2. If the application is incomplete or otherwise insufficient to allow designation, the BPCRH 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 BPCRH 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 BPCRH.

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 BPCRH 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.

DAL—Division of Administrative Law.

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

Department—the Department of Health and Hospitals.

Health Standards Section (HSS)—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.

Non-Operational—the pain management clinic is not open for business operation on designated days and hours as stated on the licensing application.

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

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

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 in Pain Management—during the course of any day a clinic is in operation, 51 percent or more of the patients seen are issued a narcotic prescription for the treatment of chronic non-malignant pain. Exception: A physician who in the course of his/her own private practice 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 his/her area 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; 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), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 41:2644 (December 2015).

§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. A pain management clinic that is not licensed by, or has not submitted a completed application to, the department for licensure on or before August 1, 2014, shall not be licensed under the exemption to §7803.B.

D. 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), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 41:2644 (December 2015).

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. A pain management clinic verified to be operating without a license shall be required to immediately cease and desist operation and discharge all patients.

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 submit a complete renewal application 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 discharge all patients and 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 change that requires a change in the license shall be accompanied by the required fee.

2. Any change in geographic location of the clinic requires that the provider requests, and satisfactorily meets the requirements of, the following prior to any patient receiving service at the new location:

a. plan review for life safety code and licensing and inspection report with approvals for occupancy from the Office of the State Fire Marshal (OSFM); and

b. a copy of the health inspection report with a recommendation for licensure or a recommendation for denial of licensure from the Office of Public Health (OPH); and

c. an on-site survey prior to issuance of new license by the department.

3. Exception. Pursuant to R.S. 40:2198.12(D)(1)(g), a pain management clinic which is exempted from the requirement of being owned and operated by a physician certified in the subspecialty of pain management may relocate and continue to be exempted from the requirement of being owned and operated by a physician certified in the subspecialty of pain management if the new location is in the same parish in which the original clinic was located.

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 unless the clinic is under common ownership and includes a geographic identifier.

F. The clinic shall not use a name which may mislead the patient or their family into believing it is owned, endorsed, or operated by the state of Louisiana.

G. Any request for a duplicate license shall be accompanied by the required fee.

H. 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 of the 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), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 41:2644 (December 2015).

§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. To be considered complete, the initial licensing application packet shall include the following:

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

2. a copy of the plan review for life safety code and licensing and the on-site inspection report with approvals for occupancy from the OSFM;

3. a copy of the health inspection report with a recommendation for licensure or a recommendation for denial of licensure from the OPH;

4. a zoning approval from local governmental authorities;

5. a statewide criminal background check on all owners conducted by the Louisiana State Police or its designee;

6. verification of the physician owner's certification in the subspecialty of pain management;

7. proof of professional liability insurance of at least $500,000;

a. proof of maintenance of professional liability insurance of at least $500,000 shall be provided to the department at the time of initial licensure, at renewal of licensure, and upon request;

8. an organizational chart identifying the name, position, and title of each person composing the governing body and key administrative personnel;

9. a floor sketch or drawing of the premises to be licensed; and

10. any other documentation or information required by the department for licensure.

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), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 41:2645 (December 2015).

§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 in accordance with R. S. 40:2009.13, et seq. for any complaint received against a clinic. A complaint survey shall be unannounced to the clinic.

D. A follow-up survey may 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.

E. Following any survey, the pain management clinic shall receive a statement of deficiencies documenting relevant findings, including the deficiency, the applicable governing rule, and the evidence supporting why the rule was not met.

1. The following statements of deficiencies issued by the department to the pain management clinic must be posted in a conspicuous place on the licensed premises:

a. the most recent annual licensing survey statement of deficiencies; and

b. any follow-up and/or complaint survey statement of deficiencies issued after the most recent annual licensing survey.

2. Any statement of deficiencies issued by the department to a pain management clinic shall be available for disclosure to the public within 30 calendar days after the pain management clinic submits an acceptable plan of correction to the deficiencies or within 90 days of receipt of the statement of deficiencies, whichever occurs first.

F. The department may require a plan of correction from a pain management clinic following any survey wherein deficiencies have been cited. The fact that a plan of correction is accepted by the department does not preclude the department from pursuing other actions against the pain management clinic as a result of the cited deficiencies.

