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Regulation 61-16

Minimum Standards for Licensing Hospitals and Institutional General Infirmaries

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SECTION 100
DEFINITIONS

101. Definitions.

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

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

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

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

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

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

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

2. Specialized Hospital: A facility which has an organized medical staff, maintains and operates organized facilities and services to accommodate two or more nonrelated persons for the diagnosis, treatment and/or care of such persons overnight and which provides a specialized service for one type of care, such as, maternity, orthopedics, pediatrics, E.E.N.T., psychiatry, etc., and 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 Infirmery: A facility which is established within the jurisdiction of a larger nonmedical institution and which maintains and operates organized facilities and services to accommodate two or more nonrelated students, residents or inmates with illness, injury or infirmity for a period exceeding 24 hours for the diagnosis, treatment and care of such persons and which provides medical, surgical and professional nursing care, and in which all diagnoses, treatment and care are performed under the direction of persons currently licensed to practice medicine and surgery in the State of S.C.

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

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

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

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

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

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

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

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

K. Live Birth: The complete expulsion or extraction from its mother of a product of human conception, irrespective of the duration of pregnancy, which after such expulsion or extraction, breathes or shows any other evidence of life such as beating of the heart, pulsation of the umbilical cord, or definite movement of the voluntary muscles, whether or not the umbilical cord has been cut or the placenta is attached. Heartbeats are to be distinguished from transient cardiac contractions and respirations are to be distinguished from fleeting respiratory efforts or gasps.

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

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

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

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

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

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

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

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

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

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

SECTION 200 ***LICENSE REQUIREMENTS AND FEES***

201. License Requirements.

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

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

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

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

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

F. Applicants for a license shall file application under oath on a form and frequency specified by the Department. An application shall be signed/authenticated by the owner, if an individual or partnership; or in the case of a corporation, by two of its officers; or in the case of a governmental unit, by the head of the governmental department having jurisdiction over it. The application shall set forth the full name and address of the facility for which the license is sought and of the owner in case his address is different from that of the facility; the names of persons in control thereof and such additional information as the Department may require, including affirmative evidence of ability to comply with reasonable standards,

rules and regulations as may be lawfully prescribed. No proposed hospital shall be named nor may an existing hospital have its name changed to the same or similar name as a hospital licensed in the State.

G. Licensing Fees. The initial and annual license fee shall be ten dollars (\$10.00) per licensed bed. Annual license fees must also include any outstanding inspection fees. Such fees shall be made payable by check or credit card to the Department.

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

1. Change of ownership by purchase or lease;
2. Change of facility's name;
3. Addition or replacement of beds (an inspection will be required prior to issuance of license);
4. Deletion of beds; or
5. Reallocation of types of beds as shown on license.

202. Exceptions to Licensing Standards.

The Department reserves the right to make exceptions to these standards where it is determined that the health and welfare of the community requires the services of the facility. When an "exception" applies to an existing facility, it will continue to meet the standards in effect at the time it was licensed.

SECTION 300 ENFORCING REGULATIONS

301. General.

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

302. Inspections and Investigations.

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

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

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

D. A facility or proposed facility found noncompliant with the standards of this regulation shall submit an acceptable plan of correction to the Department that shall be signed by the administrator and returned

by the date specified on the report of inspection or investigation. The written plan of correction shall describe: (II)

1. The actions taken to correct each cited deficiency;
2. The actions taken to prevent recurrences (actual and similar); and
3. The actual or expected completion dates of those actions.

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

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

303. Compliance.

A. A license shall not be issued until the licensee has demonstrated to the Department that the proposed facility is in compliance with the licensing standards. In the event a licensee who already has a facility or activity licensed by the Department makes application for another facility or activity or increase in licensed capacity, the currently licensed facility or activity shall be in substantial compliance with the applicable standards prior to the Department issuing a license to the proposed facility or activity or an amended license to the existing facility. Facilities shall comply with applicable State, Federal, and local laws, codes, and regulations. (II)

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

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

SECTION 400 ENFORCEMENT ACTIONS

401. General.

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

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

402. Violation Classifications.

Violations of standards in this regulation are classified as follows:

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

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

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

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

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

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

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

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

Frequency of Violation of Standard within a 24-month period	MONETARY PENALTY RANGES		
5th	5000	5000	1000-5000
6th and more	5000	5000	5000

H. In addition to or in lieu of any action taken by the Department affecting the license of any hospital, when it is established that any officer, employee, or member of the hospital medical staff has recklessly violated the provisions of Section 1210.A.5, 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 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.

A. The governing body, or the owner, or the person or persons designated by the owner as the governing authority shall be the supreme authority in the hospital responsible for the management control of the hospital and appointment of the medical staff. The governing body will work with the senior managers and leaders of the organized medical staff to annually evaluate the hospital's performance in relation to its mission, vision, and goals.

