WEST VIRGINIA SECRETARY OF STATE

MAC WARNER

ADMINISTRATIVE LAW DIVISION

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Office of West Virginia
Secretary Of State

NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE AND FILING WITH THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

AGENCY: Health And Human Resources TITLE-SERIES: 69-08

RULE TYPE: Legislative Amendment to Existing Rule: Yes Repeal of existing rule: No

RULE NAME: 69-08 Chronic Pain Management Clinic Licensure

PRIMARY CONTACT

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CITE STATUTORY AUTHORITY: W. Va. Code §16-1-4 and §16-5H-9

EXPLANATION OF THE STATUTORY AUTHORITY FOR THE LEGISLATIVE RULE, INCLUDING A DETAILED SUMMARY OF THE EFFECT OF EACH PROVISION OF THE LEGISLATIVE RULE WITH CITATION TO THE SPECIFIC STATUTORY PROVISION WHICH EMPOWERS THE AGENCY TO ENACT SUCH RULE PROVISION:

This rule establishes the specific standards and procedures for the health, safety, and protection of the rights and dignity of patients utilizing chronic pain management clinics. The rule must be updated to reflect statutory changes. This rule is necessary for the health, safety, and well-being of the people of West Virginia, as well as ensuring all West Virginia pain management clinics conform to a common set of standards and procedures.

DATE eFiled FOR NOTICE OF HEARING OR PUBLIC COMMENT PERIOD: 6/21/2018

DATE OF PUBLIC HEARING(S) OR PUBLIC COMMENT PERIOD ENDED: 7/21/2018

COMMENTS RECEIVED: No

(IF YES, PLEASE UPLOAD IN THE COMMENTS RECEIVED FIELD COMMENTS RECEIVED AND RESPONSES TO COMMENTS)

PUBLIC HEARING: No

(IF YES, PLEASE UPLOAD IN THE PUBLIC HEARING FIELD PERSONS WHO APPEARED AT THE HEARING(S) AND TRANSCRIPTS)

RELEVANT FEDERAL STATUTES OR REGULATIONS: No

WHAT OTHER NOTICE, INCLUDING ADVERTISING, DID YOU GIVE OF THE HEARING?

N/A

SUMMARY OF THE CONTENT OF THE LEGISLATIVE RULE, AND A DETAILED DESCRIPTION OF THE RULE'S PURPOSE AND ALL PROPOSED CHANGES TO THE RULE:

his rule establishes the specific standards and procedures for the health, safety, and protection of the rights and dignity of patients utilizing chronic pain management clinics.

Grammatical and citation amendments made throughout. Technical renumbering amended throughout.
Section 2 - Definitions. Definitions in licensing act incorporated by reference.
Section 3 - Pain Clinic Definition and Exemptions. Amendment to definition based on updates to licensing act as to requirements to be considered a pain clinic updated. Amendment to remove exemption for medical school due previous deletion from licensing act.
Section 4 - Licensure. Amendment to remove regulation that individual facilities complete background checks, and replaces with appropriate WV CARES language.
Section 6 - Organization and Management. Amendment to remove regulation that individual facilities complete background checks, and replaces with appropriate WV CARES language.
Section 8 - Clinic staff; training and credentialing of staff. Amendment to remove regulation that individual facilities complete background checks, and replaces with appropriate WV CARES language.
Section 16 - Advertisement disclosure. Regulation removed due to it being contained in the licensing act.

STATEMENT OF CIRCUMSTANCES WHICH REQUIRE THE RULE:

The rule must be updated to reflect statutory changes. This rule is necessary for the health, safety, and well-being of the people of West Virginia, as well as ensuring all West Virginia pain management clinics conform to a common set of standards and procedures.

SUMMARIZE IN A CLEAR AND CONCISE MANNER THE OVERALL ECONOMIC IMPACT OF THE PROPOSED LEGISLATIVE RULE:

A. ECONOMIC IMPACT ON REVENUES OF STATE GOVERNMENT:

This legislative rule establishes standards and procedures for the regulation of chronic pain management clinics.

This rule is being updated in response to changes made by the legislature in SB 273 during the 2018 legislative session. This update adds provisions for background checks through WV Clearance for Access: Registry and Employment Screening, and makes technical corrections to numbering.

The Department's Office of Inspector General (OIG) anticipates no fiscal impact to its operations resulting from these revisions.

B. ECONOMIC IMPACT OF THE LEGISLATIVE RULE ON THE STATE OR ITS RESIDENTS:

N/A

C. FISCAL NOTE DETAIL:

Effect of Proposal	Fiscal Year		
	2018 Increase/Decrease (use "-")	2019 Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	0		0
Personal Services			
Current Expenses			
Repairs and Alterations			
Assets			
Other			
2. Estimated Total Revenues	0		0

D. EXPLANATION OF ABOVE ESTIMATES (INCLUDING LONG-RANGE EFFECT):

The OIG anticipates no fiscal impact to its operations.

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENT IS TRUE AND CORRECT.

Yes

Heather J Mcdaniel -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.

TITLE 69
LEGISLATIVE RULE
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

SERIES 8
CHRONIC PAIN MANAGEMENT CLINIC LICENSURE

§69-8-1. General.

1.1. Scope. -- This legislative rule establishes standards and procedures for the regulation of chronic pain management clinics.

1.2. Authority. -- W. Va. Code §16-1-4 and §16-5H-9.

1.3. Filing Date. -- ~~April 8, 2016~~.

1.4. Effective Date. -- ~~May 1, 2016~~.

1.5. Sunset Provision. -- This rule shall terminate and have no further force or effect upon the expiration of five years from its effective date.

~~1.5.~~ 1.6. Applicability. -- This rule applies to any person, partnership, association, or corporation that operates a chronic pain management clinic.

~~1.6.~~ 1.7. Purpose. -- The purpose of this rule is to ensure all West Virginia pain management clinics conform to a common set of standards and procedures. All standards and procedures are minimum requirements whereby ~~chronic~~ pain management clinics may be surveyed and evaluated to ensure the care, treatment, health, safety, and welfare of patients treated therein.

~~1.7.~~ 1.8. Enforcement. -- This rule is enforced by the Secretary of the Department of Health and Human Resources or his or her lawful designee. For the purposes of this rule, the Secretary designates the Director of the Office of Health Facility Licensure and Certification.

§69-8-2. Definitions.

2.1. Definitions incorporated by reference. -- Those terms defined in W. Va. Code §§16-5H-1, *et seq.*, are incorporated herein by reference.

~~2.1.~~2.2. Administer -- The direct application of a drug to the body of a patient by injection, inhalation, ingestion or any other means.

~~2.2.~~2.3. Administrator -- The individual responsible for the day-to-day non-clinical, business operation of the pain management clinic. The individual shall be qualified by education and training as specified in a job description developed by the owners.

~~2.3.~~2.4. Adverse Events or Incidents -- An occurrence that may involve an immediate threat to the care or safety of an individual, whether staff member, visitor or patient; an event or circumstance that could have or did lead to harm, loss, or damage to patients or staff.

~~2.4.~~2.5. Associate -- Any person, firm or corporation that is associated with a pain management clinic through employment, an independent contract, assignment, internship, or other such arrangement that provides access to the clinic, patient records, or medications.

~~2.5.~~2.6. Clinic Staff -- All persons who work at or for a pain management clinic, paid or unpaid. Staff members may include owners, employees, associates, volunteers, or contracted agents.

~~2.6.~~2.7. Complaint or Grievance -- A verbal or written statement made by any person and filed with the clinic administrator or a state agency alleging inadequate or inappropriate service on the part of a pain management clinic.

~~2.7. Chronic Pain. – Pain that has persisted after reasonable medical efforts have been made to relieve the pain or cure its cause and that has continued, either continuously or episodically, for longer than three continuous months. Chronic pain does not include pain directly associated with a terminal condition or with a progressive disease that, in the normal course of progression, may reasonably be expected to result in a terminal condition.~~

2.8. Controlled Substances Monitoring Program Database -- The database maintained by the West Virginia Board of Pharmacy that monitors and tracks controlled substances prescribed and dispensed by prescribing practitioners or pharmacists in West Virginia.

2.9. Criminal Records Check -- An investigation of criminal records from law enforcement agencies and the Federal Bureau of Investigation.

2.10. Designated Physician Owner -- An owner of a chronic pain management clinic who is fully accountable and responsible for all the aspects of the operation of the clinic. The percentage of ownership shall be more than 25 percent and shall not be a de minimis amount.

~~2.11. Director – The Director of the Office of Health Facility Licensure and Certification within the Office of the Inspector General of the Department of Health and Human Resources.~~

~~2.12.~~2.11. Dispense -- The preparation and delivery of any medication, including ~~a~~ controlled substances, by a physician or pharmacist to a patient pursuant to an order of a physician, including the prescribing, packaging, labeling, administering, or compounding necessary to prepare that drug for delivery.

~~2.13.~~2.12. Informed Consent -- Written acknowledgement and verification by a patient stating that the patient has been informed of the risks and benefits of all aspects of the treatment provided to the patient and that the patient agrees to the treatment.

