41	35	8	64.01%			
Jasper County Total							49	41	35	8		53	12	8
Regional Medical Center of Orangeburg & Calhoun Counties 1	<18	18,549	16,622			0								
	18-64	47,057	42,273			0								
	+65	17,329	17,908			0								
	TOTAL	82,935	76,803	47,105	120	70%	171	247	209	-76	52.25%			
Orangeburg County Total							171	247	209	-76		129	-118	-76
Bamberg		12,983	11,409									20	20	20
Barnwell		20,337	18,925									32	32	32
Fairfield		20,459	18,046									31	31	31
Lee		16,197	14,642									25	25	25
McCormick		9,470	9,149									16	16	16
Marlboro		26,328	25,031									42	42	42
Saluda		18,566	16,977									29	29	29
Calhoun		13,983	13,090									22	22	22
Counties Without General Hospitals														
Statewide Total		5,177,874	5,460,568	2,385,240	6,535			12,008				0.001675		
Beds per person .0022613					SW ADC		SW Need							
Beds Per Population Multiplier		0.0016751			6,535	0.75	8,713	0						

- 1** Age cohorts not adequately reported.
- 2** SC-21-31 AnMed Health Medical Center transfer 72 acute care beds from AnMed Health Women's and Children's Hospital with zero (0) acute care beds at AnMed Health Women's and Children's Hospital.
- 3** Staff decision approving construction of a 98 acute care bed hospital through transfer of 98 acute care beds from MUSC Health Lancaster Medical. On appeal.
- 4** CON SC-22-41 issued 7/25/2023 for the addition of 50 inpatient hospital beds for a total of 607.
- 5** CON SC-19-74 issued 5/30/2019 for construction of a 100-bed hospital in Fort Mill using a combination of new and transferred hospital beds. Fort Mill Medical Center opened
- 6** E-21-01 Decrease in 49 general acute care beds resulting in a licensed bed capacity of 23 behavioral health beds.
- 7** CON SC-22-79 issued 11/16/2022 for construction for the establishment of 50 bed acute care hospital through the transfer of 50 beds from Conway Medical Center.
- 8** CON SC-19-111 issued 11/12/2019 for the addition of 32 general hospital beds.
- 9** Staff decision approving a 48 bed acute care hospital. On appeal.
- 10** CON SC-20-95 issued 11/23/2020 for the addition of 50 general hospital beds for a total of 155 general hospital beds.
- 11** Staff decision approving the expansion of an existing facility for the additon of 59 acute care beds. On appeal.
- 12** Staff decision approving a 36 bed acute care hospital. On appeal.
- 13** CON SC-20-38 issued 9/10/2020 for construction of a 25 bed hospital.
- 14** Facility did not submit JARS.
- 15** Staff decision approving a 20-bed acute care hospital in Beaufort County. On appeal.
- 16** CON SC-22-78 issued 12/5/2022 for the addition of 50 general acute care beds.
- 17** CON SC-20-25 issued 9/29/2020 approving a 128-bed acute care hospital in Berkeley County. On appeal.
- 18** E-20-23 Decrease in licensed bed capacity by 11 general acute care beds for a total of 190 general acute care beds.
- 19** CON SC-22079 issued 12/5/2022 for the addition of 50 acute care hospital beds for a total of 174 acute care hospital beds.

* Berkeley Medical Center returned CON SC-16-19 issued 5/26/2016 for the construction of a new 50 bed acute care hospital.

LONG-TERM ACUTE CARE HOSPITALS
(Chapter 5)

Facility By Region	County	2019			2020			2021		
		Beds	Pt Days	Occupancy Rate	Beds	Pt Days	Occupancy Rate	Beds	Pt Days	Occupancy Rate
Region I										
Prisma Health North Greenville Long Term Acute Care Hospital	Greenville	45	7,315	44.5%	45	5,581	34.0%	45	3,512	21.38%
Regency Hospital of Greenville	Greenville	32	8,646	74.0%	32	9,624	82.4%	32	8,980	76.88%
Spartanburg Hospital for Restorative Care	Spartanburg	97	9,710	27.4%	97	11,595	32.7%	97	11,723	33.11%
Region II										
Continuicare Hospital at Prisma Health Baptist	Richland	35	0	0.0%	35	NR	#VALUE!	35	NR	
Region III										
Regency Hospital of Florence 1	Florence	40	13,844	94.8%	40	14,359	98.3%	44	14,568	90.70%
Tidelands Health Extended Care Hospital 2	Horry									
Region IV										
Vibra Hospital of Charleston	Charleston	59	16,655	77.3%	59	14,643	68.0%	59	15,103	70.13%

0 in Pt Days is no Pt Days reported

NR in Pt Days is no JAR submitted

1 Regency Hospital of Florence: SC-21-75 issued 11/29/2021 for the addition of 4 long term acute care beds for a total of 44 long term acute care beds.

**PSYCHIATRIC PROGRAMS
(Chapter 5)**

Facility by Region	County	2021		
		Beds	Pt. Days	Occup Rate
Region I				
AnMed Health Medical Center 1	Anderson	38	7,692	55.5%
Carolina Center Behavioral Health 2	Greenville	117		0.0%
Prisma Health Greenville Memorial Hospital	Greenville	65	17,673	74.5%
Springbrook Behavioral Health	Greenville	56	13,690	67.0%
Self Regional Healthcare	Greenwood	32	2,397	20.5%
Spartanburg Medical Center 3	Spartanburg	32	802	6.9%
Spartanburg Medical Center - Mary Black Campus 3	Spartanburg	39	7,155	50.3%
Region II				
Aiken Regional Medical Centers	Aiken	44	11,176	69.6%
MUSC Health Kershaw Medical Center 4	Kershaw	20	3,175	43.5%
Rebound Behavioral Health	Lancaster	45	15,555	94.7%
MUSC Health Lancaster Medical Center 5	Lancaster	12	0	0.0%
Three Rivers Behavioral Health 6	Lexington	112	31,920	78.1%
Prisma Health Baptist	Richland	55	8,072	40.2%
Prisma Health Richland	Richland	52	8,674	45.7%
Piedmont Medical Center 7	York	20	7,080	97.0%
Region III				
McLeod Medical Center - Darlington	Darlington	23	7,130	84.9%
South Strand Medical Center 8	Horry	22	6,398	79.7%
Lighthouse Behavioral Health Hospital	Horry	76	18,615	67.1%
Region IV *				
Beaufort Memorial Hospital 9	Beaufort	18	2,508	38.2%
MUSC Medical Center	Charleston	82	28,384	94.8%
Palmetto Lowcountry Behavioral Health 10	Charleston	92	19,313	57.5%
Trident Medical Center 11	Charleston	60	8,585	39.2%
Colleton Medical Center	Colleton	19	5,206	75.1%
Regional Medical Center - Orangeburg & Calhoun	Orangeburg	15	3,560	65.0%

Government Facilities					
Patrick B. Harris Psychiatric Hospital	12	Anderson	108	39,969	101.4%
G. Werber Bryan Psychiatric Hospital	12	Richland	112	34,497	84.4%
Gilliam Psychiatric Hospital	12	Richland	82	NR	
William J McCord Adolescent Treatment Facility	12	Orangeburg	15	0	0.0%
		Total	1146	234,760	56.1%

1 SC-21-73 issued 11/18/2021 for the transfer of 38 inpatient psychiatric beds from AnMed Health Medical Center to the current Women's & Children's Hospital.

2 No 2021 Jars Reported

3 SC-20-20 issued 6/2/2020 for the relocation of 24 licensed psychiatric beds from Spartanburg Medical Center Church Street Campus to Spartanburg Medical Center-Mary Black Campus for a total of 39 psychiatric beds.

4 Formerly KershawHealth - Name change and ownership change effective 8/1/2021.

5 Bed and patient days were not reported in 2021 Jars.

6 SC-19-100 issued 9/5/2019 for the addition of 7 psychiatric beds for a total of 112 psychiatric beds.

7 SC-19-102 issued 9/9/2019 Effective 3/8/2022 the Applicant decided not to pursue the project and surrendered the CON.

8 SC-19-112 issued 11/12/2019 for the addition of 2 psychiatric beds for a total of 22 psychiatric beds.

9 SC-20-19 issued 6/2/2020 for the renovation of existing space and addition of 4 psychiatric beds for a total of 18 psychiatric beds.

10 SC-18-38 issued 8/6/2018 for the transfer of 48 psychiatric beds and 16 substance abuse beds and the addition of 39 psychiatric beds for a total of 103 beds in a newly constructed facility. On June 6, 2020, the applicant returned the CON and will not move forward with the project.

11 SC-18-37 issued 8/6/2013 for the addition of 43 psychiatric bed and the relocation of 17 psychiatric beds from Trident's main campus for a total of 60 beds.

12 State facility not operating all its licenced beds. Their utilization does not impact calculation of need.

* E-22-18 Permanent closure of Hilton Head Hospital psychiatric unit.

**PSYCHIATRIC BED NEED
(Chapter 5)**

Service Area	Age Cat	2021 Pop	2027 Pop	Existing Beds	2021 PT Days	Proj ADC	Occup Factor	Bed Need (Use)	Bed Need
Statewide Totals									
	<18	1,119,977	1,127,848						
	18-64	3,092,427	3,189,463						
	+65	965,469	1,143,256						
	TOTAL	5,177,873	5,460,567	1,146	234760	678	0.5	1357	211

**INPATIENT TREATMENT FACILITIES (SUBSTANCE ABUSE FACILITIES)*
(Chapter 5)**

Facility by Region	County	2021		
		Beds	Pt. Days	Occup Rate
Region I				
Carolina Center for Behavioral Health 1	Greenville	39	NR	#VALUE!
Springbrook Behavioral Health System	Greenville	6	291	13.3%
Region II				
Aiken Regional Medical Centers	Aiken	18	3,359	51.1%
Palmetto Health Baptist 2	Richland	10	0	0.0%
Palmetto Richland Springs (Palmetto Health Richland) 3	Richland	10	0	0.0%
Rebound Behavioral Health 4	Lancaster	18	NR	#VALUE!
Three Rivers Behavioral Health	Lexington	17	1,556	25.1%
Region III				
Lighthouse Behavioral Health Hospital	Horry	29	8,890	84.0%
Region IV				
MUSC Medical Center	Charleston	23	3,980	47.4%
Palmetto Lowcountry Behavioral Health	Charleston	16	890	15.2%
TOTAL		186	18,966	27.9%

* Morris Village is a State facility licensed for one hundred and sixty-three (163) substance abuse treatment beds that are not counted in the CON methodology.

1 Facility is licensed for 39 substance abuse treatment beds, but did not complete a 2020 JAR.

2 Facility is licensed for 10 substance abuse treatment beds, but reported 0 (zero) beds in 2020 JAR.

3 Facility is licensed for 10 substance abuse treatment beds, but reported 0 (zero) beds in 2020 JAR.

4 Facility is licensed for 18 substance abuse treatment beds, but did not complete a 2020 JAR.

INPATIENT TREATMENT BED NEED (SUBSTANCE ABUSE)
(Chapter 5)

SERVICE AREA	AGE CAT	2018 POP	2024 POP	EXISTING BEDS	2018 PT. DAYS	2018		BED NEED (USE)	+/-	BED NEED (SW)	+/-	BED NEED
						USAGE RATE	CON RATE					
Anderson, Oconee	0-17	61,467	62,585	0		0.00000	0.75	0	0	2	8	8
	18-64	163,008	168,680			0.00000	0.75	0	0	4		4
	65+	54,381	63,370			0.00000	0.75	0	0	2		2
Cherokee, Spartanburg, Union	0-17	91,457	94,915	0		0.00000	0.75	0	0	3	11	11
	18-64	240,955	254,995			0.00000	0.75	0	0	6		6
	65+	65,964	77,510			0.00000	0.75	0	0	2		2
Greenville, Pickens	0-17	142,076	151,325	35	15	0.00011	0.75	1	3	4	-18	3
	18-64	395,278	417,035		7,805	0.01975	0.75	31	0	10		10
	65+	101,796	126,285		1,188	0.01167	0.75	6	0	3		3
Abbeville, Edgefield, Greenwood, Laurens, McCormick, Saluda	0-17	45,945	44,530	0		0.00000	0.75	0	0	2	7	7
	18-64	130,068	125,500			0.00000	0.75	0	0	3		3
	65+	43,269	49,425			0.00000	0.75	0	0	2		2
Chester, Lancaster, York	0-17	94,525	104,960	18	0	0.00000	0.75	0	0	3	-5	-5
	18-64	241,874	277,210		2,443	0.01010	0.75	11	-5	7		7
	65+	65,350	86,270		265	0.00406	0.75	2	0	3		3
Fairfield, Kershaw, Lexington, Newberry, Richland	0-17	184,794	193,090	37	32	0.00017	0.75	1	0	5	-15	-15
	18-64	527,507	538,385		1,304	0.00247	0.75	5	-29	13		13
	65+	123,821	152,035		272	0.00220	0.75	2	0	4		4
Chesterfield, Dillon, Marlboro	0-17	23,032	21,445	0		0.00000	0.75	0	0	1	4	4
	18-64	61,463	57,025			0.00000	0.75	0	0	2		2
	65+	18,256	20,390			0.00000	0.75	0	0	1		1
Clarendon, Lee, Sumter	0-17	35,286	32,725	0		0.00000	0.75	0	0	1	5	5
	18-64	93,491	86,885			0.00000	0.75	0	0	3		3
	65+	28,577	32,595			0.00000	0.75	0	0	1		1
Darlington, Florence, Marion	0-17	54,489	51,170	12		0.00000	0.75	0	0	2	-4	-3
	18-64	139,200	132,285		2,428	0.01744	0.75	9	-3	4		4
	65+	42,311	47,990			0.00000	0.75	0	0	2		2

INPATIENT TREATMENT BED NEED (SUBSTANCE ABUSE)
(Chapter 5)

SERVICE AREA	AGE CAT	2018 POP	2024 POP	EXISTING BEDS	2018 PT. DAYS	2018		CON RATE	BED NEED (USE)	+ / -	BED NEED (SW)	+ / -	BED NEED
						USAGE RATE	RATE						
Georgetown, Horry, Williamsburg	0-17	79,493	82,695	29		0.00000	0.75	0	2				
	18-64	251,347	278,360		6,543	0.02603	0.75	27	7	7		-16	7
	65+	106,162	154,235		1,627	0.01533	0.75	9	4				
Aiken, Barnwell	0-17	41,885	40,850	18	481	0.01148	0.75	2	1				
	18-64	111,854	109,895		3,093	0.02765	0.75	12	3	0		-12	0
	65+	36,774	43,900		691	0.01879	0.75	4	2				
Allendale, Beaufort, Hampton, Jasper	0-17	46,708	46,420	0		0.00000	0.75	0	2				
	18-64	136,827	141,475			0.00000	0.75	0	4	0		8	8
	65+	62,405	80,945			0.00000	0.75	0	2				
Bamberg, Calhoun, Orangeburg	0-17	24,502	22,620	0		0.00000	0.75	0	1				
	18-64	67,638	59,815			0.00000	0.75	0	2	0		4	4
	65+	23,589	26,005			0.00000	0.75	0	1				
Berkeley, Charleston, Colleton, Dorchester	0-17	180,286	190,120	39	0	0.00000	0.75	0	5				
	18-64	517,757	559,505		3,910	0.00755	0.75	16	13	-21		-17	-17
	65+	127,260	167,130		238	0.00187	0.75	2	4				
Statewide Totals		5,084,127		188	32,335			140	148				17
				State									
	0-64	4,184,212	4,346,500	Usage									
	65+	899,915	1,128,085	Rate									
	Total	5,084,127	5,474,585	0.000017									

**REHABILITATION PROGRAMS
(Chapter 5)**

Facility by Region	County	2021		
		Beds	Pt. Days	Occup Rate
Region I				
AnMed Health Rehabilitation Hospital	Anderson	60	16,138	73.7%
Encompass Health Rehabilitation Hospital of Greenville 1	Greenville	40	NR	NR
Roger C. Peace (Prisma Health Greenville Memorial Hospital)	Greenville	53	11,657	60.3%
St. Francis - Downtown	Greenville	19	2,630	37.9%
Greenwood Regional Rehabilitation Hospital	Greenwood	42	9,483	61.9%
Spartanburg Medical Center - Mary Black Campus	Spartanburg	18	4,731	72.0%
Spartanburg Rehabilitation Institute 2	Spartanburg	60	14,827	67.7%
Region II				
Aiken Regional Medical Centers	Aiken	14	2,329	45.6%
PAM Health Rehabilitation Hospital of Aiken 3	Aiken	36	NR	NR
Midlands Regional Rehabilitation Hospital	Kershaw	40	7,525	51.5%
Lexington Regional Rehabilitation Hospital 4	Lexington	36	NR	NR
Encompass Health Rehabilitation Hospital of Columbia 5	Richland	79	21,199	73.5%
Encompass Health Rehabilitation Hospital of Irmo 5	Richland	27	NR	NR
Encompass Health Rehabilitation Hospital of Rock Hill	York	50	NR	0.0%
Encompass Health Rehabilitation Hospital of Fort Mill 6	York	39	NR	NR
Region III				
MUSC Health Florence Rehabilitation Center 7	Florence	40	5,773	NR
Encompass Health Rehabilitation Hospital of Florence	Florence	88	15,660	48.8%
Tidelands Health Rehabilitation Hospital an Affiliate of Encompass Health	Georgetown	29	9,348	88.3%
Grand Strand Medical Center	Horry	24	8,610	98.3%
Conway Medical Center 8	Horry	12	NR	NR
Tidelands Health Rehabilitation Hospital at Little River an Affiliate of Encompass Health	Horry	46	10,996	65.5%
Tidelands Health Rehabilitation Hospital at Carolina Bays an Affiliate of Encompass Health 9	Horry	36	NR	NR
Region IV				
Beaufort Memorial Hospital 10	Beaufort	18	2,788	42.4%
Encompass Health Rehabilitation Hospital of Bluffton	Beaufort	38	10,555	76%
Lowcountry Rehabilitation Hospital 11	Berkeley	33	NR	NR
East Cooper Medical Center 12	Charleston	10	2,571	70%
Encompass Health Rehabilitation Hospital of Charleston	Charleston	49	11,868	66.4%
Roper Hospital	Charleston	66	14,957	62.1%
Trident Medical Center	Charleston	14	4,864	95.2%
Regional Medical Center of Orangeburg & Calhoun Counties	Orangeburg	24	5,137	58.6%
TOTAL		1140	193,646	46.5%

*CON SC-16-43 issued 8/11/16 for the establishment of a new 13 bed rehabilitation unit was withdrawn 9/11/20. Prisma Health Children's Hospital has been removed from the inventory.

1 CON SC-19-113 issued 11/21/19 for the establishment of a 40 bed freestanding inpatient rehabilitation hospital in Greenville County, not yet implemented

2 CON SC-20-22 issued 6/24/20 for the addition of 15,100 sf and the addition of 20 rehabilitation beds.

3 Staff approved construction for the establishment of a 36 bed inpatient rehabilitation hospital on 2/22/2022. On appeal.

4 CON SC-21-02 issued 1/26/21 for the establishment of a 36 bed freestanding inpatient rehabilitation hospital in Lexington County, not yet implemented.

5 CON SC-21-03 issued 1/26/21 for the establishment of a 27 bed freestanding inpatient rehabilitation hospital in Richland County including the transfer of 17 beds from Encompass Health Columbia and the addition of 10 new beds, not yet implemented.

6 CON SC-21-06 issued 2/11/21 for the establishment of a 39 bed freestanding inpatient rehabilitation hospital in York County, not yet implemented.

7 CON SC-23-10 issued 2/7/2023 for the relocation of 40 inpatient rehabilitation beds from Cedar Street Campus to MUSC Health Florence Medical Center.

8 CON SC-21-01 issued 1/13/21 for the establishment of an inpatient rehabilitation unit with 12 inpatient rehabilitation beds, not yet implemented.

9 Staff approved construction for the establishment of a 36 bed inpatient Rehabilitation Hospital on 4/14/2022. On appeal.

10 CON SC-19-105 issued 9/16/19 for the addition of 4 rehabilitation beds, not yet implemented.

11 CON SC-19-82 issued 7/19/19 for the construction of a 33 bed freestanding rehabilitation hospital, not yet implemented.

12 CON SC-19-81 issued 7/19/19 for the development of a 10 bed inpatient rehabilitation unit, not yet implemented.

**REHABILITATION BED NEED
(Chapter 5)**

Service Area	>65	>65	2021	2021	2027	2027	Existing	2021	Proj	Occup	Bed	Bed	Need	Need
	Pop	Pop	Pop	Pop	Pop	Pop	Beds	PT Days	ADC	Factor	Need (Use)	+ / -	(SW)	+ / -
Anderson, Oconee	56,951	64,728	285,206	300,218	60	16,138	47	0.70	67	76	16	16		
Greenville, Pickens	110,783	132,699	667,862	723,877	112	14,287	42	0.70	60	157	45	45		
Cherokee, Spartanburg, Union	70,471	81,796	419,457	461,063	78	19,558	59	0.70	84	97	19	19		
Chester, Lancaster, York	71,215	87,782	422,061	478,692	89	0	0	0.70	0	104	15	15		
Abbeville, Edgefield, Greenwood, Laurens, McCormick, Saluda	44,141	47,850	214,512	210,298	42	9,483	25	0.70	36	57	15	15		
Fairfield, Lexington, Newberry, Richland	119,527	138,998	773,446	793,160	142	21,199	60	0.70	86	164	22	22		
Chesterfield, Darlington, Dillon, Florence, Marion, Marlboro, Williamsburg	67,552	70,337	354,088	332,242	128	21,433	55	0.70	79	83	-45	-45		
Clarendon, Kershaw, Lee, Sumter	41,424	44,759	217,524	211,386	40	7,525	20	0.70	29	37	-3	-3		
Georgetown, Horry	115,219	157,534	427,023	488,558	147	28,954	91	0.70	130	186	39	39		
Aiken, Allendale, Bamberg, Barnwell, Calhoun, Orangeburg	64,021	69,334	307,503	298,548	74	7,466	20	0.70	29	82	8	8		
Beaufort, Hampton, Jasper	64,590	76,690	236,717	245,028	56	13,343	38	0.70	54	91	35	35		
Berkeley, Charleston, Colleton, Dorchester	139,572	170,748	852,478	917,499	172	34,260	101	0.70	144	202	30	30		
Statewide Totals	965,466	1,143,255	5,177,877	5,460,569	1,140	193,646	560	1.18078	798	1334	194	194		

CRITICAL ACCESS HOSPITALS*
(Chapter 5)

Facility by Region

Region I

Abbeville Area Medical Center 1

Region II

Edgefield County Healthcare

Region III

Williamsburg Regional Hospital 2

Region IV

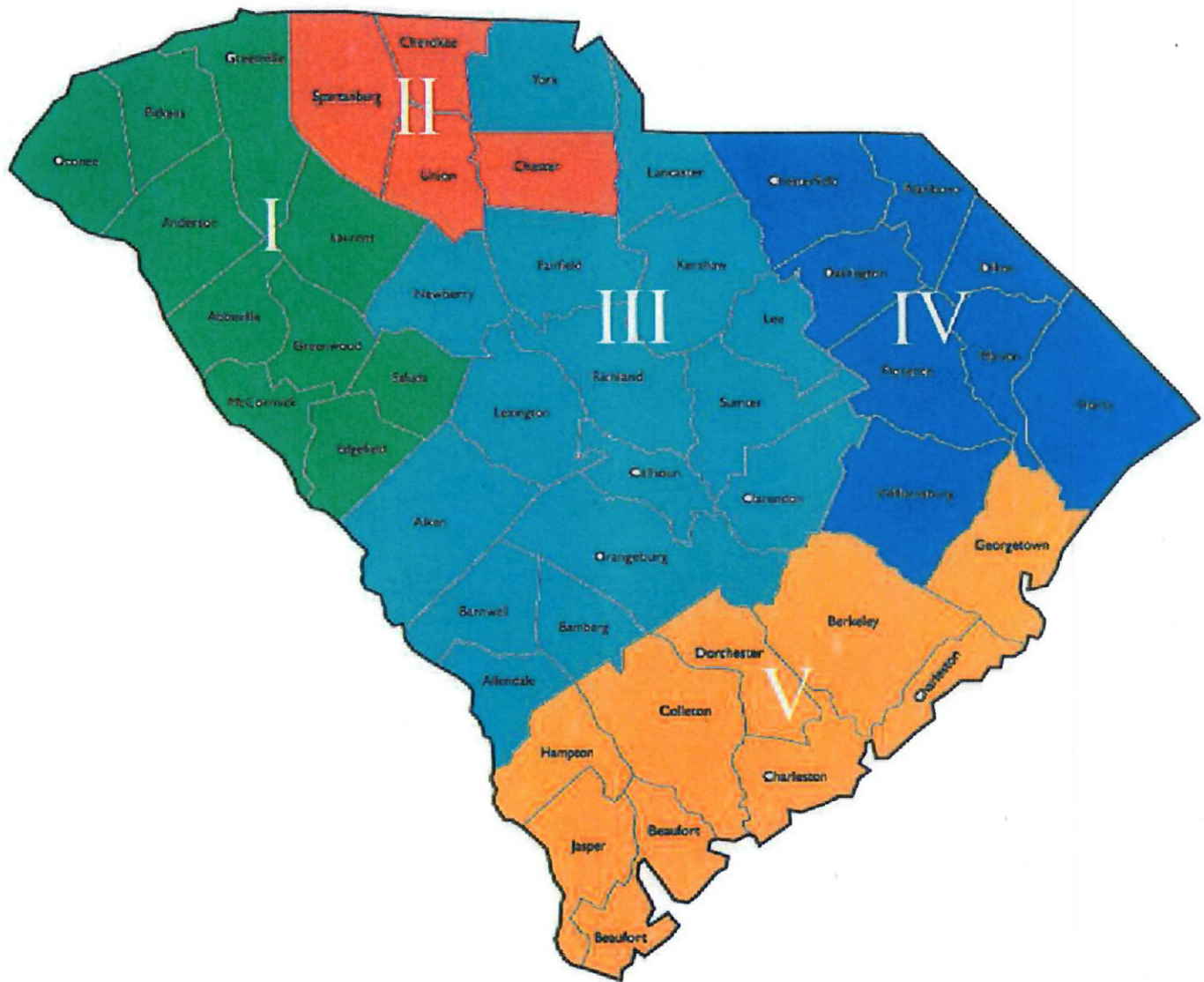
Allendale County Hospital

* Other facilities may potentially be eligible for CAH status.

