WEST VIRGINIA
SECRETARY OF STATE
NATALIE E. TENNANT
ADMINISTRATIVE LAW DIVISION

Form #3

Do Not Mark In This Box

2013 JAN -7 PM 2:01

SECRETARY OF STATE

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

AGENCY: Department of Health & Human Services TITLE NUMBER: 69

CITE AUTHORITY: §16-1-4 & § 16-5H-9

AMENDMENT TO AN EXISTING RULE: YES ____ NO X

IF YES, SERIES NUMBER OF RULE BEING AMENDED: ____

TITLE OF RULE BEING AMENDED: ____

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: 8

TITLE OF RULE BEING PROPOSED: Chronic Pain Management Clinic Licensure

THE ABOVE PROPOSED LEGISLATIVE RULE HAVING GONE TO A PUBLIC HEARING OR A PUBLIC COMMENT PERIOD IS HEREBY APPROVED BY THE PROMULGATING AGENCY FOR FILING WITH THE SECRETARY OF STATE AND THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE FOR THEIR REVIEW.

Authorized Signature

69 CSR 8

Department of Health and Human Resources
Office of Health Facilities Licensure and Certification

Brief Summary

The provisions of W. Va. Code § 16-1-4 and §16-5H-9 require the Secretary of the Department of Health and Human Resources to regulate and license all chronic pain management clinics. During the 2012 Legislative Session, the Code of West Virginia was amended by adding Article 5H to Chapter 16 of said code. Article 5H is titled the Chronic Pain Clinic Licensing Act.

This rule establishes licensing requirements for facilities that treat patients for chronic pain management in order to ensure that patients may be lawfully treated for chronic pain by physicians in facilities that are in compliance with oversight requirements as authorized by the Department of Health and Human Resources. This rule establishes definitions and establishes requirements for ownership, licensure, operation and management of pain management clinics; establishes limitations on the dispensing of controlled substances at pain clinics; requiring annual inspections of pain clinics; setting forth exemptions from the act; providing for suspension or revocation of a pain management clinic license and setting forth due process requirements; providing for prohibitions on practicing at or operating a pain clinic under certain circumstances; providing civil penalties regarding pain clinics; requiring rules for the licensure of pain management clinics; and, establishes advertisement disclosure requirements for chronic pain management clinics.

Statement of Circumstances

Prescription drug abuse and death is a major health problem in the United States and in West Virginia. The major source of prescription drugs for pain is the prescribing of these drugs by physicians. As a result of this growing health problem, S.B. 437 was passed. One of the measures contained in S.B. 437 to combat prescription drug abuse and death is the passage of the Chronic Pain Clinic Licensing Act. Under the act, the Department of Health and Human Resources is authorized with oversight and enforcement authority over chronic pain management facilities.

QUESTIONNAIRE

(Please include a copy of this form with each filing of your rule: Notice of Public Hearing or Comment Period; Proposed Rule, and if needed, Emergency and Modified Rule.)

DATE: December 3, 2012

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: (*Agency Name, Address & Phone No.*) Department of Health and Human Resources/Office of Health Facility Licensure and Certification

408 Leon Sullivan Way, Charleston, WV 25301
(304) 558-0050

LEGISLATIVE RULE TITLE: ~~Chronic Pain Management~~ Clinic Licensure

1. Authorizing statute(s) citation ~~16-1-4 and 16-5H-9~~

2. a. Date filed in State Register with Notice of Hearing or Public Comment Period:

   December 3, 2012

   b. What other notice, including advertising, did you give of the hearing?

   N/A

   c. Date of Public Hearing(s) ***or*** Public Comment Period ended:

   January 2, 2013

   d. Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments.

   Attached N/A No comments received N/A

e. Date you filed in State Register the agency approved proposed Legislative Rule following public hearing: (be exact)

f. **Name, title, address and <u>phone/fax/e-mail numbers</u>** of agency person(s) to receive all *written correspondence* regarding this rule: (Please type)

Anita Barnhouse
Department of Health and Human Resources
Office of Health Facility Licensure and Certification
408 Leon Sullivan Way
Charleston, West Virginia 25301
(304) 558-0050

g. **<u>IF DIFFERENT</u> FROM ITEM 'f'**, please give **Name, title, address and phone number(s)** of agency person(s) who wrote and/or has responsibility for the contents of this rule: (Please type)

N/A

3. If the statute under which you promulgated the submitted rules requires certain findings and determinations to be made as a condition precedent to their promulgation:

   a. Give the date upon which you filed in the State Register a notice of the time and place of a hearing for the taking of evidence and a general description of the issues to be decided.

N/A

b. Date of hearing or comment period:

N/A

c. On what date did you file in the State Register the findings and determinations required together with the reasons therefor?

N/A

d. Attach findings and determinations and reasons:

Attached

FISCAL NOTE FOR PROPOSED RULES

Rule Title: **Chronic Pain Management Clinic Licensure**

Type of Rule: x Legislative _____ Interpretive _____ Procedural

Agency: **Health and Human Resources**

Address: **One Davis Square**
Suite 100, East
Charleston, WV 25301

Phone Number: **304-558-0050** Email: Jolynn.Marra@wv.gov

Fiscal Note Summary

Summarize in a clear and concise manner what effect this measure will have on costs and revenues of state government.

The rule establishes licensing requirements for facilities that treat patients for chronic pain management. The rule further establishes oversight and compliance of the Department. Cost increase is detailed below and any revenue increase would be addressed through a licensing fee assessed by the Department.

Fiscal Note Detail

Show over-all effect in Item 1 and 2 and, in Item 3, give an explanation of Breakdown by fiscal year, including long-range effect.

Effect of Proposal	Fiscal Year		
	2012 Increase/Decrease (use"-")	2013 Increase/Decrease (use"-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost		503,202	493,335
Personal Services		286,090	286,090
Current Expenses		207,245	207,245
Repairs and Alterations		0	0
Buildings		0	0
Equipment		9,867	0
Land		0	0
Other Assets		0	0
2. Estimated Total Revenues		30,000	30,000

3. Explanation of above estimates (including long-range effect):

Please include any increase or decrease in fees in your estimated total revenues.

In order to license and survey pain clinics for compliance, the above costs include: 1 Program Manager II for program oversight; 4 Health Facility Nurse Surveyors for survey activity and 1 Office Assistant III for support services. OHFLAC does not currently have a unit or staff to absorb the activity of licensing pain clinics and assessing complaints since pain clinics are not currently required to be registered, the exact number of facilities and providers was not able to be determined. A definite number of 57 were identified, with the estimate of an actual number exceeding 100. The estimated number of pain clinics supports the additional staffing level referenced.

Memorandum

Please identify any areas of vagueness, technical defects, reasons the proposed rule **would not** have a fiscal impact, and/or any special issues **not** captured elsewhere on this form.

Date 11/29/12

Agency

Department of Health and Human Resources

Authorized Representative

Rocco S. Fucillo
Cabinet Secretary

Title 69 series 8
Chronic Pain Management Clinic Licensure
Legislative Rules
West Virginia Department of Health and Human Resources

Summary of Public Comments

1. Comment: The West Virginia Board of Medicine requests a change in language in section 8.4.c in regards to job descriptions for Physician Assistants and Board of Medicine approval of duties.

Response: Upon consideration, the Department agrees that the added language reinforces the requirement that all duties performed by a Physician Assistant be approved by the Board of Medicine. Therefore, the change was made as requested.

2. Comment: The West Virginia Academy of Family Physicians requests a replacement definition of "opioid drug product" instead of "opioid drug" at section 2.12 and gives a detailed explanation and rationale for such change.

Response: Upon consideration, the Department finds that the change in definition clarifies the intent of part of what characteristics of a non-exempt practice make it a chronic pain management clinic. Therefore, the change was made as requested.

3. Comment: Charles L. Werntz III, D.O. requests a change in the definition of "opioid drug" found at section 2.12 for clarification.

Response: Upon consideration, the Department finds clarification is needed. Please see the response to #2 for the change.

4. Comment: Kenneth Hilsbos, MD requests clarification of the definition of a pain clinic. He gives proposed revised language.

Response: Upon consideration, the Department has clarified the definition for a pain clinic at 3.1.a to "Where in any one month more than fifty (50) percent of all patients of the clinic, facility or office are treated for chronic pain resulting from non-malignant conditions and are prescribed, administered or dispensed tramadol, carisoprodol, opioid drugs or other Schedule II or Schedule III controlled substances for such diagnosis. This ratio is calculated by dividing the average monthly total of all patient encounters at the clinic, facility or office over a twelve (12) month calendar period by the number of unique patient encounters at the clinic, facility or office during any one month for a diagnosis of chronic pain and pursuant to such diagnosis were prescribed, administered or dispensed tramadol, carisoprodol, opioid drugs or other Scheduled II or Scheduled III controlled substances".

5. Comments: Kenneth Hilsbos, MD requests an exemption from the rule based upon low patient volume and for patients co-managed with a pain specialist.

Response: Upon consideration, the rule allows any facility not exempted to petition the Secretary for an exemption from the requirements of the rule. The Department feels this is sufficient for both requests.

6. Comments: The West Virginia State Medical Association requests clarification of the definition of "Associate" at section 2.3. The Association suggests to only include anyone who is associated with the provision of treatment.

Response: Upon consideration, the Department feels that all persons who have access to the clinic, patient records or medications should be included in this definition. Diversion of medications and unauthorized access to medical records have been associated with janitorial service providers and maintenance workers in clinical settings. These employees may have access to the clinic at times when no other staff is present.

7. Comments: The West Virginia State Medical Association supports the recommendation of opioid drug product as opposed to opioid drug.

Response: Upon consideration, the Department finds that the change in definition clarifies the intent of part of what characteristics of a non-exempt practice make it a chronic pain management clinic. Therefore, the change was made as requested.

8. Comments: The West Virginia State Medical Association requests, under the definition of "owner" at 2.13, that the rule be amended to state that only the physician owner be responsible for the operation of the clinic. The Association states that the statute includes this owner only.

Response: The Department feels that all owners of a chronic pain management clinic should have responsibility for the general establishment and licensure of the clinic. Upon consideration, the definition was revised to state "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 general establishment and licensure of the pain management clinic. At least one owner shall be a physician actively licensed to practice medicine, surgery or osteopathic medicine and surgery in this state."

9. Comment: The West Virginia State Medical Association requests that a portion of the definition of pain management clinic found at 3.1.a be changed to reflect all patients of a medical practice.

Response: Upon consideration, the Department has clarified the definition for a pain clinic at 3.1.a to "Where in any one month more than fifty (50) percent of all patients of the clinic, facility or office are treated for chronic pain resulting from non-malignant conditions and are prescribed, administered or dispensed tramadol, carisoprodol, opioid drugs or other Schedule II or Schedule III controlled substances for such diagnosis. This ratio is calculated by dividing the average monthly total of all patient encounters at the clinic, facility or office over a twelve (12) month calendar period by the number of unique patient encounters at the clinic, facility or office during any one month for a diagnosis of chronic pain and pursuant to such diagnosis were prescribed, administered or dispensed tramadol, carisoprodol, opioid drugs or other Scheduled II or Scheduled III controlled substances".

