

Chapter 93. Hospitals

Subchapter A. General Provisions

§9301. Purpose

A. The purpose of the hospital laws and standards is to provide for the development, establishment and enforcement of standards for the care of individuals in hospitals and for the construction, maintenance and operation of hospitals which shall promote safe and adequate treatment of individuals in hospitals.

1. Except as otherwise provided herein, hospitals shall provide directly or under arrangements the following professional departments, services, facilities and functions:

- a. organization and general services;
- b. nursing services;
- c. pharmaceutical services;
- d. radiological services;
- e. laboratory services;
- f. food and dietetic services;
- g. medical record services;
- h. quality assessment and improvement;
- i. physical environment;
- j. infection control;
- k. respiratory care services.

2. Except as otherwise provided herein, hospitals may provide the following optional services directly or under

arrangements:

- a. surgical services;
- b. anesthesia services;
- c. nuclear medicine services;
- d. outpatient services;
- e. rehabilitation services;
- f. psychiatric services;
- g. obstetrical and newborn services;
- h. pediatric services;
- i. emergency services.

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§9303. Definitions

A. The following definitions of selected terminology are used in connection with Chapter 93.

Accredited—the approval by the Joint Commission on Accreditation of Healthcare Organizations, American Osteopathic Association, or Det Norske Veritas.

Administrator—(see Chief Executive Officer).

Anesthesiologist—a physician, dentist, or osteopath physician, who has successfully completed an *approved* residency program in anesthesiology, or who is a diplomat of either the American Board of Anesthesiology or the American Osteopathic Board of Anesthesiology, or who was made a Fellow of the American College of Anesthesiology before 1972.

Approved—acceptable to the authority having jurisdiction.

Authority Having Jurisdiction—an organization, office, or individual responsible for approving equipment, an installation, or a procedure.

Certified Nurse Midwife—an advanced practice registered nurse as defined by R.S. 37:913.

Certified Registered Nurse Anesthetist—an advanced practice registered nurse as defined by R.S. 37:913.

Cessation of Business—when a hospital stops providing services to the community.

Chief Executive Officer (CEO)/Administrator—the person responsible for the operation of the hospital commensurate with the authority conferred by the governing body.

Clinical Nurse Specialist—an advanced practice registered nurse as defined by R.S. 37:913.

Crisis Receiving Center—a specialty unit of a hospital that shall receive, examine, triage, refer or treat an

individual who is experiencing a behavioral health crisis.

Department—Louisiana Department of Health and Hospitals.

Governing Body—the board of trustees, owner or person(s) designated by the owner with ultimate authority and responsibility (both moral and legal) for the management, control, conduct and functioning of the hospital.

Hospital—any institution, place, building, or agency, public or private, whether for profit or not, maintaining and operating facilities, 24 hours a day, seven days a week, having 10 licensed beds or more, properly staffed and equipped for the diagnosis, treatment and care of persons admitted for overnight stay or longer who are suffering from illness, injury, infirmity or deformity or other physical or mental condition for which medical, surgical and/or obstetrical services would be available and appropriate. This term hospital does not include the following:

a. physicians' offices, clinics or programs where patients are not kept as bed patients for 24 hours or more;

b. nursing homes providing intermediate and/or skilled care as defined by and regulated under the provisions of R.S. 40:2009-2009.23;

c. persons, schools, institutions or

organizations engaged in the care and treatment of the mentally retarded and which are required to be licensed by the provisions of R.S. 28:421-427;

d. hospitalization or care facilities maintained by the state at any of its penal or correctional institutions;

e. hospitalization or care facilities maintained by the federal government or agencies thereof;

f. infirmaries or clinics maintained solely by any college or university exclusively for treatment of faculty, students and employees.

Note: Facilities under 10 beds shall not be licensed as a hospital and shall not care for patients overnight unless authorized to do so under another state law.

Hospital Record—a compilation of the reports of the various clinical *departments* within a hospital, as well as reports from health care providers, as are customarily catalogued and maintained by the hospital medical records department. *Hospital records* include reports of procedures such as X-rays and electrocardiograms, but they do not include the image or graphic matter produced by such procedures, according to state law.

Immediate and Serious Threat—a crisis situation in which the health and safety of patients is at risk. It is a

deficient practice which indicates the operator's inability to furnish safe care and services, although it may not have resulted in actual harm. The threat of probable harm is real and important and could be perceived as something which will result in potentially severe temporary or permanent injury, disability or death.

License Under Suspensive Appeal—a full or provisional license against which the department has taken a licensing action and the hospital has filed an administrative appeal.

Licensed Bed—an adult and/or pediatric bed set up or capable of being set up within 24 hours in a hospital for the use of patients, based upon bedroom criteria expressed in these standards. Labor, delivery, newborn bassinets, emergency and recovery room beds are excluded.

Licensed Independent Practitioner—a person who is approved by his board for independent practice and who is approved by the medical staff and credentialed and approved by the Governing Board.

Licensed Nuclear Medicine Technologist—any person licensed to practice nuclear medicine technology by the Louisiana State Radiologic Technology Board of Examiners.

Licensed Practical Nurse—any person licensed to practice practical nursing and who is licensed to practice by the Louisiana State Board of Practical Nurse Examiners.

Licensed Radiation Therapy Technologist—any person licensed to practice radiation therapy technology by the Louisiana State Radiologic Technology Board of Examiners.

Licensed Radiographer—any person licensed to practice general radiography by the Louisiana State Radiologic Technology Board of Examiners.

Minor Alteration—repair or replacement of building materials and equipment with materials and equipment of a similar type that does not diminish the level of construction beyond that which existed prior to the alteration. This does not include any alteration to the "functionality" or original design of the construction. (For example, normal maintenance, re-roofing, painting, wallpapering, asbestos removal, and changes to the electrical and mechanical systems.)

Monolithic Ceiling Construction—a continuous membrane ceiling composed of plaster or gypsum wallboard, but not moveable or "lay-in" ceiling tiles.

Neonatal—newborn immediately succeeding birth and continuing through the first 28 days of life.

New Construction—any of the following started after March 1, 1995:

- a. new buildings to be used as a hospital;
- b. additions to existing buildings to be used as a hospital;

c. conversions of existing buildings or portions thereof for use as a hospital;

d. alterations other than *minor alterations* to an existing hospital;

Nurse Practitioner—an advanced practice registered nurse as defined by R.S. 37:913.

Nurses Call System—a system that audibly transmits calls electronically from its place of origin (the patient's bed) to the place of receipt (the nurses' station).

Observation Bed/Unit—outpatient service in which patients are admitted for a period of no longer than 24 hours for observation. After 24 hours, the patient must be admitted, transferred or discharged. This outpatient unit must not provide acute care nursing. A registered nurse must be on site while there are patients in this unit.

Office of the Secretary—office of the person serving as the Secretary of the Department of Health and Hospitals.

Off-Site Campus—all premises on which hospital services (inpatient and/or outpatient) are provided and that are not adjoining to the main hospital buildings or grounds. Each off-site campus of a hospital shall be licensed as a part of the main hospital. An off-site campus shall be located within 50 miles of the main hospital campus.

a. Exception. If a state-owned or operated

hospital ceases to do business and surrenders its license, the offsite campus(es) of that hospital which provided outpatient services may be licensed as an off-site campus(es) of another state-owned and/or operated hospital, provided that the off-site campus(es) is located within 100 miles of the main hospital campus of the state-owned and/or operated hospital.

Organ—a human kidney, liver, heart, lung or pancreas.

Radiologist—a doctor of medicine or osteopathy who is qualified by education and experience in radiology.

Registered Dietitian—a dietitian who is qualified based on registration by the Commission on Dietetic Registration of the American Dietetic Association and licensing by the Louisiana Board of Examiners in Dietetics and Nutrition.

Registered Nurse—any person licensed to practice nursing by the Louisiana State Board of Nursing.

Unit Definition—a licensed patient room.

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§9305. Licensing Process

A. Procedures for Initial Licensing. The Department of Health and Hospitals is the only authority for hospitals in the state of Louisiana.

1. Any person, organization or corporation desiring to operate a hospital shall make application to the Department of Health and Hospitals (DHH) on forms prescribed by the department. Such forms may be obtained from: Hospital Program Manager, Department of Health and Hospitals, Health Standards Section (HSS), Post Office Box 3767, Baton Rouge, LA 70821.

2. An initial applicant shall as a condition of licensing:

a. submit a completed initial hospital packet and other required documents;

b. submit the required nonrefundable licensing fees by certified check or money order. No application will be reviewed until payment of the application fee. Except for good cause shown, the applicant must complete all requirements of the application process within 90 days of initial submission of the application material. Upon 10 days prior notice, any incomplete or inactive applications shall be closed. A new application will be accepted only when accompanied by a nonrefundable application fee.

3. When the required documentation for licensing is

approved and the building is approved for occupancy, a survey of the facility by representatives of HSS shall be conducted at the department's discretion to determine if the facility meets the standards set forth in this Chapter 93.

4. Representatives of the HSS shall discuss the findings of the survey, including any deficiencies found, with representatives of the hospital facility.

5. The hospital shall notify the HSS in writing when the deficiencies, if any, have been corrected. Following review of the hospital's Plan of Correction (POC), HSS may schedule a survey of the facility prior to occupancy.

6. No new hospital facility shall accept patients until the hospital has written approval and/or a license issued by HSS.

7. No licensed bed shall be placed in a room that does not meet all patient room licensing criteria and which has not been previously approved by HSS.

8. The hospital shall accept only that number of inpatients for which it is licensed unless prior written approval has been secured from the department.

B. Issuance of a License

1. The agency shall have authority to issue two licenses as described below:

a. full license-issued only to those hospitals

that are in substantial compliance with the rules, the standards governing hospitals and the hospital law. The license shall be issued by the department for a period of not more than 12 months for the premises named in the application, as determined by the department;

b. if a hospital is not in substantial compliance with the rules, the standards governing hospitals and the hospital law, the department may issue a provisional license up to a period of six months if there is no immediate and serious threat to the health and safety of patients.

2. The department also has discretion in denying, suspending or revoking a license where there has been substantial noncompliance with these requirements in accordance with the hospital law. If a license is denied, suspended or revoked, an appeal may be made as outlined in the hospital law (R.S. 40:2110).

a. Suspensive Appeal. A hospital that appeals the action of the department in denying, suspending or revoking the license may file a suspensive appeal from the action of the department.

b. A renewal license shall not be issued, nor will any changes be processed to a hospital's existing license, during the pendency of an administrative suspensive appeal of the department's decision to deny, suspend or revoke a

hospital's license for substantial non-compliance. There is no additional administrative remedy to the hospital for the non-renewal of a license.

c. The license for a hospital that is suspensively operating during the pendency of the appeal process shall be considered a license under suspensive appeal.

3. The hospital license is not assignable or transferable and shall be immediately void if a hospital ceases to operate or if its ownership changes.

4. Licenses issued to hospitals with off-site locations shall be inclusive of the licensed off-site beds. In no case may the total number of inpatient beds at the off-site location exceed the number of inpatient beds at the primary campus.

C. Licensing Renewal. Licenses must be renewed at least annually. The renewal packet shall be sent by the Department to the hospital 45 days prior to the expiration of its license. The packet shall contain all forms required for renewal of the license. A hospital seeking renewal of its license shall:

1. complete all forms and return them to the department at least 15 days prior to the expiration date of its current license;

2. submit the annual fees or the amounts so specified by state law. All fees shall be submitted by certified

check or money order and are nonrefundable. All state-owned facilities are exempt from fees.

D. Display of License. The current license shall be displayed in a conspicuous place in the hospital at all times.

E. Bed Increases

1. The hospital will notify the department in writing 14 days prior to the bed increase.

2. The hospital will complete the required paperwork and submit the appropriate documents.

3. A fee of \$25 plus \$5 per licensed unit being added or the amounts so specified by state law in the future shall be submitted to the department. This shall be a certified check or money order.

4. At the discretion of the department, signed and dated attestations to compliance with these standards may be accepted in lieu of an on-site survey.

5. Written approval of the bed increase must be obtained before patients can be admitted to these additions.

6. No licensed bed shall be placed in a room that does not meet all patient room licensing criteria and which has not been previously approved by HSS.

F. Eliminating and/or Relocating Beds

1. The hospital will notify the department in writing 14 days prior to the bed decrease or relocation.

2. The hospital will complete the required paperwork and submit the appropriate documents.

3. A fee of \$25 or the amounts so specified by state law in the future shall be submitted to the Department. This remittance shall be a certified check or money order.

4. No licensed bed shall be placed in a room that does not meet all patient room licensing criteria and which has not been previously approved by HSS.

G. Adding or Eliminating Services

1. Prior to the addition or deletion of a service or services, the hospital shall notify the department in writing 45 days prior to implementation, if plan review is required, and 15 days prior to implementation if no plan review is necessary.

2. The department will determine the required documents, if any, to be provided for a new service.

3. No service shall be instituted that does not meet all licensing criteria and which has not been previously approved by the department.

H. Adding Off-Site Campuses

1. Individual licenses shall not be required for separate buildings and services located on the same or adjoining grounds or attached to the main hospital if they are operated as an integrated service of the hospital. An applicant shall as a condition of licensing:

a. submit a completed off-site campus packet and other required documents;

b. submit the required nonrefundable licensing fees by certified check or money order.

2. Except for good cause shown, all incomplete and inactive applications shall be closed 90 days after receipt of the initial off-site campus application. A new application will be accepted only when accompanied by a nonrefundable application fee.

3. At the discretion of the department, signed and dated attestations to the compliance with these standards may be accepted in lieu of an on-site survey.

4. The off-site campus will be issued a license which is a subset of the hospital's main license.

I. Closing Off-Site Campuses. The hospital is to notify the HSS in writing within 14 days of the closure of an off-site campus with the effective date of closure. The original license of the off-site campus is to be returned to HSS.

J. Duplicate and Replacement Licenses. A \$5 processing fee or the amount so specified by state law in the future shall be submitted by the hospital for issuing a duplicate facility license with no change.

K. Changes to the License. When changes to the license, such as a name change, address change or bed reduction are

requested in writing by the hospital, a fee of \$25 or the amounts so specified by state law in the future, shall be submitted.

L. Facility within a Facility

1. If more than one health care provider occupies the same building, premises or physical location, all treatment facilities and administrative offices for each health care provider shall be clearly separated from each other by a clearly delineated and recognizable boundary.

a. Treatment facilities shall include, but not be limited to consumer beds, wings and operating rooms.

b. Administrative offices shall include, but not be limited to record rooms and personnel offices.

c. There shall be clearly identifiable and distinguishable signs.

2. If more than one health care provider occupies the same building, premises or physical location, each such health care provider shall have its own entrance. The separate entrance shall have appropriate signs and shall be clearly identifiable as belonging to a particular health care provider. Nothing prohibits a health care provider occupying the same building, premises or physical location as another health care provider from utilizing the entrance, hallway, stairs, elevators or escalators of another health care provider to provide access

to its separate entrance.

3. Staff of the hospital within a hospital shall not be co-mingled with the staff of the host hospital for the delivery of services within any given shift.

4. The provisions and requirements of §9305.L are in addition to and not excluding any other statutes, laws and/or rules that regulate hospitals, as set forth in R.S. 40:2007.

M. Change of Ownership

1. Definition. *Change of Ownership (CHOW)*—the sale or transfer whether by purchase, lease, gift or otherwise of a hospital by a person/corporation of controlling interest that results in a change of ownership or control of 30 percent or greater of either the voting rights or assets of a hospital or that results in the acquiring person/corporation holding a 50 percent or greater interest in the ownership or control of the hospital. Examples of actions which constitute a change of ownership (R.S. 40:2115.11 et seq.).

a. Unincorporated Sole Proprietorship. Transfer of title and property to another party constitutes a change of ownership.

b. Corporation. The merger of the provider corporation into another corporation, or the consolidation of two or more corporations, resulting in the creation of a new corporation constitutes a change of ownership. Transfer of

corporate stock or the merger of another corporation into the provider corporation does not constitute a change of ownership.

c. Partnership. In the case of a partnership, the removal, addition or substitution of a partner, unless the partners expressly agree otherwise, as permitted by applicable state law, constitutes a change of ownership.

d. Leasing. The lease of all or part of a provider facility constitutes a change of ownership of the leased portion.

2. No later than 15 days after the effective date of the CHOW, the prospective owner(s) or provider representative shall submit to the department a completed application for hospital licensing, the bill of sale, and a licensing fee consistent with state law. Hospital licensing is not transferable from one entity or owner(s) to another.

N. Plan Review. A letter to the Department of Health and Hospitals, Division of Engineering and Architectural Services, shall accompany the floor plans with a request for a review of the hospital plans. The letter shall include the types of services offered, number of licensed beds and licensed patient rooms, geographical location, and whether it is a relocation, renovation, and/or new construction. A copy of this letter is to be sent to the Hospital Program Manager.

1. Submission of Plans

a. New Construction. All new construction shall be done in accordance with the specific requirements of the Office of State Fire Marshal and the Department of Health and Hospitals, Division of Engineering and Architectural Services. The requirements cover new construction in hospitals, including submission of preliminary plans and the final work drawings and specifications to each of these agencies. Plans and specifications for new construction shall be prepared by or under the direction of a licensed architect and/or a qualified licensed engineer and shall include scaled architectural plans stamped by an architect.

b. New Hospitals. No new hospital shall hereafter be licensed without the prior written approval of, and unless in accordance with plans and specifications approved in advance by the DHH, Division of Engineering and Architectural Services and the Office of State Fire Marshal. This includes any change in hospital type (e.g., acute care hospital to psychiatric hospital) or the establishment of a hospital in any healthcare facility or former healthcare facility. The applicant must furnish one complete set of plans and specifications to the Division of Engineering and Architectural Services and one complete set of plans and specifications to the Office of State Fire Marshal, together with fees and other information as required. Plans and specifications shall be prepared by or under

the direction of a licensed architect and/or a qualified licensed engineer and shall include scaled architectural plans stamped by an architect. The review and approval of plans and specifications shall be made in accordance with the publication entitled *Guidelines for Construction and Equipment of Hospital and Medical Facilities*, Current Edition, published by the American Institute of Architects Press and the *Standard Plumbing Code*.

c. Change(s) in Service(s)/Hospital Type.

Preliminary plans, final work drawings and specifications shall be submitted prior to any change in hospital type (e.g., acute care hospital to psychiatric hospital). The review and approval of plans and specifications shall be made in accordance with the publication entitled *Guidelines for Construction and Equipment of Hospital and Medical Facilities*, Current Edition, published by the American Institute of Architects Press and the *Standard Plumbing Code*. The applicant must furnish one complete set of plans and specifications to the Department of Health and Hospitals, Division of Engineering and Architectural Services and one complete set of plans and specifications to the Office of State Fire Marshal, together with fees and other information as required.

d. Major Alterations. No major alterations shall be made to existing hospitals without the prior written

approval of, and unless in accordance with plans and specifications approved in advance by DHH, Division of Engineering and Architectural Services and the Office of State Fire Marshal. The applicant must furnish one complete set of plans and specifications to the Division of Engineering and Architectural Services and one complete set of plans and specifications to the Office of State Fire Marshal, together with fees and other information as required. Plans and specifications shall be prepared by or under the direction of a licensed architect and/or a qualified licensed engineer and shall include scaled architectural plans stamped by an architect. The review and approval of plans and specifications shall be made in accordance with the publication entitled *Guidelines for Construction and Equipment of Hospital and Medical Facilities*, Current Edition, published by the American Institute of Architects Press and the *Standard Plumbing Code*.

2. Approval of Plans

a. Notice of satisfactory review from the Division of Engineering and Architectural Services and the Office of State Fire Marshal constitutes compliance with this requirement if construction begins within 180 days of the date of such notice. This approval shall in no way permit and/or authorize any omission or deviation from the requirements of any restrictions, laws, ordinances, codes or rules of any

responsible agency.

b. In the event that submitted materials do not appear to satisfactorily comply with the *Guidelines for Construction and Equipment of Hospital and Medical Facilities*, Current Edition, and the *Standard Plumbing Code*, the Division of Engineering and Architectural Services shall furnish a letter to the party submitting the plans which shall list the particular items in question and request further explanation and/or confirmation of necessary modifications.

3. Waivers

a. The secretary of the department may, within his sole discretion, grant waivers to building and construction guidelines. The facility must submit a waiver request in writing to the Division of Engineering and Architectural Services. The facility shall demonstrate how patient safety and the quality of care offered is not compromised by the waiver. The facility must demonstrate their ability to completely fulfill all other requirements of the service. The Department will make a written determination of the request. Waivers are not transferable in an ownership change and are subject to review or revocation upon any change in circumstances related to the waiver.

b. The secretary, in exercising his discretion, must at a minimum, require the applicant to comply with the edition of the building and construction guidelines which

immediately preceded the most current edition of the *Guidelines for Construction and Equipment of Hospital and Medical Facilities*.

O. Fire Protection. All hospitals required to be licensed by the law shall comply with the rules, established fire protection standards and enforcement policies as promulgated by the Office of State Fire Marshal. It shall be the primary responsibility of the Office of State Fire Marshal to determine if applicants are complying with those requirements. No license shall be issued or renewed without the applicant furnishing a certificate from the Office of State Fire Marshal stating that the applicant is complying with their provisions. A provisional license may be issued to the applicant if the Office of State Fire Marshal issues the applicant a conditional certificate.

P. Sanitation and Patient Safety. All hospitals required to be licensed by the law shall comply with the Rules, Sanitary Code and enforcement policies as promulgated by the Office of Public Health. It shall be the primary responsibility of the Office of Public Health to determine if applicants are complying with those requirements. No initial license shall be issued without the applicant furnishing a certificate from the Office of Public Health stating that the applicant is complying with their provisions. A provisional license may be issued to the applicant if the Office of Public Health issues the applicant a

conditional certificate.

