

able to demonstrate competency in the training areas pursuant to §7281.C.1-4.

b. Documentation of such competency evaluation of each direct care staff person shall be maintained and readily available in the agency's records.

NOTE: Such training does not permit the unlicensed employee to perform medication administration which is separate and apart from the performance of assistance of a client with the self-administration of medications.

5. Medications shall be stored in a secure central location and not stored in the client's own room.

6. The facility may require the clients to come to a designated medication area to take their medications.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:31-28:37.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:72 (January 2017).

Subchapter J. Secure Forensic Facility Module

§7285. General Provisions

A. Providers applying for the secure forensic (SF) facility module under the FSTRA facility license shall meet the core licensing requirement as well as the following module specific requirements.

B. A secure forensic facility is a secure residential facility located on the grounds of a state owned or operated hospital that provides individualized services, including personal care services and medication administration, to persons who are under a court order or court ordered forensic conditional release and who are referred by a state forensic hospital or state forensic psychiatric unit, in order to prepare such persons for transition to a less restrictive environment before transitioning to the community.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:31-28:37.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:72 (January 2017).

§7287. Operational Requirements

A. The facility shall provide 24-hour, seven day per week supervision and the care and services sufficient to meet the needs of the clients. Staffing shall consist of at least three direct care staff persons during the day and two awake staff during the night. There shall be at least two direct care staff persons in each building and/or unit at all times when clients are present.

1. The facility shall have a RN on duty during the day shift to oversee the nursing services of the facility.

a. Requirements for the level of RN supervision provided and the specified time frame for day shift shall be defined by facility policy, approved by the governing body, reviewed and documented annually.

2. The facility shall have at least one licensed nurse on duty for each shift.

3. The facility shall provide for, either directly or through contract, a licensed medical doctor on call.

B. Admission

1. The facility shall:

a. admit clients who are under a court order or court ordered forensic conditional release and who are referred by a LDH state forensic facility;

b. not admit more clients into care than the number specified on the facility's license; and

c. provide contact information, including the phone number and mailing address, for the appropriate state protection and advocacy organization.

C. Client Services

1. The facility shall provide or coordinate, to the extent needed or desired by clients, the following services:

a. assistance provided by direct care staff, either employed or contracted, with activities of daily living and all instrumental activities of daily living;

b. medication administration by the licensed nurse;

c. opportunities for individual and group socialization;

d. services for clients who have behavior problems requiring ongoing staff support, therapeutic intervention, and supervision to ensure no danger or infringement of the rights of other clients or individuals;

e. household services essential for the health and comfort of clients (e.g. floor cleaning, dusting, bed making, etc.);

f. basic personal laundry services; and

g. a planned program of recreational activities.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:31-28:37.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:73 (January 2017).

Chapter 75. Licensing of Rural Health Clinics

Subchapter A. General Provisions

§7501. Definitions and Acronyms

A. The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise.

CLIA—Clinical Laboratories Improvement Act—requires a waiver or certificate to assure quality of laboratory testing.

DHH—Louisiana Department of Health and Hospitals

Division of Research and Development—Office of Primary and Rural Health Care Unit in DHH.

HCFA—Health Care Financing Administration—federal regulatory agency for Medicaid, Medicare, and Child Health Insurance programs.

HSS—Health Standards Section in the Bureau of Health Services Financing of DHH.

Midlevel Practitioner—a certified nurse midwife, a certified nurse practitioner, or physician assistant.

OMB—Office of Management and Budget of the Executive Office of the President of the United States.

OPH—Office of Public Health in the Department of Health and Hospitals.

OSFM—Louisiana Office of State Fire Marshal.

Primary Care—services normally provided in a physician's office to diagnose, treat, or prevent illness or injury; and includes professional services provided by licensed professionals such as assessment, examination, approved laboratory services, and treatment services listed in §7519.

Professional Services—documented on-site visits at the clinic or in locations other than the clinic, such as the patient's home, for the purpose of providing professional level skilled services. *Professional Services* include physical assessment, any of the waived clinical laboratory tests and treatment/education for the illness diagnosed when provided by a qualified professional as defined below.

Qualified Professionals—one of the following professionals qualified to provide services:

- a. Physician—Doctor of Medicine (MD);
- b. Advanced Practice Registered Nurse (APRN);
- c. Licensed Physician's Assistant (PA);
- d. Licensed Social Worker—Licensed Clinical Social Worker (LCSW);
- e. Licensed Clinical Psychologist (LP).

Rural Area—a non-metropolitan statistical area, as defined by the federal Office of Management and Budget and the Census Bureau/Population and Housing Unit Counts, which has a shortage of physicians and other health care providers as determined by the Department of Health and Hospitals.

Rural Health Clinic (RHC)—an outpatient primary care clinic seeking or possessing certification by the Health Care Financing Administration (HCFA) as a rural health clinic, which provides diagnosis and treatment to the public by a qualified mid-level practitioner and a licensed physician.

Secretary—secretary of the Department of Health and Hospitals.

Standards of Practice—standards developed and issued by Louisiana professional practices boards that govern health care and allied health professions. Duties and

delegation of duties by licensed/certified personnel shall be performed within the bounds of ethical and legal standards of practice. All patient care services must be provided in accordance with the orders of licensed and certified practitioners. Standards of practice pertinent to rural health clinic practice are listed in §7523 of this document.