~~2.14.~~2.13. Opioid Drug Product -- Any finished dosage form that contains as one of its active ingredients a drug substance that has pharmacological properties similar to morphine, including its analgesic action and its addiction-forming or addiction-sustaining liability, or that can be converted by the body into a drug substance having such properties. Opioid drug products include, but are not limited to, those containing morphine, codeine, hydrocodone, and oxycodone.

~~2.15. Owner – Any person, partnership, association or corporation listed as an owner of a pain management clinic on the licensing forms and applications. Each owner is responsible for the operation of the pain management clinic and assumes responsibility for all of its employees, including any~~

~~practitioners, agents or other persons providing medical services at the clinic. At least one owner shall be a physician actively licensed to practice medicine, surgery or osteopathic medicine and surgery in this state.~~

~~2.16.~~2.14. Pain -- An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage.

~~2.17. Pain Management Clinic – All privately owned pain management clinics, facilities or offices, not otherwise exempted, which meet the criteria established in Section 3 of this rule.~~

~~2.18. Physician – An individual licensed to practice medicine or surgery by the West Virginia Board of Medicine pursuant to W. Va. Code §30-3-1, *et seq.*, or the West Virginia Board of Osteopathic Medicine pursuant to W. Va. Code §30-14-1, *et seq.*~~

~~2.19.~~2.15. Plan of Care -- A written plan of treatment and care, which includes a signed treatment agreement from the patient, developed by a patient's physician and other health care professionals in conjunction with the patient that outlines for the patient attainable short-term treatment goals that are mutually acceptable to the patient and the pain management clinic and which specifies the services to be provided and the frequency and schedule for their provision.

~~2.20. Prescriber – An individual who is authorized by law to prescribe drugs or drug therapy related devices in the course of the individual's professional practice, including only a medical or osteopathic physician authorized to practice medicine or surgery; a physician assistant or osteopathic physician assistant or an advanced practice registered nurse with prescriptive authority.~~

~~2.21.~~2.16. Plan of Correction -- A written description of the actions the pain management clinic intends to take to correct and prevent the reoccurrence of violations of a rule or policy identified by the designated state oversight agency during an investigation, inspection, or survey.

~~2.22.~~2.17. Public media -- Any form of communication intended to reach the general public, including, but not limited to, a telephone directory, medical directory, newspaper or other periodical, outdoor advertising, radio or television, or social media.

~~2.23. Secretary – The secretary of the West Virginia Department of Health and Human Resources or his or her designee.~~

~~2.24.~~2.18. Terminal Condition -- ~~a~~An illness or disease that cannot be cured and the medical prognosis is that the individual's life expectancy is six months or less if the illness runs its normal course.

~~2.25.~~2.19. Treating Physician -- A physician who maintains primary responsibility for the examination and treatment of his or her patients.

~~2.26.~~2.20. Unique Patient Encounter -- A single patient with multiple visits to a ~~chronic~~ pain management clinic, in any given month, that is counted as one clinic patient for calculation purposes.

§69-8-3. Pain Clinic Definition and Exemptions.

3.1. A pain management clinic is any privately owned, clinic, facility or office, not otherwise exempted, that treats patients for chronic pain as defined by ~~§69-8-2.6~~ W. Va. Code §16-5H-2, and;

~~3.1.a.~~ 3.1.1. The primary component of the medical practice of the clinic, facility or office is treatment of chronic pain for non-malignant conditions;

~~3.1.b.~~ 3.1.2. More than 50 percent of patients in any one month of the clinic are provided treatment for chronic pain for nonmalignant conditions that are not terminal and are prescribed, administered or dispensed ~~tramadol, carisoprodol,~~ Schedule II opioid drug products or other Schedule II ~~or Schedule III~~ controlled substances for such diagnosis;

~~3.1.c.~~ 3.1.3. The calculation of more than 50 percent of patients will be calculated by dividing the number of unique patient encounters at the clinic, facility or office during any one month for a diagnosis of chronic nonmalignant pain for conditions that are not terminal and pursuant to such diagnosis of chronic nonmalignant pain for conditions that are not terminal were prescribed, administered, or dispensed ~~tramadol, carisoprodol,~~ Schedule II opioid drugs or other Schedule II ~~or Schedule III~~ controlled substances by the total number of all patient encounters at the clinic, facility, or office during any month; and

~~3.1.d.~~ 3.1.4. Patients receiving ~~tramadol, carisoprodol,~~ Schedule II opioid drug products or other Schedule II ~~or Schedule III~~ controlled substances for treatment of any injury or illness that lasts or is expected to last 30 days or less shall not be included in the calculation of more than 50 percent of all patients. Clinics below the 50 percent patient calculation threshold will be subject to continued monitoring by the Office of Health Facility Licensure and Certification for changes in the patient ratio. Failure to cooperate with requests for information to verify patient calculations may subject the clinic to penalties and equitable relief pursuant to Section 18 of this rule.

~~3.1.e.~~ 3.1.5. A pain management clinic shall not offer a bounty, monetary, or equipment or merchandise reward, or free services for individuals in exchange for recruitment of new patients into the clinic. A pain clinic shall not recruit new patients for the purpose of attempting to circumvent the licensure requirement of this rule.

3.2. The following facilities are not pain management clinics subject to the requirements of this rule:

~~3.2.a. A facility that is affiliated with an accredited medical school at which training is provided for medical or osteopathic students, residents or fellows, podiatrists, dentists, nurses, physician assistants, veterinarians or any affiliated facility to the extent that it participates in the provision of the instruction;~~

~~3.2.b.~~3.2.1. A facility that does not prescribe or dispense controlled substances for the treatment of chronic pain;

~~3.2.c.~~3.2.2. A hospital licensed in this state, a facility located on the campus of a licensed hospital that is owned, operated or controlled by that licensed hospital, and an ambulatory health care facility as defined by W. Va. Code §16-2D-2 that is owned, operated or controlled by a licensed hospital;

~~3.2.d.~~3.2.3. A physician practice owned or controlled, in whole or in part, by a licensed hospital or by an entity that owns or controls, in part, one or more licensed hospitals;

~~3.2.e.~~3.2.4. A hospice program licensed in this state;

~~3.2.f.~~3.2.5. A nursing home licensed in this state;

~~3.2.g.~~3.2.6. An ambulatory surgical facility as defined by W. Va. Code §16-2D-2;

~~3.2.h.~~3.2.7. A facility conducting clinical research that may use controlled substances in studies approved by a hospital-based institutional review board or an institutional review board accredited by the association for the accreditation of human research protection programs; and

~~3.2.i.~~3.2.8. Any other facility granted an exemption by the secretary pursuant to W. Va. Code §16-5H-5(b), including, state owned and operated hospitals otherwise exempted from state licensure pursuant to the provisions of W. Va. Code §§16-5B-1, *et seq*.

~~3.2.i.1. State owned and operated hospitals otherwise exempted from state licensure pursuant to the provisions of W. Va. Code § 16-5B-1 are granted an exemption from the requirements of this rule.~~

3.3. Any facility that is not exempted pursuant to this section may petition the secretary for an exemption from the requirements of this rule. All such petitions are subject to the administrative procedures requirements of W. Va. Code §§29A-1-1, *et seq*.

§69-8-4. Licensure.

4.1. General Licensure Provisions.

~~4.1.a.~~ 4.1.1. No person, partnership, association, or corporation may operate a pain management clinic in the state of West Virginia without first obtaining a license.

~~4.1.b.~~ 4.1.2. A license is valid only for the location and persons named and described in the application.

~~4.1.c.~~ 4.1.3. Each pain management clinic location shall be licensed separately, regardless of whether the clinic is operated under the same business name or management as another clinic.

~~4.1.d.~~ 4.1.4. Each licensed clinic location shall designate a physician owner unique to that clinic. The designated physician owner shall practice at the clinic and be responsible for the operation of the clinic in accordance with the requirements of this rule.

~~4.1.e.~~ 4.1.5. A license is not transferable or assignable.

~~4.1.f.~~ 4.1.6. If the ownership of a pain management clinic changes, the new owner shall notify the secretary within 10 days and immediately apply for a new license. The new owner's application for a license has the effect of a valid license for three months from the date the application is received by the director.

~~4.1.g.~~ 4.1.7. The pain management clinic shall notify the secretary in writing 30 days prior to a change in the name or location of the clinic and ~~request~~ submit an application form for a license amendment.

~~4.1.h.~~ 4.1.8. If there is a change in the designated physician owner, the pain management clinic must comply with the provisions of subsection 6.4.3. of this rule.

~~4.1.i.~~ 4.1.9. Initial and renewal licenses shall expire one year from issuance.

~~4.1.j.~~ 4.1.10. If the pain management clinic is not in substantial compliance with this rule, but does not pose a significant risk to the health, safety, or rights of the patients a license expiring in less than one year may be issued.

~~4.1.k.~~ 4.1.11. A licensure survey may be conducted periodically during the course of the annual licensing term.

~~4.1.l.~~ 4.1.12. The secretary or his or her designee may enter the premises of any practice, office, or facility if the secretary has reasonable belief that it is being operated or maintained as a pain management clinic without a license.

~~4.1.m.~~ 4.1.13. If the owner or person in charge of a licensed pain management clinic or of any other unlicensed practice, office, or facility which the secretary has reasonable belief that it is being operated as a pain management clinic refuses entry pursuant to this rule, the secretary shall petition the Circuit Court of Kanawha County for an inspection warrant.