10. Comment: The West Virginia State Medical Association requests that the rule, at 4.1.g, provide more specificity as to the type/level of service that requires prior written notice when a change occurs.

Response: Upon consideration, the Department deleted the requirement for notification of a change in services provided since the core service of the provision of pain management remains the same.

11. Comment: The West Virginia State Medical Association requests that the term "reason to believe" found at 4.1.k and 4.1.l be changed to a more appropriate legal standard.

Response: Upon consideration, the Department finds the request reasonable. Therefore, "reason to believe" was changed to "reasonable belief".

12. Comment: The West Virginia State Medical Association states, in reference to 4.4.a.5, "that the requirement for the submission of construction and architectural plans for review and the assessment of costs, without limitation, for their review far exceeds the stated purpose and intent of the Act".

Response: Upon consideration, the Department finds the request reasonable. Therefore, this section was deleted.

13. Comment: In regards to 4.4.b, the West Virginia State Medical Association requests that a set fee be made for the actual costs of the initial inspection.

Response: Upon consideration, a permanent fee cannot be set for the actual costs of an initial inspection. The number of surveyors to conduct an inspection, the number of possible follow-up visits if a facility has egregious deficient practices, the varying costs of travel, the cost of inflation, are all possible variables in the total cost of an inspection.

14. Comment: In regards to 5.1 – 5.3 and 5.11, the West Virginia State Medical Association discusses unannounced inspections and patient confidentiality requirements in regards to medical record review during an inspection. The Association is concerned about the potential for conflict and confusion over confidential information.

Response: There are no federal or state requirements that prohibit the State survey agency from reviewing any medical record or any other document necessary to conduct an inspection. The Health Insurance Portability and Accountability Act (HIPAA) provides that protected health information, such as is found in medical records, may be used and disclosed to Health Oversight Agencies, such as the State survey agency. This is found in 45 CFR Parts 160 and 164. Therefore, the State survey agency can review any medical record or other document necessary to conduct an inspection.

15. Comment: In regards to 6.1, the West Virginia State Medical Association states "there is no statutorily stated requirement that all such individuals must also undergo a fingerprinting process". They also state "...Rule requires that the criminal background checks and fingerprinting results be

submitted to the secretary for review and approval, creating a potentially cumbersome and bureaucratic process.

Response: Upon consideration, the established statewide criminal background check includes fingerprinting as part of the process, therefore, fingerprinting is necessary. Also, the results of criminal background checks being reviewed by the Secretary is found in the statute at 16-5H-4(a)(5). Employment eligibility based upon criminal background checks is part of the review; otherwise submission of results would be unnecessary.

16. Comment: In regards to 6.4.c, the West Virginia State Medical Association states that the requirement for each owner being responsible for the operation of the pain management clinic and for compliance with all applicable federal and state laws, rules and regulations is more expansive and broader in scope than the statutory language. The Association requests that the requirement conform to the statutory language of the physician owner being responsible for the operation of the clinic.

Response: The Department feels that all owners of a chronic pain management clinic should have responsibility for the general establishment and licensure of the clinic. Upon consideration, 6.4.c will be revised to state "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."

17. Comment: In regards to 7.2.a, the West Virginia State Medical Association states the requirement for submission of plans to the Secretary does not further the true purpose and intent of the Act.

Response: Upon consideration, the Department will delete 7.2.a and 7.2.b, combine 7.2.c and 7.2.d and include this combination as 7.1.i.

18. Comment: Compass Healthcare Services, Inc. made general comments and requested specific changes throughout the rule.

Response: The Department held meetings and crafted this rule in conjunction with the Board of Medicine, Board of Osteopathic Medicine, WV Academy of Family Physicians, State Medical Association, Board of Pharmacy, RN Board and LPN Board. Therefore the Department feels no changes are necessary.

19. Comment: The Board of examiners for Registered Professional Nurses requested advanced practice nurse and advanced nurse practitioner be replaced with advance practice registered nurse.

Response: Upon consideration, the Department agrees and has the made the changes.

20. Comment: PPPFD, Inc made comments and requested several changes throughout the rule.

Response: The Department held meetings and crafted this rule in conjunction with the Board of Medicine, Board of Osteopathic Medicine, WV Academy of Family Physicians, State Medical Association, Board of Pharmacy, RN Board and LPN Board. Therefore the Department feels no changes are necessary.

21. Comment: Eleven form letters titled Proposed Rule- Chronic Pain Management Clinic Licensure were received from private citizens. The letters made general comments and requested a change in the definition of a pain clinic.

Response: Upon consideration, the Department has clarified the definition for a pain clinic at 3.1.a to "Where in any one month more than fifty (50) percent of all patients of the clinic, facility or office are treated for chronic pain resulting from non-malignant conditions and are prescribed, administered or dispensed tramadol, carisoprodol, opioid drugs or other Schedule II or Schedule III controlled substances for such diagnosis. This ratio is calculated by dividing the average monthly total of all patient encounters at the clinic, facility or office over a twelve (12) month calendar period by the number of unique patient encounters at the clinic, facility or office during any one month for a diagnosis of chronic pain and pursuant to such diagnosis were prescribed, administered or dispensed tramadol, carisoprodol, opioid drugs or other Scheduled II or Scheduled III controlled substances".

22. Comment: The West Virginia State Medical Association suggests clarification of the definition for 3.1.a to "Where in any one month more than fifty (50) percent of all patients of the clinic, facility or office are treated for chronic pain resulting from non-malignant conditions and are prescribed, administered or dispensed tramadol, carisoprodol, opioid drugs or other Schedule II or Schedule III controlled substances for such diagnosis. This ratio is calculated by dividing the average monthly total of all patient encounters at the clinic, facility or office over a twelve (12) month calendar period by the number of unique patient encounters at the clinic, facility or office during any one month for a diagnosis of chronic pain and pursuant to such diagnosis were prescribed, administered or dispensed tramadol, carisoprodol, opioid drugs or other Scheduled II or Scheduled III controlled substances".

Response: Upon consideration, the Department finds the clarification reasonable.

State of West Virginia
Board of Medicine

101 Dee Drive, Suite 103
Charleston, WV 25311
Telephone 304.558.2921
Fax 304.558.2084
www.wvbom.wv.gov

December 21, 2012

Anita Barnhouse
Department of Health and Human Resources
Office of Health Facility Licensure and Certification
408 Leon Sullivan Way
Charleston, WV 25301

Re: Proposed Rule 69 CSR 8; Chronic Pain Management Clinic Licensure

Dear Ms. Barnhouse:

This comment is made in reference to section 8.4 (Staff training and credentialing) of the above-referenced proposed Rule.

Legislative Rule 11-1B-13 (Physician Assistant Utilization) sets forth a standard basic job description which describes medical procedures which a Physician Assistant may perform under the supervision of a physician. Proposed Rule 69-8-8.4.c. states that a detailed job description must be developed for each staff member in a licensed pain clinic. If such specific duties are beyond those of 11-1B-13's standard job description as specified in 11-1B-13.2, the Board of Medicine must approve these duties before they are performed by the Physician Assistant.

Accordingly, please consider the following additional language for 69-8-8.4.c.:

> The pain management clinic shall develop detailed job descriptions for each staff member that clearly ~~defines~~ define the education, training, qualifications and competencies needed to provide specific services; *Provided,* that additional job duties for a Physician Assistant beyond those delineated in 11-1B-13.2 are submitted for the consideration and approval of the Board of Medicine.

This change in language will alleviate the possibility of a Physician Assistant practicing beyond his approved duties for which they may be subject to discipline.

Thank you for your consideration of this comment by the Board of Medicine.

Respectfully,

Robert C. Knittle

RCK/

WEST VIRGINA ACADEMY OF
FAMILY PHYSICIANS
STRONG MEDICINE FOR WEST VIRGINIA

December 29, 2012

Anita Barnhouse
Department of Health and Human Resources
Office of Health Facility Licensure and Certification
408 Leon Sullivan Way
Charleston, WV 25301

RE: Proposed Rule 69CSR 8 - Chronic Pain Management Clinic Licensure

This comment by the West Virginia Academy of Family Physicians is made to suggest a replacement definition of "Opioid Drug Product" instead of "Opioid Drug," following a discussion with DHHR Cabinet Secretary Rocco Fucillo and Counsel Will Jones by our health consultant Thom Stevens.

Compromise: Definition of Opioid Drug Product

Proposal:

> **2.12.2 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.**

To Replace:

~~2.12. Opioid Drug – Any drug having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability. Opioid drugs include, but are not limited to, morphine, codeine, hydrocodone, oxycodone, heroin and other medications that block the transmission of pain messages to the brain.~~

Explanation and rationale:

The term "opioid," currently appears twice in the W. Va. Code (§60A-9-5 and §60A-3-308), both references being in the context of describing addiction to opiate-like substances (i.e., "opioid addiction"). There is, therefore, utility in defining the term "Opioid Drug Product," or some variant thereof, in the rule as part of what characteristics of a non-exempt practice make it a pain management clinic.

Useful guidance can be found in the Code of Federal Regulations (21 CFR 314.3) which distinguishes between "drug substance" and "drug product." (See following page)

P.O. Box 1090, Hurricane, WV 25526 Phone (304) 562-4433 Fax: (304) 562-4469 Tax ID# 55-0419533

Drug substance means an active ingredient that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the human body, but does not include intermediates use in the synthesis of such ingredient. (emphasis added)

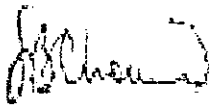
Drug product means a finished dosage form, for example, tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients. (emphasis added)

Opioid Drug Product	The Act is concerned with prescribing and dispensing. Physicians and others with prescribing authority never prescribe drug substances, even when ordering compounded drugs. They only prescribe drug products. Further, since heroin can never be in a drug product within the meaning of 21 CFR 314.3 because it is a Schedule I controlled substance under both W. Va. and federal statutes, there is no reason to include it in a definition aimed at implementing a law affecting the practice of health care professionals.
Any finished dosage form	This language comports with the CFR definition of drug product.
that contains as one of its active ingredients	This part of the proposed definition covers combination products, such as Vicodin® and Percocet®, which contain an opioid in combination with the non-controlled drug substance acetaminophen.
a drug substance that has pharmacological properties similar to morphine	This part lays out that the reference for what constitutes an "Opioid Drug" in and "Opioid Drug Product" is morphine, the quintessential opioid, both in the pharmacological and regulatory senses.
, including its analgesic action and its addiction-forming or addiction-sustaining liability,	This clause specifies the two main actions of morphine-like drug substances that are of interest in the Act: analgesia and abuse liability.
or that can be converted by the body into a drug substance having such properties.	This clause includes drug substances like codeine, which is only capable of inducing analgesia or supporting addiction in those persons who have the typical phenotype that allows them to convert codeine into morphine. In those who lack the more prevalent form of the specific enzyme, codeine has no analgesic effect or abuse liability. In addition, several pharmaceutical companies are pursuing technologies to reduce the abuse liability of opioids by converting known opioid drug substances (e.g., morphine) into prodrugs that would only be active when they were converted back into opioids by the body. This phrase would, therefore, cover codeine, but would anticipate any other similar drugs should they come to market.

