A bill to be entitled

An act relating to pain-management clinics; providing definitions; providing specific standards of practice in pain-management clinics with regard to evaluations of a patient's medical diagnosis, treatment plans, informed consent, agreements for treatment, a physician's periodic review of a patient, consultation, patient drug testing, patient medical records, denial or termination of controlled-substance therapy, facility and physical operations, infection control, health and safety, quality assurance, and data collection and reporting; amending ss. 458.3265 and 459.0137, F.S.; providing that the designated physician at a pain-management clinic is responsible for ensuring that the clinic is registered with the Department of Health; requiring a pain-management clinic to notify the department of the identity of a newly designated physician when the former designated physician is terminated or when there are any changes to the registration information; providing requirements for the registration of a pain-management clinic; holding nationally recognized accrediting agencies to the same board-determined practice standards for registering pain-management clinics; requiring the department to conduct unannounced annual inspections of clinics; requiring the designated physician to cooperate with the department's inspector and make medical records available to the inspector; requiring the department's inspector to determine compliance with specific standards of practice

in pain-management clinics; providing a procedure for when a pain-management clinic is noncompliant with specific standards of practice; requiring the inspector to forward the written results of the inspection, deficiency notice, and any subsequent documentation to the department; requiring the department to review the results and determine whether action against the clinic is merited; providing that the department's authority is not limited with regard to investigating a complaint without prior notice; requiring the designated physician to submit written notification of the current accreditation survey of the pain-management clinic under certain circumstances; requiring the designated physician to notify the Board of Medicine or Board of Osteopathic Medicine of a plan of correction if the pain-management clinic receives a provisional or conditional accreditation; conforming provisions to changes made by the act; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. (1) DEFINITIONS.—As used in this section, the term:

(a) "Controlled substance" means a substance named or described in Schedule I, Schedule II, Schedule III, Schedule IV, or Schedule V of s. 893.03, Florida Statutes.

(b) "Controlled substance agreement" means an agreement between the treating physician and the patient which establishes

guidelines for proper use of a controlled substance.

(c) "Adverse incident" means an incident set forth in s. 458.351(4)(a)-(e), Florida Statutes.

(d) "Board-certified pain-management physician" means a physician who possesses board certification:

1. By a specialty board recognized by the American Board of Medical Specialties and holds a subspecialty certification in pain medicine; or

2. In pain medicine by the American Board of Pain Medicine.

(e) "Addiction medicine specialist" means:

1. A board-certified psychiatrist who has a subspecialty certification in addiction medicine;

2. A board-certified psychiatrist who is eligible for such subspecialty certification in addiction medicine; or

3. A physician who specializes in addiction medicine and who is certified or eligible for certification by the American Society of Addiction Medicine.

(f) "Mental health addiction facility" means a facility licensed under chapter 394 or chapter 397, Florida Statutes.

(2) STANDARDS OF PRACTICE IN PAIN-MANAGEMENT CLINICS.—

(a) *Evaluation of a patient's medical diagnosis.*—Before a physician starts a patient on any treatment, the physician shall conduct a complete medical history and a physical examination and document the results of the medical history and physical examination in the patient's medical record. The exact components of the physical examination shall be left to the judgment of the physician. The physician shall document in the

medical record, at a minimum, the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, a review of prior medical records, previous diagnostic studies, and history of alcohol and substance abuse. The physician shall also document in the medical record the presence of one or more recognized medical indications for the use of a controlled substance.

(b) *Treatment plan.*—The written individualized treatment plan must include objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician shall adjust drug therapy to the individual medical needs of each patient. Other treatment modalities, including a rehabilitation program, shall be considered depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment. The physician shall document the interdisciplinary nature of the treatment plan.

