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.

Board—the Louisiana State Board of Medical Examiners.

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.

Deficient Practice—a finding of non-compliance with a licensing regulation.

Department—the Department of Health and Hospitals.

Health Standards Section—the section within the Department of Health and Hospitals with responsibility for licensing pain management clinics.

Intractable Pain–a chronic pain state in which the cause of the pain cannot be eliminated or successfully treated without the use of controlled substance therapy and, which in the generally accepted course of medical practice, no cure of the cause of pain is possible or no cure has been achieved after reasonable efforts have been attempted and documented in the patient's medical record.

Noncancer-Related Pain–pain which is not directly related to symptomatic cancer.

Non-Malignant–synonymous with noncancer-related pain.

Operated By—actively engaged in the care of patients at a clinic.

Pain Management Clinic or "Clinic"—a publicly or privately owned facility which primarily engages in the treatment of pain by prescribing narcotic medications.

Pain Specialist—a physician, licensed in Louisiana, with a certification in the subspecialty of pain management by a member board of the American Boards of Medical Specialties.

1. For urgent care facilities in operation on or before June 15, 2005, the definition of pain specialist is a physician who is licensed in the state of Louisiana, board-certified in his or her area of residency training and certified within one year from the adoption of this Rule in the subspecialty of pain management by any board or academy providing such designation such as the American Boards of Medical Specialties, American Board of Pain Management, American Academy of Pain Management or the American Board of Interventional Pain Physicians. Any conflict, inconsistency or ambiguity with any other regulations contained in this chapter shall be controlled by §7801.

Physician—an individual who:

1. possesses a current, unrestricted license from the board to practice medicine in Louisiana;

2. during the course of his practice has not been denied the privilege of prescribing, dispensing, administering, supplying, or selling any controlled dangerous substance; and

3. during the course of his practice has not had board action taken against his medical license as a result of dependency on drugs or alcohol.

Primarily Engaged—the majority of patients, 51 percent or more of the patients seen on any day a clinic is in operation, are issued a narcotic prescription for the treatment of chronic non-malignant pain. A physician who in the course of his practice, treats patients with chronic pain, shall not be considered primarily engaged in the treatment of chronic non-malignant pain by prescribing narcotic medications provided that the physician:

1. treats patients within their areas of specialty and who utilizes other treatment modalities in conjunction with narcotic medications;

2. is certified by a member board of the American Board of Medical Specialties, or is eligible for certification based upon his completion of an ACGME (Accreditation Council for Graduate Medical Education) certified residency training program; and

3. currently holds medical staff privileges that are in good standing at a hospital in this state.

Urgent Care Facility—a medical clinic which offers primary and acute health services to the public during stated hours of operation and which must accommodate walk-in patients seeking acute health services. For purposes of this definition, the treatment of chronic pain patients is not considered acute health services.

AUTHORITY NOTE: Promulgated in accordance with R.S. R.S. 40.2198.11-13.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 34:80 (January 2008), amended LR 34:1418 (July 2008).

§7803. Ownership

A. Except as specified in §7803.B, each clinic shall be 100 percent owned and operated by a physician certified in the subspecialty of pain management by a member board of the American Boards of Medical Specialties.

B. A clinic in operation on or before June 15, 2005, is exempt from §7803.A if all of the following requirements are met.

1. The clinic is not owned, either in whole or in part, by independent contract, agreement, partnership, or joint venture with a physician who during the course of his practice has:

a. been denied the privilege of prescribing, dispensing, administering, supplying, or selling any controlled dangerous substance; and

b. had board action taken against his medical license as a result of dependency on drugs or alcohol.

2. The clinic is not owned, either in whole or in part, by an individual who has been convicted of, pled guilty or nolo contendere to a felony.

3. The clinic is not owned, either in whole or in part, by an individual who has been convicted of, pled guilty or nolo contendere to a misdemeanor, the facts of which relate to the use, distribution, or illegal prescription of any controlled substance.

4. The clinic shall operate as an urgent care facility offering primary or acute health services, in addition to caring for patients with chronic pain, and shall have held itself out to the public as an urgent care facility.

C. Any change of ownership (CHOW) shall be reported in writing to the Health Standards Section within five working days of the transfer of ownership by any lawful means. The license of a clinic is not transferable or assignable between individuals, clinics or both. A license cannot be sold.