~~4.1.n.~~ 4.1.14. If the secretary finds on the basis of an inspection that any person, partnership, association, or corporation is operating as a pain management clinic without a license, the pain management clinic shall apply for a license within 10 days.

~~4.1.o.~~ 4.1.15. A pain management clinic that fails to apply for a license is subject to the penalties established by sections 17 and 18 of this rule.

~~4.1.p.~~ 4.1.16. A pain management clinic shall surrender an expired, revoked, or otherwise invalid license to the secretary upon written demand.

4.2. Initial license.

~~4.2.a.~~ 4.2.1. An applicant shall submit a completed application to the secretary, on a form prescribed by the secretary. A non-refundable fee required by section 4 of this rule shall be submitted with the application. Any person, partnership, association, corporation, or facility that qualifies as a pain management clinic under this rule, shall apply for a pain management clinic license within 90 days of the effective date of this rule.

~~4.2.a.1.~~ 4.2.1.a. A new clinic shall apply for an initial license within the first 30 days of operation.

~~4.2.a.2.~~ 4.2.1.b. An existing practice shall apply for an initial license not less than 30 days and not more than 60 days once the ~~chronic~~ pain management patient census is more than 50 percent, pursuant to the definition in this rule.

~~4.2.b.~~ 4.2.2. The application shall include:

~~4.2.b.1.~~ 4.2.2.a. The legal name, office location, mailing address, and telephone number of the pain management clinic;

~~4.2.b.2.~~ 4.2.2.b. The name, address, principal occupation, and official position for each owner. At least one owner shall be a physician with an active license in West Virginia;

~~4.2.b.3.~~ 4.2.2.c. The name and address of all other pain management clinics owned and operated by the applicant;

~~4.2.b.4.~~ 4.2.2.d. A description of the organizational structure of the pain management clinic, including the owners, designated physician owner, and administrator;

~~4.2.b.5.~~ 4.2.2.e. If applicable, a copy of a valid Certificate of Need or a letter of exemption from the West Virginia Health Care Authority;

~~4.2.b.6.~~ 4.2.2.f. A list of the owners' and physicians' names, medical licenses, drug enforcement agency numbers, and any pain management specialty certifications;

~~4.2.b.7.~~ 4.2.2.g. A list of all business licenses issued by this state, the secretary of state, the state tax department, and all other applicable business or license entities;

~~4.2.b.8.~~ 4.2.2.h. Days and times of operation;

~~4.2.b.9.~~ 4.2.2.i. A verified statement that no owner or operator applying for the license has been the owner or operator of a licensed pain management clinic that has had its license suspended or revoked in the five years preceding the date of application;

~~4.2.b.10.~~ 4.2.2.j. ~~Verification that a criminal records background check for each anticipated owner, physician, employee, volunteer, associate or contracted agent has been completed~~ Evidence that each anticipated owner, physician, employee, volunteer, associate, or contracted agent has received an eligibility fitness determination or variance from the West Virginia Clearance for Access: Registry and Employment Screening unit of the Department of Health and Human Resources; and

~~4.2.b.11.~~ 4.2.2.k. A description of services provided.

~~4.2.c.~~ 4.2.3. The secretary shall issue an initial license only after an inspection is completed at the pain management clinic which finds the clinic complies with this rule and W. Va. Code §§16-5H-1, *et seq.*

~~4.2.d.~~ 4.2.4. If, at the initial licensing survey, a pain management clinic has more than five violations of any minimum requirements or if any cited violation is determined to be of such a serious nature that it may cause or have the potential to cause harm, the secretary shall deny licensing.

~~4.2.e.~~ 4.2.5. If an application for license is denied, the clinic, upon correction of all citations, may reapply for an initial license by submitting a new application together with the applicable fee.

4.3. Renewal license.

~~4.3.a.~~ 4.3.1. An applicant shall submit a completed application to the secretary, on a form prescribed by the secretary, 60 days prior to the expiration date of the current license. A non-refundable fee required by section 4 of this rule shall be submitted with the application.

~~4.3.b.~~ 4.3.2. The secretary shall issue a renewal license when it is found the pain management clinic is determined to be in compliance with this rule and W. Va. Code §§16-5H-1, *et seq.*, and the licensee submits a completed application and the correct renewal fee.

4.4. License fees and Inspection costs.

~~4.4.a.~~ 4.4.1. All applications for an initial or renewal pain management clinic license shall be accompanied by a non-refundable license fee. The annual renewal fee is based upon the total census of the clinic. In addition to the set fee, the annual renewal fee shall be adjusted on the first day of June of each year to correspond with increases in the consumer price index. The base amounts for initial and renewal fees are as follows:

~~4.4.a.1.~~ 4.4.1.a. Initial license fee - $250;

~~4.4.a.2.~~ 4.4.1.b. Renewal fee – fewer than 500 patients - $262.46 plus adjustment;

~~4.4.a.3.~~ 4.4.1.c. Renewal fee – 500 to 1,000 patients - $524.93 plus adjustment; and

~~4.4.a.4.~~ 4.4.1.d. Renewal fee – more than 1,000 patients - $787.39 plus adjustment.

~~4.4.b.~~ 4.4.2. A pain management clinic shall pay a $400 fee plus the actual costs of the initial inspections made by the secretary prior to issuing a license. The cost shall be billed to the pain management clinic or owner(s) by the secretary after the inspections and must be paid in full before a license is issued.

4.5. Denial of License.

~~4.5.a.~~ 4.5.1. The secretary may deny an application for an initial or renewal license if:

~~4.5.a.1.~~ 4.5.1.a. The secretary determines that the application is deficient in any respect;

~~4.5.a.2.~~ 4.5.1.b. The pain management clinic will not be or is not operated in accordance with applicable federal or state standards, laws, and rules;

~~4.5.a.3.~~ 4.5.1.c. The pain management clinic will not permit an inspection or survey to proceed or will not permit in a timely manner access to records or information deemed relevant by the secretary;

~~4.5.a.4.~~ 4.5.1.d. The pain management clinic has made misrepresentations in obtaining licensure;

~~4.5.a.5.~~ 4.5.1.e. The pain management clinic has an owner, employee or associate who has ~~previously been convicted of, or pleaded guilty to, any felony in this state or another state or territory of the United States~~ received an ineligible employment fitness determination from the West Virginia

Clearance for Access: Registry and Employment Screening unit of the Department of Health and Human Resources and has not received a variance.

~~4.5.a.6.~~ 4.5.1.f. The pain management clinic fails to have a designated physician owner practicing at the clinic location; or

~~4.5.a.7.~~ 4.5.1.g. The pain management clinic fails to have an established process for maintaining current, accessible patient records from admission through discharge.

~~4.5.b.~~ 4.5.2. If the secretary determines not to issue a license, the secretary shall notify the applicant in writing of the denial and the basis for the decision. Following the denial, the clinic must follow closure procedures in section 17 of this rule, including notification of existing patients.

§ 69-8-5. Inspections.

5.1. The secretary or his or her designee shall conduct unannounced inspections of all pain management clinics that are subject to the provisions of this rule and W. Va. Code §§16-5H-1, *et seq.*, in order to determine compliance. Inspections shall include initial inspections, annual inspections, follow-up inspections, complaint investigations, and periodic inspections.

5.2. During the inspections, the pain management clinic must provide the secretary a comprehensive listing of total patients. At a minimum this shall include:

~~5.2.a.~~ 5.2.1. The identifiers of those receiving chronic pain treatment and other services;

~~5.2.b.~~ 5.2.2. The diagnosis for each patient;

~~5.2.c.~~ 5.2.3. The demographic information for each patient, including city and county of residence; and

~~5.2.d.~~ 5.2.4. A list of medications administered, dispensed, or prescribed including the date of the prescription, dispensing, or administration for each patient of the pain management clinic.

5.3. Inspections may include interviews with owners, staff, and patients; review of clinical records; observation of service delivery; review of facility documents and polices; and review of any other documents necessary for the determination of compliance with this rule and W. Va. Code §§16-5H-1, *et seq.*

5.4. The pain management clinic shall ensure immediate access to all patient records upon request of the secretary or his or her designee. If access is denied, a judge of any court of record in this state having criminal jurisdiction, and upon proper oath or affirmation showing probable cause, may issue administrative or inspection warrants for the purpose of conducting inspections and seizures of property appropriate to the inspections.

5.5. Within 20 working days of the exit date of an annual inspection, or 30 working days of the exit date of an initial inspection, the secretary shall issue a report to the pain management clinic reflecting the findings of the inspection. The report shall specify any deficiency found and the rule that forms the basis for the violation.

5.6. The designated physician owner or other owners of the pain management clinic shall submit to the secretary a plan of correction for any violation of this rule or W. Va. Code §§16-5H-1, *et seq.*, identified during an inspection within 10 working days of receipt of the findings of the inspection. The plan of correction shall include any actions taken to correct the deficiency and prevent the reoccurrence and the date of completion of each action taken.

5.7. The pain management clinic's plan of correction may be approved or rejected by the secretary in writing. If rejected, the reasons shall be stated in a letter.

5.8. The pain management clinic shall submit a revised plan of correction to the secretary within 10 working days of receipt of a rejection letter.