(c) *Informed consent and agreement for treatment.*—The physician shall discuss the risks and benefits of the use of controlled substances, including the risks of abuse and addiction as well as physical dependence and its consequences, with the patient, persons designated by the patient, or the patient's surrogate or guardian if the patient is incompetent. The physician shall employ the use of a written controlled substance agreement with the patient which outlines the

patient's responsibilities, including, but not limited to:

1. Drug testing of the patient and the results reviewed before the initial issuance or dispensing of a controlled substance prescription, and thereafter, on a random basis at least twice a year and when requested by the treating physician for the purpose of medical necessity and safety of any controlled substances that the physician may consider prescribing as part of the patient's treatment plan.

2. The number and frequency of all prescription refills.

3. Patient compliance and reasons for which drug therapy may be discontinued.

4. An agreement that controlled substances for the treatment of chronic nonmalignant pain shall be prescribed by a single treating physician unless otherwise authorized by the treating physician and documented in the medical record.

(d) *Periodic review.*—The physician shall see the patient at regular intervals, not to exceed 3 months, to assess the efficacy of treatment, ensure that controlled-substance therapy continues as indicated, evaluate the patient's progress toward treatment objectives, consider adverse drug effects, and review the etiology of the pain. Continuation or modification of therapy shall depend on the physician's evaluation of the patient's progress. If treatment goals are not being achieved, despite medication adjustments, the physician shall reevaluate the appropriateness of continued treatment. The physician shall monitor the patient's compliance in medication usage, related treatment plans, controlled substance agreements, and indications of substance abuse or diversion at a minimum of 3-

month intervals.

(e) *Consultation.*—The physician shall refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. The physician shall give special attention to those pain patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients having a history of substance abuse or having a comorbid psychiatric disorder requires extra care, monitoring, and documentation, and requires consultation with or referral to an addictionologist or psychiatrist.

(f) *Patient drug testing.*—To ensure the medical necessity and safety of any controlled substances that the physician may consider prescribing as part of the patient's treatment plan, the physician shall perform patient drug testing in accordance with one of the following collection methods:

1. A physician shall send the patient to a laboratory that is certified by the Clinical Laboratory Improvement Amendments (CLIA) or a collection site owned or operated by a CLIA-certified laboratory.

2. A physician shall collect in the office the patient specimen to be used for drug testing in a device that measures pH, specific gravity, and temperature and the specimen shall be sent to a CLIA-certified laboratory. The physician shall follow the collection procedures required by the agreement the pain-management clinic has entered into with the CLIA-certified laboratory it uses.

3. The specimen shall be collected and tested in the

physician's office. A physician shall collect and test the specimen to be used for drug testing using a CLIA-waived point-of-care test or a CLIA-approved test that uses a device that measures the pH, specific gravity, and temperature. Results of the drug test shall be read according to the manufacturer's instructions.

The treating physician shall review the results of the testing before the initial issuance or dispensing of a controlled substance prescription, and thereafter on a random basis at least twice a year and when requested by the treating physician. This paragraph does not preclude a pain-management clinic from employing additional measures to ensure the integrity of the urine specimens provided by patients. As used in this paragraph, the term "Clinical Laboratory Improvement Amendments" or "CLIA" means the amendments that were passed by Congress in 1988, 42 C.F.R. part 493, which established a program in which the Centers for Medicare and Medicaid Services regulate all laboratory testing, except research, which is performed on humans in the United States by creating quality standards for all laboratory testing and issuing certificates for clinical laboratory testing.

(g) *Patient medical records.*—

1. The physician shall keep accurate and complete records, including, but not be limited to:

a. The complete medical history and a physical examination, including history of drug abuse or dependence.

b. Diagnostic, therapeutic, and laboratory results.

c. Evaluations and consultations.

d. Treatment objectives.

e. Discussion of risks and benefits.

f. Treatments.

g. Medications, including date, type, dosage, and quantity prescribed.

h. Instructions and agreements.

i. Periodic reviews.

j. Drug testing results.

k. A photocopy of the patient's government-issued photo identification.

2. If the treating physician gives a written prescription to the patient for a controlled substance, a duplicate of the prescription must be maintained in the patient's medical record.