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§9307. Hospital Closure

A. A cessation of business is deemed to be effective with the date on which the hospital stopped providing services to the community.

1. The hospital must notify the department in writing 30 days prior to the effective date of closure.

2. The hospital shall submit a written plan for the disposition of patient medical records for approval by the department. The plan shall include the following:

a. provisions that comply with state laws on storage, maintenance, access and confidentiality of the closed hospital's patient medical records;

b. an appointed custodian who shall provide physical and environmental security that protects the records

against fire, water, intrusion, unauthorized access, loss and destruction;

c. public notice on access in the newspaper, with the largest circulation, in close proximity of the closing hospital, at least 15 days before the effective date of closure;

d. the effective date of closure.

3. The hospital must return the original license to the department.

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§9309. Exceptions

A. Exceptions to these Rules and standards governing hospitals are as follows.

1. If a hospital does not provide an optional service or department, those relating requirements shall not be applicable.

2. If a hospital is accredited by the Joint Commission on Accreditation of Healthcare Organizations or the American Osteopathic Association, the Department shall accept

such accreditation in lieu of its annual on-site re-survey. This accreditation will be accepted as evidence of satisfactory compliance with all provisions except those expressed in §9305.0 and P.

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§9311. Enforcement

A. The department shall have the authority to interpret and enforce this Chapter 93 as authorized by and in accordance with the Health Care Facilities and Services Enforcement Act, R.S. 40:2199.

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Subchapter B. Hospital Organization and Services

§9317. Governing Body

A. The hospital must have either an effective governing body or individual(s) legally responsible for the conduct of the hospital operations. No contracts/arrangements or other agreements may limit or diminish the responsibility of the governing body.

B. The governing body shall:

1. establish hospital-wide policy;
2. adopt bylaws;
3. appoint a chief executive officer or administrator;
4. maintain quality of care;
5. determine, in accordance with state law, which categories of practitioners are eligible candidates for appointment to the medical staff; and
6. provide an overall institutional plan and budget.

C. The governing body and/or their designee(s) shall develop and approve policies and procedures which define and describe the scope of services offered. They shall be revised as necessary and reviewed at least annually.

D. There shall be an organizational chart that delineates lines of authority and responsibility for all hospital personnel.

E. In addition to requirements stated herein, all

licensed hospitals shall comply with applicable local, state, and federal laws and regulations.

F. All off-site campuses operating under the license of a single provider institution (i.e., a hospital with a main facility and off-site campuses) are subject to the control and direction of one common governing body that is responsible for the operational decisions of the entire hospital enterprise.

1. The off-site campus is subject to the bylaws and operating decisions of the provider's governing body.

2. The provider has final responsibility for administrative decisions, final approval for personnel actions and final approval for medical staff appointments at the off-site campus.

3. The off-site campus functions as a department of the provider.

4. The off-site campus is included under the accreditation of the provider, if the provider is accredited by a national accrediting body, and the accrediting body recognizes the off-site campus as part of the provider.

5. The off-site campus director is under the day-to-day supervision of the provider, as evidenced by:

a. patients treated at the off-site campus are considered patients of the provider and shall have full access to all appropriate provider services;

b. the off-site campus is held out to the public as part of the hospital, i.e., patients know they are entering the provider and will be billed accordingly;

c. the off-site campus director or the individual responsible for the day-to-day operations at the site maintains a daily reporting relationship and is accountable to the provider's chief executive officer and reports through that individual to the provider's governing body; and

d. the administrative functions of the off-site campus, (i.e., QI, infection control, dietary, medical records, billing, laundry, housekeeping and purchasing) are integrated with those of the provider, as appropriate to that off-site campus.

6. All components of a single provider institution must comply with applicable state licensing laws.

G. If emergency services are not provided at the hospital, the governing body shall assure that the medical staff has written policies and procedures for appraisal of emergencies, initial treatment and transfer as appropriate.

1. These policies and procedures shall address at a minimum the following:

a. needed emergency equipment and drugs to include but not limited to, suction, oxygen and ambu bag;

b. competence of staff appropriate to the

approved use of emergency equipment and drugs;

- c. determining when an emergency exists;
- d. rendering life saving first aid;
- e. making appropriate referrals to hospitals

that are capable of providing needed services.

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§9319. Patient Rights and Privacy

A. Every patient shall have the following rights, none of which shall be abridged by the hospital or any of its staff. The hospital administrator shall be responsible for developing and implementing policies to protect patient rights and to respond to questions and grievances pertaining to patient rights. These rights shall include at least the following:

1. every patient, or his/her designated representative, shall whenever possible, be informed of the patient's rights and responsibilities in advance of furnishing or discontinuing patient care;

2. the right to have a family member, chosen

representative and/or his or her own physician notified promptly of admission to the hospital;

3. the right to receive treatment and medical services without discrimination based on race, age, religion, national origin, sex, sexual preferences, handicap, diagnosis, ability to pay or source of payment;

4. the right to be treated with consideration, respect and recognition of their individuality, including the need for privacy in treatment;

5. the right to be informed of the names and functions of all physicians and other health care professionals who are providing direct care to the patient. These people shall identify themselves by introduction and/or by wearing a name tag;

6. the right to receive, as soon as possible, the services of a translator or interpreter to facilitate communication between the patient and the hospital's health care personnel;

7. the right to participate in the development and implementation of his/her plan of care;

8. every patient or his or her representative (as allowed by state law) has the right to make informed decisions regarding his or her care;

9. the patient's rights include being informed of

his/her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate;

10. the right to be included in experimental research only when he or she gives informed, written consent to such participation, or when a guardian provides such consent for an incompetent patient in accordance with appropriate laws and regulations. The patient may refuse to participate in experimental research, including the investigations of new drugs and medical devices;

11. the right to be informed if the hospital has authorized other health care and/or educational institutions to participate in the patient's treatment. The patient shall also have a right to know the identity and function of these institutions, and may refuse to allow their participation in his/her treatment;

12. the right to formulate advance directives and have hospital staff and practitioners who provide care in the hospital comply with these directives;

13. the right to be informed by the attending physician and other providers of health care services about any continuing health care requirements after his/her discharge from

the hospital. The patient shall also have the right to receive assistance from the physician and appropriate hospital staff in arranging for required follow-up care after discharge;

14. the right to have his/her medical records, including all computerized medical information, kept confidential;

15. the right to access information contained in his/her medical records within a reasonable time frame;

16. the right to be free from restraints of any form that are not medically necessary or are used as a means of coercion, discipline, convenience or retaliation by staff;

17. the right to be free from all forms of abuse and harassment;

18. the right to receive care in a safe setting;

19. the right to examine and receive an explanation of the patient's hospital bill regardless of source of payment, and may receive upon request, information relating to financial assistance available through the hospital;

20. the right to be informed in writing about the hospital's policies and procedures for initiation, review and resolution of patient complaints, including the address and telephone number of where complaints may be filed with the department;

21. the right to be informed of his/her

responsibility to comply with hospital rules, cooperate in the patient's own treatment, provide a complete and accurate medical history, be respectful of other patients, staff and property, and provide required information regarding payment of charges;

22. except in emergencies, the patient may be transferred to another facility only with a full explanation of the reason for transfer, provisions for continuing care and acceptance by the receiving institution; and

23. the right for each inpatient or, if applicable, the patient's legal guardian, to have one opportunity to designate an uncompensated caregiver following the patient's inpatient admission into a hospital and prior to the patient's discharge, for provision of the patient's post hospital aftercare at the patient's residence.

B. The policies on patient rights and responsibilities shall also provide that patients who receive treatment for mental illness or developmental disability, in addition to the rights listed herein, have the rights provided in the Louisiana Mental Health Law.

C. Hospital staff assigned to provide direct patient care shall be informed of and demonstrate their understanding of the policies on patient rights and responsibilities through orientation and appropriate in service training activities.

AUTHORITY NOTE: Promulgated in accordance with R.S.

40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of the Secretary, LR 13:246 (April 1987), amended by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 21:177 (February 1995), LR 29:2405 (November 2003), amended by the Department of Health, Bureau of Health Services Financing, LR 43:74 (January 2017).

§9321. Medical Staff

A. The medical staff develops and adopts bylaws and rules for self-governance of professional activity and accountability to the governing body. In addition to physicians and dentists, the medical staff membership shall include licensed independent practitioners as appropriate to adequately meet the needs of the patients served by the hospital. The bylaws and rules shall contain provisions for at least the following.

1. The medical executive committee shall:

a. develop the structure of the medical staff and categories of membership;

b. develop and implement a mechanism to review credentials, at least every two years, and delineate individual privileges;

c. develop and implement a mechanism for determining that all medical staff hold current Louisiana

licenses;

d. make recommendations for membership to medical staff, for approval by the governing body, with initial appointments and reappointments not to exceed two years;

e. develop and implement a mechanism for suspension and/or termination of membership to the medical staff;

f. develop and implement a mechanism for fair hearings and appellate reviews for both potential (new) applicants and current members of the medical staff;

g. define the required functions of the medical staff to include:

i. basic medical record review, drug usage review, pharmacy and therapeutics review, infection control and utilization review;

ii. if applicable, surgical and other invasive procedures and blood usage.

2. The medical staff shall provide a mechanism to monitor and evaluate the quality of patient care and the clinical performance of individuals with delineated clinical privileges.

3. Each person admitted to the hospital shall be under the care of a member of the medical staff and shall not be admitted except on the recommendation of a medical staff member.

4. There shall be a member of the medical staff on call at all times for emergency medical care of hospital patients.

5. The medical staff bylaws shall include specifications for orders for the care or treatment of patients which are given to the hospital verbally or transmitted to the hospital electronically, whether by telephone, facsimile transmission or otherwise. Such bylaws may grant the medical staff up to 10 days following the date an order is transmitted verbally or electronically to provide the signature or countersignature for such orders.

6. There shall be a single chief medical officer who reports directly to the governing body and who is responsible for all medical staff activities of all the offsite facilities operating under the license of the hospital.

7. There shall be total integration of the organized medical staff as evidenced by these factors:

a. all medical staff members have privileges at all off-site campuses;

b. all medical staff committees are responsible for their respective areas of responsibility at all off-site campuses of the hospital; and

c. the medical director of the off-site campus (if the off-site campus has a medical director) maintains a day-

to-day reporting relationship to the chief medical officer or other similar official of the provider.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of the Secretary, LR 13:246 (April 1987), amended by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 21:177 (February 1995), LR 29:2406 (November 2003).

§9323. Administration

A. There shall be a chief executive officer or administrator who is responsible for the operation of the hospital commensurate with the authority conferred by the governing body. All administrative authority shall flow through the chief executive officer who exercises control and surveillance over the administrative activities of the hospital and of all off-site campuses. (This does not preclude the establishment of assistant executive officer positions in any off-site campus as long as the individuals are under the authority of and report to the chief executive officer.)

B. The chief executive officer or administrator of the hospital shall have at least one of the following qualifications:

1. a master's degree and at least three years of

full-time experience in progressively responsible management positions in healthcare;

2. a baccalaureate degree and at least five years of full-time experience in progressively responsible management positions in healthcare; or

3. at least 10 years of full-time experience in hospital administration;

a. hospital chief executive officers and administrators employed in Louisiana licensed hospitals at the time the final regulations are adopted and become effective shall be deemed to meet the qualifications as long as the individual holds their current position. If the individual leaves their current position as hospital administrator/chief executive officer, they must meet one of the qualifications above to be re-employed into such a position.

C. There shall be sufficient qualified personnel to properly operate each department of the hospital and provide quality patient care and related services.

D. All new employees, including volunteer workers, prior to or at the time of employment and annually thereafter shall be verified to be free of tuberculosis in a communicable state.

E. The hospital shall have policies and procedures that define how the facility will comply with current regulations regarding healthcare screenings of hospital personnel.

F. The hospital shall have policies and procedures and require all personnel to immediately report any signs or symptoms of a communicable disease or personal illness to their supervisor or administrator as appropriate for possible reassignment or other appropriate action to prevent the disease or illness from spreading to other patients or personnel.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of the Secretary, LR 13:246 (April 1987), amended by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 21:177 (February 1995), LR 29:2407 (November 2003).

§9325. Staff Orientation, Training, Education and Evaluation

A. New employees, including contract employees, shall have an orientation program of sufficient scope and duration to inform the individual about his/her responsibilities and how to fulfill them.

B. The orientation program shall include, at least, a review of policies and procedures, job descriptions, competency evaluation and performance expectations prior to the employee performing his/her responsibilities.

C. A staff development program shall be conducted by educationally competent staff and/or consultants and planned

based upon annual employee performance appraisals, patient population served by the hospital, information from quality assessment and improvement activities, and/or as determined by facility staff.

D. The hospital shall document appropriate training and orientation prior to reassignment of currently employed staff.

E. Records shall be maintained that indicate the training content, time, names of employees in attendance and the name of the presenter.

F. At least annually the performance of all hospital and contract employees shall be evaluated.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of the Secretary, LR 13:246 (April 1987), amended by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 21:177 (February 1995), LR 29:2407 (November 2003).

§9327. Emergency Services

A. If emergency services are provided, the emergency services shall be on a 24-hour/seven-day basis in an emergency care area. The hospital shall have at least 1 physician available to the emergency care area within 30 minutes through a medical call roster.

B. Organization

1. Emergency services shall have written policies and procedures which:

a. define and describe the scope of services offered;

b. assures the integration of emergency services with other hospital services, delineating when the hospital shall divert emergency patients, the criteria for the diversion, and the notification of local emergency medical services and hospitals of the diversion; and

c. governs referrals if a clinical specialty service is not provided.

2. The emergency services shall be organized under the direction of a qualified member of the medical staff and a roster of on-call medical staff with service specialties shall be maintained. The services shall be integrated with other departments of the hospital. Ancillary services routinely available at the hospital for inpatients shall be available to patients presenting with emergency medical conditions.

3. The emergency service area shall be supplied with:

a. basic trauma equipment and drugs;

b. suction and oxygen equipment; and

c. cardiopulmonary resuscitation equipment.

C. All licensed hospitals shall comply with current provisions of the Emergency Medical Treatment and Active Labor Act (EMTALA).

D. In accordance with R.S. 40:2113.6, no officer or member of the medical staff of a hospital licensed by the department shall deny emergency services available at the hospital to a person diagnosed by a licensed physician as requiring emergency services because the person is unable to establish his ability to pay for the services or his race, religion or national ancestry. In addition, the person needing the services shall not be subjected to arbitrary, capricious or unreasonable discrimination based on age, sex, physical condition or economic status. Emergency services are services that are usually and customarily available at the hospital and that must be provided immediately to stabilize a medical condition which if not stabilized could reasonably be expected to result in the loss of life, serious permanent disfigurement or loss or impairment of the function of a bodily member or organ, or for the care of a woman in active labor if the hospital is so equipped. If not so equipped, the hospital must provide treatment to allow the patient to travel to a more appropriate facility without undue risk of serious harm.

E. Personnel

1. The emergency services shall make provisions for

physician coverage at all hours and a qualified member of the medical staff shall be designated to supervise emergency services. There shall be a registered nurse and other nursing service personnel qualified in emergency care to meet written emergency procedures and needs anticipated by the hospital. All registered nurses working in emergency services shall be trained in advanced cardiac life support, pediatric trauma and pediatric advanced life support.

2. There are specific assigned duties for emergency care personnel with a clear chain of command.

F. The hospital shall maintain an emergency service register on every individual seeking care. At a minimum, the register shall contain the following data:

1. name, age and sex of patient;
2. date, time and means of arrival;
3. nature of complaint;
4. disposition;
5. time of departure;
6. name of the on-call or treating physician.

G. Trauma Center. In addition to the requirements above, all hospitals that request official designation by the Department as a "Trauma Center" must meet the requirements provided under state law (R.S. 40:2171).

AUTHORITY NOTE: Promulgated in accordance with R.S.

40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of the Secretary, LR 13:246 (April 1987), amended by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 21:177 (February 1995), LR 29:2407 (November 2003).

§9329. After Life Care

A. The hospital shall establish and implement written policies and procedures governing after life care that are reviewed annually and revised as needed. These policies shall delineate the responsibilities of the medical staff, nursing and morgue staff, and shall include procedures for at least the following:

1. identifying the body;
2. safe and proper handling to prevent damage to the body;
3. safeguarding the personal effects of the deceased and release of personal effects to the appropriate individual;
4. handling of toxic chemicals by morgue and housekeeping staff;
5. infection control, including disinfecting of equipment;
6. identifying and handling high-risk and/or infectious bodies in accordance with Centers for Disease Control

guidelines and in compliance with Louisiana law;

7. release of the body to the funeral director;

8. release of the body to the coroner upon his request for autopsy;

9. policy for autopsy requests by the physician or family and physician communication to family members regarding the autopsy requests/results;

10. availability of autopsy reports, including reports of microscopic autopsy findings, to physicians and in the medical records within specified time frames; and

11. completion of the autopsy, including microscopic and other procedures, within specified time frames.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of the Secretary, LR 13:246 (April 1987), amended by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 21:177 (February 1995), LR 29:2408 (November 2003).

§9331. Organ or Tissue Donation

A. The hospital shall have policies and procedures for organ and tissue donation and requests for donation, approved by the governing body.

B. The hospital shall have an agreement with the

designated organ procurement agency for the state and at least one tissue bank and one eye bank, if the organ procurement agency does not include these services.

C. When death is imminent or has occurred in a hospital, to a person determined to be a suitable candidate for organ or tissue donation, based on accepted medical standards, the hospital administrator or designated representative shall request the appropriate person described herein to consent to the gift of any part of the decedent's body as an anatomical gift.

D. No request shall be required when the requesting person has actual notice of contrary intention by the decedent or those persons described in this regulation according to the priority stated therein, or reason to believe that an anatomical gift is contrary to the decedent's religious beliefs.

E. Upon approval of the donation, the OPO or retrieval organization shall be notified and shall cooperate in the procurement of the anatomical gift. When a request is made, the person making the request shall complete a certificate of request for an anatomical gift on a form approved by the Department of Health and Hospitals.

F. The certificate shall include the following:

1. a statement indicating that a request for an anatomical gift was made;

2. the name and affiliation of the person making the request;

3. an indication of whether consent was granted and, if so, what organs and tissues were donated;

4. the name of the person granting or refusing the request, and his relationship to the decedent.

G. A copy of the certificate of request shall be included in the decedent's medical records.

H. The following persons shall be requested to consent to a gift, in the order of priority stated:

1. the spouse if one survives; if not:
 - a. an adult son or daughter;
 - b. either parent;
 - c. an adult brother or sister;
 - d. the curator or tutor of the decedent at the time of death;
 - e. any other person authorized or under obligation to dispose of the body.

I. Upon the arrival of a person who is dead or near death, a reasonable search for a document of gift or other information which may indicate that a person is a donor or has refused to make such a donation shall be made by the hospital.

J. If a person at or near death has been admitted or is in transit to a hospital and has been identified as a donor of

his body, organs, tissue or any part thereof, the hospital shall immediately notify the named recipient if one is named and known, and if not, the OPO federally approved organ procurement agency.

K. The hospital shall cooperate in the implementation of the anatomical gift, including the removal and release of organs and tissue, or any parts thereof.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of the Secretary, LR 13:246 (April 1987), amended by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 21:177 (February 1995), LR 29:2408 (November 2003).

§9333. Specialty Units

A. Specialty units are designated areas in a hospital organized and dedicated to providing a specific, concentrated service to a targeted group of patients.

B. Each unit shall be organized and function as a physically identifiable section with beds that are not commingled with other hospital beds.

C. Each unit shall be staffed with professional and support personnel, appropriate to the scope of services provided. Central support services such as dietary,

housekeeping, maintenance, administration and therapeutic services may be shared with the rest of the hospital.

D. There shall be written policies and procedures that define and describe the scope of services offered, including admission criteria. The policies and procedures shall be developed and approved by the governing body. They shall be reviewed at least annually and revised as necessary.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of the Secretary, LR 13:246 (April 1987), amended by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 21:177 (February 1995), LR 29:2409 (November 2003).

§9335. Emergency Preparedness

A. The hospital shall have an emergency preparedness plan designed to manage the consequences of natural disasters or other emergencies that disrupt the hospital's ability to provide care and treatment or threatens the lives or safety of the hospital patients and/or the community it serves. The emergency preparedness plan shall be made available, upon request or if mandated to do so, to local, parish, regional and/or state emergency planning organizations, DHH and the Office of the State Fire Marshal.

- B. As a minimum, the plan shall include the following:
1. identification of potential hazards that could necessitate an evacuation, including internal and external disasters such as a natural disaster, acts of bio-terrorism, weapons of mass destruction, labor work stoppage, or industrial or nuclear accidents;
 2. emergency procedures for evacuation of the hospital;
 3. comprehensive measures for receiving and managing care for a large influx of emergency patients. At a minimum, these measures shall include the following roles:
 - a. the emergency department/services;
 - b. surgical suite; and
 - c. patient care units;
 4. comprehensive plans for receiving patients who are being relocated from another facility due to a disaster. This plan shall include at least an estimate of the number and type of patients the facility would accommodate;
 5. procedures in the case of interruption of utility services in a way that affects the health and safety of patients;
 6. identification of the facility and an alternate facility to which evacuated patients would be relocated;
 7. the estimated number of patients and staff that

would require relocation in the event of an evacuation;

8. the system or procedure to ensure that medical charts accompany patients in the event of a patient evacuation and that supplies, equipment, records and medications would be transported as part of an evacuation; and

9. the roles and responsibilities of staff members in implementing the disaster plan.

C. The hospital shall assure that patients receive nursing care throughout the period of evacuation and while being returned to the original hospital.

D. The hospital shall ensure that evacuated patients, who are not discharged, are returned to the hospital after the emergency is over, unless the patient prefers to remain at the receiving facility or be discharged instead of being returned to the original hospital.

E. Any staff member who is designated as the acting administrator shall be knowledgeable about, and authorized to implement the hospital's plans in the event of an emergency.