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

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

503. Chief Executive Officer.

The Chief Executive Officer shall be the administrator of the facility and be selected by the governing body or owner and shall have charge of and be responsible for the administration of the facility in all its branches and departments and shall see that the bylaws and amendments thereto are complied with. Any change in the position of the Chief Executive Officer shall be reported immediately by the governing body or owner to the Department in writing.

504. Medical Staff Appointment. (II)

A. The hospital shall have a medical staff organized in accordance with the facility's by-laws and accountable to the governing body including, but not limited to the quality of professional services provided

by individuals with clinical privileges. Prior to a physician's initial appointment and periodic reappointment, the governing body shall assure itself that the physician is qualified and competent to practice in his profession. This organized group shall, with the approval of the hospital governing body, adopt bylaws, rules and regulations to govern its operation as an organized medical staff. Hospital bylaws shall contain renewal procedures, authority to limit or terminate staff privileges, and appeal procedures. (II)

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

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

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

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

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

G. All persons admitted to any facility covered by these Standards must be under the care of a person duly licensed to practice medicine, dentistry or osteopathy. Patients of podiatrists and dentists who are members of the medical staff of a hospital must be co-admitted by a doctor of medicine or osteopathy who is a member of the medical staff of the hospital who shall be responsible for the general medical care of the patient. Oral surgeons who have successfully completed a postgraduate program in oral surgery accredited by a nationally recognized accredited body approved by the U.S. Department of Education may admit patients without the requirement of co-admission if permitted by the bylaws of the hospital and medical staff. (I)

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

505. Nursing Services. (II)

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

B. The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse. This service must be a well organized service of the hospital and under the direction of a single registered nurse. A registered professional nurse shall be designated to act in their absence. Nurses must be currently licensed in the state of South Carolina.

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

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

E. All personnel who render nursing care services in the hospital 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.

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

506. Employees. (II)

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

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

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

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

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

verification of their license from the South Carolina Board of Nursing or verification of their multi-state license from the appropriate state Board.

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

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

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

D. The facility shall develop, establish and maintain personnel policies and practices which support sound patient care. The policies shall be in writing and made available to all employees. The policies shall be reviewed periodically but no less than annually and the date of the most recent review shall be indicated on the written policies. A procedure shall be established for notifying employees of changes in the established personnel policies.

507. Job Orientation and In-Service Training.

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

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

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

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

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

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

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

D. Drills shall be designed and conducted to:

1. Assure that all personnel are capable of performing assigned tasks or duties;
2. Assure that all personnel know the location, use and how to operate firefighting equipment;
3. Assure that all personnel are thoroughly familiar with the fire plan; and
4. Evaluate the effectiveness of plans and personnel.

SECTION 600
EMPLOYEE HEALTH (II)

601. Employee Health Program.

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

602. New Employees.

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

1. Medical Doctor or Doctor of Osteopathy;
2. Physician Assistant;
3. Nurse Practitioner; or

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

B. The health assessment must ensure that all potential hospital employees are evaluated for conditions related to infectious diseases that may have an impact on patient care, the employee, or other healthcare workers. Based upon recommendations of the CDC's Advisory Committee on Immunization Practices (ACIP) for immunization of healthcare personnel, as listed in the CDC Guideline for infection control in healthcare personnel (1998) and as amended, this evaluation must include:

1. Medical history, including immunization status and assessment for conditions that may predispose the person to acquiring or transmitting communicable diseases;
2. Tuberculosis screening, which is performed in a manner prescribed in the CDC and the Department's most current tuberculosis guidelines; and
3. Serologic screening for vaccine-preventable diseases, as deemed appropriate by the hospital.

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

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

603. Employee Records.

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

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

604. Volunteer Workers. (II)

A. All volunteer workers who handle food or provide patient care shall have a physical examination prior to their initial food handling or patient care activity.

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

SECTION 700 REPORTING (II)

701. Fire Report.

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

702. Accident and/or Incident Report.

A. A record of each accident and/or incident occurring in the facility, including serious medication errors and adverse drug reactions, shall be retained. Incidents resulting in death or serious injury shall be reported, in writing, to the Department within 10 days of the occurrence. Information included in a facilities' report that is acquired from a peer review committee shall maintain its privilege pursuant to S.C. Code of Laws Sections 40-71-20, 44-30-60, and 44-7-315. However, the duty of hospitals to report serious accidents and incidents is not affected by any privilege or confidentiality. The following incidents, including but not limited to those stated, shall be reported:

1. Suicides.
2. Wrong site surgery.
3. Medication errors resulting in death or serious injury.
4. Major fractures or head injuries resulting from falls or other events.
5. Patient death or serious injury resulting from being in a restraint.
6. Criminal events and assaults.

7. Transfusion errors.
8. Neonatal injuries.
9. Maternal deaths or injuries.
10. Elopement events.
11. Anesthesia-related events resulting in death or serious injury.
12. Ventilator errors resulting in death or serious injury.
13. Infant abductions.