G. The applicant and/or pain management clinic shall have the right to request an informal reconsideration of any deficiencies cited during any initial licensing survey, annual licensing survey, and follow-up survey.

1. The request for an informal reconsideration must be in writing and received by HSS within 10 calendar days of receipt of the statement of deficiencies. If a timely request for an informal reconsideration is received, HSS shall schedule the informal reconsideration and notify the pain management clinic in writing.

a. The request for an informal reconsideration does not delay submission of the plan of correction within the prescribed timeframe.

2. The request for an informal reconsideration must identify each disputed deficiency or deficiencies and the reason for the dispute and include any documentation that demonstrates that the determination was made in error.

3. Correction of the deficiency or deficiencies cited in any survey shall not be the basis for an informal reconsideration.

4. The pain management clinic may appear in person at the informal reconsideration and may be represented by counsel.

5. The pain management clinic shall receive written notice of the results of the informal reconsideration.

6. The results of the informal reconsideration shall be the final administrative decision regarding the deficiencies and no right to an administrative appeal shall be available.

H. Complaint Survey Informal Reconsideration. Pursuant to R.S. 40:2009.13 et seq., a pain management clinic shall have the right to request an informal reconsideration of the validity of the deficiencies cited during any complaint survey, and the complainant shall be afforded the opportunity to request an informal reconsideration of the survey findings.

1. The department shall conduct the informal reconsideration by administrative desk review.

2. The pain management clinic and/or the complainant shall receive written notice of the results of the informal reconsideration.

3. Except for the right to an administrative appeal provided in R.S. 40:2009.16(A), the results of the informal reconsideration shall be the final administrative decision and no right to an administrative appeal shall be available.

I. Sanctions. The department may impose sanctions as a result of deficiencies cited following any survey. A sanction may include, but is not limited to:

1. civil fine(s);

2. revocation of license;

3. denial of license renewal;

4. immediate suspension of license; and

5. any and all sanctions allowed under federal or state law or regulation.

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), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 41:2645 (December 2015).

§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 pain management clinic 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 pain management 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 pain management 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 may 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 allow a provisional license to expire 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), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 41:2646 (December 2015).

§7819. Initial License Denial, License Revocation or Denial of License 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 pain management 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 and in accordance with §7825;

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 areas of deficient practice;

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 denial of license renewal action, provisional licensure, or 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), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 41:2646 (December 2015).

§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 an adverse action and is 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 calendar 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. 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.

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 Division of Administrative Law (DAL), or its successor, within 30 days after receipt of the notification of the denial or revocation of a license, or within 30 days after receipt of the notification of the results of the administrative reconsideration.

1. Correction of a deficiency shall not be the basis of 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, devolutively appeal from the action of the department by filing a written request for a hearing to the DAL or its successor.

D. If an existing licensed pain management clinic has been issued a notice of license revocation and the provider's license is due for annual renewal, the department shall deny the license renewal application.

1. The denial of the license renewal application does not affect in any manner the license revocation.

2. If the final decision by the DAL or its successor is to reverse the initial license denial, the denial of license renewal, or the license revocation, the provider's license will be reinstated or granted upon the payment of any licensing or other fees due to the department.

E. There is no right to an administrative reconsideration or an administrative appeal of the issuance of a provisional initial license. An existing provider who has been issued a provisional license remains licensed and operational and also has no right to an administrative reconsideration or an administrative appeal. The issuance of a provisional license to an existing pain management clinic is not considered to be a denial of license, a denial of license renewal, or a license revocation.

1. A follow-up survey may be conducted prior to the expiration of a provisional initial license to a new pain management clinic or the expiration of a provisional license to an existing provider.

2. A new provider that is issued a provisional initial license or an existing provider that is issued a provisional license shall be required to correct all noncompliance or deficiencies at the time the follow-up survey is conducted.

3. If all noncompliance or deficiencies have not been corrected at the time of the follow-up survey, or if new deficiencies that are a threat to the health, safety, or welfare of residents are cited on the follow-up survey, the provisional initial license or provisional license shall expire on its face and the provider shall be required to begin the initial licensing process again by submitting a new initial license application packet and fee.

