

NOTICE OF INTENT

Department of Health and Hospitals
Bureau of Health Services Financing

Pain Management Clinics
Licensing Standards
(LAC 48:I.Chapter 78)

The Department of Health and Hospitals, Bureau of Health Services Financing proposes to amend LAC 48:I.Chapter 78 as authorized by R.S 36:254 and R.S. 40:2198.11-13. This proposed Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950, et seq.

The Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing amended the provisions governing the licensing standards for pain management clinics in order to further clarify the definition of pain management specialist as related to services furnished by urgent care facilities (*Louisiana Register*, Volume 34, Number 7).

Act 714 of the 2014 Regular Session of the Louisiana Legislature directed the department to amend the provisions governing the licensing of pain management clinics to provide for the expiration of licensure exemptions and related matters. The department now proposes to amend the licensing standards governing pain management clinics to comply with Act 714, and to revise these provisions to ensure that they are consistent with

the licensing standards for other health care providers and current enforcement processes.

Title 48
PUBLIC HEALTH—GENERAL
Part I. General Administration
Subpart 3. Licensing and Certification
Chapter 78. Pain Management Clinics

Subchapter A. General Provisions

§7801. Definitions

* * *

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

* * *

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

* * *

DAL—Division of Administrative Law.

* * *

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

* * *

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

* * *

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

* * *

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. ...

* * *

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:

§7803. Ownership

A. - B.4. ...

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.

1. Repealed.

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:

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. - D. ...

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:

§7813. Initial Application Process

A. ...

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

1. ...

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. ...

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:

§7815. Licensing Surveys

A. - B. ...

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:

§7817. Issuance of Licenses

A. ...

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. - 1.d. ...

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. ...

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:

§7819. Initial License Denial, License Revocation or Denial of License Renewal

A. - A.3. ...

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. - 6. ...

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. - 10. ...

11. failure to correct areas of deficient practice;

12. - C. ...

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:

§7821. Notice and Appeal Procedures

A. ...

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.

A.2. - B. ...

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. ...

a. - a.iv. Repealed.

2.b. - 4. ...

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. ...

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:

§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: §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:

Subchapter C. Clinic Administration

§7831. Medical Director

A. - B. ...

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. ...

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. ...

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

6. ...

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. - i.(a). ...

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:

§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:

§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:

§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:

§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:

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.

A.1 - B. Repealed.

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:

§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. ...

b. days and hours of operation;

2. - 6. ...

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

1. a reception area;

2. ...

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.

8. - 11. Repealed.

D. - D.7. ...

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:

§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:

A.1. - F. ...

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:

§7849. Health and Safety Requirements

A. ...

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

A.2. - B.4. ...

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. - E. ...

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. ...

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.

b.i. - d. Repealed.

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:

§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. ...

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;

A.3. - B.1. ...

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:

Subchapter E. Patient Records

§7861. Patient Records

A. - A.1. ...

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. - 3. ...

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.

c. Repealed.

B. - B.1.j. ...

k. progress or treatment notes;

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

m. - q. ...

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;

B.1.q.ii. - 3. ...

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.

B.5 - C. ...

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:

In compliance with Act 1183 of the 1999 Regular Session of the Louisiana Legislature, the impact of this proposed Rule on the family has been considered. It is anticipated that this proposed Rule will have no impact on family functioning, stability or autonomy as described in R.S. 49:972.

In compliance with Act 854 of the 2012 Regular Session of the Louisiana Legislature, the poverty impact of this proposed Rule has been considered. It is anticipated that this proposed Rule will have no impact on child, individual, or family poverty in relation to individual or community asset development as described in R.S. 49:973.

In compliance with House Concurrent Resolution (HCR) 170 of the 2014 Regular Session of the Louisiana Legislature, the

provider impact of this proposed Rule has been considered. It is anticipated that this proposed Rule will have no impact on the staffing level requirements or qualifications required to provide the same level of service and no direct or indirect cost to the provider to provide the same level of service. These provisions will have no impact the provider's ability to provide the same level of service as described in HCR 170.

In compliance with Act 820 of the 2008 Regular Session of the Louisiana Legislature, the economic impact of this proposed Rule on small businesses has been considered. It is anticipated that this proposed Rule may have an adverse impact on small businesses, as described in R.S. 49:965.2 et seq if the requirements of these licensing changes increases the financial burden on providers. With the resources available to the department, a regulatory flexibility analysis has been prepared in order to consider methods to minimize the potential adverse impact on small businesses. The department has determined that there is no less intrusive or less costly alternative methods of achieving the intended purpose since the changes result from legislative mandates.