B. 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.

703. Facility Closure.

A. Prior to the permanent closure of a facility, the Department shall be notified in writing of the intent to close and the effective closure date. Within 10 days of the closure, the facility shall notify the Department of the provisions for the maintenance of the records, the identification of displaced patients, the relocated site, and the dates and amounts of patient refunds. On the date of closure, the license shall be returned to Department.

B. In instances where a facility temporarily closes, the Department shall be given written notice within a reasonable time in advance of closure. At a minimum this notification shall include, but not be limited to: the reason for the temporary closure, the location where the patients have been/will be transferred, the manner in which the records are being stored, and the anticipated date for reopening. The Department shall consider, upon appropriate review, the necessity of inspecting and determining the applicability of current construction standards of the facility prior to its reopening. If the facility is closed for a period longer than one year, and there is a desire to re-open, the facility shall re-apply to the Department for licensure and shall be subject to all licensing requirements at the time of that application, 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 90 days or more, the facility shall notify the Department in writing that there have been no admissions, no later than the 100th day following the date of departure of the last active 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 re-apply to the Department for licensure and shall be subject to all licensing requirements at the time of that application, including construction-related requirements for a new facility.

705. Joint Annual Report.

The Department requires each health care facility to annually complete a questionnaire named “Joint Annual Report” and return this report within the time period as specified in the report’s accompanying cover letter.

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

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

SECTION 800 REQUIREMENTS OF THE LEWIS BLACKMAN ACT (I)

801. Compliance.

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

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

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

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

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

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

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

SECTION 900 DISASTER MANAGEMENT(II)

901. Emergency Evacuation.

A. All facilities shall develop, by contact and consultation with their county emergency preparedness agency, a suitable written plan for actions to be taken in the event of a disaster and/or emergency evacuation. In the event of mass casualties, the facility shall provide resources as available. Additionally, in instances

where there are applications for increases in licensed bed capacity, the emergency evacuation plan shall be updated to reflect the proposed new total licensed bed capacity. The plan shall be updated, as appropriate, annually, or as needed.

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

C. Each facility shall operate under an incident command system that is in compliance with FEMA's National Incident Management System (NIMS), and the Hospital Incident Command System (HICS).

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

1. A sheltering plan to include:

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

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

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

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

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

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

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

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

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

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

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

E. Each facility shall validate/provide the Department the information in Section 901.D. no less than annually.

902. Internal Medical Surge.

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

B. A facility desiring to activate internal medical surge and temporarily admit patients in excess of licensed bed capacity due to an emergency should do the following:

1. Request that the Department concur that an emergency situation exists.
2. During the call to the Department, the facility should be prepared to:
 - a. Describe the emergency situation;
 - b. Outline the maximum number of patients to be temporarily admitted;
 - c. Provide an anticipated date for discharge of the temporary patients; and
 - d. Describe how and where the temporary patients will be housed.

3. Patients temporarily admitted during the emergency situation will not be required to undergo tuberculin screening or submit to an admission history and physical examination.

4. The facility must notify the Department when the patient census has returned to, or moves below, normal bed capacity by discharge or transfer to licensed beds.

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

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

903. External Medical Surge.

A. Some emergency situations might overwhelm a hospital's plans for Internal Medical Surge or render the licensed inpatient hospital building(s) unusable. In such situations, a hospital 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.

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

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

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

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

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

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

1. Request that the Department concur that an emergency situation does exist.
2. As part of the activation process, the hospital shall be prepared to:
 - a. Describe the emergency situation;
 - b. Explain why activating Internal Medical Surge will not address the situation;
 - c. Identify the ACS;
 - d. Outline the maximum number of patients to be treated at the ACS; and
 - e. Provide an anticipated date for discontinuance of the ACS.

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

F. After the emergency situation is over, the hospital must notify the Department when the ACS is closed.

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

904. Emergency Call Data. (I)

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

- A. Non emergency telephone numbers of fire and police departments;
- B. Name, address, and telephone number of all personnel to be called in case of fire or emergency;
- C. Name, address, and telephone number of physician on call;
- D. Name, address, and telephone number of supervisory personnel when on call; and
- E. Address and telephone number of a poison control center.

905. Security.

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

SECTION 1000 ACCOMMODATIONS FOR PATIENTS (II)

1001. Maximum Number of Beds

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

- 1. Labor room;
- 2. Newborn nursery;
- 3. Recovery room;
- 4. Emergency room treatment;
- 5. Classroom use only.

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

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 shall not be placed in corridors, solarium or other locations not designed as patient room areas except in cases of justified emergencies.