3. Each patient's medical record at a pain-management clinic must contain the physician's full name presented in a legible manner. In addition, each clinic must maintain a log on the premises which must contain the full name, presented in a legible manner, along with a corresponding sample signature and initials of each physician, anesthesiologist assistant, and physician assistant working in the clinic.

4. Each physician at a pain-management clinic shall regularly update information in each patient's medical record, maintain the medical record in an accessible manner, and have the medical record readily available for review. The physician shall also ensure that the patient's medical record fully complies with rule 64B8-9.003, Florida Administrative Code, and s. 458.331(1)(m), Florida Statutes.

(h) *Denial or termination of controlled-substance therapy.—*

1. If a patient's initial drug testing reflects the adulteration of the specimen or the presence of illegal or controlled substances, other than medications for which there are approved prescriptions, or if the testing result is questioned by the patient or the physician, the treating physician shall send to a CLIA-certified laboratory the specimen for confirmation by gas or liquid chromatography or mass spectrometry. If the result of the testing of the liquid chromatography or mass spectrometry is positive, the physician shall refer the patient for further consultation with a board-certified pain-management physician, an addiction medicine specialist, or to a mental health addiction facility as it pertains to drug abuse or addiction. After consultation is obtained, the physician shall document in the medical record the results of the consultation. The treating physician may not prescribe or dispense any controlled substances until there is a written concurrence of medical necessity of continued controlled-substance therapy provided by a board-certified pain-management physician, an addiction medicine specialist, or from a mental health addiction facility. If the treating physician is a board-certified pain-management physician or an addiction specialist, the physician need not refer the patient for further consultation. If the physician suspects diversion, the physician shall discharge the patient and document all of the results of testing and actions taken by the physician in the patient's medical record.

2. For a patient currently in treatment by the physician or any other physician in the same pain-management clinic, the physician shall immediately refer the patient who has signs or symptoms of substance abuse to a board-certified pain-management physician, an addiction medicine specialist, or a mental health addiction facility as it pertains to drug abuse or addiction unless the physician is board-certified or board-eligible in pain management. Throughout the period before receiving the consultant's report, a prescribing physician shall clearly and completely document medical justification for continued treatment with controlled substances and those steps taken to ensure the medically appropriate use of controlled substances by the patient. Upon receipt of the consultant's written report, the prescribing physician shall incorporate the consultant's recommendations for continuing, modifying, or discontinuing controlled-substance therapy. The physician shall document the resulting changes in treatment in the patient's medical record.

3. For patients who are currently in treatment by the physician or any other physician in the same pain-management clinic, the physician shall discontinue the controlled-substance therapy if the patient demonstrates evidence or behavioral indications of diversion. The physician shall document all results of testing and actions taken by the physician in the patient's medical record.

(i) *Facility and physical operations.*—

1. A pain-management clinic must be located and operated at a publicly accessible fixed location and contain:

a. A sign that can be viewed by the public which contains

the clinic name, hours of operations, and a street address.

b. A publicly listed telephone number and a dedicated telephone number to send and receive facsimiles, with a facsimile machine that operates 24 hours per day.

c. An emergency lighting and communications system.

d. A reception and waiting area.

e. A restroom.

f. An administrative area, including a room for storage of medical records, supplies, and equipment.

g. A private examination room for patients.

h. A treatment room if treatment is being provided to the patient.

i. A printed sign located in a conspicuous place in the waiting room which is viewable by the public and discloses the name and contact information of the clinic's designated physician and the names of each physician practicing in the clinic.

2. A pain-management clinic that stores and dispenses prescription drugs must comply with ss. 499.0121 and 893.07, Florida Statutes, and rule 64F-12.012, Florida Administrative Code.

3. This paragraph does not excuse a physician from providing any treatment or performing any medical duty without the proper equipment and materials as required by the standard of care.