Interested persons may submit written comments to Cecile Castello, Health Standards Section, P.O. Box 3767, Baton Rouge, LA 70821 or by email to MedicaidPolicy@la.gov. Ms. Castello is responsible for responding to inquiries regarding this proposed

Rule. A public hearing on this proposed Rule is scheduled for Thursday, October 29, 2015 at 9:30 a.m. in Room 118, Bienville Building, 628 North Fourth Street, Baton Rouge, LA. At that time all interested persons will be afforded an opportunity to submit data, views or arguments either orally or in writing. The deadline for receipt of all written comments is 4:30 p.m. on the next business day following the public hearing.

Kathy H. Kliebert

Secretary

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

Person
Preparing Statement: Robert Andrepont Dept.: Health and Hospitals
Phone: 342-8769 Office: Bureau of Health Services
Financing

Return Address: P.O. Box 91030 Rule Title: Pain Management Clinics
Baton Rouge, LA Licensing Standards

Date Rule Takes Effect: December 20, 2015

SUMMARY

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a fiscal and economic impact statement on the rule proposed for adoption, repeal or amendment. The following summary statements, based on the attached worksheets, will be published in the Louisiana Register with the proposed agency rule.

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENTAL UNITS (SUMMARY)

It is anticipated that implementation of this proposed rule will have no programmatic fiscal impact to the state other than the cost of promulgation for FY 15-16. It is anticipated that \$5,184 (SGF) will be expended in FY 15-16 for the state's administrative expense for promulgation of this proposed rule and the final rule.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

It is anticipated that the implementation of this proposed rule will not affect revenue collections since the licensing fees, in the same amounts, will continue to be collected.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NON-GOVERNMENTAL GROUPS (Summary)

This proposed rule amends the provisions governing the licensing of pain management clinics to provide for the expiration of licensure exemptions and related matters in compliance with Act 714 of the 2014 Regular Session of the Louisiana Legislature, and to revise these provisions to ensure that they are consistent with licensing standards for other health care providers and current enforcement processes. It is anticipated that implementation of this proposed rule will have no economic costs or benefits to pain management clinics for FY 15-16, FY 16-17, and FY 17-18.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

This rule has no known effect on competition and employment.

Cecile Castello
Signature of Agency Head
or Designee

Evan Brassel, Staff Director
Legislative Fiscal Officer
or Designee

Cecile Castello,
Health Standards Section Director
Typed name and Title of
Agency Head or Designee

9/10/15
Date of Signature

Jan (K) ...
DHH/BHSF Budget Head

9/9/15
Date of Signature

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

The following information is required in order to assist the Legislative Fiscal Office in its review of the fiscal and economic impact statement and to assist the appropriate legislative oversight subcommittee in its deliberations on the proposed rule.

- A. Provide a brief summary of the content of the rule (if proposed for adoption or repeal) or a brief summary of the change in the rule (if proposed for amendment). Attach a copy of the notice of intent and a copy of the rule proposed for initial adoption or repeal (or, in the case of a rule change, copies of both the current and proposed rules with amended portions indicated).

This proposed rule amends the provisions governing the licensing of pain management clinics to provide for the expiration of licensure exemptions and related matters in compliance with Act 714 of the 2014 Regular Session of the Louisiana Legislature, and to revise these provisions to ensure that they are consistent with licensing standards for other health care providers and current enforcement processes.

- B. Summarize the circumstances that require this action. If the action is required by federal regulations, attach a copy of the applicable regulation.

The Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing amended the provisions governing the licensing standards for pain management clinics in order to further clarify the definition of pain management specialist as related to services furnished by urgent care facilities (Louisiana Register, Volume 34, Number 7).

Act 714 of the 2014 Regular Session of the Louisiana Legislature directed the department to amend the provisions governing the licensing of pain management clinics to provide for the expiration of licensure exemptions and related matters. The department now proposes to amend the licensing standards governing pain management clinics to comply with Act 714, and to revise these provisions to ensure that they are consistent with the licensing standards for other health care providers and current enforcement processes.