F. The hospital administrator shall appoint an individual who shall be responsible for disaster planning for the hospital.

G. While developing the hospital's plan for evacuating patients, the disaster planner shall communicate with the facility or facilities designated to receive relocated patients.

H. The hospital shall conduct at least one evacuation

drill each year, either simulated or using selected patients. An actual evacuation shall be considered a drill, if it is documented.

I. The hospital shall conduct at least one drill each year, in which a large influx of emergency patients is simulated. An actual emergency of this type shall be considered a drill, if it is documented.

J. In case of an emergency, the hospital shall have a policy for supply of food and water.

K. The hospital shall have a policy for the provision of emergency sources of critical utilities such as electricity, natural gas, water and fuel during any period in which the normal supply is temporarily disrupted.

L. The hospital's plan shall be developed in coordination with the local/parish office of emergency preparedness, utilizing community wide resources.

M. A hospital may temporarily exceed its licensed capacity in emergency situations, such as natural disasters or disease related emergencies. Such hospitals shall notify DHH in writing of the situation within 24 hours or as soon as practical thereafter.

N. Effective immediately, upon declaration of the secretary and notification to the Louisiana Hospital Association, all hospitals licensed in Louisiana shall file an

electronic report with the EMSsystem, or a successor operating system during a declared emergency, disaster or public health emergency.

1. The electronic report shall be filed twice daily at 7:30 a.m. and 2:30 p.m. throughout the duration of the disaster or emergency event.

2. The electronic report shall include, but not be limited to the following:

a. status of operation (open, limited or closed);

b. availability of beds by category (medical/surgery, intensive care unit, pediatric, psychiatric, etc.);

c. other resources that may be needed by a hospital in an emergency (blood products, fuel, pharmaceuticals, personnel, etc.);

d. generator status;

e. evacuation status; and

f. shelter in place status.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 21:177 (February 1995), amended LR

29:2409 (November 2003), LR 35:245 (February 2009).

§9337. Smoking Prohibition

A. Smoking shall be prohibited in all areas of the hospital that are heated and air-conditioned. At the discretion of the hospital's governing body, smoking may be permitted in patient rooms, but only:

1. upon the consent of the patient's primary treating physician;
2. with the consent of all patients in the room;
3. in accordance with all standards established by the Joint Commission on Accreditation of Health Care Organizations and all other applicable state and federal laws.

B. Notwithstanding the provisions of the above, the hospital's governing body may designate a well-ventilated area for smokers. Additionally, the governing body of a psychiatric hospital shall establish policies to reasonably accommodate inpatients that smoke.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of the Secretary, LR 13:246 (April 1987), amended by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 21:177 (February 1995), LR 29:2410 (November 2003).

Subchapter C. Nursing Services

§9343. Organization and Staffing

A. There shall be an organized nursing service that provides 24-hour nursing services. The nursing services shall be under the direction and supervision of a registered nurse licensed to practice in Louisiana, employed full time, 40 hours per week. There shall be a similarly qualified registered nurse to act in the absence of the director of nursing services.

B. Written nursing policies and procedures shall define and describe the patient care provided. There shall be a written procedure to ensure that all licensed nurses providing care in the hospital have a valid and current Louisiana license to practice, prior to providing any care.

C. Nursing services are either furnished or supervised and evaluated by a registered nurse.

D. There shall be at least one registered nurse on duty at all times, assigned to each inpatient nurse's station.

E. A registered nurse shall assign the nursing service staff for each patient in the hospital. Staffing shall be planned in accordance with the nursing needs of the patients, as demonstrated by a specific assessment process, specialized qualifications and competence of the nursing staff available.

F. The nursing staff shall be assigned clinical and/or management responsibilities according to education, experience

and assessment of current competency and applicable laws.

G. There shall be at least two hospital employees, one of whom shall be a registered nurse, physically present in the hospital when there is one or more hospitalized patients.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of the Secretary, LR 13:246 (April 1987), amended by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 21:177 (February 1995), LR 29:2410 (November 2003).

§9345. Delivery of Services

A. A registered nurse shall perform an initial assessment of the patient upon admission and identify problems for each patient. The registered nurse may delegate part(s) of the data collection to other nursing personnel, however the registered nurse shall by signature validate the assessment.

B. A nursing plan of care shall be developed based on identified nursing diagnoses and/or patient care needs and patient care standards, implemented in accordance with the Louisiana Nurse Practice Act, and shall be consistent with the plan of all other health care disciplines.

C. Isolation precautions shall be instituted when appropriate to prevent the spread of communicable diseases

within the hospital.

D. All drugs and biologicals shall be administered in accordance with the orders of the practitioner(s) responsible for the patient's care and accepted standards of practice.

E. Blood transfusions and intravenous medications shall be handled, labeled and administered according to state law and approved medical staff and nursing service policies and procedures.

F. Blood and blood products shall be refrigerated separately from food, beverages and laboratory specimens.

G. An appropriate patient consent form shall be signed prior to blood transfusion administration.

H. There shall be policies and procedures for reporting transfusion reactions, adverse drug reactions and errors in the administration of drugs. It shall include immediate oral reporting to the treating physician, a written report to the director of pharmacy and the appropriate hospital committee, and an appropriate entry in the patient's record.

I. Safety policies and procedures shall be established for the care of patients, who because of their condition, are not responsible for their acts.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health

and Human Resources, Office of the Secretary, LR 13:246 (April 1987), amended by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 21:177 (February 1995), LR 29:2410 (November 2003).

Subchapter D. Pharmaceutical Services

§9349. General Provisions

A. The hospital shall provide pharmaceutical services that meet the needs of the patients. The hospital shall have a pharmacy directed by a registered pharmacist or a drug storage area supervised by a registered pharmacist. The hospital pharmacy shall have a permit, issued by the Louisiana Board of Pharmacy, allowing the ordering, storage, dispensing and delivering of legend prescription orders. The hospital shall have a current controlled dangerous substance (CDS) license to dispense controlled substances to patients in the hospital.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of the Secretary, LR 13:246 (April 1987), amended by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 21:177 (February 1995), LR 29:2411 (November 2003).

§9351. Organization and Staffing

A. Pharmaceutical services shall be directed by a

registered pharmacist, licensed to practice in Louisiana on either a full-time, part-time or consulting basis. The director of pharmacy shall be responsible for the procurement, storage, dispensing, supervision and management of all legend and non-legend drugs for the hospital, and shall maintain complete and accurate records of all drug transactions by the pharmacy. There shall be an adequate number of personnel to ensure quality services, including emergency services, 24 hours per day, seven days per week. A pharmacist shall be on call after hours, whenever the pharmacy does not provide 24-hour service.

B. Hospital pharmacies that are not staffed on a 24-hour basis shall have an adequate security detection device.

C. Hospital pharmacies that are not open after regular working hours shall make drugs available for the staff by use of a night drug cabinet. The hospital pharmacy shall maintain an inventory and a list of these drugs, which are approved by the pharmacy director and the appropriate hospital committee.

D. Each off-site campus shall have a site specific controlled dangerous substance (CDS) license if they will be dispensing controlled dangerous substances.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of the Secretary, LR 13:246 (April

1987), amended by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 21:177 (February 1995), LR 29:2411 (November 2003).

§9353. Delivery of Services

A. All compounding, packaging, and dispensing of drugs, biologicals, legend and controlled substances shall be accomplished in accordance with Louisiana law and Board of Pharmacy regulations and be performed by or under the direct supervision of a registered pharmacist currently licensed to practice in Louisiana.

B. Dispensing of prescription legend or controlled substance drugs direct to the public or patient by vending machines is prohibited.

C. Current and accurate records shall be maintained on the receipt, distribution and dispensing of all scheduled drugs in such a manner as to facilitate complete accounting for the handling of these controlled substances. An annual inventory, at the same time each year, shall be conducted for all schedule I, II, III, IV and V drugs.

D. A hospital outpatient pharmacy shall maintain all records and inventory separate and apart from that of the inpatient pharmacy, and shall require a separate pharmacy permit to operate.

E. Medications are to be dispensed only upon written

orders, electromechanical facsimile, or oral orders from a physician or other legally authorized prescriber, and be taken by a qualified professional.

F. All inpatient drug containers shall be labeled to show at least the patient's full name, room number, the chemical or generic drug's name, strength, quantity and date dispensed unless a unit dose system is utilized. Appropriate accessory and cautionary statements as well as the expiration date shall be included. Floor stock containers shall contain the name and strength of the drug, lot and control number or equivalent, and the expiration date. In unit dose systems, each single unit dose package shall contain the name and strength of the drug, lot and control number or equivalent, and expiration date. Outpatient drug containers shall be labeled to show at least the patient's full name, the prescriber's name, the chemical or generic drug's name, directions, name of the pharmacy and pharmacist, prescription number, and appropriate accessory and cautionary statements. Outdated, mislabeled or otherwise unusable drugs and biologicals shall be separated from useable stock, shall not be available for patient or other use and shall be returned to an authorized agency for credit or destroyed according to current state or federal laws as applicable.

G. Drugs and biologicals not specifically prescribed as to time or number of doses shall automatically be stopped after

a reasonable time that is predetermined by the medical staff.

H. The director of pharmacy shall develop and implement a procedure that in the event of a drug recall, all employees involved with the procurement, storage, prescribing, dispensing and administering of recalled drugs in the facility will be notified to return these drugs to the pharmacy for proper disposition.

I. Drug administration errors, adverse drug reactions, and incompatibilities shall be immediately reported to the attending physician, pharmacist and, if appropriate, to the hospital-wide quality assessment and improvement program. An entry shall be made in the patient's record.

J. Abuses and losses of controlled substances shall be reported to the individual responsible for pharmaceutical services, the chief executive officer, the Louisiana Board of Pharmacy, and to the Regional Drug Enforcement Administration (DEA) office, as appropriate.

K. Information relating to drug interactions, drug therapy, side effects, toxicology, dosage, indications for use and routes of administration shall be available to the staff.

L. A formulary system shall be established by the appropriate hospital committee to assure quality pharmaceuticals at reasonable costs, subject only to the restrictions of R.S. 37:1226.1 and LAC 46:LIII.1109.B.6.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of the Secretary, LR 13:246 (April 1987), amended by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 21:177 (February 1995), LR 29:2411 (November 2003).

§9355. Environment

A. All drugs and biologicals shall be kept in a locked, well illuminated clean medicine cupboard, closet, cabinet, or room under proper temperature controls and accessible only to individuals authorized to administer or dispense drugs. A list of authorized individuals shall be developed in cooperation with the medical, nursing, administrative and pharmaceutical staff. Compartments appropriately marked shall be provided for the storage of poisons and external use drugs and biologicals, separate from internal and injectable medications.

B. All controlled substances shall be kept separately from other non-controlled substances in a locked cabinet or compartment. Exceptions may be made, if listed in the pharmacy policy and procedures manual and deemed necessary by the director of pharmacy, to allow some abusable nonscheduled drugs to be maintained in the same locked compartment.

C. Drugs and biologicals that require refrigeration shall

be stored separately from food, beverages, blood and laboratory specimens.

D. The area within the pharmacy used for the compounding of sterile parenteral preparations shall be separate and apart, shall meet the requirements of the Board of Pharmacy regulation §2541 and be designed and equipped to facilitate controlled aseptic conditions.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of the Secretary, LR 13:246 (April 1987), amended by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 21:177 (February 1995), LR 29:2412 (November 2003).

Subchapter E. Radiologic Services

§9361. General Provisions

A. The hospital shall maintain, or have available through written contract, radiologic services according to the needs of the patients. If therapeutic services are also provided, they, as well as the diagnostic services, shall meet professionally approved standards for safety and personnel qualifications. The hospital shall comply with periodic inspections by the Department of Environmental Quality, Radiation Protection Division and shall promptly correct any identified hazards.

B. Radiologic services shall be supervised by a qualified radiologist on either a full-time, part-time or consulting basis.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing LR 21:177 (February 1995), amended LR 29:2412 (November 2003).

§9363. Safety

A. The radiologic services, particularly ionizing radiology, shall adopt written policies and procedures to provide for the safety and health of patients and hospital personnel. The policies and procedures shall be available to all staff in the radiology department. At a minimum, the policies and procedures shall cover the following:

1. shielding for patients, personnel and facilities;
2. storage, use and disposal of radioactive materials;
3. periodic inspection of equipment and handling of identified hazards;
4. periodic checks by exposure meters or test badges on radiation workers;
5. radiologic services provided on the orders of

practitioners with clinical privileges or other practitioners authorized by the medical staff and the governing body to order the service; and

6. managing medical emergencies in the radiologic department.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing LR 21:177 (February 1995), amended LR 29:2412 (November 2003).

§9365. Personnel

A. A qualified full-time, part-time, or consulting radiologist must supervise the ionizing radiology services and must interpret only those radiologic tests that are determined by the medical staff to require a radiologist's specialized knowledge. The radiologist shall have clinical privileges delineated by the medical staff.

B. Only personnel who are registered and/or licensed in the appropriate radiologic technology modality or category by the Louisiana State Radiologic Technology Board of Examiners and designated as qualified by the medical staff may use the radiologic equipment and administer procedures under the direction of a physician.

AUTHORITY NOTE: Promulgated in accordance with R.S.
40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health
and Hospitals, Office of the Secretary, Bureau of Health
Services Financing LR 21:177 (February 1995), amended LR 29:2413
(November 2003).

§9367. Records

A. Radiologic reports shall be signed by the practitioner
who reads and interprets them.

AUTHORITY NOTE: Promulgated in accordance with R.S.
40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health
and Hospitals, Office of the Secretary, LR 13:246 (April 1987),
amended LR 21:177 (February 1995), LR 29:2413 (November 2003).

Subchapter F. Laboratory Services

§9371. Organization and Staffing

A. The hospital shall provide laboratory services or make
contractual arrangements with a laboratory certified in
accordance with the Clinical Laboratory Improvement Amendments
(CLIA) of 1988 to perform services commensurate with patient
needs as determined by the medical staff on a 24-hour basis.
Laboratory services shall be directed by an individual who meets
appropriate qualifications of a director and is credentialed by
the medical staff.

B. There shall be sufficient licensed qualified clinical laboratory scientists with documented training and experience to supervise the testing and sufficient numbers of licensed clinical laboratory scientists and supportive technical staff to perform the tests required of the clinical laboratory services.

C. The hospital shall have policies and procedures that address the administration of potentially HIV infectious blood or blood products, and the notification of patient, legal representative or relative within a specified time frame.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing LR 21:177 (February 1995), amended LR 29:2413 (November 2003).

§9373. Equipment and Records

A. There shall be sufficient supplies, equipment and space to perform the required volume of work with optimal accuracy, precision, efficiency, timeliness and safety.

B. The laboratory shall ensure that satisfactory provisions are maintained for an instrumentation preventive maintenance program, an acceptable quality control program and an approved proficiency testing program covering all types of analysis performed by the laboratory services. Records and

reports shall be maintained, retrievable, and as appropriate, filed in the patient's medical record.

C. The hospital shall make adequate provisions for the immediate pathological examination of tissue specimens by a pathologist.

D. The hospital shall make provisions for the procurement, storage and transfusion of blood and blood products.

E. The administration of blood shall be monitored to detect any adverse reaction as soon as it occurs. Prompt investigation of the cause of an adverse reaction shall be instituted. The results of all tests performed in the evaluation of an actual or suspected blood transfusion reaction shall be a permanent part of the patient's medical record.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing LR 21:177 (February 1995), amended LR 29:2413 (November 2003).

Subchapter G. Food and Dietetic Services

§9377. General Provisions

A. There shall be an organized dietary service that provides nutritional care to patients. All hospital contracts or

arrangements for off-site food preparation shall be with a provider who is licensed by the department's healthcare division or operating under the authority of the federal government.

B. A hospital may meet the requirements of §9377.A through a contractual agreement with a provider who is licensed by the department's Health Standards Section or through a contract with an outside food management company. If the hospital has a contract with an outside food management company, the following requirements shall be met.

1. The hospital must provide written notices to the department's Health Standards Section and to the department's Office of Public Health within 10 calendar days of the effective date of the contract.

2. The outside food management company must possess a valid Department of Health and Hospitals, Office of Public Health retail food permit and meet all of the requirements for operating a retail food establishment that serves a highly susceptible population, in accordance with the most current version of the provisions found in Title 51, Part XXIII, Chapter 19, §1911.

3. Either the hospital or the food management company must employ or contract with a dietician who serves the hospital on a full-time, part-time, or consultant basis to ensure that the nutritional needs of the patients are met in

accordance with the practitioners' orders and acceptable standards of practice.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing LR 21:177 (February 1995), amended LR 29:2413 (November 2003), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 38:1413 (June 2012).

§9379. Organization and Staffing

A. Food and dietetic services shall be under the supervision of a registered dietitian, licensed to practice in Louisiana, who is employed either full time, part time or on a consulting basis. If the registered dietitian is not full time, there shall be a full time dietary manager.

B. The dietary manager shall:

1. be a qualified dietitian; or
2. be a graduate of a dietetic technician program, correspondence program or otherwise approved by the American Dietetics Association; or
3. have successfully completed a course of study, by correspondence or classroom, which meets the eligibility requirements for certification by the Dietary Manager's

Association; or

4. have successfully completed a training course at a state approved school, vocational or university, which includes course work in foods and food service, supervision and diet therapy. Documentation of an eight-hour course of formalized instruction in diet therapy conducted by the employing facility's qualified dietitian is permissible if the course meets only the foods, food service and supervision requirements.

a. Exception. Hospitals with 25 or fewer beds that do not have on site food preparation for patient meals and contract for food services, another full-time employee, i.e., RN or LPN, will be allowed to carry out the responsibilities of the dietary manager. The RN or LPN must be qualified by training and experience and employed full time. The director of nursing shall not hold this position.

C. The registered dietitian shall be responsible for assuring that quality nutritional care is provided to patients. This shall be accomplished by providing and supervising the nutritional aspects of patient care including nutritional screening, nutritional assessments of patients at nutritional risk, patient education related to nutritional intake and diet therapy, and recording information in the medical record regarding the nutritional status and care of the patient and the

patient's response to the therapeutic diet.

D. The hospital shall employ sufficient support personnel, competent in their respective duties, to carry out the function of the dietary service.

E. For hospitals that provide dietary services in accordance with §9377 above, a registered dietician shall be employed or under contract to assure proper dietary services are being provided in accordance with §9379.B.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing LR 21:177 (February 1995), amended LR 29:2413 (November 2003).

§9381. Menus and Therapeutic Diets

A. Menus shall be prepared in advance, meet the nutritional needs of the patients in accordance with the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences, or as modified in accordance with the orders of the practitioner(s) responsible for the care of the patient, and followed as planned.

B. Therapeutic diets shall be prescribed by the licensed practitioner(s) responsible for the care of the patient.

Therapeutic diets, and laboratory tests to monitor the effectiveness of the dietary plan, may be prescribed by a licensed dietitian/nutritionist subject to the approval of, and authorization by, the facility's medical staff or bylaws and in accordance with state law. Each patient's nutritional intake shall be documented in the patient's medical record. Nutritional intake includes both enteral and parenteral nutrition.

C. There shall be a procedure for the accurate transmittal of dietary orders to the dietary service and for informing the dietary service when the patient does not receive the ordered diet, or is unable to consume the prescribed diet.

D. There shall be a current therapeutic diet manual, which shall be the guide used for ordering and serving diets and other nutritional intake. The manual shall be approved by the dietitian and medical staff and be readily available to all medical, nursing and food service personnel.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing LR 21:177 (February 1995), amended LR 29:2414 (November 2003), amended by the Department of Health, Bureau of Health Services Financing, LR 43:74 (January 2017).

§9383. Sanitary Conditions

A. Food shall be in good condition, free from spoilage, filth, or other contamination and shall be safe for human consumption. All food shall be procured from sources that comply with all laws and regulations related to food and food labeling. The use of food in hermetically sealed containers that was not prepared in a food processing establishment is prohibited.

B. All food shall be stored, prepared, distributed and served under sanitary conditions to prevent food borne illness. This includes keeping all readily perishable food and drink at or below 41°F, except when being prepared and served. Refrigerator temperatures shall be maintained at 41°F. or below, freezers at 0°F or below.

C. Hot foods shall leave the kitchen or steam table at or above 140°F., and cold foods at or below 41°F In-room delivery temperatures shall be maintained at 120°F or above for hot foods and 50°F or below for cold items, except for milk which shall be stored at 41°F. Food shall be transported to the patients' rooms in a manner that protects it from contamination, while maintaining required temperatures.

D. All equipment and utensils used in the preparation and serving of food shall be properly cleansed, sanitized and stored. This includes maintaining a water temperature in dish washing machines at 140°F during the wash cycle (or according to

the manufacturer's specifications or instructions) and 180°F for the final rinse. Low temperature machines shall maintain a water temperature of 120°F with 50 parts per million (ppm) of hypochlorite (household bleach) on dish surfaces. For manual washing in a 3 compartment sink, a wash water temperature of 75°F with 50 ppm of hypochlorite or equivalent, or 12.5 ppm of iodine; or a hot water immersion at 170°F for at least 30 seconds shall be maintained. An approved lavatory shall be convenient and equipped with hot and cold water tempered by means of a mixing valve or combination faucet for dietary services staff use. Any self-closing, slow-closing, or metering faucet shall be designed to provide a flow of water for at least 15 seconds without the need to reactivate the faucet. Effective with the promulgation of these requirements, an additional lavatory shall be provided in the dishwasher area in newly constructed hospitals or in existing hospitals undergoing major dietary alterations.

E. Dietary staff shall not store personal items within the food preparation and storage areas.

F. Dietary staff shall use good hygienic practices. Staff with communicable diseases or infected skin lesions shall not have contact with food, if that contact will transmit the disease.