1 Formerly Abbeville Memorial Hospital

2 (E-23-04) Facility Closed 12/17/2022

PERINATAL REGIONS MAP



**PERINATAL-CAPABLE FACILITIES
(Chapter 3)**

<u>Facility by Service Level</u>	<u>Perinatal Region</u>
Regional Perinatal Centers (RPCs)	
Prisma Health Greenville Memorial Hospital	I
Spartanburg Medical Center	II
Prisma Health Richland Memorial	III
McLeod Regional Medical Center of the Pee Dee	IV
MUSC Medical Center (Level IV)	V
Subspecialty Perinatal Center (Level III Hospital)	
Self Regional Healthcare	I
Prisma Health Baptist	III
Piedmont Medical Center	III
Specialty Perinatal Centers (Level II Hospitals) *	
AnMed Health Women's and Children's Hospital	I
Baptist Easley Hospital	I
Prisma Health Greer Memorial Hospital **	I
Prisma Health Patewood **	I
St. Francis - Eastside	I
Aiken Regional Medical Centers	III
Lexington Medical Center	III
Regional Medical Center of Orangeburg & Calhoun Counties	III
MUSC Health Lancaster Medical Center	III
Prisma Health Baptist - Parkridge **	III
Prisma Health Tuomey	III
Coastal Carolina Hospital **	IV
MUSC Health Marion Medical Center	IV
Carolina Pines Regional Medical Center	IV
Conway Hospital	IV
Grand Strand Medical Center	IV
MUSC Health Florence Women's Pavilion	IV
Beaufort Memorial Hospital	V
Bon Secours - St. Francis Xavier Hospital	V
East Cooper Medical Center	V
Tidelands Georgetown Memorial Hospital	V
Summerville Medical Center	V
Trident Medical Center	V
Tidelands Waccamaw Community Hospital	V
<i>* Removed from list</i>	
Baptist Easley Hospital	I
MUSC Health Marion Medical Center	IV
Trident Medical Center	V
** New Designation	

**INTENSIVE AND INTERMEDIATE BASSINETS
(Chapter 5)**

<u>Facility by Perinatal Region</u>	<u>Service Level</u>	<u>Existing Bassinets</u>	
		<u>Intensive</u>	<u>Intermediate</u>
Region I - Greenville Memorial			
Prisma Greenville Memorial Hospital	RPC	12	68
Self Regional Healthcare	Level III	7	7
AnMed Health Women's & Children's Hospital	Level II	0	13
St. Francis - Eastside	Level II	0	14
Prisma Health Greer Memorial Hospital	Level II	0	1
Prisma Health Patewood Hospital	Level II	0	4
Subtotal		19	107
Region II - Spartanburg Regional			
Spartanburg Medical Center	RPC	13	22
Subtotal		13	22
Region III - Palmetto Health Richland			
Prisma Health Richland	RPC	31	38
Prisma Health Baptist	Level III	8	23
Piedmont Medical Center	Level III	12	0
Aiken Regional Medical Centers	Level II	0	8
Lexington Medical Center	Level II	0	20
Regional Medical Center of Orangeburg & Calhoun Counties	Level II	0	0
MUSC Health Lancaster Medical Center	Level II	0	4
Prisma Health Tuomey	Level II	0	10
Prisma Health Baptist - Parkridge	Level II	0	2
Subtotal		51	105
Region IV - McLeod Regional			
McLeod Regional Medical Center of the Pee Dee	RPC	25	23
Carolina Pines Regional Medical Center	Level II	0	4
Conway Hospital	Level II	0	6
Grand Strand Medical Center	Level II	0	0
MUSC Health Florence Women's Pavilion	Level II	0	11
Subtotal		25	44
Region V - MUSC Medical			
MUSC Medical Center	RPC/Level IV	46	36
Beaufort Memorial Hospital	Level II	0	3
Bon Secours St. Francis Xavier Hospital	Level II	0	11
East Cooper Medical Center	Level II	0	10
Tidelands Georgetown Memorial Hospital	Level II	0	0
Summerville Medical Center	Level II	0	16
Tidelands Waccamaw Community Hospital	Level II	0	2
Subtotal		46	78
Totals		154	356

**UTILIZATION OF NEONATAL SPECIAL CARE UNITS
(Chapter 5)**

2021

Facility by Perinatal Region	Service Level	Intensive		Intermediate		Total		Total Pt Days	Total Occupancy
		Bassinets	Pt Days	Bassinets	Pt Days	Bassinets	Pt Days		
Region I - Greenville Memorial									
Prisma Greenville Memorial Hospital	RPC	12	0	68	0	80	25,736	88.1%	
Self Regional Healthcare	Level III	7	632	7	1,032	14	1,664	32.6%	
AnMed Health Women's & Children's Hospital	Level II	0	0	13	1,517	13	1,517	32.0%	
St. Francis - Eastside	Level II	0	0	14	1,516	14	1,516	29.7%	
Prisma Health Greer Memorial Hospital	Level II	0	0	1	44	1	44	12.1%	
Prisma Health Patewood Hospital	Level 11	0	0	4	337	4	337	23.1%	
SUBTOTAL		19	632	107	4,446	126	30,814	67.0%	
Region II - Spartanburg Regional									
Spartanburg Medical Center	RPC	13	3,921	22	4,798	35	8,719	68.3%	
SUBTOTAL		13	3,921	22	4,798	35	8,719	68.3%	
Region III - Palmetto Health Richland									
Prisma Health Richland	RPC	31	13,815	38	6,539	69	20,354	80.8%	
Prisma Health Baptist	Level III	8	855	23	3,881	31	4,736	41.9%	
Piedmont Medical Center	Level III	12	1,947	0	0	12	1,947	44.5%	
Aiken Regional Medical Centers	Level II	0	0	8	200	8	200	6.8%	
Lexington Medical Center	Level II	0	0	20	2,803	20	2,803	38.4%	
Regional Medical Center of Orangeburg & Calhoun Counties	Level 11	0	0	0	0	0	0	#DIV/0!	
MUSC Health Lancaster Medical Center	Level II	0	0	4	264	4	264	18.1%	
Prisma Health Tuomey	Level II	0	0	10	623	10	623	17.1%	
Prisma Health Baptist Parkridge	Level II	0	0	2	319	2	319	43.7%	
SUBTOTAL		51	16,617	105	14,629	156	31,246	54.9%	

Region IV- Mcleod Regional									
Mcleod Regional Medical Center of the Pee Dee	RPC	25	4,013	23	7,833	48	11,846	67.6%	
Carolina Pines Regional Medical Center	Level 11	0	0	4	275	4	275	18.8%	
Conway Hospital	Level II	0	0	6	1,294	6	1,294	59.1%	
Grand Strand Medical Center	Level II	0	0	0	0	0	0	#DIV/0!	
MUSC Health Florence Women's Pavilion	Level II	0	0	11	994	11	994	24.8%	
SUBTOTAL		25	4,013	44	10,396	69	14,409	57.2%	

Region V- MUSC Medical									
MUSC Medical Center	RPC/Level IV	34	12,692	48	12,730	82	25,422	84.9%	
Beaufort Memorial Hospital	Level II	0	0	3	169	3	169	15.4%	
Bon Secours-St. Francis Xavier Hospital	Level 11	0	0	11	2,372	11	2,372	59.1%	
East Cooper Medical Center	Level II	0	0	10	1,768	10	1,768	48.4%	
Tidelands Georgetown Memorial Hospital	Level II	0	0	0	0	0	0	#DIV/0!	
Summerville Medical Center	Level II	0	0	16	2,991	16	2,991	51.2%	
Tidelands Waccamaw Community Hospital	Level II	0	0	2	726	2	726	99.5%	
SUBTOTAL		34	12,692	90	20,756	124	33,448	73.9%	

GRAND TOTAL		142	37,875	368	55,025	510	118,636	63.7%	
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GLOSSARY

TERM	DEFINITION	SOURCE
Affiliated Facilities	Two or more nursing homes or hospitals, whether owned, leased, or who have a formal legal relationship with a central organization and whose relationship has been established for reasons other than for transferring beds.	South Carolina Health Plan
Basic Perinatal Center with Well Newborn Nursery (Level I)	Level I hospitals provide services for normal uncomplicated pregnancies. A full list of the requirements for a Level I Basic Perinatal Center with Well Newborn Nursery can be found at Regulation 61-16, Section 1306.A.	Regulation 61-16
Bed Capacity	Bed space designated exclusively for inpatient care, including space originally designed or remodeled for inpatient beds, even though temporarily not used for such purposes.	South Carolina Health Plan
Complex Neonatal Intensive Care Unit (Level IV)	In addition to complying with the requirements of Regulation 61-16, 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. A full list of the requirements for a Complex Neonatal Intensive Care Unit can be found at <u>Regulation 61-16, Section 1306.E</u> . A Level IV hospital need not act as a Regional Perinatal Center (RPC).	Regulation 61-16
Continuing Care Retirement Community Home Health Agency	<p>A licensed continuing care retirement community that also incorporates a skilled nursing facility may provide home health services.</p> <ol style="list-style-type: none"> a. The continuing care retirement furnishes or offers to furnish home health services only to residents who reside in living units provided by the continuing care retirement community pursuant to a continuing care contract; b. The continuing care retirement community maintains a current license and meets the applicable home health agency licensing standards; and c. Residents of the continuing care retirement community may choose to obtain home health services from other licensed home health agencies. 	South Carolina Health Plan

Critical Access Hospital (CAH)	Hospitals eligible for increased reimbursement without having to meet all criteria for full-service acute care hospitals. They are intended to provide essential health services to rural communities. In order to qualify as a CAH, a hospital must be located in a rural county and be located more than 35 miles from any other hospital or CAH (15 miles for areas with only secondary roads). It must be part of a rural health network with at least one full-service hospital. They can have a maximum of 25 licensed beds and the annual average length of stay must be less than 4 days. Emergency services must be available 24 hours a day.	South Carolina Health Plan
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 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 South Carolina.	S.C. Code of Regulations 61-16, Section 101(E)(1)
Health Care Facility	Acute care hospitals, psychiatric hospitals, alcohol and substance abuse hospitals, nursing homes, ambulatory surgical facilities, hospice facilities, radiation therapy facilities, rehabilitation facilities, residential treatment facilities for children and adolescents, intermediate care facilities for person with intellectual disability, narcotic (opioid) treatment programs, and any other facility for which Certificate of Need review is required by law.	S.C. Code Ann. Section 44-7-130(15)
Health Service	Clinically related, diagnostic, treatment, or rehabilitative services and includes alcohol, drug abuse, and mental health services.	S.C. Code Ann. Section 44-7-130(16)
Home Health Agency	A public, nonprofit, or proprietary organization, whether owned or operated by one or more persons or legal entities, which furnishes or offers to furnish home health services.	S.C. Code Ann. Section 44-69-20(4)
Home Health Service	Home health services means those items and services furnished to an individual by a home health agency, or by others under arrangement with the home health agency, on a visiting basis and except for (d) below, in a place of temporary or permanent residence used as the individual's home as follows:	S.C. Code Ann. 44-69-20(5)
	Part-time or intermittent skilled nursing care as ordered by a physician, an Advanced Practice Registered Nurse	

(APRN), or a Physician Assistant (PA) and provided by or under the supervision of a registered nurse and at least one other service listed below: (a) physical, occupational, or speech therapy; (b) medical social services, home health aide services, and other therapeutic services; (c) medical supplies as indicated in the treatment plan and the use of medical appliances, to include durable medical equipment; and (d) any of the above items and services provided on an outpatient basis under arrangements made by the home health agency with a hospital, nursing home or rehabilitation center and the furnishing of which involves the use of equipment of such a nature that the items/services cannot readily be made available to the individual in his/her home, or which are furnished at one of the above facilities while the patient is there to receive such items or services. Transportation of the individual in connection with any such items or services is not included.

Hospital

A facility that is organized and administered to provide overnight medical or surgical or nursing care for an illness, injury, or infirmity and must provide on-campus emergency services; that may provide obstetrical care; and in which all diagnoses, treatment, or care is administered by or under the direction of persons currently licensed to practice medicine, surgery, or osteopathy.

[S.C. Code
Ann. Section
44-7-130\(17\)](#)

Hospital may include a residential treatment facility for children, adolescents, or young adults in need of mental health treatment that is physically a part of a licensed psychiatric hospital. This definition does not include facilities that are licensed by the Department of Social Services. A residential treatment facility for children, adolescents, or young adults in need of mental health treatment that is physically part of a licensed psychiatric hospital is not required to provide on-campus emergency services.

Hospital Bed

A bed for an adult or child patient. Bassinets for the newborn in a maternity unit nursery, beds in labor rooms, recovery rooms, and other beds used exclusively for emergency purposes are not included in this definition.

South
Carolina
Health Plan

Inpatient Psychiatric
Services

Those services provided to patients who are admitted to institutions for the evaluation, diagnosis, and treatment of mental, emotional, or behavioral disorders. Services may be provided in either psychiatric units of general hospitals or freestanding psychiatric hospitals.

South
Carolina
Health Plan

Inpatient Treatment Facility	Short-term treatment service for persons who are in need of an organized intensive program of alcohol and/or drug rehabilitation, but who are without serious debilitating medical complications. These facilities may provide detoxification for their patients, as needed, in the inpatient treatment beds. These facilities are licensed either as a specialized hospital or as part of a hospital.	South Carolina Health Plan
Institutional Nursing Home	A nursing facility established within the jurisdiction of a larger non-medical institution that maintains and operates organized facilities and services to accommodate only residents of the institution. These facilities provide necessary services for retirement communities as established by church, fraternal, or other organizations. Such beds must serve only the residents of the housing complex and either be developed after the housing has been established or be developed as a part of a total housing construction program that has documented that the entire complex is one inseparable project.	South Carolina Health Plan
Long-Term Acute Care Hospital (LTACH)	Hospitals with an average Medicare inpatient length of stay of greater than 25 days, including all covered and non-covered days of stay of Medicare patients. They provide treatment to patients with complex medical conditions, such as strokes, cardiac care, ventilator dependency, wound care and post-surgical care.	South Carolina Health Plan
Nursing Homes	Facilities with an organized nursing staff to maintain and operate organized facilities and services to accommodate two or more unrelated persons over a period exceeding twenty-four hours which is operated either in connection with a hospital or as a freestanding facility for the express or implied purpose of providing intermediate or skilled nursing care for persons who are not in need of hospital care.	South Carolina Health Plan
Pediatric Home Health Agency	Due to the limited number of home health providers available to treat children 18 years or younger, an exception to the home health criteria may be made for a Certificate of Need for a Home Health Agency restricted to providing intermittent home health skilled nursing services to patients 18 years or younger. The license for the agency will be restricted to serving children 18 years or younger and will ensure access to necessary and appropriate intermittent home health skilled nursing services to these patients. Any such agencies are not counted in the county inventories for need projection purposes.	South Carolina Health Plan

Person	An individual, a trust or estate, a partnership, a corporation including an association, joint stock company, insurance company, and a health maintenance organization, a health care facility, a state, a political subdivision, or an instrumentality including a municipal corporation of a state, or any legal entity recognized by the State.	S.C. Code Ann. Section 44-7-130(21)
Regional Perinatal Center with Neonatal Intensive Care Unit (RPC)	In addition to complying with the requirements of Regulation 61-16, Sections 1306.A through 1306.C, RPCs provide consultative, outreach, and support services to other hospitals in the region. A full list of the requirements for a Regional Perinatal Center can be found at Regulation 61-16, Section 1306.D. No more than one Regional Perinatal Center will be approved in each perinatal region.	Regulation 61-16
Specialty Perinatal Center with Special Care Nursery (Level II)	In addition to complying with the requirements of Regulation 61-16, Section 1306.A, Level II hospitals provide services for both normal and selected high-risk obstetrical and neonatal patients. A full list of the requirements for a Level II Specialty Perinatal Center can be found at Regulation 61-16, Section 1306.B.	Regulation 61-16
Subspecialty Perinatal Center with Neonatal Intensive Care Unit (Level III)	In addition to complying with the requirements of Regulation 61-16, Sections 1306.A and 1306.B, Level III hospitals 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 <i>Guidelines for Perinatal Care</i> (GPC) by the American Academy of Pediatrics (AAP) and The American College of Obstetricians and Gynecologists. A full list of the requirements for a Level III Subspecialty Perinatal Center with Neonatal Intensive Care Unit can be found at Regulation 61-16, Section 1306.C.	Regulation 61-16
Swing-Bed	The Social Security Act (Section 1883(a)(1), [42 U.S.C. 1395tt]) permits certain small, rural hospitals to enter into a "Swing Bed" agreement, under which the hospital can use its beds to provide either acute or skilled nursing facility (SNF) care, as needed. The hospital must be located in a rural area and have fewer than 100 beds.	South Carolina Health Plan

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CAROLINA
HEALTH PLAN



Healthy People. Healthy Communities

SOUTH CAROLINA HEALTH PLANNING COMMITTEE

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<u>Gokul Gondi, M.D.</u> <u>McKenzie Speed</u>	<u>Provider</u> <u>3rd District</u>	<u>6/30/2021</u> <u>2026</u>
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<u>Vacant</u> <u>Elbert R. Malone</u>	<u>Finance/Business</u> <u>6th District</u>	<u>6/30/2015</u> <u>2025</u>
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<u>Sarah C. Harrell</u> <u>Bradley W. Moorhouse</u>	<u>Finance/Business</u> <u>Admin of licensed For Profit Nursing Home</u>	<u>6/30/2018</u> <u>2016</u>
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CHAPTER 1

INTRODUCTION

SOUTH CAROLINA HEALTH PLAN

The South Carolina Code of Laws requires the Department of Health and Environmental Control (“Department”) to prepare a South Carolina Health Plan (“Plan”), with the advice of the Health Planning Committee, for use in the administration of the Certificate of Need Program. See [§ 44-7-180\(B\)](#).

CERTIFICATE OF NEED

~~Certificate of Need (CON) must be obtained from the Department before undertaking certain health care related projects. Specifically, a person or nursing home is required to obtain a CON prior to undertaking: the construction or other establishment of a new nursing home; a change in the existing bed complement of a nursing home through the addition of one or more beds or change in the classification of licensure of one or more beds; and other projects enumerated in statute. See § 44-7-160(A). A home health agency shall obtain a CON before licensure. See § 44-69-75(A). Finally, a person or health care facility is required to obtain a CON prior to undertaking: the construction or other establishment of a hospital; and a change in the existing bed complement of a hospital through the addition of one or more beds or change in the classification of licensure of one or more beds. See § 44-7-160(B). Effective January 1, 2027, the CON requirements for hospitals are repealed. See § 44-7-160(C). The purpose of the Certificate of Need Program, as set forth in the *State Certification of Need and Health Facility Licensure Act* (“Certificate of Need Act”), is to promote cost containment, prevent unnecessary duplication of health care facilities and services, guide the establishment of health facilities and services which will best serve public needs, and ensure that high quality services are provided in health facilities in this State. To achieve these purposes, the Certificate of Need Act requires a person or health care facility to obtain a Certificate of Need from the Department before undertaking certain health care related projects. See §§ 44-7-120 and 44-7-160.~~

HEALTH PLANNING COMMITTEE

The Health Planning Committee advises the Department in the drafting of the South Carolina Health Plan. It is comprised of fourteen members, twelve of whom are appointed by the Governor, which must include at least one member from each congressional district. One member is appointed by the chairman of the Department’s Board, and by virtue of his office, the final member is either the South Carolina Consumer Advocate or his designee. Health care consumers, health care financiers (including business and insurance), and health care providers (which must include at least one administrator of a for-profit nursing home) are

equally represented. The Health Planning Committee reviews the South Carolina Health Plan and submits it to the Board of Health and Environmental Control for final revision and adoption. See [§ 44-7-180](#).

STATUTORY REQUIREMENTS

In accordance with [§ 44-7-180\(B\)](#), this Plan contains (1) an *inventory* of existing and **CON approved** health care facilities, beds, specified health services and equipment; (2) *projections of need* for additional healthcare facilities, beds, specified health services, and equipment; (3) *standards for distribution* of healthcare facilities, beds, specified health services, and equipment (“Certificate of Need Standards”); and (4) **a general statement as to** the *project review criteria* considered to be the most important in evaluating Certificate of Need applications for each type of facility, service and equipment.

(1) INVENTORY

[Chapter 2](#) of this Plan identifies the inventory regions and service areas used in the administration of the Certificate of Need Program. Healthcare facilities, specified health services, beds and equipment are inventoried where applicable.

(2) PROJECTIONS OF NEED

Chapters 3 through [415](#) of this Plan discuss the need for additional healthcare facilities, beds, specified health services and equipment in the State. While the methodologies used to determine these needs vary depending on the type of healthcare facility, bed, specified health service, or equipment, a determination of projected need is calculated for most areas addressed by the Plan.

(3) CERTIFICATE OF NEED STANDARDS

In consultation with the Health Planning Committee, the Department formulated these standards to guide health providers throughout the State. Inclusion of these standards in the application process is designed to give applicants notice of its requirements and to elicit from them a commitment to incorporate these standards into both their applications and finished projects.

(4) PROJECT REVIEW CRITERIA

A general statement has been added to most sections of the Plan setting forth the Project Review Criteria considered to be the most important in reviewing Certificate of Need applications for each type of healthcare facility, bed, specified health service, and equipment. The staff may reorder the relative importance of the Project Review Criteria no more than one (1) time. The staff’s reordering of the relative importance

~~of the Project Review does not extend the review period. These criteria are not listed in order of importance, but sequentially, as they are can be found in Regulation 61-15.~~ Where appropriate, the Plan contains a finding as to whether the benefits of improved accessibility to each such type of facility, service and equipment may outweigh the adverse effects caused by the duplication of any existing facility, service or equipment.

DISCLAIMERS

- (1) The hyperlinks provided throughout this Plan were checked for accuracy immediately prior to publication. Due to factors outside our control, we cannot guarantee the links will not expire or otherwise become unavailable after publication. Should you be unable to access the hyperlinked information, please feel free to request the information from the Certificate of Need Program via e-mail to coninfo@dhec.sc.gov.
- (2) The population data set forth in this Plan was received from the South Carolina Revenue and Fiscal Affairs Office in ~~August of 2019~~October of 2022. The material includes population projections that are subject to the following conditions:

~~These projections offer only one scenario of future population change using the most current data available. The overall accuracy of the projections depends on the extent to which~~They are intended to demonstrate a likely scenario if future events unfold in a manner that reflects previous trends observed within each group. The model cannot account for unprecedented events that may significantly alter an area's demographic composition in the future. The possible events include large factory openings or closings, changes in technology, public health crises, environmental events, or other conditions that could ~~have an effect on migration, affect~~ birth rates, ~~or~~ death rates, ~~or~~ domestic and international migration. This means that population projections are likely to be more accurate in the immediate future than in distant years into the future. ~~The projections will be updated regularly as new data becomes available and future events unfold. Annual county population estimates released by the Census Bureau will be monitored along with birth and death data released each year, and adjustments will be made to the projected population results as appropriate.~~

CHAPTER 2

INVENTORY REGIONS AND SERVICE AREAS

INVENTORY REGIONS

This Plan has adopted the [Department's regions](#) for the purpose of inventorying [Health Care Facilities](#) and [Health Services](#) as designated and enumerated below:

<u>Region</u>	<u>Counties</u>
I - Upstate	Abbeville, Anderson, Cherokee, Greenville, Greenwood, Laurens, McCormick, Oconee, Pickens, Spartanburg, and Union
II - Midlands	Aiken, Barnwell, Chester, Edgefield, Fairfield, Kershaw, Lancaster, Lexington, Newberry, Richland, Saluda and York
III - Pee Dee	Chesterfield, Clarendon, Darlington, Dillon, Florence, Georgetown, Horry, Lee, Marion, Marlboro, Sumter and Williamsburg
IV - Lowcountry	Allendale, Bamberg, Beaufort, Berkeley, Calhoun, Charleston, Colleton, Dorchester, Hampton, Jasper and Orangeburg

NEED FOR HEALTH CARE FACILITIES AND ~~HEALTH SERVICES~~BEDS

This Plan calculates the need for certain Health Care Facilities and Health Services throughout South Carolina based on certain formulae and criteria set forth in detail in this Plan. For example:

- The need for hospital beds is based on the utilization of individual facilities.
- The need for acute psychiatric ~~services~~beds, alcohol and drug abuse services, and comprehensive rehabilitation ~~services~~beds is based on various service areas and utilization methodologies specified in this Plan.
- ~~—The need for most health services (e.g., cardiac catheterization, open heart surgery) is based upon the service standard, which is a combination of utilization criteria and travel time requirements.~~
- The need for long-term care and skilled nursing ~~service~~beds is projected by county.

SERVICE AREAS

In addition to inventory regions, this Plan designates service areas for certain Health Care Facilities and Health Services. These service areas may be comprised of one or more

counties. Service areas may cross the inventory regions identified above. The need for a service is analyzed by assessment of existing resources and need in the relevant service area, along with other factors set forth in this Plan, applicable statutes and regulations.

BED TRANSFER BETWEEN AFFILIATED FACILITIES

Given the ever-changing nature of the health care delivery system, affiliated facilities may want to transfer or exchange ~~specific equipment, services, or licensed beds~~ in order to better meet an identified need. Affiliated facilities are two or more ~~health care facilities~~ nursing homes or hospitals, whether ~~inpatient or outpatient~~, owned, leased, or who have a formal legal relationship with a central organization and whose relationship has been established for reasons other than for transferring ~~beds, equipment or services~~. In certain instances such a transfer or exchange of ~~acute services~~ beds could be accomplished in a cost-effective manner and result in a more efficient allocation of health care resources. This transfer or exchange of services applies to both inpatient and outpatient services. *A Certificate of Need is required to transfer or exchange beds, services, and/or equipment.* In order to evaluate a proposal for the transfer or exchange of ~~any health care equipment or technology~~ beds reviewed under the Certificate of Need program, the following criteria must be applied to it:

1. A transfer or exchange of ~~beds, services, and/or equipment~~ may be approved only if there is no overall increase in the number or amount of such ~~beds and/or services~~.
2. A transfer or exchange initiated under this Chapter may only occur within the service area(s) established in this Plan.
3. The facility receiving the ~~beds, services, and/or equipment~~ must demonstrate the need for the additional capacity based on historical and/or projected utilization patterns.
4. The applicants must explain the impact of transferring the ~~beds, services, and/or equipment~~ on the health care delivery system of the county and/or service area from which it is to be taken; any negative impact must be detailed, along with the perceived benefits of the proposal.
5. The facility giving up ~~beds, services, and/or equipment~~ may not use the loss of such ~~beds, services, and/or equipment~~ as justification for a subsequent request to establish or re-establish such ~~beds, services, and/or equipment~~.
6. A written contract or agreement between the governing bodies of the affiliated facilities approving the transfer or exchange of ~~beds, services, and/or equipment~~ must be included in the Certificate of Need process.
7. Each facility giving up ~~beds, services, and/or equipment~~ must acknowledge in writing

that this exchange is permanent; any further transfers would be subject to this same process.

ESTIMATED STATE CIVILIAN POPULATION

Where these projections were required for calculations, this Plan has been developed using the estimated civilian population of 5,084,127, 5,177,874 for ~~2018~~2021 and projected population of 5,474,585, 5,460,568 for ~~2024~~2027. All population data (county, planning area, and statewide) were provided by the South Carolina Revenue and Fiscal Affairs Office, Health and Demographics Section, in ~~August 2019~~October 2022.

INVENTORY DATES

Only those facilities reviewed under the Certificate of Need program are included in the inventory. The cut-off date for inclusion of information in this Plan was ~~January 17, 2020~~December 31, 2022. Inventory and utilization data set forth in this Plan is derived from the ~~2018~~2021 Joint Annual Reports (JARs). The period of time in which the individual data was collected is set forth by the reporting entity in its individual JAR submission.

CHAPTER 113

LONG-TERM CARE FACILITIES AND SERVICES NURSING HOMES

NURSING FACILITIES HOMES

Nursing facilities provide inpatient care for convalescent or chronic disease residents who require nursing care and related medical services. This care is performed under the general direction of persons licensed to practice medicine, ~~or~~ surgery, or osteopathy in the State. Facilities furnishing primarily domiciliary care are not included. The licensing list of nursing facilities also denotes the facilities that have Alzheimer's units. For more specific detail about nursing facilities, refer to [Regulation 61-17](#) (*Standards for Licensing Nursing Homes*).

Since the vast majority of patients utilizing nursing facilities are 65 years of age or older, only this segment of the population is used in the need calculations. County bed needs are projected through ~~2022~~2027. A two-year projection is used because nursing facilities can be constructed and become operational in two years.

CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

1. Based on observations of methodologies from other states operating a Certificate of Need regime, and recognizing that potential reliance on long-term skilled nursing services increases with age, bed need is calculated on a county basis using the following ratios:
 - a) 10 beds/1,000 population aged 65-74; and
 - b) 58 beds/1,000 population aged 75 and over
2. For each county, these needs are calculated separately. The individual age-group needs are then added together, and the existing bed count subtracted from that total to determine the deficit or (surplus) of beds.
3. When a county shows surplus beds, additional beds will not be approved, except to allow an individual nursing facility to add some additional beds in order to make more economical nursing units. These additions are envisioned as small increments in order to increase the efficiency of the nursing home. This exception for additional beds will not be approved if it results in a three bed ward. A nursing facility may add up to 16 additional beds per nursing unit to create either 44 or 60 bed nursing units, regardless of the projected bed need for the county. The nursing facility must document how these additional beds will make a more economical unit(s).