5.9. The pain management clinic shall immediately correct any violation that the secretary finds constitutes a severe risk to the health or safety of a patient.

5.10. Any person may file a complaint with the secretary alleging violations of this rule and W. Va. Code §§16-5H-1, *et seq.* If a complaint investigation is completed, the secretary shall notify the complainant of any violations discovered upon written request made by the complainant.

5.11. The secretary shall keep on file a report of any inspection of a pain management clinic.

~~5.12. The secretary shall make the statement of deficiencies and plan of correction available to the public upon written request and at ohflac.wv.gov. A reasonable fee may be charged to cover the cost of research and copying.~~

~~5.13.~~5.12. Nothing contained in this section shall be construed to require or permit the public disclosure of confidential medical, social, personal or financial records of any patient or clinic, nor any information required to be kept confidential by state or federal law.

§69-8-6. Organization and Management.

6.1. All owners, employees, volunteers or associates of the clinic shall ~~undergo a criminal records background check and a fingerprinting process prior to operation of the clinic and prior to being hired and engaging in any work, paid or otherwise. The clinic shall complete a criminal records background check and fingerprinting process for any new or subsequent owner, physician, employee, volunteer or associate of the clinic and submit the results to the secretary for review and approval~~ be subject to the provisions of the West Virginia Clearance for Access: Registry and Employment Screening Act, W. Va. Code §§16-49-1, *et seq.*, and W. Va. Code R. §§69-10-1, *et seq*.

~~6.2. No person may own, be employed by or associated with a pain management clinic if that person has previously been convicted of or pleaded guilty to any felony in this state or another state or territory of the United States.~~

~~6.3.~~6.2. The clinic may not be owned by, nor may it employ or associate with, any physician or prescriber:

~~6.3.a.~~6.2.1. Whose Drug Enforcement Administration number has ever been revoked;

~~6.3.b.~~6.2.2. Whose application for a license to prescribe, dispense or administer a controlled substance has been denied, restricted or denotes any disciplinary action by any jurisdiction; or

~~6.3.c.~~6.2.3. Who, in any jurisdiction of this state or any other state or territory of the United States, has ~~been convicted of or plead guilty or nolo contendere to an offense that constitutes a felony for receipt of illicit and diverted drugs, including controlled substances, as defined by W. Va. Code § 60A-1-101~~ received an ineligible employment fitness determination from the West Virginia Clearance for Access: Registry and Employment Screening unit of the Department of Health and Human Resources and has not received a variance.

~~6.4.~~6.3. Owner.

~~6.4.a.~~6.3.1. The owner of a pain management clinic is any person, partnership, association, or corporation named in the application for licensure of a pain management clinic. A pain management clinic may have more than one owner.

~~6.4.b.~~6.3.2. At least one owner of the pain management clinic shall be a physician actively licensed to practice medicine and surgery or osteopathic medicine and surgery in this state.

~~6.4.c.~~6.3.3. Each owner is responsible for the general establishment and licensure of the pain management clinic and is subject to all applicable federal and state laws, rules, and regulations.

~~6.4.d.~~6.3.4. The owner~~(s)~~ or owners and administrator shall meet at least annually to review the pain management clinic's total operation and document the meeting by signed meeting minutes. The review shall include, at a minimum, policy review; review of utilization and quality of patient care, quality assessment, and performance improvement reports and actions; review of assets and funds; and any other reviews necessary to determine adequate care, treatment, health, safety, and welfare of patients.

~~6.5.~~6.4. Designated physician owner.

~~6.5.a.~~6.4.1. Each pain management clinic shall have a designated physician owner who shall practice at the clinic and who will be responsible for the operation of the clinic pursuant to the federal, state, and local laws and ~~per~~ the requirements in this rule.

~~6.5.b.~~6.4.2. The designated physician owner shall:

~~6.5.b.1.~~6.4.2.a. Have a full, active, and unencumbered license to practice medicine and surgery or osteopathic medicine and surgery in this state;

~~6.5.b.2.~~6.4.2.b. Meet one of the following training requirements:

~~6.5.b.2.A.~~6.4.2.b.1. Complete a pain medicine fellowship that is accredited by the Accreditation Council for Graduate Medical Education (ACGME) or such other similar program as may be approved by the secretary in consultation with the appropriate licensing board; or

~~6.5.b.2.B.~~6.4.2.b.2. Hold current board certification by the American Board of Pain Medicine (ABPM), ~~or~~ the American Board of Interventional Pain Physicians, or the American Board of Anesthesiology (ABA); hold current subspecialty certification in pain management by the American Board of Medical Specialties; hold a current certificate of added qualification in pain management by the

American Osteopathic Association Bureau of Osteopathic Specialists; hold Competency Certification in Controlled Substances Management; or hold current board certification from such other program as may be approved by the secretary;

~~6.5.b.3.~~6.4.2.c. Practice a minimum of 32 hours per week at the licensed pain management clinic for which the physician has assumed responsibility;

~~6.5.b.4.~~6.4.2.d. Supervise, control, and direct the activities of each individual working or operating at the facility, including any employee, volunteer, or individual under contract who provides treatment of chronic pain at the clinic or is associated with the provision of that treatment;

~~6.5.b.5.~~6.4.2.e. Develop operation and clinical policies and procedures;

~~6.5.b.6.~~6.4.2.f. Supervise all medical services offered by the pain management clinic;

~~6.5.b.7.~~6.4.2.g. Ensure the pain management clinic is in compliance with all applicable federal, state, and local laws, rules, and regulations;

~~6.5.b.8.~~6.4.2.h. Approve the basic and continuing educational programs of all physicians and clinic staff employed by or volunteering at the pain management clinic;

~~6.5.b.9.~~6.4.2.i. Periodically conduct appraisals of the medical staff as defined by clinic policy;

~~6.5.b.10.~~6.4.2.j. Periodically examine credentials of candidates for medical staff membership;

~~6.5.b.11.~~6.4.2.k. Supervise all clinical quality assessment and performance improvement activities;

~~6.5.b.12.~~6.4.2.l. Be responsible for complying with all requirements related to the licensing and operation of the clinic; and

~~6.5.b.13.~~6.4.2.m. Hold a 25 percent ownership interest in the clinic. The designated physician owner shall not be a contracted individual.

~~6.5.c.~~6.4.3. Within 10 days after the withdrawal or termination of a designated physician owner, the remaining owners of the clinic shall notify the secretary of the identity of another designated physician for that clinic. During the interim, not to exceed 60 days, another licensed physician shall be present during all hours of operation and shall assume the duties of the designated physician owner on a temporary basis until such time as a new designated physician owner is identified and begins work at the clinic. The interim physician may be another owner of the clinic or a physician employed by or associated with the clinic.

~~6.6.~~6.5. Administrator.

~~6.6.a.~~6.5.1. The administrator is responsible for the day-to-day non-clinical business operation of the pain management clinic.

~~6.6.b.~~6.5.2. The administrator shall be qualified by education and training as specified in a job description developed by the owners.

~~6.6.c.~~6.5.3. Duties of the administrator include:

~~6.6.c.1.~~6.5.3.a. Maintenance and security of the clinic;

~~6.6.c.2.~~6.5.3.b. Employment, credentialing, evaluation, scheduling, training, and management of staff;

~~6.6.c.3.~~6.5.3.c. Responsibility for the compliance process;

~~6.6.c.4.~~6.5.3.d. Protection of patient rights as outlined in section 9 of this rule;

~~6.6.c.5.~~6.5.3.e. Conformity of the clinic's program with state and federal confidentiality requirements;

~~6.6.c.6.~~6.5.3.f. Security of medication storage and safe handling of medications; and

~~6.6.c.7.~~6.5.3.g. Management of the clinic budget.

§69-8-7. Clinic and Facility Environment and Operation.

7.1. Each pain management clinic facility shall have:

~~7.1.a.~~ 7.1.1. Sufficient space and adequate equipment for the provision of all services specified in the pain management clinic's description of treatment services;

~~7.1.b.~~ 7.1.2. Clean, safe, and well-maintained patient and staff areas;

~~7.1.c.~~ 7.1.3. A secure room with lockable equipment for all information contained in patient records;

~~7.1.d.~~ 7.1.4. Policies and procedures regarding the confidentiality of all information in patient records which specify the requirements for access to the secure room and to electronic records, including levels of access;

~~7.1.e.~~ 7.1.5. A double-locked area to prevent access to controlled substances by any unauthorized personnel;

~~7.1.f.~~ 7.1.6. Sanitary and secure dosing areas;

~~7.1.g.~~ 7.1.7. Sufficient restrooms for the estimated patient population with separate restrooms for observation of specimen production, if necessary;

~~7.1.h.~~ 7.1.8. Adequate parking areas for the expected flow of traffic; and

~~7.1.i.~~ 7.1.9. Procedures to ensure that the premises are kept free from rodent and insect infestation.

~~7.1.j.~~ 7.2. All pain management clinic facilities must meet all requirements of applicable federal, state, and local regulatory or oversight agencies, including the State Fire Commission.

§69-8-8. Clinic Staff; Training and Credentialing of Staff.

8.1. All employees, volunteers, contracted individuals, and associates of a pain management clinic are subject to the restrictions, prohibitions, and requirements established in this rule.