4. The department shall issue written notice to the clinic of the results of the follow-up survey.

5. A provider with a provisional initial license or an existing provider with a provisional license that expires due to noncompliance or deficiencies cited at the follow-up survey, shall have the right to an administrative reconsideration and the right to an administrative appeal of the deficiencies cited at the follow-up survey.

a. The correction of a violation, noncompliance, or deficiency after the follow-up survey shall not be the basis for the administrative reconsideration or for the administrative appeal.

b. The administrative reconsideration and the administrative appeal are limited to whether the deficiencies were properly cited at the follow-up survey.

c. The provider must request the administrative reconsideration of the deficiencies in writing, which shall be received by the HSS within five calendar days of receipt of the notice of the results of the follow-up survey from the department. The request for an administrative reconsideration must identify each disputed deficiency or deficiencies and the reason for the dispute and include any documentation that demonstrates that the determination was made in error.

d. The provider must request the administrative appeal within 15 calendar days of receipt of the notice of the results of the follow-up survey from the department. The request for administrative appeal shall be in writing and shall be submitted to the DAL or its successor. The request for an administrative appeal must identify each disputed deficiency or deficiencies and the reason for the dispute and include any documentation that demonstrates that the determination was made in error.

e. A provider with a provisional initial license or an existing provider with a provisional license that expires under the provisions of this Section must cease providing services unless the DAL or its successor issues a stay of the expiration. The stay may be granted by the DAL or its successor upon application by the provider at the time the administrative appeal is filed and only after a contradictory hearing, and only upon a showing that there is no potential harm to the residents being served by the pain management 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 34:83 (January 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 41:2646 (December 2015).

§7823. Cessation of Business

A. Except as provided in Section §7825 of these licensing regulations, a license shall be immediately null and void if a pain management clinic becomes non-operational.

B. A cessation of business is deemed to be effective the date on which the pain management clinic stopped offering or providing services to the community.

C. Upon the cessation of business, the pain management clinic shall immediately return the original license to the department.

D. Cessation of business is deemed to be a voluntary action on the part of the pain management clinic. The clinic does not have a right to appeal a cessation of business.

E. The pain management clinic shall notify the department in writing 30 days prior to the effective date of the closure or cessation. In addition to the notice, the provider shall submit a written plan for the disposition of

patient medical records for approval by the department. The plan shall include the following:

1. the effective date of the closure;

2. provisions that comply with federal and state laws on storage, maintenance, access, and confidentiality of the closed provider's patients medical records;

3. an appointed custodian(s) who shall provide the following:

a. access to records and copies of records to the patient or authorized representative, upon presentation of proper authorization(s); and

b. physical and environmental security that protects the records against fire, water, intrusion, unauthorized access, loss and destruction; and

4. public notice regarding access to records, in the newspaper with the largest circulation in close proximity to the closing clinic, at least 15 days prior to the effective date of closure.

F. Failure to comply with the provisions concerning submission of a written plan for the disposition of patient medical records to the department may result in the provider being prohibited from obtaining a license for any provider type issued by the department.

G. Once the pain management clinic has ceased doing business, the provider shall not provide services until the clinic has obtained a new initial license.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 41:2647 (December 2015).

§7825. Inactivation of License due to Declared Disaster or Emergency

A. A licensed pain management clinic in an area or areas which have been affected by an executive order or proclamation of emergency or disaster issued in accordance with R.S. 29:724 or R.S. 29:766 may seek to inactivate its license for a period not to exceed two years, provided that the following conditions are met:

1. the licensed pain management clinic shall submit written notification to the Health Standards Section within 60 days of the date of the executive order or proclamation of emergency or disaster that:

a. the pain management clinic has experienced an interruption in the provisions of services as a result of events that are the subject of such executive order or proclamation of emergency or disaster issued in accordance with R.S. 29:724 or R.S. 29:766;

b. the licensed pain management clinic intends to resume operation as a pain management clinic in the same service area; and

c. includes an attestation that the emergency or disaster is the sole causal factor in the interruption of the provision of services;

NOTE: Pursuant to these provisions, an extension of the 60-day deadline may be granted at the discretion of the department.