4. Some Institutional Nursing Facilities are dually licensed, with some beds restricted to residents of the retirement community and the remaining beds are available to the general public. The beds restricted to residents of the retirement community are not eligible to be certified for Medicare or Medicaid. Should such a facility have restricted beds that are inadvertently certified, the facility will be allowed to apply for a Certificate of Need to convert these beds to general nursing home beds, regardless of the projected bed need for that county.

The ~~Long-Term Care~~Nursing Home Inventory and Bed Need Chart are located at the end of this Chapter.

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

The following project review criteria are considered the most important in evaluating Certificate of Need applications for these beds or facilities:

1. Community Need Documentation;
2. Distribution (accessibility);
3. Staff Resources; and
4. Record of the Applicant.

Because nursing facilities are located within approximately 30 minutes' travel time for the majority of the residents of the State and at least one nursing facility is located in every county, no justification exists for approving additional nursing facilities or beds that are not indicated as needed in this Plan. The major accessibility problem is caused by the lack of Medicaid funding since the Medicaid Program pays for approximately 65% of all nursing facility residents. This Plan projects the need for nursing facility beds by county. The benefits of improved accessibility ~~do not outweigh the adverse effects caused by the duplication of any existing beds or the placement of Medicaid funds for the beds~~ will be equally weighed with the adverse effects of duplication in evaluating Certificate of Need applications for this service.

MEDICAID NURSING HOME PERMITS

The Medicaid Nursing Home Permit Act, formerly known as the Nursing Home Licensing Act of 1987, sets forth a regulatory scheme whereby Medicaid nursing home permits and Medicaid patient days are allocated in South Carolina. A long-term care facility (nursing home) must obtain a Medicaid ~~Nursing Home Permit~~nursing home permit from the Department in order to serve Medicaid patients. A Medicaid patient is a person who is eligible for Medicaid (Title XIX) sponsored long-term care services. Each year, the South Carolina General Assembly establishes the maximum number of Medicaid patient days the Department is authorized to issue. A Medicaid patient day is a day of nursing home care for which the holder of a Medicaid nursing home ~~Permit~~permit can receive Medicaid

reimbursement. The South Carolina Department of Health and Human Services provides ~~the Department with the total number of Medicaid patient days available so the Department may distribute those patient days amongst Permit holdersthe number of Medicaid patient days available to the Department within thirty (30) days after the effective date of the annual appropriations act.~~

The Medicaid Patient Days and Medicaid Beds Requested & Authorized Chart is located at the end of this Chapter.

COMMUNITY LONG-TERM CARE (CLTC) PROGRAM

~~South Carolina is seeking to increase access to long-term care facilities through a number of different programs. The Community Long-Term Care Project (CLTC) provides mandatory pre-admission screening and case management to Medicaid-eligible individuals who are in need of applying for nursing facility placement under the Medicaid program. It also provides several community-based services for Medicaid participants who prefer to receive care in the community rather than institutional care. In certain counties, those services include:~~

~~Adult Day Healthcare: CLTC offers Adult Day Health Care to individuals enrolled in the Community Choices Waiver. This is medically supervised care and services provided at a licensed day care center. Transportation to and from the home is provided within 15 miles of the center.~~

~~Attendant/Personal Assistance: CLTC offers attendant services to individuals enrolled in the Community Choices Waiver. Nurses assist by observing care and helping consumers develop skills in managing their attendant. Services may include assistance with general household activities; help with activities such as bathing, dressing, preparing meals, and housekeeping; and observing health signs.~~

~~Care Management (Case Management - Service Coordination): CLTC assigns a nurse to help determine the services for which the participant qualifies and what services will best meet the needs of an individual enrolled in the Community Choices Waiver. Nursing Facility Transition Services may also be offered to help a participant residing in a nursing facility return to the community.~~

~~Companion (Sitter): CLTC provides an approved companion to provide supervision of an individual and short-term relief for regular caregivers to individuals enrolled in the Community Choices Waiver.~~

~~Home Repair/Modification Assistance: CLTC helps provide pest control services, ramps, heater fans and air conditioners to individuals enrolled in the Community Choices Waiver. It can also help make minor adaptations to non-rental property for the safety and health of the Medicaid participant.~~

~~Medical Equipment/Personal Care Supplies: CLTC provides limited durable medical equipment and incontinence supplies (diapers, underpads, wipes, etc.) to individuals enrolled in the Community Choices Waiver.~~

~~Nutritional Supplement Assistance: CLTC's Community Choices Program provides two cases per month of Nutritional Supplements to its participants.~~

~~The Program for All-Inclusive Care for the Elderly (PACE) is a Medicaid State option that provides comprehensive long-term care to primarily elderly residents of the State. PACE is available to Medicaid participants who are certified as "nursing home" eligible, but prefer care from community services. GHS Senior Care, Palmetto SeniorCare, and The Methodist Oaks currently operate PACE programs in the State.~~

SPECIAL NEEDS FACILITIES

~~The South Carolina Department of Disabilities and Special Needs (DDSN) provides 24-hour care to individuals with complex, severe disabilities through five in-state regional facilities located in Columbia, Florence, Clinton, Summerville and Hartsville. These facilities serve those individuals who cannot be adequately cared for by one of DDSN's community living options and focus on those with special needs, head and spinal cord injuries and pervasive development disorders. In 2014, the Centers for Medicare and Medicaid Services (CMS) issued its final rule on Home and Community Based Services (HCBS) that will, inter alia, ensure that individuals who receive services through Medicaid's HCBS programs have access to the benefits of community living. DDSN believes the HCBS initiative will affect its Day Programs and where its clients live. The South Carolina Department of Health and Human Services (DHHS) will be the lead agency in implementing HCBS which will be phased in over the next five (5) years.~~

INSTITUTIONAL NURSING FACILITYHOME (RETIREMENT COMMUNITY NURSING FACILITYHOME)

An institutional nursing ~~facility~~home means a nursing facility (established within the jurisdiction of a larger non-medical institution) that maintains and operates organized facilities and services to accommodate ~~only students~~, residents ~~or inmates~~ of the institution. These facilities provide necessary services for retirement communities as established by church, fraternal, or other organizations. Such beds must serve only the residents of the housing complex and either be developed after the housing has been established or be developed as a part of a total housing construction program that has documented that the entire complex is one inseparable project.

CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

To be considered under this special bed category, the following criteria must be met:

1. The nursing ~~facility~~home must be a part of and located on the campus of the retirement community.
2. It must restrict admissions to campus residents.
3. The facility may not participate in the Medicaid program.

There is no projection of need for this bed category. The applicant must demonstrate that the proposed number of beds is justified and that the facility meets the above qualifications. If approved by the Department, such a facility would be licensed as an "Institutional Nursing Home" and the beds generated by such a project will be placed in the statewide inventory ~~in~~at the end of this Chapter 44. These beds are not counted against the projected need of the county where the facility is located. For established retirement communities, a generally accepted ratio of nursing ~~facility~~home beds to retirement beds is 1:4.

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

The following project review criteria, ~~as outlined in Chapter 8 of Regulation 61-15,~~ are considered the most important in evaluating Certificate of Need applications for these beds or facilities:

1. Community Need Documentation;
2. Acceptability; and
3. Record of the Applicant.

Because Institutional Nursing ~~Facility~~Home Beds are used solely by the residents of the retirement community, there is no justification for approving this type of nursing ~~facility~~home unless the need can be documented by the retirement center. The benefits of improved accessibility ~~do not outweigh the adverse effects caused by the duplication of any existing beds or facilities~~will be equally weighed with the adverse effects of duplication in evaluating Certificate of Need applications for these beds or facilities.

SWING-BEDS

A Certificate of Need is not required to participate in the Swing Bed Program in South Carolina; however, the hospital must obtain Medicare certification.

The Social Security Act (Section 1883(a)(1), [42 U.S.C. 1395tt]) permits certain small, rural hospitals to enter into a swing bed agreement, under which the hospital can use its beds to

provide either acute or SNF care, as needed. The hospital must be located in a rural area and have fewer than 100 beds.

Medicare Part A covers the services furnished in a swing bed hospital under the SNF PPS. The PPS classifies residents into one of 44 categories for payment purposes. To qualify for SNF-level services, a beneficiary is required to receive acute care as a hospital inpatient for a stay of at least three consecutive days, although it does not have to be from the same hospital as the swing bed. Typical medical criteria include daily physical, occupational and/or speech therapy, IV or nutritional therapy, complex wound treatment, pain management, and end-of-life care.

The Swing-Bed Participants Chart is located at the end of this Chapter.

HOSPICE FACILITIES AND HOSPICE PROGRAMS

~~Hospice is a centrally administered, interdisciplinary health care program, which provides a continuum of medically supervised palliative and supportive care for the terminally ill patient and the family or responsible party, including, but not limited to home, outpatient and inpatient services provided directly or through written agreement. Inpatient services include, but are not limited to, services provided by a hospice in a licensed hospice facility.~~

~~A Hospice Facility means an institution, place or building licensed by the Department to provide room, board and appropriate hospice care on a 24-hour basis to individuals requiring such services pursuant to the orders of a physician.~~

~~The Inpatient Hospice Facilities Chart is located at the end of this Chapter.~~

~~A Hospice Program means an entity licensed by the Department that provides appropriate hospice care to individuals as described in the first paragraph above, exclusive of the services provided by a hospice facility.~~

CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

- ~~1. — A Certificate of Need is only required for an Inpatient Hospice Facility; it is not required for the establishment of a Hospice Program.~~
- ~~2. — An Inpatient Hospice Facility must be owned or operated either directly or through contractual agreement with a licensed hospice program.~~
- ~~3. — The applicant must document the need for the facility and justify the number of inpatient beds that are being requested.~~
- ~~4. — The proposed facility must consider the impact on other existing inpatient hospice~~

facilities.

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

The following Project Review Criteria are considered to be the most important in evaluating Certificate of Need applications for this service:

1. — Community Need Documentation;
2. — Distribution (Accessibility);
3. — Record of the Applicant; and
4. — Staff Resources.

Hospice services should be available within sixty (60) minutes' travel time for the majority of residents of the State. The benefits of improved accessibility will be weighed equally with the adverse effects of duplication in evaluating Certificate of Need applications for this facility type.

HOME HEALTH

Home Health Agencies

Home Health Agency means a public, nonprofit, or proprietary organization, whether owned or operated by one or more persons or legal entities, which furnishes or offers to furnish home health services. Home health services means those items and services furnished to an individual by a home health agency, or by others under arrangement with the home health agency, on a visiting basis and except for (f) below, in a place of temporary or permanent residence used as the individual's home as follows:

Part-time or intermittent skilled nursing care as ordered by a physician or podiatrist and provided by or under the supervision of a registered nurse and at least one other therapeutic service listed below: (a) physical, occupational, or speech therapy; (b) medical social services; (c) home health aide services; (d) other therapeutic services; (e) medical supplies as indicated in the treatment plan and the use of medical appliances, to include durable medical equipment and (f) any of the above items and services provided on an outpatient basis under arrangements made by the home health agency with a hospital, nursing home or rehabilitation center and the furnishing of which involves the use of equipment of such a nature that the items/services cannot readily be made available to the individual in his/her home, or which are furnished at one of the above facilities while the patient is there to receive such items or services. Transportation of the individual in connection with any such items or services is not included.

CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

- ~~1. An applicant must propose home health services to cover the geographic area of an entire county and agree to serve residents throughout the entire county.~~
- ~~2. A separate application is required for each county in which services are to be provided.~~
- ~~3. A new home health agency may be approved if an applicant can demonstrate it will serve 50 or more patients projected to be in need in non-rural counties, or 25 or more patients projected to be in need in rural counties, through evidence that may include, but would not be limited to, the following:
 - ~~a. Letters of support that identify need for additional home health services from physicians and other referral sources.~~
 - ~~b. Evidence of underutilization of home health services.~~
 - ~~c. Evidence of limited scope home health agency service including skilled nursing, physical therapy, occupational therapy, speech therapy, home health aides, and medical social workers.~~
 - ~~d. Evidence of the denial or delay in the provision of home health services, including but not limited to long waiting lists or delays which exceed industry standards.~~
 - ~~e. Evidence that one or more existing home health agencies has failed to meet the minimum patient service requirements set forth in Standard 8 of this section of the Plan within two years of the initiation of patient services after receiving a home health license.~~~~
- ~~4. For the purposes of this Section, a rural county shall mean a county with a population of less than 50,000, according to the most recent projections of the South Carolina Revenue and Fiscal Affairs office as of the time the current Plan was adopted.~~
- ~~5. All home health agency services (Skilled Nursing, Physical Therapy, Occupational Therapy, Speech Therapy, Home Health Aide, and Medical Social Worker) should be available within a county. If there is no hospital in a county and the existing licensed home health agencies between them do not provide all of the services identified above, this may be cited as potential justification for the approval of an additional agency that intends to offer these services.~~
- ~~6. Specialty home health providers are exempt from the need calculation applicable to full-service home health agencies, but are otherwise subject to Certificate of Need.~~
- ~~7. The applicant should have a track record that demonstrates a commitment to quality~~

~~services. There should be no history of prosecution, consent order, abandonment of patients in other business operations, or loss of license. However, any consent orders or loss of licenses related to licenses that were obtained from the Department between July 1, 2013 and May 22, 2014 without a Certificate of Need shall not be grounds for denial of a Certificate of Need application pursuant to this Section. The applicant must provide a list of all licensed home health agencies it operates and the state(s) where it operates them.~~

~~8. The applicant must document that it can serve at least 25 patients annually in each rural county for which it is licensed and 50 patients annually in each non-rural county for which it is licensed within two years of initiation of services. The applicant must assure the Department that, should it fail to reach this threshold number two years after initiation of services in a county, it will voluntarily relinquish its license for that county.~~

~~9. Nothing in this Section is intended to restrict the ability of the Department to approve more than one new Home Health Agency in a county at any given time.~~

~~The Home Health Agency Inventory Chart is located at the end of this Chapter.~~

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

~~The following project review criteria, as outlined in Chapter 8 of Regulation 61-15, are considered to be the most important in reviewing Certificate of Need applications for this service:~~

- ~~1. Community Need Documentation;~~
- ~~2. Distribution (Accessibility); and~~
- ~~3. Medically Underserved Groups.~~

~~The benefits of improved accessibility outweigh the adverse effects caused by the duplication of any existing service.~~

Pediatric Home Health Agencies

~~Due to the limited number of home health providers available to treat children 18 years or younger, an exception to the above criteria may be made for a Certificate of Need for a Home Health Agency restricted to providing intermittent home health skilled nursing services to patients 18 years or younger. The license for the agency will be restricted to serving children 18 years or younger and will ensure access to necessary and appropriate intermittent home health skilled nursing services to these patients. Any such approved agency will not be counted in the county inventories for need projection purposes.~~

CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

- ~~1. A separate Certificate of Need application will be required for each county for an agency that proposes to provide this specialized service to pediatric patients in multiple counties.~~
- ~~2. The applicant must document that there is an unmet need for this service in the county of application, and the agency will limit such services to the pediatric population 18 years or younger.~~
- ~~3. The applicant must document the full range of services that they intend to provide to pediatric patients.~~

Continuing Care Retirement Community Home Health Agencies

~~A licensed continuing care retirement community that also incorporates a skilled nursing facility may provide home health services and does not require Certificate of Need review provided:~~

- ~~a. The continuing care retirement furnishes or offers to furnish home health services only to residents who reside in living units provided by the continuing care retirement community pursuant to a continuing care contract;~~
- ~~b. The continuing care retirement community maintains a current license and meets the applicable home health agency licensing standards; and~~
- ~~c. Residents of the continuing care retirement community may choose to obtain home health services from other licensed home health agencies.~~

~~Staff from other areas of the continuing care retirement community may deliver the home health services, but at no time may staffing levels in any area of the continuing care retirement community fall below minimum licensing standards or impair the services provided. If the continuing care retirement community includes charges for home health services in its base contract, it is prohibited from billing additional fees for those services. Continuing care retirement communities certified for Medicare or Medicaid, or both, must comply with government reimbursement requirements concerning charges for home health services. The continuing care retirement community shall not bill in excess of its costs. These costs will be determined on non-facility-based Medicare and/or Medicaid standards.~~

CHAPTER 4

PSYCHIATRIC SERVICES HOME HEALTH AGENCIES

COMMUNITY PSYCHIATRIC BEDS

~~Inpatient psychiatric services are those services provided to patients who are admitted to institutions for the evaluation, diagnosis and treatment of mental, emotional or behavioral disorders. Services may be provided in either psychiatric units of general hospitals or freestanding psychiatric hospitals.~~

~~Special units for children, adolescents and geriatric patients have been developed throughout the State. If any additional beds are approved, they must come from the calculated psychiatric bed need in this Plan. These specialty psychiatric services should be identifiable units with sufficient space to have available areas for sleeping, dining, education, recreation, occupational therapy and offices of evaluation and therapy. The unit should be staffed with an appropriate multi-disciplinary care team of psychiatrists, psychologists, social workers, nurses, occupation therapists, recreational therapists, and psychiatric technicians. Other consultants should be available as needed.~~

~~The Psychiatric Programs Chart is located at the end of this Chapter.~~

CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

- ~~1. — Need projections are based on psychiatric service areas. The service areas are consistent for psychiatric services and inpatient alcohol and drug abuse facilities.~~
- ~~2. — The methodology for calculating psychiatric bed need is as follows:
 - ~~a. — For the service area, take the greater of the service area utilization rate or the statewide utilization rate for psychiatric beds by age cohort. The statewide utilization rate for each age cohort will be used for those service areas where no beds currently exist.~~
 - ~~b. — Multiply the applicable utilization rate by the projected population for the year 2024 for each age cohort (where such data is available) and divide by 365 to obtain a projected average daily census by age cohort.~~
 - ~~c. — Take the sum of average daily censuses by age cohort and divide by the target occupancy rate of 70% to determine the number of beds needed in the service area.~~~~

- d. — The number of additional beds needed or excess beds for the service area is obtained by subtracting the number of existing beds from the bed need.
3. — Should the service area show a need for additional beds, a general acute care hospital which has no licensed or CON-approved psychiatric beds may be approved for the maximum of the actual projected bed need or up to 20 additional beds ("20 Bed Rule") to establish an economical unit ("Unit"). An applicant seeking more beds than are projected may not use such beds for the establishment of a specialty psychiatric unit. Any beds sought in excess of the projected bed need in the service area must be used for the provision of general adult psychiatric services in order to address the growing number of psychiatric patients being held in hospital emergency departments. Finally, although more than one general acute care hospital per service area may apply for beds under this provision, the Department may approve no more than 19 beds, in any combination, beyond the need shown in this Plan for each service area.
4. — In the absence of a projected need for beds in a psychiatric service area, an existing facility can apply to add up to eight additional beds, given that it has achieved an occupancy rate of at least 70% as reported on the most recent Joint Annual Report ("JAR"). Up to ten additional beds may be added in a facility which has achieved an occupancy rate of at least 90% as reported on the most recent JAR.
5. — Priority should be given to excess general hospital beds that can be economically and cost effectively converted for use as a specialized psychiatric unit over the construction of new beds, if such beds will be accessible to the target population.

The Psychiatric Bed Need Chart is located at the end of this Chapter.

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

The following project review criteria are considered to be the most important in evaluating Certificate of Need applications for this service:

1. — Community Need Documentation;
2. — Distribution (Accessibility);
3. — Record of the Applicant; and
4. — Staff Resources.

Psychiatric beds are planned for and located within 60 minutes' travel time for the majority of the residents of the State. In addition, current utilization and population growth are factored into the methodology for determining psychiatric bed need. The benefits of improved accessibility will be equally weighed with the adverse effects of duplication in evaluating Certificate of Need applications for these services.

STATE MENTAL HEALTH FACILITIES

Psychiatric Hospital Beds

~~DMH operates a variety of psychiatric facilities. DMH has analyzed the patient population and plans to provide psychiatric services in the least restrictive environment, maintain patients in the community and keep hospitalization to a minimum. Since DMH cannot refuse any patient assigned to them by a court, renovation, replacement and expansion of the component programs should be allowed as long as the overall psychiatric hospital complement is maintained or reduced. As long as DMH does not add any additional beds over the 3,720 beds that were in existence on July 1, 1988, any changes in facility bed capacity would not require Certificate of Need review.~~

Local Inpatient Crisis Stabilization Beds

~~DMH reports there are an insufficient number of adult inpatient psychiatric beds in a number of regions of the State. As a result of this situation, significant numbers of persons in a behavioral crisis are being held in hospital emergency rooms for inordinate periods of time until an appropriate inpatient psychiatric bed becomes available. These emergency room patients may not have a source of funding.~~

~~DMH has attempted to alleviate this problem by means of its "Crisis Stabilization Program." Within available funding limits, the "Crisis Stabilization Program" is to provide short-term emergency stabilization of psychiatric patients in the local community, by use of both local hospital beds and non-hospital residential programs, such as community residential care facilities, for those patients who do not require a hospital level of care. For patients needing stabilization in a hospital, subject to available funding, DMH contracts with one or more local hospitals willing to admit indigent patients assessed by DMH as needing acute care in return for a daily rate for a defined period. These patients can be cared for in licensed general acute care beds or licensed psychiatric beds.~~

~~To assist in alleviating this problem, the following policies will apply:~~

- ~~a. — A Certificate of Need is not required to convert existing acute care beds or existing psychiatric beds to create Crisis Stabilization services pursuant to a contract with DMH.~~
- ~~b. — A Certificate of Need is required to add psychiatric beds pursuant to a contract with DMH to provide Crisis Stabilization services. These additional beds could be approved if the Plan indicates a need for additional beds or some small number (ten beds or less) of additional beds could be approved for crisis stabilization patients only. These beds would not be restricted to any specific~~

~~age group except that the patients would have to be over age 18.~~

~~c. — An application for a Certificate of Need for Crisis Stabilization patients only must be accompanied by information from DMH to verify this additional need, such as the number of patients currently awaiting treatment, the estimated average length of stay, the pay source for the patients, the number of patients emergently admitted to DMH hospitals over the past year from the area, the number of crisis patients that are expected to require this service annually, and other information to justify these additional psychiatric beds. In addition, DMH will supply verification that it made contact with all hospitals in the county and contiguous counties to notify them of the potential for adding some psychiatric beds to the area. The hospital seeking the Certificate of Need will provide the necessary care for these individuals referred by DMH and may be reimbursed for the care of the patients if there are sufficient funds, but the hospital must identify the minimum number of indigent (no source of funding) patient days it will provide to patients referred by DMH. Should the contract with DMH terminate for any reason or should the hospital fail to provide care to the patients referred from DMH, the license for these beds will be voided.~~

~~If justified by DMH, the Department will consider converting inpatient psychiatric beds to other levels of care provided that alternative community-based resources are not available. Patients appropriate for de-institutionalization should be discharged when the appropriate community support services are in place.~~

HOME HEALTH

Home Health Agencies

Home Health Agency means a public, nonprofit, or proprietary organization, whether owned or operated by one or more persons or legal entities, which furnishes or offers to furnish home health services. Home health services means those items and services furnished to an individual by a home health agency, or by others under arrangement with the home health agency, on a visiting basis and except for ~~(d)~~ below, in a place of temporary or permanent residence used as the individual's home as follows:

Part-time or intermittent skilled nursing care as ordered by a physician or ~~podiatrist~~ Advanced Practice Registered Nurse (APRN) or Physician Assistant (PA) and provided by or under the supervision of a registered nurse and at least one other therapeutic service listed below: (a) physical, occupational, or speech therapy; (b) medical social services; ~~(c)~~ home health aide services; and (d) other therapeutic services; ~~(e)~~ (c) medical supplies as indicated in the treatment plan and the use of medical appliances, to include durable medical equipment and ~~(d)~~ any of the above items and services provided on an outpatient basis under arrangements made by the home health agency with a hospital, nursing home or rehabilitation center and the furnishing of which involves the use of equipment of such a nature that the items/services cannot readily be made available to the individual in his/her home, or which are furnished at one of the above facilities while the patient is there to receive such items or services. Transportation of the individual in connection with any such items or services is not included. For more specific details about home health agencies, refer to Regulation 61-77 (Standards for Licensing Home Health Agencies).

CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

1. An applicant must propose home health services to cover the geographic area of an entire county and agree to serve residents throughout the entire county.
2. ~~A separate application is required for each county in which services are to be provided~~ An application is required for the counties identified by the applicant in which services are to be provided.
3. A new home health agency or expansion of an existing home health agency may be approved if an applicant can demonstrate it will serve 50 or more patients projected to be in need in non-rural counties, or 25 or more patients projected to be in need in rural counties, through evidence that may include, but would not be limited to, the following:
 - a. Letters of support that identify need for additional home health services from physicians and other referral sources.

- b. Evidence of underutilization of home health services.
 - c. Evidence of limited scope home health agency service including skilled nursing, physical therapy, occupational therapy, speech therapy, home health aides, and medical social workers.
 - d. Evidence of the denial or delay in the provision of home health services, including but not limited to long waiting lists or delays which exceed industry standards.
 - e. Evidence that one or more existing home health agencies has failed to meet the minimum patient service requirements set forth in Standard 8 of this section of the Plan within two years of the initiation of patient services after receiving a home health license.
4. For the purposes of this Section, a rural county shall mean a county with a population of less than 50,000, according to the most recent projections of the South Carolina Revenue and Fiscal Affairs office as of the time the current Plan was adopted.
 5. All home health agency services (Skilled Nursing, Physical Therapy, Occupational Therapy, Speech Therapy, Home Health Aide, and Medical Social Worker) should be available within a county. If there is no hospital in a county and the existing licensed home health agencies between them do not provide all of the services identified above, this may be cited as potential justification for the approval of an additional agency that intends to offer these services.
 6. Specialty home health providers are exempt from the need calculation applicable to full-service home health agencies, but are otherwise subject to Certificate of Need.
 7. The applicant should have a track record that demonstrates a commitment to quality services. There should be no history of prosecution, consent order, abandonment of patients in other business operations, or loss of license. However, any consent orders or loss of licenses related to licenses that were obtained from the Department between July 1, 2013 and May 22, 2014 without a Certificate of Need shall not be grounds for denial of a Certificate of Need application pursuant to this Section. The applicant must provide a list of all licensed home health agencies it operates and the state(s) where it operates them.
 8. The applicant must document that it can serve at least 25 patients annually in each rural county for which it is licensed and 50 patients annually in each non-rural county for which it is licensed within two years of initiation of services. The applicant must assure the Department that, should it fail to reach this threshold number two years after initiation of services in a county, it will voluntarily relinquish its license for that

county.

9. Nothing in this Section is intended to restrict the ability of the Department to approve more than one new Home Health Agency in a county at any given time.

The Home Health Agency Inventory Chart is located at the end of this Chapter.

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

The following project review criteria, as outlined in Chapter 8 of Regulation 61-15, are considered to be the most important in reviewing Certificate of Need applications for this service:

1. Community Need Documentation;
2. Distribution (Accessibility); and
3. Medically Underserved Groups.

The benefits of improved accessibility outweigh the adverse effects caused by the duplication of any existing service.

Pediatric Home Health Agencies

Due to the limited number of home health providers available to treat children 18 years or younger, an exception to the above criteria may be made for a Certificate of Need for a Home Health Agency restricted to providing intermittent home health skilled nursing services to patients 18 years or younger. The license for the agency will be restricted to serving children 18 years or younger and will ensure access to necessary and appropriate intermittent home health skilled nursing services to these patients. Any such approved agency will not be counted in the county inventories for need projection purposes.

CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

1. A separate Certificate of Need application will be required for each county for an agency that proposes to provide this specialized service to pediatric patients in multiple counties.
2. The applicant must document that there is an unmet need for this service in the county of application, and the agency will limit such services to the pediatric population 18 years or younger.
3. The applicant must document the full range of services that they intend to provide to pediatric patients.

Continuing Care Retirement Community Home Health Agencies

A licensed continuing care retirement community that also incorporates a skilled nursing facility may provide home health services and *does not require Certificate of Need review provided:*

- a. The continuing care retirement furnishes or offers to furnish home health services only to residents who reside in living units provided by the continuing care retirement community pursuant to a continuing care contract;
- b. The continuing care retirement community maintains a current license and meets the applicable home health agency licensing standards; and
- c. Residents of the continuing care retirement community may choose to obtain home health services from other licensed home health agencies.

Staff from other areas of the continuing care retirement community may deliver the home health services, but at no time may staffing levels in any area of the continuing care retirement community fall below minimum licensing standards or impair the services provided. If the continuing care retirement community includes charges for home health services in its base contract, it is prohibited from billing additional fees for those services. Continuing care retirement communities certified for Medicare or Medicaid, or both, must comply with government reimbursement requirements concerning charges for home health services. The continuing care retirement community shall not bill in excess of its costs. These costs will be determined on non-facility-based Medicare and/or Medicaid standards.

CHAPTER 35

GENERAL HOSPITALS

GENERAL HOSPITALS

Relevant Definitions Hospital

~~"Hospital"~~Hospital means a facility organized and administered to provide overnight medical, or surgical, care or nursing care ~~offor an~~ illness, injury, or infirmity and may provide ~~obstetrical care, on-campus emergency services; that may provide obstetrical care;~~ and in which all diagnoses, treatment, or care is administered by or under the direction of persons currently licensed to practice medicine, surgery, or osteopathy.

Hospital may include a residential treatment facilities for children, ~~and~~ adolescents, ~~or young adults~~ in need of mental health treatment ~~which are~~that is physically a part of a licensed psychiatric hospital. This definition does not include facilities which are licensed by the Department of Social Services. A residential treatment facility for children, adolescents, or young adults in need of mental health treatment that is physically part of a licensed psychiatric hospital is not required to provide on-campus emergency services.

Hospital Bed

~~"Hospital Bed"~~ means a bed for an adult or child patient. Bassinets for the newborn in a maternity unit nursery, beds in labor rooms, recovery rooms, and other beds used exclusively for emergency purposes are not included in this definition.

Bed Capacity

For existing beds, capacity is considered bed space designated exclusively for inpatient care, including space originally designed or remodeled for inpatient beds, even though temporarily not used for such purposes. The number of beds counted in any patient room is the maximum number for which adequate square footage is provided, except that single beds in single rooms have been counted even if the room contained inadequate square footage.

Inventory and Bed Need

All licensed general hospitals, including Federal facilities, and CON-approved general hospitals are listed in the inventory. Patient days and admissions are as reported by the hospital in its Joint Annual Report (JAR). The number of patient days utilized for the general hospital bed need calculations does not include days of care rendered in licensed psychiatric

units, substance abuse units, or comprehensive rehabilitation units of hospitals. These days of care are shown in the corresponding inventories for each type of service. In addition, the days of care provided in Long-Term Care hospitals are not included in the general bed need calculations.

Total capacity by survey refers to a total designed capacity or maximum number of beds that may be accommodated as determined by an on-site survey. This capacity may exceed the number of beds actually set up and in use. It may also differ from the licensed capacity, which is based on State laws and regulations. Beds have been classified as conforming and nonconforming, according to standards of plant evaluation.

Variable Occupancy Rate

The General Acute Hospital bed need methodology uses the following variable occupancy rate factors:

- 0 - 174 bed hospitals → 65%
- 175 - 349 bed hospitals → 70%
- 350+ bed hospital → 75%

The population and associated utilization are broken down by age groups. The use rates and projected average daily census are made for the age cohorts of 0-17, 18-64, and 65 and over, in recognition that different population groups have different hospital utilization rates.

Where the term "hospital bed need" is used, these figures are based upon utilization data for the general acute hospitals. This term does not suggest that facilities cannot operate at higher occupancy rates than used in the calculations without adding additional beds.

Availability

The need for general hospital beds is determined through the consideration of current utilization and projected population growth with the goal of having beds available within approximately 30 minutes' travel time for the majority of the residents of the State.

CERTIFICATE OF NEED PROJECTION AND STANDARDS

1. Calculations of hospital bed need are made for individual hospitals and for service areas.
2. For individual hospitals, the methodology for calculating bed need is as follows:
 - a. Determine the current facility use rate by dividing the 20182021 patient days by the 20182021 population in each of the three age cohorts.

- b. Multiply the current facility use rate for each age cohort by the projected population by age cohort and divide by 365 to obtain a projected average daily census (ADC) by age cohort.
 - c. Divide the sum of the age cohort projected ADC by the variable occupancy factor (.65/.70/.75) to determine the hospital's bed need.
 - d. The number of additional beds needed or excess beds for the hospital is obtained by subtracting the number of existing and approved beds from the hospital's bed need.
 3. The methodology for calculating the statewide utilization bed need for a service area is as follows:
 - a. Divide the statewide total patient days by 365 to determine the statewide average daily census.
 - b. Divide the statewide average daily census by the statewide occupancy factor (.75) to determine the total statewide bed need.
 - c. Divide the statewide bed need by the ~~2018~~2021 statewide population to generate a bed-per-population (BPP) multiplier.
 - d. For each service area, multiply the projected population by the BPP multiplier to determine the service area bed need, then subtract the total number of existing and approved beds to determine the statewide utilization bed need for the service area.
 4. The bed need for each service area is the combined bed need for all individual hospitals in the service area. The bed need for service areas with no hospital, or for service areas in which no hospital has reported any utilization data on the most recent JAR, is the statewide utilization bed need.
 5. If a service area indicates a surplus of beds, then no additional beds will be approved unless an individual hospital in the service area indicates a need for additional beds. Should an individual hospital indicate a need for additional beds, then a maximum of the actual projected bed need or up to 50 additional beds may be approved for that hospital to allow for the construction of an economical unit at either the existing hospital site or another site, if the existing hospital is relocating or has relocated in whole or in part to that site. The hospital requesting the addition must document the need for additional beds beyond those indicated as needed by the methodology stated above, based on historical and projected utilization, as well as projected

population growth or other factors demonstrating the need for the proposed beds. Additional beds will only be approved for the specific hospital indicating a need.

6. If there is a need for additional hospital beds in the service area, then any entity may apply to add these beds within the service area, and any entity may be awarded the Certificate of Need for these beds. If the number of beds needed is less than 50, then up to a total of 50 beds could be approved for any entity at any location within the service area. An applicant requesting additional beds beyond those indicated as needed by the methodology stated above must document the need for additional beds based on historical and projected utilization, projected population growth that has not been considered in this Plan or other factors demonstrating the need for the proposed beds. It is up to the applicant to document the need and the potential negative impact on the existing facilities.
7. A facility may apply to create a new additional hospital at a different site within the same service area through the transfer of existing licensed beds, the projected bed need for the facility, or a combination of both existing beds and projected bed need. The facility is not required to have a projected need for additional beds in order to create a new additional hospital. There is no required minimum number of beds in order to approve the CON application. The applicant must justify, through patient origin and other data, the need for a new hospital at the chosen site and the potential adverse impact a new hospital at the chosen site could have on the existing hospitals in the service area.
8. No additional hospital will be approved unless it is a general hospital and will provide:
 - a. A 24-hour emergency services department that meets the requirements ~~to be a Level III emergency service as defined in the Emergency Services section~~ of [Regulation 61-16](#);
 - b. Inpatient medical services to both surgical and non-surgical patients; and
 - c. Medical and surgical services on a daily basis within at least six of the major diagnostic categories as recognized by Centers for Medicare and Medicaid Services (CMS). Any applicant for a new hospital must provide a written commitment that the facility will accept Medicare and Medicaid patients and that unreimbursed services for indigent and charity patients are provided at a percentage that meets or exceeds other hospitals in the service area. The CMS Diagnostic Categories Chart is located at the end of this Chapter.
9. Due to the low utilization and the low capital cost of converting hospital-based nursing home, psychiatric, rehabilitation and/or substance abuse beds to general acute care hospital beds, the following policies may apply:

- a. Hospitals that have licensed nursing home beds within the hospital may be allowed to convert nursing home beds to general acute care hospital beds only within the hospital, provided the hospital can document an actual need for additional general acute care beds. Need will be based on actual utilization, using current information. *A Certificate of Need is required for this conversion.*
 - b. Existing acute care hospitals that have inpatient psychiatric, rehabilitation, or substance abuse beds may be allowed to convert such beds to acute care hospital beds, regardless of the projected need for general acute care hospital beds. *A Certificate of Need is required for this conversion.*
10. In some areas of South Carolina, a considerable influx of tourists is not counted in the permanent population. If an individual hospital in these areas can document and demonstrate the need for additional beds due to non-resident (tourist) population and seasonal utilization fluctuations due to this population, then, based on further analysis, the Department may approve some additional beds at the existing hospital.
11. Should the deletion of services at a federal facility result in an immediate impact on the utilization of a hospital, then the Department may approve a request for additional beds at the affected hospital. The affected hospital must document the increase in demand and explain why additional beds are needed to accommodate patients previously served at the federal facility.
12. Changes in the delivery system due to health care reform have resulted in the consolidation of facilities and the establishment of provider networks. These consolidations and agreements may lead to situations where affiliated hospitals may wish to transfer beds between themselves in order to serve their patients in a more efficient manner. *A proposal to transfer or exchange hospital beds requires a Certificate of Need* and must comply with the provisions outlined in Chapter 2, Transfer between Affiliated Facilities.
13. Factors to be considered regarding modernization of facilities include:
 - a. Functional arrangement of the facility as it relates to efficient handling of patients and related workloads.
 - b. The ability to update medical technology within the existing plant.
 - c. Existence of The Joint Commission (TJC) or other accreditation body deficiencies or “grandfathered” licensure deficiencies.
 - d. Cost efficiency of the existing physical plant versus plant revision, etc.

- e. Private rooms are now considered the industry standard.
14. Each modernization proposal must be evaluated on the basis of merit, cost efficiency, and impact on healthcare delivery within the service area.

The Hospital Bed Need Chart is located at the end of this Chapter.

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

The following project review criteria are considered to be the most important in evaluating Certificate of Need applications for this service:

1. Compliance with the Need Outlined in this Section of this Plan;
2. Community Need Documentation;
3. Distribution (Accessibility);
4. Acceptability;
5. Ability to Complete the Project; and
6. Adverse Effects on Other Facilities.

General hospital beds are typically located within approximately thirty (30) minutes' travel time for the majority of the residents of the State. The benefits of improved accessibility will be equally weighed with the adverse effects of duplication in evaluating Certificate of Need applications for these beds.

LONG-TERM ACUTE CARE HOSPITALS

Long-Term Acute Care Hospitals (LTACHs) are hospitals with an average Medicare inpatient length of stay of greater than 25 days, including all covered and non-covered days of stay of Medicare patients. They provide treatment to patients with complex medical conditions, such as strokes, cardiac care, ventilator dependency, wound care and post-surgical care.

A LTACH may be either a freestanding facility or may occupy space in another hospital ("hospital-within-a-hospital"). Hospitals must meet additional federal criteria in order to qualify as a LTACH under the "hospital-within-a-hospital" model:

1. The new LTACH must have a governing body, which is distinct and separate from the governing body of the host hospital, and the new body cannot be under the control of the host hospital or any third entity that controls both hospitals.
2. The LTACH must have a separate Chief Executive Officer through whom all administrative authority flows, who is not employed by, or under contract with, the host hospital or any third entity that controls both hospitals.

3. The LTACH must have a separate Chief Medical Officer who reports directly to the governing body and is responsible for all medical staff activities. The Chief Medical Officer cannot be under contract with the host hospital or any third entity that controls both hospitals.
4. The LTACH must have a separate medical staff which reports directly to the governing body, and adopt bylaws governing medical care, including granting privileges to individual practitioners.

CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

1. An application for a LTACH must be in compliance with the relevant standards in [Regulation 61-16](#) (*Minimum Standards for Licensing Hospitals and Institutional General Infirmaries*).
2. Although LTACH beds are not considered to be a separate category for licensing purposes, they will be inventoried separately from general acute care hospital beds for planning purposes.
3. The utilization of LTACHs is not included in the bed need for general acute care hospital beds. No bed need will be calculated for LTACH beds. An applicant must document the need for LTACH beds based on the utilization of existing LTACH beds.
4. A hospital that has leased general beds to a LTACH shall be entitled to regain these beds once the lease is terminated. No entity other than the hospital (or its successor) that initially leased the general acute beds to the LTACH shall be entitled to the beds upon termination of the lease. *A Certificate of Need application is required:*
 - a. A hospital may be allowed to convert these former LTACH beds to general acute hospital beds regardless of the projected need for general acute beds;
 - b. A hospital may be allowed to convert these former LTACH beds to psychiatric, inpatient treatment facility, rehabilitation, or other specialty beds only if there is a bed need projected for this proposed other category of licensed beds.
5. A hospital which seeks to be designated as a LTACH, and has been awarded a CON for that purpose, must be certified as a LTACH by CMS within 24 months of accepting its first patient, or the CON issued to that hospital for that purpose shall be revoked. The entity that has had its CON revoked shall not have the authority to operate as a general acute care hospital.
6. A hospital that desires to be designated as a Pediatric LTACH must restrict admissions

to patients under the age of 21 who require long-term medical care. Should the facility attempt to provide care that is inconsistent with this requirement or patient demand or other economic conditions require the facility to close, the Certificate of Need issued to that hospital for that purpose shall be revoked.

The Long-Term Acute Care Hospitals Chart is located at the end of this Chapter.

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

The following project review criteria are considered to be the most important in evaluating Certificate of Need applications for this service:

1. Compliance with the Need Outlined in this Section of this Plan;
2. Community Need Documentation;
3. Distribution (Accessibility);
4. Record of the Applicant.

Long-Term Acute Care Hospital beds are located within approximately 60 minutes' travel time for the majority of the residents of the State. The benefits of improved accessibility will be equally weighed with the adverse effects of duplication in evaluating Certificate of Need applications for these beds.

COMMUNITY PSYCHIATRIC BEDS

Inpatient psychiatric services are those services provided to patients who are admitted to institutions for the evaluation, diagnosis and treatment of mental, emotional or behavioral disorders. Services may be provided in either psychiatric units of general hospitals or freestanding psychiatric hospitals.

Special units for children, adolescents and geriatric patients have been developed throughout the State. If any additional beds are approved, they must come from the calculated psychiatric bed need in this Plan. These specialty psychiatric services should be identifiable units with sufficient space to have available areas for sleeping, dining, education, recreation, occupational therapy and offices of evaluation and therapy. The unit should be staffed with an appropriate multi-disciplinary care team of psychiatrists, psychologists, social workers, nurses, occupation therapists, recreational therapists, and psychiatric technicians. Other consultants should be available as needed.

The Psychiatric Programs Chart is located at the end of this Chapter.

CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

1. Need projections are calculated on a statewide basis to serve the needs of this

population based on psychiatric service areas. The service areas are consistent for psychiatric services and inpatient alcohol and drug abuse facilities.

2. The applicant must document the need for the expansion of or the addition of psychiatric services based on the most current utilization data available. The existing resources must be considered, and documentation presented as to why these resources are not adequate to meet the needs of the community.
2. The methodology for calculating psychiatric bed need is as follows:
 - a. For the service area, take the greater of the service area utilization rate or the statewide utilization rate for psychiatric beds by age cohort. The statewide utilization rate for each age cohort will be used for those service areas where no beds currently exist. The statewide utilization rate for psychiatric beds will be used for each age cohort.
 - b. Multiply the applicable utilization rate by the projected population for the year 2024-2028 for each age cohort (where such data is available) and divide by 365 to obtain a projected average daily census by age cohort.
 - c. Take the sum of average daily censuses by age cohort and divide by the target occupancy rate of 70-75% to determine the number of beds needed in the service area statewide.
 - d. The number of additional beds needed or excess beds for the service area statewide is obtained by subtracting the number of existing beds from the bed need.
3. Should the service area show a need for additional beds, a general acute care hospital which has no licensed or CON-approved psychiatric beds may be approved for the maximum of the actual projected bed need or up to 20 additional beds ("20 Bed Rule") to establish an economical unit ("Unit"). An applicant seeking more beds than are projected may not use such beds for the establishment of a specialty psychiatric unit. Any beds sought in excess of the projected bed need in the service area must be used for the provision of general adult psychiatric services in order to address the growing number of psychiatric patients being held in hospital emergency departments. Finally, although more than one general acute care hospital per service area may apply for beds under this provision, the Department may approve no more than 19 beds, in any combination, beyond the need shown in this Plan for each service area.
4. In the absence of a projected need for beds in a psychiatric service area, an existing facility can apply to add up to eight additional beds, given that it has achieved an occupancy rate of at least 70% as reported on the most recent Joint Annual Report

("JAR"). Up to ten additional beds may be added in a facility which has achieved an occupancy rate of at least 90% as reported on the most recent JAR at the time the application is filed with the Department.

5. Priority should be given to excess general hospital beds that can be economically and cost effectively converted for use as a specialized psychiatric unit over the construction of new beds, if such beds will be accessible to the target population.

The Psychiatric Bed Need Chart is located at the end of this Chapter.

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

The following project review criteria are considered to be the most important in evaluating Certificate of Need applications for this service:

1. Community Need Documentation;
2. Distribution (Accessibility);
3. Record of the Applicant; and
4. Staff Resources.

Psychiatric beds are planned for and located within 60 minutes' travel time for the majority of the residents of the State. In addition, current utilization and population growth are factored into the methodology for determining psychiatric bed need. The benefits of improved accessibility will be equally weighed with the adverse effects of duplication in evaluating Certificate of Need applications for these services.

STATE MENTAL HEALTH FACILITIES

Psychiatric Hospital Beds

Department of Mental Health (DMH) operates a variety of psychiatric facilities. DMH has analyzed the patient population and plans to provide psychiatric services in the least restrictive environment, maintain patients in the community and keep hospitalization to a minimum. Since DMH cannot refuse any patient assigned to them by a court, renovation, replacement and expansion of the component programs should be allowed as long as the overall psychiatric hospital complement is maintained or reduced. As long as DMH does not add any additional beds over the 3,720 beds that were in existence on July 1, 1988, any changes in facility bed capacity *would not require Certificate of Need review.*

INPATIENT TREATMENT FACILITIES (SUBSTANCE ABUSE BEDS)

An inpatient treatment facility is a short-term treatment service for persons who are in need of an organized intensive program of alcohol and/or drug rehabilitation, but who are without

serious debilitating medical complications. These facilities may provide detoxification for their patients, as needed, in the inpatient treatment beds. These facilities are licensed either as a specialized hospital or as part of a hospital. For reference purposes only, these facilities are also subject to compliance with Regulation 61-16.

The Inpatient Treatment Facilities Chart is located at the end of this Chapter.

CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

1. Need projections are calculated by service area. Because patients in need of alcohol and/or drug abuse treatment frequently require psychiatric treatment services as well, the inpatient treatment service areas mirror the psychiatric service areas (e.g., Anderson/Oconee, Greenville/Pickens, etc.) to facilitate planning in a manner that recognizes the comorbidity of this patient population.
2. The methodology for calculating inpatient treatment bed need is as follows:
 - a. For the service area, take the greater of the service area utilization rate or the statewide utilization rate for inpatient treatment beds by age cohort. The statewide utilization rate for each age cohort will be used for those service areas where no beds currently exist.
 - b. Multiply the applicable utilization rate by the projected population for the year 2024-2027 for each age cohort (where such data is available) and divide by 365 to obtain a projected average daily census by age cohort.
 - c. Take the sum of average daily censuses by age cohort and divide by the target occupancy rate of 75% to determine the number of beds needed in the service area.
 - d. The number of additional beds needed or excess beds for the service area is obtained by subtracting the number of existing beds from the bed need.
3. Because a minimum of 20 beds is needed for an inpatient program, a 20-bed unit may be approved in a service area that does not have any existing beds provided the applicant can document the need. The significant prevalence of patients with mixed psychiatric/addictive etiologies presenting to hospitals with inpatient psychiatric beds, in the absence of a projected need statewide for inpatient treatment facility beds (substance abuse beds), a hospital or inpatient psychiatric facility without substance abuse beds may apply for a Certificate of Need to add up to eight (8) substance abuse beds if it can demonstrate need for the substance abuse beds at its facility, demonstrate an improvement in access to substance abuse beds statewide, and avoid materially adversely affecting existing inpatient treatment facilities .

4. In the absence of a projected need in the service area, an existing inpatient treatment facility can apply to add up to eight additional inpatient treatment beds if it has achieved an occupancy rate of at least 70% as reported on its most recent Joint Annual Report ("JAR") at the time the application is filed with the Department.
5. ~~Inpatient treatment facilities are physically distinct from freestanding detoxification centers. Applicants may not combine the bed need for freestanding detoxification with the bed need for inpatient treatment in order to generate a higher bed need for an inpatient facility. There are no prohibitions against an inpatient facility providing detoxification services to its clients as needed, but the bed need projections refer to two distinct treatment modes that cannot be commingled.~~
6. The establishment of a regional treatment center to serve more than a single service area may be proposed in order to improve access to care for patients in service areas that are not currently well served. Such a proposed center would be allowed to combine the bed need for separate, contiguous service areas, provided that each service area to be combined shows a positive bed need. The applicant must document with patient origin data the historical utilization of the residents in the service area that is to be combined, or why it is in the best interest of these residents for their projected bed need to be used to form a regional treatment facility.
7. It is frequently impossible for a facility to totally predict or control short-term deviation in the number of patients with mixed psychiatric/addictive etiology. Therefore, in the case of facilities with licensed beds for both psychiatric and substance abuse treatment, 75% of licensed substance abuse beds may be utilized alternatively for the treatment of patients having diagnoses of both psychiatric and substance abuse disorders.

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

The following Project Review Criteria are considered to be the most important in evaluating Certificate of Need applications for this service:

1. Community Need Documentation
2. Distribution (Accessibility); and
3. Staff Resources.

Services are accessible within 60 minutes' travel time for the majority of residents of the state. The benefits of improved accessibility will be equally weighed with the adverse effects of duplication in evaluating Certificate of Need applications for this service.

The Inpatient Treatment Bed Need Chart is located at the end of this Chapter.

REHABILITATION FACILITIES (REHABILITATION BEDS)

A Rehabilitation Facility is operated for the primary purpose of providing comprehensive physical rehabilitation services through an intensive, coordinated team approach for patients with severe physical ailments. These facilities should be located where an extensive variety of professionals representing medical, psychological, social, and vocational rehabilitation evaluation and services are available. These beds are viewed as being comprehensive in nature and not limited only to a particular service or specialty. CMS identifies 13 specific conditions for which facilities must treat 60% of their patients ("the compliance threshold") in order to qualify for Medicare reimbursement. Certain comorbidities as specified in 42 CFR 412.29(b)(1) must be used to determine the compliance threshold.

Most general hospitals and other health care facilities offer physical rehabilitation services such as physical therapy, occupational therapy, speech therapy, or occupational therapy without the involvement of a formal interdisciplinary program. In addition, some hospitals have consolidated their rehabilitation services into a single unit to improve the coordination of care for acute patients in their facilities. These consolidations are intended to improve the quality of care for patients currently being treated in the facility and are not considered to be providing comprehensive physical rehabilitation services as defined in this section of the Plan.

The Rehabilitation Programs Chart is located at the end of this Chapter.

CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

1. The need for beds is calculated based on rehabilitation service areas.
2. The methodology takes the greater of the actual utilization of the facilities in the service area or the statewide average number of beds per 1,000 of the 65+ population cohort to project need.
3. In the absence of a projected need for beds in a rehabilitation facility service area, an existing facility can apply to add up to eight additional beds, given that it has achieved an occupancy rate of at least 70% as reported on the most recent Joint Annual Report ("JAR"). Up to ten additional beds may be added in a facility which has achieved an occupancy rate of at least 90% as reported on the most recent JAR.

The Rehabilitation Bed Need Chart is located at the end of this Chapter.

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

The following project review criteria are considered to be the most important in evaluating Certificate of Need applications for this service:

1. Community Need Documentation;
2. Distribution (Accessibility); and
3. Ability to Complete the Project.

Rehabilitation facilities are now located throughout the state and are available within approximately 60 minutes' travel time for the majority of residents. Such facilities should be located where an extensive variety of health care professionals are available. The benefits of improved accessibility will be equally weighed with the adverse effects of duplication in evaluating Certificate of Need applications for this service.

Statewide Programs

The South Carolina Vocational Rehabilitation Center operates a 30-bed facility in West Columbia to serve the vocational training needs of the disabled.

CRITICAL ACCESS HOSPITALS (CAH)

The South Carolina Department of Health and Human Services administers programs through the Medicaid program to assist struggling rural hospitals. One such program designates rural hospitals as Critical Access Hospitals (CAH) who are then eligible for more favorable Medicaid reimbursement methodology.

A CAH is intended to provide essential health services to rural communities. Converting a struggling rural hospital to a CAH can allow a community to maintain local health access that would otherwise be lost. CAHs are subject to review by the Independent Payment Advisory Board (IPAB), whereas other hospitals are not currently subject to IPAB review.

The impact of the Critical Access Hospital Program in South Carolina is a financial one, allowing cost-based reimbursement from Medicare for a facility choosing to participate. The designation as a CAH does not require a change in the licensing of an existing hospital. However, a hospital may be required to de-license a number of beds in order to meet the 25-bed requirement.

The designation of a hospital as a Critical Access Hospital *does not require Certificate of Need review* because it does not change the licensing category of the facility. However, an exemption from Certificate of Need review is required for a hospital to reduce its number of licensed beds in order to meet the criteria for a CAH. *Should a hospital later desire to revert*

to a general acute hospital, a Certificate of Need is required, but the facility may be permitted to increase the number of licensed hospital beds up to the prior number of beds without regard or affect to the current bed need shown in the service area.

The Critical Access Hospitals Chart is located at the end of this Chapter.

PERINATAL REGIONS

The Perinatal Regions referred to in the Obstetrical Services and Neonatal Services sections below are distinct from the Department’s Regions defined in Chapter 2 of this Plan, and are identified by the name of its designated Regional Perinatal Center.

<u>Perinatal Region</u>	<u>Counties</u>
I - Greenville Memorial Prisma Health Greenville Memorial	Abbeville, Anderson, Edgefield, Greenville, Greenwood, Laurens, McCormick, Oconee, Pickens, Saluda
II - Spartanburg Regional	Cherokee, Chester, Spartanburg, Union
III - Palmetto Prisma Health Richland	Aiken, Allendale, Bamberg, Barnwell, Calhoun, Clarendon, Fairfield, Kershaw, Lancaster, Lee, Lexington, Newberry, Orangeburg, Richland, Sumter, York
IV - McLeod Regional	Chesterfield, Darlington, Dillon, Florence, Horry, Marion, Marlboro, Williamsburg
V - MUSC Medical	Beaufort, Berkeley, Charleston, Colleton, Dorchester, Hampton, Jasper, Georgetown

PERINATAL SERVICE LEVELS

Because the cost of high-risk obstetrical and neonatal services is so great, it is not desirable or cost-effective for all hospitals in the State to provide the higher levels of care. Over the years, a regionalized approach to perinatal care has been implemented in South Carolina to address the need for high quality, risk-appropriate, cost-effective perinatal health care. Regionalization provides a coordinated system of perinatal care for a well-defined population group. Each hospital providing perinatal services is designated by the Department's Division of Health Licensing as a Level I, II, III, or IV Perinatal Hospital, or a Regional Perinatal Center (RPC). Each Level I, II, III and IV hospital maintains a relationship with its designated RPC for consultation, transport and continuing education. Patients are transferred to the appropriate RPC when medically appropriate, if beds are available. True regionalization for the optimization of perinatal care includes a stated goal of back-transporting infants when they no longer require the highest level of care. Convalescing

infants benefit from a community-based program closer to home that promotes parent education and family bonding to facilitate a safe and timely discharge. In this way, quality care is provided to mothers and newborn infants, and specially trained perinatal personnel and intensive care facilities can be used efficiently and cost-effectively.