G. Toxic items such as insecticides, detergents, polishes and the like shall be properly stored, labeled and used.

H. Garbage and refuse shall be kept in durable, easily cleanable, insect and rodent-proof containers that do not leak and do not absorb liquids. Containers used in food preparation and utensil washing areas shall be kept covered after they are filled.

I. The physical environment in which all food preparation takes place shall be kept clean and in good repair.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing LR 21:177 (February 1995), amended LR 29:2414 (November 2003).

Subchapter H. Medical Record Services

§9387. Organization and Staffing

A. There shall be a medical records department that has administrative responsibility for maintaining medical records for every person evaluated or treated as an inpatient, outpatient or emergency patient. Medical records for patients at off-site campuses shall be integrated into the unified records system of the provider.

B. Medical records shall be under the supervision of a

medical records practitioner (i.e., registered record administrator or accredited record technician) on either a full-time, part-time or consulting basis.

C. Medical records shall be legibly and accurately written in ink, dated and signed by the recording person or, if a computerized medical records system is used, authenticated, complete, properly filed and retained, and accessible.

D. If a facsimile communications system (fax) is used, the hospital shall take precautions when thermal paper is used to ensure that a legible copy is retained as long as the medical record is retained.

E. Written orders signed by a member of the medical staff shall be required for all medications and treatments administered to patients. There shall be a reliable method for personal identification of each patient. The medical staff bylaws shall include specifications for orders for the care or treatment of patients which are given to the hospital verbally or transmitted to the hospital electronically, whether by telephone, facsimile transmission or otherwise. The bylaws may grant the medical staff up to ten days following the date an order is transmitted verbally or electronically to provide the signature or countersignature for such order.

F. If rubber stamp signatures are authorized for physician use, the administrative office shall have on file a

signed statement from the medical staff member whose stamp is involved that ensures that he/she is the only one who has the stamp and uses it. The delegation of their use by others is prohibited.

G. If electronic signatures are used, the hospital shall develop a procedure to assure the confidentiality of each electronic signature and to prohibit the improper or unauthorized use of any computer generated signature.

H. There shall be adequate medical record personnel to ensure prompt completion, filing and retrieval of records.

I. The hospital shall have a system of coding and indexing medical records. The system shall allow for timely retrieval by diagnosis and procedure, in order to support quality assessment and improvement evaluations.

J. The hospital shall ensure that all medical records are completed within 30 days following discharge.

K. A patient or his/her personal representative shall be given reasonable access to the information contained in his/her hospital record. The hospital shall, upon request in writing signed and dated by either the patient or personal representative initiating the request, furnish a copy of the hospital record as soon as practicable, not to exceed 15 days following the receipt of the request and written authorization and upon payment of the reasonable cost of reproduction in

accordance with Louisiana R.S. 40:1299.96. However, the hospital may deny the patient access if a licensed health care professional has determined, in the exercise of professional judgment, that the access requested is reasonably likely to endanger the life or physical safety of the patient or another person.

L. A hospital record may be kept in any written, photographic, microfilm, or other similar method or may be kept by any magnetic, electronic, optical or similar form of data compilation which is approved for such use by the department. No magnetic, electronic, optical or similar method shall be approved unless it provides reasonable safeguards against erasure or alteration.

M. A hospital may at its discretion, cause any hospital record or part to be microfilmed, or similarly reproduced, in order to accomplish efficient storage and preservation of hospital records.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing LR 21:177 (February 1995), amended LR 29:2415 (November 2003).

§9389. Content

A. The medical record shall contain the following minimum data:

1. unique patient identification data;
2. admission and discharge dates;
3. complete history and physical examination, in accordance with medical staff policies and procedures;
4. provisional admitting diagnosis and final diagnosis;
5. medical staff orders;
6. progress notes;
7. nursing documentation and care plans;
8. record of all medical care or treatments; and
9. discharge summary.

B. The medical record shall contain the following when applicable:

1. clinical laboratory, pathological, nuclear medicine, radiological and/or diagnostic reports;
2. consultation reports;
3. pre-anesthesia note, anesthesia record, and post-anesthesia notes;
4. operative reports;
5. obstetrical records, including:
 - a. record of mother's labor, delivery, and postpartum period;

b. separate infant record containing date and time of birth, condition at birth, sex, weight at birth if condition permits weighing, and condition of infant at time of discharge;

c. autopsy reports; and/or

d. any other reports pertinent to the patient's care.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing LR 21:177 (February 1995), amended LR 29:2415 (November 2003).

§9391. Registers and Reports

A. The hospital shall have the following registers and reports, where applicable, which may be computer generated:

1. patients' register;
2. emergency room register;
3. birth register;
4. delivery room register;
5. operating room register;
6. death register;
7. analysis of hospital service via the quality

assessment and improvement program, based on patient statistics;

and

8. daily census report of admissions, births, discharges and deaths.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing LR 21:177 (February 1995), amended LR 29:2416 (November 2003).

§9393. Confidentiality

A. The hospital shall ensure the confidentiality of patient records, including information in a computerized medical record system, in accordance with the HIPAA Privacy Regulations (Title 45, Part 164, Subpart E of the Code of Federal Regulations) and any Louisiana state laws and regulations which provide a more stringent standard of confidentiality than the HIPAA Privacy Regulations. Information from or copies of records may be released only to authorized individuals, and the hospital must ensure that unauthorized individuals cannot gain access to or alter patient records. Original medical records shall not be released outside the hospital unless under court order or subpoena or in order to safeguard the record in the event of a physical plant emergency or natural disaster. Psychiatric medical records shall be segregated to ensure confidentiality.

AUTHORITY NOTE: Promulgated in accordance with R.S.
40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health
and Hospitals, Office of the Secretary, Bureau of Health
Services Financing LR 21:177 (February 1995), amended LR 29:2416
(November 2003).

§9395. Retention

A. Hospital records shall be retained by the hospital in
their original, microfilmed or similarly reproduced form for a
minimum period of 10 years from the date a patient is
discharged.

B. Graphic matter, images, x-ray films, nuclear medicine
reports and like matter that were necessary to produce a
diagnostic or therapeutic report shall be retained, preserved
and properly stored by the hospital in their original,
microfilmed or similarly reproduced form for a minimum period of
three years from the date a patient is discharged. (Note:
Medicare and/or Medicaid participating hospitals must maintain
copies of reports and printouts, films, scans and other image
records for at least five years). Such graphic matter, images,
x-ray film and like matter shall be retained for longer periods
when requested in writing by any one of the following:

1. an attending or consulting physician of the
patient;

2. the patient or someone acting legally in his/her behalf;

3. legal counsel for a party having an interest affected by the patient's medical records.

C. A hospital that is closing shall notify the department in writing at least 30 days prior to cessation of operation for approval of their plan for the disposition of patients' medical records. The plan shall contain provisions that comply with state laws on the storage, maintenance, access and confidentiality of the closed hospital's patient medical records. It shall consist of an appointed custodian who shall provide physical and environmental security that protects against fire, water, intrusion, unauthorized access, loss and destruction. The plan shall also provide public notice on access in the newspaper, with the largest circulation, in close proximity of the closing hospital.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing LR 21:177 (February 1995), amended LR 29:2416 (November 2003).

Subchapter I. Quality Assessment and Improvement

§9399. General Provisions

A. The governing body shall ensure that there is an effective, written, ongoing, hospital-wide program designed to assess and improve the quality of patient care.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing LR 21:177 (February 1995), amended LR 29:2416 (November 2003).

§9401. Clinical Plan

A. There is a written plan for assessing and improving quality that describes the objectives, organization, scope and mechanisms for overseeing the effectiveness of monitoring, evaluation, and improvement activities. All organized services related to patient care, including services furnished by a contractor, shall be evaluated. Nosocomial infections and medication therapy shall be evaluated. All medical and surgical services and other invasive procedures performed in the hospital shall be evaluated as they relate to appropriateness of diagnosis and treatment. The services provided by each practitioner with hospital privileges shall be periodically evaluated to determine whether they are of an acceptable level of quality and appropriateness.

B. Each department or service of the hospital shall

address:

1. patient care problems;
2. cause of problems;
3. documented corrective actions; and
4. monitoring or follow-up to determine

effectiveness of corrective actions taken.

AUTHORITY NOTE: Promulgated in accordance with R.S.
40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health
and Hospitals, Office of the Secretary, Bureau of Health
Services Financing LR 21:177 (February 1995), amended LR 29:2416
(November 2003).

§9403. Implementation

A. Each department or service of the hospital, through
its governing body, shall take and document appropriate remedial
action to address deficiencies found through the quality
assessment and improvement program. The hospital shall document
the outcome of all remedial actions.

AUTHORITY NOTE: Promulgated in accordance with R.S.
40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health
and Hospitals, Office of the Secretary, Bureau of Health
Services Financing LR 21:177 (February 1995), amended LR 29:2417
(November 2003).

§9405. Patient Care Services

A. The hospital shall have an on-going plan, consistent with available community and hospital resources, to provide or make available social work, psychological and educational services to meet the medically related needs of its patients.

B. The hospital shall also have an effective, on-going discharge planning program that facilitates the provision of follow-up care. Each patient's record shall be annotated with a note regarding the nature of post hospital care arrangements. Discharge planning shall be initiated in a timely manner. Patients, along with necessary medical information (e.g., the patient's functional capacity, nursing and other care requirements, discharge summary, referral forms) shall be transferred or referred to appropriate facilities, agencies or outpatient services, as needed, for follow-up or ancillary care.

1. If a patient has designated an uncompensated caregiver for aftercare, a hospital shall make a good faith attempt to notify the patient's designated caregiver of the patient's discharge to the patient's residence as soon as possible prior to the patient's discharge. If the hospital is unable to contact the designated caregiver, the lack of contact may not interfere with, delay or otherwise affect the medical care provided to the patient, or an appropriate discharge of the patient.

a. For purposes of §9405.B.1-3, a residence does not include any rehabilitation facility, hospital, nursing home, assisted living facility or group home.

2. As soon as practicable prior to the patient's discharge, the hospital shall make a reasonable effort to consult with the designated caregiver along with the patient, taking into account the capabilities and limitations of the caregiver, to accomplish the aftercare tasks that may be included in a discharge care plan that describes the patient's aftercare needs at his residence.

3. The hospital shall educate and instruct the caregiver concerning the aftercare needs of the patient in a manner that is consistent with the discharge plan and is based on the learning needs of the caregiver. In addition, the hospital shall also provide an opportunity for the caregiver and patient to ask questions and receive explanations about the aftercare tasks.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing LR 21:177 (February 1995), amended LR 29:2417 (November 2003), amended by the Department of Health, Bureau of Health Services Financing, LR 43:74 (January 2017).

Subchapter J. Physical Environment

§9409. General Provisions

A. The hospital shall be constructed, arranged and maintained to ensure the safety and well being of the patient.

B. Hospitals with specialty units such as psychiatric or rehabilitative units must also comply with the physical environment requirements as expressed within those particular chapters.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing LR 21:177 (February 1995), amended LR 29:2417 (November 2003).

§9411. Buildings

A. The buildings shall reflect good housekeeping and shall by means of an effective pest control program, be free of insects and rodents.

B. The hospital shall maintain hospital-wide ventilation, lighting and temperature controls.

C. There shall be a provision of emergency sources of critical utilities such as electricity, natural gas, water and fuel during any period in which the normal supply is temporarily disrupted.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing LR 21:177 (February 1995), amended LR 29:2417 (November 2003).

§9413. Nursing Units

A. A nurses' station equipped with a telephone and a nurse call system shall be provided in a suitable location on each nursing unit.

B. An adequate and properly equipped utility space or area shall be provided on each nursing unit for the preparation, cleaning and storage of nursing supplies and equipment used on the nursing unit. This utility space shall be so arranged as to provide for separation of clean and soiled supplies and equipment.

1. Grab bars properly located and securely mounted shall be provided at patient bathing facilities and toilet bowl with accessories.

2. A lavatory basin shall be provided in or convenient to every toilet bowl with accessories.

3. Paper towels in a satisfactory dispenser or some other acceptable type of single use towel and a satisfactory receptacle for used towels shall be provided at all lavatories.

C. Areas for the isolation of patients with communicable diseases may be established on a temporary basis as the need arises. A private room or a corridor wing may be used provided appropriate isolation techniques are enforced, including identifying signs to warn and restrict the public.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing LR 21:177 (February 1995), amended LR 29:2417 (November 2003).

§9415. Patient Rooms

A. Except as provided for in intensive care units, all patient rooms shall be outside rooms with a window area of clear glass of not less than 12 square feet.

B. In hospitals constructed prior to November 20, 1990 single rooms shall contain at least 80 square feet and multi-bed rooms shall contain at least 70 square feet per bed. In hospitals constructed subsequent to November 20, 1990 single rooms must contain at least 100 square feet and multi-bed rooms shall contain at least 80 square feet per bed, exclusive of fixed cabinets, fixtures, and equipment, in accordance with *Guidelines for Construction and Equipment of Hospital and Medical Facilities*, 1987 Edition. In hospitals constructed

subsequent to March 1, 1995, single rooms must contain at least 120 square feet and multi-bed rooms shall contain at least 100 square feet per bed, exclusive of fixed cabinets, fixtures, and equipment, in accordance with *Guidelines for Construction and Equipment of Hospitals and Medical Facilities, Current Edition*. Any patient room shall not contain more than four beds. Rooms shall have at least a 7 1/2 foot ceiling height over the required area.

C. There shall be at least 3 feet between beds.

D. Rooms shall be arranged so as to permit the movement of a wheeled stretcher to the side of each bed.

E. There shall be sufficient and satisfactory separate storage space for clothing, toilet articles and other personal belongings of patients.

F. Every patient room shall have a lavatory. This lavatory is not necessary in rooms with an adjoining toilet or bathroom that has a lavatory. In new construction, lavatory requirements will be directed by *Guidelines for Construction and Equipment of Hospitals and Medical Facilities Current Edition*.

G. There shall be at least one toilet bowl with accessories, lavatory basin and bathing facility reserved for patient use on each patient floor and additional toilets, lavatories, and bathing facilities to adequately meet the needs of employees, professional personnel and patients on each

nursing unit.

AUTHORITY NOTE: Promulgated in accordance with R.S.
40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health
and Hospitals, Office of the Secretary, Bureau of Health
Services Financing LR 21:177 (February 1995), amended LR 29:2417
(November 2003).

§9417. Patient Room Furnishings

A. A hospital type bed with suitable mattress, pillow and
necessary coverings shall be provided for each patient. There
shall be a bedside stand, chair, and wardrobe, locker, or closet
suitable for hanging full-length garments and storing personal
effects for each patient.

B. A nurses call system, within easy reach of each bed,
shall be provided. The call system shall also be provided in
each patient toilet and bathing area.

C. Each bed in multi-bed rooms shall have approved
ceiling suspended curtains, which extend around the bed to
provide total visual privacy in combination with adjacent walls
and curtains. A properly designed lamp or over-bed light, which
can be operated by the patient, shall be provided at each bed.

AUTHORITY NOTE: Promulgated in accordance with R.S.
40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health

and Hospitals, Office of the Secretary, Bureau of Health Services Financing LR 21:177 (February 1995), amended LR 29:2418 (November 2003).

§9419. Equipment

A. Equipment shall be clean and in good repair for the safety and well-being of the patients.

B. Therapeutic, diagnostic and other patient care equipment shall be maintained and serviced in accordance with the manufacturer's recommendations.

C. All patients, when appropriate due to diagnosis, shall be provided with patient care items such as a bedpan, washbasin, emesis basin, drinking glass and soap dish. These supplies and equipment shall be properly cleaned and in appropriate cases shall be sterilized between use for different patients if disposable items are not used.

D. Methods for cleaning, sanitizing, handling and storing of all supplies and equipment shall be such as to prevent the transmission of infection through their use.

E. After discharge of a patient, the bed, mattress, cover, bedside furniture, and equipment shall be properly cleaned. Mattresses, blankets and pillows assigned to patients shall be in a sanitary condition. The mattress, blankets and pillows used for a patient with an infection shall be sanitized in an acceptable manner before they are assigned to another

patient.

AUTHORITY NOTE: Promulgated in accordance with R.S.
40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health
and Hospitals, Office of the Secretary, Bureau of Health
Services Financing LR 21:177 (February 1995), amended LR 29:2418
(November 2003).

Subchapter K. Infection Control

§9423. Organization and Policies

A. The hospital shall provide a sanitary environment to
avoid sources and transmission of infections and communicable
diseases.

B. There shall be an effective infection control program
for the prevention, control, investigation and reporting of
communicable disease and infections. The infection control
program shall meet or exceed the latest criteria established by
the following:

1. Centers for Disease Control;
2. Occupational Safety and Health Administration;

and

3. *Sanitary Code* of the state of Louisiana.

C. A person or persons qualified by education and
experience and competent in infection control practices shall be
designated as infection control officer(s). This individual(s)

shall be responsible for the development and implementation of a hospital-wide infection control program.

D. The infection control officer(s) shall develop, with approval of the medical director and governing body, policies and procedures for identifying, reporting, investigating, preventing and controlling infections and communicable diseases of patients and hospital personnel. The infection control officer(s) shall maintain a log of incidents related to infections and communicable diseases.

E. Employees with symptoms of illness that have the potential of being communicable (i.e. diarrhea, skin lesions, respiratory symptoms) shall be either evaluated by hospital staff or restricted from patient care activities during the infectious stage.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing LR 21:177 (February 1995), amended LR 29:2418 (November 2003).

§9425. Responsibilities

A. The chief executive officer or administrator, the medical staff and the director of nursing services shall ensure that the hospital-wide quality assessment and improvement

program and training programs address problems identified by the infection control officer(s). They shall be responsible for the implementation of successful corrective action plans in affected problem areas. Infection control activities or programs conducted or instituted in different departments of the hospital shall have the approval of the infection control officer(s).

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing LR 21:177 (February 1995), amended LR 29:2419 (November 2003).

§9427. Laundry Services

A. A supply of clean linen, sufficient to meet the requirements of the patients, shall be provided by a laundry service either in-house, contracted with another healthcare facility or in accordance with an outside commercial laundry service. All linens shall be handled, cleaned, sanitized, stored and transported in such a way as to prevent infection.

B. Clean linen shall be delivered in such a way as to minimize microbial contamination from surface contact or airborne deposition. Soiled linen shall be collected in such a manner as to minimize microbial dissemination into the environment. All linen shall be laundered between patient use.

C. Contaminated laundry shall be specially handled according to the hospital's written protocol, which is approved by the infection control officer(s). If laundry chutes exist, linen shall be bagged and the chutes shall empty into an enclosed collection room.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing LR 21:177 (February 1995), amended LR 29:2419 (November 2003).

§9429. Central Supply

A. Space shall be provided for the preparation, storage, handling and distribution of sterile supplies and other patient care items. Functional design shall provide for the separation of soiled and contaminated supplies from those that are clean and sterile. All central supply departments shall adhere to strict traffic control in their departments. Air circulation systems in central supply shall be negative pressure in decontamination and ethylene oxide areas and positive pressure in all clean areas.

B. Hand washing facilities shall be provided in all work areas. There shall be written policies and procedures for the decontamination and sterilization of supplies and equipment,

shelf life of all stored sterile items and reuse of disposable items in accordance with the latest criteria established by the Centers for Disease Control.

C. All steam sterilizing equipment shall have live bacteriological spore monitoring performed at least weekly and with each load containing an implantable device. If tests are positive, a system shall be in place to recall supplies.

D. All ethylene oxide sterilizing equipment shall have live bacteriological spore monitoring performed with each load. There shall be ventilation of the room used for this sterilization to the outside atmosphere and there shall be a system in place to monitor trace gases of ethylene oxide at least monthly.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing LR 21:177 (February 1995), amended LR 29:2419 (November 2003).

§9431. Isolation

A. The hospital shall have appropriate facilities and procedures for infection control and the isolation of patients as necessary.

AUTHORITY NOTE: Promulgated in accordance with R.S.

40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing LR 21:177 (February 1995), amended LR 29:2419 (November 2003).

§9433. Waste and Hazardous Materials Management

A. The hospital shall have a written and implemented waste management program that identifies and controls wastes and hazardous materials. The program shall comply with all applicable laws and regulations governing wastes and hazardous materials.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing LR 21:177 (February 1995), amended LR 29:2419 (November 2003).

Subchapter L. Surgical Services (Optional)

§9437. General Provisions

A. Surgical services are provided. The services shall be well organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered, the services shall be consistent in quality with inpatient care in accordance with the complexity of services

offered.

AUTHORITY NOTE: Promulgated in accordance with R.S.
40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health
and Hospitals, Office of the Secretary, Bureau of Health
Services Financing LR 21:177 (February 1995), amended LR 29:2419
(November 2003).

§9439. Organization and Staffing

A. Surgical services shall be under the medical direction
of a qualified physician who is a member of the medical staff
and appointed by the governing body.

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

C. The surgical suite shall be supervised by a registered
nurse experienced and competent in the management of surgical
services.

D. A qualified registered nurse shall perform circulating
duties for surgical procedures performed. In accordance with the
needs of patients and the complexity of services performed,
licensed practical nurses and operating room technicians may
assist in circulatory duties under the supervision of a

registered nurse who is immediately available to respond to emergencies. Licensed practical nurses and operating room technicians may perform scrub functions under the supervision of a registered nurse.

E. The operating room register shall be complete and up-to-date. It shall include at least the following:

1. patient's name;
 2. patient's hospital identification number;
 3. date of the operation;
 4. inclusive or total time of the operation;
 5. name of the surgeon and any assistant(s);
 6. name of nursing personnel (scrub and circulating);
 7. type of anesthesia used;
 8. name of the person administering the anesthesia;
- and
9. operation performed.