2. the licensed pain management clinic resumes operating as a pain management clinic in the same service area within two years of the approval of construction plans by all required agencies upon issuance of an executive order or proclamation of emergency or disaster in accordance with R.S. 29:724 or R.S. 29:766;

3. the licensed pain management clinic continues to pay all fees and costs due and owed to the department including, but not limited to, annual licensing fees and outstanding civil monetary penalties and/or civil fines; and

4. the licensed pain management clinic continues to submit required documentation and information to the department, including but not limited to cost reports.

B. Upon receiving a completed written request to inactivate a pain management clinic license, the department shall issue a notice of inactivation of license to the pain management clinic.

C. Upon completion of repairs, renovations, rebuilding or replacement of the facility, a pain management clinic which has received a notice of inactivation of its license from the department shall be allowed to reinstate its license upon the following conditions being met:

1. the pain management clinic shall submit a written license reinstatement request to the licensing agency of the department within two years of the executive order or proclamation of emergency or disaster issued in accordance with R.S. 29:724 or R.S. 29:766;

2. the license reinstatement request shall inform the department of the anticipated date of opening and shall request scheduling of a licensing survey; and

3. the license reinstatement request shall include a completed licensing application with the appropriate licensing fees.

D. Upon receiving a completed written request to reinstate a pain management clinic license, the department shall conduct a licensing survey. If the pain management clinic meets the requirements for licensure and the requirements under this Section, the department shall issue a notice of reinstatement of the pain management clinic license.

E. No change of ownership in the pain management clinic shall occur until such pain management clinic has completed repairs, renovations, rebuilding or replacement construction and has resumed operations as a pain management clinic.

F. The provisions of this Section shall not apply to a pain management clinic which has voluntarily surrendered its license and ceased operation.

G. Failure to comply with any of the provisions of this Section shall be deemed a voluntary surrender of the pain management clinic license.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 41:2648 (December 2015).

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 licensed pain management clinic which has been verified by the department 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 clinical operation and shall be on-site, at a minimum, 50 percent of the time during the operational hours of the clinic. When 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 staff 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 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 procedures.

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 the clinic's 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, evaluated, and documented 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), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 41:2648 (December 2015).

§7832. Administrator

A. The pain management clinic shall have an administrator designated by the governing body who is responsible for the day-to-day management, supervision, and non-medical operation of the clinic. The administrator shall be available during the designated business hours. The provisions of this Chapter do not prohibit the medical director dually serving as the administrator.

1. Qualifications. The administrator shall be at least 18 years of age and possess a high school diploma or equivalent.

2. The pain management clinic shall designate a person to act in the administrator's absence, and shall ensure this person meets the qualifications of the administrator pursuant to this Chapter. The pain management clinic shall maintain documentation on the licensed premises identifying this person and evidence of their qualifications.

3. Duties and Responsibilities. The administrator shall be responsible for:

a. employing licensed and non-licensed qualified personnel to provide the medical and clinical care services to meet the needs of the patients being served;

b. ensuring that upon hire and prior to providing care to patients, each employee is provided with orientation, training, and evaluation for competency as provided in this Chapter;

c. ensuring that written policies and procedures for the management of medical emergencies are developed, implemented, monitored, enforced, and annually reviewed, and readily accessible to all staff;

d. ensuring that disaster plans for both internal and external occurrences are developed, implemented, monitored, enforced, and annually reviewed and that annual emergency preparedness drills are held in accordance with the disaster plan. The pain management clinic shall maintain documentation on the licensed premises indicating the date, type of drill, participants, and materials;

e. maintaining current credentialing and/or personnel files on each employee that shall include documentation of the following:

i. a completed employment application;

ii. job description;

iii. a copy of current health screening reports conducted in accordance with the clinic's policies and procedures and in compliance with all applicable federal, state, and local statutes, laws, rules, regulations, and ordinances, including department rules, and regulations;

iv. documentation that each employee has successfully completed orientation, training, and evaluation for competency related to each job skill as delineated in their respective job description; and

v. documentation that all licensed nurses, if employed, shall:

(a). have successfully completed a Basic Life Support course; and

(b). be in good standing and hold current licensure with their respective state nurse licensing board;

f. ensuring all credentialing and/or personnel files are current and maintained on the licensed premises at all times, including but not limited to, documentation of employee health screening reports; and

g. ensuring that appropriate law enforcement agency(s) are notified when it has been determined that a staff member has been diverting drugs or participating in the illegal use of drugs.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 41:2649 (December 2015).

