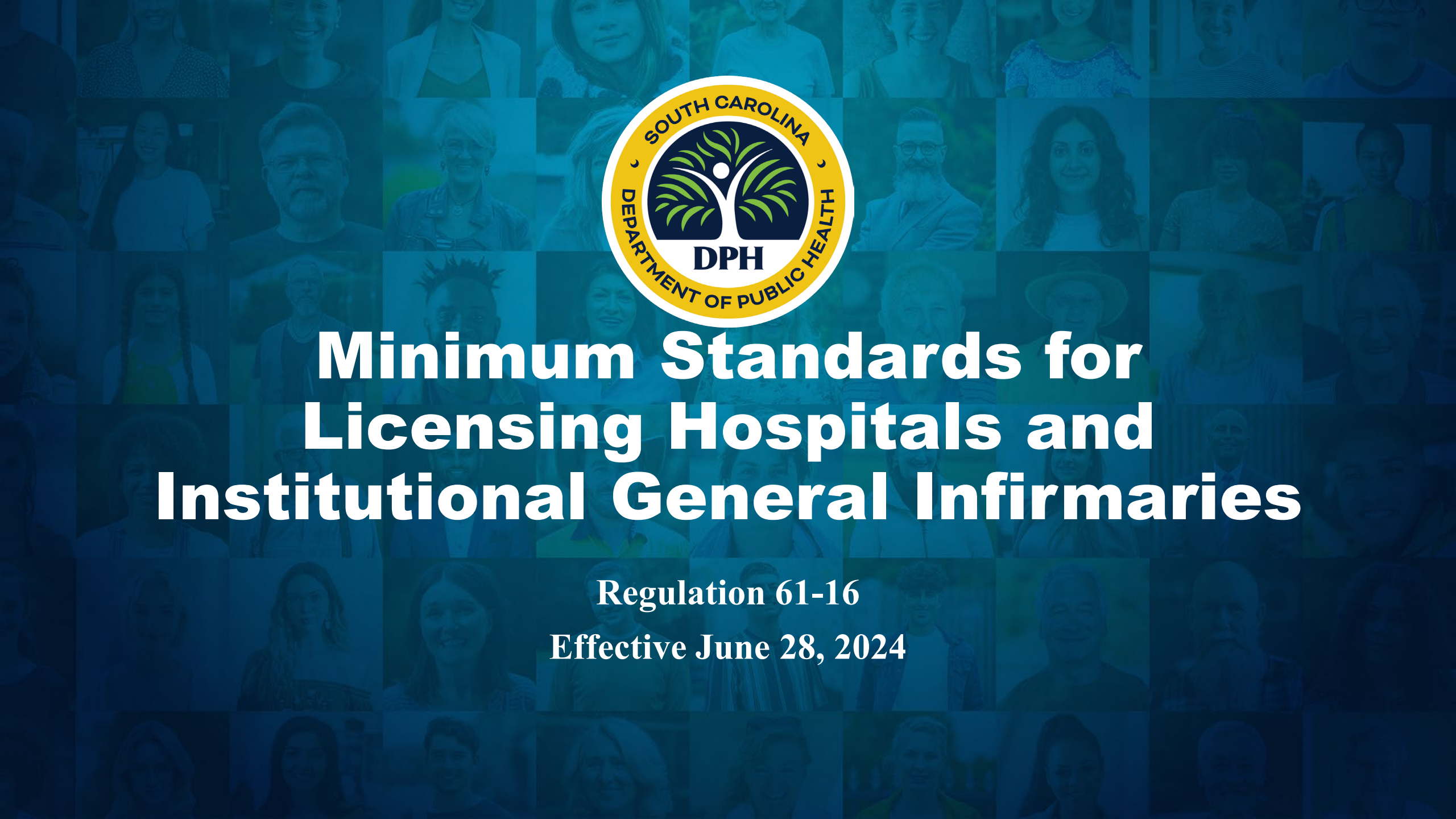

Minimum Standards for Licensing Hospitals and Institutional General Infirmaries

Regulation 61-16

Effective June 28, 2024

Note:

Questions or comments regarding R.61-16 changes can be sent to HTLsupport@dph.sc.gov.

Key changes in the regulation are highlighted in yellow throughout this document.

SECTION 100 - DEFINITIONS

General Hospital- A facility with an organized medical staff to maintain... must provide on-campus emergency services; that may provide obstetrical care, and in which all diagnoses, treatment or care are administered by or performed under the direction of persons currently licensed to practice medicine, surgery, or osteopathy in the state of S.C.

Specialized hospital- A facility which has an organized medical staff, maintains and operated organized facilities…must provide on-campus emergency services; and in which all diagnoses, treatment or care are under the direction of persons currently licensed to practice medicine, surgery, osteopathy in the state of S.C.

LICENSE REQUIREMENTS AND FEES CONT'D

202. Variance to Licensing Standards

A variance is an alternative method that ensures the equivalent level of compliance with the standards in this regulation. The facility may request a variance to this regulation in a format as determined by the department. Variances shall be considered on a case by case by the department. The Department may revoke issued variances as determined to be appropriate by the department.