8.2. Professional Medical Staff.

~~8.2.a.~~ 8.2.1. The pain management clinic may employ, contract with, and use physicians and other licensed health care professionals working within their scope of practice who have received sufficient training and experience in accordance with clinic policies and procedures developed by the designated physician owner.

~~8.2.b.~~ 8.2.2. All physicians and licensed health care professionals employed or contracted by the pain management clinic shall be actively licensed in West Virginia and shall have:

~~8.2.b.1.~~ 8.2.2.a. A minimum of one year of experience in chronic pain management; or

~~8.2.b.2.~~ 8.2.2.b. Active enrollment in a training program for obtaining competence in chronic pain management that is approved by the designated physician owner. The designated physician owner shall certify the individual's satisfactory completion of the training.

~~8.2.c.~~ 8.2.3. During all hours of operation when the designated physician owner of the pain management clinic is not present, a physician, physician assistant, or advanced practice registered nurse with an active license in this state shall be on site.

~~8.2.d.~~ 8.2.4. The clinic must ensure that there is trained staff on duty at all times who are proficient in cardiopulmonary resuscitation and management of medication overdose.

~~8.2.e.~~ 8.2.5. A person may not dispense any medication, including a controlled substance, on the premises of a licensed pain management clinic unless he or she is a physician or pharmacist licensed in this state.

8.3. Unlicensed Clinic Staff and Volunteers.

~~8.3.a.~~ 8.3.1. A pain management clinic may employ or utilize unlicensed staff, contracted individuals, and volunteers to assist in the operation of the clinic.

~~8.3.b.~~ 8.3.2. The clinic shall develop policies and procedures that specify the job descriptions and responsibilities of unlicensed employees, contracted individuals, and volunteers. Documentation of the responsibilities, training, and other obligations of unlicensed employees, contracted individuals, or volunteers shall be included in the personnel file of the employees or volunteers.

~~8.3.c.~~ 8.3.3. All unlicensed staff, contracted individuals, and volunteers shall receive appropriate supervision by a physician, physician assistant, advanced practice registered nurse, registered nurse, or licensed practical nurse and shall be provided with assistance and directions as to their responsibilities.

8.4. Staff training and credentialing.

~~8.4.a.~~ 8.4.1. The pain management clinic shall ensure that all physician assistants, advanced practice registered nurses, contracted individuals, and all other licensed or certified professional care providers comply with the credentialing requirements of their respective professions, obtain and maintain current licenses, and complete all continuing education requirements of their respective licensing boards and this rule.

~~8.4.b.~~ 8.4.2. All clinic staff members, contracted individuals, and volunteers shall complete initial and continuing education and training that is specific to their job function and is consistent with the requirements of applicable federal and state laws, rules, regulations and guidelines. Documentation of all completed education and training courses or programs shall be maintained in the personnel file of each staff member or volunteer.

~~8.4.c.~~ 8.4.3. The pain management clinic shall develop detailed job descriptions for each staff member, including contracted individuals, that clearly define the education, training, qualifications, and competencies needed to provide specific service: *Provided*, That additional job duties for a physician assistant beyond those delineated in ~~11CSR1B-13.2~~ W. Va. Code R. §11-1B-13.2. are submitted for the consideration and approval of the Board of Medicine.

~~8.4.d.~~ 8.4.4. Upon hire of any new clinical staff member or contracted individual, the pain management clinic shall provide orientation as to the person's primary job responsibilities, including, but not limited to, confidentiality requirements, on the first day of employment. Documentation of the completed orientation shall be included in the personnel file of each staff member.

~~8.4.e.~~ 8.4.5. The pain management clinic shall maintain confidential individual personnel files for every staff member, including contracted individuals. Personnel files shall contain, at a minimum:

~~8.4.e.1.~~ 8.4.5.a. The application for employment, contract, or request to work as a volunteer;

~~8.4.e.2.~~ 8.4.5.b. Documentation of the date of employment;

~~8.4.e.3.~~ 8.4.5.c. Identifying information and emergency contacts;

~~8.4.e.4.~~ 8.4.5.d. Documentation of completion of orientation, trainings, and continuing education;

~~8.4.e.5.~~ 8.4.5.e. Documentation of all licenses, certifications, or other credentials;

~~8.4.e.6.~~ 8.4.5.f. Documentation relating to performance, supervision, disciplinary actions, and termination summaries;

~~8.4.e.7.~~ 8.4.5.g. Detailed job descriptions; and

~~8.4.e.8.~~ 8.4.5.h. Evidence that the ~~pain management clinic has determined that the employee, independent contractor or volunteer has never been convicted of a felony~~ employee, independent contractor, or volunteer has received an eligibility fitness determination or variance from

the West Virginia Clearance for Access: Registry and Employment Screening unit of the Department of Health and Human Resources.

§69-8-9. Patient Rights.

9.1. Each pain management clinic shall have policies and procedures that guarantee the following rights to patients:

~~9.1.a.~~ 9.1.1. The right to be informed, both verbally and in writing, of clinic fees, rules, and regulations and patient's rights and responsibilities in advance of the clinic providing care. The rights and responsibilities shall be posted prominently and reviewed with the patient at the initial visit and at any time changes in the rights and responsibilities occur. The rights shall be explained to the patient in a manner in which the patient can understand, including the use of interpreters and personnel experienced in communication with vision and hearing impaired individuals;

~~9.1.b.~~ 9.1.2. The right to receive treatment provided in a fair and impartial manner regardless of race, sex, age, sexual orientation, ~~and/~~or religion;

~~9.1.c.~~ 9.1.3. The right to participate in the development and implementation of his or her plan of care and to make decisions regarding that care. The written plan of care shall be reviewed with the patient at least every 90 days by the patient's physician and shall be maintained in the patient's chart;

~~9.1.d.~~ 9.1.4. The right to be informed that prior to dispensing or prescribing a controlled substance, the treating physician must access the Controlled Substances Monitoring Program database maintained by the West Virginia Board of Pharmacy to ensure that the patient is not seeking controlled substances from multiple sources. The treating physician shall also review the database at each patient examination, or at least every 90 days during the course of ongoing treatment;

~~9.1.e.~~ 9.1.5. The right to be informed that the patient may be required to submit to drug testing and that the collection of specimens may be observed, if deemed necessary;

~~9.1.f.~~ 9.1.6. The right to treatment at a pain management clinic that provides an adequate number of competent, qualified, and experienced professional staff to implement and supervise the written plan of care;

~~9.1.g.~~ 9.1.7. The right to be informed of the extent of confidentiality, including the conditions under which information can be released without consent, the use of identifying information for the purposes of clinical evaluations, billing, and statutory requirements for reporting abuse; and

~~9.1.h.~~ 9.1.8. The right to care in a safe setting.

9.2. The clinic shall establish a patient grievance process which shall be displayed in the patient care area. A grievance may be verbal or written. The grievance process shall include:

~~9.2.a.~~ 9.2.1. Who to contact to file a grievance;

~~9.2.b.~~ 9.2.2. Time frames for review of the grievance;

~~9.2.c.~~ 9.2.3. Provision of a response to the grievant that contains the name of the clinic contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion of the investigation;

~~9.2.d.~~ 9.2.4. The right of a patient to initiate grievance procedures without fear of reprisal; and

~~9.2.e.~~ 9.2.5. The address and telephone number of the Office of Health Facility Licensure and Certification.

9.3. The clinic shall have policies and procedures which address safety and security issues for patients and staff, including training staff to handle physical or verbal threats, acts of violence, and inappropriate behavior or other escalating and potentially dangerous situations, with emphasis on when security guards or police need to be summoned. In regard to security personnel, the use of guns, handcuffs, and mace is prohibited.

§69-8-10. Provision and Coordination of Patient Care.

10.1. Each pain management clinic shall develop and maintain current policies and procedures, patient protocols, treatment plans, and profiles for the treatment of patients seeking treatment for chronic pain.

10.2. Assessments.

~~10.2.a.~~ 10.2.1. All patients shall undergo an initial assessment in order to determine the patient's condition, diagnosis, and treatment. The assessment shall be conducted by one or more physicians who specialize in the treatment of the area, system, or organ of the body perceived as the source of the pain.

~~10.2.b.~~ 10.2.2. The initial assessment shall include documentation of:

~~10.2.b.1.~~ 10.2.2.a. A physical examination, by a qualified medical professional working within their scope of practice;

~~10.2.b.2.~~ 10.2.2.b. The patient's health history;

~~10.2.b.3.~~ 10.2.2.c. All current medications, prescription or otherwise;

~~10.2.b.4.~~ 10.2.2.d. The patient's use of alcohol, tobacco, or other substances;

~~10.2.b.5.~~ 10.2.2.e. Determination of current dependence on controlled substances;

~~10.2.b.6.~~ 10.2.2.f. An inquiry to and report from the Controlled Substances Monitoring Program;

~~10.2.b.7.~~ 10.2.2.g. Laboratory tests;

~~10.2.b.8.~~ 10.2.2.h. A full toxicology screen;

~~10.2.b.9.~~ 10.2.2.i. An inquiry whether the patient is being treated at any other pain management clinic;

~~10.2.b.10.~~ 10.2.2.j. The diagnosis of all conditions, including a diagnosis of chronic pain, if applicable, including signs, symptoms, and causes;

~~10.2.b.11.~~ 10.2.2.k. A copy of the report by the referring physician and any medical records from other providers; and

~~10.2.b.12.~~ 10.2.2.l. The dates, amounts, and dosage forms of any drugs prescribed, dispensed, and administered.

