



SOUTH CAROLINA
DEPARTMENT OF
PUBLIC HEALTH

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

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2100 Bull Street
Columbia, SC 29201

Statutory Authority:

S.C. Code Sections 44-7-110 through 44-7-394, 44-37-40, 44-37-50, and 63-7-40

Regulation History as Published in State Register			
Date	Document Number	Volume	Issue
April 23, 1979	-	3	8, Part 4
June 13, 1980	-	4	11
June 27, 1980 (Errata)	-	4	12
June 11, 1982	213	6	9
August 27, 1982 (Errata)	213	6	12
February 24, 1984	342	8	2
February 27, 1987	686	11	2
February 23, 1990	1056	14	3
April 24, 1992	1375	16	4
April 26, 2002	2518	26	4
June 25, 2010 (Errata)	1375	34	6
June 27, 2014	4430	38	6
June 26, 2015	4461	39	6
May 25, 2018	4740	42	5
June 28, 2024	5265	48	6

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SECTION 100
DEFINITIONS

101. 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, and must provide on-campus emergency services; and in which all diagnoses, treatment or care are under the direction of persons currently licensed to practice medicine, surgery, osteopathy in the State of S.C.

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

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

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

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. 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 of beds (an inspection will be required prior to issuance of license);
4. Deletion of beds;
5. Reallocation of types of beds as shown on license; or
6. Relocation of a facility.

202. Variance to Licensing Standards.

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.

304. Enforcement Actions.

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.

305. Violation Classifications.

Violations of standards in this regulation are classified as follows:

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

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

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

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

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

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

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

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

H. In addition to or in lieu of any action taken by the Department affecting the license of any hospital, when it is established that any officer, employee, or member of the hospital medical staff has recklessly violated the provisions of Section 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)

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.

503. Chief Executive Officer.

The Facility shall appoint a Chief Executive Officer (CEO) who is responsible for the administration of the facility and all its branches and departments. The Facility shall notify the Department of any change in the Chief Executive Officer 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 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 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. 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 Facility without meeting the criteria for membership established by the governing body of the respective 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 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, 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 licensed to practice medicine, dentistry or osteopathy. Patients of podiatrists and dentists who are members of the medical staff of a Facility must be co-admitted by a doctor of medicine or osteopathy who is a member of the medical staff of the 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 Facility and medical staff. (I)

H. All 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 Facility policy and position descriptions.

B. The Facility must have an organized nursing service that provides 24-hour nursing services. This service must be under the direction of a Chief Nursing Officer (CNO), who is a registered nurse. A registered nurse shall be designated in writing to act in the absence of the CNO.

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. Facility personnel 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 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.

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 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 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.

3. Records of pre-employment health assessment as described in Section 602.

D. 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.

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.

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.

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. 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 the incident, these records shall be kept on site and readily available at that Facility.

B. The Facility shall report the following types of incidents to the Department and the patient, 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. Initial reports to the Department are intended to collect basic information as may be known at the time about the incident to include, at a minimum, the location of the incident, the type of incident, the date the incident is believed to have occurred or the date the report was filed, the number of residents, clients or patients injured by the incident, as well as contact information for the individual making the report. If the Facility does not have all the information requested, it shall provide a partial report with the information available to the Facility. The following types of incidents require an initial report to the Department as specified in this section:

1. Surgery or other invasive procedure performed on the wrong patient.
2. Surgery or other invasive procedure performed on the wrong site.
3. Wrong surgical or other invasive procedure performed on a patient.
4. Patient death or serious injury associated with patient elopement (disappearance).
5. Patient suicide, attempted suicide, or self-harm that results in serious injury, while being cared for in a healthcare setting.
6. Any incident in which systems designated for oxygen or other gas to be delivered to a patient contain no gas, the wrong gas, or are contaminated by toxic substances.
7. Patient death or serious injury associated with the use of restraints or bedrails while being cared for in a healthcare setting.
8. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider.
9. Abduction of any patient of any age.

C. In addition to the initial report as may be required by Subsection (B), Facilities shall submit a separate written investigation report for the following types of incidents 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. Investigation 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. The following types of incidents require a written investigation report to the Department as specified in this section:

1. 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/post procedure 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.

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 be subject to all licensing requirements 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 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 Facility prior to any new and/or re-admissions to the Facility. If the Facility has no patients for a period longer than one year, and there is a desire to admit a patient, the Facility shall be subject to all licensing requirements prior to admission of a patient, including construction-related requirements for a new facility.

705. Joint Annual Report.

The Facility shall submit a “Joint Annual Report” as specified by the Department.

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

The Facility shall collect data and submit reports to the Department on hospital acquired infection rates and methods and adequacy of selected infection control process pursuant to S.C. Code of Laws Sections 44-7-2410 through 44-7-2460.

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
EMERGENCY PREPAREDNESS

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

A. All facilities shall develop, implement, and maintain a written all-hazards emergency operations plan for actions to be taken in the event of a disaster and/or emergency evacuation. Additionally, in instances where there are applications for increases in licensed bed capacity or a change in ownership, the emergency plan shall be updated to reflect the proposed new total licensed bed capacity and/or change in ownership. The Facility shall review the plan at least annually.