(j) *Infection control.*—The designated physician at a pain-management clinic shall:

1. Maintain equipment and supplies to support infection

prevention and control activities.

2. Identify infection risks based on:

a. The geographic location, community, and population served;

b. The care, treatment, and services it provides; and

c. An analysis of its infection surveillance and control data.

3. Maintain written infection-prevention policies and procedures that address:

a. The prioritized risks;

b. A limitation on unprotected exposure to pathogens;

c. A limitation on the transmission of infections associated with procedures performed in the clinic; and

d. A limitation on the transmission of infections associated with the use of medical equipment, devices, and supplies at the pain-management clinic.

(k) *Health and safety.*—

1. The pain-management clinic, including its grounds, buildings, furniture, appliances, and equipment, must be structurally sound, in good repair, clean, and free from health and safety hazards.

2. The pain-management clinic must have evacuation procedures if an emergency occurs which include provisions for the evacuation of disabled patients and employees.

3. The pain-management clinic must have a written facility-specific disaster plan that sets forth actions that are taken if the clinic closes due to unforeseen disasters. This plan must include provisions for the protection of medical

records and any controlled substances.

4. At least one employee who is certified in basic life support and trained in reacting to accidents and medical emergencies must be on the premises of a pain-management clinic during patient-care hours.

(l) *Quality assurance.*—Each pain-management clinic must have an ongoing quality assurance program that objectively and systematically monitors and evaluates the quality and appropriateness of patient care, evaluates methods to improve patient care, identifies and corrects deficiencies within the facility, alerts the designated physician to identify and resolve recurring problems, and provides for opportunities to improve the facility's performance and to enhance and improve the quality of care provided to the public. The designated physician shall establish a quality assurance program that includes the following components:

1. The identification, investigation, and analysis of the frequency and causes of adverse incidents to patients.

2. The identification of trends or patterns of incidents.

3. The development of measures to correct, reduce, minimize, or eliminate the risk of adverse incidents to patients.

4. The documentation and periodic review of these functions in subparagraphs 1., 2., and 3. at least quarterly by the designated physician.

A state-licensed risk manager shall review the quality assurance program once every 3 years, provide the Department of Health

with documentation of the review and any corrective action plan within 30 days after the review, and maintain the review for inspection purposes.

(m) *Data collection and reporting.*—

1. The designated physician for each pain-management clinic shall report all adverse incidents to the Department of Health as set forth in s. 458.351, Florida Statutes.

2. The designated physician shall also report to the Board of Medicine each quarter, in writing, the following data:

a. The number of new and repeat patients seen and treated at the pain-management clinic who were prescribed or dispensed controlled substances for the treatment of chronic, nonmalignant pain.

b. The number of patients discharged due to drug abuse.

c. The number of patients discharged due to drug diversion.

d. The number of patients treated at the pain-management clinic whose domicile is located somewhere other than in this state. A patient's domicile is the patient's fixed or permanent home to which the patient intends to return even though he or she may temporarily reside elsewhere.

3. A physician that practices in a pain-management clinic shall advise the Board of Medicine, in writing, within 10 calendar days after beginning or ending his or her practice at a pain-management clinic.

Section 2. Paragraph (c) of subsection (1) and subsections (3) and (4) of section 458.3265, Florida Statutes, are amended to read:

458.3265 Pain-management clinics.—

(1) REGISTRATION.—

(c)1. As a part of registration, a clinic must designate a physician who is responsible for complying with all requirements related to registration and operation of the clinic in compliance with this section. It is the designated physician's responsibility to ensure that the clinic is registered, regardless of whether other physicians are practicing in the same office or whether the office is not owned by a physician. Within 10 days after termination of a designated physician, the clinic must notify the department of the identity of another designated physician for that clinic or of any changes to the registration information. The designated physician shall have a full, active, and unencumbered license under this chapter or chapter 459 and shall practice at the clinic location for which the physician has assumed responsibility. Failing to have a licensed designated physician practicing at the location of the registered clinic may be the basis for a summary suspension of the clinic registration certificate as described in s. 456.073(8) for a license or s. 120.60(6).