SECTION 400 - POLICIES AND PROCEDURES

401. General (II).

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

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

POLICIES AND PROCEDURES CONT'D

402. Quality of Care (II).

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

SECTION 500 - STAFF AND TRAINING

502. Control (II).

The facility shall have a governing body which is effective in carrying out its responsibilities for the conduct of the facility. In the absence of an organized governing body, the facility shall maintain written documentation that identifies the individual or individuals that are legally responsible for the conduct of the facility's operation.

SECTION 600 - EMPLOYEE HEALTH (II)

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

SECTION 700 - REPORTING (II)

A. The Facility shall document every incident, and include an incident review, investigation, and evaluation as well as corrective taken, if any. The Facility shall retain all documented incidents reported pursuant to this section for three (3) years following the incident. For the first year following the incident, these records shall be kept on site and readily available at that Facility.

REPORTING CONT'D

701.B:

The Facility shall report the following types of incidents to the Department and the patient, patient's responsible party, sponsor, emergency contact within twenty-four (24) hours or by the next regular business day from when the facility had reasonable cause to believe an incident occurred. The Facility shall notify the Department via the Department's electronic reporting system or as otherwise determined by the Department.

REPORTING CONT'D

The following types of incidents, require an initial report to the Department as specified in this section:

1. Surgery or other invasive procedure performed on the wrong patient.
2. Surgery or other invasive procedure performed on the wrong site.
3. Wrong surgical or other invasive procedure performed on a patient.
4. Patient death or serious injury associated with patient elopement (disappearance).
5. Patient suicide, attempted suicide, or self-harm that results in serious injury, while being cared for healthcare setting.

REPORTING CONT'D

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

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

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

9. Abduction of any patient of any age.

REPORTING CONT'D

701.C In addition to the initial report as may be required by subsection (B), Facilities shall submit a separate written investigation report for the following types of incidents within seven (7) business days from when the facility had reasonable cause to believe an incident occurred via the Department's electronic reporting system or as otherwise determined by the Department. Investigation reports submitted to the Department shall contain at a minimum: facility name, patient age and sex, date of incident, location, witness names, extent and type of injury and how treated, e.g., hospitalization, identified cause of incident, internal investigation results if cause unknown, identity of other agencies notified of incident and the date of the report. The following types of incidents require a written investigation report to the Department as specified in this section:

REPORTING CONT'D

1. Surgical or Invasive Procedure Events.

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

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

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

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

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

REPORTING CONT'D

2. Product or Device Events

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

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

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

REPORTING CONT'D

3. Patient Protection Events

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

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

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

REPORTING CONT'D

4. Care Management Events.

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

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

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

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

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

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

REPORTING CONT'D

5.Environmental Events

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

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

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

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

REPORTING CONT'D

6. Radiologic Events

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

7. Potential Criminal Events.

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

b. Abduction of patient of any age;

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

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

702. LOSS OF ESSENTIAL SERVICES

Should a facility experience a loss of an essential service such as cooling, potable water, or electrical power, the facility shall notify the Department after ensuring the safety of the patients, but not to exceed twenty-four (24) hours from the loss of service.

SECTION 1000 - ACCOMODATIONS FOR PATIENTS (II).

1001. C. The Facility shall have the capability to set up the number of beds stated on the face of its license.

1002. Locations of Beds.

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

SECTION 1200 - PATIENT CARE AND SERVICES

1201. Basic Facility Functions. (I)

A. Pharmaceutical Services

A. The facility must have pharmaceutical services that meet the needs of the patients. The facility must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the facility's organized pharmaceutical service.

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

PATIENT CARE AND SERVICES CONT'D

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

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

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

PATIENT CARE AND SERVICES CONT'D

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

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

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

PATIENT CARE AND SERVICES CONT'D

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

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

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

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

PATIENT CARE AND SERVICES CONT'D

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

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

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

PATIENT CARE AND SERVICES CONT'D

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

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

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

PATIENT CARE AND SERVICES CONT'D

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

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

PATIENT CARE AND SERVICES CONT'D

B. Radiological Services

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

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

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

PATIENT CARE AND SERVICES CONT'D

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

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

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

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

PATIENT CARE AND SERVICES CONT'D

3. Personnel must adhere to the following:

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

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

4. Records of radiologic services must be maintained.

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

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

i. Copies of reports and printouts

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

PATIENT CARE AND SERVICES CONT'D

C. Laboratory Services.

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

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

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

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

PATIENT CARE AND SERVICES CONT'D

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

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

6. The facility must maintain:

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

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

PATIENT CARE AND SERVICES CONT'D

D. Emergency Services.

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

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

PATIENT CARE AND SERVICES CONT'D

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

PATIENT CARE AND SERVICES CONT'D

4. On its initial and renewal licensure applications, each hospital shall classify itself to indicate its capability in providing emergency care. Such classification will be for the hospital's on-campus emergency service and, if applicable, its off-campus emergency services General hospitals shall be classified as Type I,II, or III, except that an existing General Hospital that was approved and licensed without either Type I, II, or III emergency service may classify itself as a Type IV emergency service. Specialized Hospitals shall be classified as a Type I, II, III, or IV. Off-campus emergency services may be the same type as or a lower-level type than the hospital's on-campus emergency services may not be a Type I.