The complete descriptions of the five levels of perinatal services described briefly below are outlined in the Section of [Regulation 61-16](#) entitled *Designation of Inpatient Perinatal Care Services*.

[Basic Perinatal Center with Well Newborn Nursery \(Level I\)](#). Level I hospitals provide services for normal uncomplicated pregnancies. A full list of the requirements for a Level I Basic Perinatal Center with Well Newborn Nursery can be found at Regulation 61-16, Section 1306.A. *Certificate of Need review is not required to establish a Level I program.*

[Specialty Perinatal Center with Special Care Nursery \(Level II\)](#). In addition to the requirements of Regulation 61-16, Section 1306.A, Level II hospitals provide services for both normal and selected high-risk obstetrical and neonatal patients. A full list of the requirements for a Level II Specialty Perinatal Center can be found at Regulation 61-16, Section 1306.B. *Certificate of Need review is not required to establish a Level II program.*

[Subspecialty Perinatal Center with Neonatal Intensive Care Unit \(Level III\)](#). In addition to the requirements of Regulation 61-16, Sections 1306.A and 1306.B, Level III hospitals 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. A full list of the requirements for a Level III Subspecialty Perinatal Center with Neonatal Intensive Care Unit can be found at Regulation 61-16, Section 1306.C. Neonatal transport may only be performed by Regional Perinatal Centers. *Certificate of Need Review is required to establish a Level III program.*

[Regional Perinatal Center with Neonatal Intensive Care Unit \(RPC\)](#). In addition to the requirements of Regulation 61-16, Sections 1306.A through 1306.C, RPCs provide consultative, outreach, and support services to other hospitals in the region. A full list of the requirements for a Regional Perinatal Center can be found at Regulation 61-16, Section 1306.D. No more than one Regional Perinatal Center will be approved in each perinatal region. *Certificate of Need Review is required to establish a RPC.*

[Complex Neonatal Intensive Care Unit \(Level IV\)](#). In addition to the requirements of Regulation 61-16, 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. A full list of the requirements for a Complex Neonatal Intensive Care Unit can be found at Regulation 61-16, Section 1306.E. A Level IV hospital need not act as a Regional

Perinatal Center (RPC). *Certificate of Need Review is required to establish a Level IV program.*

The Perinatal-Capable Facilities Chart is located at the end of this Chapter.

OBSTETRICAL SERVICES

~~Advances in obstetrical and newborn intensive care offer the promise of lower perinatal mortality and improvement in the quality of life for survivors. The high cost of intensive care and the limited availability of skilled personnel have created the requirement for a more efficient method of resource allocation.~~

~~Maternal, fetal, and neonatal mortality and morbidity rates can be significantly reduced if patients at high risk are identified early in the pregnancy and optimum techniques for the care of both the mother and infant are applied. High-risk deliveries are a small percent of total annual deliveries, but these patients require a high degree of specialized care. In 2017, 76% of all Very Low Birthweight (VLB) babies were born in either a Level III center or a Regional Perinatal Center, whereas the Healthy People 2020 national objective was 83.7%.~~

~~Infant mortality is defined as the death of babies from birth until their first birthday. South Carolina's infant mortality rate for 2017 was 6.5 infant deaths per 1,000 live births versus the national rate of 5.79 infant deaths per 1,000 births in 2017.~~

~~Neonatal mortality is the death rate for infants up to 28 days old. For 2016, South Carolina's neonatal mortality rate for all races was 4.4 neonatal deaths per 1,000 live births, while the Healthy People 2020 national objective was 4.1 neonatal deaths per 1,000 live births.~~

~~The need for obstetrical beds will be evaluated based on information supplied by the Joint Annual Report of Hospitals and other sources. Those facilities experiencing low utilization and in close proximity to one another should consider consolidating services, where appropriate.~~

~~The OB Utilization and Births Chart is located at the end of this Chapter.~~

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

~~The following project review criteria are considered the most important in evaluating Certificate of Need applications for an obstetrical service:~~

- ~~1. — Compliance with the Need Outlined in this Section of this Plan;~~
- ~~2. — Distribution (Accessibility);~~
- ~~3. — Acceptability;~~
- ~~4. — Record of the Applicant; and~~
- ~~5. — Adverse Effects on Other Facilities.~~

~~The benefits of improved accessibility will be equally weighed with the adverse effects of duplication in evaluating Certificate of Need applications for this service.~~

NEONATAL SERVICES (NEONATAL INTENSIVE CARE BASSINETS)

Neonatal services are highly specialized and are only required by a very small percentage of infants. The need for these services is affected by the incidence of high-risk deliveries, the percentage of live births requiring neonatal services, and the average length of stay. The limited need for these services requires that they be planned for on a regional basis, fostering the location of these specialized units in hospitals that have the necessary staff, equipment, and consultative services and facilities. Referral networks facilitate the transfer of infants requiring this level of services from other facilities.

CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

1. The projected need for neonatal intensive care bassinets is calculated on a regional basis:
 - a. For each region take the average number of births from ~~2016-2018~~2019-2021 and the average population of women age 15-44 for ~~2016-2018~~2019-2021 to generate an average birth rate.
 - b. Multiply the average birth rate against the projected ~~2023~~2026 population of women age 15-44 to project the number of births in ~~2023~~2026.
 - c. Generate the projected number of intensive care bassinets needed in a region by applying a constant of 3.25 bassinets per 1,000 live births to the projected birth rate and subtracting the existing bassinets from this total.
 - d. Any Level III, Level IV, or RPC neonatal unit may request additional intensive care bassinets beyond those indicated as needed by the methodology above. The Level III, Level IV, or RPC neonatal unit requesting the addition must document the need for additional intensive care bassinets based on historical and projected utilization, projected population growth, routine swing of intermediate care bassinets into the intensive care setting, or other factors demonstrating the need for the proposed bassinets.
 - e. In the absence of a projected need for Level III Intensive Care bassinets in a Perinatal Region as set forth in this Chapter, an existing Level II facility can be approved for a Certificate of Need to become a Subspecialty Perinatal Center and establish up to eight (8) neonatal intensive care bassinets (NICU beds), provided the applicant can demonstrate, during the 12 month period

immediately prior to the month in which the CON application is submitted to the Department, a minimum of 1,500 births and 2,500 intermediate patient days at its facility.

2. Only Level III, Level IV, and RPCs neonatal units have intensive care bassinets.

The Intensive and Intermediate Bassinets Chart, Utilization of Neonatal Special Care Units Chart and NICU Bed Need Chart are located at the end of this Chapter.

The addition of neonatal intermediate care bassinets does not require Certificate of Need review.

In some areas the number of intensive care bassinets should be increased. The intermediate care bassinets should be better utilized in Level II facilities so babies can be transferred back closer to their home community, potentially alleviating the high utilization of the current intensive/intermediate care bassinets in RPC facilities in some areas of the State. To improve the availability of the existing RPC neonatal intensive care bassinets, utilization of the back transport concept should be supported. This component of regionalized care involves the transfer of infants who no longer require neonatal intensive care to facilities with intermediate or continuing care bassinets appropriate to the individual baby's care needs. If more back transfers to the Level II facilities occurred, then some of the overcrowding problems of the existing RPC units would be alleviated.

It should be noted that some RPC, Level III, and Level IV facilities with intensive care bassinets may at times have intermediate type infants in intensive care bassinets and vice versa as the patient load changes within the unit. RPCs may use intermediate and intensive care bassinets interchangeably as the level of care required by the neonate varies.

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

The following criteria are considered the most important in evaluating Certificate of Need applications for a neonatal service:

1. Compliance with the Need Outlined in this Section of this Plan;
2. Distribution (Accessibility);
3. Record of the Applicant; and
4. Adverse Effects on Other Facilities.

Because neonatal services are planned and located regionally due to the small percentage of infants requiring neonatal services, this service is available within approximately 30 minutes' travel time for the majority of the population. The benefits of improved accessibility will be equally weighed with the adverse effects of duplication in evaluating Certificate of Need applications for this service.

CHAPTER 6

ALCOHOL AND DRUG ABUSE FACILITIES

There are five types of licensed substance abuse treatment facilities in South Carolina. These are (1) outpatient facilities, (2) social detoxification centers, (3) residential treatment programs, (4) inpatient treatment services, and (5) opioid (narcotic) treatment programs.

OUTPATIENT FACILITIES

An outpatient facility provides treatment, care and services to individuals dependent upon or addicted to psychoactive substances and their families based on an individual treatment plan in a nonresidential setting. The length and intensity of outpatient treatment varies according to the severity of the individual's illness and response to treatment. There are currently 84 licensed "Outpatient Facilities that Treat Individuals for Psychoactive Substance Abuse or Dependence" in South Carolina, with a total of 113 locations.

A Certificate of Need is not required for outpatient facilities as described above.

SOCIAL DETOXIFICATION FACILITIES

A social detoxification facility provides supervised withdrawal from alcohol or other drugs in which neither the client's level of intoxication nor physical condition is severe enough to warrant direct medical supervision or the use of medications to assist in withdrawal, but which maintains medical backup and provides a structured program of counseling, if appropriate, educational services, and referral for further rehabilitation. It provides 24-hour-a-day observation of the client until discharge.

A Certificate of Need is not required for a social detoxification facility.

RESIDENTIAL TREATMENT PROGRAM FACILITIES

A residential treatment program facility is a 24-hour facility offering an organized service in a residential setting, which is designed to improve the client's ability to structure and organize the tasks of daily living and recovery through planned clinical activities, counseling, and clinical monitoring in order to promote successful involvement or re-involvement in regular, productive, daily activity, and, as indicated, successful reintegration into family living. Residential treatment programs utilize a multi-disciplinary staff for clients whose biomedical and emotional/behavioral problems are severe enough to require residential services and who are in need of a stable and supportive environment to aid in their recovery and transition back into the community. Twenty-four hour observation, monitoring, and treatment shall be available.

~~A Certificate of Need is not required for a Residential Treatment Program.~~

~~INPATIENT TREATMENT FACILITIES~~

~~An inpatient treatment facility is a short-term treatment service for persons who are in need of an organized intensive program of alcohol and/or drug rehabilitation, but who are without serious debilitating medical complications. These facilities may provide detoxification for their patients, as needed, in the inpatient treatment beds. These facilities are licensed either as a specialized hospital or as part of a hospital. For reference purposes only, these facilities are also subject to compliance with Regulation 61-16.~~

~~The Inpatient Treatment Facilities Chart is located at the end of this Chapter.~~

~~CERTIFICATE OF NEED PROJECTIONS AND STANDARDS~~

- ~~1. — Need projections are calculated by service area. Because patients in need of alcohol and/or drug abuse treatment frequently require psychiatric treatment services as well, the inpatient treatment service areas mirror the psychiatric service areas (e.g., Anderson/Oconee, Greenville/Pickens, etc.) to facilitate planning in a manner that recognizes the comorbidity of this patient population.~~
- ~~2. — The methodology for calculating inpatient treatment bed need is as follows:~~
 - ~~a. — For the service area, take the greater of the service area utilization rate or the statewide utilization rate for inpatient treatment beds by age cohort. The statewide utilization rate for each age cohort will be used for those service areas where no beds currently exist.~~
 - ~~b. — Multiply the applicable utilization rate by the projected population for the year 2024 for each age cohort (where such data is available) and divide by 365 to obtain a projected average daily census by age cohort.~~
 - ~~c. — Take the sum of average daily censuses by age cohort and divide by the target occupancy rate of 75% to determine the number of beds needed in the service area.~~
 - ~~d. — The number of additional beds needed or excess beds for the service area is obtained by subtracting the number of existing beds from the bed need.~~
- ~~3. — Because a minimum of 20 beds is needed for an inpatient program, a 20-bed unit may be approved in a service area that does not have any existing beds provided the applicant can document the need.~~

4. In the absence of a projected need in the service area, an existing inpatient treatment facility can apply to add up to eight additional inpatient treatment beds if it has achieved an occupancy rate of at least 70% as reported on its most recent Joint Annual Report ("JAR").
5. Inpatient treatment facilities are physically distinct from freestanding detoxification centers. Applicants may not combine the bed need for freestanding detoxification with the bed need for inpatient treatment in order to generate a higher bed need for an inpatient facility. There are no prohibitions against an inpatient facility providing detoxification services to its clients as needed, but the bed need projections refer to two distinct treatment modes that cannot be commingled.
6. The establishment of a regional treatment center to serve more than a single service area may be proposed in order to improve access to care for patients in service areas that are not currently well served. Such a proposed center would be allowed to combine the bed need for separate, contiguous service areas, provided that each service area to be combined shows a positive bed need. The applicant must document with patient origin data the historical utilization of the residents in the service area that is to be combined, or why it is in the best interest of these residents for their projected bed need to be used to form a regional treatment facility.
7. It is frequently impossible for a facility to totally predict or control short-term deviation in the number of patients with mixed psychiatric/addictive etiology. Therefore, in the case of facilities with licensed beds for both psychiatric and substance abuse treatment, 75% of licensed substance abuse beds may be utilized alternatively for the treatment of patients having diagnoses of both psychiatric and substance abuse disorders.

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

The following Project Review Criteria are considered to be the most important in evaluating Certificate of Need applications for this service:

1. Community Need Documentation
2. Distribution (Accessibility); and
3. Staff Resources.

Services are accessible within 60 minutes' travel time for the majority of residents of the state. The benefits of improved accessibility will be equally weighed with the adverse effects of duplication in evaluating Certificate of Need applications for this service.

The Inpatient Treatment Bed Need Chart is located at the end of this Chapter.

OPIOID TREATMENT PROGRAMS

Opioid treatment programs provide medications for the rehabilitation of persons dependent on opium, morphine, heroin or any derivative or synthetic drug. Opioid maintenance therapy (OMT) is an umbrella term that encompasses a variety of pharmacologic and non-pharmacologic treatment modalities, including the therapeutic use of specialized opioid compounds such as methadone, suboxone and buprenorphine to psychopharmacologically occupy opiate receptors in the brain, extinguish drug craving and thus establish a maintenance state. OMT is a separate service that can be provided in any level of care, as determined by the client's needs. For reference purposes only, Opioid (narcotic) treatment programs are described in Regulation 61-93.

Charges for medication usually range between \$11 and \$17 per day. A Registered Pharmacist must dispense the medication.

The Opioid Treatment Programs Chart is located at the end of this Chapter.

CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

1. Because clients must usually attend a center 6 days per week to receive their dose of medication, these centers should be located throughout the state, with at least one center per county. To improve accessibility, opioid treatment programs should be developed in counties where none exist.
2. An additional treatment program can only be approved in a county with an existing program if the applicant is able to document sufficient need for the service.
3. For reference purposes only, Regulation 61-93 states that a narcotic (opioid) treatment program shall not operate within 500 feet of: the property line of a church, the property line of a public or private elementary or secondary school, a boundary of any residential district, a public park adjacent to any residential district, or the property line of a lot devoted to residential use.

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

The following Project Review Criteria are considered to be the most important in evaluating Certificate of Need applications for this service:

1. Community Need Documentation;
2. Distribution (Accessibility);
3. Record of the Applicant;

~~Due to the increasing number of opioid deaths in South Carolina, additional facilities are needed for the services to be accessible within 30 minutes' travel time for the majority of state residents. The benefits of improved accessibility will outweigh the adverse effects of the duplication of this existing service.~~

CHAPTER 7

RESIDENTIAL TREATMENT FACILITIES FOR CHILDREN AND ADOLESCENTS

~~A Residential Treatment Facility for Children and Adolescents (RTF) is operated for the assessment, diagnosis, treatment, and care of two or more children and/or adolescents in need of mental health treatment. Children and/or adolescents up to age 21 who manifest a substantial disorder of cognitive or emotional process which lessens or impairs to a marked degree their capacity either to develop or to exercise age-appropriate or age-adequate behavior are treated by these facilities.~~

~~These facilities provide medium to long-term care (six months or longer). Treatment modalities are both medical and behavioral in nature. Some facilities contract with the South Carolina Continuum of Care (COC) to provide these services.~~

~~Services available, at a minimum, should include the following:~~

- ~~1. 24-hour, awake supervision in a secure facility;~~
- ~~2. individual treatment plans to assess the problems and determine specific patient goals;~~
- ~~3. psychiatric consultation and professional psychological services for treatment supervision and consultation;~~
- ~~4. nursing services, as required;~~
- ~~5. regularly scheduled individual, group, and/or family counseling in keeping with the needs of each client;~~
- ~~6. recreational facilities with an organized youth development program;~~
- ~~7. a special education program with a minimum program defined by the South Carolina Department of Education; and~~
- ~~8. discharge planning including a final assessment of the patient's condition and an aftercare plan indicating any referrals to follow-up treatment and self-help groups.~~

~~Each facility shall have a written plan for cooperation with other public and private organizations, such as schools, social service agencies, etc., to ensure that each child under its care will receive comprehensive treatment. In addition, each facility shall have a written transfer agreement with one or more hospitals for the transfer of emergency cases when~~

such hospitalization becomes necessary. A proposal for Residential Treatment Facilities for Children and Adolescents should have letters of support from the Department of Social Services (DSS), DMH, and COC.

The Residential Treatment Facilities for Children & Adolescents Chart is located at the end of this Chapter.

CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

1. ~~The establishment or expansion of an RTF requires a Certificate of Need.~~
2. ~~Need projections are calculated on a statewide basis to serve the needs of this population.~~
3. ~~The applicant must document the need for the expansion of or the addition of an RTF based on the most current utilization data available. The existing resources must be considered and documentation presented as to why these resources are not adequate to meet the needs of the community.~~
4. ~~An existing facility that can demonstrate a 70% or greater occupancy rate for the most recent year can apply to add up to five additional beds outside of the need identified in this Plan. An existing facility that can demonstrate an 80% or greater occupancy rate for the most recent year can apply to add up to ten additional beds, outside of the need identified in this Plan. An existing facility that can demonstrate a 90% or greater occupancy rate for the most recent year can apply to add up to fifteen additional beds, outside of the need identified in this Plan.~~
5. ~~An existing facility seeking to establish a specialty unit of the RTF (i.e., full-service autism spectrum treatment), or a new facility proposing to include such a specialty unit, can apply to add or include up to 20 such beds, outside the need identified in this Plan, by demonstrating need through utilization and diagnostic data of the most recent year.~~
6. ~~For a new facility, the applicant must document where the potential patients for the facility will come from and where they are currently being served, to include the expected shift in patient volume from existing providers and the expected number of out-of-state children expected to utilized beds in the facility. For the expansion of an existing facility, the applicant must provide patient origin information on the current facility, and any expected shift in patient origin from within or outside of South Carolina.~~
7. ~~The applicant must document the potential impact that the proposed new RTF or expansion will have upon the existing service providers and referral patterns.~~
8. ~~The applicant must provide a written commitment that the facility will provide services~~

~~for indigent and charity patients at a percentage that is comparable to other health care facilities in the service area.~~

- ~~9. The applicant agrees to provide utilization data on the operation of the facility to the Department.~~

~~To account for a substantial increase in out-of-state children being placed in South Carolina RTFs, the bed need methodology to be used in South Carolina is based upon a standard of 70 beds per 100,000 children. Since few, if any, children under five years of age would be candidates for this type of care, the bed need will be based on the population age 5-21.~~

~~The Projected Bed Need for Residential Treatment Facilities for Children & Adolescents Chart is located at the end of this Chapter.~~

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

~~The following project review criteria are considered to be the most important in evaluating Certificate of Need applications for this service:~~

- ~~1. Community Need Documentation;~~
- ~~2. Distribution (Accessibility);~~
- ~~3. Record of the Applicant;~~
- ~~4. Staff Resources; and~~
- ~~5. Medically Underserved Groups.~~

~~Residential treatment facility beds for children and adolescents are distributed statewide and are located within 60 minutes' travel time for the majority of residents of the State. The benefits of improved accessibility will be equally weighed with the adverse effects of duplication in evaluating Certificate of Need applications for this service.~~

CHAPTER 8

CARDIOVASCULAR CARE

~~Current guidelines issued by the Society for Cardiovascular Angiography and Interventions (SCAI), the American College of Cardiology (ACC), and the American Heart Association (AHA) allow for Emergent/Primary PCI as well as Elective PCI in facilities without on-site open heart surgery backup. Hospitals without an open heart surgery program shall be allowed to provide Emergent/Primary and/or Elective PCIs only if they comply with all sections of Standard 7 or 8 of the Standards for Cardiac Catheterization.~~

~~In 2013, SCAI, ACC, and AHA updated their joint statement on clinical competence regarding coronary artery intervention procedures. The joint statement defined certain requirements for PCI operator competence and PCI facility volume requirements. The statement also noted an overall decrease in PCI volumes.~~

~~Both cardiac catheterization and open heart surgery programs require highly skilled staffs and expensive equipment. Appropriately equipped and staffed programs serving larger populations are preferable to multiple, minimum population programs. Underutilized programs may reflect unnecessary duplication of services in an area, which may seriously compromise quality and safety of procedures and increase the cost of care. Optimal performance requires a caseload of adequate size to maintain the skills and efficiency of the staff. Cardiac catheterization laboratories should perform a minimum of 200 procedures per year. Emergent PCI operators should perform a minimum of 36 PCIs annually; all other PCI operators should perform a minimum of 200 combined procedures annually. Individual providers should perform a minimum of 50 PCIs annually (averaged over two years), including no less than 11 emergent/primary PCIs annually. It is recommended these be performed in facilities meeting a 200 procedure-per-year threshold.~~

CARDIAC CATHETERIZATION

Relevant Definitions

~~“Cardiac Catheterization Procedure” is an invasive procedure where a thin, flexible catheter is inserted into a blood vessel; the physician then manipulates the free end of the catheter into the chambers or vessels of the heart. All activities performed during one clinical session, including angiocardiography, coronary arteriography, pulmonary arteriography, coronary angioplasty and other diagnostic or therapeutic measures and physiologic studies shall be considered one procedure.~~

~~“Comprehensive Catheterization Laboratory” means a dedicated room or suite of rooms in which PCIs as well as diagnostic and therapeutic catheterizations are performed, in a facility~~

with on-site open heart surgery backup.

~~“Diagnostic Catheterization” refers to a cardiac catheterization during which any or all of the following diagnostic procedures or measures are performed: Blood Pressure; Oxygen Content and Flow Measurements; Angiocardiology, Coronary Arteriography; and Pulmonary Arteriography.~~

~~“Diagnostic Catheterization Laboratory” means a dedicated room in which only diagnostic catheterizations are performed.~~

~~“Percutaneous Coronary Intervention (PCI)” refers to a therapeutic procedure to relieve coronary narrowing, such as Percutaneous Transluminal Coronary Angioplasty (PTCA) or Coronary Stent Implantation. These procedures may be performed on an emergent or elective basis. “Emergent or Primary” means that a patient needs immediate PCI because, in the treating physician’s best clinical judgment, delay would result in undue harm or risk to the patient. An “Elective” PCI is scheduled in advance and performed on a patient with cardiac function that has been stable in the days prior to the procedure.~~

~~“Therapeutic Catheterization” refers to a PCI or cardiac catheterization during which, in addition to any diagnostic catheterization procedure, any or all of the following interventional procedures are performed: PTCA; Thrombolytic Agent Infusion; Directional Coronary Atherectomy; Rotational Atherectomy; Extraction Atherectomy; Coronary Stent Implants and Cardiac Valvuloplasty.~~

~~“Therapeutic Catheterization Laboratory” means a room in which therapeutic catheterizations are performed in addition to any diagnostic catheterizations as referenced in the above definition of “Therapeutic Catheterization”.~~

Scope of Services

The following services should be available in both adult and pediatric catheterization laboratories:

- ~~1. Each cardiac catheterization lab should be competent to provide a range of angiographic (angiocardiology, coronary arteriography, pulmonary arteriography), hemodynamic, and physiologic (cardiac output measurement, intracardiac pressure, etc.) studies. These facilities should be available in one laboratory so that the patient need not be moved during a procedure.~~
- ~~2. The lab should have the capability of immediate endocardiac catheter pacemaking in cardiac arrest, a crash cart, and defibrillator.~~
- ~~3. A full range of non-invasive cardiac/circulatory diagnostic support services, such as~~

~~the following, should be available within the hospital:~~

- ~~a. Nuclear Cardiology~~
- ~~b. Echocardiography~~
- ~~c. Pulmonary Function Testing~~
- ~~d. Exercise Testing~~
- ~~e. Electrocardiography~~
- ~~f. Cardiac Chest X-ray and Cardiac Fluoroscopy~~
- ~~g. Clinical Pathology and Blood Chemistry Analysis~~
- ~~h. Phonocardiography~~
- ~~i. Coronary Care Units (CCUs)~~
- ~~j. Medical Telemetry/Progressive Care~~

- ~~4. Each applicant shall document plans for providing cardiac rehabilitation services to its patients or plans for establishing referral agreements with facilities offering cardiac rehabilitation services.~~

~~CERTIFICATE OF NEED PROJECTIONS AND STANDARDS~~

- ~~1. The capacity of a fixed cardiac catheterization laboratory shall be 1,200 procedures per year, as measured on an equivalent basis. Each adult diagnostic cardiac catheterization shall carry a weight of 1.0 procedures, while each adult therapeutic catheterization performed in the fixed laboratory shall carry a weight of 2.0 procedures. For pediatric and adult congenital catheterization labs, diagnostic catheterizations shall carry the weight of 2.0 procedures, therapeutic catheterizations shall carry the weight of 3.0 procedures, electrophysiology (EP) studies shall carry the weight of 2.0 procedures, and biopsies performed after heart transplants shall carry the weight of 1.0 procedures. The capacity of mobile cardiac catheterization labs will be calculated based on the number of days of operation per week.~~
- ~~2. The service area for a diagnostic or therapeutic catheterization laboratory is defined as all facilities within 30 minutes' emergency medical transport time¹; for comprehensive cardiac catheterization laboratories the service area is all facilities within 60 minutes' emergency medical transport time; a pediatric cardiac program should serve a population encompassing at least 30,000 births per year, or roughly two million people.~~

~~1 Emergency medical transport time shall be determined by the DHEC Bureau of EMS and Trauma, and for the purposes of this Plan shall mean transport by ground ambulance. Potential applicants may obtain this information for any laboratory or proposed laboratory by calling 803-545-4489.~~

Diagnostic and Mobile Catheterization Services

3. ~~New diagnostic catheterization services, including mobile services, shall be approved only if all existing labs in the service area have performed a minimum of 200 diagnostic catheterization procedures per laboratory during the most recent year;~~
4. ~~An applicant for a fixed diagnostic service must project that the proposed service will perform a minimum of 200 procedures annually within three years of initiation of services, without reducing the utilization of the existing diagnostic catheterization services in the service area below 200 diagnostic cardiac catheterization procedures per laboratory.~~
5. ~~Expansion of an existing diagnostic catheterization service shall only be approved if the service has operated at a minimum use rate of 80% of capacity (i.e., 960 procedures by equivalent measure) for each of the past two years and can project a minimum of 200 procedures per year on the additional equipment within three years of its implementation.~~
6. ~~An applicant for a mobile diagnostic catheterization laboratory must be able to project a minimum of 75 diagnostic procedures annually for each day of the week that the mobile lab is located at the applicant's facility by the end of the third year following initiation of the service, without reducing the utilization of the existing diagnostic catheterization services in the service area below 200 diagnostic catheterization procedures per laboratory. In addition:~~
 - a. ~~The applicant must document that the specific mobile unit utilized by the vendor will perform a combined minimum of 200 procedures per year;~~
 - b. ~~The applicant must include vendor documentation of the complication rate of the mobile units operated by the vendor; and~~
 - c. ~~If an application for a mobile lab is approved and the applicant subsequently desires to change vendors, the Department must approve such change in order to ensure that appropriate minimum utilization can be documented.~~
7. ~~An applicant for provision of diagnostic catheterization service agrees, as a condition for issuance of its Certificate of Need for such service, to discontinue such services and surrender the Certificate of Need for that service if they have failed to achieve 200 diagnostic catheterizations per year by the expiration of the first three years of operation of such services.~~