Waiver or Variance—written permission granted by the HSS or DHH Secretary or his designee to a facility to operate out of compliance with a specific portion of the standards when it is determined that the health and safety of the patients will not be jeopardized.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2197.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 25:1846 (October 1999), amended LR 28:508 (March 2002).

§7503. Licensing

A. General Provisions. Rural Health Clinics shall:

1. operate in accordance with rules, regulations and standards contained in this document;
2. meet and maintain compliance with all current DHH minimum licensing standards;
3. maintain a sufficient number of qualified professional personnel to provide services appropriate to level of care and the number of patients served; and
4. maintain at least \$500,000 of general liability insurance and \$500,000 of professional liability insurance and provide to DHH proof of insurance upon request;
5. The rural health clinic license shall be posted within public view in a conspicuous place within the facility.

B. Initial Licensing

1. Policies
 - a. All applications shall be original documents submitted to HSS in accordance with current procedures.
 - b. Incomplete applications will be closed and discarded 90 days from date of original submission of data. An application is not considered pending until the day a complete application has been received and approved.
 - c. Any misrepresentation or falsification of documentation will nullify the application and automatically restrict the applicant from participation in any programs licensed by HSS for at least one year.
 - d. Fees or payments for charges submitted to HSS shall be in the form of a company check, certified check or money order made payable to DHH and are non-refundable and non-transferable.

2. Procedures

- a. Obtain a packet from HSS (packet is informational and current for approximately 90 days from date of purchase).

b. Complete and submit an original rural health clinic licensing application.

c. Submit the appropriate licensing fee.

d. Submit the following documentation:

i. all documentation pertinent to the proposed location from the Division of Research and Development, Office of Primary and Rural Health Care Unit and dated within 30 days prior to application;

ii. written approval of site/building plans by DHH planning review section;

iii. required jurisdictional approvalsXlocal, state, and federal such as zoning, Fire Marshal, and sanitation;

iv. letter of intent which shall include:

(a). proposed operational hours;

(b). proposed target population including clinic location, service area, and pertinent demographics;

(c). copy of site plan and sketch of the floor plan of the building;

(d). proposed date to begin operation;

(e). services to be provided;

(f). relationships and/or agreements with other entities (hospitals, emergency transportation, etc.);

(g). other licenses, contracts with state, such as Community Care, Kid Med, managed care, etc.;

v. appropriate CLIA approval prior to any initial survey.

3. Survey. Prior to issuing an initial license, DHH/HSS will make a comprehensive on-site assessment to determine the capability of the facility to provide primary care services. A facility shall be operational prior to survey and must have seen at least five patients at the time of survey.

C. Types of License

1. Full, Unrestricted. This license type indicates that the facility is in full compliance with licensing standards, and is valid for one year unless revoked, suspended, or denied. The license is non-transferable.

2. Provisional. This license type is issued for a specific length of time in order to designate that the facility is not in full compliance with licensing standards. A provisional license may be issued for the following reasons:

a. any repeat violation;

b. serious violation during any survey or on-site visit;

c. isolated incidence of non-compliance that has the potential for serious harm if not corrected immediately; or

d. determination that the facility has potential for serious violation or potential harm due to personnel turnovers, ownership changes, management changes, etc.

D. Informal Dispute Resolution. Following each survey, the provider will have one opportunity to question citations of deficient practice through an informal dispute resolution process. Notice is sent with each statement of deficiencies and provides instructions on how to request the informal dispute resolution.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 and R.S. 40:2197.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 25:1846 (October 1999), amended LR 28:508 (March 2002).

§7505. Denial, Revocation, or Non-Renewal of License

A. The Secretary of DHH may deny an application for a license, refuse to renew a license or revoke a license when an investigation reveals that the applicant or licensee is not in conformance with or in violation of the provisions of R.S. 40:2197, provided that in all such cases, the Secretary shall furnish the applicant or licensee 30 calendar days written notice specifying the reasons for the action.

B. A rural health clinic license may be denied, revoked, or non-renewed for any of, but not limited to, the following reasons:

1. failure to meet any of the minimum standards, rules and regulations as prescribed under R.S. 40:2197;

2. conviction of a felony, as shown by a certified copy of the applicant's record of the court of conviction, or if the applicant is a firm or corporation, on any of its members or officers, or of the person designated to manage or supervise the facility; or if the supervisor of the facility is not reputable; or if the staff or a member of the staff is temperamentally or otherwise unsuited for the care of the patients in the facility. For the purposes of this Paragraph, *conviction of a felony* means and includes:

a. conviction of a criminal offense related to that person's involvement in any program under Medicare or Medicaid, since the inception of those programs;

b. conviction of a felony relating to violence, abuse and/or neglect of a person;

c. conviction of a felony related to the misappropriation of property belonging to another person;

3. failure to comply with all federal, state and local laws;

4. failure of the facility to protect patients/persons in the community from harmful actions of the clinic employees, including but not limited to:

a. health;

b. safety;

c. coercion;

- d. threat;
 - e. intimidation;
 - f. solicitation; and
 - g. harassment;
5. failure to maintain adequate staff to provide necessary services to current active patients;
 6. failure to employ qualified personnel;
 7. failure to remain fully operational at all times for any reason other than a disaster;
 8. failure to submit fees, including but not limited to, annual renewal fee at least 30 days prior to the license expiration date;
 9. failure to allow entry to the rural health clinic or access to any requested records during any state or federal survey;
 10. cruelty to patients.