~~10.2.c.~~ 10.2.3. Subsequent patient assessments shall include documentation of:

~~10.2.c.1.~~ 10.2.3.a. Follow-up physical examinations, by a qualified medical professional working within their scope of practice;

~~10.2.c.2.~~ 10.2.3.b. The patient's response to treatment;

~~10.2.c.3.~~ 10.2.3.c. Any modification to the plan of treatment;

~~10.2.c.4.~~ 10.2.3.d. The dates on which any medications were prescribed, dispensed, or administered;

~~10.2.c.5.~~ 10.2.3.e. The amounts and dosage forms for any drugs prescribed, dispensed, or administered;

~~10.2.c.6.~~ 10.2.3.f. Laboratory tests, according to the pain management clinic's policy, but at least every 60 days; and

~~10.2.c.7.~~ 10.2.3.g. Full toxicology screen, according to the pain management clinic's policy, but at least every 90 days.

~~10.2.d.~~ 10.2.4. A physician, physician assistant, certified registered nurse anesthetist, or advance practice registered nurse shall perform a physical examination of a patient on the same day that the physician initially prescribes, dispenses, or administers a controlled substance to a patient. If the patient continues to be treated for chronic pain at the clinic, a physical examination shall be performed at least four times, or every 90 days, per year thereafter. All examinations shall be performed according to accepted and prevailing standards for medical care.

10.3. Plan of care.

~~10.3.a.~~ 10.3.1. The treating physician and other health care professionals, working within their scope of practice, directly involved in the care of the patient shall develop a written individualized plan of care for every patient.

~~10.3.b.~~ 10.3.2. The plan of care shall include, at a minimum:

~~10.3.b.1.~~ 10.3.2.a. Information required for the initial assessment;

~~10.3.b.2.~~ 10.3.2.b. Documentation of the patient's diagnoses, the proposed medical treatment, medication dosages, and administration;

~~10.3.b.3.~~ 10.3.2.c. Documentation of the patient's current physical condition and whether the patient requires other health care;

~~10.3.b.4.~~ 10.3.2.d. Laboratory test results;

~~10.3.b.5.~~ 10.3.2.e. Follow-up on any identified medical, physical, or behavioral health issues;

~~10.3.b.6.~~ 10.3.2.f. Documentation of any education regarding the management of chronic pain, suggested pain management programs or counseling sessions and resolution of other issues unique to the needs of the patient;

~~10.3.b.7.~~ 10.3.2.g. Such other information as recommended by the guidelines and treatment model utilized for the patient;

~~10.3.b.8.~~ 10.3.2.h. Specific goals and outcomes to improve or maintain the optimal health of the patient which are based on the assessment of the patient; and

~~10.3.b.9.~~ 10.3.2.i. A description of services and their frequency to be provided for the patient and primarily directed to achieve the expected goals and outcomes.

~~10.3.c.~~ 10.3.3. Delivery of patient care and treatment interventions shall be based on the needs identified in the plan of care.

~~10.3.d.~~ 10.3.4. The plan of care shall be reviewed by the patient and health care professionals directly involved in the care of the patient at least every 90 days and documented in the patient record. Reviews shall address each of the objectives identified on the initial plan of care; document all treatment, medications, and other services rendered to the patient; and document the patient's progress. A revised plan of care may be implemented with each review. Paper and electronic plans of care, including all reviews and updates, must be acknowledged by the patient.

~~10.3.e.~~ 10.3.5. When a physician diagnoses an individual with chronic pain, the physician may treat the pain by managing it with medications in amounts or combinations that may not be appropriate when treating other medical conditions.

10.4. Medication Security and Administration.

~~10.4.a.~~ 10.4.1. A person may not dispense any medication, including a controlled substance, on the premises of a licensed pain management clinic unless he or she is a physician or pharmacist licensed in this state. A pain management clinic physician or pharmacist shall not dispense to any patient more than a 72 hour supply of any controlled substance.

~~10.4.b.~~ 10.4.2. The pain management clinic shall comply with policies and procedures developed by the West Virginia Board of Pharmacy that permit physicians access to the Controlled Substances Monitoring Program database maintained by the West Virginia Board of Pharmacy. The treating physician shall access the Controlled Substances Monitoring Program database in order to ensure that the patient

is not seeking prescription medication from multiple sources. The results obtained from the database shall be maintained with the patient records. Treating physicians shall access the database:

~~10.4.b.1.~~ 10.4.2.a. At the patient's intake;

~~10.4.b.2.~~ 10.4.2.b. Before administering, dispensing, or prescribing any controlled substance;

~~10.4.b.3.~~ 10.4.2.c. At each 90-day examination;

~~10.4.b.4.~~ 10.4.2.d. After any positive drug test; and

~~10.4.b.5.~~ 10.4.2.e. Whenever the treating physician, in his or her discretion, believes a review of the database is warranted.

~~10.4.c.~~ 10.4.3. The pain management clinic shall have policies and procedures that comply with all relevant federal and state laws, rules, and regulations regarding the storage, management, administration, and dispensing of medications kept at the facility. In addition, the policies and procedures shall include measures that:

~~10.4.c.1.~~ 10.4.3.a. Ensure responsible handling and appropriately locked storage of all medications kept, received, stored, administered, or dispensed at the facility;

~~10.4.c.2.~~ 10.4.3.b. Ensure accurate documentation of all medications kept, received, stored, administered, and dispensed at the facility; ~~and~~

~~10.4.c.3.~~ 10.4.3.c. Ensure that only authorized personnel may access the storage areas where any medications are kept; and

~~10.4.c.4.~~ 10.4.3.d. Ensure any outdated drugs and drug containers with worn, illegible, or missing labels are removed from the pain management clinic in accordance with the requirements for safe medication disposal from the Board of Pharmacy, as well as the pain management clinic policy.

~~10.4.d.~~ 10.4.4. The pain management clinic shall maintain current policies and procedures which ensure that all medications are administered or dispensed in accordance with approved product labeling. The procedures must ensure that any significant deviations from the approved labeling, including deviations with regard to dose frequency, or the conditions of use described in the approved labeling, are specifically documented in the patient's record.

~~10.4.e.~~ 10.4.5. Each pain management clinic shall calibrate medication dispensing instruments consistent with the manufacturer's recommendations to ensure accurate patient dosing and substance tracking.

~~10.4.f.~~ 10.4.6. Each pain management clinic is responsible for proper documentation of medications kept, received, stored, administered, or dispensed. Documentation of medication administered or dispensed requires, at a minimum, the following:

~~10.4.f.1.~~ 10.4.6.a. The signature or initials of the qualified person administering or dispensing medication;

~~10.4.f.2.~~ 10.4.6.b. The date and time of dispensing;

~~10.4.f.3.~~ 10.4.6.c. The exact number of milligrams of the substance administered or dispensed;

~~10.4.f.4.~~ 10.4.6.d. The daily totals of the substance administered or dispensed;

~~10.4.f.5.~~ 10.4.6.e. Each dosage administered, ~~or~~ dispensed, prepared, or received shall be recorded and accounted for by written, signed notation in a manner that creates a perpetual and accurate inventory of all medications in stock at all times;

~~10.4.f.6.~~ 10.4.6.f. Each medication order and dosage change shall be written on an acceptable order sheet and signed and dated by only the treating physician. If the initials are used, the full signature of the qualified person administering or dispensing shall appear at the end of each page of the medication sheet; and

~~10.4.f.7.~~ 10.4.6.g. At the time any medication is administered or dispensed, each dose shall be recorded on an administration sheet; in the medication dose history included in the patient's plan of care and patient chart; and in the inventory control program used by the facility to monitor and ensure an accurate inventory of all medication on the premises.

~~10.4.g.~~ 10.4.7. The pain management clinic shall establish policies and procedures for monitoring medications to prevent diversion. The policies and procedures may include random call backs of individuals who are prescribed controlled substances on an ongoing basis, required clinic appointments, random toxicology screens, and random medication counts.

~~10.4.h.~~ 10.4.8. Every pain management clinic physician authorized to prescribe controlled substances is responsible for maintaining the control and security of his or her prescription blanks and any other method used for prescribing controlled substance pain medication.

~~10.4.h.1.~~ 10.4.8.a. Each physician shall comply with all state and federal requirements for tamper-resistant prescription paper.

~~10.4.h.2.~~ 10.4.8.b. In addition to any other requirements imposed by statute or rule, each physician shall notify the secretary in writing within 24 hours following any theft or loss of a prescription blank or a breach of any other method for prescribing pain medication.

~~10.4.i.~~ 10.4.9. The pain management clinic shall establish policies and procedures regarding safe keeping, monitoring, destruction, and accounting for any medications the patient brings into the clinic.

~~10.4.j.~~ 10.4.10. Every pain management clinic must develop procedures for the destruction of medications in accordance with the Board of Pharmacy requirements and to include at least two employees, one of which must be a licensed medical professional.

§69-8-11. Records.