B. 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. 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. 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, the facility shall provide the information required for the Department's Emergency Evacuation Plan Summary. 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. 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:

1. A description of the emergency situation;
2. An outline of the maximum number of patients to be admitted;
3. An anticipated date of discharge of the patients; and
4. 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, 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 Facility's plans for Internal Medical Surge or render the licensed inpatient hospital building(s) unusable. In such situations, a 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 Facility desires to be approved to operate an ACS, the Facility shall:

1. Conduct an assessment of the proposed ACS location utilizing the Department's Alternate Care Site Preliminary Assessment Form. 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 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 Facility.

2. Once a location has been identified, the Department will meet with Facility staff to discuss the details of the ACS. When appropriate, the Department will send written confirmation that the location has been 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.

C. Prior to activating an Alternate Care Site, the Facility shall do the following:

1. Have prior approval of the ACS from the Department as described in Section 903.B; and
2. 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.

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

E. Other issues such as staffing, food service, equipment requirements, medication management, medical records, and physicians' orders shall be resolved 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 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.

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; age; date of birth; sex; marital status; religion; race and ethnicity; health insurance number; provisional diagnosis; case number; days of care; social security number; name and telephone number of person or persons to be notified in the event of emergency; name of referring physician; name 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. 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;

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

6. Drugs taken during pregnancy, labor and delivery;

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

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

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

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

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

12. Estimated amount and description of amniotic fluid;

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;

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

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. Basic Facility Functions. (I)

A. Pharmaceutical Services.

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.

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

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

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

B. Radiological Services.

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

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

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

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

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

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

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

3. Personnel must adhere to the following:

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

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

4. Records of radiologic services must be maintained.

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

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

i. Copies of reports and printouts.

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

C. Laboratory Services.

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, except that an existing General Hospital that was approved and licensed without either a Type I, II, or III emergency service may classify itself as a Type IV emergency service. 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.

E. Central Supply.

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

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

3. There shall be written policies and procedures for the decontamination and sterilization activities performed in central supply and elsewhere in the Facility. These policies and procedures shall address the following:

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.

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.

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.

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.

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.

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

1202. Optional Hospital Services. (I)

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.

B. Anesthesia Services.

1. Anesthesia shall be administered according to the South Carolina Code of Laws and the South Carolina Code of State Regulations 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), 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

e. 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.

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

3. 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.

4. 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.

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.

D. Outpatient 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.

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.

H. Inpatient Dialysis Services.

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

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

2. Renal Dialysis Service Equipment and Supplies

a. Equipment and supplies shall include at least:

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

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

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

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

c. A written preventive maintenance program for all equipment used in dialysis and related procedures including, but not limited to, all patient monitoring equipment, isolated electrical systems,

conductive flooring, patient ground systems, and medical gas systems shall be developed and implemented. This equipment shall be checked and/or tested at such intervals to ensure proper operation and a state of good repair. After repairs and/or alterations are made to any equipment or system, the equipment or system shall be thoroughly tested for proper operation before returning it to service. Records shall be maintained on each piece of equipment to indicate its history of testing and maintenance.

I. Chemical and Substance Abuse Treatment Services.

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.

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

2. A registered nurse who has had at least two years training and/or experience in chemical and substance abuse care shall be responsible for the nursing care of this service. At least one registered nurse shall be on duty in each nursing unit at all times who has demonstrable training in chemical and substance abuse treatment. Relevant content of this training shall include physical and psychological assessment, psychopharmacology, basic counseling and intervention techniques, and the role of self-help groups in the recovery process. The training may be received through on-the-job training, specialized workshops, or classroom experience.

J. Pediatric Services.

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

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

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

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

K. Cardiovascular Care Services.

1. 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 with standards at least equal to those of the Accreditation for Cardiovascular Excellence or American College of Cardiologists. 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 until the hospital is accredited or re-accredited.

2. 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 Regulation 61-19 for definition of live birth). The record should be filed as prescribed within five (5) days of delivery per 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 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 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 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 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 Regulation 61-25.
- B. All contaminated dressings, pathological, and/or similar waste shall be properly disposed of in accordance with Regulation 61-105.
- C. All radioactive waste shall be disposed of by a method in accordance with Regulation 61-63.
- D. All outside areas, grounds and/or adjacent buildings on the premises shall be maintained neat and clean.

SECTION 1800 INFECTIOUS 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. 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 may be permitted in the facility in accordance with the Americans with Disability Act and other applicable state or federal statutes or regulations.

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*; 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 ADDITIONS

1901. General. (II)

The Facility shall be planned, designed, and equipped to provide for and promote the care, safety, and 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)

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. 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. 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 . 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 Permits. (II)

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. The Facility shall ensure that all curtains are flame proof (including cubicle curtains).

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

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

1906. Signal System. (II)

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

1907. Nurses Station.

The Facility shall ensure each nurses' station serves no 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 showing how the additional beds served will not adversely affect the care provided to each patient.

1908. Utility Rooms.

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

B. Clean Utility Room. The Facility shall ensure at least one clean utility room per main/central nurses' station is provided, which contains a counter with hand wash sink, 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.

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.

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 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.