SECTION 1100 MEDICAL RECORDS (II)

1101. Physician's Responsibility.

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

1102. Organization.

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

1103. Indexing.

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

1104. Ownership.

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

1105. Contents.

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

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

2. History and physical within 48 hours after admission;

3. Provisional or working diagnosis;

4. Pre-operative diagnosis;

5. Plan of care;
 6. Complete surgical record, if any, including technique of operation and findings, statement of tissue and organs removed and post-operative diagnosis;
 7. Report of anesthesia;
 8. Nurses' notes;
 9. Progress notes;
 10. Gross pathological findings and microscopic, if applicable;
 11. Vital signs and other measurements appropriate to patient;
 12. Medication Administration Record or similar document for recording of medications, treatments and other pertinent data. This record shall be signed/authenticated after each medication administered or treatment is rendered;
 13. Final diagnosis and discharge summary;
 14. Date and time of discharge summary;
 15. In case of death, cause and autopsy findings, if autopsy is performed, unless the death becomes subject to review by the coroner's office, and;
 16. Special examinations, if any, e.g., consultations, clinical laboratory, x-ray and other examinations.
- B. Contingent upon the availability of pertinent information in the perinatal records of the mother, newborn records should include the following:
1. History of hereditary conditions in mother's and/or father's family;
 2. First day of the last menstrual period (L.M.P.) and estimated day of confinement (E.D.C.);
 3. Mother's blood group and RH type - evidence of sensitization and/or immunization (such as, administration of anti-D hyperimmune globulin);
 4. Serological test including dates performed for syphilis, HIV, Rubella, and Hepatitis B, results of any other tests performed during pregnancy (e.g., Group B Strep, Chlamydia, Gonorrhea, Herpes);
 5. Number, duration and outcome of previous pregnancies, with dates;
 6. Maternal disease (e.g., diabetes, hypertension, pre-eclampsia, infections);
 7. Drugs taken during pregnancy, labor and delivery;
 8. Results of measurements of fetal maturity and well-being (e.g., lung maturity and ultrasonography);
 9. Duration of ruptured membranes and labor, including length of second stage;

10. Method of delivery, including indications for operative or instrumental interference;
11. Complications of labor and delivery (e.g., hemorrhage or evidence of fetal distress), including a representative strip of the fetal ECG if recorded;
12. Description of placenta at delivery, including number of umbilical vessels;
13. Estimated amount and description of amniotic fluid;
14. Apgar scores at one and five minutes of age. Description of resuscitations, if required, detailed description of abnormalities and problems occurring from birth until transfer to the special nursery or the referral facility;
15. Results and date specimen was collected for neonatal testing to detect inborn metabolic errors and hemoglobinopathies, including PKU, hypothyroidism and various other metabolic disorders. Exception: Parents may object because of religious grounds only, and in writing using a form promulgated by the Department; and
16. Results and dates of pulse oximetry screening and/or follow up of evaluation for critical congenital heart defects.

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

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

1106. Orders for Medication and Treatment.

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

1107. Storage.

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

1. Records of minors must be retained until after the expiration of the period of election following achievement of majority as prescribed by statute; and
2. The hospital retains a register, either electronic or paper based.

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

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

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

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

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

1109. Maintenance and Disposal.

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

1110. Access to Medical Records.

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

***SECTION 1200
PATIENT CARE AND SERVICES***

1201. Medications. (I)

A. Drugs and biologicals must be prepared and administered in accordance with the orders of the legally authorized healthcare provider(s) responsible for the patient's care as specified under the hospital's governing body as it pertains to the care of the patient. All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with approved medical staff policies and procedures.

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

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

D. 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.

1202. Laboratory. (II)

A. Organization:

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

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

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

B. The laboratory shall:

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

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

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

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

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

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

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

- a. Number and frequency of controls,
- b. Tolerance limits and,
- c. Corrective actions based on quality control data.

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

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

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

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

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

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

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

1203. Radiology. (II)

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

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

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

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

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

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

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

1204. Pharmacy Services. (I)

A. The pharmaceutical service shall be directed by a registered pharmacist either on a full or part-time basis. The pharmacist directing the pharmaceutical services is responsible to the administration of the hospital for developing, supervising and coordinating all of the activities of the pharmacy department, which should include, but are not limited to, the following:

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

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

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

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

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

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

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

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

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

1205. Drug Distribution and Control.

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

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

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

1206. Physical Facilities and Storage.

A. Drug storage on the nursing units shall be reviewed monthly by the pharmacist or a properly trained individual designated by the pharmacist; a record of each review shall be maintained. All floor stocks shall

be properly controlled. Medications requiring refrigeration shall be kept in a secured refrigerator used exclusively for medications, or in a secured manner in which medications are separated from other items kept in a refrigerator (e.g. Lock Box). Refrigerators shall be provided with a thermometer accurate to plus or minus 2 degrees F. Documentation of appropriate temperature control is required by manual or electronic means.