C. Any involuntary termination, failure to renew, or voluntary termination of the facility's license to avoid adverse action will automatically prevent the facility, the facility owners, professional staff, administrative staff, family members and others as appropriate from applying for a RHC license, or from owning or working with a rural health clinic, for at least one year. Persons who own 5 percent or more of a facility are considered owners.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 and R.S. 40:2197.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 25:1846 (October 1999), amended LR 28:508 (March 2002).

§7507. Changes/Reporting

A. Data Submission. Information requests will be sent to the clinic by various offices of DHH or its contractors. All requests must be answered promptly and must be current at time of renewal or license will not be issued.

1. Each facility shall notify DHH/HSS if facility contracts to provide services under another program such as Community Care, Kid Med, managed care, etc.

2. Failure to return requested information shall result in adverse action including, but not limited to, sanctions, and/or revocation of license.

B. Notifications. The rural health clinic must notify HSS at least fifteen days prior to any operational changes. A license is non-transferable; therefore, invalid for any other location or owner except as originally issued. Any break in the operation of the facility will invalidate the license.

1. Change of Ownership. The following information must be submitted:

- a. certified copy of bill of sale;
- b. application reflecting changes; and

- c. letter of intent, narrative explanation of changes.
2. Change of Address(Location). Submit the following information:
 - a. same zip code:
 - i. letter for approval by DHH/HSS;
 - ii. fire marshal's approval;
 - iii. fee to re-issue license; and
 - iv. copy of current license;
 - b. different zip code-site approval letter in addition to above requirements.
 3. Change in Services. The following information must be submitted:
 - a. letter to file listing current services; additional/deleted services;
 - b. copy of license;
 - c. professional and management staffing changes; and
 - d. use of a contract mid-level practitioner instead of the employee for any period of time greater than 30 days.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 and R.S. 40:2197.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 25:1846 (October 1999), amended LR 28:509 (March 2002).

§7509. Annual Licensing Renewal

A. Department of Health and Hospital Responsibilities. It is the responsibility of DHH to:

1. send a letter of notification of license renewal to the facility approximately 45 days prior to expiration of the license;
2. conduct an annual survey to assure that the facility provides quality care and adheres to licensing requirements; and
3. make a determination and take appropriate action regarding licensing.

B. Rural Health Clinic Responsibilities. It is the responsibility of the RHC to:

1. notify DHH if the renewal letter is not received in a timely manner;
2. complete the licensing application and obtain and submit other required data; and
3. submit the appropriate license fee.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 and R.S. 40:2197.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 25:1846 (October 1999), amended LR 28:509 (March 2002).

§7511. Notice and Appeal Procedures

A. Administrative Appeal. In accordance with the Administrative Procedure Act, the facility may request an administrative appeal when notice is received of denial of initial license, denial of a license renewal or revocation of the license. The request for the administrative appeal must be submitted in writing to the Department of Health and Hospitals, Office of the Secretary, within 30 days of receipt of the notice of the adverse action.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 and R.S. 40:2197.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 25:1846 (October 1999), amended LR 28:509 (March 2002).

§7513. Complaint Procedures

A. All complaints and appeals from complaints will be investigated by the HSS in accordance with Louisiana R.S. 40:2009.13 et. seq.

B. Deficiencies or violations noted during complaint investigations may result in adverse actions, sanctions, terminations, and/or require immediate or routine corrective action as determined by DHH.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2197.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 25:1848 (October 1999).

§7515. Voluntary Cessation of Business

A. Cessation of Business. If at any time the facility ceases to operate (regardless of length of time), the license shall be deemed invalid and shall be returned to DHH/HSS within five working days.

1. The agency owner is responsible for notifying DHH of the location of all records required to be maintained by the facility.

2. If the facility fails to surrender its license, the facility and its owners and administrative officers may be prohibited from operating for at least one year as a rural health clinic.

B. Expiration of License. Failure to renew a license prior to its expiration date shall result in non-renewal of the license.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 and R.S. 40:2197.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 25:1846 (October 1999), amended LR 28:509 (March 2002).

§7517. Personnel Qualifications/Responsibilities

A. Responsibility. The administration is responsible for assuring that:

1. all staff members are aware of their job responsibilities and are capable of performing assigned tasks;

2. a facility's staffing is adequate to produce the desired treatment outcomes and must reflect the volume of the patients, patient acuity, and number of services provided;

3. a facility develop and utilize a specific process to determine appropriate staffing levels.

B. Qualification. All personnel shall be licensed in accordance with their respective professions and be either board certified or board eligible as required by their respective certifying organizations. In addition, a facility shall be responsible for verifying and monitoring that professional certified personnel maintain continuous license/certification.

1. Physician Services. The physician shall provide on-site supervision of the mid-level practitioner(s) as required by the payment source and professional boards or at least every other week. All rural health clinic records and care provided by a mid-level practitioner(s) shall be assessed by a physician on a periodic basis or as the situation dictates to assure proper treatment and progress toward positive patient outcomes.

a. Medical Director. The medical director shall be credentialed to provide primary care. He/she is responsible for providing the medical direction for the clinic's activities, consultation for and supervision of the mid-level practitioner. The Medical Director, in conjunction with the mid-level practitioner, participates in the development and periodic review of the clinic's policies and services. He/She periodically reviews the patient records, issues medical orders and provides medical care services to the rural health clinic patients.

b. Other. Licensed physician credentialed to provide services provided as part of the rural health clinic services.