PATIENT CARE AND SERVICES CONT'D

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

PATIENT CARE AND SERVICES CONT'D

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

PATIENT CARE AND SERVICES CONT'D

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

PATIENT CARE AND SERVICES CONT'D

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

PATIENT CARE AND SERVICES CONT'D

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

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

PATIENT CARE AND SERVICES CONT'D

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

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

PATIENT CARE AND SERVICES CONT'D

9. Diversion Status- Inability to Deliver Emergency Services.

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

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

PATIENT CARE AND SERVICES CONT'D

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

PATIENT CARE AND SERVICES CONT'D

1202. Optional Hospital Services (I).

A. Surgical Services

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

PATIENT CARE AND SERVICES CONT'D

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

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

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

PATIENT CARE AND SERVICES CONT'D

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

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

PATIENT CARE AND SERVICES CONT'D

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

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

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

PATIENT CARE AND SERVICES CONT'D

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

PATIENT CARE AND SERVICES CONT'D

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

PATIENT CARE AND SERVICES CONT'D

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

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

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

PATIENT CARE AND SERVICES CONT'D

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

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

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

PATIENT CARE AND SERVICES CONT'D

C. Nuclear Medicine Services.

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

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

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

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

PATIENT CARE AND SERVICES CONT'D

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

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

PATIENT CARE AND SERVICES CONT'D

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

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

PATIENT CARE AND SERVICES CONT'D

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

a. Maintained in safe operating condition; and

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

PATIENT CARE AND SERVICES CONT'D

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

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

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

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

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

PATIENT CARE AND SERVICES CONT'D

D. Outpatient Services.

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

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

2.The hospital must:

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

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

PATIENT CARE AND SERVICES CONT'D

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

a. Is responsible for the care of the patient

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

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

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

PATIENT CARE AND SERVICES CONT'D

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

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

PATIENT CARE AND SERVICES CONT'D

E. Rehabilitation Services.

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

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

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

PATIENT CARE AND SERVICES CONT'D

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

PATIENT CARE AND SERVICES CONT'D

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

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

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

PATIENT CARE AND SERVICES CONT'D

F. Psychiatric Services.

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

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

2. A registered nurse who has had at least two years 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.

PATIENT CARE AND SERVICES CONT'D

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

a. Be completed within 60 hours of admission;

b. Include a medical history;

c. Contain a record of mental status;

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

e. Describe attitudes and behavior;

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

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

PATIENT CARE AND SERVICES CONT'D

4. Treatment plan:

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

i. A substantiated diagnosis

ii. Short-term and long-range goals;

iii. The specific treatment modalities

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

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

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

PATIENT CARE AND SERVICES CONT'D

5. Progress notes for the patient must be documented, in accordance with applicable State scope-of-practice laws and hospital policies, by the following qualified practitioners: Doctor(s) of medicine or osteopathy, or other licensed practitioner(s), who is responsible for the care of the patient; nurse(s) and social worker(s) (or social service staff) involved in the care of the patient; and, when appropriate, others significantly involved in the patient's active treatment modalities. The frequency of progress notes is determined by the condition of the patient but must be recorded at least weekly for the first 12 months and at least once a month thereafter and must contain recommendations for revisions in the treatment plan as indicated, as well as precise assessment of the patient's progress in accordance with the original or revised treatment plan.

PATIENT CARE AND SERVICES CONT'D

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

PATIENT CARE AND SERVICES CONT'D

G. Respiratory Care Services.

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

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

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

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

PATIENT CARE AND SERVICES CONT'D

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

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

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

PATIENT CARE AND SERVICES CONT'D

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

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

PATIENT CARE AND SERVICES CONT'D

H. Inpatient Dialysis Services.

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

PATIENT CARE AND SERVICES CONT'D

I. Chemical and Substance Abuse Treatment Services

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

J. Pediatrics Services

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

PATIENT CARE AND SERVICES CONT'D

K. Cardiovascular Care Services.

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

PATIENT CARE AND SERVICES CONT'D

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

SECTION 2000 - FIRE PROTECTION, PREVENTION AND LIFE SAFETY

2003. Fire Reports. (II)

The Facility shall immediately notify the Department by email to firewatch@dph.sc.gov or other email address prescribed by the Department regarding any fire, regardless of size or damage that occurs in the facility and followed by a complete written report to include fire department reports, if any, to be submitted within a time period determined by the facility, but not to exceed 7 business days.

FIRE PROTECTION, PREVENTION AND LIFE SAFETY CONT'D

2004. Fire Safety. (II)

The facility shall comply with the provisions of the codes officially adopted by the South Carolina Building Codes Council, and the South Carolina State Fire Marshal.

Reminder:

Questions or comments regarding R.61-16 changes can be sent to HTLsupport@dph.sc.gov.