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

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

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

1207. Labeling of Medications. (I)

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

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

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

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

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

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

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

1208. Central Supply. (I)

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

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

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

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

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

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

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

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

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

1209. Surgery. (II)

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

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

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

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

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

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

1210. Facilities.

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

1211. Equipment. (I)

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

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

1212. Anesthesia. (I)

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

1. A qualified anesthesiologist;
2. A doctor of medicine or osteopathy other than an anesthesiologist;
3. A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law;
4. A certified registered nurse anesthetist (CRNA), as defined in S.C. Code Ann. Section 40-33-20(20), is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed; or
5. An anesthesiologist's assistant, as defined in S.C. Code Ann. Section 40-47-1210(2), who is under the supervision of an anesthesiologist who is immediately available if needed.

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

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

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

1213. Outpatient Services. (II)

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

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

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

1214. Emergency Services. (I)

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

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

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

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

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

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

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

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

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

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

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

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

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

1215. Inpatient Dialysis Services. (I)

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

B. Renal Dialysis Service Equipment and Supplies

1. Equipment and supplies shall include at least:

- a. A dialysis machine or equivalent (with appropriate monitoring equipment) for each bed or station.
- b. Dialysis equipment appropriate for pediatric patients, if treated.

2. 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

ELEMENTS	LIMIT IN MILLIGRAMS PER LITER
Selenium	.090
Silver	.005
Sodium	70.0
Sulfates	100.0
Zinc	.100
Bacteria	200 colonies per milliliter

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

1216. Dental Surgery. (II)

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

1217. Physical Therapy. (II)

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

1218. Occupational Therapy. (II)

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

1219. Psychiatric Services. (II)

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

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

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

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

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

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

1221. Pediatrics. (II)

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

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

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

SECTION 1300 PERINATAL SERVICES

1301. Newborn Hearing Screening.

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

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

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

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

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

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

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

1303. Providing a Safe Haven for Abandoned Babies.

Facilities and outpatient facilities shall:

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

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

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

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

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

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

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

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

1. Written materials about paternity establishment.

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

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

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

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

1305. Perinatal Organization.

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

specific neonatal mortality data readily available for Department review relative to hospitals in the state of the same designation.

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

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

1306. Designation of Inpatient Perinatal Care Services.

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

B. Specialty Perinatal Center with Special Care Nursery (Level II). In addition to complying with all requirements of Section 1306.A, Level II hospitals shall provide services for both normal and selected high-risk obstetrical and neonatal patients. Level II hospital care shall include management of neonates who are at least 32 weeks of gestation with an anticipated birth weight of at least 1500 grams and problems expected to resolve rapidly (neonates not in need of sub-specialty services on an urgent basis). Level II hospitals shall provide care for infants convalescing after intensive care. Level II hospital shall stabilize infants born before 32 weeks of gestation and weigh less than 1500 grams until transfer to a neonatal intensive care facility. Level II hospitals shall have experienced personnel capable of providing continuous positive pressure airway pressure or mechanical ventilation for a brief period (less than 24 hours) or both until the infant's condition improves or the infant can be transferred to a higher-level facility. Level II hospitals shall have equipment (e.g. portable x-ray equipment, blood gas laboratory) and personnel (e.g. physicians, specialized nurses, respiratory therapists, radiology technicians, and laboratory technicians) available at all times to provide ongoing care and address emergencies. Referral to a higher level of care should occur for all infants when needed, for medical or subspecialty intervention. Support personnel shall include respiratory therapists, radiology technicians, laboratory technicians, and a lactation consultant. A board-certified or board-eligible pediatrician shall be in the hospital or on site within 30 minutes, 24 hours a day. There shall be no limit on the duration of Nasopharyngeal Continuous Positive Airway Pressure (NCPAP)

or Nasal Prong Continuous Positive Airway Pressure (NPCPAP) when cared for by a neonatologist. The provision of CPAP or mechanical ventilation beyond the immediate stabilization period requires the immediate availability of respiratory therapists with neonatal training (including intubation of premature infants), nursing support with training to identify and respond to complications of ventilation, and the immediate availability of personnel and equipment to evacuate a pneumothorax. Level II hospitals with a board certified or board eligible neonatologist having responsibilities limited to a single center and in house or within 30 minutes of the unit at all times may provide care for patients requiring mechanical ventilation for up to 24 hours. For shared neonatology coverage, a certified Neonatal Nurse Practitioner having responsibilities limited to a single center and in house may provide coverage for that center. Neonates requiring the initiation of mechanical ventilator support beyond 24 hours of age shall be referred to the RPC. Neonates shall not require high-frequency ventilation support. These hospitals shall manage no less than an average of 500 deliveries annually, calculated over the previous three years based on the individual hospital statistics. This calculation shall include the number of maternal transfers made prior to delivery to higher level perinatal hospitals. A Level II hospital shall not admit outborn neonates into its nursery without prior concurrence with the RPC. Level II units shall not transport neonates between hospitals. Hospitals at this level shall not provide care or services which are designated only for higher level hospitals, except under unforeseen, emergent circumstances. In this situation, the Department shall be notified within 24 hours.