2. In order to register a pain-management clinic, the designated physician shall:

a. Pay an inspection fee of $1,500 for each location required to be inspected;

b. Pay a registration fee of $145. The fee must also be paid if the physical location of the clinic changes or the ownership changes. An additional fee of $5 shall be added to the cost of registration to cover unlicensed activity as required by

s. 456.065(3); and

c. Provide documentation to support compliance with section 1 of this act.

3. The designated physician shall post the documentation of registration in a conspicuous place in the waiting room which is viewable by the public.

(3) INSPECTION.—

(a) The department shall inspect the pain-management clinic annually, including a review of the patient records, to ensure that it complies with this section and the rules of the Board of Medicine adopted pursuant to subsection (4) unless the clinic is accredited by a nationally recognized accrediting agency approved by the Board of Medicine. Each nationally recognized accrediting agency shall be held to the same board-determined practice standards for registering pain-management clinic in this state.

(b) The department shall conduct unannounced annual inspections of clinics pursuant to this subsection. ~~During an onsite inspection, the department shall make a reasonable attempt to discuss each violation with the owner or designated physician of the pain-management clinic before issuing a formal written notification.~~

(c) The designated physician shall cooperate with the inspector, make medical records available to the inspector, and be responsive to all reasonable requests. ~~Any action taken to correct a violation shall be documented in writing by the owner or designated physician of the pain-management clinic and verified by followup visits by departmental personnel.~~

(d) The inspector shall determine compliance with the requirements of section 1 of this act. These requirements include a review of a random selection of patient records for patients who are treated for pain. The inspector shall select such patient records from each physician practicing in the clinic or who has practiced in the clinic during the past 6 months.

(e) If the clinic is determined to be in noncompliance, the inspector shall notify the designated physician and give the designated physician a written statement at the time of inspection. Such written notice shall specify the deficiencies in the inspection. Unless the deficiencies constitute an immediate and imminent danger to the public, the designated physician shall be given 30 days after the date of inspection to correct any documented deficiencies and notify the department of a corrective action plan. Upon written notification from the designated physician that all deficiencies have been corrected, the department may reinspect for compliance. If the designated physician fails to submit a corrective action plan within 30 days after the inspection, the department may reinspect the clinic to ensure that the deficiencies have been corrected.

(f) The inspector shall forward to the department the written results of the inspection, deficiency notice, and any subsequent documentation, including, but not limited to:

1. Whether the deficiencies constituted an immediate and serious danger to the public;

2. Whether the designated physician provided the department with documentation of correction of all deficiencies

within 30 days after the date of inspection; and

3. The results of any reinspection.

(g) The department shall review the results of the inspection and determine whether action against the clinic's registration is merited.

(h) The department's authority is not limited with regard to investigating a complaint without prior notice.

(i) If the clinic is accredited by a nationally recognized accrediting agency that is approved by the board, the designated physician shall submit written notification of the current accreditation survey of his or her clinic in lieu of undergoing an inspection by the department.

(j) The designated physician shall submit, within 30 days after accreditation, a copy of the current accreditation survey of the clinic and shall immediately notify the board of any accreditation changes that occur. For purposes of initial registration, the designated physician shall submit a copy of the most recent accreditation survey of the clinic in lieu of undergoing an inspection by the department.

(k) If a provisional or conditional accreditation is received, the designated physician shall notify the board in writing and include a plan of correction.

(4) RULEMAKING.—

~~(a) The department shall adopt rules necessary to administer the registration and inspection of pain-management clinics which establish the specific requirements, procedures, forms, and fees~~.

(a)~~(b)~~ The department shall adopt a rule defining what

constitutes practice by a designated physician at the clinic location for which the physician has assumed responsibility, as set forth in subsection (1). When adopting the rule, the department shall consider the number of clinic employees, the location of the pain-management clinic, the clinic's hours of operation, and the amount of controlled substances being prescribed, dispensed, or administered at the pain-management clinic.