2. Mid-level Practitioner. The mid-level practitioner shall be appropriately licensed and credentialed as either an advanced practice registered nurse (family nurse practitioner) or physician's assistant. The mid-level practitioner(s) shall be required to maintain Advanced Cardiac Life Support (ACLS) certification to assure his/her proficiency in accepted standards of emergency care. If a facility has a current written agreement with an advanced life support provider, who can provide care within 10 minutes, then the mid-level practitioner and/or physician are exempt from this required certification.

a. Waivers will not be accepted for a mid-level practitioner.

b. Mid-level practitioners may be contracted to fulfill staffing requirements for 120 days each calendar year (January 1-December 31) with no accrual of days from year to year.

3. Support Staff. The facility should be adequately staffed to provide necessary support to the professionals. Additional staff may include pharmacists, administrators, managers, and clerical and medical records personnel.

C. Governing Body. All owners of a Rural Health Clinic shall be disclosed. Ownership of five percent or more

constitutes ownership. In the case of a corporation, members of the board of directors must be identified and minutes of the board meetings shall be made available to DHH/HSS. The board shall meet at least once a year.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 and R.S. 40:2197.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 25:1846 (October 1999), amended LR 28:509 (March 2002).

§7519. Services

A. Preventive Services

1. **Health.** Community-wide immunization efforts; wellness/fitness programs; educational programs; and health screening shall be provided.

2. **Dental.** Educational information and a current list of local dental providers shall be available.

B. Diagnostic Services. The clinic must have the capacity to evaluate and make initial diagnoses on-site in order to refer the patient to the appropriate facility for treatment and/or more definitive diagnoses. RHCs shall, as a minimum, provide basic laboratory services essential to the immediate diagnosis and treatment of the patient. This includes:

1. chemical examinations of urine by stick or tablet method, or both (including urine ketones);
2. hemoglobin or hematocrit;
3. blood glucose;
4. examination of stool specimens for occult blood;
5. pregnancy tests; and
6. primary culturing for transmittal to a certified laboratory.

C. Treatment Services

1. **Primary Care.** The clinic shall provide primary care services, as defined in §7501 to all citizens of the community. Required primary care components include:

- a. prevention of illness, education in wellness and preventive measures;
- b. assessment and physical examination; and
- c. diagnosis and treatment.

2. **Emergency Care.** The clinic shall maintain emergency equipment, medications and personnel to provide pre-hospital advanced cardiac life support until emergency transportation can arrive and assume care of those in need of services.

a. Facilities within ten minutes of Advanced Life Support (ALS) services may opt to have written agreement with a provider to provide services in lieu of certain equipment such as defibrillators and monitors, but must have equipment required for Basic Life Support.

b. All facilities shall have written agreement with emergency transportation provider to transport to the nearest hospital.

3. **Contracted Treatment Services.** Written agreements with full-service hospitals and credentialed practitioner(s) for specialty care must be current, clearly written, and reviewed annually. The facility retains responsibility for all medical care provided until the patient is referred to or admitted into another facility. Agreements must be signed and dated by all parties.

D. Miscellaneous Services

1. **Family Services.** The Rural Health Clinic shall maintain a current list of local/nearest support organizations and assist (whenever necessary) with accessing those entities. Examples of services that may be listed by the clinic shall include such organizations as the Public Health Unit, Office of Family Support, school clinics, hospices agencies, home health agencies, American Cancer Society, and services for substance abuse and mental illness.

2. Coordination of services for complex cases is the responsibility of the RHC professional staff.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 and R.S. 40:2197.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 25:1846 (October 1999), amended LR 28:509 (March 2002).

§7521. Agency Operations

A. Municipals. A facility shall function as a community resource for all citizens of the service area and shall promote improvement of the health of the entire community by providing educational opportunities where feasible, resource lists for referrals, assistance with accessing other resources, wellness programs, and participation in community efforts to promote health and safety. A facility shall demonstrate the following.

1. **Telemedicine Capacity/Resource.** Computer access is recommended.

2. **Emergency Preparedness.** A facility shall:

- a. maintain a disaster plan appropriate to region and community;
- b. have facility protocols for medical and non-medical emergencies;
- c. maintain emergency supplies to provide basic emergency care in the case of a disaster in the community; and
- d. participate in the development of local community disaster plan.

B. Agreements. Written agreements shall be clearly worded, dated, reviewed and signed by all parties. All agreements shall be updated as needed to reflect any changes in relationships, provision of services, or other pertinent information.

C. Operation Hours. A facility shall provide:

1. primary care services at least 36 hours per week. For rural health clinics located in parishes designated as priority access, mobile units and RHC's with low caseloads, the Department may waive such requirement if:

a. the RHC demonstrates to the satisfaction of the Health Standards Section of DHH that by providing primary care services less than 36 hours per week, patients are not denied access to care;

b. the Department determines that a waiver of the requirement will not endanger the health or safety of patients needing RHC services; and

c. a waiver granted by the Department is subject to annual review;

2. on-call qualified professional assistance for 24 hours per day, seven days per week;

3. appropriately qualified professional staff on duty during all hours of operation. Failure to do so will result in immediate adverse action.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 and R.S. 40:2197.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 25:1846 (October 1999), amended LR 28:510 (March 2002).