Opioid drug products include, but are not limited to, those containing codeine, hydrocodone, and oxycodone.	This sentence lays out specific drug substances that are of concern, but also states that this is not an exhaustive list. By eliminating the language "other medications that block the transmission of pain messages to the brain," this precludes local anesthetics (e.g., lidocaine patches used for treating chronic pain after an outbreak of shingles) from being inadvertently captured in a definition aimed at morphine-like drugs.

Please note that the West Virginia Board of Medicine, the West Virginia Primary Care Association and the West Virginia State Medical Association support this recommendation.

Respectfully,



Sarah Chouinard, MD
President

C: Rocco Fucillo, DHHR Cabinet Secretary
Will Jones, DHHR Counsel
Thom Stevens, WVAFP Health Consultant

WVU Healthcare

Institute of Occupational and Environmental Health
3860 Robert C. Byrd Health Sciences Center
PO Box 9145
Morgantown, WV 26506-9145
Phone number: 304-293-3693
Fax number: 304-293-2629

Anita Barnhouse
WV DHHR
Office of Health Facility Licensure and Certification
408 Leon Sullivan Way
Charleston, WV 25301

December 19, 2012

In re: Proposed pain clinic rule

Dear Madame,

After reviewing the proposed rule, I am writing to offer a few comments.

As proposed:

2.12. Opioid Drug – Any drug having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability. Opioid drugs include, but are not limited to, morphine, codeine, hydrocodone, oxycodone, heroin and other medications that block the transmission of pain messages to the brain.

This definition of opioid drug is overly broad. There are no conjunctions in the definition, so it is unclear if the various definitions mentioned should be joined by "and" or "or". Focusing on "drugs having such addiction-forming or addiction-sustaining liability" rather than the pharmacology is confusing. If one focuses on the addictive potential portion of this definition it would seem that many classes of drugs including benzodiazipines, amphetamines, and perhaps even nicotine or alcohol would be included. If one focuses on "blocking the transmission of pain messages to the brain", numerous non-schedule medications like lidocaine, Tylenol, and aspirin would be included. I understand the intent of this section, but I am not sure that it is being properly conveyed. I worry about subsequent interpretations for the calculation of the percentage of a clinics patients using opioids when this definition is so all-inclusive.

To aid this I did a brief online literature search, finding:

The Free Dictionary by Farley:

> Opioid: Any morphine-like synthetic narcotic that produces the same effects as drugs derived from the opium poppy (opiates), such as pain relief, sedation, constipation and respiratory depression.
>
> Opioid: Any of a group of substances that resemble morphine in their physiological or pharmacological effects, esp in their pain-relieving properties
>
> Narcotic: Narcotics are natural opioid drugs derived from the Asian poppy *Palaver somniferous* or semi-synthetic or synthetic substitutes for these drugs.

Wikipedia:

An **opioid** is a psychoactive chemical that works by binding to [redacted], which are found principally in the [redacted] and [redacted] and the [redacted].

Proposed Alternate wording:

2.12 – Opioid: Any substance that works by binding to opioid receptors and which resemble morphine in their physiological or pharmacological effects, such as pain relief, sedation, constipation, and respiratory depression.

It would be reasonable to list these at some point, but I understand that the rule should be structured so that it does not need to be amended every time a new drug is marketed

I hope that this suggestion is helpful in formulating the final rule.

Charles L. Werntz III, D.O., MPH, FACOEM
Associate Professor, Clinical Emphasis
Associate Program Director - Occupational Medicine Residency

Kenneth Hilsbos, MD
Hilsbos Family Care, PLLC
403 Virginia Ave., Suite 202
Fairmont WV 26554
304-366-7766
Fax 304-366-7763
info@hilsbosfamilycare.com

January 2, 2013

Anita Barnhouse
Department of Health and Human Resources
Office of Health Facility Licensure and Certification
408 Leon Sullivan Way
Charleston, West Virginia 25301

Re: Proposed Rule—Chronic Pain Management Clinic Licensure

Dear Ms. Barnhouse:

We all want to put a stop to "pill mills" that prescribe enormous quantities of pain pills with little or no medical reason.

However, the proposed rule on Chronic Pain Management Clinic Licensure has been written in a way that could unintentionally harm many legitimate chronic pain patients.

Fifteen per cent of Americans suffer from chronic pain. Many of them go untreated or undertreated. Access to care is a serious problem. Even in populated areas near my practice, there is unmet need.

Enclosed please find changes I recommend, to help avoid unintended consequences affecting many West Virginians.

Without these changes, the new rule will hurt many legitimate chronic pain patients in unforeseen ways. For example, good primary care doctors will close their practices to people in pain, or even worse, move their offices to nearby states that still value the full range of what these doctors have to offer.

Thank you for carefully considering corrections to flaws in a needed regulation.

Sincerely,

Kenneth Hilsbos, MD
Family Medicine (Board Certified by American Board of Family Medicine)
President, Marion County Medical Society

Enclosure

How to Fix the Pain Clinic Licensure Proposed Rule—Which Facilities Are Pain Clinics?

69-8-3.1.a of the Pain Clinic Licensure Proposed Rule

"Where in any one month more than fifty (50) percent of all patients treated at the clinic, facility or office are treated for chronic pain resulting from non-malignant conditions and are prescribed administered or dispensed tramadol, carisoprodol, opioid drugs or other Schedule II or Schedule III controlled substances for such diagnosis. This ratio is calculated by assessing *the total number of patients treated during any one month and then determining the number of patients treated for a diagnosis of chronic pain* and pursuant to such diagnosis were prescribed, administered or dispensed tramadol, carisoprodol, opioid drugs or other Scheduled II or Scheduled III controlled substances."

Comments

1. We all want to stop "pill mills".

2. Regulating independent pain clinics is a good idea.

3. In defining who is subject to the new pain clinic requirements, let's be careful we don't "throw the baby out with the bathwater".

The proposed regulation seeks to clarify the definition of a pain clinic, but in the process changes it substantially.

The issue is to draw the line in the right place—to draw a line that has all independent pain clinics on one side of the line, and all legitimate independent non-pain-clinic prescribers on the other side of the line.

If we define pain clinics too broadly, this will shut down legitimate chronic pain management by independent prescribers in places where legitimate pain patients have no where else to go. To my knowledge, these places include not only where I practice, but also large areas of the state, covering a large proportion of the state's population.

Both the version of the definition in the law and the version in the proposed regulation involve the question, "What proportion of the facility's patients are chronic pain patients?" We are to divide the number of "pain patients" by the number of "all patients". How we get each of these numbers can make a big difference.

The law says "Where in any one month more than fifty (50) percent of patients of the prescribers or dispensers". The proposed regulation says "Where in any one month more than fifty (50) percent of all patients treated". The change in the wording, going from the law to the proposed regulation, fails to clarify enough, but it does open the door to possible interpretations with undesirable consequences.

To me, the wording in the law suggests that "all patients" (the denominator, or bottom number in the ratio) means "all of the prescriber's patient population". Family practitioners and general internists would usually take that to mean all the patients seen within the last 3 years.

In contrast, the wording in the proposed regulation might mean that "all patients" are "all patients treated during that month". If this unclear wording is allowed to take on that meaning, it drastically reduces the number of "all patients".

Both definitions do make it clear that we are not to look beyond the one month in question when counting "pain patients" (the numerator, or top number in the ratio). How to count "pain patients" is still unclear in other ways. To make this clear, we should specify "unique patients". That gets rid of double counting in the event that a pain patient was seen more than once in a month.

A pain clinic that manages outpatient pain medication prescribes controlled pain medications to more than half their patients. Legitimate pain patients in a legitimate practice such as in primary care are seen much more often than other patients.

It is possible to pinpoint the ratio while remaining within the wide range of possible meanings set out by the definition in the law.

Putting it all together, here is proposed revised language for the second of two sentences in 69-8--3.1.a.:

> "This ratio is calculated by assessing the total number of unique patients seen during a continuous period of 3 years and then determining, during that period, the average number of unique patients seen per calendar month for a principle diagnosis of chronic pain who, pursuant to such a diagnosis, were prescribed, administered or dispensed tramadol, carisoprodol, opioid medication, or another Schedule II or Schedule III controlled substance."

If we leave in place a definition that leaves room to skew the ratio too much, the practical effect could be that many qualified, legitimate prescribers will just stop nearly all chronic pain medication prescribing.

We also risk getting that result if we base the ratio on data that will be too hard for doctors to collect.

4. There should be an exclusion for a low volume. If the practice has less than, say, 100 chronic pain visits in a month, it should be excluded from the definition of a pain clinic. For example, this would allow a new independent family practice to disregard the ratio until the practice reached a certain size.

5. There should be an exclusion for patients co-managed with a pain specialist.

6. There are not very many pain specialists in the area where I practice. As far as I know, they only do invasive procedures and do not prescribe controlled pain medication even when they recommend that the primary care doctor do so. Where are these patients going to go if DHHR shuts down prescribing by those who are qualified to do it but do not have the specific certification required by the rule? If DHHR imposes a "quota" on family practitioners and general internists, the new rule will have a greater adverse impact on those who are more rural, more elderly, more disabled, or more poor.

7. The drug diversion problem is large and has multiple facets. Regulating pain clinics is only one part of the package needed to address the problem. If the other parts of the needed package do not get enough of our attention, we will not make much of a dent in the problem of prescription medication misuse. This regulation cannot substitute for strategies to deal with gaping holes in law enforcement policy, corrections policy, and substance use disorder treatment funding,

Some other facets of the drug diversion problem call for measures outside the boundaries of West Virginia. Our state government should advocate creatively for those efforts. For example, the lack of a controlled prescription data base in Pennsylvania hurts us in counties nearby. Ohio has a data base, but no way check across the river that so many people cross just to buy, say, a bottle of Tylenol. Has West Virginia sought limited, secure reciprocity with Ohio?

8. It's all about patients. This regulation could affect many people in West Virginia. Let's draw the line in the right place. Let's avoid unintended consequences.

Kenneth Klein, MD

January 2, 2013

Anita Barnhouse
Department of Health and Human Resources
Office of Health Facility Licensure and Certification
408 Leon Sullivan Way
Charleston, WV 25301

Re: Proposed Rule 69 CSR 8 – Chronic Pain Management Clinic Licensure

Earlier this year, Governor Earl Ray Tomblin proposed legislation (SB 437) to address the use, misuse and abuse of controlled substances in our state. SB 437 was a comprehensive package of reforms crafted with public input, broad stakeholder involvement, and leadership from health care advocates, including the West Virginia State Medical Association (WVSMA). SB 437 was approved by the West Virginia Legislature, signed into law by Governor Tomblin and imposes new responsibilities on patients, controlled substance dispensers and prescribers alike.