1. The new owner shall submit all documents required for a new license including the licensing fee. Once all application requirements are completed and approved by the department, a new license shall be issued to the new owner.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40.2198.11-13.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 34:80 (January 2008).

Subchapter B. Licensing Procedures

§7811. General Provisions

A. It shall be unlawful to operate a clinic without obtaining a license issued by the department. The department is the only licensing agency for pain management clinics in the state of Louisiana.

B. A clinic shall renew its license annually. A renewal application and licensing fee shall be submitted at least 30 days before the expiration of the current license. Failure to do so shall be deemed to be a voluntary termination and expiration of the facility's license. The license shall be surrendered to the department within 10 days, and the facility shall immediately cease providing services.

C. A license shall be valid only for the clinic to which it is issued and only for that specific geographic address. A license shall not be subject to sale, assignment, or other transfer, voluntary or involuntary. The license shall be conspicuously posted in the clinic.

D. Any change regarding the clinic's name, geographical or mailing address, phone number, or key administrative staff or any combination thereof, shall be reported in writing to the Health Standards Section within five working days of the change.

1. Any name change requires a change in the license and shall be accompanied by a $25 fee.

E. A separately licensed clinic shall not use a name which is substantially the same as the name of another clinic licensed by the department.

F. Any request for a duplicate license shall be accompanied by a $5 fee.

G. A clinic intending to have controlled dangerous medications on the premises shall make application for a

Controlled Dangerous Substance (CDS) License, and shall comply with all federal and state regulations regarding procurement, maintenance and disposition of such medications.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40.2198.11-13.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 34:81 (January 2008).

§7813. Initial Application Process

A. An application packet for licensing as a pain management clinic shall be obtained from the Department of Health and Hospitals. A completed application packet for a clinic shall be submitted to and approved by the department prior to an applicant providing services.

B. An initial applicant shall submit a completed application packet including:

1. the current non-refundable licensing fee pursuant to R. S. 40:2198.13;

2. an approval for occupancy from the Office of the State Fire Marshal;

3. a recommendation for licensure from the Office of Public Health (OPH) based on an OPH inspection;

4. a zoning approval from local governmental authorities;

5. a criminal background check on all owners;

6. verification of the physician owner's certification in the subspecialty of pain management unless said owner meets the exemption at §7403(B); and

7. proof of operation as an urgent care facility if the pain management clinic was in operation on or before June 15, 2005:

a. this proof shall be an occupational license or certificate of operation issued by local governmental authorities, in addition to verifying information that indicates the facility held itself out to the public as an urgent care facility.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40.2198.11-13.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 34:81 (January 2008).

§7815. Licensing Surveys

A. After approval of the initial application by the department, a clinic shall undergo an initial licensing survey to determine that the clinic is in compliance with all licensing regulations. The clinic will receive advance notification of this survey.

1. No patient shall be provided service until the initial licensing survey has been performed and the clinic found to be in compliance.

2. In the event the initial licensing survey finds that a clinic is not in compliance with regulations of this Chapter, the department shall deny the initial license.

B. After the initial licensing survey, the department shall conduct a licensing survey at regular intervals as it deems necessary to determine compliance with licensing regulations. These surveys shall be unannounced to the clinic.

C. The department may conduct a complaint investigation for any complaint received against a clinic. A complaint survey shall be unannounced to the clinic.

D. A follow-up survey shall be done following any licensing survey or any complaint survey to ensure correction of a deficient practice cited on the previous survey. Such surveys shall be unannounced to the clinic.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40.2198.11-13.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 34:81 (January 2008).

§7817. Issuance of Licenses

A. The department shall have authority to issue two types of licenses: a full license or provisional license.

B. A full license may be issued only to applicants that are in compliance with all applicable federal, state and local laws and regulations. This license shall be valid until the expiration date shown on the license, unless the license has been revoked, terminated, or suspended.

C. A provisional license may be issued to those existing licensed clinics that do not meet the criteria for full licensure. This license shall be valid for no more than six months, unless the license has been revoked, terminated, or suspended.

1. A provisional license may be issued by the department for one of the following reasons, including but not limited to:

a. the clinic has more than five deficient practices during any one survey;

b. the clinic has more than three valid complaints in a one-year period;

c. there is a documented incident of placing a patient at risk;

d. the clinic fails to correct deficient practices within 60 days of being cited or at the time of the follow-up survey, whichever occurs first.