§7523. Procedural Standards

A. The following processes are required for rural health clinics in Louisiana:

1. Access to Care. Rural health clinics shall:

a. be in compliance with R.S. 40:2007 if the RHC is located within another health care provider;

b. be located away from metropolitan areas;

c. provide services to all citizens of the community across all life cycles;

d. provide service delivery to accommodate the majority of residents of the community; and

e. provide professional coverage as required by §7517 and §7519.C.

2. Patient Assessment. Documentation of an assessment shall include:

a. comprehensive scope of information with updates as indicated by changes in the patient's status;

b. physical examination and medical history, that identifies the patient's condition and care needs, and an estimate of his/her continuing care needs;

c. indicators that identify the need for further assessment/treatment such as the signs/symptoms of substance abuse, which requires a substance abuse assessment be included as part of the mental status evaluation; and

d. pertinent and comprehensive information relative to the reason for the encounter.

3. Care Planning. The plan of care shall be based upon the needs documented in the assessment and may be generic if original assessment and physical examination indicates the patient is generally healthy. The plan of care shall be modified to reflect any changes in the patient's condition.

4. Continuity of Care. The clinic staff shall:

a. provide orderly and efficient transition between levels of care without duplication or disruption of services;

b. provide post-hospitalization care based on the hospital's discharge assessment, possibly a Uniform Needs Assessment Instrument (UNAI), but includes at least a description of the patient's functional status, nursing and/or other care requirements, and the availability of family/care givers;

c. update comprehensive care plan as indicated and provide clinic services as indicated in the plan of care;

d. coordinate care and treatment interventions by all relevant disciplines;

e. evaluate progress and adjust actual care as needed to achieve progress.

5. Infection Control. A facility shall maintain a written and dated effective infection control program that protects the patients and staff from infections and communicable diseases.

6. Information Management. A facility shall maintain a record keeping system to communicate and measure clinic performance to assure that patient needs are documented and met. This system shall include accurate documentation of a patient visit for quality assessment and performance improvement purposes. The facility shall ensure the integrity, effectiveness, confidentiality, and security of the facility's data system.

7. Clinical Protocols. Written clinical protocols shall be established between mid-level practitioner(s) and the physician and the treatment(s) of choice shall be easy to identify.

8. The facility must have a grievance process and must indicate who the patient can contact to express a grievance. Records of all grievances, steps taken to investigate, and results of interventions must be available to surveyors upon request.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 and R.S. 40:2197.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 25:1846 (October 1999), amended LR 28:510 (March 2002).

§7525. Record Keeping

A. Medical Records

1. **Identifying Information.** The patient identification information such as name or ID number must appear on each page.

2. **Entry Identification.** Entries must be dated, signed, and credentials identified (MD, RN, etc.).

3. **Contents.** Each patient record must contain the following:

a. personal/biographical data including full name, age, sex, address, employer, home and work telephone numbers, and marital status;

b. next of kin or contact person;

c. pertinent medical history/information.

4. **Storage.** All medical records shall be protected from theft, fire, and unauthorized use. Open shelving may be utilized only when the patients/visitors do not have access to the storage area. Closed records must be maintained by the facility or its designee in accordance with the following:

a. a minimum of seven years from the date of last entry. After two years, records may be maintained electronically;

b. until the age of majority, plus seven years in the case of children or adolescents.

B. **Facility Records.** A facility must maintain records of credentials and other evidence that facility is in compliance with current standards of practice and licensing standards as listed below:

1. personnel records;

2. advisory board meeting minutes;

3. policies/procedures with annual approvals;

4. governing board meeting minutes; and

5. proof of hours worked for professional employees.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2197.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 25:1850 (October 1999).

§7529. Quality Assurance

A. Definitions

Scope of Care/Services—a facility shall delineate their scope of practice to include:

a. the range of services provided, including conditions prevented, managed, or treated;

b. treatments and/or procedures provided;

c. patient populations served;

d. hours when care or services are provided; and,

e. types of professional disciplines and/or specialists providing services.

Evaluation—the review and assessment of the quality and appropriateness is an important aspect of care. The review and assessment is designed to identify problems and develop procedures to prevent and resolve the problems.

Important Aspects of Care—clinical activities that involve a high volume of patients, that entail a high degree of risk for patients, or that tend to produce problems for staff or the patients are deemed most important for purposes of monitoring and evaluation.

Monitoring—a process of surveillance, and/or auditing to identify systemic or localized problem area(s) where improvement may be indicated.

Performance Indicators—the measurement tool used to monitor and evaluate the facility's quality of management, clinical services, and support functions.

Pursuit of Opportunity to Further Improve Care—applies pro-active efforts to identify and implement improvements.

Quality Improvement—a management led and patient focused systematic method of improving systems and processes. Its basis is a statistical process control.

Quality of Patient Care—the degree to which patient care services increase the probability of desired patient outcomes and reduce the probability of undesired outcomes.

B. Process

1. **Utilization Review.** At least 10 percent of all encounters shall be reviewed quarterly by the medical director and/or physician member of the advisory board.

2. **Internal Evaluation.** Facility shall develop and conduct an annual internal evaluation process to provide necessary data to formulate a plan for continuous quality improvement/quality assurance.