The new law (and the subject of Proposed Rule 69 CSR 8) creates Article 5H in Chapter 16 of the West Virginia Code entitled Chronic Pain Clinic Licensing Act ("Act") to "...establish licensing requirements for facilities that treat patients for chronic pain management... ."

The WVSMA provides the following comments to the above-referenced Proposed Rule:

Sec. 69-8-2 Definitions, 2.3 Associate

The Proposed Rule too broadly defines the term "Associate" to include individuals who are not otherwise included in the definition on "Clinic Staff" but through an "arrangement" have "access to the clinic." This would arguably include persons such as maintenance workers, janitorial service providers, copier service employees, etc. The Proposed Rule imposes strict obligations including, recordkeeping, training, criminal background checks and fingerprinting for such individuals.

The WVSMA believes the statutory language demonstrates a more narrow legislative intent. Under 16-5H-4(a)(3)(E), the statute imposes supervisory responsibility by the designated physician owner of "any employee, volunteer or individual under contract, **who provides treatment** of chronic pain at the clinic **or is associated with the provision of the treatment**." [Emphasis added.]

The WVSMA recommends the definition of "Associate" be clarified to limit its application to those individuals who provide treatment or who are associated with the provision of treatment at a licensed pain management clinic.

West Virginia State Medical Association
4307 MacCorkle Avenue, SE
P. O. Box 4106 ◦ Charleston, West Virginia 25364
Phone: 304-925-0342 ◦ Toll Free 800-257-4747 ◦ Fax: 304-925-0345
www.wvsma.com

Sec. 69-8-2 Definitions, 2.12 Opioid Drug

The WVSMA supports the recommendation of the West Virginia Academy of Family Physicians to substitute for "Opioid Drug" a definition for "Opioid Drug Product" as outlined in their Comment Letter.

Sec. 69-8-2 Definitions, 2.13 Owner

The Proposed Rule states that "**[e]ach owner** is responsible for the operation of the pain management clinic and assumes responsibility for all of its employees... ."[Emphasis added.] The statutory language, however, requires that a specific physician owner be designated and it is that person who is assigned operational responsibilities by statute. WV Code 16-5H-4(a)(3) states that "[e]ach pain management clinic shall designate **a physician owner** who shall practice at the clinic and **who will be responsible for the operation of the clinic**." [Emphasis added.]

The WVSMA recommends the Proposed Rule be amended to match the statutory language.

Sec. 69-8-3Pain Clinic Definition and Exemptions. 3.1.a

The cornerstone of the Act is the threshold at which a medical practice is deemed under the law to be a 'chronic pain management clinic' and thus subject to the Act's licensure and regulatory obligations. WV Code16-5H-2(d)(1)draws the line "[w]here in any month more than fifty percent of patients of the prescribers or dispensers are prescribed or dispensed opioids or other controlled substances...for chronic pain resulting from non-malignant conditions."

Unfortunately, as so often is the case, when it comes time to craft a Rule to implement the statute it becomes obvious an inherent ambiguity exists in the statutory language. That is the case here and thus it is critical that through the Rule, a bright-line be established so that every medical practice can easily determine whether it is above or below the threshold requiring licensure.

In the instant case, the statute essentially requires each medical practice to calculate a mathematical fraction with a numerator and denominator. The statute sets the bar at "fifty percent" but the problem is trying to answer the question, 'fifty percent of what?' The statute is relatively clear on what patients are to be included in the numerator. The Proposed Rule provides that the numerator be, during one month, "the number of patients treated for a diagnosis of chronic pain and pursuant to such diagnosis were prescribed, administered or dispensed tramadol, carisoprodol, opioid drugs or other Schedule II or Scheduled III controlled substances." The only recommended change to this provision is to more closely follow medical terminology and refer to 'patient encounters' rather 'patients treated.'

The more difficult issue is defining the denominator. The statute simply refers to this population as the "patients of the prescribers or dispensers." It is unclear if it is all patients physically seen during a given month (encounters), or all patients under the care of a physician, whether actually seen or not. Another interpretation could reasonably be the statute intended to include in the denominator 'all patients' of the medical practice, whether being actively seen or treated or not. The Proposed Rule defining the denominator as "the total number of patients treated during any month" is too narrow. The WVSMA recommends the Proposed Rule defining the

denominator be clarified to include all patients of the medical practice, not just those who had a patient encounter during one particular month.

Patients suffering from chronic, non-malignant pain receive safe, clinically appropriate care from physicians practicing in a broad range of medical specialties. Family physicians, internal medicine, anesthesiologists, orthopedic surgeons, neurosurgeons and many other medical specialty and sub-specialty physicians routinely treat pain patients in their day-to-day practices. A devastating consequence of allowing a vague and/or inappropriate threshold to be established would be for patients to lose the care and treatment of their physician because of the chilling effect of the new law.

Sec.69-8-4. Licensure 4.1.g

This provision requires the pain management clinic, in addition to a change of name or location, to notify in writing the secretary of DHHR (or his/her designee) of any change in "services provided". Failure to provide such notice can result in administrative fines and license revocation. The WVSMA recommends that because 'services' is not otherwise defined, the Proposed Rule should provide more specificity as to the type/level of service that require prior written notice when a change occurs.

Sec.69-8-4. Licensure 4.1.k – 4.1.m

These provisions of the Proposed Rule grant authority to the secretary of DHHR to enter any "practice, office or facility" to conduct an "inspection" if the secretary has "reason to believe" it is being operated as a pain management clinic. If access is denied, the secretary can petition the Circuit Court of Kanawha County for an inspection warrant. The WVSMA recommends a more appropriate legal standard such as 'probable cause' or 'reasonable belief' be used rather than "reason to believe."

Sec.69-8-4. Licensure 4.4.a.5

The WVSMA believes that the requirement for the submission of construction and architectural plans for review and the assessment of costs, without limitation, for their review far exceeds the stated purpose and intent of the Act.

Sec.69-8-4. Licensure 4.4.b

This Proposed Rule requires, in addition to the payment of a specifically set fee, that a pain management clinic must pay "the actual costs of the initial inspection made by the secretary." The WVSMA recommends that a specific amount be set to cover any inspection.

Sec.69-8-5. Inspections. 5.1 – 5.3, 5.11

The Proposed Rule mandates that the secretary of DHHR (or his/her designee) conduct unannounced inspections and provides broad authority during such inspections to review clinical records and observe services being delivered. However, other sections of the Proposed Rule (69-8-11.1 and 11.7) impose strict patient confidentiality requirements of the facility's designated physician owner and administrator. These provisions create an inherent conflict within the Rule and will cause confusion over what medical records can or cannot be reviewed when conducting an inspection.

The confidentiality protection stated in this section as it relates to Inspections only limits "public disclosure" of confidential information. The WVSMA believes strongly this is insufficient and creates significant potential for conflict and confusion for health care providers who practice under strict state and federal requirements relating to patient confidentiality.

Sec.69-8-6. Organization and Management. 6.1

The Proposed Rules mandates that all "owners, employees, volunteers or associates of the clinic shall undergo a criminal records background check and a fingerprint process prior to operation of the clinic and prior to being hired... ." While the statute does require a criminal background check, there is no statutorily stated requirement that all such individuals must also undergo a fingerprinting process. Additionally, the Proposed Rule requires that the criminal background checks and fingerprinting results be submitted "to the secretary for review and approval," creating a potentially cumbersome and bureaucratic process.

Sec.69-8-6. Organization and Management. 6.4.c

The Proposed Rule imposes on each owner responsibility for the operations of the pain management clinic and for compliance with all applicable federal and state laws, rules and regulations. This language is more expansive and broader in scope than the statutory language. WV Code 16-5H-4(a)(3) states that "[e]ach pain management clinic shall designate a physician owner who shall practice at the clinic and **who will be responsible for the operation of the clinic**." [Emphasis added.] The WVSMA suggests this Proposed Rule be amended to conform to the statutory language.

Sec.69-8-7. Clinic and Facility Environment and Operations. 7.2.a

The WVSMA believes the requirement for the submission to the secretary of DHHR all "drawings and specifications for the architectural, structural and mechanical design and work" does not further the true purpose and intent of the Act. Moreover, the Proposed Rule does not set forth any criteria or standards by which the secretary is to follow during the review process.

Respectfully,

Hoyt J. Burdick, M.D.

Hoyt J. Burdick, MD
President

COMPASS HEALTHCARE SERVICES, INC.
Suite 1, 134 Goff Mt. Rd. Cross Lanes, WV 25313 ph: 304-769-5618 fax: 304-769-5621

January 1, 2013

Anita Barnhouse
WV DHHR
OHFLAC
408 Leon Sullivan Way
Charleston, WV 25301
Via hand delivery

Re: Comments on Proposed Chronic Pain Management Clinic Licensure Rule

Dear Ms. Barnhouse;

Enclosed please find the comments of Compass Healthcare Services, Inc. on OHFLAC's proposed Chronic Pain Management Clinic Licensure rule.

Thank you for your prompt consideration of these comments.

Sincerely,

John E. Cornell, M.D.

WV DHHR's Office of Health Facilities Licensure and Certification ("OHFLAC") is charged with developing this rule under the power given to it by the WV legislature pursuant to WV Code Chapter 16, Article 5H and the Chronic Pain Clinic Licensing Act. The WV legislature's stated purpose for enacting this law was "to establish licensing requirements for facilities that treat patients for chronic pain management *in order to ensure that patients may be lawfully treated for chronic pain* by physicians in facilities that comply with oversight requirements developed by the [DHHR]." *WV Code §16-5H-1 (emphasis added).* Several provisions in OHFLAC's proposed rule would unreasonably limit, and most likely deny, many West Virginians access to legitimate treatment for their chronic pain. These provisions must be reevaluated and altered to ensure the WV legislature's stated purpose for the law is met. Those provisions are:

1. §69-8-6.5.

OHFLAC's rule *unreasonably limits the number of individuals in* the State of WV who will be qualified to serve as a designated physician owner. This will necessarily limit the number of chronic pain clinics available to WV residents. Such an unreasonable limitation is in direct opposition to the WV legislature's stated purpose for the law; the inevitable consequence of such an unreasonable limitation will assuredly result in law-abiding citizens of WV being unable to find providers who can legally prescribe medication for their chronic pain.

There are currently approximately 130 physicians in WV qualified to be a designated physician owner under the current qualification requirements. Most of these physicians practice interventional pain management (and not medical pain management) in large group practices or for pain clinics exempted from this law and proposed rule. These doctors will not utilize 32 hours per week of their time for medical pain management-it is simply not lucrative or feasible for them to do so. (Interventional pain management is already accessible to WV patients. It is medical pain management that is becoming more and more difficult for patients to access.)