2. A clinic with a provisional license may be issued a full license if at the follow-up survey the clinic has corrected the deficient practice. A full license will be issued for the remainder of the year until the clinic's license anniversary date.

3. The department may re-issue a provisional license or initiate a license revocation of a provisional license when the clinic fails to correct deficient practice within 60 days of

being cited or at the time of the follow-up survey, whichever occurs first.

4. The department may also issue a provisional license if there is documented evidence that any representative of the clinic has (without the knowledge or consent of clinic's owner, medical director and/or administrator) bribed, harassed, offered, paid for or received something of economic value for the referral of an individual to use the services of a particular clinic.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40.2198.11-13.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 34:82 (January 2008).

§7819. License Denial, Revocation or Non-Renewal

A. Pursuant to R.S. 49:950, the Administrative Procedures Act, the department may:

1. deny an application for a license;

2. refuse to renew a license; or

3. revoke a license.

B. A clinic license may not be renewed or may be revoked for any of the following reasons, including but not limited to:

1. failure to be in substantial compliance with pain management clinic licensing regulations;

2. failure to uphold patient rights whereby deficient practice may result in harm, injury or death of a patient;

3. failure of the clinic to protect a patient from a harmful act by a clinic employee or other patient(s) on the premises, including but not limited to:

a. an action posing a threat to patient or public health and safety;

b. coercion;

c. threat or intimidation;

d. harassment;

e. abuse; or

f. neglect;

4. failure to notify proper authorities of all suspected cases of neglect, criminal activity, mental or physical abuse, or any combination thereof;

5. failure to maintain sufficient staff to meet the needs of the patient;

6. failure to employ qualified personnel;

7. failure to remain operational on the days, and during the hours, the clinic has reported to the department that it will be open, unless the closure is unavoidable due to a man-made or natural disaster;

8. failure to submit fees, including but not limited to:

a. fee for the change of address or name;

b. any fine assessed by the department; or

c. fee for a CHOW;

9. failure to allow entry to a clinic or access to requested records during a survey;

10. failure to protect patients from unsafe care by an individual employed by a clinic;

11. failure to correct deficient practice for which a provisional license has been issued;

12. when clinic staff or owner has knowingly, or with reason to know, made a false statement of a material fact in any of the following:

a. application for licensure;

b. data forms;

c. clinical records;

d. matters under investigation by the department;

e. information submitted for reimbursement from any payment source; or

f. advertising;

13. clinic staff misrepresented or fraudulently operated a clinic;

14. conviction of a felony, or entering a plea of guilty or nolo contendere to a felony by an owner, administrator, director of nursing, or medical director as evidenced by a certified copy of the conviction;

15. failure to comply with all reporting requirements in a timely manner as requested by the department; or

16. action taken by the board against a physician owning, employed or under contract to a clinic for violation of the board's Pain Management Rules or other violations of the Medical Practice Act which would make him ineligible for licensure.

C. In the event a clinic's license is revoked or denied renewal, no other license application shall be accepted by the department from the owners of the revoked or denied clinic for a period of two years from the date of the final disposition of the revocation or denial action.

D. When a clinic is under a license revocation action, that clinic is prohibited from undergoing a change of ownership.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40.2198.11-13.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 34:82 (January 2008).

§7821. Notice and Appeal Procedures

A. The department shall furnish the applicant or clinic with written notice of the department's decision to deny a license, revoke a license, or refusal to renew a license.

1. The notice shall specify reasons for the action and shall notify the applicant or clinic of the right to request an administrative reconsideration or to request an appeal. A

voluntary termination or expiration of the license is not considered an adverse action and is therefore not appealable.

2. The clinic shall have the right to file a suspensive appeal from the department's decision to revoke the clinic's license.

B. Administrative Reconsideration. A clinic may request an administrative reconsideration of the department's decision to revoke, deny, or refuse to renew a license.

1. A request for an administrative reconsideration shall be submitted in writing to the Health Standards Section within 15 days of receipt of notification of the department's action.