C. Subspecialty Perinatal Center with Neonatal Intensive Care Unit (Level III). In addition to complying with all requirements of Sections 1306.A through 1306.B, Level III hospitals shall provide all aspects of perinatal care, including intensive care and a range of continuously available subspecialty consultation as recommended in the most recent edition of the *Guidelines for Perinatal Care* (GPC) by the American Academy of Pediatrics (AAP) and The American College of Obstetricians and Gynecologists. Level III hospitals shall provide care for mothers and infants at less than 32 weeks gestation, estimated fetal weight less than 1500 grams, and anticipated complex medical or surgical conditions for mother or infant that may require sub-specialty services. Level III hospitals shall also provide care for infants born at less than 32 weeks of gestation and weigh less than 1500 grams at birth or have actual or anticipated complex medical or surgical conditions regardless of gestational age. Level III hospital care shall include expertise in neonatology and maternal-fetal medicine. Level III neonatal intensive care units (NICUs) shall include continuously available personnel (neonatologists, neonatal nurses, and respiratory therapists) and equipment available to provide life support as long as needed. Level III facilities shall provide ongoing assisted ventilation for periods longer than 24 hours, which may include conventional ventilation, high-frequency ventilation, and inhaled nitric oxide. Level III hospitals shall provide services and care for women and fetuses at high risk, both admitted and transferred to the facility. Level III hospitals shall have advanced respiratory support and physiologic monitoring equipment, laboratory and imaging facilities, nutrition and pharmacy support with pediatric expertise, social services, and pastoral care. Pediatric ophthalmology services and an organized program for the monitoring, treatment, and follow-up of retinopathy of prematurity shall also be readily available in Level III hospitals. Level III hospitals shall have the capability to perform advanced imaging with interpretation on an urgent basis, including computed tomography, magnetic resonance imaging, and echocardiography. Level III hospitals shall also have the capability to perform major surgery on site or at a closely related institution. A board-certified or board-eligible neonatologist shall be in the hospital or on site within 30 minutes, 24 hours a day. A board-certified maternal-fetal medicine specialist (perinatologist) shall be available for supervision and consultation, 24 hours a day. Perinatal consultation requirements may be met via telemedicine arrangements with a RPC. In addition to the Level II capabilities, Level III hospitals shall have the staffing and technical capability to manage high-risk obstetric and complex neonatal patients, including neonates requiring prolonged ventilatory support, surgical intervention, or 24-hour availability of multispecialty management. Hospitals with Level III designation shall manage no less than an average of 1500 deliveries annually, calculated over the previous three years, and at least an average of 100 neonate admissions who weigh less than 1500 grams each, require ventilatory support for over twenty-four (24) hours, or require surgery based on individual

hospital statistics. This calculation shall include the number of maternal transfers made prior to delivery to higher level perinatal hospitals. The NICU budget shall include support for outcomes measurement, including data collection and membership in a multi-institutional collaborative quality improvement data base. Level III hospitals shall collect data to assess outcomes within their facility and to compare with other hospitals within their level. Hospitals at this level shall not provide additional care or services designated only for RPC's, or perform neonatal transport, except under unforeseen, emergent circumstances. In this situation, the Department shall be notified within 24 hours.

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

E. Complex Neonatal Intensive Care Unit (Level IV). In addition to complying with all requirements of Sections 1306.A through 1306.C, Level IV hospitals shall include additional capabilities and considerable experience in the care of the most complex and critically ill newborn infants and have pediatric medical and surgical specialty consultants available 24 hours a day. Level IV hospitals shall have capability to perform surgical repair of complex congenital or acquired conditions (e.g. Congenital malformations that require cardiopulmonary bypass with or without extracorporeal membrane oxygenation). Level IV hospitals shall maintain a full range of pediatric medical subspecialists, pediatric surgical subspecialists, and pediatric anesthesiologists at the facility. Not all Level IV hospitals need to act as regional centers. Regional organization of perinatal health care services requires that there be coordination in the development of specialized services, professional continuing education to maintain competency, facilitation of opportunities for transport and return transport, and collection of data on long-term outcomes to evaluate both the effectiveness of delivery of perinatal health care services and the safety and efficacy of new therapies. Level IV hospitals shall collect data to assess outcomes within their facility, and to compare with other hospitals within their level, if applicable.

1307. Personnel.

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

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

1. Level I shall include:

a. Membership: Physician designated as physician-in-charge of obstetric services, physician designated for supervision of newborn care, anesthesia personnel with credentials to administer obstetric

anesthesia available within 30 minutes, 24-hours a day, one person capable of initiating neonatal resuscitation available at every delivery.

b. Consultation: Obstetrician, pediatrician, general surgeon.