Other states' qualifications for physicians in pain management clinics range from the highly restrictive ones listed under WV law, to much less restrictive ones, including: a sub-specialty in hospice and palliative medicine (Ohio & Kent); board certification in anesthesiology, psychiatry, neurology, physical medicine and rehabilitation, occupational medicine, or rheumatology in conjunction with demonstration of conformance with minimal standards of care (Ohio); completion of 40 hours of in-person, live participatory AMA Category I CME courses in pain management (Tenn); just being a physician who practices under an unrestricted license (Texas); just being a physician who practices full-time under and *unrestricted license (Miss); or, a physician with 3 years of* practice/experience in pain management (Fla). WV does not even require an anesthesiologist to be present in surgeries, yet OHFLAC will now requires one to

be present for a pain clinic to prescribe a 78 year old's pain medicine for her arthritis?

OHFLAC must expand the qualifications so that other, competent physicians learned in pain medical management may qualify as a designated owner.

2. §69-8-4.1.d and 6.5.b.3.
OHFLAC's requirement that each individually licensed clinic must have a unique designated physician owner (section 4.1.d.), along with the requirement that the designated physician owner must practice at the clinic 32 hours per week (6.5.b.3.) further limits the number of qualified physicians in the state who will be available to serve in this role.

There are medical pain management clinics that serve the primary care physician community (accepting their chronic pain patients for medication management). At least one does not even operate 32 hours per week and, thus, could never meet the qualification of designated pain clinic. Clinics that are serious about rejecting questionable patients and only serving those with established physician referrals and legitimate chronic pain may not need to operate 32 hours per week. *No other state makes this requirement.* A preferable approach would be for the designated physician owner to remain the "buck stops here" owner (as the law now provides), and require active oversight through personally reviewing patient charts and seeing each patient every so many visits, much like the requirements for physicians supervising physician assistants. This would ensure appropriate level of oversight while still ensuring a sufficient number of medical pain management clinics for WV patients to access.

Qualified physicians should be able to be the designated physician owner of more than one clinic. OHFLAC's fiscal note accompanying this proposed rule states it expects there are in excess of 100 pain clinics in WV. With only approximately 130 physicians qualified to be designated owner, and many of those practicing in large interventional pain management clinic groups and/or for facilities that are exempted from these rules, this requirement will necessarily eliminate many of those clinics. Interventional pain management clinics are lucrative endeavors. The likelihood that those physicians will leave those lucrative practices or expand their current practices to practice 32 hours per week doing medical pain management is, to put it lightly, low. Even if OHFLAC were to broaden the qualifications for a designated physician owner, there will still be a small number of WV physicians who will be qualified and willing to be a designated physician owner of a chronic pain management clinic. Necessitating *each clinic to be licensed separately is fine. But allowing* physician-owned corporations to have satellite clinics with central management and designated physician owners is fiscally responsible and promotes business growth in WV in accordance with Governor Tomblin's initiatives.

Without these changes in the proposed rule, OHFLAC will force its legitimate local providers to open clinics in border states of Kentucky and Ohio which, while decreasing the amount of survey and licensure work for OHFLAC, will

result in WV residents having to travel long distances to obtain medical treatment for their chronic pain.

3. §69-8-2.3.

The definition of "associate" is overly broad and/or vague. As it currently reads, the term associate would include janitors/cleaning services, handymen, attorneys, accountants and others who may provide professional business services to the physician and/or business, landlords, OHFLAC employees/agents, fire marshal, police, etc. *Because there are restrictions on "associates"* throughout this rule that would be absurd as applied to this broad group (e.g., 6.1. which requires all associates to undergo fingerprint criminal background checks), OFHALC should revisit this definition if it wishes it to withstand a legal challenge.

4. §69-8-6.2 and 8.4.e.8.

These sections prohibit owners, employees or associates from being affiliated with a clinic if that person has been convicted of or plead guilty to any felony. There are many felonies that are not reasonably related to the legitimate precautions the state should take in ensuring pain clinics employ appropriate staff. For instance, *a curfew and loitering violation (a felony in some states)* incurred when an individual was an18 year old high school student would prevent an experienced, highly educated, pain management physician from being associated with a pain clinic in WV. The nursing home rules, in comparison, require the past crime to have been related in some way to that work setting. This prohibition as written is overly broad and would likely not withstand judicial scrutiny.

5. §69-8-6.1 .

This section prohibits clinics from hiring employees or becoming associated with any person until such time as the fingerprint check is completed and the results have been submitted to the DHHR for review and approval. With the current time frame associated with the new company, L-1, used by the state for fingerprint background checks, and DHHR's well-meaning, yet inefficient review and approval rate for almost anything in which it does not have an established deadline for response, this rule would effectively delay new hirings for up to 6 months. Even in the nursing home setting, OHFLAC does not have this requirement. This prior approval is unnecessary and detrimental to running a business in the state of WV.

6. §69-8-3.1.a.

The drugs listed in 3.1.a. do not all fall under the definition of opioid drug, found in section 2.12. Tramadol represents one of those drugs that should not be included in this list.

7. §69-8-9.

Patients at pain clinics certainly have some rights. However, the actual wording used in this section appears to give patients an absolute RIGHT to demand to be seen and treated at private pain clinics. For instance, 9.1.b. states that patients have "the right to receive treatment" and that the treatment must be "provided

in a fair and impartial manner regardless of race, sex, age, sexual orientation and/or religion". Section 9.1.f. refers to "the right to treatment at a pain management clinic" and goes on to discuss that the clinic must be adequately staffed. Patients cannot demand to be seen and treated and this rule cannot use wording that, even inadvertently, states so. Especially in this field of medical treatment, patients are dismissed due to abuses, including diversion, of medications/drugs. This unfortunate language will give patients fodder for challenging pain clinic physician's dismissal of them and create a new legal liability for physicians. Likewise, the grievance process is completely inappropriate in this field of medical practice. Patients have access to complaints via the Board of Medicine. Creating a duplicate complaint system is not meaningful or economical. If a physician has determined that it is appropriate to dismiss a patient because he has determined the patient is diverting medications or in possession of/has ingested a controlled substance for which he does not hold a prescription, the physician now will have to deal with a claim of reprisal under 9.2.d. Chronic pain management clinics are not in-patient settings in which these types of patient rights are applicable and appropriate.

8. §69-8-10.2.a.

According to the rule, a patient's initial assessment at the pain clinic "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." This would require any pain clinic, interventional or medical, to have numerous specialists available for the initial patient assessment. This requirement makes no logical sense and is not a reflection of the reality of the practice of medicine in any known culture or country in the world. The pain management clinics accept referrals from physicians, some specialists, some non-specialists. The patients have been deemed to have chronic pain. This could have been determined by specialists or by another type of provider not commonly thought of as a specialist. The pain management physicians should concur with the chronic pain diagnosis by review of the referral and the supporting data (the referring physician's records, various imaging studies, test results, etc.) To then require a pain clinic to furnish an additional initial assessment by a specialist in every area of the body for which an 80 year old is experiencing chronic pain is unnecessary and serves no legitimate purpose with the other safeguards found in other sections of this rule.

9. §69-8-10.2.b.5.

The requirement found in these sections, that the physician determine a patient's current dependence on a controlled substance, is outside of the scope of practice of a pain management physician. Dependency can be physiological or psychological and there is a vast difference between the two. Importantly, though, pain physicians are not addiction specialists and determining dependence is within an addiction specialist's scope of practice. Dependence and addiction are not required areas of specialty training for even the highest level of pain management physicians.

10. §69-8-10.2, 10.3, 10.4 and 9.1.c. etc..

The rule requires patients to be treated by the pain clinic physician every 90 days. It requires review of the patient plan of care every 90 days. This requirement is true even if the patient isn't actively being treated or seen by the clinic. Even if the patient and physician agree that the patient is successfully managing his/her chronic pain and can return for care on an as needed basis, this rule would now require the patient to return every 90 days for an examination whether the patient or physician deem it necessary. These requirements will force some patients and health care insurers, including the State of WV, to incur unnecessary medical costs, and serve to replace the medical judgment of physicians. OHFLAC should carefully reconsider these requirements.

11. §69-8-10.4.b.4.

OHFLAC should clarify what it means by "positive drug test." Does this mean positive for a drug other than what the pain clinic physician is prescribing? Positive for an illegal drug such as marijuana? Positive for any drugs, opiod drugs, the drugs listed under 3.1.a. or any for controlled substances? This section is unclear as written.

12. §69-8-11.1.

In this section, as well as other sections, the rule states that facilities must comply with all applicable state and federal laws, rules, regulations, etc. That is an appropriate and sufficiently broad requirement for OHFLAC to include. However, OHFLAC certainly has no authority to command that entities are subject to a federal law merely because OHFLAC wishes them to be. HIPAA recognizes that there are health care providers that are not subject to its requirements. If a WV health care provider is not subject to HIPAA pursuant to HIPAA's own terms, OHFLAC has no legal authority under this rule to impose HIPAA's requirements on that WV provider. Many of the provisions of HIPAA are not reasonably related to the purpose of this rule. The last sentence of 11.1 must be deleted in its entirety. This sentence could not withstand a legal challenge on this issue.

13. **Unnecessary Oversight Provisions.**

While it is appreciated that OHFLAC's survey experience and expertise lies in the long-term care setting industry, and somewhat so in the hospital setting, it is more than surprising to see how many of those requirements have made their way into this licensure requirement. Many of them have no logical bearing whatsoever on legitimate chronic pain management clinic oversight. In addition to the items set forth above, other example include, the requirement of an administrator (§69-8-6.6); an infection control designee with background, education and experience in infection control (§69-8-14); incident and adverse events reporting (of seriously questionable data unsupported by any standard of medical practice) (§69-8-15), the requirement that a medical office receive pre-approval for facility construction or renovations plans (§69-8-7.2); the credentialing requirements akin to those found in a hospital where physicians are granted specific privileges (§69-8-8.4); and the voluminous quality assurance and performance improvement requirements(§69-8-13). Few of these

requirements *may* be applicable to large, interventional pain medicine practices. Many are not necessary to accomplish the purposes set forth by this legislation. Most are clearly overly burdensome to small, medical pain management practices. All must be reevaluated. In particular, the adverse events list in §69-8-15.2 places a harsh burden on physicians, requiring them at times to violate a physician-patient confidence. Under 15.2.b., if a patient reports she attempted suicide, the physician is required to broadcast that to "the appropriate authority" and complete a thorough investigation? What does a thorough investigation entail? Does it includes further broadcasting of the suicide attempt, a uniquely person and highly confidential event, to family, friends, other local authorities? If elimination of these requirements is not feasible for all chronic pain management clinics, OHFLAC needs to recognize the differences in types and sizes of clinics and regulate accordingly, as other states have done.

Governor Tomblin's own announcement on the new WV code provisions, one of which is the Chronic Pain Clinic Licensing Act, states: "The new law cracks down hard on the underlying causes of our state's drug problem by strengthening many of our enforcement guidelines and implementing many critical reforms. It allows us to shut down so-called "pill mills" and stop "doctor shopping" ***while also protecting legitimate pain clinics and making sure those with real chronic pain can receive treatment.***" *(Governor's website announcement regarding the passage of SB 437.)* Unfortunately, this rule is so overarching that it does not protect the legitimate pain clinics and will not ensure West Virginia's access to legitimate medication needs. What it does ensure is that legitimate medical pain management clinics will not be able to operate, creating yet another significant barrier to pain management for West Virginians. As a result, though, it also ensures much less work for OHFLAC.