2. Administrative reconsideration is an informal process and shall be conducted by a designated official of the department who did not participate in the initial decision to impose the action taken.

a. The designated official shall have the authority to:

i. affirm the department's decision;

ii. rescind the department's decision;

iii. affirm part or rescind part of the department's decision; or

iv. request additional information from either the department or the clinic.

b. A department spokesman and a clinic spokesman may make an oral presentation to the designated official during the administrative reconsideration.

3. Administrative reconsideration may be made solely on the basis of documents or oral presentations, or both, before the designated official and shall include:

a. the statement of deficient practice; and

b. any documentation the clinic may submit to the department at the time of the clinic's request for such reconsideration.

4. Correction of a deficiency shall not be a basis for administrative reconsideration.

5. An administrative reconsideration is not in lieu of the administrative appeals process and does not extend the time limits for filing an administrative appeal under the provisions of the Administrative Procedures Act.

C. Administrative Appeal Process. Upon denial or revocation of a license by the department, the clinic shall have the right to appeal such action by submitting a written request to the secretary of the department within 30 days after receipt of the notification of the denial or revocation of a license.

1. Correction of a deficiency shall not be the basis of an administrative appeal. Request for administrative reconsideration does not affect time frames for requesting an administrative appeal.

2. Notwithstanding the provisions of §7821.C, the department may immediately revoke a license in any case in which the health and safety of a client or the community may be at risk.

a. The clinic which is adversely affected by the action of the department in immediately revoking a license may, within 30 days of the closing, appeal devolutively from the action of the department by filing a written request for a hearing to the secretary of the department.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40.2198.11-13.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 34:83 (January 2008).

Subchapter C. Clinic Administration

§7831. Medical Director

A. Each clinic shall be under the direction of a medical director who shall be a physician who:

1. possesses a current, unrestricted license from the board to practice medicine in Louisiana;

2. during the course of his practice, has not been denied the privilege of prescribing, dispensing, administering, supplying, or selling any controlled dangerous substance; and

3. during the course of his practice has not had any board action taken against his medical license as a result of dependency on drugs or alcohol.

B. The medical director shall be a physician certified in the subspecialty of pain management by a member board of the American Boards of Medical Specialties, except for the following exemption.

1. A clinic which has been verified as being in operation on or before June 15, 2005, is required to have a medical director, but is exempt from having a medical director who is certified in the subspecialty of pain management by a member board of the American Boards of Medical Specialties.

C. Responsibilities. The medical director is responsible for the day-to-day operation of a clinic and shall be on-site 50 percent of the time during the operational hours of the clinic. In the event the medical director is not on-site during the hours of operation, then the medical director shall be available by telecommunications and shall be able to be on-site within 30 minutes.

1. The medical director shall oversee all medical services provided at the clinic.

2. The medical director shall ensure that all qualified personnel perform the treatments or procedures for which each is assigned. The clinic shall retain documentation of proficiency and training.

3. The medical director, or his designee, is responsible for ensuring a medical referral is made to an addiction facility, when it has been determined that a patient or staff

member has been diverting drugs or participating in the illegal use of drugs.

4. The medical director is responsible for ensuring a urine drug screen of each patient is obtained as part of the initial medical evaluation and intermittently, no less than quarterly, during the course of treatment for chronic pain.

5. The medical director shall ensure that patients are informed of after-hours contact and treatment procedure.

6. The medical director is responsible for applying to access and query the Louisiana Prescription Monitoring Program (PMP).

a. The PMP is to be utilized by the medical director and the pain specialist as part of a clinics' quality assurance program to ensure adherence to the treatment agreement signed by the patient.

i. The treatment agreement states that the patient has been informed that he shall only obtain and receive narcotic prescriptions from the clinic where he is being treated for chronic pain.

(a). The patient shall be subject to periodic unannounced drug screens and shall not participate in diversion of any controlled dangerous substance.

b. Compliance to this agreement is to be determined and evaluated at each subsequent visit to a clinic when the patient receives a prescription for a controlled dangerous substance.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40.2198.11-13.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 34:83 (January 2008).

§7833. Clinic Operations

A. A clinic shall establish and implement policies and procedures consistent with all pain management rules and regulations issued by the board.

B. A clinic shall verify the identity of each patient who is seen and treated for chronic pain management and who is prescribed a controlled dangerous substance.