(b) ~~(c)~~ The Board of Medicine shall adopt a rule establishing the maximum number of prescriptions for Schedule II or Schedule III controlled substances or the controlled substance Alprazolam which may be written at any one registered pain-management clinic during any 24-hour period.

~~(d) The Board of Medicine shall adopt rules setting forth standards of practice for physicians practicing in privately owned pain-management clinics that primarily engage in the treatment of pain by prescribing or dispensing controlled substance medications. Such rules shall address, but need not be limited to:~~

~~1. Facility operations;~~

~~2. Physical operations;~~

~~3. Infection control requirements;~~

~~4. Health and safety requirements;~~

~~5. Quality assurance requirements;~~

~~6. Patient records;~~

~~7. Training requirements for all facility health care practitioners who are not regulated by another board;~~

~~8. Inspections; and~~

~~9. Data collection and reporting requirements.~~

~~A physician is primarily engaged in the treatment of pain by prescribing or dispensing controlled substance medications when the majority of the patients seen are prescribed or dispensed controlled substance medications for the treatment of chronic nonmalignant pain. Chronic nonmalignant pain is pain unrelated to cancer which persists beyond the usual course of the disease or the injury that is the cause of the pain or more than 90 days after surgery.~~

Section 3. Paragraph (c) of subsection (1) and subsections (3) and (4) of section 459.0137, Florida Statutes, are amended to read:

459.0137 Pain-management clinics.—

(1) REGISTRATION.—

(c)1. As a part of registration, a clinic must designate an osteopathic physician who is responsible for complying with all requirements related to registration and operation of the clinic in compliance with this section. It is the designated osteopathic physician's responsibility to ensure that the clinic is registered, regardless of whether other physicians are practicing in the same office or whether the office is not owned by a physician. Within 10 days after termination of a designated osteopathic physician, the clinic must notify the department of the identity of another designated physician for that clinic of any changes to the registration information. The designated physician shall have a full, active, and unencumbered license under chapter 458 or this chapter and shall practice at the

clinic location for which the physician has assumed responsibility. Failing to have a licensed designated osteopathic physician practicing at the location of the registered clinic may be the basis for a summary suspension of the clinic registration certificate as described in s. 456.073(8) for a license or s. 120.60(6).

2. In order to register a clinic, the designated osteopathic physician shall:

a. Pay an inspection fee of $1,500 for each location required to be inspected;

b. Pay a registration fee of $145. The fee must also be paid if the physical location of the clinic changes or the ownership changes. An additional fee of $5 shall be added to the cost of registration to cover unlicensed activity as required by s. 456.065(3); and

c. Provide documentation to support compliance with section 1 of this act.

3. The designated osteopathic physician shall post the documentation of registration in a conspicuous place in the waiting room which is viewable by the public.

(3) INSPECTION.—

(a) The department shall inspect the pain-management clinic annually, including a review of the patient records, to ensure that it complies with this section and the rules of the Board of Osteopathic Medicine adopted pursuant to subsection (4) unless the clinic is accredited by a nationally recognized accrediting agency approved by the Board of Osteopathic Medicine. Each nationally recognized accrediting agency shall be

held to the same board-determined practice standards for registering a clinic in this state.

(b) The department shall conduct unannounced annual inspections of clinics pursuant to this subsection. ~~During an onsite inspection, the department shall make a reasonable attempt to discuss each violation with the owner or designated physician of the pain-management clinic before issuing a formal written notification.~~

(c) The designated osteopathic physician shall cooperate with the inspector, make medical records available to the inspector, and be responsive to all reasonable requests. ~~Any action taken to correct a violation shall be documented in writing by the owner or designated physician of the pain-management clinic and verified by followup visits by departmental personnel.~~

(d) The inspector shall determine compliance with the requirements of section 1 of this act. These requirements include a review of a random selection of patient records for patients who are treated for pain. The inspector shall select such patient records from each osteopathic physician practicing in the clinic or who has practiced in the clinic during the past 6 months.