11.1. The pain management clinic shall maintain patient records and business records according to clinic policy. Clinic policy shall be in compliance with state and federal law, including but not limited to the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

11.2. The pain management clinic shall establish policies and procedures specifying who may use the records, under what conditions the records may be removed from the clinic and under what conditions the information from the records may be released.

11.3. The pain management clinic shall establish procedures to ensure security of all records, including electronic records.

11.4. The pain management clinic shall establish and maintain a recordkeeping system that is adequate to document and monitor patient care. The system shall comply with all federal and state reporting requirements relevant to prescription drugs approved for use in treatment of chronic pain management.

11.5. Patient records shall contain sufficient information to identify the patient, support the diagnosis, justify the treatment and document the course and results of treatment accurately.

11.6. Patient records shall be current and easily accessible from admission through discharge.

11.7. Patient records shall include, at a minimum:

~~11.7.a.~~ 11.7.1. Patient identification and demographic data;

~~11.7.b.~~ 11.7.2. Properly executed informed consent forms for procedures and treatments;

~~11.7.c.~~ 11.7.3. Copy of signed patient rights;

~~11.7.d.~~ 11.7.4. A complete patient history and physical examination, including any history of drug abuse or dependence;

~~11.7.e.~~ 11.7.5. Patient assessments and plans of care;

~~11.7.f.~~ 11.7.6. Progress notes and practitioners orders;

~~11.7.g.~~ 11.7.7. Diagnostic, therapeutic, and laboratory results, including drug testing results;

~~11.7.h.~~ 11.7.8. Reports of evaluations, consultations, and hospitalizations;

~~11.7.i.~~ 11.7.9. Treatment objectives, including discussion of risks and benefits;

~~11.7.j.~~ 11.7.10. Records of drugs prescribed, dispensed, or administered, including the date, type, and dosage;

~~11.7.k.~~ 11.7.11. Treatments;

~~11.7.l.~~ 11.7.12. Receipt and assessment of drug database or prescription monitoring program reports;

~~11.7.m.~~ 11.7.13. Copies of records, reports, or other documentation obtained from other health care practitioners at the request of the physician used for determining appropriate treatment of the patient. Records provided by the patient shall be designated as such; and

~~11.7.n.~~ 11.7.14. A record of all cash transactions.

11.8. All patient records shall be maintained for a minimum of five years from the time that the last documented treatment is provided. In the event a patient is a juvenile, the records shall be kept for a minimum of five ~~(5)~~ years from the time the patient reaches the age of 18 years.

11.9. All patient records shall be kept confidential in accordance with all applicable federal and state requirements.

11.10. Each entry in the medical record shall be completed within 24 hours of the patient contact and shall be dated and signed by the medical staff person involved.

11.11. Information in patient medical records shall be entered only by physicians and other licensed health professionals. Entries shall be legible and organized in an effective manner, allowing materials to be easily retrieved.

§69-8-12. Laboratory Services.

12.1. Each pain management clinic shall have the capability of obtaining medication blood levels and urine samples when clinically indicated. Collection and testing shall be done in a manner that assures a method of confirmation for positive results and documents the chain of custody of the collection.

12.2. All lab services provided to patients are performed in a facility certified in accordance with 42 CFR § 493 and the 1988 Clinical Laboratory Improvement Amendments (CLIA).

§69-8-13. Quality Assurance and Performance Improvement.

13.1. The designated physician owner, medical staff, and clinic administration are responsible for and shall review at least annually the development, implementation, maintenance, and effective evaluation of quality assessments for performance improvement. This process systematically collects, measures, analyzes, and tracks objective indicators of patient care and clinic operations. This evaluation plan should reflect the complexity of the pain management clinic's organization and services.

13.2. The pain management clinic shall maintain current quality assessment and performance improvement policies that objectively and systematically monitor and evaluate the quality and appropriateness of patient care, evaluate the methods to improve patient care, identify and correct deficiencies within the clinic, and provide for opportunities to improve the clinic's performance and quality of care.

13.3. The clinic shall make available to the secretary the results of peer review and quality assessment and performance improvement information upon request.

13.4. Quality assessment and performance improvement policies and areas of measurement shall include, but not be limited to:

~~13.4.a.~~ 13.4.1. Staff, administrative, and practitioner performance;

~~13.4.b.~~ 13.4.2. Grievance findings;

~~13.4.c.~~ 13.4.3. Evaluation of diagnostic and therapeutic services provided;

~~13.4.d.~~ 13.4.4. Medication errors, drug diversion, and other incidents or occurrences;

~~13.4.e.~~ 13.4.5. Drug therapy and adverse drug reactions;

~~13.4.f.~~ 13.4.6. Evaluation of all services provided to patients by staff accountable to the clinic through employment or contract;

~~13.4.g.~~ 13.4.7. Review and verification of staff credentials, training, periodic education, and licensure;

~~13.4.h.~~ 13.4.8. Review of clinic policies and procedures;

~~13.4.i.~~ 13.4.9. Review of patient satisfaction of services;

~~13.4.j.~~ 13.4.10. Infection control issues in regard to universal infection control guidelines as set forth by the Centers for Disease Control; and

~~13.4.k.~~ 13.4.11. Review of patient outcomes and treatment outcomes.

§69-8-14. Infection Control.

14.1. The pain management clinic shall maintain an effective infection control program that protects the patients, their families, and clinic personnel by preventing and controlling infections and communicable diseases.

14.2. The program shall include the implementation of a nationally recognized system of infection control guidelines.

14.3. The pain management clinic shall have an active surveillance and education program for the prevention, early detection, control, and investigation of infections and communicable diseases.

14.4. The pain management clinic shall designate a person or persons, with appropriate education and training, as infection control officers to develop and implement policies and governing control of infections and communicable diseases for patients and personnel.

§69-8-15. Incident Reporting and Adverse Events.

15.1. The pain management clinic shall develop policies and procedures for comprehensively documenting, investigating, taking corrective action, and tracking instances of adverse events or incidents.

15.2. Adverse events or incidents may include, but not be limited to:

~~15.2.a.~~ 15.2.1. Medication errors;

~~15.2.b.~~ 15.2.2. Patient suicide attempts;

~~15.2.c.~~ 15.2.3. Patients deaths;

~~15.2.d.~~ 15.2.4. Harm to family members or others from ingesting a patient's medication;

~~15.2.e.~~ 15.2.5. Selling drugs on the premises;

~~15.2.f.~~ 15.2.6. Medication diversion;

~~15.2.g.~~ 15.2.7. Harassment or abuse of patients by staff;

~~15.2.h.~~ 15.2.8. Threats and intimidation of staff by patients; and,

~~15.2.i.~~ 15.2.9. Violence.

15.3. Adverse events or incidents shall be reviewed on a quarterly basis by the designated physician owner and administrator, who shall make recommendations to the owners and quality assessment and performance improvement program regarding improvements in the process to prevent further incidents.

15.4. Upon the occurrence of an adverse event or incident, the clinic shall:

~~15.4.a.~~ 15.4.1. Fully document the event or incident and report the matter to the Office of Health Facility Licensure and Certification on the prescribed form and to any other applicable state agencies within 24 hours according to procedures established by the secretary;

~~15.4.b.~~ 15.4.2. Immediately investigate and review the situation surrounding the event or incident;

~~15.4.c.~~ 15.4.3. Take corrective action within 10 days, unless an extension is requested and granted;

~~15.4.d.~~ 15.4.4. Conduct ongoing monitoring of any corrective action that takes place until effectiveness of the action is established.

15.5. The designated physician owner or administrator of the pain management clinic shall report any death involving drug overdose or drug-related complications to the secretary within 48 hours of any person at the clinic receiving notification of the mortality.

~~**§69-8-16. Advertisement disclosure.**~~

~~Any advertisement made by or on behalf of a pain management clinic through public media, such as a telephone directory, medical directory, newspaper or other periodical, outdoor advertising, radio or television, or through written or recorded communication, concerning the treatment of chronic pain shall include the name of, at a minimum, one physician owner responsible for the content of the advertisement.~~

§69-8-~~17~~16. License Revocations, Suspensions, and Denials.

~~17.1.~~ 16.1. Grounds for Suspension, Revocation, or Denial.

~~17.1.a.~~ 16.1.1. The secretary may revoke, suspend, or deny a license issued pursuant to this rule if any provisions of federal or state law or this rule are violated. The secretary may revoke a license and prohibit all physicians associated with that pain management clinic from practicing at the clinic location based upon the findings and results of an annual or periodic inspection and evaluation. The period of suspension for the license of a pain management clinic shall be prescribed by the secretary, but may not exceed one year.