C. A clinic shall establish practice standards to assure quality of care, including but not limited to, requiring that a prescription for a controlled dangerous substance may have a maximum quantity of a 30 day supply and shall not be refillable.

D. On each visit to the clinic which results in a controlled dangerous substance being prescribed to a patient, the patient shall be personally examined by a pain specialist.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40.2198.11-13.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 34:84 (January 2008).

Subchapter D. Facility Requirements

§7843. Facility Inspections

A. The clinic shall pass all required inspections and maintain a current file of reports and other documentation demonstrating compliance with applicable laws and regulations. The inspections shall be signed, dated, and free of any outstanding corrective actions.

1. The following inspections are required:

a. annual fire marshal inspection;

b. annual inspection by the Office of Public Health;

c. quarterly fire alarm system test by facility staff; and

d. regular inspections of the clinic elevators, if any.

B. A certificate of occupancy, as required by local authorities, shall be on file in the clinic.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40.2198.11-13.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 34:84 (January 2008).

§7845. Physical Environment

A. A clinic shall be constructed, arranged and maintained to ensure the safety and well being of the patient and the general public.

B. The clinic premises shall meet the following requirements including, but is not limited:

1. a sign maintained on the clinic premises that can be viewed by the public which shall contain, at a minimum, the:

a. name of the clinic; and

b. hours of operation;

2. a neat and clean general appearance of the clinic with established policies and procedures for maintaining a clean and sanitary environment on a regular basis;

3. an effective pest control program shall be maintained to ensure the clinic is free of insects and rodents;

4. proper ventilation, lighting and temperature controls in all areas of the clinic;

5. provisions for emergency lighting and communications, in the event of sudden interruptions in utilities to the clinic; and

6. clearly marked exits and exit pathways with exit signs in appropriate locations.

C. Administrative and public areas of the clinic shall include at least the following:

1. a reception area with a counter or desk, or both;

2. a waiting area with seating containing not less than two seating spaces for each examination or treatment room;

3. a conveniently located, handicapped accessible, public toilet with a lavatory for hand washing with hot and cold water;

4. a conveniently accessible public telephone;

5. a conveniently accessible drinking fountain;

6. at least one consultation room large enough to accommodate family members, in addition to treatment rooms;

7. designated rooms or areas for administrative and clerical staff to conduct business transactions, store records and carry out administrative functions, separate from public areas and treatment areas;

8. a multipurpose room for conferences, meetings, and health education purposes which may be used for the consultation room;

9. filing cabinets and storage for medical records, such records shall be protected from theft, fire, and unauthorized access and having provisions for systematic retrieval of such records;

10. adequate storage for the staff's personal effects; and

11. general storage facilities for supplies and equipment.

D. Clinical Facilities shall at least include the following.

1. General-Purpose Examination Room. Each room shall allow at least a minimum floor area of 80 square feet, excluding vestibules, toilets, and closets. Room arrangement should permit at least 2 feet 8 inches clearance at each side and at the foot of the examination table. A hand washing station and a counter or shelf space adequate for writing shall be provided.

2. Treatment Room. A room for minor surgical and cast procedures, in the event such services are provided, shall have a minimum of 120 square feet, excluding vestibules, toilets, and closets. The minimum room dimension shall be 10 feet by 12 feet. A lavatory and a counter or shelf space for writing shall be provided.

3. Medication Storage Area. All drugs and biologicals shall be kept under proper temperature controls in a locked, well illuminated, clean medicine cupboard, closet, cabinet or room.

a. Drugs and biologicals shall be accessible only to individuals authorized to administer or dispense such drugs or biologicals;

b. All controlled dangerous drugs or biologicals shall be kept separately from non-controlled drugs or biologicals in a locked cabinet or compartment;

c. Drugs or biologicals that require refrigeration shall be maintained and monitored under proper temperature controls in a separate refrigerator.

4. Clean Storage Area. A separate room or closet for storing clean and sterile supplies shall be provided.

5. Soiled Utility Room. Provisions shall be made for separate collection, storage, and disposal of soiled materials.

6. Sterilization Area. An area in the clinic shall be designated for sterilizing equipment if sterilization of supplies, equipment, utensils and solutions are performed in the clinic.

7. Housekeeping Room. A separate housekeeping room shall contain a service sink and storage for housekeeping supplies and equipment.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40.2198.11-13.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 34:84 (January 2008).