F. An operative report describing techniques, findings, and tissue removed or altered shall be written or dictated immediately following surgery and signed by the surgeon. It shall include at least:

1. the name and hospital identification number of the patient;
2. date of surgery;

3. name of the surgeon and assistant(s);
4. pre-operative and post-operative diagnoses;
5. name of the specific surgical procedure(s) performed;
6. type of anesthesia administered;
7. complications, if any;
8. a description of techniques, findings, and the tissues removed or altered; and
9. prosthetic devices or implants used, if any.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing LR 21:177 (February 1995), amended LR 29:2419 (November 2003).

§9441. Delivery of Service

A. There shall be a complete history and physical work-up in the chart of every patient prior to surgery, except in emergency surgery. If the history and physical has been dictated, but not yet recorded in the patient's chart, there shall be a statement to that effect and an admission note in the chart by the practitioner who admitted the patient.

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

in emergencies. The consent form shall contain at least the following:

1. name of the patient;
2. hospital and patient identification number;
3. name of the procedure(s) or operation;
4. the reasonably foreseeable risks and benefits

involved;

5. name of the practitioner(s);
6. signature of the patient or legal guardian;
7. date and time the consent is obtained; and
8. signature and professional designation of the

person witnessing the consent.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing LR 21:177 (February 1995), amended LR 29:2420 (November 2003).

§9443. Surgery Suite and Equipment

A. The surgical suite shall be appropriately equipped and consist of a clear floor area to accommodate the equipment and personnel required, allowing for aseptic technique.

B. The surgical suite(s) shall be located in a segregated area out of the line of traffic of visitors and personnel from

other departments and arranged so as to prevent traffic through them.

C. There shall be scrub-up facilities in the surgical suite providing hot and cold running water and equipped with knee, foot or elbow faucet controls.

D. There shall be a provision for washing instruments and equipment, which are to be cleaned within the surgical suite. If an autoclave is present, the same operating requirements referenced in Subchapter K, Infection Control shall be implemented.

E. There shall be policies and procedures, approved by the Infection Control Committee that addresses terminal cleaning of the operating room as well as cleaning of the room between surgical cases.

F. The emergency equipment in the surgical suite shall include:

1. a communication system that connects each operating room with a control center;
2. cardiac monitor;
3. resuscitator;
4. defibrillator;
5. aspirator; and
6. tracheotomy set.

AUTHORITY NOTE: Promulgated in accordance with R.S.

40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing LR 21:177 (February 1995), amended LR 29:2420 (November 2003).

§9445. Post-Operative Area

A. There shall be a post-operative care area (recovery room) which is a separate area of the hospital, unless provisions are made for close observation of the patient until they have regained consciousness (e.g., direct observation by an RN in the patient's room). Access shall be limited to authorized personnel. There shall be policies and procedures which specify transfer requirements to and from the post-operative area.

B. There shall be at least two health care personnel, one of which is a registered nurse, present whenever there is a patient. There shall be emergency equipment and monitoring equipment in the immediate area of the post-operative area. The equipment shall be commensurate with the surgical procedure and the medical requirements of the patient. That equipment shall include, but not be limited to, the following:

1. EKG/ECG monitor;
2. pulse oxymeter monitor;
3. temperature monitoring equipment;
4. equipment to administer oxygen;

5. equipment necessary to monitor vital signs.

AUTHORITY NOTE: Promulgated in accordance with R.S.
40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health
and Hospitals, Office of the Secretary, Bureau of Health
Services Financing LR 21:177 (February 1995), amended LR 29:2420
(November 2003).

Subchapter M. Anesthesia Services (Optional)

§9449. General Provisions

A. If anesthesia services are provided, which is
mandatory when surgical or obstetric services are provided, they
must be provided in a well organized manner under the direction
of a qualified doctor of medicine or osteopathy.

B. The standards in this Chapter apply to services for
all patients who:

1. receive general, spinal, or other major regional
anesthesia; or

2. undergo surgery or other invasive procedures when
receiving general, spinal, or other major regional anesthesia
and/or intravenous, intramuscular, or inhalation
sedation/analgesia, including conscious sedation, that, in the
manner used in the hospital, may result in the loss of the
patient's protective reflexes.

C. Invasive procedures include, but are not limited to,

percutaneous aspirations and biopsies, cardiac and vascular catheterization, and endoscopies.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing LR 21:177 (February 1995), amended LR 29:2421 (November 2003).

§9451. Organization and Staffing

A. Anesthesia services shall be administered by practitioners with appropriate clinical privileges obtained through a mechanism that assures that each practitioner provide only those services for which they have been licensed, trained and deemed to be competent to administer anesthesia within the scope of their practice. Those practitioners include:

1. a qualified anesthesiologist;
2. a doctor of medicine or osteopathy;
3. a dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under state law;
4. a certified registered nurse anesthetist (CRNA) licensed by the Louisiana State Board of Nursing who is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed as defined in the medical staff bylaws; or

5. a bona fide student enrolled in a school of nurse anesthesia accredited by the Council on Accreditation of Nurse Anesthesia educational programs whose graduates are acceptable for certification by a nationally recognized certifying body may administer anesthesia as related to such course of study under the direct supervision of a certified registered nurse anesthetist or an anesthesiologist.

B. The individual administering the anesthesia shall be present throughout its administration and attending the patient until the patient is under the care of post-anesthesia staff.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing LR 21:177 (February 1995), amended LR 29:2421 (November 2003).

§9453. Delivery of Service

A. Policies on anesthesia procedures must include the delineation of pre-anesthesia and post-anesthesia responsibilities. As a minimum, they shall address:

1. the qualifications, responsibilities and supervision required of all personnel who administer anesthesia;
2. patient consent for anesthesia;
3. infection control measures;

4. safety practices in all anesthetizing areas;
5. protocol for supportive life functions, e.g., cardiac and respiratory emergencies;
6. reporting requirements;
7. documentation requirements;
8. inspection and maintenance reports on all supplies and equipment used in anesthesia; and
9. trace gas reports.

B. The policies must also ensure that the following are provided for each patient:

1. a pre-anesthesia evaluation performed and recorded within 48 hours prior to surgery by an individual qualified to administer anesthesia;
2. a reevaluation of each patient immediately prior to induction of anesthesia;
3. an intra-operative anesthesia record that records monitoring of the patient during anesthesia and documentation of at least the following:
 - a. prior to induction of the anesthesia, all anesthesia drugs and equipment to be used have been checked and are immediately available and are determined to be functional by the practitioner who is to administer the anesthetic;
 - b. dosages and total dosages of all drugs and agents used;

- c. type and amount of all fluid administered, including blood and blood products;
- d. technique(s) used;
- e. unusual events during the anesthesia period;
- f. the status of the patient at the conclusion of anesthesia;

- g. a post-anesthesia follow-up report written within 48 hours after surgery on inpatients and prior to discharge for patients undergoing one-day/same-day surgery by the individual who administers the anesthesia or another fully qualified practitioner within the anesthesia section; and

- h. a post-anesthesia evaluation on outpatients for proper anesthesia recovery performed in accordance with policies and procedures approved by the medical staff.

C. The anesthesia policy and procedure manual shall ensure that the following are provided for each patient undergoing:

- 1. general anesthesia:
 - a. the use of an anesthesia machine that provides the availability and use of safety devices including, but not limited to, an oxygen analyzer, pressure and disconnect alarm, pin-index safety system, gas-scavenging system, and oxygen pressure interlock system;

- b. continuous monitoring of the patient's

temperature and vital signs, as well as the continuous use of an EKG/ECG , pulse oximeter monitor, end tidal carbon dioxide volume monitor, and peripheral nerve stimulator monitor;

2. regional anesthesia (major nerve blocks):

a. all equipment listed in the above list for general anesthesia shall be immediately available and in the operating room where the procedure is being performed; and

b. continuous monitoring of the patient's vital signs, and temperature, as well as the continuous use of an EKG/ECG, and pulse oximeter monitor; and

c. monitored by the practitioner who administered the regional anesthetic or individuals identified as a practitioner listed in §9451.A;

3. local anesthesia (infiltration or topical). There shall be:

a. continuous monitoring of the patient's vital signs and temperature as well as the continuous use of an EKG/ECG, and pulse oximeter monitor; and

b. monitoring by the practitioner who administered the local anesthetic or a practitioner listed within §9451.A.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health

and Hospitals, Office of the Secretary, Bureau of Health Services Financing LR 21:177 (February 1995), amended LR 29:2421 (November 2003).

Subchapter N. Nuclear Medicine Services (Optional)

§9457. General Provisions

A. If the hospital provides nuclear medicine services or contracts for the services, those services must meet the needs of the patients in accordance with acceptable standards of practice and be provided in a safe and effective manner.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing LR 21:177 (February 1995), amended LR 29:2422 (November 2003).

§9459. Organization and Staffing

A. The organization of the nuclear medicine services shall be appropriate to the scope and complexity of the services offered. There shall be a director who is a doctor of medicine or osteopathy qualified in nuclear medicine and named in the Department of Environmental Quality, Radiation Protection Division radioactive material license as authorized to use radioactive materials in humans.

B. Nuclear medicine services shall be ordered only by a

practitioner whose scope of federal or state licensing and defined staff privileges allow such referrals.

C. The performance of nuclear medicine diagnostic procedures and the administration of radioactive material to humans may be accomplished only by the licensed physician practitioner or by the licensed nuclear medicine technologist.

AUTHORITY NOTE: promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing LR 21:177 (February 1995), amended LR 29:2422 (November 2003).

§9461. Delivery of Service

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

B. In-house preparation of radiopharmaceuticals shall be by, or under the supervision of an appropriately trained registered pharmacist or a doctor of medicine or osteopathy whose use of radioactive materials is authorized in the facility's Department of Environmental Quality, Radiation Protection Division radioactive material license.

C. There shall be proper storage and disposal of radioactive materials. If clinical laboratory tests are

performed in the nuclear medicine service, the service shall meet the requirements for clinical laboratories with respect to management, adequacy of facilities, proficiency testing and quality control.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing LR 21:177 (February 1995), amended LR 29:2422 (November 2003).

§9463. Facilities

A. Equipment and supplies shall be appropriate for the types of nuclear medicine services offered and shall be maintained for safe and efficient performance.

B. The equipment shall be maintained in safe operating condition, and inspected, tested, and calibrated at least annually by qualified personnel. The nuclear medicine service shall have and follow a preventive maintenance schedule.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing LR 21:177 (February 1995), amended LR 29:2422 (November 2003).

§9465. Records

A. The hospital shall maintain signed and dated reports of nuclear medicine interpretations, consultations and procedures. The hospital shall maintain copies of nuclear medicine reports in accordance with the retention requirement specified in Subchapter H, Medical Record Services.

B. The practitioner approved by the medical staff and authorized by the facility's Department of Environmental Quality, Radiation Protection Division radioactive material license to interpret diagnostic procedures shall sign and date the interpretations of these tests.

C. The hospital shall maintain records of the receipt and disposition of radiopharmaceuticals.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing LR 21:177 (February 1995), amended LR 29:2422 (November 2003).

Subchapter O. Outpatient Services (Optional)

§9469. General Provisions and Organization

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

B. Outpatient services shall be appropriately organized, integrated with and provided in accordance with the standards applicable to the same service provided by the hospital on an inpatient basis.

1. Outpatient services shall be provided only under conditions stated in Subparagraphs a, b, or Clauses b.i.-ii below.

a. Outpatient services may be provided by a hospital if that hospital provides inpatient services for the same area of service. For example, a hospital may provide psychiatric outpatient services if that hospital provides psychiatric services on an inpatient basis.

b. Outpatient services may be provided by a hospital that does not provide inpatient services for the same area of service only if that hospital has a written policy and procedure to ensure a patient's placement and admission into an inpatient program to receive inpatient services for that area of service. The policy and procedure must ensure that the hospital is responsible for coordination of admission into an inpatient facility and must include, but not be limited to, the following:

i. the hospital personnel and/or staff responsible for coordination of placement and admission into an inpatient facility; and

ii. the procedure for securing inpatient

services for that patient.

2. For all outpatient services, there shall be established methods of communication as well as established procedures to assure integration with inpatient services that provide continuity of care.

3. When patients are admitted, pertinent information from the outpatient record shall be provided to the inpatient facility so that it may be included in the inpatient record.

C. Any room designated for procedures or treatment involving conscious sedation shall have policies and procedures established by the medical staff to insure quality of care and safety of patients. Such guidelines shall include at a minimum:

1. pre-procedure preparation;
2. patient monitoring;
3. discharge criteria; and
4. staff competency requirements.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing LR 21:177 (February 1995), amended LR 29:2423 (November 2003), LR 33:284 (February 2007).

§9471. Personnel

A. The hospital shall assign an individual to be

responsible for the outpatient services. There shall be appropriate professional and non-professional personnel available.

B. There must be a registered nurse on the observation unit as long as there are patients admitted to the unit.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing LR 21:177 (February 1995), amended LR 29:2423 (November 2003).

§9473. Facilities

A. All outpatient facilities shall be accessible to and usable by handicapped employees, staff, visitors and patients.

Where appropriate, there shall be at least:

1. a receptionist desk;
2. waiting space;
3. an examination room equipped with a lavatory and nurse call system;
4. public toilet facilities;
5. public telephone; and
6. drinking fountain.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing LR 21:177 (February 1995), amended LR 29:2423 (November 2003).

Subchapter P. Rehabilitation Services (Optional)

§9477. General Provisions

A. If the hospital provides a range of rehabilitation services, including but not limited to physical therapy, occupational therapy, audiology or speech pathology services, the services shall be organized, operated and staffed in accordance with the provisions of this Subchapter P to ensure the health and safety of patients.

B. A rehabilitation unit or facility is defined as a designated unit or hospital that primarily provides physiological rehabilitation services to inpatients and/or outpatients.

C. For rehabilitation services that have multiple geographic locations, each geographical site shall meet the requirements in §9483.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing LR 21:177 (February 1995), amended LR 29:2423

(November 2003).

§9479. Organization and Staffing

A. The organization of services shall be appropriate to the scope of the services offered. The rehabilitation service shall employ and define the leadership structure in accordance with the facility administration. The medical director of rehabilitation services shall:

1. be a doctor of medicine or osteopathy;
 2. be licensed to practice medicine or surgery in accordance with state law;
 3. have completed a one year hospital internship;
- and
4. have had at least two years of training or experience, within the last five years, in the medical management of patients requiring rehabilitation services.

B. Medical Director

1. It is expected that the experience and training of the medical director of rehabilitation services will be sufficient to provide the expertise to perform all of the functions within the service.

2. The medical director of rehabilitation services will be responsible to ensure that the objectives of each of the therapeutic disciplines of the rehabilitation program are efficiently conducted within the stated mission of the program

and in accordance with current standards of rehabilitation medicine.

C. Physical therapy, occupational therapy, psychology/neuropsychology, speech therapy and audiology services shall be provided by staff that meet the qualifications in accordance with Louisiana law. All rehabilitation staff shall be duly licensed to practice in the areas in which they provide service.

D. A rehabilitation unit in a general hospital shall employ a full-time registered nurse as director of rehabilitation nursing services who is not shared with any other hospital department and who has three years clinical nursing experience, one of which shall be in providing rehabilitative nursing care. The unit shall provide 24-hour registered nurse coverage with an adequate number of licensed nurses and rehabilitative workers to provide the nursing care necessary under each patient's active treatment program.

E. In a rehabilitation hospital, the director of nursing services shall be a full-time registered nurse who has three years clinical nursing experience, one of which shall be in providing rehabilitative nursing care. In addition to the director of nursing services, the hospital shall provide 24-hour registered nurse coverage with an adequate number of licensed nurses and rehabilitative workers to provide the nursing care

necessary under each patient's active treatment program.

F. If provided, psychological services shall be provided by or supervised by a psychologist licensed by the Louisiana State Board of Examiners of Psychologists.

G. Social services shall be provided by a licensed clinical social worker and shall meet the needs of the patients.

H. If the hospital provides a range of rehabilitation services, the services must define criteria for admission to the inpatient rehabilitation program and discharge from the inpatient program.

I. There shall be an interdisciplinary team which should include, but not be limited to:

1. a registered nurse with rehabilitation experience on each shift;

2. restorative nursing assistants and/or certified nursing aides;

3. a physical therapist;

4. an occupational therapist;

5. a psychologist/neuropsychologist;

6. a physician experienced in rehabilitation medicine;

7. a social worker;

8. a speech-language pathologist.

J. The program should provide or make arrangements for:

1. audiology services;
2. driver assessment;
3. driver education;
4. medical nutrition therapy;
5. orthotic services;
6. prosthetic services;
7. rehabilitation resources (independent centers);
8. vocational rehabilitation;
9. durable medical equipment;
10. specialty consultants;
11. other services consistent with the criteria for

admission.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing LR 21:177 (February 1995), amended LR 29:2423 (November 2003).

§9481. Delivery of Services

A. Rehabilitation services shall be furnished in accordance with a written plan of treatment based upon an assessment performed by the qualified professional. The written plan of treatment shall be established prior to the beginning of treatment. The plan of treatment shall consist of at least the

treatment goals, type, amount, frequency and duration of services.

B. Rehabilitation services shall be given in accordance with the orders of practitioners who are authorized by the medical staff to order the services. The orders shall be incorporated in the patient's medical record.

C. The patient's progress shall be documented on a timely and regular basis in accordance with written policies and procedures.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing LR 21:177 (February 1995), amended LR 29:2424 (November 2003).

§9483. Facilities—Physical Space

A. Space and equipment shall be appropriate for the types of rehabilitation services offered and shall be maintained for safe and efficient performance and in accordance with the Rehabilitation Chapter and General Hospital Chapter of the *AIA Guidelines for Design and Construction of Hospital and Health Care Facilities*, 2001 (or most recent edition).

B. The Activities of Daily Living (ADL) room is in addition to the licensed bed capacity.

AUTHORITY NOTE: Promulgated in accordance with R.S.
40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health
and Hospitals, Office of the Secretary, Bureau of Health
Services Financing LR 21:177 (February 1995), amended LR 29:2424
(November 2003).

Subchapter Q. Respiratory Care Services (Mandatory)

§9487. General Provisions

A. The hospital shall provide respiratory care services.
The services shall meet the needs of the patients in accordance
with acceptable standards of practice.

AUTHORITY NOTE: Promulgated in accordance with R.S.
40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health
and Hospitals, Office of the Secretary, Bureau of Health
Services Financing LR 21:177 (February 1995), amended LR 29:2424
(November 2003).

§9489. Organization and Staffing

A. The organization of the respiratory care services
shall be appropriate to the scope and complexity of the services
offered. There shall be a director of the service who shall have
the administrative authority and responsibility for implementing
the hospital's policies. The director shall be a doctor of
medicine or osteopathy with the knowledge, experience and

capabilities to supervise and administer the services properly. The director may serve on either a full-time or part-time basis.

B. There shall be adequate numbers of respiratory therapists, respiratory therapy technicians and other personnel who meet the qualifications specified by the medical staff and approved by the governing body, consistent with Louisiana law.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing LR 21:177 (February 1995), amended LR 29:2424 (November 2003).

§9491. Delivery of Services

A. Respiratory care services shall be delivered in accordance with medical staff directives and incorporated in the patient's medical record. The order shall specify the type, frequency and duration of treatment, and as appropriate, the type and dose of medication, type of diluent, and the oxygen concentration. All respiratory care services provided shall be documented in the patient's medical record, including the type of therapy, date and time of administration, effects of therapy, and any adverse reactions.

B. Personnel qualified to perform specific procedures and the amount of supervision required for personnel to carry out

specific procedures shall be designated in writing.

C. If blood gases or other clinical laboratory tests are performed in the respiratory care unit, the unit shall meet the requirement for clinical laboratories with respect to management, adequacy of facilities, proficiency testing and quality control as set forth in Subchapter F of these requirements.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing LR 21:177 (February 1995), amended LR 29:2425 (November 2003).

Subchapter R. Psychiatric Services (Optional)

§9495. General Provisions

A. These requirements are applicable to those hospitals which are primarily engaged in providing psychiatric services for the diagnosis and treatment of mentally ill persons or have organized a physically and functionally distinct part unit within the hospital to provide these services. Pediatric and adolescent psychiatric units shall be physically separated from adult psychiatric units. Facilities without separate pediatric and adolescent units shall have policies and procedures that prevent adult patients from co-mingling with pediatric and/or

adolescent psychiatric patients.

B. For psychiatric services/facilities that have multiple geographic locations, each geographical site shall meet the requirements in §9497, §9499 and §9501.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing LR 21:177 (February 1995), amended LR 29:2425 (November 2003).

§9497. Facilities

A. The layout, design of details, equipment and furnishings shall be such that patients shall be under close observation and shall not be afforded opportunities for hiding, escape or injury to themselves or others. The environment of the unit shall be characterized by a feeling of openness with emphasis on natural light and exterior views. Interior finishes, lighting and furnishings shall suggest a residential rather than an institutional setting while conforming with applicable fire safety codes. Security and safety devices shall not be presented in a manner to attract or challenge tampering by patients.

B. Windows or vents shall be arranged and located so that they can be opened from the inside to permit venting of combustion products and to permit occupants direct access to

fresh air in emergencies. The operation of windows shall be restricted to inhibit possible escape or suicide. Where windows or vents require the use of tools or keys for operation, the tools or keys shall be either located on the same floor in a prominent location accessible to staff or carried by every staff member. With hospitals that have approved engineered smoke control systems, the windows may be fixed. Where glass fragments pose a hazard to certain patients, safety glazing and/or other appropriate security features shall be used. There shall be no curtain or venetian blind chords.

C. Where grab bars are provided, they shall be institutional type, shall not rotate within their fittings, be securely fastened with tamper-proof screw heads, and shall be free of any sharp or abrasive elements. If grab bars are mounted adjacent to a wall, the space between the wall and the grab bar shall be 1 1/2 inches.