3. **Quality Assurance/Continuous Quality Improvement.** The facility shall have ongoing programs to assure that the overall function of the clinic is in compliance with federal, state, and local laws, and is meeting the needs of the citizens of the area, as well as attaining the goals and objectives developed from the mission statement established by the facility.

4. **Quality Improvement Program.** The facility shall have a written quality improvement program that addresses at least the following elements:

a. facility philosophy/mission/goals/objectives/
scope of care/services;

b. personnel roles/responsibilities/physician supervision/nurse practitioner, credentialing/re-credentialing policy/procedures/annual review/evaluation and drug policy and procedures;

c. important aspects of care/quality of care studies;

d. performance indicators relative to, but not limited to, identified problem areas of the clinic or healthy outcomes;

- e. monitoring and evaluation procedures/documentation of findings;
- f. patients' rights, responsibilities, grievance and appeal policies/procedures;
- g. utilization review/medical records audit; and
- h. patient satisfaction surveys.

5. Systemic Quality Improvements. A facility shall:

- a. participate in a continuous effort to improve its performance;
- b. focus on improving patient outcomes and patient satisfaction;
- c. have objective measures to allow tracking of performance over time to ensure that improvements are sustained;
- d. develop/adopt quality indicators that are predictive of desired outcomes or are outcomes that can be measured, analyzed and tracked;
- e. identify its own measure of performance for the activities it identifies as priorities in quality assessment and performance improvement strategy;
- f. conduct distinct successful improvement activities proportionately to the scope and complexity of the clinic operations;
- g. immediately correct problems that are identified through its quality assessment and improvement program that actually or potentially affect the health and safety of the patients;
- h. make an aggressive and continuous effort to improve overall performance of clinic and personnel; and
- i. use the process of improvement (identification of patient care and service components; application of performance measures; and continuous use of a method of data collection and evaluation) to identify or trigger further opportunities for improvement.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2197.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 25:1851 (October 1999).

§7531. Patient's Rights and Responsibilities

A. The facility shall provide education to personnel regarding patient rights during orientation at least annually, and post a copy of the patient's rights in a conspicuous place.

- 1. Patients of Rural Health Clinics shall have the right to:
 - a. be treated equally and receive care without regard to age, sex, religion, race or creed;
 - b. receive care that is not determined by patient's ability to pay for service;
 - c. confidentiality of his/her clinical records;

d. be informed of all costs and expected payment from other resources;

e. be treated with respect for the individual patient's comfort, dignity and privacy;

f. be informed of his/her rights in advance of care being provided;

g. access information contained in his/her clinical records within a reasonable time frame;

h. make decisions regarding his/her care;

i. formulate advance directives and have staff/practitioners to comply with those directives;

j. maintain personal privacy and receive care in a safe setting; and

k. be free from verbal or physical abuse or harassment from staff.

2. Patients of Rural Health Clinics are responsible for:

a. providing, to the extent possible, information needed by professional staff in caring for the patient;

b. following instructions and guidelines given by those providing health care services.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2197.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 25:1852 (October 1999).

§7533. Advisory Committee

A. All members of the advisory committee shall be designated in writing and approved by the governing board. The advisory committee shall be composed of two medical professionals, and at least one consumer of services, not employed by the facility. However, facility staff should attend meetings.

1. Qualifications

a. Medical professionals may be any Louisiana licensed health care professional, including but not limited to, medical doctor, registered nurse, board certified social worker, pharmacist, or physical therapist.

b. Consumers must be members of the local community, over 21 years of age, and not affiliated by employment, family, finance or contract with the facility or its owners.

2. Responsibilities. The Advisory Committee shall:

a. meet annually to review the facility's mission/philosophy, operations, finances, policies and planned activities to assure that the facility is improving access and health care to the community; and

b. provide suggestions regarding facility changes based upon community needs, growth, and support.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 and R.S. 40:2197, and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 25:1846 (October 1999), amended LR 28:510 (March 2002).

§7535. Physical Environment

A. Occupancy. The facility shall have written approval from the appropriate agency to verify compliance with Office of the State Fire Marshal.

B. Safety. The following are fundamental to the effective management of a facility:

1. preventing, reporting and correcting threatening situations, equipment failures, and actual incidents that involve injury or damage to property;

2. proper safety management;

3. emergency preparedness;

4. proper storage and disposal of trash and medical waste;

5. proper temperature control, light and ventilation;

6. proper storage of drugs and cleaning material; and

7. clean and free of hazards;

a. bathrooms shall be vented to outside and have adequate soap, hand towels and hot water to promote infection control;

b. general appearance of facility shall be neat and clean;

8. exits shall not be obstructed and facility shall have:

a. a minimum of two exits spaced as widely apart as possible;

b. exit doors that are at least 34 inches wide but less than 48 inches;

c. exit corridors that are at least 44 inches wide and do not pass through a storage room, mechanical room, or kitchen;

d. clearly marked exits and exit pathways with exit signs and arrows;

e. adequate light at all times. If the facility is occupied at night, all exit signs must be internally lighted and corridors must have emergency light units;

f. doors which can be opened from inside the room or area without a key or special knowledge; and

g. exit signs over each exit door and also at every corridor junction. At least one exit sign must be visible from any location in the building;

9. locks:

a. no door equipped with a self closure device (except entry/exit doors) may ever be blocked open;

b. every lock must be operable from inside the room or area;