§7847. Infection Control Requirements

A. The clinic shall have policies and procedures to address the following:

1. decontamination;

2. disinfection;

3. sterilization;

4. storage of sterile supplies;

5. disposal of biomedical and hazardous waste; and

6. training of all staff in universal precautions upon initial employment and annually thereafter.

B. The clinic shall make adequate provisions for furnishing properly sterilized supplies, equipment, utensils and solutions.

1. Some disposable supplies and equipment shall be utilized but when sterilizers and autoclaves are utilized to sterilize supplies, equipment, utensils and solutions, they shall be of the proper type and necessary capacity to adequately sterilize such implements as needed by the clinic.

2. The clinic shall have policies and procedures that address the proper use of sterilizing equipment and monitoring performed to ensure that supplies, equipment, utensils and solutions are sterile according to the manufacturers' recommendations and standards of practice.

a. Such procedures and policies shall be in writing and readily available to personnel responsible for sterilizing procedures.

3. To avoid contamination, appropriate standards of care techniques for handling sterilized and contaminated supplies and equipment shall be utilized.

C. There shall be a separate sink for cleaning instruments and disposal of non-infectious liquid waste.

D. Each clinic shall develop, implement and enforce written policies and procedures for the handling, processing, storing and transporting of clean and dirty laundry.

1. In the event a clinic provides an in-house laundry, the areas shall be designed in accordance with appropriate clinic laundry design in which a soiled laundry holding area

is provided and physically separated from the clean laundry area. Dirty or contaminated laundry shall not be stored or transported through the clean laundry area.

2. In the event an in-house laundry is utilized, special cleaning and decontamination processes shall be used for contaminated linens, if any.

E. A clinic shall provide housekeeping services which assure a safe and clean environment. Housekeeping procedures shall be in writing. Housekeeping supplies shall be made available to adequately maintain the cleanliness of the clinic.

F. Garbage and biohazardous or non-biohazardous waste shall be collected, stored and disposed of in a manner which prevents the transmission of contagious diseases and to control flies, insects, and animals.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40.2198.11-13.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 34:85 (January 2008).

§7849. Health and Safety Requirements

A. Environmental Requirements. The clinic, including its grounds, buildings, furniture, appliances, and equipment, shall be structurally sound, in good repair, clean, and free from health and safety hazards.

1. The environment of the clinic shall enhance patient dignity and confidentiality.

2. The clinic shall prohibit weapons of any kind in the clinic or on the clinic premises.

B. Evacuation Procedures and First Aid. The clinic shall respond effectively during a fire or other emergency. Each clinic shall:

1. have an emergency evacuation procedure including provisions for the handicapped;

2. conduct fire drills at least quarterly and correct identified problems promptly;

3. be able to evacuate the building safely and in a timely manner;

4. post exit diagrams conspicuously throughout the clinic; and

5. post emergency telephone numbers by all telephones, including but not limited to the patient telephone in the waiting area.

C. A clinic shall take all precautions to protect its staff, patients and visitors from accidents of any nature.

D. The clinic shall have a written, facility-specific, disaster plan and its staff shall be knowledgeable about the plan and the location of the plan.

E. Emergency Care.

1. At least one employee on-site at each clinic shall be certified in Advanced Cardiac Life Support (ACLS) and be trained in dealing with accidents and medical emergencies until emergency medical personnel and equipment arrive at the clinic.

2. A clinic shall have first aid supplies which are visible and easy to access.

3. The following equipment and supplies shall be maintained and immediately available to provide emergency medical care for problems which may arise:

a. emergency medication, as designated by the medical director;

b. oxygen and appropriate delivery supplies, including and not limited to:

i. nasal cannula; and

ii. masks;

c. intravenous fluids; and

d. sterile dressings.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40.2198.11-13.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 34:85 (January 2008).