Emergent and Elective PCI without On-Site Cardiac Backup

8. ~~Hospitals with diagnostic laboratories may be approved to perform emergency PCI without an on-site open heart surgery program only if all of the following criteria are met:~~
 - a. ~~Therapeutic catheterizations must be limited to Percutaneous Coronary Interventions (PCIs) performed only in emergent circumstances (Primary PCIs). Elective PCI may not be performed at institutions that do not provide on-site cardiac surgery except as provided for below.~~
 - b. ~~The applicant has performed a minimum of 200 diagnostic catheterization procedures in the most recent year and can reasonably demonstrate that it will continue to perform a minimum of 200 diagnostic catheterizations annually within three years of the initiation of services.~~
 - c. ~~The hospital must acquire an intra-aortic balloon pump (IABP) dedicated solely to this purpose.~~
 - d. ~~The chief executive officer of the hospital must sign an affidavit assuring that the current guidelines mentioned below are and will continue to be met at all times.~~
 - e. ~~An application shall be approved only if it is consistent with current guidelines established by SCAI/ACC/AHA as they appear at the time an application for a CON is filed under this Chapter. A complete copy of the current guidelines for PCI can be found at: www.acc.org/guidelines.~~
 - f. ~~An applicant for provision of emergent/primary PCI without on-site surgical backup agrees, as a condition for issuance of its Certificate of Need for such service, to discontinue such services and surrender the Certificate of Need for that service if they have failed to achieve 200 diagnostic catheterizations per year by the expiration of the first three years of operation of such services.~~
9. ~~In 2014, the SCAI/ACC/AHA affirmed that elective PCI may be safely performed in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished and rigorous clinical and angiographic criteria are used for proper patient selection. Hospitals with diagnostic laboratories that have been approved to perform primary PCI without on-site open heart surgical backup *must obtain a Certificate of Need* in order to upgrade to a designation as providing elective PCI without on-site cardiac surgery backup. The following standards must be met:~~

- a. ~~The applicant has performed a minimum of 200 diagnostic catheterization procedures in the most recent year and can reasonably demonstrate that it will continue to perform a minimum of 200 diagnostic catheterizations annually within three years of the initiation of services.~~
- b. ~~All existing comprehensive cardiac catheterization facilities in the service area performed a minimum of 200 therapeutic catheterizations (PCIs) in the most recent year.~~
- c. ~~An applicant must project that the proposed service will perform a minimum of 200 therapeutic catheterization procedures annually within three years of initiation of services, without reducing the cardiac catheterizations performed at existing comprehensive catheterization programs in the service area below the minimum thresholds of 200 therapeutic procedures and 200 diagnostic procedures at each facility.~~
- d. ~~The physicians must be experienced interventionalists who perform a minimum of 50 elective PCI cases per year and preferably at least 11 PCI procedures for STEMI each year. Ideally, operators with an annual procedure volume of fewer than 50 procedures per year should only work at institutions with an activity level of more than 600 procedures per year. Operators who perform fewer than 50 procedures per year should develop a defined mentoring relationship with a highly experienced operator who has an annual procedural volume of at least 150 procedures.~~
- e. ~~For catheterization labs in facilities without on-site surgical backup, there must be formalized written protocols in place for immediate (emergency transport beginning with 30 minutes and arriving at surgical facility within 60 minutes) and efficient transfer of patients to the nearest cardiac surgical facility that are reviewed and tested on a regular basis.~~
 - ~~Applicants must provide documentation of an agreement with an ambulance or transport service capable of advanced life support and intra-aortic balloon pump and that guarantees a 30 minute or less response time from contact.~~
- f. ~~The catheterization laboratory must be well-equipped, with optimal imaging systems, resuscitative equipment, intra-aortic balloon pump (IABP) support, and must be well-stocked with a broad array of interventional equipment.~~
- g. ~~The nursing and technical catheterization laboratory staff must be experienced in handling acutely ill patients and comfortable with interventional equipment. They must have acquired experience in dedicated~~

~~interventional laboratories at a surgical center. They participate in a 24-hour, 365-day call schedule, and must be available within 30 minutes of facility call-back.~~

- ~~h. The cardiac care unit nurses must be adept in hemodynamic monitoring and IABP management.~~
- ~~i. Applicants must offer primary percutaneous coronary intervention (PCI) services and procedures twenty-four (24) hours a day, seven (7) days a week, three hundred and sixty five (365) days a year.~~
- ~~j. Applicants must provide documentation to show that guidelines for determining patients appropriate for PCI procedures in a setting without on-site open heart backup consistent with standards of the American College of Cardiology have been developed and will be maintained.~~
- ~~k. Applicants must agree to participate in the South Carolina STEMI Mission Lifeline Program.~~
- ~~l. Every therapeutic catheterization program should operate a quality-improvement program that routinely:
 - ~~1) reviews quality and outcomes of the entire program;~~
 - ~~2) reviews results of individual operators;~~
 - ~~3) includes risk adjustment;~~
 - ~~4) provides peer review of difficult or complicated cases; and~~
 - ~~5) performs random case reviews.~~~~
- ~~m. Every PCI program must participate in a regional or national PCI registry for the purpose of benchmarking its outcomes against current national norms.~~
- ~~n. Hospitals with diagnostic laboratories may propose to develop primary PCI and elective PCI simultaneously.~~
- ~~o. An applicant for provision of elective PCI without on-site surgical backup agrees, as a condition for issuance of its Certificate of Need for such service, to discontinue therapeutic catheterization services and surrender the Certificate of Need for that service if they have failed to achieve 200 therapeutic catheterizations (PCIs) per year by the expiration of the first three years of operation of such services.~~

Comprehensive Catheterization Services

10. ~~Comprehensive catheterization laboratories, which perform diagnostic catheterizations, PCI and other therapeutic procedures, shall only be located in hospitals that provide open heart surgery. New comprehensive cardiac catheterization services shall be approved only if the following conditions are met:~~
 - a. ~~All existing comprehensive cardiac catheterization facilities in the service area performed a minimum of 200 therapeutic catheterizations (PCIs) in the most recent year; and~~
 - b. ~~An applicant must project that the proposed service will perform a minimum of 200 therapeutic catheterization procedures annually within three years of initiation of services, without reducing the therapeutic catheterizations performed at existing comprehensive catheterization programs in the service area below 200 procedures at each facility.~~
11. ~~Applications which propose the provision of Transcatheter Aortic Valve Replacement (TAVR) procedures shall only be approved in facilities which currently offer, or propose to offer on the basis of the Application, comprehensive catheterization services.~~
12. ~~To prevent the unnecessary duplication of comprehensive cardiac catheterization services, expansion of an existing comprehensive cardiac catheterization service shall be approved only if the service has operated at a minimum use rate of 80% of capacity (960 equivalents per lab) for each of the past two years and can project a minimum of 600 procedures, as measured on an equivalent basis, per year on the additional equipment within three years of its implementation. The 600 equivalents may consist of a combination of diagnostic and therapeutic procedures.~~
13. ~~An applicant for expansion of comprehensive cardiac catheterization agrees, as a condition for issuance of its Certificate of Need for such expansion, to discontinue the expanded services and surrender the Certificate of Need for that expanded service if they have failed to achieve 600 procedures, as measured on an equivalent basis, per year within three years of its implementation.~~

Pediatric Catheterization Services

14. ~~New pediatric cardiac catheterization services shall be approved only if the following conditions are met:~~
 - a. ~~All existing facilities have performed at a combined use rate of 80% of capacity for the most recent year; and~~

- ~~b. An applicant must project that the proposed service will perform a minimum of 200 procedures annually within three years of initiation of services.~~
- ~~15. Expansion of an existing pediatric cardiac catheterization service shall only be approved if the service has operated at a minimum use rate of 80% of capacity (960 equivalents) for each of the past two years and can project a minimum of 200 procedures per year, on the additional equipment within three years of its implementation.~~

General Standards

- ~~16. Documentation of need for the proposed service:
 - ~~a. The applicant shall provide epidemiologic evidence of the incidence and prevalence of conditions for which diagnostic, comprehensive or pediatric catheterization is appropriate within the proposed service area, to include the number of potential candidates for these procedures;~~
 - ~~b. The applicant shall project the utilization of the service and the effect of its projected utilization on other cardiac catheterization services within its service area, to include:
 - ~~1) The number of patients of the applicant hospital who were referred to other cardiac catheterization services in the preceding three years and the number of those patients who could have been served by the proposed service;~~
 - ~~2) The number of additional patients, if any, who will be generated through changes in referral patterns, recruitment of specific physicians, or other changes in circumstances. The applicant shall document the services, if any, from which these patients will be drawn; and~~
 - ~~3) Existing and projected patient origin information and referral patterns for each cardiac catheterization service serving patients from the area proposed to be served shall be provided.~~~~~~
- ~~17. Both fixed and mobile diagnostic cardiac catheterization laboratories must provide a written agreement with at least one hospital providing open heart surgery, which states specified arrangements for referral and transfer of patients, to include:
 - ~~a. Criteria for referral of patients on both a routine and an emergency back-up basis;~~~~

- ~~b. Regular communications between cardiologists performing catheterizations and surgeons to whom patients are referred;~~
 - ~~c. Acceptability of diagnostic results from the cardiac catheterization service to the receiving surgical service to the greatest extent possible to prevent duplication of services; and~~
 - ~~d. Development of linkages with the receiving institution's peer review mechanism.~~
- ~~18. The application shall include standards adopted or to be adopted by the service, consistent with current medical practice as published by clinical professional organizations, such as the American College of Cardiology or the American Heart Association, defining high-risk procedures and patients who, because of their conditions, are at high risk. For diagnostic catheterization laboratories, this description of patient selection criteria shall include referral arrangements for high-risk patients. For comprehensive laboratories, these high-risk procedures should only be performed with open heart surgery back-up. The cardiac team must be promptly available and capable of successfully operating on unstable, acute, ischemic patients in an emergency setting.~~
- ~~19. Cardiac catheterization services should be staffed by a minimum of two physicians licensed by the State of South Carolina who possess the qualifications specified by the governing body of the facility. Protocols should be established that govern initial and continuing granting of clinical staff privileges to physicians to perform diagnostic, therapeutic and/or pediatric catheterizations. Applicants must provide documentation that one (1) or more interventional cardiologist(s) will be required to respond to a call in a timely manner consistent with the hospital Medical Staff bylaws and clinical indications. In addition, standards should be established to assure that each physician using the service would be involved in adequate numbers of applicable types of cardiac catheterization procedures to maintain proficiency.~~
- ~~20. Applicants must agree to report annual data on the number of PCI procedures, type, and outcomes to the National Cardiovascular Data Registry Cat/PCI registry.
 - ~~a. Applicants must agree to provide accurate and timely data, including outcomes analysis and formal periodic external and internal case review by appropriate entities.~~
 - ~~b. The Department encourages all applicants and providers to share their outcomes data with appropriate registries and research studies designed to improve the quality of cardiac care.~~~~

The Cardiac Catheterization Procedures Chart is located at the end of this Chapter.

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

The following project review criteria are considered to be the most important in evaluating Certificate of Need applications for this service:

1. ~~Community Need Documentation;~~
2. ~~Distribution (Accessibility);~~
3. ~~Staff Resources; and~~
4. ~~Adverse Effects on Other Facilities.~~

The Department finds that:

- (1) ~~Diagnostic catheterization services are generally available within 45 minutes' and therapeutic catheterization services within 90 minutes' travel time for the majority of South Carolina residents;~~
- (2) ~~Significant cardiac catheterization capacity exists in most areas of the State; and~~
- (3) ~~The preponderance of the literature on the subject indicates that a minimum number of procedures are recommended per year in order to develop and maintain physician and staff competency in performing these procedures.~~

The benefits of improved accessibility will be equally weighed with the adverse effects of duplication in evaluating Certificate of Need applications for this service.

OPEN HEART SURGERY

Relevant Definitions

"Open Heart Surgery" refers to an operation performed on the heart or intrathoracic great vessels.

An "Open Heart Surgery Unit" is an operating room, which may be included within a suite of rooms, equipped and staffed to perform open heart surgery procedures; such designation does not preclude its use for other related surgeries, such as vascular surgical procedures. A hospital with an open heart surgery program may have one or more open heart surgery units.

"Open Heart Surgical Procedure" means an operation performed on the heart or intrathoracic great vessels within an open heart surgical unit. All activities performed during

~~one clinical session shall be considered one procedure.~~

~~"Open Heart Surgical Program" means the combination of staff, equipment, physical space and support services used to perform open heart surgery. Adult open heart surgical programs should have the capacity to perform a full range of procedures, including:~~

- ~~1. — repair/replacement of heart valves by traditional surgical means~~
- ~~2. — repair of congenital defects~~
- ~~3. — cardiac revascularization~~
- ~~4. — repair/reconstruction of intrathoracic vessels~~
- ~~5. — treatment of cardiac traumas~~

~~In addition, open heart programs must have the ability to implement and apply circulatory assist devices such as intra-aortic balloon and prolonged cardiopulmonary partial bypass.~~

Scope of Services

~~A range of non-invasive cardiac and circulatory diagnostic services should be available within the hospital, including the following:~~

- ~~1. — services for hematology and coagulation disorders~~
- ~~2. — electrocardiography, including exercise stress testing~~
- ~~3. — diagnostic radiology~~
- ~~4. — clinical pathology services which include blood chemistry and blood gas analysis~~
- ~~5. — nuclear medicine services which include nuclear cardiology~~
- ~~6. — echocardiography~~
- ~~7. — pulmonary function testing~~
- ~~8. — microbiology studies~~
- ~~9. — Coronary Care Units (CCU's)~~
- ~~10. — medical telemetry/progressive care~~
- ~~11. — perfusion~~

~~Backup physician personnel in the following specialties should be available in emergency situations:~~

- ~~1. — cardiology~~
- ~~2. — anesthesiology~~
- ~~3. — pathology~~
- ~~4. — thoracic surgery~~
- ~~5. — radiology~~

~~Each applicant shall document plans for providing cardiac rehabilitation services to its patients or plans for establishing referral agreements with facilities offering cardiac rehabilitation services.~~

~~Adult open heart surgery services should be available within 60 minutes' one-way automobile travel for 90% of the population. A pediatric cardiac surgical service should provide services for a minimum service area population with 30,000 live births, or roughly two million people. Open heart surgery for elective procedures should be available at least 40 hours per week, and elective open heart surgery should be accessible with a waiting time of no more than two weeks. All facilities providing open heart surgery must conform to local, state, and federal regulatory requirements and should meet the full accreditation standards for The Joint Commission (TJC), if the facility is TJC accredited.~~

~~CERTIFICATE OF NEED PROJECTIONS AND STANDARDS~~

- ~~1. — The establishment of an open heart surgery program requires Certificate of Need review.~~
- ~~2. — Comprehensive cardiac catheterization laboratories shall only be located in hospitals that provide open heart surgery.~~
- ~~3. — The capacity of an open heart surgery program is 500 open heart procedures per year per open heart surgery unit (i.e., each operating room equipped and staffed to perform open heart surgery has a maximum capacity of 500 procedures annually).~~
- ~~4. — There should be a minimum of 200 adult open heart surgery procedures performed annually per open heart surgery unit within three years after initiation in any institution in which open heart surgery is performed for adults. In institutions performing pediatric open heart surgery there should be a minimum of 100 pediatric heart operations per open heart surgery unit; at least 75 should be open heart surgery.~~
- ~~5. — New open heart surgery services shall be approved only if the following conditions are met:
 - ~~a. — Each existing unit in the service area (defined as all facilities within 60 minutes' one way automobile travel, excluding any facilities located in either North Carolina or Georgia) is performing an annual minimum of 350 open heart surgery procedures per open heart surgery unit for adult services (70 percent of functional capacity). The standard for pediatric open heart cases in pediatric services is 130 procedures per unit. An exception to this requirement may be authorized should an applicant meet both of the following criteria:
 - ~~1) — There are no open heart surgery programs located in the same county as the applicant; and~~
 - ~~2) — The proposed facility currently offers cardiac catheterization services~~~~~~

~~and provided a minimum of 1,200 diagnostic procedures, as measured on an equivalent basis, in the previous year of operation.~~

- ~~b. — An applicant must project that the proposed service will perform a minimum of 200 adult open heart surgery procedures annually per open heart surgery unit within three years after initiation (the standard for pediatric open heart surgery shall be 100 procedures annually per open heart surgery unit within three years after initiation):~~
 - ~~1) — The applicant shall provide epidemiological evidence of the incidence and prevalence of conditions for which open heart surgery is appropriate within the proposed service area, to include the number of potential candidates for these procedures;~~
 - ~~2) — The applicant shall provide an explanation of how the applicant projects the utilization of the service and the effect of its projected utilization on other open heart surgery services, including:
 - ~~a) — The number of patients of the applicant hospital who were referred to other open heart surgery services in the preceding three years and the number of these patients who could have been served by the proposed service;~~
 - ~~b) — The number of additional patients, if any, who will be generated through changes in referral patterns, recruitment of specific physicians, or other changes in circumstances. The applicant shall document the services, if any, from which these patients will be drawn; and~~
 - ~~c) — The existing and projected patient origin information and referral patterns for each open heart surgery service serving patients from the area proposed to be served shall be provided.~~~~
- ~~6. — No new open heart surgery programs shall be approved if the new program will cause the annual caseload of other programs within the proposed service area to drop below 350 adult procedures or 130 pediatric procedures per open heart surgery unit.~~
- ~~7. — A one-time incremental expansion of one open heart surgery unit shall not be considered a substantial expansion of a health service, and therefore shall not be grounds for Certificate of Need review. Expansion of an existing open heart surgery service beyond the one-time incremental increase of one open heart unit shall only be approved if the service has operated at a minimum use rate of 70 percent of capacity for each of the past two years and can project a minimum of 200 procedures per year in the new~~

~~open heart surgery unit. The applicant shall document the other service providers, if any, from which these additional patients will be drawn.~~

- ~~8. The application shall include standards adopted or to be adopted by the service, consistent with current medical practice as published by clinical professional organizations, such as the American College of Cardiology or the American Heart Association, defining high risk procedures and patients who, because of their conditions, are at high risk and shall state whether high risk cases are or will be performed or high risk patients will be served.~~
- ~~9. Open heart surgery services should be staffed by a minimum of two physicians licensed by the State of South Carolina who possess the qualifications specified by the governing body of the facility. Protocols should be established that govern initial and continuing granting of clinical staff privileges to physicians to perform open heart surgery and therapeutic cardiac catheterizations. In addition, standards should be established to assure that each physician using the service will be involved in adequate numbers of applicable types of open heart surgery and therapeutic cardiac catheterizations to maintain proficiency.~~
- ~~10. The open heart surgery service will have the capability for emergency coronary artery surgery, including:
 - ~~a. Sufficient personnel and facilities available to conduct the coronary artery surgery on an immediate, emergency basis, 24 hours a day, 7 days a week;~~
 - ~~b. Location of the cardiac catheterization laboratory(ies) in which therapeutic catheterizations will be performed near the open heart surgery operating rooms; and~~
 - ~~c. A predetermined protocol adopted by the cardiac catheterization service governing the provision of percutaneous transluminal coronary angioplasty (PTCA) and other therapeutic or high risk cardiac catheterization procedures or the catheterization of patients at high risk and defining the plans for the patients' emergency care. These high risk procedures should only be performed with open heart surgery backup. The cardiac team must be promptly available and capable of successfully operating on unstable acute ischemic patients in an emergency setting.~~~~
- ~~11. The Department encourages all applicants and providers to share their outcomes data with appropriate registries and research studies designed to improve the quality of cardiac care.~~

12. — ~~An applicant for open heart surgery service agrees, as a condition for issuance of its Certificate of Need for such service, to discontinue services and surrender the Certificate of Need for that service if they have failed to achieve 200 open heart procedures per open heart unit per year by the expiration of the first three years of operation of such services. One time incremental expansions of one open heart unit are subject to the same threshold, and any such unit shall be closed if it does not achieve 200 open heart procedures within three years of the expansion.~~
13. — ~~The expansion of an existing open heart surgery service beyond the incremental expansion described above shall only be approved if the service has operated at a minimum use rate of 70 percent of capacity, overall, for each of the past two years and can project a minimum of 200 procedures per year in the new open heart surgery units. The applicant shall document the other service providers, if any, from which these additional patients will be drawn.~~

~~The Open Heart Units Chart is located at the end of this Chapter.~~

~~RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA~~

~~The following project review criteria are considered to be the most important in evaluating Certificate of Need applications for this service:~~

1. — ~~Community Need Documentation;~~
2. — ~~Distribution (Accessibility);~~
3. — ~~Staff Resources; and~~
4. — ~~Adverse Effects on Other Facilities.~~

~~The Department makes the following findings:~~

- (1) — ~~Open heart surgery services are available within 60 minutes' travel time for the majority of residents of South Carolina;~~
- (2) — ~~Based upon the standards cited above, most of the open heart surgery providers are currently utilizing less than the functional capability (i.e., 70% of maximum capacity) of their existing surgical suites;~~
- (3) — ~~The preponderance of the literature on the subject indicates that a minimum number of procedures is recommended per year in order to develop and maintain physician and staff competency in performing these procedures; and~~
- (4) — ~~Increasing geographic access may create lower volumes in existing programs causing a potential reduction in quality and efficiency, exacerbate existing problems regarding the availability of nursing staff and other personnel, and not necessarily~~

reduce waiting time since other factors (such as the referring physician's preference) would still need to be addressed.

- (5) — Research has shown a positive relationship between the volume of open heart surgeries performed annually at a facility and patient outcomes. Thus, the Department establishes minimum standards that must be met by a hospital in order to provide open heart surgery. Specifically, a hospital is required to project a minimum of 200 open heart surgeries annually within three years of initiation of services. This number is considered to be the minimum caseload required to operate a program that maintains the skill and efficiency of hospital staff and reflects an efficient use of an expensive resource. It is in the public's interest that facilities achieve their projected volumes.
- (6) — The Department recognizes the important correlation between volume and proficiency. The Department further recognizes that the number of open heart surgery cases is decreasing and that maintaining volume in programs is very important to the provision of quality care to the community.

The benefits of improved accessibility will not outweigh the adverse effects of duplication in evaluating Certificate of Need applications for this service.

CHAPTER 9

RADIATION ONCOLOGY

Cancer is a group of related diseases that involve out-of-control growth and spread of abnormal cells. These cells accumulate and form tumors that invade and destroy normal tissue. The American Cancer Society (ACS) estimates that 39 out of 100 men and 38 out of 100 women will suffer from cancer during their lifetimes. The most common types of cancer include prostate cancer for men, breast cancer for women, whereas lung and colon cancer are a common occurrence in both genders. The Department tracks the occurrence of cancer in the State, including identification of “cancer cluster” locations, through the South Carolina Central Cancer Registry.

Megavoltage radiation has been utilized for decades as a standard modality for cancer treatment. It is best known as Radiation Therapy, but is also called Radiotherapy, X-Ray Therapy, or Irradiation. Beams of ionizing radiation are aimed to meet at a specific point and deliver radiation to that precise location. The amount of radiation used is measured in “gray” (Gy) and varies depending on the type and stage of cancer being treated. Radiation damages both cancer cells and normal cells, so the goal is to damage as many cancer cells as possible, while limiting harm to nearby healthy tissue. A typical course of treatment is five times per week, Monday through Friday, and lasts for three to nine weeks, depending on the type of cancer and the treatment goal.

Relevant Definitions

There are varying types of radiation treatment, and definitions are often used interchangeably. The following definitions apply:

“Adaptive Radiation Therapy (ART)” – Patient setup and/or radiation delivery is evaluated and modified periodically during the treatment course based on imaging and dose measurements made prior to or during treatment.

“Three-Dimensional Conformal Radiation Therapy (3D-CRT)” – Uses the results of imaging tests such as MRI and special computers to map the location of the tumor precisely to deliver radiation beams from different directions designed to match the shape of the tumor. This helps to reduce radiation damage to normal tissues and better kill the cancer by focusing the radiation dose on the tumor.

“Electronic Portal Imaging Devices (EPIDs)” have been developed because of the increased complexity of treatment planning and delivery techniques. The most common EPIDs are video-based systems wherein on-line digital port images are captured and analyzed before or during treatment. These systems are used for pre-treatment verification of Intensity Modulated Radiation Therapy fields and to reduce errors in patient positioning.

~~“Fractionation” is the practice of providing only a small fraction of the entire prescribed dose of radiation in each treatment or session. Individual treatment plans are created to minimize the side effects for normal tissue. The typical fractionation schedule for adults is once per day, five days a week. Hyperfractionation (Superfractionation) refers to radiation given in smaller doses twice a day. In Hypofractionation, individual doses are given less often than daily, such as in two-five sessions.~~

~~“Helical-tomotherapy” is a form of IRMT that delivers radiation inside a large “donut.” For this treatment, the patient lies on a table that slowly slides through the donut as the machine spirals around the patient. It delivers many small beams of radiation at the tumor from different angles around the body. This allows for even more precisely focused radiation.~~

~~“Image-Guided Radiation Therapy (IGRT)” Is a form of 3D-CRT where imaging scans (like a CT scan) are done before each treatment. This allows the radiation oncologist to adjust the position of the patient or re-focus the radiation as needed to hit the tumor and limit other damage.~~

~~“Intensity Modulated Radiation Therapy (IMRT)” --Is like 3D-CRT, but it also changes the strength of some of the beams in certain areas. This gets stronger doses to certain parts of the tumor and helps lessen damage to nearby normal body tissues.~~

~~“Conformal Proton Beam Radiation Therapy” uses proton beams instead of photons or electrons. Protons are positive parts of atoms that cause little damage to tissues they pass through but are very good at killing cells at the end of their path. Proton beam radiation delivers more radiation to the tumor while reducing side effects on normal tissues. Protons can only be put out by a special machine called a cyclotron or sychrontron.~~

~~“Stereotactic Body Radiation Therapy (SBRT)” is a precision radiation therapy delivery concept derived from cranial (brain) stereotactic radiosurgery.—It is an external beam radiation therapy method used to very precisely deliver a high dose of radiation to an extracranial target within the body, using either a single dose or a small number of fractions. SBRT has become an established treatment technique for lung, liver, and spinal lesions.~~

~~“Stereotactic Radiosurgery (SRS)” is a non-surgical radiation therapy used to treat functional abnormalities and small tumors of the brain. It can deliver precisely-targeted radiation in fewer high-dose treatments than traditional therapy, which can help preserve healthy tissue. It is also known as Stereotaxic Radiosurgery or Radiation Surgery.~~

~~“Stereotactic Radiation Therapy (SRT)” is an approach similar to Stereotactic Radiosurgery that delivers radiation to the target tissue. However, the total dose of radiation is divided into several smaller doses given over several days, rather than a single large dose. It can be used to treat both brain and extracranial tumors.~~

TYPES OF RADIATION EQUIPMENT

Linear Accelerator (LINAC)

The LINAC produces high energy x-rays that are collected to form a beam that matches the size and shape of the patient's tumor. Radiation can be delivered to the tumor from any angle by a rotating robotic arm. A LINAC must be located in a room with lead and concrete walls to keep the rays from escaping.