D. Where towel racks, closet and shower curtain rods are provided, they shall be the breakaway type.

E. Plastic bags and/or trash can liners shall not be used in patient care areas.

F. Electrical receptacles shall be of the safety type or protected by 5-milliampere ground-fault-interrupters.

G. There shall be outdoor space for patient recreation.

H. Patient Rooms

1. A nurses call system is not required, but if it is included, provisions shall be made for easy removal, or for covering call button outlets. A hospital shall have written policies and procedures to address call where no electronic system is in place.

2. Bedpan-flushing devices may be omitted from patient room toilets in psychiatric nursing units.

3. Visual privacy (e.g., cubicle curtains) in multi-bed rooms is not required.

4. Free standing closets shall be secured to the wall.

5. Electric patient beds are not to be used.

I. Service Areas

1. A secured storage area controlled by staff shall be provided for patients' belongings that are determined to be potentially harmful (e.g., razors, nail files, cigarette lighters).

2. Drugs and biologicals shall be stored in locked compartments under proper temperature controls, and only authorized personnel shall have access to the keys.

3. Food service may be one or a combination of the following:

a. a nourishment station;

b. a kitchenette designed for patient use with

staff control of heating and cooking devices;

c. a kitchen service including a hand washing fixture, storage space, refrigerator, and facilities for meal preparation.

4. Storage space for stretchers and wheelchairs may be outside the psychiatric unit, provided that provisions are made for convenient access as needed for handicapped patients.

5. A separate charting area shall be provided with provisions for acoustical privacy. A viewing window to permit observation of patient areas by the charting nurse or physician may be used if the arrangement is such that patient files cannot be read from outside the charting space.

6. At least two separate social spaces, one appropriate for noisy activities and one for quiet activities shall be provided. The combined area shall be at least 40 square feet per patient with at least 120 square feet for each of the two spaces. This space may be shared by dining activities.

7. Space for group therapy shall be provided. This may be combined with the quiet space noted above when the unit accommodates not more than 12 patients, and when at least 225 square feet of enclosed private space is available for group therapy activities.

8. An automatic washer and dryer shall be provided for patient laundry.

9. Room(s) for examination and treatment with a minimum area of 120 square feet shall be provided within or in close proximity to the unit.

10. Separate consultation room(s) with minimum floor space of 100 square feet each, provided at a room-to-bed ratio of one consultation room for each 12 psychiatric beds shall be provided within the unit for interviews with patients and their families. The room(s) shall be designed for acoustical and visual privacy and constructed to achieve a noise reduction of at least 45 decibels.

11. Psychiatric hospitals or units shall provide 15 square feet of separate space per patient for occupational therapy, with a minimum total area of at least 200 square feet, whichever is greater. This space shall include provision for hand washing, work counter(s), storage and displays. Occupational therapy areas may serve more than one nursing unit. When the psychiatric nursing unit(s) contain fewer than 12 beds, the occupational therapy functions may be performed within the noisy activities area, if at least an additional 10 square feet per patient served is included.

12. A conference and treatment planning room for use by the psychiatric unit shall be provided. This room may be combined with the charting room.

J. Seclusion Treatment Room

1. There shall be at least one seclusion room for up to 24 beds or a major fraction thereof. It is intended for short-term occupancy by violent or suicidal patients and provides for patients requiring security and protection. The room(s) shall be either located for direct nursing staff supervision or observed through the use of electronic monitoring equipment.

2. If electronic monitoring equipment is used, it shall be connected to the hospital's emergency electrical source.

3. Each room shall be for single occupancy and contain at least 60 square feet. It shall be constructed to prevent patient hiding, escape, injury or suicide.

4. Where restraint beds are required by the functional program, 80 square feet shall be required.

5. If a facility has more than one psychiatric unit, located at the same geographical address, the number of seclusion rooms shall be determined by the total number of psychiatric beds at that location. However, if there are psychiatric units located at multiple and different geographical addresses, there shall be a seclusion room that meets these requirements at each off-site campus that offers inpatient psychiatric services.

6. Special fixtures and hardware for electrical

circuits shall be used.

7. The minimum ceiling height shall be 9 feet.

8. Doors shall be 3 feet 8 inches wide, and shall permit staff observation of the patient while also maintaining provisions for patient privacy.

9. Seclusion rooms shall be accessed by an anteroom or vestibule which also provides direct access to a toilet room.

K. Ceiling construction in psychiatric patient rooms and seclusion room(s) shall be monolithic or tamper proof.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing LR 21:177 (February 1995), amended LR 29:2425 (November 2003).

§9499. Supplies and Equipment

A. Restraint equipment shall be immediately available and accessible to staff.

B. Recreational supplies and therapy equipment shall be available and in locked storage.

C. Locked storage areas shall be available for safekeeping of patient luggage and contraband items.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 29:2426 (November 2003).

§9501. Staffing

A. The hospital or unit shall provide qualified professional, technical and consultative personnel to evaluate patients, formulate written individualized comprehensive treatment plans, provide active treatment measures and engage in discharge planning.

B. The hospital or unit shall employ a clinical director, who meets the training and experience requirements for examination by the American Board of Psychiatry and Neurology, or the American Osteopathic Board of Neurology and Psychiatry. The clinical director shall monitor and evaluate the quality and appropriateness of services and treatment provided by the medical staff.

C. The hospital or unit shall employ a full-time registered nurse as director of psychiatric nursing services, who is not shared with any other hospital department and who has:

1. a master's degree in psychiatric or mental health nursing; or
2. a master's degree in a related field such as psychology or nursing education and five years nursing

experience and three years providing nursing care to the mentally ill; or

3. a bachelor's, associate degree or diploma in nursing with documented evidence of educational programs focused on treating psychiatric patients, which has occurred at intervals sufficient enough to keep the nurse current on psychiatric nursing techniques. In addition, the nurse shall have at least five years of nursing experience, three years of which were providing nursing care to the mentally ill, or receive regular, documented supervision/consultation from a master's prepared psychiatric nurse.

D. In addition to the director of psychiatric nursing service, the hospital or unit shall provide 24-hour registered nurse coverage with an adequate number of licensed nurses and mental health workers to provide the nursing care necessary under each patient's active treatment program.

E. Psychological services shall be provided by or supervised by a psychologist licensed by the Louisiana State Board of Examiners of Psychologists.

F. Social services shall be provided by a director who is a licensed clinical social worker and is experienced in the social service needs of the mentally ill.

G. Therapeutic activities shall be clinically supervised and provided by therapeutic recreational therapists adequate in

number to respond to the therapeutic activity needs of the patient population being served.

1. An individual who clinically supervises therapeutic recreation activities shall meet the following qualifications:

a. have a degree in therapeutic recreation therapy from an accredited post-secondary institution; or

b. have a degree in another field of study and has also attained certification in accordance with the National Council for Therapeutic Recreation Certification requirements.

2. An individual who provides therapeutic recreational services shall have the following qualifications:

a. a degree in therapeutic recreation from an accredited post-secondary institution; or

b. a degree in another field of study and has also attained certification in accordance with the National Council for Therapeutic Recreation Certification requirements; or

c. a minimum of 10 years' experience providing therapeutic recreational services; or

d. be currently employed as a therapeutic recreational specialist 2 per Louisiana Civil Service requirements.

3. Individuals currently providing therapeutic

recreational services who do not meet the qualifications of §9501.G.1-2.d, shall have two years from the effective date of this Rule to qualify as therapeutic recreational therapists.

4. Licensed hospitals providing therapeutic recreational services pursuant to §9501 and whose staff do not meet the qualifications of §9501.G.2.a-d within the time frame provided for in §9501.G.3, shall submit to the department documentation which:

a. clearly indicates why the qualifications have not been met; and

b. provides evidence of a barrier to access of such services in the hospital's service area.

5. No hospital shall submit the documentation allowed for in §9501.G.4 more than once and the submission shall cover a period of no more than 12 months from the date of receipt by the department.

6. Recreational therapy shall be designed to:

a. restore, remediate and rehabilitate a person's level of functioning and independence in life activities;

b. promote health and wellness; and

c. reduce or eliminate the activity limitations and restrictions to participation in life situations caused by an illness or disabling condition.

NOTE: Examples of intervention modalities include, but are not limited to, creative arts (e.g., crafts, music, dance, drama, among others), sports, adventure programming, dance/movement, and leisure education.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 29:2426 (November 2003), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 41:1489 (August 2015).

Subchapter S. Obstetrical and Newborn Services (Optional)

§9505. General Provisions

A. This Subchapter S requires that the level of care on the neonatal intensive care unit shall match or exceed the level of obstetrical care for each level of obstetric service, except for free standing children's hospitals. All hospitals with existing obstetrical and neonatal services shall be in compliance with this Subchapter S within one year of the promulgation date of this Rule. All new providers of obstetrical and neonatal services shall be required to be in compliance with this Subchapter S immediately upon promulgation.

NOTE: For facilities that change the level of care and services of the facility's NICU unit, either decreasing or

increasing the level provided, the facility shall submit an attestation of this change to the department's Health Standards Section (HSS) in writing and on the appropriate state neonatal services Medicaid attestation form. Such notice shall be submitted to HSS within 90 days of the facility's change in NICU level provided. For facilities that change the level of care and services of the facility's obstetric unit, by either decreasing or increasing the level provided, the facility shall submit written notice of this change to HSS within 90 days of such change.

B. For purposes of this Subchapter, hospital privileges are such privileges that are unrestricted and approved by the medical staff committee and the governing body that allows the practitioner to perform all duties within their scope of practice and certification(s) at the hospital in which the privileges are granted and such duties are performed.

1. The requirements for privileges, such as active privileges, inpatient privileges or full privileges, shall be defined in hospital policy and approved by each hospital's governing body.

C. In accordance with R.S. 40:2109, a hospital located in a parish with a population of 250,000 people or less shall not be required to maintain personnel in-house with credentials to administer obstetric anesthesia on a 24-hour basis in order to

qualify for Medicaid reimbursement for level III, neonatal or obstetric medical services, or as a prerequisite for licensure to provide such services. Personnel with such credentials may be required to be on staff and readily available on a 24-hour on-call basis and demonstrate ability to provide anesthesia services within 20 minutes.

NOTE: The provisions of §9505.C shall not apply to any hospital with level IIIS, IIIR or IV obstetrical and neonatal services.

D. For purposes of this Subchapter, the requirements for hospital staff and/or equipment as being immediately or readily available shall be defined by hospital policy and approved by each hospital's governing body.

E. Any transfer agreements shall be in writing and approved by the hospital medical staff and by each hospital's governing body. Transfer agreements shall be reviewed at least annually and revised as needed.

F. For those hospitals providing transports, the qualifications of the transport team shall be in writing, defined by hospital policy and approved by each hospital's governing body. Such qualifications shall be reviewed at least annually and revised as needed.

G. The hospital shall have data collection and retrieval capabilities in use, and shall cooperate and report the

requested data to the appropriate supervisory agencies to review.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 29:2427 (November 2003), amended LR 33:284 (February 2007), amended by the Department of Health, Bureau of Health Services Financing, LR 43:75 (January 2017).

§9507. Obstetrical Units

A. These requirements are applicable to those hospitals which provide obstetrical and neonatal services.

B. Levels of Care Units. There are five established obstetrical levels of care units:

1. obstetrical level I unit;
2. obstetrical level II unit;
3. obstetrical level III unit;
4. obstetrical level III regional unit; and
5. obstetrical level IV.

C. Obstetrical services shall be provided in accordance with acceptable standards of practice as delineated in the 2014 *AAP/ACOG Guidelines for Perinatal Care*. Each advanced level of care unit shall provide all services and meet the personnel requirements of the lower designated units, as applicable, i.e.,

a level IV unit must meet the requirements of a level I, II, III and III regional unit.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 29:2427 (November 2003), amended LR 33:284 (February 2007), amended by the Department of Health, Bureau of Health Services Financing, LR 43:75 (January 2017).

§9509. Obstetrical Unit Functions

A. Obstetrical Level I Unit

1. General Provisions

a. Care and supervision for low risk pregnancies greater or equal to 35 weeks gestation shall be provided.

b. There shall be a triage system present in policies and procedures for identification, stabilization and referral of high risk maternal and fetal conditions beyond the scope of care of a level I unit.

c. There shall be protocols and capabilities for massive transfusion, emergency release of blood products, and management of multiple component therapy available on-site.

d. Postpartum care facilities shall be available on-site.

e. There shall be capability to provide for resuscitation and stabilization of inborn neonates.

f. The hospital shall have a policy for infant security and an organized program to prevent infant abductions.

g. The hospital shall have a program in place to address the needs of the family, including parent-sibling-neonate visitation.

h. The hospital shall have a written transfer agreement with another hospital that has an approved appropriate higher level of care.

2. Personnel Requirements

a. Obstetrical services shall be under the medical direction of a qualified physician who is a member of the medical staff with obstetric privileges. The physician shall be board certified or board eligible in obstetrics/gynecology or family practice medicine. The physician has the responsibility of coordinating perinatal services with the pediatric chief of service.

b. The nursing staff shall be adequately trained and staffed to provide patient care at the appropriate level of service. Registered nurse to patient ratios may vary in accordance with patient needs.

c. The unit shall provide credentialed medical staff to ensure the capability to perform emergency Cesarean

delivery within 30 minutes of the decision to operate (30 minutes from decision to incision).

d. Anesthesia, radiology, ultrasound, electronic fetal monitoring (along with personnel skilled in the use of these) and laboratory services shall be available on a 24-hour basis. Anesthesia services shall be available to ensure performance of a Cesarean delivery within 30 minutes as specified in Subparagraph c above.

e. At least one credentialed physician or certified registered nurse midwife shall attend all deliveries, and at least one individual who is American Academy of Pediatrics (AAP) certified in neonatal resuscitation and capable of neonatal resuscitation shall attend all deliveries.

f. The nurse manager shall be a registered nurse (RN) with specific training and experience in obstetric care. The RN manager shall participate in the development of written policies, procedures for the obstetrical care areas, and coordinate staff education and budget preparation with the chief of service. The RN manager shall name qualified substitutes to fulfill duties during absences.

g. A facility shall have at least one individual with additional education in breastfeeding who is available for support, counseling and assessment of breastfeeding mothers.

h. A facility shall have ability to initiate education and quality improvement programs to maximize patient safety, and/or collaborate with higher-level facilities to do so.

3. Physical Plant

a. Obstetrical patients shall not be placed in rooms with non-obstetrical patients.

b. Each room shall have at least one toilet and lavatory basin for the use of obstetrical patients.

c. The arrangement of the rooms and areas used for obstetrical patients shall be such as to minimize traffic of patients, visitors, and personnel from other departments and prevent traffic through the delivery room(s).

d. There shall be an isolation room provided with hand washing facilities for immediate segregation and isolation of a mother and/or baby with a known or suspected communicable disease.

e. For any new construction or major alteration of the obstetrical unit/suite, the hospital shall ensure that the OB unit has a Cesarean delivery room (surgical operative room) to perform Cesarean deliveries at all times.

B. Obstetrical Level II Unit

1. General Provisions

a. The role of an obstetrical Level II unit is

to provide care for most obstetric conditions in its population, but not to accept transports of obstetrical patients with gestation age of less than 32 weeks or 1,500 grams if delivery of a viable infant is likely to occur.

b. Women with conditions that would result in the delivery of an infant weighing less than 1,500 grams or less than 32 weeks gestation shall be referred to an approved level III or above unit unless the attending physician has documented that the patient is unstable to transport safely. Written transfer agreements with approved obstetrical level III and above units for transfer of these patients shall exist for all obstetrical level II units.

c. Ultrasound equipment shall be on site, in the hospital, and available to labor and delivery 24 hours a day.

2. Personnel Requirements

a. The chief of obstetric services shall be a board-certified obstetrician or a board eligible candidate for certification in obstetrics. This obstetrician has the responsibility of coordinating perinatal services with the neonatologist in charge of the neonatal intensive care unit (NICU).

b. A board-certified radiologist and a board-certified clinical pathologist shall be available 24 hours a

day. Specialized medical and surgical consultation shall be readily available.

c. There shall be a continuous availability of qualified RNs with the ability to stabilize and transfer high-risk women.

d. A board-certified or board eligible OB-GYN physician shall be available 24 hours a day.

EXCEPTION: For those hospitals whose staff OB-GYN physician(s) do not meet the provisions of §9509.B(2)d, such physician(s) may be grandfathered as satisfying the requirement of §9509.B(2)d when the hospital has documented evidence that the OB-GYN physician(s) was granted clinical staff privileges by the hospital prior to the effective date of this Rule. This exception applies only to the physician at the licensed hospital location and is not transferrable.

e. A licensed physician board-certified in maternal fetal medicine (MFM) shall be available 24 hours a day for consultation onsite, by telephone, or by telemedicine, as needed.

f. Anesthesia services shall be available 24 hours a day to provide labor analgesia and surgical anesthesia.

g. A board-certified anesthesiologist with specialized training or experience in obstetric anesthesia shall be available 24 hours a day for consultation.

h. Medical and surgical consultants shall be available 24 hours a day to stabilize obstetric patients who have been admitted to the facility or transferred from other facilities.

C. Obstetrical Level III Unit

1. General Provisions

a. Women with conditions requiring a medical team approach not available to the perinatologist in an obstetrical level III unit shall be transported to a higher-level unit.

b. The unit shall have written cooperative transfer agreements with approved higher level units for the transport of mothers and fetuses requiring care unavailable in an obstetrical level III unit or that are better coordinated at a higher level unit.

c. The hospital shall have advanced imaging services available 24 hours a day which will include magnetic resonance imaging (MRI) and computed topography (CT).

d. The hospital shall have medical and surgical ICUs to accept pregnant women and have qualified critical care providers available as needed to actively collaborate with MFM physicians 24 hours a day.

e. Participation is required in a statewide quality collaborative and database selected by the Medicaid

Quality Committee, Maternity Subcommittee, with a focus on quality of maternity care. Proof of such participation will be available from the LDH website.

f. Equipment and qualified personnel, adequate in number, shall be available onsite to ventilate and monitor women in labor and delivery until they can be safely transferred to the ICU.

g. This unit shall accept maternal transfers as deemed appropriate by the medical staff and governing body.

2. Personnel Requirements

a. The delivery of safe and effective perinatal nursing care requires appropriately qualified registered nurses in adequate numbers to meet the nursing needs of each patient. The hospital shall develop, maintain and adhere to an acuity-based classification system based on nationally recognized staffing guidelines and shall have documentation of such.

b. A board-certified or board-eligible MFM physician with inpatient privileges shall be available 24 hours a day, either onsite, by telephone, or by telemedicine.

c. The director of MFM services shall be a board-certified or board eligible MFM physician.

d. The director of obstetric service shall be a board-certified OB-GYN with active staff privileges in obstetrical care.

e. Anesthesia services shall be available 24 hours a day onsite.

f. A board-certified anesthesiologist with specialized training or experience in obstetric anesthesia shall be in charge of obstetric anesthesia services and shall be available onsite as needed.

g. A full complement of subspecialists, including subspecialists in critical care, general surgery, infectious disease, urology, hematology, cardiology, nephrology, neurology, neonatology and pulmonology shall be available for inpatient consultations.

h. A lactation consultant or counselor shall be on staff to assist breastfeeding mothers as needed.

i. The lactation consultant or counselor shall be certified by a nationally recognized board on breastfeeding.

i. A nutritionist and a social worker shall be on staff and available for the care of these patients as needed.

D. Obstetrical Level III Regional Unit

1. General Provisions

a. This unit shall provide care for the most challenging of perinatal conditions. Women with such conditions requiring a medical team approach not available to the MFM physician in an obstetrical level III Regional unit shall be

transported to a level IV unit.

b. This unit shall have written cooperative transfer agreements with a level IV unit for the transport of mothers and fetuses requiring care that is unavailable in the level III regional unit or that is better coordinated at a level IV.

c. This unit shall accept maternal transfers as deemed appropriate by the medical staff and hospital governing body.

2. Personnel Requirements

a. This unit shall have a board-certified or board-eligible OB/GYN available onsite 24 hours a day.

b. The director of MFM services for this unit shall be board-certified in MFM.

c. This unit shall have an anesthesiologist qualified in the delivery of obstetric anesthesia services available to be onsite 24 hours a day.

E. Obstetrical Level IV Unit

1. General Provisions

a. This unit shall provide onsite medical and surgical care of the most complex maternal conditions and critically ill pregnant women and fetuses throughout antepartum, intrapartum, and postpartum care.

2. Unit Requirements

a. This unit shall have perinatal system leadership, including facilitation of maternal referral and transport, outreach education for facilities and health care providers in the region and analysis and evaluation of regional data, including perinatal complications and outcomes and quality improvement.

b. Participation is required in the department's designated statewide quality collaborative program.

NOTE: The hospital shall acquire and maintain documented proof of participation.

3. Personnel

a. This unit shall have a MFM care team with the expertise to assume responsibility for pregnant women and women in the postpartum period who are in critical condition or have complex medical conditions. This includes co-management of ICU-admitted obstetric patients. The MFM team members shall have full privileges and shall be available 24 hours per day for onsite consultation and management. This team shall be led by a board-certified MFM physician.

b. The director of obstetric services for this unit shall be a board-certified MFM physician.

c. This unit shall have qualified subspecialists on staff to provide consultation in the care of critically ill pregnant women in the following areas:

AUTHORITY NOTE: Promulgated in accordance with R.S.
40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health
and Hospitals, Office of the Secretary, Bureau of Health
Services Financing, LR 29:2427 (November 2003), amended LR
33:284 (February 2007).

§9511. Neonatal Intensive Care

A. This §9511 is applicable to those hospitals which
provide obstetrical and neonatal services.

B. Levels of Care. There are five established neonatal
levels of care units:

1. neonatal level I unit;
2. neonatal level II unit;
3. level III NICU unit;
4. level III surgical NICU; and
5. level IV NICU unit.

C. Each advanced level of care unit shall provide all
services and meet the personnel requirements of the lower
designated units, as applicable, i.e., a level III surgical unit
must meet the requirements of the level I, II, and III units.