This rule, as outlined in all the issues set forth above, does not set up a workable pain clinic licensure oversight. It merely makes it virtually impossible for many legitimate clinics to exist in WV. With the elderly population in this state, many primary care offices will find themselves to be considered a chronic pain clinic. Many will not be able to meet the requirements of this rule. The effect will be force patients to ERs and urgent care centers for their medical pain management needs, creating a measurable strain on the current system of patient care. While oversight of pain clinics is long overdue in WV, oversight needs to be balanced carefully with the needs of patients for access to care. This rule does not represent that balance.

Laura S. Rhodes, M.S.N., R.N.
Executive Director

email: mboard@wv.gov
web address: www.wvrnboard.com

TELEPHONE:
(304) 558-3596
FAX (304) 558-3666

STATE OF WEST VIRGINIA
BOARD OF EXAMINERS FOR REGISTERED PROFESSIONAL NURSES
101 Dee Drive, Suite 102
Charleston, WV 25311-1620

January 3, 2013

Anita Barnhouse
Department of Health and Human Resources
Office of Health Facility Licensure and Certification
408 Leon Sullivan Way
Charleston, WV 25301

Dear Ms. Barnhouse,

In review of the Series 8 rule Chronic Pain Management Clinic Licensure the term used in 8.2.c., 8.3.c., and 8.4.a., advanced practice nurse is incorrect and needs replaced with the term advanced practice registered nurse to be congruent with current law.

The term used in 10.2.d advanced nurse practitioner is incorrect and needs replaced with the term advanced practice registered nurse to be congruent with current law.

For the Board,

Laura Rhodes RN

Laura Rhodes, MSN, RN
Executive Director
WV RN Board
101 Dee Drive, Suite 102
Charleston, WV 25311-1620

Barnhouse, Anita L

From: trustworthyllp@msn.com on behalf of Mark Radcliffe [mark@protectpaincare.org]
Sent: Wednesday, January 02, 2013 10:49 AM
To: Barnhouse, Anita L
Cc: Mark Radcliffe, President, PPPFD, Inc
Subject: Proposed Rule Comments: Chronic Pain Mgmt Clinic Licensure
Attachments: PPPFD Comments WV Pain Clinic Licensure.doc

Dear Ms. Barnhouse,

The proposed rule is a GREAT start on a serious problem!

Thank YOU so much for this opportunity to write to you our most urgent concerns about the proposed rule.

Attached to this email are the comments we are mailing by noon today, January 2, 2013. (My laptop clock is set up one day later (Jan 3) because of calibration for veracity technology research we are doing in the Middle East. I hope the date and time you receive my email reflects today, January 2, 2013.)

The mission of our organization is to develop innovative technology designed to protect the pain care of law-abiding chronic pain patients while we work to screen out and prosecute the law-breaking patients who hurt society.

We are very pleased with **most** of the Proposed Chronic Pain Management Clinic Licensure Legislative Rule!

However, you will read about some serious concerns we have with a few aspects of the proposed rule.

The BIGGEST concern we have is the degradation of care that could result if sufficient time and flexibility is not granted for Designated Physician Owners to obtain the mostly irrelevant training requirement certification detailed in 6.5.b.2.

We have a variety of other miscellaneous questions and concerns but our most serious concerns are attached.

Will we receive a response to our concerns listed in this correspondence? If so, in what venue and when?

Again, thank you for the opportunity to comment!

Mark Radcliffe
Office 304-860-8825
www.protectpaincare.org

PPPFD, Inc.
213 Pinewood Drive
Shady Spring, WV 25918

Comments on Proposed Rules: Chronic Pain Management Clinic Licensure

To: Anita Barnhouse, Department of Health and Human Resources

Dear Ms. Barnhouse, January 2, 2013

First and foremost, please accept our compliments on a great start in addressing a HUGE problem!

However we have major concerns over segments of these proposed rules that will likely serve only to make it **more difficult for us law-abiding patients** to get the pain medicine we legitimately need. Concerns:

1. CONFLICT OF INTEREST: A member of our organization heard Doctor Paul Skaff boast that he "helped" Delegate Doug Skaff "write the pain law." Doctor Skaff is certified by the American Board of Anesthesiology (ABA) as an anesthesiologist. His influence apparently resulted in the pain law requiring interventional specialty credentialing as a training requirement for Designated Physician Owners. Why? What do "needle jockeys" know about appropriate **oral** opiate pharmacotherapy? Many, if not most, interventional pain specialists refuse to prescribe oral opiate pain meds! The few who do, know that they can **require** patients to receive expensive, painful, yet frequently ineffective injections BEFORE agreeing to prescribe an oral opiate analgesic. Many chronic pain patients report having to endure **painful** injections that "don't help relieve my pain" in order to receive their pain meds. Doesn't that qualify as a fraudulent practice costing the state and private insurances millions?
2. WHY NOT SIMPLY ENFORCE THE PAIN MEDICINE GUIDELINES? The American Pain Society (APS) and the American Academy of Pain Medicine (AAPM) published the first comprehensive, evidence-based clinical practice guideline to assist clinicians in prescribing potent opiate pain medications for patients with chronic non-cancer pain. The guideline was published in the February 2009 issue of *The Journal of Pain*. Why not require ALL pain management clinic physicians (owners and prescribers) to be certified and **tested periodically by the Licensure Office** on this guideline?
3. WHY NOT REQUIRE A CHRONIC PAIN DIAGNOSIS CODE ON THE PRESCRIPTION before the pharmacist is permitted to dispense the opiate pain medicine for chronic pain? Why not track the chronic pain diagnosis codes along with the pain medicine in the Board of Pharmacy database?
4. PHARMACOVIGILANCE GUIDELINES: The Pain Medicine Guidelines also detail techniques for stratifying patients into diversion risk categories of Low, Moderate, or High Risk. For example, the frequency of random urine drug tests and pill counts can be established systematically based on patient histories. It is also important to recognize that fraudulent patients will borrow or rent pills from friends, family, or co-conspirators in order to pass random pill counts. Drugs.com has an excellent pill identifier tool that can help pain clinic staff identify "street pills" brought into the clinic for random pill counts.
5. SHOULDN'T **ALL** TOXICOLOGY RESULTS BE CONFIRMED? For example, if a patient is prescribed oxycodone on a chronic basis and their point of care drug screen shows a "positive" for oxycodone, the urine may in fact be "negative" for oxymorphone (primary analgesic metabolite of oxycodone). Therefore, shouldn't that toxicology test result be confirmed by LCMS technology?

Law-abiding chronic pain patients want to help STOP law-breaking chronic pain patients! Thank You!

Mark Radcliffe Signed Original Sent in U. S. Mail

Mark Radcliffe, PPPFD President
mark@protectpaincare.org
304-860-8825

Barnhouse, Anita L

From: trustworthyllp@msn.com on behalf of Mark Radcliffe [mark@protectpaincare.org]
Sent: Wednesday, January 02, 2013 11:48 AM
To: Barnhouse, Anita L
Subject: RE: Proposed Rule Comments: Chronic Pain Mgmt Clinic Licensure

Ms. Barnhouse,

I just returned from mailing the original comments via U.S. Mail to you before noon, January 2, 2013.

One last comment before noon today: I recommend DHHR institute a rule prohibiting interventional procedures (injections, implants, etc) from being done by the same physician who signs the opiate pain medicine prescription.

Ideally, the opiate pain medicine prescriptions should be signed by a physician in a completely different practice to create a Separation of Duties that will drastically reduce an expensive monetary drain on the chronic pain healthcare budget for Medicaid, Medicare, and private insurances!

Please reply back to me by email confirming receipt of my emails today, okay? Thanks!

Mark Radcliffe
Office 304-860-8825
www.protectpaincare.org

From: mark@protectpaincare.org
To: anita.l.barnhouse@wv.gov
CC: mark@protectpaincare.org
Subject: Proposed Rule Comments: Chronic Pain Mgmt Clinic Licensure
Date: Wed, 2 Jan 2013 10:48:58 -0500

Dear Ms. Barnhouse,

The proposed rule is a GREAT start on a serious problem!

Thank YOU so much for this opportunity to write to you our most urgent concerns about the proposed rule.

Attached to this email are the comments we are mailing by noon today, January 2, 2013. (My laptop clock is set up one day later (Jan 3) because of calibration for veracity technology research we are doing in the Middle East. I hope the date and time you receive my email reflects today, January 2, 2013.)

The mission of our organization is to develop innovative technology designed to protect the pain care of law-abiding chronic pain patients while we work to screen out and prosecute the law-breaking patients who hurt society.

We are very pleased with **most** of the Proposed Chronic Pain Management Clinic Licensure Legislative Rule!

However, you will read about some serious concerns we have with a few aspects of the proposed rule.

The BIGGEST concern we have is the degradation of care that could result if sufficient time and flexibility is not granted for Designated Physician Owners to obtain the mostly irrelevant training requirement certification detailed in 6.5.b.2.

We have a variety of other miscellaneous questions and concerns but our most serious concerns are attached.

Will we receive a response to our concerns listed in this correspondence? If so, in what venue and when?

Again, thank you for the opportunity to comment!

Mark Radcliffe
Office 304-860-8825
www.protectpaincare.org

Warren Hilsbos
448 E. Brockway Ave.
Morgantown, WV 26501

Dec. 26, 2012

Anita Barnhouse
Department of Health and Human Services
Office of Health Facility Licensure and Certification
408 Leon Sullivan Way
Charleston, West Virginia 25301

Re: Proposed Rule – Chronic Pain Management Clinic Licensure

Dear Ms. Barnhouse:

No conscientious, informed citizen can deny that West Virginia has a severe problem with prescription pill abuse. We all want "pill mills" relegated to history.

As the son of a family physician, however, I also know that there are many people in despeate need of treatment for excruciating pain.

As one of those citizens whose job it is to oversee the crafting the laws of our state, it is your duty to conduct the utmost due diligence to ensure that each law achieves its goal without undue harm to good people.

That is why I request you strongly consider the proposed changes attached. The problem with the proposed rule is simply that is vague. Though it is "simply" that does not lessen its importance, but makes more egregious the error should it be made law. I say error because I do believe it is unintentional. From this point on, this rule and its impact can only be intentional

and so will be considered a monumental failure.

We all want the abuse of medication stopped and patients to recieve treatment. Let us not forsake one for the other.

Sincerely,

Warren Kuhl

How to Fix the Pain Clinic Licensure Rule—
Which Facilities Are Pain Clinics?

Pain Clinic Licensure Rule (69-8-3.1.a)

"Where in any one month more than fifty (50) percent of all patients treated at the clinic, facility or office are treated for chronic pain resulting from non-malignant conditions and are prescribed administered or dispensed tramadol, carisoprodol, opioid drugs or other Schedule II or Schedule III controlled substances for such diagnosis. This ratio is calculated by assessing *the total number of patients treated during any one month and then determining the number of patients treated for a diagnosis of chronic pain* and pursuant to such diagnosis were prescribed, administered or dispensed tramadol, carisoprodol, opioid drugs or other Scheduled II or Scheduled III controlled substances."