- C. Compliance with Act 11 of the 1986 First Extraordinary Session

- (1) Will the proposed rule change result in any increase in the expenditure of funds? If so, specify amount and source of funding.

No. It is anticipated that implementation of this proposed rule will have no programmatic fiscal impact to the state other than the cost of promulgation for FY 15-16. It is anticipated that \$5,184 will be expended in FY 15-16 for the state's administrative expense for promulgation of this proposed rule and the final rule.

- (2) If the answer to (1) above is yes, has the Legislature specifically appropriated the funds necessary for the associated expenditure increase?

- (a) If yes, attach documentation.
(b) If no, provide justification as to why this rule change should be published at this time.

FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET

I. A. COST OR SAVINGS TO STATE AGENCIES RESULTING FROM THE ACTION PROPOSED

1. What is the anticipated increase or (decrease) in cost to implement the proposed action?

COST	FY 15-16	FY 16-17	FY 17-18
PERSONAL SERVICES			
OPERATING EXPENSES	\$5,184	\$0	\$0
PROFESSIONAL SERVICES			
OTHER CHARGES			
REPAIR & CONSTR.			
POSITIONS (#)			
TOTAL	\$5,184	\$0	\$0

2. Provide a narrative explanation of the costs or savings shown in "A.1.", including the increase or reduction in workload or additional paperwork (number of new forms, additional documentation, etc.) anticipated as a result of the implementation of the proposed action. Describe all data, assumptions, and methods used in calculating these costs.

In FY 15-16, \$5,184 will be spent for the state's administrative expense for promulgation of this proposed rule and the final rule.

3. Sources of funding for implementing the proposed rule or rule change.

Source	FY 15-16	FY 16-17	FY 17-18
STATE GENERAL FUND	\$5,184	\$0	\$0
SELF-GENERATED			
FEDERAL FUND	\$0	\$0	\$0
OTHER (Specify)			
Total	\$5,184	\$0	\$0

4. Does your agency currently have sufficient funds to implement the proposed action? If not, how and when do you anticipate obtaining such funds?

Yes, sufficient funds are available to implement this rule.

B. COST OR SAVINGS TO LOCAL GOVERNMENTAL UNITS RESULTING FROM THIS PROPOSED ACTION.

1. Provide an estimate of the anticipated impact of the proposed action on local governmental units, including adjustment in workload and paperwork requirements. Describe all data, assumptions and methods used in calculating this impact.

This proposed rule has no known impact on local governmental units.

FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET

2. Indicate the sources of funding of the local governmental unit that will be affected by these costs or savings.

There is no known impact on the sources of local governmental unit funding.

II. EFFECT ON REVENUE COLLECTIONS OF STATE AND LOCAL GOVERNMENTAL UNITS

- A. What increase or (decrease) in revenues can be expected from the proposed action?

REVENUE INCREASE/DECREASE	FY 15-16	FY 16-17	FY 17-18
STATE GENERAL FUND			
AGENCY SELF-GENERATED			
RESTRICTED FUNDS*			
FEDERAL FUNDS			
LOCAL FUNDS			
Total			

**Specify the particular fund being impacted*

- B. Provide a narrative explanation of each increase or decrease in revenue shown in "A". Describe all data, assumptions, and methods used in calculating these increases or decreases.

III. COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NON-GOVERNMENTAL GROUPS

- A. What persons or non-governmental groups would be directly affected by the proposed action? For each, provide an estimate and a narrative description of any effects on costs, including workload adjustments and additional paperwork (number of new forms, additional documentation, etc.)

This proposed rule amends the provisions governing the licensing of pain management clinics to provide for the expiration of licensure exemptions and related matters in compliance with Act 714 of the 2014 Regular Session of the Louisiana Legislature, and to revise these provisions to ensure that they are consistent with licensing standards for other health care providers and current enforcement processes.

- B. Also, provide an estimate of any revenue impact resulting from this rule or rule change to these groups.

It is anticipated that implementation of this proposed rule will have no economic costs or benefits to pain management clinics for FY 15-16, FY 16-17, and FY 17-18.

IV. EFFECTS ON COMPETITION AND EMPLOYMENT

Identify and provide estimates of the impact of the proposed action on competition and employment in the public and private sectors. Include a summary of any data, assumptions and methods used in making these estimates.

This rule has no known effect on competition and employment.