§7833. Clinic Operations

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

B. A licensed pain management 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 licensed pain management 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 and such shall be documented in the patient's clinical record.

E. A pain management clinic shall have enough qualified personnel who are available to provide direct patient care as needed to all patients and to provide administrative and nonclinical services needed to maintain the operation of the clinic in accordance with the provisions of this Chapter.

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), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 41:2649 (December 2015).

§7835. Governing Body

A. A pain management clinic shall be in compliance with all applicable federal, state, and local statutes, laws, rules, regulations, and ordinances.

B. A pain management clinic shall have a governing body that assumes full responsibility for the total operation of the pain management clinic.

1. The governing body shall consist of at least one individual who assumes full responsibility.

2. The pain management clinic shall maintain documentation on the licensed premises identifying the following information for each member of the governing body:

a. name;

b. contact information;

c. address; and

d. terms of membership.

3. The governing body shall develop and adopt bylaws which address its duties and responsibilities.

4. The governing body shall, at minimum, meet annually and maintain minutes of such meetings documenting the discharge of its duties and responsibilities.

C. The governing body shall be responsible for:

1. ensuring the pain management clinic's continued compliance with all applicable federal, state, and local statutes, laws, rules, regulations, and ordinances, including department rules, regulations, and fees;

2. designating a person to act as the administrator and delegating sufficient authority to this person to manage the non-medical day-to-day operations of the facility;

a. provisions of this Chapter do not prohibit the medical director dually serving as the administrator with responsibility for both medical and non-medical operations of the clinic;

3. designating a person to act as the medical director and delegating authority to this person to allow him/her to direct the medical staff, nursing personnel, and medical services provided to each patient consistent with all pain management rules and regulations issued by the Board;

4. evaluating the administrator and medical director's performance annually, and maintaining documentation of such in their respective personnel files;

5. ensuring that upon hire and prior to providing care to patients, and annually thereafter, each employee is provided with orientation, training, and evaluation for competency according to their respective job descriptions in accordance with the provider's policies and procedures;

6. developing, implementing, enforcing, monitoring, and annually reviewing in collaboration with the administrator and medical director written policies and procedures governing the following:

a. the scope of medical services offered;

b. personnel practices, including, but not limited to:

i. developing job descriptions for licensed and non-licensed personnel consistent with the applicable scope of practice as defined by federal and state law;

ii. developing a program for orientation, training, and evaluation for competency; and

iii. developing a program for health screening;

c. the management of medical emergencies; and

d. disaster plans for both internal and external occurrences;

7. approving all bylaws, rules, policies, and procedures formulated in accordance with all applicable state laws, rules, and regulations;

8. ensuring all bylaws, rules, policies, and procedures formulated in accordance with all applicable state laws, rules, and regulations are maintained on the licensed premises and readily accessible to all staff;

9. maintaining organization and administration of the pain management clinic;

10. acting upon recommendations from the medical director relative to appointments of persons to the medical staff;

11. ensuring that the pain management clinic is equipped and staffed to meet the needs of its patients;

12. ensuring services that are provided through a contract with an outside source, if any, are provided in a safe and effective manner;

13. ensuring that the pain management clinic develops, implements, monitors, enforces, and reviews at a minimum, quarterly, a quality assurance and performance improvement (QA) program;

14. developing, implementing, monitoring, enforcing, and annually reviewing written policies and procedures relating to communication with the administrator, medical director, and medical staff to address problems, including, but not limited to, patient care, cost containment, and improved practices;

15. ensuring that disaster plans for both internal and external occurrences are developed, implemented, monitored, enforced, and annually reviewed and that annual emergency preparedness drills are held in accordance with the disaster plan. The pain management clinic shall maintain documentation on the licensed premises indicating the date, type of drill, participants, and materials;