The capacity standards for a linear accelerator vary by the capability of the equipment and are addressed in the Standards below.

There is also LINAC equipment designed strictly to provide Stereotactic Radiotherapy. These specialized LINACs have an even lower capacity because of the treatment time associated with this type of care. The capacity for such equipment is established as 1,500 treatments per year per unit.

Proton Beam Therapy Unit

This modality is a type of external beam radiation therapy that uses protons rather than x-rays to treat cancer. A proton is a positively charged particle. A synchrotron or cyclotron speeds up protons to create high energy. This energy makes the protons travel to the desired depth in the body where the protons give the targeted radiation dose in the tumor.

Cobalt-60 (Photon)

This modality, best known by the trade name of Gamma Knife, is used to perform Stereotactic Radiosurgery. It is primarily used to treat brain tumors, although it can also be used for other neurological conditions like Parkinson's Disease and Epilepsy. Its use is generally reserved for cancers that are difficult or dangerous to treat with surgery. The radiation damages the genetic code of the tumor in a single treatment, preventing it from replicating and causing it to slowly shrink.

The Gamma Knife consists of a large shield surrounding a large helmet-shaped device with separate, fixed ports that allow the radiation to enter the patient's head in small beams that converge on the designated target. A rigid frame is attached to the patient's skull to provide a solid reference for both targeting and treatment. The patient is then sent for imaging, to accurately determine the position of the target. The computer system develops a treatment plan to position the patient and the paths and doses of radiation. The patient is positioned with the head affixed to the couch, and the treatment is delivered.

CERTIFICATE OF NEED PROJECTIONS AND STANDARDS FOR RADIOTHERAPY

1. ~~The capacity of a conventional linear accelerator, either with or without EPID, is 7,000 treatments per year.~~
2. ~~Linear accelerators with IMRT or IGRT capabilities have a capacity of 5,000 treatments per year. A facility must document that it is providing or will provide these specialized treatments in sufficient volume to justify why it should be held to this planning capacity.~~
3. ~~IMRT/IGRT linear accelerators with stereotactic procedures capabilities have a capacity of 4,500 treatments per year. A facility must document that it is providing or will provide these specialized treatments in sufficient volume to justify why it should be held to this planning capacity.~~
4. ~~Linear Accelerators designed strictly to provide Stereotactic Radiotherapy have a capacity of 1,500 treatments per year. A facility must document that it is providing or will provide these specialized treatments in sufficient volume to justify why it should be held to this planning capacity.~~
5. ~~There are 13 service areas established for Radiotherapy units.~~
6. ~~New Radiotherapy services shall only be approved if the following conditions are met:~~
 - a. ~~All existing units in the service area have performed at a combined use rate of 80 percent of capacity as evidenced in the most recent Joint Annual Reports preceding the filing of the applicant's Certificate of Need application; and~~
 - b. ~~An applicant must project that the proposed service will perform a minimum number of treatments equal to 50 percent of capacity annually within three years of initiation of services, without reducing the utilization of the existing machines in the service area below the 80 percent threshold. The applicant must document where the potential patients for this new service will come from and where they are currently being served, to include the expected shift in patient volume from existing providers.~~
7. ~~Expansion of an existing service, whether the expansion occurs at the existing site or at an alternate location in the service area, shall only be approved if the service has operated at a minimum use rate of 80 percent of capacity for each of the past two years and can project a minimum use rate of 50 percent of capacity per year on the additional equipment within three years of its implementation.~~
8. ~~The applicant shall project the utilization of the service and document referral sources for patients within its service area, including letters of support from physicians and~~

~~health care facilities indicating a willingness to refer patients to the proposed service.~~

~~9. The applicant must affirm the following:~~

- ~~a. All treatments provided will be under the control of a board certified or board eligible radiation oncologist;~~
- ~~b. The applicant will have access to a radiation physicist certified or eligible for certification by the American Board of Radiology or its equivalent;~~
- ~~c. The applicant will have access to simulation equipment capable of precisely producing the geometric relationships of the equipment to be used for treatment of the patient;~~
- ~~d. The applicant will have access to a custom block design and cutting system; and~~
- ~~e. The institution shall operate its own tumor registry or actively participate in a central tumor registry.~~

~~The Megavoltage Visits Chart and Radiotherapy Chart are located at the end of this Chapter.~~

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

~~The following project review criteria are considered to be the most important in evaluating Certificate of Need applications for these services:~~

- ~~1. Community Need Documentation;~~
- ~~2. Distribution (Accessibility); and~~
- ~~3. Medically Underserved Groups.~~

~~Radiotherapy services are distributed statewide and are located within 60 minutes' travel time for the majority of residents of the State. Because a typical course of treatment is five times per week, Monday through Friday, and lasts for three to nine weeks, the benefits of improved accessibility may outweigh the adverse effects of duplication in evaluating Certificate of Need applications for this service.~~

CERTIFICATE OF NEED PROJECTIONS AND STANDARDS FOR STEREOTACTIC RADIOSURGERY

- ~~1. The capacity of a dedicated Stereotactic Radiosurgery unit is 300 procedures annually. This is based on an average of two procedures per day times three days per week times 50 weeks per year.~~
- ~~2. New Radiosurgery services shall only be approved if the following conditions are met:~~

- ~~a. All existing dedicated Stereotactic Radiosurgery units in the service area have performed at a combined use rate of 80 percent of capacity as evidenced in the most recent Joint Annual Reports; and~~
 - ~~b. An applicant must project that the proposed service will perform a minimum of 200 procedures annually within three years of initiation of service, without reducing the utilization of existing units below the 80 percent threshold.~~
- ~~3. Expansion of an existing radiosurgery service shall only be approved if the service has operated at a minimum use rate of 80 percent of capacity for each of the prior two years and can project a minimum of 200 procedures per year on the additional equipment within three years of its implementation.~~
- ~~4. The applicant shall project the utilization of the service, to include:
 - ~~a. Epidemiological evidence of the incidence and prevalence of conditions for which radiosurgery treatment is appropriate, to include the number of potential patients for these procedures;~~
 - ~~b. The number of patients of the applicant who were referred to other radiosurgery providers in the preceding three years and the number of those patients who could have been served by the proposed service; and~~
 - ~~c. Current and projected patient origin information and referral patterns for the facility's existing radiation therapy services. The applicant shall document the number of additional patients, if any, that will be generated through changes in referral patterns, recruitment of specific physicians or other changes in circumstances.~~~~
- ~~5. The applicant must include letters of support from physicians and health care facilities indicating a willingness to refer patients to the proposed service.~~
- ~~6. The applicant must document that protocols will be established to assure that all clinical radiosurgery procedures performed are medically necessary and that alternative treatment modalities have been considered.~~
- ~~7. The applicant must affirm the following:
 - ~~a. The radiosurgery unit will have a board certified neurosurgeon and a board certified radiation oncologist, both of whom are trained in stereotactic radiosurgery;~~
 - ~~b. The applicant will have access to a radiation physicist certified or eligible for certification by the American Board of Radiology or its equivalent;~~~~

- ~~c. Dosimetry and calibration equipment and a computer with the appropriate software for performing radiosurgical procedures will be available;~~
 - ~~d. The applicant has access to a full range of diagnostic technology, including CT, MRI and angiography; and~~
 - ~~e. The institution shall operate its own tumor registry or actively participate in a central tumor registry.~~
- ~~8. Due to the unique nature and limited need for this type of equipment, the applicant should document how it intends to provide accessibility for graduate medical education students in such fields as neurosurgery and oncology.~~

~~RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA~~

~~The following project review criteria are considered to be the most important in evaluating Certificate of Need applications for these services:~~

- ~~1. Community Need Documentation;~~
- ~~2. Distribution (Accessibility);~~
- ~~3. Record of the Applicant; and~~
- ~~4. Medically Underserved Groups.~~

~~The service area for a dedicated Stereotactic Radiosurgery unit is defined as all facilities within 90 minutes' travel time. The benefits of improved accessibility will be equally weighed with the adverse effects of duplication in evaluating Certificate of Need applications for this service.~~

CHAPTER 10

OUTPATIENT FACILITIES

~~Outpatient facilities provide community service for the diagnosis and treatment of ambulatory patients that is operated in connection with a hospital or as a freestanding facility under the professional supervision of a licensed physician. These facilities serve patients who do not require hospitalization and makes available a range of diagnostic and treatment services. Hospital-based outpatient departments vary in scope, but generally include diagnostic laboratory, radiology, and clinical referral services.~~

AMBULATORY SURGICAL FACILITY

~~Ambulatory surgery, often described as outpatient or same-day surgery, may be provided in a freestanding Ambulatory Surgical Facility (ASF). An ASF is a distinct, freestanding, entity that is organized, administered, equipped and operated exclusively for the purpose of performing surgical procedures or related care, treatment, procedures, and/or services, for which patients are scheduled to arrive, receive surgery, or related care, treatment, procedures, and/or services, and be discharged on the same day, as defined in Regulation 61-91, Section 101.RR. The owner or operator makes the facility available to other providers who comprise an organized professional staff (open medical staff). This definition does not apply to any facility used as an office or clinic for the private practice of licensed health care professionals.~~

~~For purposes of this Plan, an endoscope is defined as a flexible, semi-flexible or rigid instrument, which may or may not have a light attached, that is inserted into a natural orifice in a non-sterile, clean environment, to visually inspect for purposes of screening and diagnosis and to perform therapeutic treatment of the interior of a bodily canal or a hollow organ (such as the colon, bladder, stomach or nasal sinuses).~~

~~A substantial increase has occurred in both the number and percentage of ambulatory surgeries performed and in the number of approved ASFs. This trend has generally been encouraged because many surgical procedures can be safely performed on an outpatient basis at a lower cost.~~

CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

- ~~1. The county in which the proposed facility is to be located is considered to be the service area for inventory purposes. The applicant may define a proposed service area that encompasses additional counties.~~
- ~~2. The applicant must identify the physicians who are affiliated or have an ownership~~

interest in the proposed facility by medical specialty. These physicians must identify where they currently perform their surgeries and whether they anticipate making any changes in staff privileges or coverage should the application be approved.

3. For a new facility, the applicant must document where the potential patients for the facility will come from and where they are currently being served, to include the expected shift in patient volume from existing providers. For the expansion of an existing facility, the applicant must provide patient origin information on the current facility.
4. The applicant must document the need for the expansion of or the addition of an ASF, based on the most current utilization data available. This need documentation must include the projected number of surgeries or endoscopic procedures to be performed by medical specialty. The existing resources must be considered and documentation presented as to why the existing resources are not adequate to meet the needs of the community.
5. The applicant must document the potential impact that the proposed new ASF or expansion of an existing ASF will have upon the existing service providers.
6. The applicant must document whether it will restrict surgeries by specialty. Applicants that wish to restrict surgeries by specialty understand that *another Certificate of Need would be required* before the ASF could provide other surgical specialties. Applicants seeking to perform only endoscopic procedures are considered restricted.
7. Before an application for a new general Ambulatory Surgery Facility can be accepted for filing in a county having a current population of less than 100,000 people, all general ASFs in the county must have been licensed by the Department and operational for an entire year and must have submitted data on the Department's annual questionnaire to allow for a determination of their utilization. The requirements that all ASFs must have been licensed and operational for an entire year and submitted utilization data to the Department will not be applied to applicants for an ASF filing in a county having a current population of greater than 100,000 people.
8. Endoscopy suites are considered separately from other operating rooms and therefore are not considered competing applicants for Certificate of Need review purposes. Before an application for a new endoscopy-only ASF can be accepted for filing in a county having a current population of less than 100,000 people, all ASFs with endoscopy suites in the county must have been licensed by the Department and operational for an entire year and must have submitted data on the Department's annual questionnaire to allow for a determination of their utilization. The requirements that all ASFs with endoscopy suites must have been licensed and

~~operational for an entire year and submitted utilization data to the Department will not be applied to applicants for a new endoscopy-only ASF filing in a county having a current population of greater than 100,000 people.~~

- ~~9. The approval of a new general or endoscopy-only ASF in a county does not preclude an existing facility from applying to expand its number of operating rooms and/or endoscopy suites. The merger of two existing ASFs in a county to construct a consolidated ASF does not constitute a "new ASF" for the purpose of interpreting Standards 8 and 9.~~
- ~~10. The applicant for a new ambulatory surgery facility must provide a written commitment that the facility will accept Medicare and Medicaid patients, and that unreimbursed services for indigent and charity patients will be provided at a percentage that is comparable to all other existing ambulatory surgery facilities, if any, in the service area.~~

~~Facilities providing ambulatory surgery services must conform to local, state, and federal regulatory requirements and must commit to seek accreditation from CMS or any accrediting body with deemed status. Ambulatory surgical services are generally available within 30 minutes' one-way automobile travel time of most South Carolina residents. Most ASFs operate five days a week, with elective surgery being scheduled several days in advance.~~

~~The Ambulatory Surgical Facility Utilization Chart is located at the end of this Chapter.~~

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

~~The following project review criteria are considered to be the most important in evaluating Certificate of Need applications for this service:~~

- ~~1. Community Need Documentation;~~
- ~~2. Distribution (Accessibility);~~
- ~~3. Medically Underserved Groups; and~~
- ~~4. Staff Resources.~~

~~The benefits of improved accessibility will be equally weighed with the adverse effects of duplication in evaluating Certificate of Need applications for this service.~~

FREESTANDING EMERGENCY HOSPITAL SERVICES

~~The popularity of freestanding emergency hospital services is increasing as a means of providing ready access to such services at the community level.~~

CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

1. — ~~A Certificate of Need is required to establish a freestanding emergency service.~~
2. — ~~All off-campus emergency services must be an extension of an existing hospital's emergency service in the same county, unless the applicant is proposing to establish a freestanding emergency service in a county that does not have a licensed hospital. The hospital must have a license that is in good standing and must be in operation to support the off-campus emergency services.~~
3. — ~~Regulation 61-16 will be used to survey off-campus emergency services, specifically including 24-hour/7-day per week physician coverage on site.~~
4. — ~~An off-campus emergency service must have written agreements with Emergency Medical Services providers and surrounding hospitals regarding serious medical problems, which the off-campus emergency service cannot handle.~~
5. — ~~The applicant must demonstrate need for this service by documenting capacity constraints within existing emergency departments in the service area and/or a travel time of greater than 15 minutes to an existing emergency department in the service area.~~

The Freestanding Emergency Services Chart is located at the end of this Chapter.

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

The following project review criteria are considered to be the most important in evaluating Certificate of Need applications for this service:

1. — ~~Community Need Documentation;~~
2. — ~~Distribution (Accessibility);~~
3. — ~~Medically Underserved Groups; and~~
4. — ~~Staff Resources.~~

~~Access to emergency medical services should be available within 15 minutes travel time for the majority of residents of the State. The benefits of improved accessibility will outweigh the adverse effects of duplication in evaluating applications for this service.~~

CHAPTER 14

LONG-TERM CARE FACILITIES AND SERVICES

NURSING FACILITIES

~~Nursing facilities provide inpatient care for convalescent or chronic disease residents who require nursing care and related medical services. This care is performed under the general direction of persons licensed to practice medicine or surgery in the State. Facilities furnishing primarily domiciliary care are not included. The licensing list of nursing facilities also denotes the facilities that have Alzheimer's units. For more specific detail about nursing facilities, refer to Regulation 61-17 (*Standards for Licensing Nursing Homes*).~~

~~Since the vast majority of patients utilizing nursing facilities are 65 years of age or older, only this segment of the population is used in the need calculations. County bed needs are projected through 2022. A two-year projection is used because nursing facilities can be constructed and become operational in two years.~~

CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

- ~~1. Based on observations of methodologies from other states operating a Certificate of Need regime, and recognizing that potential reliance on long-term skilled nursing services increases with age, bed need is calculated on a county basis using the following ratios:
 - a) 10 beds/1,000 population aged 65-74; and
 - b) 58 beds/1,000 population aged 75 and over~~
- ~~2. For each county, these needs are calculated separately. The individual age-group needs are then added together, and the existing bed count subtracted from that total to determine the deficit or (surplus) of beds.~~
- ~~3. When a county shows surplus beds, additional beds will not be approved, except to allow an individual nursing facility to add some additional beds in order to make more economical nursing units. These additions are envisioned as small increments in order to increase the efficiency of the nursing home. This exception for additional beds will not be approved if it results in a three bed ward. A nursing facility may add up to 16 additional beds per nursing unit to create either 44 or 60 bed nursing units, regardless of the projected bed need for the county. The nursing facility must document how these additional beds will make a more economical unit(s).~~

4. ~~Some Institutional Nursing Facilities are dually licensed, with some beds restricted to residents of the retirement community and the remaining beds are available to the general public. The beds restricted to residents of the retirement community are not eligible to be certified for Medicare or Medicaid. Should such a facility have restricted beds that are inadvertently certified, the facility will be allowed to apply for a Certificate of Need to convert these beds to general nursing home beds, regardless of the projected bed need for that county.~~

~~The Long-Term Care Inventory and Bed Need Chart are located at the end of this Chapter.~~

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

~~The following project review criteria are considered the most important in evaluating Certificate of Need applications for these beds or facilities:~~

1. ~~Community Need Documentation;~~
2. ~~Distribution (accessibility);~~
3. ~~Staff Resources; and~~
4. ~~Record of the Applicant.~~

~~Because nursing facilities are located within approximately 30 minutes' travel time for the majority of the residents of the State and at least one nursing facility is located in every county, no justification exists for approving additional nursing facilities or beds that are not indicated as needed in this Plan. The major accessibility problem is caused by the lack of Medicaid funding since the Medicaid Program pays for approximately 65% of all nursing facility residents. This Plan projects the need for nursing facility beds by county. The benefits of improved accessibility do not outweigh the adverse effects caused by the duplication of any existing beds or the placement of Medicaid funds for the beds.~~

MEDICAID NURSING HOME PERMITS

~~The Medicaid Nursing Home Permit Act, formerly known as the Nursing Home Licensing Act of 1987, sets forth a regulatory scheme whereby Medicaid nursing home permits and Medicaid patient days are allocated in South Carolina. A long-term care facility (nursing home) must obtain a Medicaid Nursing Home Permit from the Department in order to serve Medicaid patients. A Medicaid patient is a person who is eligible for Medicaid (Title XIX) sponsored long-term care services. Each year, the South Carolina General Assembly establishes the maximum number of Medicaid patient days the Department is authorized to issue. A Medicaid patient day is a day of nursing home care for which the holder of a Medicaid nursing home Permit can receive Medicaid reimbursement. The South Carolina Department of Health and Human Services provides the Department with the total number of Medicaid patient days available so the Department may distribute those patient days amongst Permit holders.~~

~~The Medicaid Patient Days and Medicaid Beds Requested & Authorized Chart is located at the end of this Chapter.~~

COMMUNITY LONG-TERM CARE (CLTC) PROGRAM

~~South Carolina is seeking to increase access to long-term care facilities through a number of different programs. The Community Long-Term Care Project (CLTC) provides mandatory pre-admission screening and case management to Medicaid-eligible individuals who are in need of applying for nursing facility placement under the Medicaid program. It also provides several community-based services for Medicaid participants who prefer to receive care in the community rather than institutional care. In certain counties, those services include:~~

~~Adult Day Healthcare: CLTC offers Adult Day Health Care to individuals enrolled in the Community Choices Waiver. This is medically supervised care and services provided at a licensed day care center. Transportation to and from the home is provided within 15 miles of the center.~~

~~Attendant/Personal Assistance: CLTC offers attendant services to individuals enrolled in the Community Choices Waiver. Nurses assist by observing care and helping consumers develop skills in managing their attendant. Services may include assistance with general household activities; help with activities such as bathing, dressing, preparing meals, and housekeeping; and observing health signs.~~

~~Care Management (Case Management - Service Coordination): CLTC assigns a nurse to help determine the services for which the participant qualifies and what services will best meet the needs of an individual enrolled in the Community Choices Waiver. Nursing Facility Transition Services may also be offered to help a participant residing in a nursing facility return to the community.~~

~~Companion (Sitter): CLTC provides an approved companion to provide supervision of an individual and short-term relief for regular caregivers to individuals enrolled in the Community Choices Waiver.~~

~~Home Repair/Modification Assistance: CLTC helps provide pest control services, ramps, heater fans and air conditioners to individuals enrolled in the Community Choices Waiver. It can also help make minor adaptations to non-rental property for the safety and health of the Medicaid participant.~~

~~Medical Equipment/Personal Care Supplies: CLTC provides limited durable medical equipment and incontinence supplies (diapers, underpads, wipes, etc.) to individuals enrolled in the Community Choices Waiver.~~

Nutritional Supplement Assistance: CLTC's Community Choices Program provides two cases per month of Nutritional Supplements to its participants.

The Program for All-Inclusive Care for the Elderly (PACE) is a Medicaid State option that provides comprehensive long-term care to primarily elderly residents of the State. PACE is available to Medicaid participants who are certified as "nursing home" eligible, but prefer care from community services. GHS Senior Care, Palmetto SeniorCare, and The Methodist Oaks currently operate PACE programs in the State.

SPECIAL NEEDS FACILITIES

The South Carolina Department of Disabilities and Special Needs (DDSN) provides 24-hour care to individuals with complex, severe disabilities through five in-state regional facilities located in Columbia, Florence, Clinton, Summerville and Hartsville. These facilities serve those individuals who cannot be adequately cared for by one of DDSN's community living options and focus on those with special needs, head and spinal cord injuries and pervasive development disorders. In 2014, the Centers for Medicare and Medicaid Services (CMS) issued its final rule on Home and Community Based Services (HCBS) that will, inter alia, ensure that individuals who receive services through Medicaid's HCBS programs have access to the benefits of community living. DDSN believes the HCBS initiative will affect its Day Programs and where its clients live. The South Carolina Department of Health and Human Services (DHHS) will be the lead agency in implementing HCBS which will be phased in over the next five (5) years.

INSTITUTIONAL NURSING FACILITY (RETIREMENT COMMUNITY NURSING FACILITY)

An institutional nursing facility means a nursing facility (established within the jurisdiction of a larger non-medical institution) that maintains and operates organized facilities and services to accommodate only students, residents or inmates of the institution. These facilities provide necessary services for retirement communities as established by church, fraternal, or other organizations. Such beds must serve only the residents of the housing complex and either be developed after the housing has been established or be developed as a part of a total housing construction program that has documented that the entire complex is one inseparable project.

CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

To be considered under this special bed category, the following criteria must be met:

1. The nursing facility must be a part of and located on the campus of the retirement community.
2. It must restrict admissions to campus residents.

3. — The facility may not participate in the Medicaid program.

~~There is no projection of need for this bed category. The applicant must demonstrate that the proposed number of beds is justified and that the facility meets the above qualifications. If approved by the Department, such a facility would be licensed as an “Institutional Nursing Home” and the beds generated by such a project will be placed in the statewide inventory in Chapter 11. These beds are not counted against the projected need of the county where the facility is located. For established retirement communities, a generally accepted ratio of nursing facility beds to retirement beds is 1:4.~~

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

~~The following project review criteria, as outlined in Chapter 8 of Regulation 61-15, are considered the most important in evaluating Certificate of Need applications for these beds or facilities:~~

- ~~1. — Community Need Documentation;~~
- ~~2. — Acceptability; and~~
- ~~3. — Record of the Applicant.~~

~~Because Institutional Nursing Facility Beds are used solely by the residents of the retirement community, there is no justification for approving this type of nursing facility unless the need can be documented by the retirement center. The benefits of improved accessibility do not outweigh the adverse effects caused by the duplication of any existing beds or facilities.~~

SWING-BEDS

~~A Certificate of Need is not required to participate in the Swing-Bed Program in South Carolina; however, the hospital must obtain Medicare certification.~~

~~The Social Security Act (Section 1883(a)(1), [42 U.S.C. 1395tt]) permits certain small, rural hospitals to enter into a swing bed agreement, under which the hospital can use its beds to provide either acute or SNF care, as needed. The hospital must be located in a rural area and have fewer than 100 beds.~~

~~Medicare Part A covers the services furnished in a swing bed hospital under the SNF PPS. The PPS classifies residents into one of 44 categories for payment purposes. To qualify for SNF-level services, a beneficiary is required to receive acute care as a hospital inpatient for a stay of at least three consecutive days, although it does not have to be from the same hospital as the swing bed. Typical medical criteria include daily physical, occupational and/or speech therapy, IV or nutritional therapy, complex wound treatment, pain management, and end-of-life care.~~

The Swing-Bed Participants Chart is located at the end of this Chapter.

HOSPICE FACILITIES AND HOSPICE PROGRAMS

Hospice is a centrally administered, interdisciplinary health care program, which provides a continuum of medically supervised palliative and supportive care for the terminally ill patient and the family or responsible party, including, but not limited to home, outpatient and inpatient services provided directly or through written agreement. Inpatient services include, but are not limited to, services provided by a hospice in a licensed hospice facility.

A Hospice Facility means an institution, place or building licensed by the Department to provide room, board and appropriate hospice care on a 24-hour basis to individuals requiring such services pursuant to the orders of a physician.

The Inpatient Hospice Facilities Chart is located at the end of this Chapter.

A Hospice Program means an entity licensed by the Department that provides appropriate hospice care to individuals as described in the first paragraph above, exclusive of the services provided by a hospice facility.

CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

1. ~~A Certificate of Need is only required for an Inpatient Hospice Facility; it is not required for the establishment of a Hospice Program.~~
2. ~~An Inpatient Hospice Facility must be owned or operated either directly or through contractual agreement with a licensed hospice program.~~
3. ~~The applicant must document the need for the facility and justify the number of inpatient beds that are being requested.~~
4. ~~The proposed facility must consider the impact on other existing inpatient hospice facilities.~~

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

The following Project Review Criteria are considered to be the most important in evaluating Certificate of Need applications for this service:

1. ~~Community Need Documentation;~~
2. ~~Distribution (Accessibility);~~
3. ~~Record of the Applicant; and~~
4. ~~Staff Resources.~~

~~Hospice services should be available within sixty (60) minutes' travel time for the majority of residents of the State. The benefits of improved accessibility will be weighed equally with the adverse effects of duplication in evaluating Certificate of Need applications for this facility type.~~

HOME HEALTH

Home Health Agencies

~~Home Health Agency means a public, nonprofit, or proprietary organization, whether owned or operated by one or more persons or legal entities, which furnishes or offers to furnish home health services. Home health services means those items and services furnished to an individual by a home health agency, or by others under arrangement with the home health agency, on a visiting basis and except for (f) below, in a place of temporary or permanent residence used as the individual's home as follows:~~

~~Part time or intermittent skilled nursing care as ordered by a physician or podiatrist and provided by or under the supervision of a registered nurse and at least one other therapeutic service listed below: (a) physical, occupational, or speech therapy; (b) medical social services; (c) home health aide services; (d) other therapeutic services; (e) medical supplies as indicated in the treatment plan and the use of medical appliances, to include durable medical equipment and (f) any of the above items and services provided on an outpatient basis under arrangements made by the home health agency with a hospital, nursing home or rehabilitation center and the furnishing of which involves the use of equipment of such a nature that the items/services cannot readily be made available to the individual in his/her home, or which are furnished at one of the above facilities while the patient is there to receive such items or services. Transportation of the individual in connection with any such items or services is not included.~~

CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

- ~~1. — An applicant must propose home health services to cover the geographic area of an entire county and agree to serve residents throughout the entire county.~~
- ~~2. — A separate application is required for each county in which services are to be provided.~~
- ~~3. — A new home health agency may be approved if an applicant can demonstrate it will serve 50 or more patients projected to be in need in non-rural counties, or 25 or more patients projected to be in need in rural counties, through evidence that may include, but would not be limited to, the following:~~

- a. ~~Letters of support that identify need for additional home health services from physicians and other referral sources.~~
 - b. ~~Evidence of underutilization of home health services.~~
 - c. ~~Evidence of limited scope home health agency service including skilled nursing, physical therapy, occupational therapy, speech therapy, home health aides, and medical social workers.~~
 - d. ~~Evidence of the denial or delay in the provision of home health services, including but not limited to long waiting lists or delays which exceed industry standards.~~
 - e. ~~Evidence that one or more existing home health agencies has failed to meet the minimum patient service requirements set forth in Standard 8 of this section of the Plan within two years of the initiation of patient services after receiving a home health license.~~
4. ~~For the purposes of this Section, a rural county shall mean a county with a population of less than 50,000, according to the most recent projections of the South Carolina Revenue and Fiscal Affairs office as of the time the current Plan was adopted.~~
-
5. ~~All home health agency services (Skilled Nursing, Physical Therapy, Occupational Therapy, Speech Therapy, Home Health Aide, and Medical Social Worker) should be available within a county. If there is no hospital in a county and the existing licensed home health agencies between them do not provide all of the services identified above, this may be cited as potential justification for the approval of an additional agency that intends to offer these services.~~
6. ~~Specialty home health providers are exempt from the need calculation applicable to full-service home health agencies, but are otherwise subject to Certificate of Need.~~
7. ~~The applicant should have a track record that demonstrates a commitment to quality services. There should be no history of prosecution, consent order, abandonment of patients in other business operations, or loss of license. However, any consent orders or loss of licenses related to licenses that were obtained from the Department between July 1, 2013 and May 22, 2014 without a Certificate of Need shall not be grounds for denial of a Certificate of Need application pursuant to this Section. The applicant must provide a list of all licensed home health agencies it operates and the state(s) where it operates them.~~
8. ~~The applicant must document that it can serve at least 25 patients annually in each rural county for which it is licensed and 50 patients annually in each non-rural county for which it is licensed within two years of initiation of services. The applicant must assure the Department that, should it fail to reach this threshold number two years~~

~~after initiation of services in a county, it will voluntarily relinquish its license for that county.~~

- ~~9. Nothing in this Section is intended to restrict the ability of the Department to approve more than one new Home Health Agency in a county at any given time.~~

~~The Home Health Agency Inventory Chart is located at the end of this Chapter.~~

RELATIVE IMPORTANCE OF PROJECT REVIEW CRITERIA

~~The following project review criteria, as outlined in Chapter 8 of Regulation 61-15, are considered to be the most important in reviewing Certificate of Need applications for this service:~~

- ~~1. Community Need Documentation;~~
- ~~2. Distribution (Accessibility); and~~
- ~~3. Medically Underserved Groups.~~

~~The benefits of improved accessibility outweigh the adverse effects caused by the duplication of any existing service.~~

Pediatric Home Health Agencies

~~Due to the limited number of home health providers available to treat children 18 years or younger, an exception to the above criteria may be made for a Certificate of Need for a Home Health Agency restricted to providing intermittent home health skilled nursing services to patients 18 years or younger. The license for the agency will be restricted to serving children 18 years or younger and will ensure access to necessary and appropriate intermittent home health skilled nursing services to these patients. Any such approved agency will not be counted in the county inventories for need projection purposes.~~

CERTIFICATE OF NEED PROJECTIONS AND STANDARDS

- ~~1. A separate Certificate of Need application will be required for each county for an agency that proposes to provide this specialized service to pediatric patients in multiple counties.~~
- ~~2. The applicant must document that there is an unmet need for this service in the county of application, and the agency will limit such services to the pediatric population 18 years or younger.~~
- ~~3. The applicant must document the full range of services that they intend to provide to pediatric patients.~~

Continuing Care Retirement Community Home Health Agencies

~~A licensed continuing care retirement community that also incorporates a skilled nursing facility may provide home health services and does not require Certificate of Need review provided:~~

- ~~a. — The continuing care retirement furnishes or offers to furnish home health services only to residents who reside in living units provided by the continuing care retirement community pursuant to a continuing care contract;~~
- ~~b. — The continuing care retirement community maintains a current license and meets the applicable home health agency licensing standards; and~~
- ~~c. — Residents of the continuing care retirement community may choose to obtain home health services from other licensed home health agencies.~~

~~Staff from other areas of the continuing care retirement community may deliver the home health services, but at no time may staffing levels in any area of the continuing care retirement community fall below minimum licensing standards or impair the services provided. If the continuing care retirement community includes charges for home health services in its base contract, it is prohibited from billing additional fees for those services. Continuing care retirement communities certified for Medicare or Medicaid, or both, must comply with government reimbursement requirements concerning charges for home health services. The continuing care retirement community shall not bill in excess of its costs. These costs will be determined on non-facility-based Medicare and/or Medicaid standards.~~

GLOSSARY

TERM	DEFINITION	SOURCE
Adaptive Radiation Therapy (ART)	Patient setup and/or radiation delivery is evaluated and modified periodically during the treatment course based on imaging and dose measurements made prior to or during treatment.	South Carolina Health Plan
Affiliated Facilities	Two or more health care facilities <u>nursing homes or hospitals</u> , whether inpatient or outpatient , owned, leased, or who have a formal legal relationship with a central organization and whose relationship has been established for reasons other than for transferring beds, equipment or services .	South Carolina Health Plan
Ambulatory Surgical Facility (ASF)	A distinct, freestanding, entity that is organized, administered, equipped and operated exclusively for the purpose of performing surgical procedures or related care, treatment, procedures, and/or services, for which patients are scheduled to arrive, receive surgery, or related care, treatment, procedures, and/or services, and be discharged on the same day. The owner or operator makes the facility available to other providers who comprise an organized professional staff (open medical staff). This definition does not apply to any facility used as an office or clinic for the private practice of licensed health care professionals.	South Carolina Health Plan
Basic Perinatal Center with Well Newborn Nursery (Level I)	Level I hospitals provide services for normal uncomplicated pregnancies. A full list of the requirements for a Level I Basic Perinatal Center with Well Newborn Nursery can be found at Regulation 61-16, Section 1306.A. <i>Certificate of Need review is not required to establish a Level I program.</i>	South Carolina Health <u>Plan Regulation 61-16</u>
Bed Capacity	Bed space designated exclusively for inpatient care, including space originally designed or remodeled for inpatient beds, even though temporarily not used for such purposes.	South Carolina Health Plan
Cardiac	An invasive procedure where a thin, flexible	South Carolina

Catheterization Procedure	catheter is inserted into a blood vessel; the physician then manipulates the free end of the catheter into the chambers or vessels of the heart. All activities performed during one clinical session, including <u>angiocardiology, coronary arteriography, pulmonary arteriography, coronary angioplasty and other diagnostic or therapeutic measures and physiologic studies shall be considered one procedure.</u>	Health Plan
Complex Neonatal Intensive Care Unit (Level IV)	In addition to the requirements of Regulation 61-16, 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. A full list of the requirements for a Complex Neonatal Intensive Care Unit can be found at <u>Regulation 61-16, Section 1306.E</u> . A Level IV hospital need not act as a Regional Perinatal Center (RPC). <i>Certificate of Need Review is required to establish a Level IV program.</i>	South Carolina Health Plan <u>Regulation 61-16</u>
Comprehensive Catheterization Laboratory	A dedicated room or suite of rooms in which PCI as well as diagnostic and therapeutic catheterizations are performed. They are located only in hospitals approved to provide open heart surgery, although diagnostic laboratories are allowed to perform emergent <u>and/or elective</u> therapeutic catheterizations in compliance with Standard 7 or 8 in the Plan.	South Carolina Health Plan
Conformal Proton Beam Radiation Therapy	Uses proton beams instead of photons or electrons. Protons are positive parts of atoms that cause little damage to tissues they pass through but are very good at killing cells at the end of their path. Proton beam radiation delivers more radiation to the tumor while reducing side effects on normal tissues. Protons can only be put out by a special machine called a synchrotron or cyclotron.	South Carolina Health Plan
Continuing Care Retirement	A licensed continuing care retirement community that also incorporates a skilled nursing facility may	South Carolina Health Plan

Community Home Health Agency

provide home health services, ~~and does not require Certificate of Need review provided:~~

- a. The continuing care retirement furnishes or offers to furnish home health services only to residents who reside in living units provided by the continuing care retirement community pursuant to a continuing care contract;
- b. The continuing care retirement community maintains a current license and meets the applicable home health agency licensing standards; and
- c. Residents of the continuing care retirement community may choose to obtain home health services from other licensed home health agencies.

Critical Access Hospital (CAH)

Hospitals eligible for increased reimbursement without having to meet all criteria for full-service acute care hospitals. They are intended to provide essential health services to rural communities. In order to qualify as a CAH, a hospital must be located in a rural county and be located more than 35 miles from any other hospital or CAH (15 miles for areas with only secondary roads). It must be part of a rural health network with at least one full-service hospital. They can have a maximum of 25 licensed beds and the annual average length of stay must be less than 4 days. Emergency services must be available 24 hours a day.

South Carolina Health Plan

~~Diagnostic Catheterization~~

~~A cardiac catheterization during which any or all of the following diagnostic procedures or measures are performed: Blood Pressure; Oxygen Content and Flow Measurements; Angiocardiology, Coronary Arteriography; and Pulmonary Arteriography.~~

~~South Carolina Health Plan~~

Diagnostic Catheterization Laboratory	A dedicated room in which only diagnostic catheterizations are performed.	South Carolina Health Plan
Elective PCI	Scheduled in advance and performed on a patient with cardiac function that has been stable in the days prior to the procedure.	South Carolina Health Plan
Electronic Portal Imaging Devices (EPIDs)	EPIDs have been developed because of the increased complexity of treatment planning and delivery techniques. The most common EPIDs are video-based systems wherein on-line digital port images are captured and analyzed before or during treatment. These systems are used for pre-treatment verification of Intensity Modulated Radiation Therapy fields and to reduce errors in patient positioning.	South Carolina Health Plan
Emergent or Primary PCI	Means that a patient needs immediate PCI because, in the treating physician's best clinical judgment, delay would result in undue harm or risk to the patient.	South Carolina Health Plan
Endoscope	A flexible, semi-flexible or rigid instrument, which may or may not have a light attached, that is inserted into a natural orifice in a non-sterile, clean environment, to visually inspect for purposes of screening and diagnosis and to perform therapeutic treatment of the interior of a bodily canal or a hollow organ (such as the colon, bladder, stomach or nasal sinuses).	South Carolina Health Plan
Existing Health Care Facility	Means any healthcare facility which has received CON approval, when applicable under law, and for which a Health Facility License has been issued by the Department.	South Carolina Health Plan
Existing Health Service	Means any health service which has received CON approval, when applicable under law, and which is currently operating as approved.	South Carolina Health Plan
Fractionation	The practice of providing only a small fraction of the entire prescribed dose of radiation in each	South Carolina Health Plan

~~treatment or session. Individual treatment plans are created to minimize the side effects for normal tissue. The typical fractionation schedule for adults is once per day, five days a week. Hyperfractionation (Superfractionation) refers to radiation given in smaller doses twice a day. In Hypofractionation, individual doses are given less often than daily, such as in two-five sessions.~~

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 over a period exceeding 24 hours and provides medical and surgical care of acute illness, injury or infirmity and 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 and surgery in the State of South Carolina.	S.C. Code of Regulations 61-16, Section 101(1)(A)(E) (1)
Health Care Facility	Acute care, hospitals, psychiatric hospitals, alcohol and substance abuse hospitals, nursing homes, ambulatory surgical facilities, hospice facilities, radiation therapy facilities, rehabilitation facilities, residential treatment facilities for children and adolescents, intermediate care facilities for person with intellectual disability, narcotic (opioid) treatment programs, and any other facility for which Certificate of Need review is required by federal law.	S.C. Code Ann. Section 44-7-130(10)
Health Facility License	A license issued or amended by the Department's Bureau of Health Facilities Licensing for the operation of certain facilities and services.	S.C. Code Ann. Section 44-7-260(A)
Health Service	Clinically related, diagnostic, treatment, or rehabilitative services and includes alcohol, drug abuse, and mental health services for which specific standards or criteria are prescribed in the South	S.C. Code Ann. Section 44-7-130(11)(16)

~~Carolina Health Plan.~~

Helical-
tomotherapy

~~A form of IRMT that delivers radiation inside a large “donut.” For this treatment, the patient lies on a table that slowly slides through the donut as the machine spirals around the patient. It delivers many small beams of radiation at the tumor from different angles around the body. This allows for even more precisely focused radiation.~~

~~South Carolina
Health Plan~~

Home Health
Agency

A public, nonprofit, or proprietary organization, whether owned or operated by one or more persons or legal entities, which furnishes or offers to furnish home health services.

~~South Carolina
Health Plan~~S.C.
Code Ann.
Section 44-69-
20(4)

Home Health
Service

Home health services means those items and services furnished to an individual by a home health agency, or by others under arrangement with the home health agency, on a visiting basis and except for ~~(f)(d)~~ below, in a place of temporary or permanent residence used as the individual's home as follows:

~~South Carolina
Health Plan~~S. C.
Code Ann. 44-
69-20(5)

Part-time or intermittent skilled nursing care as ordered by a physician, an Advanced Practice Registered Nurse (APRN), or a Physician Assistant (PA) or podiatrist and provided by or under the supervision of a registered nurse and at least one other ~~therapeutic~~ service listed below: (a) physical, occupational, or speech therapy; (b) medical social services; ~~home health aide services, and other therapeutic services;~~ (c) home health aide services~~medical supplies as indicated in the treatment plan and the use of medical appliances, to include durable medical equipment;~~ and (d) other therapeutic services; ~~(e) medical supplies as indicated in the treatment plan and the use of medical appliances, to include durable medical equipment;~~ and (f) any of the above items and services provided on an outpatient basis under arrangements made by the home health agency with a hospital, nursing home or rehabilitation

center and the furnishing of which involves the use of equipment of such a nature that the items/services cannot readily be made available to the individual in his/her home, or which are furnished at one of the above facilities while the patient is there to receive such items or services. Transportation of the individual in connection with any such items or services is not included.

Hospice	A centrally administered, interdisciplinary health care program, which provides a continuum of medically supervised palliative and supportive care for the terminally ill patient and the family or responsible party, including, but not limited to home, outpatient and inpatient services provided directly or through written agreement. Home-based and outpatient hospice programs do not require Certificate of Need review.	South Carolina Health Plan
Hospice Facility	An institution, place or building licensed by the Department to provide room, board and appropriate hospice care on a 24-hour basis to individuals requiring such services pursuant to the orders of a physician. A Certificate of Need is required for a hospice facility.	South Carolina Health Plan
Hospice Program	An entity licensed by the Department that provides appropriate hospice care to individuals as described in the first paragraph above, exclusive of the services provided by a hospice facility. A Certificate of Need is not required for a hospice program.	South Carolina Health Plan
Hospital	A facility <u>that is</u> organized and administered to provide overnight medical, <u>or</u> surgical, or nursing care of illness, injury, or infirmity and may provide <u>obstetrical care on-campus emergency services</u> , that may provide <u>obstetrical care</u> ; and in which all diagnoses, treatment, or care is administered by or under the direction of persons currently licensed to practice medicine, surgery, or osteopathy.	S.C. Code Ann. Section 44-7-130(12)

Hospital may include a residential treatment facilities for children, and adolescents, or young adults in need of mental health treatment which are that is physically a part of a licensed psychiatric hospital. This definition does not include facilities which that are licensed by the Department of Social Services. A residential treatment facility for children, adolescents, or young adults in need of mental health treatment that is physically part of a licensed psychiatric hospital is not required to provide on-campus emergency services.

Hospital Bed	A bed for an adult or child patient. Bassinets for the newborn in a maternity unit nursery, beds in labor rooms, recovery rooms, and other beds used exclusively for emergency purposes are not included in this definition.	South Carolina Health Plan
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Image-Guided Radiation Therapy (IGRT)	Is a form of 3D-CRT where imaging scans (like a CT scan) are done before each treatment. This allows the radiation oncologist to adjust the position of the patient or re-focus the radiation as needed to hit the tumor and limit other damage.	South Carolina Health Plan
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Inpatient Psychiatric Services	Those services provided to patients who are admitted to institutions for the evaluation, diagnosis, and treatment of mental, emotional, or behavioral disorders. Services may be provided in either psychiatric units of general hospitals or freestanding psychiatric hospitals.	South Carolina Health Plan
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Inpatient Treatment Facility	Short-term treatment service for persons who are in need of an organized intensive program of alcohol and/or drug rehabilitation, but who are without serious debilitating medical complications. These facilities may provide detoxification for their patients, as needed, in the inpatient treatment beds. These facilities are licensed either as a specialized hospital or as part of a hospital. <u>A Certificate of Need is required for an Inpatient Treatment Facility.</u>	South Carolina Health Plan
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Institutional
Nursing
FacilityHome

~~A nursing facility established within the jurisdiction of a larger non-medical institution that maintains and operates organized facilities and services to accommodate only students, residents or inmates of the institution. These facilities provide necessary services for retirement communities as established by church, fraternal, or other organizations. Such beds must serve only the residents of the housing complex and either be developed after the housing has been established or be developed as a part of a total housing construction program that has documented that the entire complex is one inseparable project. To be considered under this special bed category, the following criteria must be met:~~

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- ~~1. The nursing facility must be a part of and located on the campus of the retirement community.~~
- ~~2. It must restrict admissions to campus residents.~~
- ~~3. The facility may not participate in the Medicaid program.~~

~~There is no projection of need for this bed category. The applicant must demonstrate that the proposed number of beds is justified and that the facility meets the above qualifications.~~

Intensity
Modulated
Radiation Therapy
(IMRT)

~~Is like a 3D-CRT, but it also changes the strength of some of the beams in certain areas. This get stronger doses to certain parts of the tumor and helps lessen damage to nearby normal body tissues.~~

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Health Plan

Long-Term Acute
Care Hospital
(LTACH)

Hospitals with an average Medicare inpatient length of stay of greater than 25 days, including all covered and non-covered days of stay of Medicare patients. They provide treatment to patients with complex medical conditions, such as strokes, cardiac care, ventilator dependency, wound care and post-

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surgical care.

Nursing
FacilityHome

~~Facilities with an organized nursing staff to maintain and organized facilities and services to accommodate two or more unrelated persons over a period exceeding twenty-four hours which is operated either in connection with a hospital or as a freestanding facility for the express or implied purpose of providing intermediate or skilled nursing care for persons who are not in need of hospital care which provide inpatient care for convalescent or chronic disease residents who require nursing care and related medical services. Such nursing care and medical services are prescribed by, or are performed under the general direction of, persons licensed to practice medicine or surgery in the State. Facilities furnishing primarily domiciliary care are not included.~~

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Health Plan

Open Heart
Surgery

~~An operation performed on the heart or intrathoracic great vessels.~~

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Open Heart
Surgical Procedure

~~An operation performed on the heart or intrathoracic great vessels within an open heart surgical unit. All activities performed during one clinical session shall be considered one procedure.~~

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Open Heart
Surgical Program

~~The combination of staff, equipment, physical space and support services which is used to perform open heart surgery. Adult open heart surgical programs should have the capacity to perform a full range of procedures, including:~~

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Health Plan

- ~~1. repair/replacement of heart valves;~~
- ~~2. repair of congenital defects;~~
- ~~3. cardiac revascularization;~~
- ~~4. repair/reconstruction of intrathoracic vessels; and~~
- ~~5. treatment of cardiac traumas.~~

Open Heart Surgery Unit	<p>In addition, open heart programs must have the ability to implement and apply circulatory assist devices such as intra-aortic balloon and prolonged cardiopulmonary partial bypass.</p> <p>An operating room or suite of rooms equipped and staffed to perform open heart surgery procedures; such designation does not preclude its use for other related surgeries, such as vascular surgical procedures. A hospital with an open heart surgery program may have one or more open heart surgery units.</p>	South Carolina Health Plan
Opioid Treatment Program	<p>Provide medications for the rehabilitation of persons dependent on opium, morphine, heroin or any derivative or synthetic drug of that group. Opioid maintenance therapy (OMT) is an umbrella term that encompasses a variety of pharmacologic and nonpharmacologic treatment modalities, including the therapeutic use of specialized opioid compounds such as methadone, suboxone and buprenorphine to psychopharmacologically occupy opiate receptors in the brain, extinguish drug craving and thus establish a maintenance state. A Certificate of Need is required for an Opioid Treatment Program.</p>	South Carolina Health Plan
Outpatient Facility	<p>Provide treatment/care/services to individuals dependent upon or addicted to psychoactive substances and their families based on an individual treatment plan in a nonresidential setting. A Certificate of Need is not required for outpatient facilities.</p>	South Carolina Health Plan
Pediatric Home Health Agency	<p>Due to the limited number of home health providers available to treat children 18 years or younger, an exception to the home health criteria may be made for a Certificate of Need for a Home Health Agency restricted to providing intermittent home health skilled nursing services to patients 18 years or younger. The license for the agency will be restricted to serving children 18 years or younger and will ensure access to necessary and</p>	South Carolina Health Plan

appropriate intermittent home health skilled nursing services to these patients. Any such agencies are not counted in the county inventories for need projection purposes.

~~Percutaneous
Coronary
Intervention (PCI)~~

~~A therapeutic procedure to relieve coronary narrowing, such as Percutaneous Transluminal Coronary Angioplasty (PTCA) or Coronary Stent Implantation. These procedures may be performed on an emergent or elective basis. "Emergent or Primary" means that a patient needs immediate PCI because, in the treating physician's best clinical judgment, delay would result in undue harm or risk to the patient. An "Elective" PCI is scheduled in advance and performed on a patient with cardiac function that has been stable in the days prior to the procedure. A therapeutic catheterization procedure used to revascularize occluded or partially occluded coronary arteries. A catheter with a balloon or a stent is inserted into the blood vessel and guided to the site of the constriction in the vessel. These procedures may be performed on an emergent or elective basis.~~

~~South Carolina
Health Plan~~

Person

An individual, a trust or estate, a partnership, a corporation including an association, joint stock company, insurance company, and a health maintenance organization, a health care facility, a state, a political subdivision, or an instrumentality including a municipal corporation of a state, or any legal entity recognized by the State.

[S.C. Code Ann.
Section 44-7-
130\(15\)\(21\)](#)

~~Proton-Beam
Therapy Unit~~

~~This modality is a type of external beam radiation therapy that uses protons rather than x-rays to treat cancer. A proton is a positively charged particle. A synchrotron or cyclotron speeds up protons to create high energy. This energy makes the protons travel to the desired depth in the body where the protons give the targeted radiation dose in the tumor.~~

~~South Carolina
Health Plan~~

Regional Perinatal Center with Neonatal Intensive Care Unit (RPC)	In addition to the requirements of Regulation 61-16, Sections 1306.A through 1306.C, RPCs provide consultative, outreach, and support services to other hospitals in the region. A full list of the requirements for a Regional Perinatal Center can be found at Regulation 61-16, Section 1306.D. No more than one Regional Perinatal Center will be approved in each perinatal region. The establishment of a Regional Perinatal Center requires Certificate of Need review.	South Carolina Health Plan Regulation 61-16
Residential Treatment Facility for Children and Adolescents	Operated for the assessment, diagnosis, treatment, and care of children and adolescents in need of mental health treatment. This means a child or adolescent up to age 21 who manifests a substantial disorder of cognitive or emotional process, which lessens or impairs to a marked degree that child's capacity either to develop or to exercise age-appropriate or age-adequate behavior. The behavior includes, but is not limited to, marked disorders of mood or thought processes, severe difficulties with self-control and judgment, including behavior dangerous to self or others, and serious disturbances in the ability to care for and relate to others. These facilities provide medium to long-term care (6 months or longer). Treatment modalities are both medical and behavioral in nature.	South Carolina Health Plan
Residential Treatment Program Facility	24-hour facilities offering an organized service in a residential setting, which is designed to improve the client's ability to structure and organize the tasks of daily living and recovery through planned clinical activities, counseling, and clinical monitoring in order to promote successful involvement or re-involvement in regular, productive, daily activity, and, as indicated, successful reintegration into family living. A Certificate of Need is not required for a Residential Treatment Program.	South Carolina Health Plan
Social Detoxification Facility	Facilities which provide supervised withdrawal from alcohol or other drugs in which neither the client's level of intoxication nor physical condition is severe	South Carolina Health Plan

~~enough to warrant direct medical supervision or the use of medications to assist in withdrawal, but which maintains medical backup and provides a structured program of counseling, if appropriate, educational services, and referral for further rehabilitation. A Certificate of Need is not required for these facilities.~~

Specialty Perinatal Center with Special Care Nursery (Level II)	In addition to the requirements of Regulation 61-16, Section 1306.A, Level II hospitals provide services for both normal and selected high-risk obstetrical and neonatal patients. A full list of the requirements for a Level II Specialty Perinatal Center can be found at Regulation 61-16, Section 1306.B. Certificate of Need review is not required to establish a Level II program.	South Carolina Health Plan Regulation 61-16
Stereotactic Body Radiation Therapy (SBRT)	A precision radiation therapy delivery concept derived from cranial stereotactic radiosurgery. It is an external beam radiation therapy method used to very precisely deliver a high dose of radiation to an extracranial target within the body, using either a single dose or a small number of fractions. SBRT has become an established treatment technique for lung, liver, and spinal lesions.	South Carolina Health Plan
Stereotactic Radiation Therapy (SRT)	An approach similar to Stereotactic Radiosurgery that delivers radiation to the target tissue. However, the total dose of radiation is divided into several smaller doses given over several days, rather than a single large dose. It can be used to treat both brain and extracranial tumors.	South Carolina Health Plan
Stereotactic Radiosurgery (SRS)	A non-surgical radiation therapy used to treat functional abnormalities and small tumors of the brain. It can deliver precisely-targeted radiation in fewer high-dose treatments than traditional therapy, which can help preserve healthy tissue. It is also known as Stereotaxic Radiosurgery or Radiation Surgery.	South Carolina Health Plan
Subspecialty Perinatal Center	In addition to the requirements of Regulation 61-16, Sections 1306.A and 1306.B, Level III hospitals	South Carolina Health

with Neonatal Intensive Care Unit (Level III)	provide all aspects of perinatal care, including intensive care and a range of continuously available, sub-specialty consultation as recommended in the most recent edition of the <i>Guidelines for Perinatal Care</i> (GPC) by the American Academy of Pediatrics (AAP) and The American College of Obstetricians and Gynecologists. A full list of the requirements for a Level III Subspecialty Perinatal Center with Neonatal Intensive Care Unit can be found at Regulation 61-16, Section 1306.C. Certificate of Need Review is required to establish a Level III program.	<u>Plan Regulation 61-16</u>
Swing-Bed	<u>The Social Security Act (Section 1883(a)(1), [42 U.S.C. 1395tt])</u> permits certain small, rural hospitals to enter into a "Swing Bed" agreement, under which the hospital can use its beds to provide either acute or skilled nursing care, as needed. The hospital must be located in a rural area and have fewer than 100 beds. A Certificate of Need is not required to participate in the Swing Bed Program.	South Carolina Health Plan
Therapeutic Catheterization	A PCI or cardiac catheterization during which, in addition to any diagnostic catheterization procedure, any or all of the following interventional procedures are performed: PTCA; Thrombolytic Agent Infusion; Directional Coronary Atherectomy; Rotational Atherectomy; Extraction Atherectomy; Coronary Stent Implants and Cardiac Valvuloplasty.	South Carolina Health Plan
Therapeutic Catheterization Laboratory	A room in which therapeutic catheterizations are performed in addition to any diagnostic catheterizations as referenced in the above definition of "Therapeutic Catheterization".	South Carolina Health Plan
Three-Dimensional Conformal Radiation Therapy (3D-CRT)	Uses the results of imaging tests such as MRI and special computers to map the location of the tumor precisely to deliver radiation beams from different directions designed to match the shape of the tumor. This helps to reduce radiation damage to normal tissues and better kill the cancer by focusing the radiation dose on the tumor.	South Carolina Health Plan