(e) If the clinic is determined to be in noncompliance, the inspector shall notify the designated osteopathic physician and give the designated osteopathic physician a written statement at the time of inspection. Such written notice shall specify the deficiencies. Unless the deficiencies constitute an immediate and imminent danger to the public, the designated

osteopathic physician shall be given 30 days after the date of inspection to correct any documented deficiencies and notify the department of corrective action plan. Upon written notification from the designated osteopathic physician that all deficiencies have been corrected, the department may reinspect for compliance. If the designated osteopathic physician fails to submit a corrective action plan within 30 days after the inspection, the department may reinspect the office to ensure that the deficiencies have been corrected.

(f) The inspector shall forward to the department the written results of the inspection, deficiency notice and any subsequent documentation, including, but not limited to:

1. Whether the deficiencies constituted an immediate and serious danger to the public;

2. Whether the designated osteopathic physician provided the department with documentation of correction of all deficiencies within 30 days after the date of inspection; and

3. The results of any reinspection.

(g) The department shall review the results of the inspection and determine whether action against the clinic's registration is merited.

(h) The department's authority is not limited with regard to investigating a complaint without prior notice.

(i) If the clinic is accredited by a nationally recognized accrediting agency approved by the board, the designated osteopathic physician shall submit written notification of the current accreditation survey of his or her clinic in lieu of undergoing an inspection by the department.

(j) The designated osteopathic physician shall submit, within 30 days after accreditation, a copy of the current accreditation survey of the clinic and shall immediately notify the board of any accreditation changes that occur. For purposes of initial registration, the designated osteopathic physician shall submit a copy of the most recent accreditation survey of the clinic in lieu of undergoing an inspection by the department.

(k) If a provisional or conditional accreditation is received, the designated osteopathic physician shall notify the board in writing and shall include a plan of correction.

(4) RULEMAKING.—

~~(a) The department shall adopt rules necessary to administer the registration and inspection of pain-management clinics which establish the specific requirements, procedures, forms, and fees.~~

(a) ~~(b)~~ The department shall adopt a rule defining what constitutes practice by a designated osteopathic physician at the clinic location for which the physician has assumed responsibility, as set forth in subsection (1). When adopting the rule, the department shall consider the number of clinic employees, the location of the pain-management clinic, the clinic's hours of operation, and the amount of controlled substances being prescribed, dispensed, or administered at the pain-management clinic.

(b) ~~(c)~~ The Board of Osteopathic Medicine shall adopt a rule establishing the maximum number of prescriptions for Schedule II or Schedule III controlled substances or the

controlled substance Alprazolam which may be written at any one registered pain-management clinic during any 24-hour period.

~~(d) The Board of Osteopathic Medicine shall adopt rules setting forth standards of practice for osteopathic physicians practicing in privately owned pain-management clinics that primarily engage in the treatment of pain by prescribing or dispensing controlled substance medications. Such rules shall address, but need not be limited to:~~

~~1. Facility operations;~~

~~2. Physical operations;~~

~~3. Infection control requirements;~~

~~4. Health and safety requirements;~~

~~5. Quality assurance requirements;~~

~~6. Patient records;~~

~~7. Training requirements for all facility health care practitioners who are not regulated by another board;~~

~~8. Inspections; and~~

~~9. Data collection and reporting requirements.~~

~~An osteopathic physician is primarily engaged in the treatment of pain by prescribing or dispensing controlled substance medications when the majority of the patients seen are prescribed or dispensed controlled substance medications for the treatment of chronic nonmalignant pain. Chronic nonmalignant pain is pain unrelated to cancer which persists beyond the usual course of the disease or the injury that is the cause of the pain or more than 90 days after surgery.~~

Section 4. This act shall take effect July 1, 2011.