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

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

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

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

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

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

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

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

1308. Neonatal Intensive Care Nurse Staffing.

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

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

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

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

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

E. Chest tubes required;

- F. Cardio-pulmonary resuscitation required in the previous 24 hours;
- G. Vital signs required every hour or more frequently;
- H. Umbilical artery or vein catheterization or three or more intravenous sites required;
- I. Pressor agent (excluding initial stabilization) or inotropic support required, e.g., dopamine (doses for renal perfusion maintenance excluded);
- J. Complex diagnostic/assessment support required; or
- K. Evidence of seizure activity/unstable neurologic status.

1309. General Facility and Care Requirements.

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

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

1. Admission criteria and documentation;
2. Preterm labor;
3. Maternal transfer to another hospital;
4. Induction and augmentation;
5. Analgesia and anesthesia;
6. Labor process;
7. Capability to perform cesarean delivery within 30 minutes of the decision to do so;
8. Immediate neonatal care/resuscitation;
9. Recovery room care; and
10. Postpartum care.

1310. Neonatal Care.

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

1311. Neonatal Resuscitation.

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

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

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

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

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

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

1. Communication between referring hospitals and the RPC, transport teams and medical control, and perinatal providers and families;
2. Indications for both acute phase and return transport between perinatal hospitals, to include essential contact persons and telephone numbers for referral and transport; and
3. A list of all medical record copies and additional materials to accompany each patient in transport.

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

1313. Evaluation of Perinatal Care.

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

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

1. Analysis of total perinatal mortality with identification of deaths attributable to various categories of complication;
2. Analysis of perinatal morbidity and related factors.

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

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

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

SECTION 1400 VITAL STATISTICS

1401. General.

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

1402. Birth Certificates.

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

B. A licensee shall be responsible for filing a birth certificate for outpatient newborns brought to the emergency room when a live birth was delivered either at home or en route to the hospital. If the live birth is delivered by a licensed midwife or other practitioner, the licensee shall not be responsible for filing a birth certificate.

1403. Death Certificates.

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

SECTION 1500 FOOD AND NUTRITION SERVICE (II)

1501. Approval.

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

1502. Services.

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

1503. Management.

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

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

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

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

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

1504. Personnel.

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

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

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

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

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

1505. Diets.

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

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

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

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

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

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

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

1. Order or prescribe patient diets, including therapeutic diets;
2. Order laboratory tests to monitor the effectiveness of dietary plans and orders; and/or
3. Make subsequent modifications to patient diets based on the results of laboratory tests.

1506. Planning of Menus and Food Supplies.

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

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

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

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

1507. Preparation and Serving of Food.

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

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

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

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

1508. Dietary and Food Sanitation.

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

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

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

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

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

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

1509. Meal Service.

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

1510. Ice and Drinking Water.

Ice and water that meets the approval of the Department shall be available and precautions shall be taken to prevent contamination. Ice delivered to patient areas in bulk shall be in nonporous, easily cleanable covered containers. The ice scoop shall be stored in a sanitary manner with the handle at no time coming in contact with the ice. Clean, sanitary drinking water shall be available and accessible in adequate amounts at all times.

SECTION 1600 MAINTENANCE (II)

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

SECTION 1700 HOUSEKEEPING AND REFUSE DISPOSAL (II)

1701. Housekeeping.

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

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

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

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

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

1702. Refuse Disposal.

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

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

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

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

SECTION 1800 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;
4. CDC's Guidelines for Environmental Infection Control in Health-Care Facilities;
5. CDC's Guideline for Disinfection and Sterilization in Healthcare Facilities;
6. CDC's Guidelines for the Management of Multidrug-Resistant Organisms In Healthcare Settings;
7. DHEC Regulation 61-105;
8. CDC's Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings; and
9. CDC's Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005.

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

1802. Infection Control Training.

A. The hospital shall require annual education regarding infection prevention and control for all employees, students, and volunteers who have contact with patients or who handle or potentially handle blood, body fluids, or tissue. If any of these persons work or perform tasks at more than one hospital, the hospital may accept infection prevention and control education received at another hospital or at an in-person or online seminar to meet this requirement, but only if the education is reported to and documented by the hospital.

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

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

1803. Patient/Public Education and Disclosure.

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

1804. Live Animals.

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

1805. Laundry and Linens.

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

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

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

D. The hospital shall have policies addressing the storage, handling, distribution, collection, and reprocessing of linen for the hospital. If the hospital uses an off-site laundry, the hospital must ensure through contract that the linen is handled and cleaned properly to institutional standards. The hospital will assure that laundry services whether operated by the hospital or contracted will exercise necessary precautions to render all linen to be safe for reuse.