AUTHORITY NOTE: Promulgated in accordance with R.S.
40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health
and Hospitals, Office of the Secretary, Bureau of Health

Services Financing, LR 29:2428 (November 2003), amended LR 33:286 (February 2007), amended by the Department of Health, Bureau of Health Services Financing, LR 43:78 (January 2017).

§9513. Neonatal Unit Functions

A. Level I Neonatal Unit (Well Newborn Nursery)

1. General Provisions

a. This unit shall have the capability for resuscitation and stabilization of all inborn neonates in accordance with Neonatal Resuscitation Program (NRP) guidelines. The unit shall stabilize unexpectedly small or sick neonates before transfer to the appropriate advanced level of care.

b. The unit shall stabilize and provide care for infants born at 35 weeks or greater gestation and who remain physiologically stable. The requirements for maternal transport at lesser gestations for transfer to a higher level of care shall be determined by the medical staff and approved by the hospital governing body.

c. This unit shall have the capability to stabilize newborns born at less than 35 weeks gestational age for transfer to higher level of care.

d. This unit shall maintain consultation and written transfer agreements with an approved Level II or III as appropriate.

e. This unit shall have a defined, secured

nursery area with limited public access and/or secured rooming-in facilities with supervision of access.

f. Parent and/or sibling visitation/interaction with the neonate shall be provided.

2. Personnel Requirements

a. The unit's chief of service shall be a physician who is board-certified or board-eligible in pediatric or family practice medicine.

b. The nurse manager shall be a registered nurse with specific training and experience in neonatal care. The RN manager shall participate in the development of written policies and procedures for the neonatal care areas, and coordinate staff education and budget preparation with the chief of service. The RN manager shall name qualified substitutes to fulfill duties during absences.

c. Registered nurse to patient ratios may vary in accordance with patient needs. If couplet care or rooming-in is used, a registered nurse who is responsible for the mother shall coordinate and administer neonatal care. If direct assignment of the nurse is also made to the nursery to cover the newborn's care, there shall be double assignment (one nurse for the mother-neonate couplet and one for just the neonate if returned to the nursery). A registered nurse shall be available 24 hours a day, but only one may be necessary as most neonates

will not be physically present in the nursery. Direct care of neonates in the nursery may be provided by ancillary personnel under the registered nurse's direct supervision. Adequate staff is needed to respond to acute and emergency situations.

B. Neonatal Level II Unit (Special Care Nursery)

1. General Provisions

a. This unit shall provide care for infants born at more than 32 weeks gestation and weighing more than 1,500 grams.

i. infants who have medical problems that are expected to resolve rapidly and are not anticipated to need emergent subspecialty services from a higher level NICU as determined by the attending medical staff.

b. This unit shall have the capability to provide mechanical ventilation and/or CPAP for a brief duration (less than 24 hours) for infants born at more than 32 weeks and weighing more than 1,500 grams.

c. Neonates requiring greater than 24 hours of continuous ventilator support shall be transferred to a higher-level neonatal intensive care facility.

d. This unit shall have the ability to stabilize infants born before 32 weeks gestation and/or weighing less than 1,500 grams until transfer to a higher level neonatal intensive care facility.

e. Neonates requiring transfer to a higher-level neonatal intensive care facility may be returned to a level II unit for convalescence.

2. Personnel Requirements

a. A board-certified neonatologist shall be the chief of service.

NOTE: This unit shall have continuously available medical staff defined as available 24 hours per day/7 days per week/365 days per year on call for consultation as defined by medical staff bylaws.

b. Registered nurse to patient ratios may vary in accordance with patient needs.

c. This unit shall have at least one full-time social worker to be available as needed to assist with the socioeconomic and psychosocial problems of high-risk mothers, sick neonates, and their families.

d. This unit shall have at least one occupational or physical therapist to be available as needed to assist with the care of the newborn.

e. This unit shall have at least one registered dietitian/nutritionist to be available as needed who can plan diets as required to meet the special needs of mothers and high-risk neonates.

f. This unit shall have staff available 24

hours per day who have the demonstrated knowledge, skills, abilities and training to provide the care and services to infants in this unit, such as but not limited to:

- i. nurses;
- ii. respiratory therapists;
- iii. radiology technicians; and
- iv. laboratory technicians.

3. Equipment Requirements

a. This unit shall have hospital based equipment to provide care to infants available 24 hours per day, such as but not limited to:

- i. portable x-ray machine;
- ii. blood gas analyzer.

C. Level III NICU

1. General Provisions

a. There shall be a written neonatal transport agreement with an approved level III surgical unit or level IV unit.

b. This unit shall have either a neonatologist or a neonatal nurse practitioner or a neonatology fellow in-house 24 hours per day.

c. The staffing of this unit shall be based on patient acuity and consistent with the recommended staffing guidelines of the 2012 Seventh Edition of the *AAP Guidelines for*

Perinatal Care. For medical sub-specialty requirements, refer to Table 1, Neonatal Medical Subspecialties and Transport Requirements.

NOTE: All provisions of level III NICUs are required of level IIIS and IV NICUs.

2. Personnel Requirements

a. The chief of service of a level III NICU shall be a board-certified neonatologist.

EXCEPTION: In 1995, those physicians in existing units who were designated as the chief of service of the unit and who were not neonatal or perinatal board-certified, were granted a waiver by written application to the Office of the Secretary, Department of Health and Hospitals. This waiver shall be maintained as it applies only to the hospital where that chief of service's position is held. The physician cannot relocate to another hospital nor can the hospital replace the chief of service for whom the exception was granted and retain the exception.

b. This unit shall have at least one full-time social worker available as needed who has experience with the socioeconomic and psychosocial problems of high-risk mothers and fetuses, sick neonates, and their families. For units with greater than thirty patients, the social worker staffing ratios shall be at least one social worker to thirty patients (additional social workers may be required in accordance with

hospital staffing guidelines.

c. This unit shall have at least one occupational or physical therapist available as needed with neonatal expertise and at least one individual skilled in evaluation and management of neonatal feeding and swallowing disorders (e.g., speech-language pathologist).

d. This unit shall have at least one registered dietitian/nutritionist available as needed who has training or experience in perinatal nutrition and can plan diets that meet the special needs of high-risk mothers and neonates.

e. Delivery of safe and effective perinatal nursing care requires this unit to have qualified registered nurses in adequate numbers to meet the nursing needs of each patient. To meet the nursing needs of this unit, hospitals shall develop and adhere to an acuity based classification system based on nationally recognized staffing guidelines and have documentation available on such guidelines.

f. This unit shall have the following support personnel immediately available as needed to be on-site in the hospital, including but not limited to,

i. licensed respiratory therapists or registered nurses with specialized training who can supervise the assisted ventilation of neonates with cardiopulmonary disease.

3. Equipment Requirements

a. This unit shall have the following support equipment, in sufficient number, immediately available as needed in the hospital that includes, but is not limited to:

i. advanced imaging with interpretation on an urgent basis (computed tomography, ultrasound (including cranial ultrasound), MRI, echocardiography and electroencephalography); and

ii. respiratory support that allows provision of continuous mechanical ventilation for infants less than 32 weeks gestation and weighing less than 1,500 grams.

4. Transport

a. It is optional for level III NICUs to provide transports. If the unit performs transports, the unit shall have a qualified transport team and provide for and coordinate neonatal transport with level I and level II units throughout the state.

b. Transport shall be in accordance with national standards as published by the American Academy of Pediatrics' section on neonatal and pediatric transport and in accordance with applicable Louisiana statutes.

5. Quality Improvement Collaborative

a. Facilities with level III NICUs and above shall participate in a quality improvement collaborative and a

database selected by the Medicaid Quality Committee, Neonatology sub-committee.

b. Proof of current participation by the facility will be available from the Louisiana DHH website.

D. Level III Surgical NICU

1. General Provisions

a. This unit shall have a transport team and provide for and coordinate neonatal transport with level I, level II units and level III NICUs throughout the state as requested. Transport shall be in accordance with national standards as published by the American Academy of Pediatrics' section on neonatal and pediatric transport and in accordance with applicable Louisiana statutes.

NOTE: All provisions of level III NICUs are required of level IIIS and IV NICUs.

2. Personnel Requirements

a. For medical sub-specialty requirements refer to Table 1—Neonatal Medical Subspecialties and Transport Requirements.

EXCEPTION: Those hospitals which do not have a member of the medical staff who is a board certified/eligible pediatric anesthesiologist but whose anesthesiologist has been granted staff privileges to perform pediatric anesthesiology, such physician(s) may be grandfathered as

satisfying the requirement of §9513(2)a when the hospital has documented evidence that the anesthesiologist was granted clinical staff privileges by the hospital prior to the effective date of this Rule. This exception applies only to such physician at the licensed hospital location and is not transferrable.

3. Equipment Requirements

a. This unit shall have the following support equipment, in sufficient number, immediately available as needed in the hospital that includes, but is not limited to:

i. a full range of respiratory support that includes high frequency ventilation and inhaled nitric oxide.

E. Level IV NICU

1. General Provisions

a. This unit shall be located within an institution with the capability to provide surgical repair of complex conditions (e.g. congenital cardiac malformations that require cardiopulmonary bypass with or without extracorporeal membrane oxygenation).

2. Personnel Requirements

a. for medical sub-specialty requirements, refer to Table 1—Neonatal Medical Subspecialties and Transport Requirements.

NOTE: All provisions of level IIIS NICUs are required of level IV NICUs.

b. Neonatal Medical Subspecialties and Transport Requirements

Table 1—Neonatal Medical Subspecialties and Transport Requirements				
Text denoted with asterisks (*) indicates physician shall be available in person on site as needed by the facility. Each higher level NICU unit shall meet the requirements of each lower level NICU unit.				
Level I (Well Nursery)	Level II	Level III	Level IIIS	Level IV
Board Certified/Eligible Pediatric or Family Practice Physician	Board Certified/Eligible Pediatric or Family Practice Physician	Pediatric Cardiology ¹	Pediatric Surgery ⁴	Pediatric Surgery ⁴
	Board Certified Neonatologist	Ophthalmology ²	Pediatric Anesthesiology ⁵ §9513(2)a—See Exception	Pediatric Anesthesiology ⁵
	Social Worker		Neonatal Transport	Neonatal Transport
	Occupational Therapist	Social Worker Ratio 1:30	Ophthalmology ^{2*}	Ophthalmology ^{2*}
	Physical Therapist	OT or PT/neonatal expertise	Pediatric Cardiology*	Pediatric Cardiology*
	Respiratory Therapists	RD/training in perinatal nutrition	Pediatric Gastroenterology*	Pediatric Cardiothoracic Surgery*
	Registered dietician/nutritionist	RT/training in neonate ventilation	Pediatric Infectious Disease*	Pediatric Endocrinology*
	Laboratory Technicians	Neonatal feeding/swallowing- SLP/ST	Pediatric Nephrology*	Pediatric Gastroenterology*
	Radiology Technicians		Pediatric Neurology ^{3*}	Pediatric Genetics*
			Pediatric Neurosurgery*	Pediatric Hematology-Oncology*
			Pediatric Orthopedic Surgery*	Pediatric Infectious Disease*
			Pediatric Otolaryngology ^{6*}	Pediatric Nephrology*
			Pediatric Pulmonology*	Pediatric Neurology ^{3*}
				Pediatric Neurosurgery
				Pediatric Orthopedic Surgery
				Pediatric Otolaryngology ^{7*}
				Pediatric Pulmonology*

Table 1—Neonatal Medical Subspecialties and Transport Requirements

Text denoted with asterisks (*) indicates physician shall be available in person on site as needed by the facility. Each higher level NICU unit shall meet the requirements of each lower level NICU unit.

Level I (Well Nursery)	Level II	Level III	Level IIIS	Level IV
				Pediatric Radiology*
				Pediatric Urologic Surgery*
			Transport note:	
¹ There shall be at least one board certified or board eligible pediatric cardiologist as a member of medical staff. For Level III facilities, staff using telemedicine shall be continuously available.			Transport shall be in accordance with national standards as published by the American Academy of Pediatrics' Section on neonatal and pediatric transport and in accordance with applicable Louisiana statutes.	
² There shall be at least one board certified or board eligible ophthalmologist with sufficient knowledge and experience in retinopathy or prematurity as a member of the medical staff. An organized program for monitoring retinotherapy of prematurity shall be readily available in Level III and for treatment and follow-up of these patients in Level IIIS and IV facilities.				
³ There shall be at least one board certified or board eligible pediatric neurologist as a member of medical staff.				
⁴ For pediatric surgery, the expectation is that there is a				

Table 1—Neonatal Medical Subspecialties and Transport Requirements				
Text denoted with asterisks (*) indicates physician shall be available in person on site as needed by the facility. Each higher level NICU unit shall meet the requirements of each lower level NICU unit.				
Level I (Well Nursery)	Level II	Level III	Level IIIS	Level IV
board certified or eligible pediatric surgeon who is continuously available to operate at that facility.				
⁵ There shall be at least one board certified or board eligible pediatric anesthesiologist as a member of the medical staff.				
⁶ Board eligible or certified in Otolaryngology; special interest in Pediatric Otolaryngology or completion of Pediatric Otolaryngology Fellowship.				
⁷ Board eligible or certified in Otolaryngology; completion of Pediatric Otolaryngology Fellowship.				
For specialties listed above staff shall be board eligible or board certified in their respective fields with the exception of otolaryngology as this field has not yet pursued certification.				

AUTHORITY NOTE: Promulgated in accordance with R.S.

40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health

and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 29:2429 (November 2003), amended LR 33:286 (February 2007), amended by the Department of Health, Bureau of Health Services Financing, LR 43:78 (January 2017), LR 43:1979 (October 2017).

§9515. Additional Support Requirements

A. A bioethics committee shall be available for consultation with care providers at all times.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 29:2429 (November 2003), amended LR 33:288 (February 2007), amended by the Department of Health, Bureau of Health Services Financing, LR 43:82 (January 2017).

Subchapter T. Pediatric Services (Optional)

§9525. General Provisions

A. Pediatric services shall be under the medical direction of a qualified physician who is a member of the medical staff with pediatric privileges and appointed by the governing body. Hospitals admitting children shall have proper facilities for their care apart from adult patients and the newborn. Children under 14 years of age shall not be placed in rooms with adult patients.

B. In hospitals with a separate designated pediatric unit in existence prior to March 1, 1995, the maximum number of beds permitted in each pediatric room shall be eight and shall meet the same spatial standards as specified in Subchapter J of these requirements. In hospitals with a separate designated pediatric unit subsequent to March 1, 1995, the maximum number of beds permitted in each pediatric room shall be four and shall meet the same spatial standards as specified in Subchapter J of these requirements. Patient rooms containing cribs shall provide at least 60 square feet minimum clear floor area for each crib, with no more than six cribs in each room. Provisions for hygiene, toilets, sleeping and personal belongings shall be included where the program indicates that parents are allowed to remain with pediatric patients. Equipment and supplies shall be readily available and appropriate for pediatric services.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 29:2431 (November 2003).

§9527. Personnel

A. Every registered nurse who works in the pediatric unit shall be trained in an emergency pediatric nursing course that includes training in pediatric trauma and pediatric advanced

life support and that has been conducted pursuant to guidelines established by the Louisiana State Board of Nursing.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 29:2431 (November 2003).

§9529. Pediatric Intensive Care Units

A. There are two levels of pediatric care units: Level I; and Level II. If pediatric intensive care services are provided, the hospital shall satisfy the Level II PICU requirements.

B. Levels I and II units shall have a PICU Committee established as a standing committee of the hospital. It shall be composed of at least physicians, nurses, respiratory therapists and other disciplines as appropriate to the specific hospital unit. The committee shall participate in the delineation of privileges for all personnel (both MD and non-MD) within the unit. Policies and procedures shall be established by the medical director and the registered nurse manager in collaboration with the committee and with approval of the medical staff and the governing body. These written policies and procedures shall include, but not be limited to, safety procedures infection control, visitation, admission and discharge criteria, patient monitoring and record keeping,

equipment preventive maintenance and repair.

AUTHORITY NOTE: Promulgated in accordance with R.S.
40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health
and Hospitals, Office of the Secretary, Bureau of Health
Services Financing, LR 29:2431 (November 2003).

§9531. Facilities

A. The Levels I and II shall be distinct, separate units within the hospital. There shall be clean and soiled utility rooms, isolation room capabilities, medication and a conference area available on the units.

B. Level I units shall be located in the Category 1 facility as defined by the American Academy of Pediatrics.

C. The Emergency Department (ED) shall have a separate covered entrance. Two or more areas within the ED shall have the capacity and equipment to resuscitate any pediatric patient with any medical, surgical or traumatic illness within facilities with Level I units. Hospitals with Level II units only need one such area. The emergency room shall be staffed 24 hours a day in facilities with either Level I or II units.

D. There shall be an operating suite with one room available within 30 minutes and a second room within 45 minutes, 24 hours a day. Hospitals with Level I units must have the capability of providing cardiopulmonary bypass, pediatric

bronchoscopy and radiography.

E. Clinical Laboratories

1. Clinical laboratories shall have microspecimen capability and the capability to perform clotting studies with one-hour turn around. There must also be the capability to perform:

- a. complete blood cell count;
- b. differential count;
- c. platelet count;
- d. urinalysis;
- e. electrolytes;
- f. blood urea nitrogen;
- g. creatinine;
- h. glucose calcium;
- i. prothrombin time;
- j. partial thromboplastin time; and
- k. cerebrospinal fluid cell counts.

2. Preparation of gram stains and bacteriologic cultures shall be available 24 hours per day. Blood gas values must be available within 15 minutes. Results of drug screening and levels of serum ammonia, serum and urine osmolarity, phosphorus and magnesium shall be available within three hours for Level I units.

F. There must be a blood bank able to provide all blood

components 24 hours a day in both Levels I and II. Cross matching shall allow for transfusions within one hour unless some unusual antibody is encountered.

G. Hospitals with Level I units must have radiology services capable of radiography, fluoroscopy, computerized tomography scanning, ultrasonography and nuclear scanning angiography.

H. Diagnostic cardiac and neurologic studies shall be available to both Levels I and II unit facilities.

I. A catheterization laboratory or angiography suite must be present in facilities with Level I units.

J. Level I units shall have the capability to provide hemodialysis 24 hours a day.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 29:2431 (November 2003).

§9533. Patient Rooms

A. The head of each bed and/or crib shall be rapidly accessible for emergency airway management.

B. Electrical power, oxygen, medical compressed air and vacuum outlets shall be available at each bed/crib.

C. There shall be walls or curtains available at each

bedside to provide for full visual privacy.

AUTHORITY NOTE: Promulgated in accordance with R.S.
40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health
and Hospitals, Office of the Secretary, Bureau of Health
Services Financing, LR 29:2432 (November 2003).

§9535. Medical Staff

A. The medical director in Level I units shall be:

1. board certified in pediatrics and board certified
or in the process of board certification in pediatric critical
care medicine (certification must be completed within five
years);

2. board certified in anesthesiology with practice
limited to infants and children with special qualifications (as
defined by the American Board of Anesthesiology) in critical
care medicine; or

3. board certified in pediatric care medicine (as
defined by the American Board of Surgery). A Level II medical
director shall meet the same criteria of Level I except the
board certification in Pediatric Critical Medicine is not
required. The medical director shall name a qualified alternate
to serve in his or her absence.

B. In existing units, consideration will be given to
waiving this requirement for board certified pediatricians with

a minimum of five years experience in pediatric care who are currently serving as medical directors of Levels I and II units. The request for waiver shall be made in writing to the Office of the Secretary.

C. Levels I and II units must have at least one physician of at least the postgraduate year two assigned to the PICU in-house 24 hours per day.

D. Other physicians including the attending physician or designee shall be available within 30 minutes.

E. Level I units shall have on staff a pediatric anesthesiologist, surgeon, cardiothoracic surgeon, neurosurgeon, intensivist, cardiologist, neurologist, pulmonologist, hematologist/oncologist, endocrinologist, gastroenterologist, allergist or immunologist, as well as a radiologist, pathologist, and psychiatrist or psychologist. Level II units shall meet the above medical staffing requirements, except the cardiothoracic surgeon and the pediatric subspecialties. There shall be a five-year phase in period with regard to staffing requirements.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 29:2432 (November 2003).

§9537. Staffing

A. Levels I and II shall have a unit manager dedicated to the unit who is a registered nurse with specific training and experience in pediatric critical care. The Level I manager shall be certified in critical-care nursing. The registered nurse manager shall name a qualified alternate to act in his/her absence.

1. The staff to patient ratio shall vary with the acuity of the patients; however, the minimum shall be 1:3.

2. There shall be an organized written orientation program as well as an ongoing in-service/continuing education program.

B. For the Level I units the respiratory therapy staff assigned to a unit shall be in-house 24 hours per day.

1. Biomedical technicians shall be available within one hour, 24 hours a day.

2. The unit clerk shall be readily available to the unit 24 hours a day.

3. A pharmacist and licensed radiographer shall be in-house 24 hours per day.

4. Social workers, physical therapists and nutritionists shall be assigned to the unit as applicable.

C. For Level II Units the respiratory therapist shall be in-house 24 hours a day.

1. The biomedical technician shall be available within one hour, 24 hours a day.

2. The pharmacist and radiologist shall be on call 24 hours a day.

3. Unit clerks, social workers, physical therapists and nutritionists shall be available as applicable.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 29:2432 (November 2003).

§9539. Supplies and Equipment

A. There shall be lifesaving, therapeutic and monitoring equipment present in Level I and II units. There shall be a complete "code" or "crash" cart available on both Level I and II units. The cart contents available on Level I and II units should include, but not be limited to, approved medications, a defibrillator/cardioverter, automated blood pressure apparatus devices. All equipment shall be of proper size for infants and children. Oxygen tanks are needed for transport and backup for both Levels I and II units.