§7851. Quality Assurance

A. A clinic, with active participation of its medical staff, shall conduct an ongoing, comprehensive quality assurance (QA) program which shall be a self-assessment of the quality of care provided at the clinic. Quality indicators shall be developed to track and trend potential problematic areas. These quality indicators shall include, at a minimum, the following:

1. the medical necessity of procedures performed, complications as a result of such performed procedures, and appropriateness of care;

2. any significant adverse affects of medical treatment or medical therapy, including the number of overdoses of prescribed medications or the number of deaths resulting from such overdoses, or both;

3. the number of patients referred to other health care providers for additional treatment or to an addiction facility;

4. the number of patient or family complaints or grievances and their resolutions;

5. the number of patients the clinic refuses to continue to treat due to misuse, diversion of medications, or non-compliance with prescribed medication treatment regimen;

6. identified infection control incidents; and

7. the monitoring of patients who have been treated with prescribed narcotic pain medication for a continuous period of 12 months and longer.

B. At least quarterly, the clinic shall systematically analyze all data and develop a corrective action plan for identified problems determined through the clinic's QA process.

1. When appropriate, the clinic shall make revisions to its policies and procedures and provide written documentation that the corrective action plan has been monitored for continued sustained compliance to the appropriate standard of care.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40.2198.11-13.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 34:86 (January 2008).

Subchapter E. Patient Records

§7861. Patient Records

A. Retention of Patient Records

1. The clinic shall establish and maintain a medical record on each patient. The record shall be maintained to assure that the medical treatment of each patient is completely and accurately documented, records are readily available and systematically organized to facilitate the compilation and copying of such information.

a. Safeguards shall be established to maintain confidentiality and protection of the medical record from fire, water, or other sources of damage.

2. The department shall have access to all business records, patient records or other documents maintained by or on behalf of the clinic to the extent necessary to ensure compliance with this Chapter.

a. Ensuring compliance includes, but is not limited to:

i. permitting photocopying of records by the department; and

ii. providing photocopies to the department of any record or other information the department may deem necessary to determine or verify compliance with this Chapter.

3. Patient records shall be kept for a period of six years from the date a patient is last treated by the clinic. The patient records shall:

a. remain in the custody of the clinic;

b. be maintained on the premises for at least two years from the date the patient was last treated at the clinic; and

c. not be removed except under court order or subpoena.

B. Content of Medical Record

1. A medical record shall include, but is not limited to, the following data on each patient:

a. patient identification information;

b. medical and social history, including results from an inquiry to the Prescription Monitoring Program (PMP), if any;

c. physical examination;

d. chief complaint or diagnosis;

e. clinical laboratory reports, including drug screens, if any;

f. pathology report (when applicable), if any;

g. physicians orders;

h. radiological report (when applicable), if any;

i. consultation reports (when applicable), if any;

j. current medical and surgical treatment, if any;

k. progress notes;

l. nurses' notes of care, including progress notes and medication administration records;

m. authorizations, consents, releases, and emergency patient or family contact number;

o. special procedures reports, if any;

p. an informed consent for chronic pain narcotic therapy; and

q. an agreement signed by the patient stating that he/she:

i. has been informed and agrees to obtain and receive narcotic prescriptions only from the clinic where he is receiving treatment for chronic pain;

ii. shall be subject to quarterly, periodic, unannounced urine drug screens;

iii. shall not participate in diversion of any controlled dangerous substance or narcotic medications, or both;

iv. shall not participate in illicit drug use; and

v. acknowledges that non-compliance with this agreement may be a reason for the clinic's refusal to treat.

2. An individualized treatment plan shall be formulated and documented in the patient's medical record. The treatment plan shall be in accordance with the board's pain rules and shall include, but is not limited to, the following:

a. medical justification for chronic pain narcotic therapy;

b. documentation of other medically reasonable alternative treatment for relief of the patient's pain have been considered or attempted without adequate or reasonable success; and

c. the intended prognosis of chronic pain narcotic therapy which shall be specific to the individual medical needs of the patient.

3. Signatures. Clinical entries shall be signed by a physician, as appropriate, i.e., attending physician, consulting physician, anesthesiologist, pathologist, etc.

Nursing progress notes and assessments shall be signed by the nurse.

4. Nurses' Notes. All pertinent assessments, treatments and medications given to the patient shall be recorded in the nurses' progress notes. All other notes, relative to specific instructions from the physician, shall also be recorded.

5. Completion of the medical record shall be the responsibility of the patient's physician.

C. Provided the regulations herein are met, nothing in this Section shall prohibit the use of automated or centralized computer systems, or any other electronic or non-electronic techniques used for the storage of patient medical records.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40.2198.11-13.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 34:86 (January 2008).