16. ensuring that the pain management clinic procures emergency medical equipment and medications that will be used to provide for basic life support until emergency medical services arrive and assume care;

17. ensuring that the pain management clinic orders and maintains a supply of emergency drugs for stabilizing and/or treating medical conditions on the licensed premises, subject to approval by the medical director; and

18. ensuring that the pain management clinic develops, implements, enforces, monitors, and annually reviews written policies and procedures to ensure compliance with all applicable federal, state, and local statutes, laws, ordinances, and department rules and regulations, including but not limited to, appropriate referrals when it has been determined that a patient or staff member has been diverting drugs or participating in the illegal use of drugs.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 41:2649 (December 2015).

§7837. Orientation and Training

A. Orientation and Training. The administrator shall develop, implement, enforce, monitor, and annually review, in collaboration with the medical director, written policies and procedures regarding orientation and training of all employees.

1. Orientation. Upon hire and prior to providing care to patients, all employees shall be provided orientation related to the clinic's written policies and procedures governing:

a. organizational structure;

b. confidentiality;

c. grievance process;

d. disaster plan for internal and external occurrences;

e. emergency medical treatment;

f. program mission;

g. personnel practices;

h. reporting requirements; and

i. basic skills required to meet the health needs of the patients.

2. Training. Upon hire, and at a minimum, annually, all employees shall be provided training in each job skill as delineated in their respective job description.

a. Medical training of a licensed medical professional shall only be provided by a medical professional with an equivalent or higher license.

b. Training of a non-licensed employee related to the performance of job skills relative to medical and clinical services shall only be provided by a licensed medical professional consistent with the applicable standards of practice.

c. All training programs and materials used shall be available for review by HSS.

d. The administrator shall maintain documentation of all of the training provided in each employee's personnel files.

B. Evaluation for Competency. Upon hire, and at a minimum, annually, the clinic shall conduct an evaluation for competency of all employees related to each job skill as delineated in their respective job description.

1. The evaluation for competency shall include the observation of job skills and return demonstration by the employee.

2. Evaluation for competency of a licensed medical professional shall only be provided by a medical professional with an equivalent or higher license.

3. Evaluation for competency of a non-licensed employee related to the performance of job skills relative to medical and clinical services shall only be provided by a licensed medical professional consistent with their applicable scope of practice.

4. The administrator shall maintain documentation of all evaluations for competencies in each employee's personnel file.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 41:2650 (December 2015).

Subchapter D. Facility Requirements

§7843. Facility Inspections

A. A licensed pain management clinic shall successfully complete all of the required inspections and maintain a current file of reports and other documentation that is readily available for review demonstrating compliance with all applicable laws and regulations. The inspections shall indicate current approval for occupancy.

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), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 41:2651 (December 2015).

§7845. Physical Environment

A. A licensed pain management clinic shall be constructed, arranged and maintained to ensure the safety and well-being of the clinic's patients and the general public.

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

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. days and 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;

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

3. at least one multipurpose room large enough to accommodate family members for consultations or for staff meetings, in addition to treatment rooms;

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

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

6. electronic medical records keeping systems for providers utilizing electronic records, such equipment shall be protected from unauthorized access and having provisions for systematic retrieval of such records; and

7. secured 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), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 41:2651 (December 2015).

§7847. Infection Control Requirements

A. A pain management clinic shall have written policies and procedures, annually reviewed and signed by the medical director, 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), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 41:2651 (December 2015).

§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 ensure 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.

C. The clinic shall take all necessary 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 basic cardiac life support (BCLS) and be trained in dealing with accidents and medical emergencies until emergency medical personnel and equipment arrive at the clinic.

2. A licensed pain management clinic shall have first aid supplies which are easily accessible to the clinic staff.

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

a. emergency medications, as designated by the medical director; and

b. any emergency medical supplies deemed necessary by the medical director and/or the governing body.

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), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 41:2651 (December 2015).

§7851. Quality Assurance

A. A licensed pain management 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 effects 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), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 41:2652 (December 2015).

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, whether stored electronically or in paper form, from fire, water, or other sources of damage and from unauthorized access.