B. There shall be additional equipment available to meet the needs of the patient population.

C. Level I units shall have the capability of ventilator

support.

D. There shall be bedside monitoring in Level I and II PICUs with the capability for continuously monitoring heart rate and rhythm, respiratory rate, temperature and one hemodynamic pressure. Level I units shall also have the ability to monitor systemic arterial, central venous, pulmonary arterial and intracranial pressures. The monitors must have alarms with both high and low settings and they must also have both audible and visible capability. There shall be a maintenance and calibration schedule maintained for all monitoring devices.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 29:2432 (November 2003).

§9541. Miscellaneous

A. PICUs shall be integrated with the regional EMS system as available. Rapid access to a poison control center is essential. Each PICU shall have or be affiliated with a transport system and team to assist other hospitals in arranging safe patient transport.

B. Each Level I PICU shall offer pediatric critical care education for EMS providers, emergency department and transport personnel as well as for the general public. The staff nurses

and respiratory therapists must also have basic life support certification.

C. Level I PICUs offering a fellowship program in pediatric critical care will possess sufficient patient volume, teaching expertise, and research capability to support such a fellowship. Programs providing sub-specialty training in critical care must possess approval by the residency review committee of the Accreditation Council on Graduate Medical Education. Research is essential for improving our understanding of the pathophysiology affecting vital organ systems. Such knowledge is vital to improve patient care techniques and therapies and thereby decrease morbidity and mortality.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 29:2433 (November 2003).

Subchapter U. Alternative Birthing Units

§9551. General Provisions

A. An alternative birthing unit (ABU) is a unit that is housed within a licensed hospital that provides both obstetrical and neonatal intensive care unit (NICU) level one status at that location. The ABU shall be its own designated unit, separate and apart from any other unit within the hospital.

B. An ABU shall be in compliance with the:

1. American Midwifery Certification Board;
2. American Academy of Pediatrics; and
3. American College of Obstetrics and Gynecology

guidelines.

C. An ABU shall be in compliance with all federal, state and local statutes, laws, rules, regulations and ordinances as applicable.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 40:1099 (June 2014).

§9553. Definitions

Active Labor—contractions resulting in progressive effacement and dilation of the cervix.

Alternative Birthing Unit (ABU)—a unit located within a hospital in which delivery is expected following a low risk, normal, and uncomplicated pregnancy. Care and services provided prior to, during, and following childbirth are under the direction of a certified nurse midwife.

Antepartum Care (Prenatal Care)—occurring or existing before birth. The prenatal period (also known as antenatal care) refers to the regular medical and nursing care recommended for

women during pregnancy. Prenatal care is a type of preventative care with the goal of providing regular check-ups that allow doctors or certified nurse midwives to treat and prevent potential health problems throughout the course of the pregnancy.

Certified Nurse Midwife (CNM)—an advanced practice registered nurse educated in the disciplines of nursing and midwifery and certified according to a nationally recognized certifying body, such as the American College of Nurse Midwives Certification Council, as approved by the Board, and who is authorized to manage the nurse midwifery care of newborns and women in the antepartum, intrapartum, postpartum and/or gynecological periods pursuant to Title 46, Part XLVII, Chapter 45, §4503.B.1 et seq.

Complications—any condition as defined by the medical staff/governing body that contraindicates continued care in the alternative birthing center.

Doula—a nonmedical person, certified by Doula of North America (DONA) who assists a woman before, during or after childbirth, as well as her partner and/or family, by providing information, physical assistance and emotional support.

Family—individuals selected by the pregnant woman to be present and/or in attendance during her admission to the ABU.

Intrapartum—the period beginning with active labor to the

expulsion of the placenta.

Licensed Practitioner—for purposes of this Rule refers to a licensed physician and/or a certified nurse midwife.

Low Risk Pregnancy—a normal uncomplicated term pregnancy as determined by a generally accepted course of prenatal care. The expectation of a normal uncomplicated birth as shall be defined by the medical staff/governing body.

Medical Director—a physician licensed to practice medicine by the Louisiana State Board of Medical Examiners (LSBME), who is board certified as an obstetrician and gynecologist (OB/GYN) and credentialed and privileged for the hospital's obstetrical/gynecological services.

Postmature—gestational age of greater than 42 weeks.

Postpartum—the period beginning immediately after childbirth.

Preterm—prior to the thirty-seventh week of gestation.

Term—gestational age of greater or equal to 37 weeks.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 40:1099 (June 2014).

§9555. Program Requirements

A. An ABU shall have policies/procedures and written

criteria for the evaluation of risk status, admission, transfer, discharge, and complications requiring medical or surgical intervention. The policies/procedures and written criteria shall be developed, implemented, enforced, monitored, and reviewed annually by the clinical staff and approved by the governing body.

1. In order for a pregnant woman to be admitted to an ABU, the following admission requirements must be met.

a. The pregnancy shall be deemed low-risk by the licensed practitioner with the expectation of a singleton, vertex, and spontaneous vaginal birth at term without complication.

b. The pregnant woman shall have had consistent prenatal care which began no later than 28 weeks gestation with consistent prenatal screening.

c. A maternal/fetal assessment performed by the CNM shall be completed and documented within one hour of admission to the ABU.

2. The facility shall have policies and procedures readily available in the event the condition of the mother and/or newborn require transfer to an acute care unit within the hospital or emergent transfer to another hospital.

3. The facility shall have policies and procedures for discharge planning of the mother and newborn.

B. A patient who meets any of the following criteria/conditions shall not be admitted for delivery in an ABU:

1. females below 18 years of age;
2. a patient with any of the below documented condition(s) in the maternal medical history, based on an assessment by a licensed practitioner:
 - a. cardiovascular disease;
 - b. pulmonary disease and/or history of pulmonary embolus;
 - c. renal disease;
 - d. insulin-dependent diabetes;
 - e. bleeding disorder or hemolytic disease;
 - f. fetal malpresentation;
 - g. placenta previa;
 - h. preeclampsia;
 - i. oligohydramnios;
 - j. polyhydramnios;
 - k. ruptured membranes greater than 18 hours prior to onset of labor;
 - l. previous Rh sensitization;
 - m. vaginal birth following C-section (VBAC);
 - n. multiple births;
 - o. preterm labor;

- p. post-maturity; or
- q. fetal abnormality; or

3. a patient with a high risk pregnancy as determined by a licensed practitioner.

C. The following services shall be prohibited in the ABU:

- 1. general, intravenous, and/or conductive analgesia/anesthesia to include spinal and epidural analgesia/anesthesia;
- 2. conscious sedation;
- 3. caesarean sections and operative obstetrics to include tubal ligations;
- 4. stimulation or augmentation with chemical agents, e.g., oxytocin during the first and second stages of labor; and
- 5. vacuum extractors and/or forceps.

D. Prenatal Screening Requirements

- 1. Pregnant women shall be screened by either/or an OB/GYN, a certified nurse midwife (CNM), or an advanced practice registered nurse (APRN). Documentation of the screening shall include, but not be limited to:
 - a. social, family, medical, reproductive, nutritional, drug and alcohol use;
 - b. violence screen, depression screen and mental health history;
 - c. physical examination to include Papanicolaou

smear and assessment for sexually transmitted diseases as determined by a licensed practitioner;

- d. a prenatal laboratory profile to include a:
 - i. complete blood count, blood type and Rh antibody screen;
 - ii. glucose tolerance test;
 - iii. urinalysis; and
 - iv. other diagnostic testing as medically indicated; and
- e. a repeat evaluation of the hemoglobin or hematocrit between 28 and 36 weeks gestation.

E. Newborn Requirements. The ABU shall be in compliance with current state laws, rules and regulations for screening of newborn health conditions.

F. Patient and/or Patient's Family Educational Requirements. The following educational programs are required to be completed by the patient and/or patient's family as determined by the policy and procedures of the ABU prior to discharge:

- 1. anticipated physiological and psychological changes during pregnancy;
- 2. fetal development;
- 3. normal nutrition;
- 4. warning signs of pregnancy complications;

5. self-care to include:
 - a. information on the dangers of smoking, alcohol and substance abuse; and
 - b. the need for dental care;
6. stages of labor;
7. non-pharmacologic techniques to promote comfort and relaxation during labor;
8. delivery process;
9. newborn care;
10. normal postpartum;
11. bonding;
12. breast-feeding;
13. importance of immunization;
14. criteria for discharge from the center;
15. child safety to include the use of car seats and safe sleeping practices;
16. directions for obtaining laboratory tests for newborns as required by the Department of Health and Hospitals;
17. instruction as to the clothing/supplies needed at the time of discharge from the center; and
18. a family instructional program.

G. In order for the family to participate in the birth process in the ABU, the following requirements shall be met.

1. The number of individuals/family members present

at the time of birth shall be determined by the ABU's policy which takes into account room size and the need for infection control.

2. Individuals/family members shall abide by the facility's infection control policies.

3. An adult not involved in the birthing process shall be in charge of all minor children.

4. Only service animals shall be allowed in the ABU.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 40:1099 (June 2014).

§9557. Policies and Procedures

A. An ABU shall develop, implement, enforce, monitor, and review annually the policies and procedures specific to the care and services of the mother and newborn. The policies and procedures shall be jointly developed by the medical director and professional staff and adopted by the governing body. These policies and procedures shall include, but are not limited to:

1. staffing;
2. admission criteria;
3. educational services;
4. consent for medical treatment and care;

5. initial and continuing risk assessment by the
CNM;
6. criteria for consultation with collaborative
physicians;
7. water birth;
8. external fetal monitoring (EFM);
9. nursing assessments;
10. medication administration;
11. laboratory and diagnostic services;
12. dietary services;
13. obstetric and pediatric consultation services;
14. newborn care, including:
 - a. pulse oximetry heart disease screening; and
 - b. circumcision of a male newborn by a licensed
OB/GYN or other qualified physician as determined by the
governing body;
15. emergency procedures for the mother and/or
newborn, including:
 - a. maternal emergent care policy;
 - b. newborn emergent care policy;
 - c. maternal transfer to an acute care unit
within the hospital or transfer to another hospital;
 - d. newborn transfer to an acute care unit
within the hospital or transfer to another hospital;

- e. precipitous delivery; and
- f. newborn abduction;
- 16. family support and participation, including:
 - a. criteria for labor and delivery attendance;
- and
- b. doula;
- 17. unique identification for mother and newborn;
- 18. delivery log;
- 19. mother/baby couplet aftercare, including:
 - a. lactation support services;
 - b. social services; and
 - c. home health care services, if applicable;
- 20. maternal and newborn discharge, including:
 - a. length of stay; and
 - b. child passenger restraint system;
- 21. follow-up postpartum and newborn care; and
- 22. hospital staff on call policy and procedure.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 40:1101 (June 2014).

§9559. Physical Environment

- A. An ABU shall submit, meet, and obtain approval for

facility plan review from the Office of State Fire Marshall prior to construction.

1. An ABU shall:

- a. consist of a minimum of two birthing rooms and one examination room;
- b. be located to ensure privacy;
- c. be located out of the path of unrelated traffic; and
- d. be under the direct supervision of the unit staff.

2. Birthing rooms shall:

- a. be single occupancy;
- b. have a minimum clear floor area of 200 square feet, including the newborn care area and a minimum clear dimension of 12 feet;
- c. have an outside window;
- d. have windows or doors within a normal sightline that would permit observation into the room and shall be arranged or draped as necessary for mother and newborn privacy;
- e. have a hands-free hand-washing station; and
- f. have direct access to a private bathroom that includes a:
 - i. hand-washing station;

ii. toilet; and

iii. shower or tub.

B. The newborn care area shall be a separately located area within the birthing room.

C. The reception and administration area shall be located as to control and monitor traffic flow/access to the ABU.

D. The staff work area shall:

1. be provided for the ABU staff;
2. have space for counters and storage; and
3. have convenient access to hand-washing

facilities.

E. Hand-washing stations shall be readily accessible to families, visitors, and staff.

F. Medication Preparation Location

1. Provisions shall be made for the distribution of medications from a medicine preparation room or area, from a self-contained medicine dispensing unit, or by another approved system.

2. The medication preparation room or area shall:

a. be under the visual control of the staff;

and

b. contain the following:

i. a work counter;

ii. a hand-washing station;

- iii. a lockable refrigerator; and
- iv. a locked storage for controlled drugs.

3. When a medication preparation room or area is to be used to store self-contained medication dispensing units, the room shall be designed with adequate space to prepare medicines with the self-contained medicine-dispensing units present.

G. Self-Contained Medication-Dispensing Unit

1. The location of a self-contained medicine-dispensing unit shall be permitted in the clean workroom or in an alcove, provided the ABU has adequate security for medications and adequate lighting to easily identify drugs.

2. The self-contained medicine-dispensing unit shall provide convenient access to hand-washing stations.

H. Nourishment Area

1. A nourishment area shall have the following:
- a. a sink;
 - b. a work counter;
 - c. a refrigerator;
 - d. storage cabinets;
 - e. equipment for hot and cold nourishment;
 - f. provisions and space for separate temporary storage of unused and soiled dietary trays not picked up during meal time; and
 - g. immediate accessible hand-washing stations

in or near the nourishment area.

2. Ice-making equipment shall:

a. be provided for treatments and nourishment;
b. be permitted in the clean workroom or the
nourishment room; and

c. ice intended for human consumption shall be
provided in the nourishment station and shall be served from
self-dispensing ice-makers.

I. A clean workroom shall be separate from and have no
direct connection with soiled workrooms or soiled holding rooms.

1. If the room is used for preparing care items for
mothers and newborns, it shall contain:

a. a work counter;
b. a hand-washing station; and
c. storage facilities for clean and sterile
supplies and equipment.

2. Storage for hazardous cleaning solutions,
compounds, and substances shall be labeled and kept in an
enclosed storage area or approved cabinet separate from other
cleaning materials.

J. A soiled workroom or soiled holding room shall be
separate from and have no direct connection with clean work
rooms or clean supply rooms.

1. A soiled workroom or soiled holding room shall

contain:

a. a clinical sink (or equivalent flushing rim fixture) and a hand-washing station; and

b. a work counter and space for separate covered container for soiled linen and a variety of waste types.

2. Omission of the clinical sink and work counter shall be permitted in rooms used only for temporary holding of soiled material. If the flushing-rim clinical sink is not provided, the facilities for cleaning bedpans shall be provided in the mothers' toilet rooms.

K. Environmental Services Room. An environmental services room shall be provided for the exclusive use of the ABU and include:

1. a service sink or floor receptor; and

2. a space for storage of supplies, housekeeping equipment, and housekeeping carts.

L. Examination Rooms. An examination room shall:

1. preserve patient privacy from outside observation;

2. be located convenient to nursing the station;

3. have a bathroom immediately accessible that

includes:

a. ventilation with a minimum of 10 air changes per hour; and

- b. have an exhaust;
 - 4. have a hand-washing station;
 - 5. have the following space requirements:
 - a. a minimum clear floor area of 80 square feet;
 - b. a minimum continuous clearance of 2 feet 8 inches at each side of the examination table; and
 - c. have counter and shelf space;
 - 6. have ventilation with a minimum of six air changes per hour;
 - 7. have lighting with fixed and portable features;
- and
- 8. have an examination table with access to at least two duplex receptacles.

M. Support areas provided for staff shall include:

- 1. a changing room;
- 2. a lounge;
- 3. a bathroom; and
- 4. securable lockers, closets and cabinet compartments.

N. Engineering and maintenance services shall have sufficient space for mechanical and electrical equipment and for the proper maintenance of equipment.

O. Building Codes and Architectural Details

1. The facility shall meet the business occupancy provisions of applicable life safety and building codes.
2. Corridors shall have a minimum corridor width of 5 feet and minimum height of 7 feet 8 inches.
3. Ceilings shall have a minimum height of 7 feet 10 inches with the following exceptions:
 - a. ceilings heights for storage rooms, toilet rooms, etc. shall not be less than 7 feet 8 inches; and
 - b. rooms containing ceiling mounted equipment/light fixtures shall be of sufficient height to accommodate the equipment or fixtures and normal movement.
4. Birthing Room Surfaces. Birthing room surfaces shall have:
 - a. finishes selected to facilitate cleaning and to resist strong detergents; and
 - b. finishes in the dietary area to ensure the ability to be cleaned and disinfected.

P. Building Systems

1. Heating, ventilation and air-conditioning, electrical, plumbing and related systems shall meet state and local building codes.
2. Heating, ventilation and air-conditioning systems in the environmental services (housekeeping) room shall be exhausted at a rate consistent with approved infection control

guidelines.

Q. Electrical Systems

1. Lighting shall:

a. provide both subdued indirect lighting and special lighting capable of providing at least 70 foot-candles in the delivery and newborn care area(s); and

b. have emergency lighting available.

R. Oxygen and vacuum outlets shall be available.

1. Use of portable equipment shall be permitted.

S. Security systems shall be designed for active and passive security systems. Locking arrangements, security alarms, and monitoring devices shall be placed not to interfere with the life safety feature necessary to operate and maintain a healthy and functional environment.

T. Elevators shall be equipped with a cab with minimum dimensions of 5 feet 8 inches wide by 7 feet 6 inches deep.

U. Corridors, attics, and passageways shall be free of storage. Exits shall not be blocked by storage of furniture or equipment at any time.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 40:1101 (June 2014).

§9561. Equipment

A. The governing body and medical staff shall specify the types of equipment that is required for an ABU. This shall include at a minimum:

1. emergency equipment including:
 - a. an adult emergent care cart labeled and stocked accordingly; and
 - b. a neonatal emergent care cart labeled and stocked accordingly;
2. equipment and supplies used for labor and delivery including:
 - a. fetal heart rate doppler, fetoscope, and/or external fetal monitor;
 - b. a birthing tub; and
 - c. a bed;
3. equipment and supplies used for the newborn including:
 - a. a newborn crib, bassinet or newborn examination unit; and
 - b. calibrated newborn scales;
4. oxygen and supplies;
5. pulse oximetry supplies;
6. suction and supplies for mother and newborn;
7. maternal and newborn airways;

8. a wall clock synchronized with hospital system;
9. supplies for unique identification of mother and newborn;

10. a secure medication dispensing system;
11. emergency call and lighting systems; and
12. ancillary support equipment as needed.

B. The facility shall have a newborn abduction emergency alert system.

C. All hand-washing facilities shall be equipped with hands-free handles, disposable soap dispenser, paper towel dispenser and trash receptacle.

D. Vertical and horizontal transport systems shall be operated and maintained in a manner to provide for safe transport.

E. The facility shall have functional emergency communication, including:

1. telephone;
2. nurse call; and
3. internal/external paging system.

F. An ABU shall have storage for hazardous cleaning solutions, compounds, and substances.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health

and Hospitals, Bureau of Health Services Financing, LR 40:1103
(June 2014).

§9563. Services

A. The ABU shall have patient care services policies that delineate the organization of the unit, qualifications of the staff and requirements for staff to patient ratio.

B. Unit Organization

1. Care in an ABU shall be under the direction of a CNM.

a. A CNM and a registered nurse shall be available per hospital on call policy to ensure 24-hour coverage for patient care.

b. Qualified professional clinical staff shall monitor the patient's progress in labor with ongoing assessments of maternal/fetal reactions to the process of labor, within accepted professional standards.

2. Authority and responsibilities of all patient care staff shall be clearly defined in written policies.

3. The functions of the ABU shall be under the direction of perinatal services. These functions shall include, but are not limited to:

a. the development, implementation, enforcement, monitoring, and annual review of policies and procedures related to patient care;

b. the orientation and training of qualified staff for provision of care; and

c. provisions for current educational and reference materials.

C. Staff Qualifications

1. The CNM shall provide documentation of current licensure and certification, as required by the Louisiana State Board of Nursing (LSBN). The documentation shall be maintained as part of the credential file for each CNM.

2. Licensed nursing personnel shall practice in accordance with the Louisiana State Nurse Practice Act and demonstrate current licensure by LSBN.

3. All clinical staff of the ABU shall be required to provide documentation of training and continued competence in Adult Basic Cardiopulmonary Life Support (BCLS) and Neonatal Resuscitation Program (NRP) or its equivalent.

4. Documented, dated, and signed demonstration of skills competencies shall be maintained in the personnel file for each staff member.

D. Requirements for Staff to Patient Ratio

1. A CNM must be present at all times while a laboring patient is in the ABU.

2. A registered nurse (RN) shall provide 1:1 maternal care during labor, delivery and post-delivery.

3. There shall be sufficient professional and support staff on duty and on call to meet the following patient's needs:

- a. for services routinely provided;
- b. to assure patient safety and satisfaction;

and

c. to ensure that no patient in active labor is left unattended.

4. During the second stage of labor, 2:1 patient care is required, with one of the clinical staff being a CNM and one other RN.

5. Staffing per shift shall be based on acuity and census of the ABU.

6. Each RN shall be responsible for 1:1 labor care and/or 1:2 couplet care.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 40:1103 (June 2014).

§9565. Medical Records Requirements

A. The medical record of the mother and newborn shall include, but not be limited to, the following documentation:

- 1. informed consent signed by the patient and the

CNM;

2. demographic and patient information;
3. family, medical, social, reproductive, nutrition and behavioral history;
4. initial maternal assessment and examination;
5. evaluation of maternal/fetal risk factors;
6. written orders for maternal/fetal and newborn care;
7. laboratory and/or diagnostic test results;
8. documentation of maternal/fetal and newborn monitoring;
9. postpartum assessments;
10. physical assessment of newborn, (e.g., Apgar score, weights, measurements);
11. labor and discharge summaries; and
12. educational instructions for postpartum and newborn home care, follow ups, and referrals.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 40:1103 (June 2014).

§9567. Pharmaceutical Services

- A. The ABU shall follow hospital policies and procedures

for pharmaceutical services regarding the procurement, storage, distribution and control of all medications. The ABU shall be in compliance with all local, state, and federal regulations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2100-2115.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 40:1104 (June 2014).