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

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

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

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

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

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

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

1806. Waste Management.

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

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

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

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

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

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

1807. Water Requirements.

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

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

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

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

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

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

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

1. Adhere to any advisory to boil water issued by the municipal water utility;
2. Alert patients, families, employees, volunteers, students and visitors not to consume water from drinking fountains, ice, or drinks made from municipal tap water, while the advisory is in effect, unless the water has been disinfected;
3. After the advisory is lifted, run faucets and drinking fountains at full flow for greater than 5 minutes, or use high-temperature water flushing or chlorination;
4. All ice and drinks that may have been contaminated must be disposed and storage containers cleaned; and
5. Decontaminate the hot water system as necessary after a disruption in service or a cross-connection with sewer lines has occurred.

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

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

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

SECTION 1900 DESIGN AND CONSTRUCTION

1901. General.

Every facility shall be planned, designed and equipped to provide adequate facilities for the care, safety, and treatment of each patient.

1902. Codes and Standards.

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

1903. Submission of Plans.

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

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

etc., that are required to have a flame spread rating or other safety criteria shall be documented with copies of the documentation and certifications, kept on file at the facility and made available to the Department.

C. All subsequent addenda, change orders, field orders, and documents altering the Department review must be submitted. Any substantial deviation from the accepted documents shall require written notification, review and re approval from the Department.

D. 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

1904. Construction Inspections.

Construction work which violates codes or standards will be required to be brought into compliance. All projects shall obtain all required permits from the locality having jurisdiction. Construction without proper permitting shall not be inspected by Department.

1905. Patient Rooms.

A. Cubicle curtains with built-in curtain tracks shall be provided in all multiple bed rooms which will shield each patient completely. Curtains will be flameproof.

B. Beds must be placed at least three feet apart.

C. At least one private room shall be provided in each nursing unit for purposes of medical isolation, incompatibility, personality conflicts, etc.

1906. Signal System.

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.

A nurses’ station shall serve not more than 44 beds, unless additional services and facilities are provided. In order for a nurses’ station to be permitted to serve more than 44 beds, justification must be furnished showing how the additional beds served will not adversely affect the health care provided to each patient.

1908. Utility Rooms.

A. Soiled Utility Room: At least one soiled utility room per nurses’ station shall be provided which contains a clinical sink, work counter, waste receptacle and soiled linen receptacle.

B. Clean Utility Room At least one clean utility room per nurses’ station shall be provided which contains a counter with handwashing sink and space for the storage and assembly of supplies for nursing procedures.

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

1909. Temperature and Humidity. (II)

A. Minimum design temperature of 75 degrees F. (23.9 degrees C.) at winter design conditions and 81 degrees F. maximum summer design conditions shall be provided for all occupied areas not listed below. The systems shall be designed to provide the following temperatures and humidities in the areas noted:

Area Designation	Temperature		Relative Humidity	
	F	C	Minimum	Maximum
Operating Room	68-75	20.0-24.0	20	60
Recovery Rooms	75	23.9	30	60
Intensive Care Units	75-80	23.9-26.7	30	60

B. Perinatal design temperature and humidity shall follow the current edition of *Guidelines for Perinatal Care*.

**SECTION 2000
FIRE PROTECTION, PREVENTION AND LIFE SAFETY (I)**

2001. Alarms.

A. A partial, manual, automatic, supervised fire alarm system shall be provided. The system shall be arranged to transmit an alarm automatically to a third party by an approved method. The alarm system shall notify by audible and visual alarm all areas and floors of the building. The alarm system shall shut down central recirculating systems and outside air units that serve the area(s) of alarm origination as a minimum.

B. There must be a fire alarm pull station in or near each nurses station.

C. All fire, smoke, heat, sprinkler flow, or manual fire alarming devices or systems must be connected to the main fire alarm system and trigger the system when they are activated.

2002. Emergency Generator Service.

A. Facilities shall provide certification that construction and installation of emergency generator service complies with requirements of all adopted State, Federal, or local codes, ordinances, and regulations.

B. An emergency generator shall be provided to deliver emergency electrical service during interruption of the normal electrical service and shall be provided to the distribution system as follows:

1. Exit lights and exit directional signs;
2. Exit access corridor lighting;
3. Lighting of means of egress and staff work areas;
4. Fire detection and alarm systems;
5. In patient care areas;
6. Signal system;
7. Equipment necessary for maintaining telephone service;
8. Elevator service that will reach every patient floor when rooms are located on other than the ground floor;
9. Fire pump;
10. Equipment for heating patient rooms;
11. Public restrooms;
12. Essential mechanical equipment rooms;
13. Battery-operated lighting and a receptacle in the vicinity of the emergency generator;
14. Alarm systems, water flow alarm devices, and alarms required for medical gas systems;
15. Patient records when solely electronically based.

SECTION 2100
PREVENTIVE MAINTENANCE OF LIFE SUPPORT EQUIPMENT

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

SECTION 2200
GENERAL

Conditions which have not been covered in these regulations shall be handled in accordance with the best practices as interpreted by the Department.