10. miscellaneous:

a. the facility shall have one fire extinguisher (minimum size 2A) for each 1500 square feet. It must be inspected and tagged annually; and, the gauge must show in the white, green, or "overcharged" areas. It may be Type A or Type ABC;

b. Any storage room over 50 square feet must have an automatic door closure device. No flammable liquids (such as gasoline, diesel, etc.) may be stored inside the facility. However, alcohol and cleaning supplies are allowed in reasonable quantities;

c. any compressed gas cylinder, regardless of type and/or amount of contents, must be on a rack or chained to avoid tipping;

d. at a minimum a fire wall rated for one hour must separate the facility from any other occupied area. Criteria for the wall include:

i. one layer of 5/8 inch fire code sheetrock or other limited or non-combustible material on each side;

ii. separation wall must extend completely to the roof deck with no unsealed penetrations or holes;

iii. one and 3/4 inch doors (if doors are present) must be solid core with automatic self-closure device.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2197.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 25:1852 (October 1999).

Chapter 76. Medicare Rural Hospital Flexibility Program (MRHF)

Subchapter A. Critical Access Hospitals

§7601. Definitions

A. The following word and terms, when used in this Chapter 76 shall have the following meanings, unless the context clearly indicates otherwise.

BPCRH—Department of Health and Hospital, Office of the Secretary, Bureau of Primary Care and Rural Health.

CAH—Critical Access Hospital.

CMS—Centers for Medicare and Medicaid Services.

EACH/RPCH—Essential Access Community Hospital/Rural Primary Care Hospital—a limited service rural hospital program.

EMS—Emergency Medical Services.

Health Care Network—an organization consisting of at least one CAH and one acute care hospital with agreements for patient referrals, emergency/non-emergency transportation and other services as feasible.

HPSA—Health Professional Shortage Area.

HSS—Department of Health and Hospitals, Bureau of Health Services Financing, Health Standards Section.

MRHF—Medicare Rural Hospital Flexibility Program.

MSA—Metropolitan Statistical Area.

MUA—Medically Underserved Area designated by the federal Office of Shortage Designations.

Necessary Provider—a facility located in a primary care HPSA or MUA; or located in a parish in which the percentage of Medicare beneficiaries is higher than the percentage of Medicare beneficiaries residing in the state; or a facility located in a parish in which the percentage of the population under 100 percent of the federal poverty level is higher than the percentage of the state population under 100 percent of the federal poverty level or qualifies as a "rural hospital" under the Louisiana Rural Preservation Act.

Not-for Profit—incorporated as a non-profit corporate entity.

Primary Care—basic ambulatory health services that provide preventive, diagnostic and therapeutic care.

Primary Care Physicians—includes general, family and internal medicine, pediatrics and obstetrics/gynecology.

QIO—Quality Improvement Organization

Public Hospital—hospital supported by public funds including city, service district and state hospitals.

Rural—The CAH is located outside any area that is a Metropolitan Statistical Area, as defined by the Office of Management and Budget or qualifies as a rural hospital under the Louisiana Rural Preservation Act.

AUTHORITY NOTE: Promulgated in accordance with the Balanced Budget Act of 1997 (P.L. 105-33) and Title XVIII of the Social Security Act; amended by Medicare, Medicaid, SCHIP Balance Budget Refinement Act of 1999.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Management and Finance, Division of Research and Development, LR 25:1478 (August 1999), amended LR 26:1480 (July 2000), amended by the Department of Health and Hospitals, Office of the Secretary, Bureau of Primary Care and Rural Health, LR 32:99 (January 2006).

§7603. Criteria for Designation as a CAH

A. A hospital must submit an application to the BPCRHR and must meet the following criteria, or affirm that it can meet these criteria at the time of certification, to be designated as a CAH:

1. be a licensed hospital;
2. be currently participating in the Medicare program and meet applicable conditions of participation;
3. be located in a rural area:
 - a. may be a rural census tract in a Metropolitan Statistical Area as determined under the Goldsmith Modification, originally published in the *Federal Register* on February 27, 1992 and updated October 1, 2004; or
 - b. qualifies as a "rural hospital" under the Rural Preservation Act, RS 40:100.143;

4.a. be located more than a 35-mile drive or a 15-mile drive in mountainous terrain or areas with secondary roads, from the nearest hospital or CAH; or

b. be certified as a necessary provider by qualifying as a "rural hospital" under the Louisiana Rural Hospital Preservation Act RS 40:1300.143; and meeting at least one of the following:

i. be located in a primary care health professional shortage area (HPSA) or a medically underserved area (MUA); or

ii. be located in a parish in which the percentage of Medicare beneficiaries is higher than the percentage of Medicare beneficiaries residing in the state; or

iii. be located in a parish in which the percentage of the population under 100 percent of the federal poverty level is higher than the percentage of the state population under 100 percent of the federal poverty level;

c. provide not more than 25 acute care inpatient beds or swing-beds, meeting such standards as the secretary may establish, for providing inpatient care that does not exceed, as determined on an annual, average basis, 96 hours per patient.