Comment

The new law defines a pain clinic. The proposed regulation seeks to give a more clear definition, and in the process changes it substantially. Both versions of the definition involve the question, "What proportion of the facility's patients are chronic pain patients?" We are to divide the number of "pain patients" by the number of "all patients". How we get each of these numbers can make a big difference.

The law says "Where in any one month more than fifty (50) percent of patients of the prescribers or dispensers". The proposed regulation says "Where in any one month more than fifty (50) percent of all patients treated". The definition in the law is not very clear. The definition in the regulation is not any more clear.

To me, the wording in the law suggests that "all patients" means "all of the prescriber's patient population". Those in the field would usually take that to mean all the patients seen within the last 2 years.

In contrast, the wording in the proposed regulation might mean that "all patients" are "all patients treated during that month". If this unclear wording is allowed to take on that meaning, it drastically reduces the number of "all patients".

Both definitions do make it clear that we are not to look beyond the one month in question when counting "pain patients". It is still unclear inother ways. To make this clear, we should specify "unique patients". That gets rid of double counting in the event that a pain patient was seen more than once in a month.

Putting it all together, here is proposed revised language for the second of two sentences in 3.1.a.:

> "This ratio is calculated by assessing the total number of patients visits (encounters) during a continuous period of 2 years and then determining the number of unique patients seen during one calendar month for a principle diagnosis of chronic pain who, pursuant to such a diagnosis, were prescribed, administered or dispensed tramadol, carisoprodol, opioid medication, or another Schedule II or Schedule III controlled substance."

December 20, 2012

Anita Barnhouse
Department of Health and Human Resources
Office of Health Facility Licensure and Certification
408 Leon Sullivan Way
Charleston, West Virginia 25301

Re: Proposed Rule—Chronic Pain Management Clinic Licensure

Dear Ms. Barnhouse:

We all want to put a stop to "pill mills" that prescribe enormous quantities of pain pills with little or no medical reason.

Fifteen per cent of Americans suffer from chronic pain. Many of them go untreated or undertreated. Access to care is a serious problem. Even in populated areas around here, there is unmet need.

The proposed rule on Chronic Pain Management Clinic Licensure has been written in a way that could harm many pain patients.

Please see the attachment to this letter for an outline of changes in the proposed rule that would help to avoid unintended consequences affecting many West Virginians.

Without these changes, the new rule will hurt many of us in ways not foreseen by those who drafted this proposed rule.

Without these changes, good doctors will close their practices to people in pain, or even worse, move their offices to nearby states that still value the full range of what these doctors have to offer.

Thank you for your careful consideration of ways to correct what is wrong with a regulation whose core purpose we all agree with.

Sincerely,

John B. Wilson

How to Fix the Pain Clinic Licensure Rule—
Which Facilities Are Pain Clinics?

Pain Clinic Licensure Rule (69-8-3.1.a)

"Where in any one month more than fifty (50) percent of all patients treated at the clinic, facility or office are treated for chronic pain resulting from non-malignant conditions and are prescribed administered or dispensed tramadol, carisoprodol, opioid drugs or other Schedule II or Schedule III controlled substances for such diagnosis. This ratio is calculated by assessing *the total number of patients treated during any one month and then determining the number of patients treated for a diagnosis of chronic pain* and pursuant to such diagnosis were prescribed, administered or dispensed tramadol, carisoprodol, opioid drugs or other Scheduled II or Scheduled III controlled substances."

Comment

The new law defines a pain clinic. The proposed regulation seeks to give a more clear definition, and in the process changes it substantially. Both versions of the definition involve the question, "What proportion of the facility's patients are chronic pain patients?" We are to divide the number of "pain patients" by the number of "all patients". How we get each of these numbers can make a big difference.

The law says "Where in any one month more than fifty (50) percent of patients of the prescribers or dispensers". The proposed regulation says "Where in any one month more than fifty (50) percent of all patients treated". The definition in the law is not very clear. The definition in the regulation is not any more clear.

To me, the wording in the law suggests that "all patients" means "all of the prescriber's patient population". Those in the field would usually take that to mean all the patients seen within the last 2 years.

In contrast, the wording in the proposed regulation might mean that "all patients" are "all patients treated during that month". If this unclear wording is allowed to take on that meaning, it drastically reduces the number of "all patients".

Both definitions do make it clear that we are not to look beyond the one month in question when counting "pain patients". It is still unclear inother ways. To make this clear, we should specify "unique patients". That gets rid of double counting in the event that a pain patient was seen more than once in a month.

Putting it all together, here is proposed revised language for the second of two sentences in 3.1.a.:

> "This ratio is calculated by assessing the total number of patients visits (encounters) during a continuous period of 2 years and then determining the number of unique patients seen during one calendar month for a principle diagnosis of chronic pain who, pursuant to such a diagnosis, were prescribed, administered or dispensed tramadol, carisoprodol, opioid medication, or another Schedule II or Schedule III controlled substance."

December 20, 2012

Anita Barnhouse
Department of Health and Human Resources
Office of Health Facility Licensure and Certification
408 Leon Sullivan Way
Charleston, West Virginia 25301

Re: Proposed Rule—Chronic Pain Management Clinic Licensure

Dear Ms. Barnhouse:

We all want to put a stop to "pill mills" that prescribe enormous quantities of pain pills with little or no medical reason.

Fifteen per cent of Americans suffer from chronic pain. Many of them go untreated or undertreated. Access to care is a serious problem. Even in populated areas around here, there is unmet need.

The proposed rule on Chronic Pain Management Clinic Licensure has been written in a way that could harm many pain patients.

Please see the attachment to this letter for an outline of changes in the proposed rule that would help to avoid unintended consequences affecting many West Virginians.

Without these changes, the new rule will hurt many of us in ways not foreseen by those who drafted this proposed rule.

Without these changes, good doctors will close their practices to people in pain, or even worse, move their offices to nearby states that still value the full range of what these doctors have to offer.

Thank you for your careful consideration of ways to correct what is wrong with a regulation whose core purpose we all agree with.

Sincerely,

Jacqueline K. Stiles

December 20, 2012

Anita Barnhouse
Department of Health and Human Resources
Office of Health Facility Licensure and Certification
408 Leon Sullivan Way
Charleston, West Virginia 25301

Re: Proposed Rule—Chronic Pain Management Clinic Licensure

Dear Ms. Barnhouse:

We all want to put a stop to "pill mills" that prescribe enormous quantities of pain pills with little or no medical reason.

Fifteen per cent of Americans suffer from chronic pain. Many of them go untreated or undertreated. Access to care is a serious problem. Even in populated areas around here, there is unmet need.

The proposed rule on Chronic Pain Management Clinic Licensure has been written in a way that could harm many pain patients.

Please see the attachment to this letter for an outline of changes in the proposed rule that would help to avoid unintended consequences affecting many West Virginians.

Without these changes, the new rule will hurt many of us in ways not foreseen by those who drafted this proposed rule.

Without these changes, good doctors will close their practices to people in pain, or even worse, move their offices to nearby states that still value the full range of what these doctors have to offer.

Thank you for your careful consideration of ways to correct what is wrong with a regulation whose core purpose we all agree with.

Sincerely, Paul M Gilstorf Jr.

How to Fix the Pain Clinic Licensure Rule—
Which Facilities Are Pain Clinics?

Pain Clinic Licensure Rule (69-8-3.1.a)

"Where in any one month more than fifty (50) percent of all patients treated at the clinic, facility or office are treated for chronic pain resulting from non-malignant conditions and are prescribed administered or dispensed tramadol, carisoprodol, opioid drugs or other Schedule II or Schedule III controlled substances for such diagnosis. This ratio is calculated by assessing *the total number of patients treated during any one month and then determining the number of patients treated for a diagnosis of chronic pain* and pursuant to such diagnosis were prescribed, administered or dispensed tramadol, carisoprodol, opioid drugs or other Scheduled II or Scheduled III controlled substances."

Comment

The new law defines a pain clinic. The proposed regulation seeks to give a more clear definition, and in the process changes it substantially. Both versions of the definition involve the question, "What proportion of the facility's patients are chronic pain patients?" We are to divide the number of "pain patients" by the number of "all patients". How we get each of these numbers can make a big difference.

The law says "Where in any one month more than fifty (50) percent of patients of the prescribers or dispensers". The proposed regulation says "Where in any one month more than fifty (50) percent of all patients treated". The definition in the law is not very clear. The definition in the regulation is not any more clear.

To me, the wording in the law suggests that "all patients" means "all of the prescriber's patient population". Those in the field would usually take that to mean all the patients seen within the last 2 years.

In contrast, the wording in the proposed regulation might mean that "all patients" are "all patients treated during that month". If this unclear wording is allowed to take on that meaning, it drastically reduces the number of "all patients".

Both definitions do make it clear that we are not to look beyond the one month in question when counting "pain patients". It is still unclear inother ways. To make this clear, we should specify "unique patients". That gets rid of double counting in the event that a pain patient was seen more than once in a month.

Putting it all together, here is proposed revised language for the second of two sentences in 3.1.a.:

> "This ratio is calculated by assessing the total number of patients visits (encounters) during a continuous period of 2 years and then determining the number of unique patients seen during one calendar month for a principle diagnosis of chronic pain who, pursuant to such a diagnosis, were prescribed, administered or dispensed tramadol, carisoprodol, opioid medication, or another Schedule II or Schedule III controlled substance."

Anita Barnhouse
DHHR
Ofc. of Health Facility Licensure & Certification
408 Leon Sullivan Way
Charleston, WV 25301

Dear Ms. Barnhouse,

I understand a new law is waiting to be passed into law regarding prescription pain medication. I further understand that many people abuse and lie to obtain prescription pain pills. According to a television public announcement that says the majority of child abuse, child neglect and death of children abused and/or neglected are done so by parents who abuse drugs. Those who do abuse, lie to obtain, or buy illegal prescription medications do need dealt with by preventing them from obtaining these medications.

However, with the way the law is written now, I feel it will

prohibit patients from seeking medical attention or following up with their primary care doctor because of the way it is written. Doctors will be "picking and choosing" who they will treat because of this law. I am not asking you to not pass this law, but reword it or simplify it and clarify the wording so the doctors that "feed" their patients pain pills and the patients who lie or cause injury to themselves to obtain them can be eliminated.

My husband is currently prescribed pain medication from a back injury. Since his injury he suffers, also, from degenerative disc disease. Between the injury and the disease, he is classified as having chronic pain. He opted to have surgery, however, the surgeon refused to do any back/disc repair surgery due to the "worsening" of symptoms. My husband takes his medication as prescribed, often times he has either good days or bad days

when speaking of his pain. Without his medication I fear my husband would not be able to function as well as he does, nor tolerate the "break through" pain he experiences. He was recently diagnosed as being bi-polar. With the two diseases he suffers uncertainty on a daily basis.