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, whether stored in paper form or electronically, in clinic or off-site; and

b. be readily available to department surveyors as necessary and relevant to complete licensing surveys or investigations.

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 or treatment notes;

l. nurses' notes of care, if any, 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 licensed pain management 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. Progress Notes. All pertinent assessments, treatments and medications given to the patient shall be recorded in the 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), amended by the

Department of Health and Hospitals, Bureau of Health Services Financing, LR 41:2652 (December 2015).

Chapter 80. Children's Respite Care Centers

Subchapter A. General Provisions

§8001. Definitions

Activities of Daily Living (ADL's)—the following functions or tasks performed either independently or with supervision or assistance:

1. mobility;
2. transferring;
3. walking;
4. grooming;
5. bathing;
6. dressing and undressing;
7. eating;
8. toileting.

Advance Directives—an instruction given to the patient's family (see definition of family) such as a durable power of attorney for health care, a directive pursuant to patient self-determination initiatives, a living will, or an oral directive which either states a person's choices for medical treatment, or in the event the person is unable to make treatment choices, designates who shall make those decisions.

Attending/Primary Physician—a person who is a doctor of medicine or osteopathy fully licensed to practice medicine in the state of Louisiana, who is designated by the patient as the physician responsible for his/her medical care.

Bereavement Services—organized services provided under the supervision of a qualified professional to help the family cope with death related grief and loss issues. This is to be provided for at least one year following the death of the patient.

Branch—a location or site from which a children's respite care center (CRCC) agency provides services within a portion of the total geographic area served by the parent agency. The branch office is part of the parent CRCC agency and is located within a 50-mile radius of the parent agency and shares administration and supervision.

Bureau—the Bureau of Health Services Financing of the Department of Health and Hospitals.

Care Giver—the person whom the patient designates to provide his/her emotional support and/or physical care.

Children's Respite Care Center (CRCC)—an autonomous, centrally administered, pediatric medical respite program providing a continuum of home, outpatient, and homelike inpatient care for children living with life-limiting illnesses and their families. The CRCC employs an interdisciplinary team to assist in providing palliative and supportive care combined with curative treatment to meet the special needs arising out of physical, emotional, spiritual, social, and economic stresses experienced during life-limiting illnesses as well as during dying and bereavement if a cure is not attained.

Contracted Services—services provided to a CRCC provider or its patients by a third party under a legally binding agreement that defines the roles and responsibilities of the CRCC and service provider.

Core Services—medical respite program services, nursing services, physician services, social work services, counseling services, including bereavement counseling, pastoral counseling, and any other counseling services provided to meet the needs of the individual and family, and support services including trained volunteers. These services must be provided by employees of the CRCC, through contracted services and/or volunteers.

CRCC Premises—the physical site where the CRCC maintains staff to perform administrative functions, maintains personnel records, maintains client service records, provides a homelike environment for inpatient respite care, and holds itself out to the public as being a location for receipt of client referrals.

CRCC Services—a coordinated program of a continuum of care to children with life-threatening conditions, their families and caregivers, which allows access to palliative care while continuing with aggressive and curative treatment from the time of admission through bereavement, in the child's home, at the CRCC, and/or in medical facilities.

Department—the Department of Health and Hospitals (DHH).

Discharge—the point at which the patient's active involvement with the CRCC program is ended and the program no longer has active responsibility for the care of the patient.

Do Not Resuscitate Orders—orders written by the patient's physician which stipulate that in the event the patient has a cardiac or respiratory arrest, no cardiopulmonary resuscitation will be initiated or carried out.

Emotional Support—counseling provided to assist the individual and/or family in coping with stress, grief, and loss.

Employee—an individual whom the CRCC pays directly for services performed on an hourly or per visit basis and the CRCC is required to issue a form W-2 on his/her behalf. If a contracting service or another agency pays the individual, and is required to issue a form W-2 on the individual's behalf, or the individual is self-employed, the individual is not considered a CRCC employee. An individual is also considered a CRCC employee if the individual is a volunteer under the jurisdiction of the CRCC.

Family—a group of two or more individuals related by ties of blood, legal status, or affection who consider themselves a family.