~~17.1.b.~~ 16.1.2. The secretary may revoke, or suspend, or deny a pain management clinic license for one of more of the following reasons:

~~17.1.b.1.~~ 16.1.2.a. The secretary makes a determination that fraud or other illegal action has been committed by any owner of the pain management clinic;

~~17.1.b.2.~~ 16.1.2.b. The pain management clinic has violated federal, state, or local law relating to licensure, building, health, fire protection, safety, sanitation, or zoning;

~~17.1.b.3.~~ 16.1.2.c. The pain management clinic engages in practices that jeopardize the health, safety, welfare, or clinical treatment of a patient;

~~17.1.b.4.~~ 16.1.2.d. The pain management clinic has failed or refused to submit reports or make records available as requested by the secretary;

~~17.1.b.5.~~ 16.1.2.e. A pain management clinic has refused to provide access to its location or records as requested by the secretary;

~~17.1.b.6.~~ 16.1.2.f. A pain management clinic's designated physician owner has knowingly and intentionally misrepresented actions taken to correct a violation;

~~17.1.b.7.~~ 16.1.2.g. An owner or designated physician owner of a pain management clinic concurrently operates an unlicensed pain management clinic;

~~17.1.b.8.~~ 16.1.2.h. A physician or any owner knowingly operates, owns, or manages an unlicensed pain management clinic that is required to be licensed;

~~17.1.b.9.~~ 16.1.2.i. The owners of a licensed pain management clinic fail to apply for a new license for the clinic upon a change of ownership and operate the clinic under the new ownership;

~~17.1.b.10.~~ 16.1.2.j. A physician or any owner acquires or attempts to acquire a license for a pain management clinic through misrepresentation or fraud or procures or attempts to procure a license for a pain management clinic for any other person by making or causing to be made any false representation; or

~~17.1.b.11.~~ 16.1.2.k. The pain management clinic fails to have a licensed designated physician owner practicing at the location as required by this rule.

~~17.2.~~ 16.2. Effect of Suspension, Revocation, or Denial.

~~17.2.a.~~ 16.2.1. If a license for a pain management clinic has been revoked, the secretary may stay the effective date of the revocation if the designated physician owner and administrator of the clinic can show that the stay is necessary to ensure appropriate referral and placement of patients.

~~17.2.b.~~ 16.2.2. If the license of a pain management clinic is revoked, suspended, or denied no person, firm, association, or corporation may operate the facility as a pain management clinic as of the effective date of the suspension, revocation, or denial. The owners of the pain management clinic are responsible for removing all signs and symbols identifying the premises as a pain management clinic within 30 days from the date of the revocation, suspension, or denial.

~~17.2.c.~~ 16.2.3. If a license for a pain management clinic has been revoked, suspended, or denied the clinic must supply, at a minimum, a copy of the following information to the secretary:

~~17.2.c.1.~~ 16.2.3.a. A closure notice to be mailed to all active patients meeting the guidelines set forth by their respective board;

~~17.2.c.2.~~ 16.2.3.b. The date the closure letter will be mailed to all active patients;

~~17.2.c.3.~~ 16.2.3.c. The number of active patients to receive the closure notice;

~~17.2.c.4.~~ 16.2.3.d. A Class II legal advertisement that complies with the requirements of ~~Article 3, Chapter 59 of the West Virginia Code~~ W. Va. Code §§59-3-1, *et seq.*, regarding the clinic closure, including the dates the notice will appear and the name of the newspaper; and

~~17.2.c.5.~~ 16.2.3.e. Contact information the clinic has supplied to patients who may need help locating a new treating physician or clinic.

~~17.2.d.~~ 16.2.4. Upon the effective date of the suspension, revocation, or denial the designated physician owner of the pain management clinic shall advise the secretary and the Board of Pharmacy of the disposition of all drugs located on the premises. The disposition is subject to the supervision and approval of the secretary and the Drug Enforcement Agency. Drugs that are purchased or held by a pain management clinic that is not licensed may be deemed adulterated.

~~17.2.e.~~ 16.2.5. If the license of a pain management clinic license is revoked or denied, a new application for a license shall be considered by the secretary if, when and after the conditions upon which revocation or denial was based have been corrected and evidence of this fact has been furnished. A new license may then be granted after proper inspection has been made and the secretary makes a written finding that all provisions of this article and rules promulgated pursuant to this article have been satisfied.

§69-8-~~18~~17. Penalties and Equitable Relief.

~~18.1.~~ 17.1. Grounds for Penalties and Injunctions.

~~18.1.a.~~ 17.1.1. Any person, partnership, association, or corporation which establishes, conducts, manages, or operates a pain management clinic without first obtaining a license therefore or which violates any provisions of law or rule shall be assessed a civil money penalty by the secretary in accordance with this rule.

~~18.1.b.~~ 17.1.2. Each day of continuing violation after notification of the infraction shall be considered a separate violation.

~~18.1.c.~~ 17.1.3. If the clinic's designated physician owner knowingly and intentionally misrepresents actions taken to correct a violation, the secretary may impose a civil money penalty not to exceed $10,000 and revoke or deny the pain management clinic's license.

~~18.1.d.~~ 17.1.4. If an owner or designated physician owner of pain management clinic concurrently operates an unlicensed pain management clinic, the secretary may impose a civil money penalty upon the owner or physician, or both, not to exceed $5,000 per day;

~~18.1.e.~~ 17.1.5. If the owner of a pain management clinic that requires a license under this article fails to apply for a new license for the clinic upon a change of ownership and operates the clinic under the new ownership, the secretary may impose a civil money penalty not to exceed $5,000.

~~18.1.f.~~ 17.1.6. If a physician knowingly operates, owns, or manages an unlicensed pain management clinic that is required to be licensed pursuant to this article; knowingly prescribes or dispenses, or causes to be prescribed or dispensed, controlled substances in an unlicensed pain management clinic that is required to be licensed; or obtains a license to operate a pain management clinic for any other person by making or causing to be made any false representation, the secretary may assess a civil money penalty of not more than $20,000. The penalty may be in addition to or in lieu of any other action that may be taken by the secretary or any other board, court, or entity.

~~18.2.~~ 17.2. Notwithstanding the existence or pursuit of any other remedy, the secretary may, in the manner provided by law, maintain an action in the name of the state for an injunction against any person, partnership, association, and/or corporation to restrain or prevent the establishment, conduct, management, or operation of any pain management clinic or violation of any provisions of this article or any rule lawfully promulgated thereunder without first obtaining a license therefore in the manner hereinbefore provided.

~~18.2.a.~~ 17.2.1. The secretary may also seek injunctive relief if the establishment, conduct, or management or operation of any pain clinic, whether licensed or not, jeopardizes the health, safety, and/or welfare of any or all of its patients.

~~18.2.b.~~ 17.2.2. In determining whether a penalty is to be imposed and in fixing the amount of the penalty, the secretary shall consider the following factors:

~~18.2.b.1.~~ 17.2.2.a. The gravity of the violation, including the probability that death or serious physical or emotional harm to a patient has resulted, or could have resulted, from the pain management clinic's actions or the actions of the designated physician owner or any treating physician employed by or associated with the clinic, the severity of the action or potential harm, and the extent to which the provisions of the applicable laws or rules were violated;

~~18.2.b.2.~~ 17.2.2.b. What actions, if any, the designated physician owner or treating physician took to correct the violations;

~~18.2.b.3.~~ 17.2.2.c. Whether there were any previous violations at the pain management clinic; and

~~18.2.b.4.~~ 17.2.2.d. The financial benefits that the pain management clinic derived from committing or continuing to commit the violation.

~~18.3.~~ 17.3. Upon finding that a physician has violated the provisions of this article or rules adopted pursuant to this article, the secretary shall provide notice of the violation to the applicable licensing board.

§69-8-~~19~~18. Administrative Due Process.

18.1. Before any pain management clinic license is denied, suspended, or revoked, written notice shall be given to the owner~~(s)~~ or owners of the clinic, stating the grounds of the complaint and the date, time, and place set for the hearing on the complaint, which date shall not be less than 30 days from the time the notice is given.

~~19.a.~~ 18.1.1. The notice shall be sent by certified mail to the owner~~(s)~~ or owners at the address where the pain management clinic concerned is located.

~~19.b.~~ 18.1.2. Nothing prohibits the parties from requesting an administrative hearing or in an informal meeting to address and resolve the findings of the licensing review prior to the hearing and nothing prohibits the parties from continuing the hearing upon good cause shown as determined by the secretary.

~~19.c.~~ 18.1.3. The pain management clinic and its owner~~(s)~~ or owners shall be entitled to be represented by legal counsel at the informal meeting or at the hearing at their own expense.

~~19.d.~~ 18.1.4. All of the pertinent provisions of W. Va. Code §§29A-5-1, *et seq.*, and ~~69CSR1~~ W. Va. Code R. §§69-1-1, *et seq.*, shall apply to and govern any hearing authorized by this rule.

~~19.e.~~ 18.1.5. If an owner fails to request a hearing within the time frame specified, he~~/~~ or she shall be subject to the full penalty imposed.

~~19.f.~~ 18.1.6. The filing of a request for a hearing does not stay or supersede enforcement of the final decision or order of the director or the secretary. The secretary may, upon good cause shown, stay such enforcement.

§ 69-8-~~20~~19. Administrative Appeals and Judicial Review.

19.1. Any owner of a pain management clinic who disagrees with the decision of the secretary as a result of the hearing may, within 30 days after receiving notice of the decision, appeal the decision to the Circuit Court of Kanawha County or in the county where the petitioner resides or does business.

~~20.a.~~ 19.1.1. The filing of a petition for appeal does not stay or supersede enforcement of the final decision or order of the secretary. An appellant may apply to the circuit court for a stay of or to supersede the final decision or order.

~~20.b.~~ 19.1.2. The Circuit Court may affirm, modify, or reverse the decision of the secretary. The owner~~(s)~~ or owners or the secretary may appeal the court's decision to the Supreme Court of Appeals.