AUTHORITY NOTE: Promulgated in accordance with the Balanced Budget Act of 1997 (P.L. 105-33) and Title XVIII of the Social Security Act; amended by Medicare, Medicaid, SCHIP Balance Budget Refinement Act of 1999.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Management and Finance, Division of Research and Development, LR 25:1478 (August 1999), amended LR 26:1480 (July 2000), amended by the Department of Health and Hospitals, Office of the Secretary, Bureau of Primary Care and Rural Health, LR 32:99 (January 2006)

§7609. Application Submission and Review

A. A hospital that wishes to be designated as a CAH is required to submit an application to the BPCRHR. Application forms may be requested and submitted by interested hospitals at any time following HCFA approval of the state's Rural Health Care Plan and application.

B. On receipt of an application, the BPCRHR will conduct a review to determine the eligibility of the applicant hospital for conversion and consistency with the criteria for designation detailed in §7603.

C. The supporting information to be included with the application is:

1. documentation of ownership, including names of owners and percent of ownership;
2. board resolution to seek CAH certification;
3. documentation of Medicare participation;
4. notification from BPCRHR that location is in a HPSA or MUA;
5. affirmation that 24-hour emergency medical care services and medical control agreements are available including information on staffing arrangements;

6. documentation that facility meets rural hospital staffing requirements with the following exceptions:

a. the facility need not meet hospital standards regarding the number of hours per day or days of the week in which it must be open and fully staffed, except as required to make emergency medical care services available and to have nursing staff present if an inpatient is in the facility;

b. the facility may provide the services of a dietician, pharmacist, laboratory technician, medical technologist, and/or radiological technologist on a part-time, off site basis; and

c. inpatient care may be provided by a physician assistant, nurse practitioner, or clinical nurse specialist, subject to the oversight of a physician who need not be present in the facility but immediately available in accordance with state requirements for scope of practice;

7. copy of a needs assessment, if available;

8. copy of a strategic plan for conversion;

9. copy of financial feasibility assessment.

D. Decision. If an application is complete, and all supporting documentation provided, the BPCRHR will provide written notice to the applicant hospital.

1. If the application and required documentation supports conversion to a MRHF, after the effective date of the published rule, the BPCRHR will provide a written notice of the designation to the applicant hospital and HSS.

2. If the application is incomplete or otherwise insufficient to allow designation, the BPCRHR will provide written notice to the applicant outlining the actions necessary to correct the deficiencies. The hospital may then address the deficiencies and resubmit its application.

E. Once designated, a hospital may apply to the Bureau of Health Services Financing, Health Standards Section (HSS) of the Department of Health and Hospitals for an onsite survey.

AUTHORITY NOTE: Promulgated in accordance with the Balanced Budget Act of 1997 (P.L. 105-33) and Title XVIII of the Social Security Act; amended by Medicare, Medicaid, SCHIP Balance Budget Refinement Act of 1999.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Management and Finance, Division of Research and Development, LR 25:1479 (August 1999), amended LR 26:1480 (July 2000), amended by the Office of the Secretary, Bureau of Primary Care and Rural Health, LR 32:100 (January 2006).

§7611. Technical Assistance

A. The BPCRHR is available to furnish basic technical assistance to hospitals and communities interested in CAH conversion such as providing program information helping with interpretation and completion of the application for designation, and identifying other sources of assistance and information.

AUTHORITY NOTE: Promulgated in accordance with the Balanced Budget Act of 1997 (P.L. 105-33) and Title XVIII of the

Social Security Act; amended by Medicare, Medicaid, SCHIP Balance Budget Refinement Act of 1999.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Management and Finance, Division of Research and Development, LR 25:1480 (August 1999), amended LR 26:1480 (July 2000), amended by the Department of Health and Hospitals, Office of the Secretary, Bureau of Primary Care and Rural Health, LR 32:100 (January 2006).

§7613. Program Monitoring and Evaluation

A. Ongoing monitoring and evaluation of the program will be conducted by the Quality Management Section of the BPCRHR.

1. Strengths and weaknesses of the program and state policy affecting CAHs will be assessed, with the goal of identifying problem areas and developing solutions.

2. Results will be reported to the BPCRHR Director who will assign program staff to work with other state agencies and interested parties to determine the necessity of changes and updates to the Plan and state policy.

3. All Plan changes will be forwarded to HCFA for review and approval.

AUTHORITY NOTE: Promulgated in accordance with the Balanced Budget Act of 1997 (P.L. 105-33) and Title XVIII of the Social Security Act; amended by Medicare, Medicaid, SCHIP Balance Budget Refinement Act of 1999.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Management and Finance, Division of Research and Development, LR 25:1480 (August 1999), amended LR 26:1480 (July 2000), amended by the Department of Health and Hospitals, Office of the Secretary, Bureau of Primary Care and Rural Health LR 32:100 (January 2006).

Chapter 78. Pain Management Clinics

Subchapter A. General Provisions

§7801. Definitions

Addiction Facility—a facility that is licensed for the treatment of addiction to, or abuse of illicit drugs or alcohol, or both.

Administrator—the person responsible for the day-to-day management, supervision, and non-medical operation of the pain management clinic.

Board—the Louisiana State Board of Medical Examiners.

Cessation of Business—provider is non-operational and has stopped offering or providing services to the community.

Chronic Pain—pain which persists beyond the usual course of a disease, beyond the expected time for healing from bodily trauma, or pain associated with a long-term incurable or intractable medical illness or disease.

Controlled Substance—any substance defined, enumerated or included in federal or state statute or regulations 21 C.F.R. §1308.11-15 or R.S.40:964, or any substance which may hereafter be designated as a controlled substance by amendment or supplementation of such regulations and statutes.