Instead of passing laws to eliminate or limit the patients doctors see for pain management, have doctors focus only on those patients that have a legitimate stack (that took years to diagnose) of medical records, MRI's, and other x-rays and tests that show this injury and disease.

Let us as a nation find ways to help those that need help and truly try to help themselves.

Thank you for your time in this matter and all the hard work you do.

Sincerely

Teri McClellon

How to Fix the Pain Clinic Licensure Rule—
Which Facilities Are Pain Clinics?

Pain Clinic Licensure Rule (69-8-3.1.a)

"Where in any one month more than fifty (50) percent of all patients treated at the clinic, facility or office are treated for chronic pain resulting from non-malignant conditions and are prescribed administered or dispensed tramadol, carisoprodol, opioid drugs or other Schedule II or Schedule III controlled substances for such diagnosis. This ratio is calculated by assessing *the total number of patients treated during any one month and then determining the number of patients treated for a diagnosis of chronic pain* and pursuant to such diagnosis were prescribed, administered or dispensed tramadol, carisoprodol, opioid drugs or other Scheduled II or Scheduled III controlled substances."

Comment

The new law defines a pain clinic. The proposed regulation seeks to give a more clear definition, and in the process changes it substantially. Both versions of the definition involve the question, "What proportion of the facility's patients are chronic pain patients?" We are to divide the number of "pain patients" by the number of "all patients". How we get each of these numbers can make a big difference.

The law says "Where in any one month more than fifty (50) percent of patients of the prescribers or dispensers". The proposed regulation says "Where in any one month more than fifty (50) percent of all patients treated". The definition in the law is not very clear. The definition in the regulation is not any more clear.

To me, the wording in the law suggests that "all patients" means "all of the prescriber's patient population". Those in the field would usually take that to mean all the patients seen within the last 2 years.

In contrast, the wording in the proposed regulation might mean that "all patients" are "all patients treated during that month". If this unclear wording is allowed to take on that meaning, it drastically reduces the number of "all patients".

Both definitions do make it clear that we are not to look beyond the one month in question when counting "pain patients". It is still unclear inother ways. To make this clear, we should specify "unique patients". That gets rid of double counting in the event that a pain patient was seen more than once in a month.

Putting it all together, here is proposed revised language for the second of two sentences in 3.1.a.:

> "This ratio is calculated by assessing the total number of patients visits (encounters) during a continuous period of 2 years and then determining the number of unique patients seen during one calendar month for a principle diagnosis of chronic pain who, pursuant to such a diagnosis, were prescribed, administered or dispensed tramadol, carisoprodol, opioid medication, or another Schedule II or Schedule III controlled substance."

DECEMBER 30, 2012

Sunday, December 30, 2012
12:42 PM

ANTIA BARNHOUSE
DEPARTMENT OF HEALTH & HUMAN RESOURCES
OFFICE OF HEALTH FACILITY LICENSURE & CERTIFICATION
408 LEON SULLIVAN WAY
CHARLESTION, WEST VIRGINIA 25301
RE: PROPOSED RULE-CHRONIC PAIN MANAGEMENT CLIENT LICENSURE

WENDY K. MORRIS
RR# 8, BOX 155
FAIRMONT, WV 26554
304-363-0021 (HOME)

DEAR MS. BARNHOUSE,

MY MAME IS WENDY K. MORRIS AND I AM A PERSON THAT SUFFERS FROM CHRONIC PAIN. I WAS BORN IN 1964 AT SEYMOUR JOHNSON AIR FORCE BASE LOCATED NEAR GOLDSBORO, NORTH CAROLINA. I WAS BORN WITHOUT A HIPSOCKET. MY MOTHER KNEW THERE WAS SOMETHING WRONG BECAUSE EVERY TIME SHE CHANGED MY DIAPER I WOULD CRY OUT FOR DURNIG AND FOR HOURS AFTERWARDS. THE PHYSICIAN AT THE AIR FORCE MEDICAL CENTER WAS VERY OLD AND CONTINOUSLY INFORMED MY PARENTS THERE WAS NOTHING WRONG. THANK GOD MY FATHER WAS TRANSFERRED TO AN AIR FORCE BASE LOCATED NEAR COLUMBUS, OHIO WHEN I WAS APPROX. SIX MONTHS OLD. THE MEDICAL FACILITY AND PHYSICIANS (SURGEONS) AVAILABLE TO SERVICE MEN AND THEIR FAMILILES WAS IN OHIO WAS MUCH MORE ADVANCED AND SURGERY WAS PERFORMED IMMEDIATELY IN AN ATTEMPT TO FORM A HIPSOCKET FOR MY LEFT HIP. THE INTIAL SURGERY CONSISTED OF CUTTING THE MUSCLES AND BONE IN MY LEFT HIP & THIGH. A PIN WAS ALSO PLACED IN MY THIGH IN AN ATTEMPT TO MAKE THE BONE HEAL. I WAS LAYED ON A BOARD AND MY LEFT LEG WAS PLACED STRAIGHT OUT TO THE LEFT AND SAND BAGS WERE PUT ON IT IN ORDER FOR IT TO BE IMMOVABLE. THIS WAS A NEW TYPE OF SURGERY, ACTUALLY IT WAS EXPERMENTAL AT THAT TIME, THEREFORE THE PHYSICIAN'S (SURGEONS) DID NOT HAVE THE KNOWLEDGE NECESSARY TO PERFORM THE SURGERY AND/OR RECOVERY PROCEDURES IN ORDER TO MAKE THE PROCESS SUCCESSFUL. MY LEG WAS LEFT STRAIGHT OUT TO THE LEFT OF MY BODY TOO LONG THEREFORE, IT FORMED JUST AS THEY HAD PUT IT (STRAIGHT OUT TO THE LEFT). THE SECOND SURGERY WAS PERFORMED JUST AS THE FIRST WAS BUT THIS TIME THEY PLACED MY LEFT LEG IN A CAST FROM MY FOOT TO MY WAIST AND THE CAST EXTENDED DOWN MY RIGHT LET TO MY KNEE. I WORE THIS CAST UNTIL I WAS ALMOST FOUR YEARS OLD. WHEN THE CAST WAS REMOVED MY HIPSOCKET HAD FORMED CORRECTLY AS WELL AS MY LEG, WHICH NOW EXTENDED DOWN STRAIGHT IN UNISON WITH MY RIGHT LEG. I NEVER TOOK MY FIRST STEP UNTIL AFTER I WAS FOUR YEARS OLD. I AM EXTREMELY THANKFUL THAT I HAD ACCESS TO SURGEONS WHICH WERE NOT AFRAID TO EXPERMENT WITH NEW TECHNIQUES.

I HAVE HAD TO BE EXTREMELY CAREFUL MY ENTIRE LIFE NOT TO DISLOCATE MY LEFT HIP BECAUSE IF THIS HAPPENS I WILL BE IN A WHEELCHAIR FOR THE REMAINDER OF MY LIFE. MY LEFT LET IS OVER ONE INCH SHORTER THAN MY RIGHT LEG WHICH HAS CAUSED MY SPINE TO BE EXTREMELY CROOKED HAS CAUSED ME TO SUFFER FROM NECK AND SHOULDER PAIN WHICH IS UNBEARABLE 50% OF THE TIME. THE CAST WHICH WAS TO MY WAIST CAUSED MY LOWER BACK TO BE DEFORMED WHICH CAUSES ME TO SUFFER FROM LOWER BACK PAIN 80% OF THE TIME. MEDICALLY, I NEEDED A BUILT UP SHOE TO WEAR ON MY LEFT FOOT BUT, MY FATHER WAS TRANSFERRED AGAIN AND AGAIN THEREFORE, MY PARENTS DID NOT RECEIVE THAT MEDICAL ADVICE AND WHEN I DID GET THAT ADVICE IT WAS MUCH TOO LATE TO ATTEMPT TO STRAIGHTEN OUT THE MEDICAL PROBLEMS.

APPROX. 12 YEARS AGO MY PRIMARY PHYSICIAN PRESCRIPED METHADONE FOR MY PAIN. MY QUALITY OF LIFE WAS EXTREMELY POOR PRIOR TO RECEIVING THIS WONDER DRUG. I WAS UNABLE TO PARTICIPATE IN FAMILY VACATIONS BECAUSE I WAS TOO MUCH OF A BURDEN UPON MY CHILDREN AND MY HUSBAND. THE LAST FEW VACATIONS I DID GO ON WITH MY FAMILY PRIOR TO BEING PRECSRIBED PAIN MEDICATION, MY HUSBAND HAD TO PUSH ME AROUND IN A WHEELCHAIR WHICH MADE IT IMPOSSIBLE FOR HIM TO ENJOY HIS VACATION AND MY CHILDREN WERE NOT ABLE TO EXPERIENCE MUCH JOY EITHER. SINCE I HAVE BEEN RECEIVING PRESCRIPTION PAIN MEDICATION MY QUALITY OF LIFE HAS IMPROVED GREATLY. MY CHILDREN ARE GROWN NOW AND I HAVE A GRANDCHILD. IF I AM UNABLE TO CONTINUE TO RECEIVE MONTHLY PRESCRIPTIONS FROM MY PRIMARY CARE PHYSICIAN DUE TO THIS NEW LAW OR RULE MY QUALTIY OF LIFE WILL DECLINE TO SUCH AN EXTENT THAT I WILL BE TOO MUCH OF A BURDEN UPON MY FAMILY. I AM ALMOST 50 YEARS OLD AND SUFFER FROM MANY OTHER AILMENTS WHICH REQUIRE MEDICATION AS WELL BUT, WITHOUT ACCESS TO THE PAIN MEDICATION I FEAR I WILL HAVE TO BE INSTITIONALIZED SO THAT I WILL NOT RUIN THE LIFE OF MY HUSBAND AND CHILDREN. I HAVE HEALTH INSURANCE THROUGH MY HUSBAND'S EMPLOYER BUT, IT DOES NOT COVER TREATMENT AT A CHRONIC PAIN MANAGENMENT FACILITY. IF I AM UNABLE TO CONTINUE RECEIVING MY PAIN MEDICATION FROM MY PRIMARY CARE PHYSICIAN (WHICH MY INSURANCE COVERS AND I AM ONLY RESPONSIBLE TO PAY A SMALL COPAYMENT FOR EACH VISIT) MY LIFE AS I KNOW IT WILL ABSOUTLEY BE OVER. I AM AMONG THE 15% OF AMERICANS THAT SUFFER FROM CHRONIC PAIN AND THIS NEW LAW OR RULE ENDANGERS ALL OF US FROM RECEIVING THE MEDICAL TREATMENT WE ARE ENTITLED TO RECEIVE. I UNDERSTAND THAT SO MANY PEOPLE HAVE TAKEN ADVANTAGE OF THE SYSTEM AND RECEIVED PRESCTIPTIONS FOR PAIN MEDICATION WHICH THEY DID NOT ACTUALLY NEED BUT, WHY SHOULD I AND THE OTHER PEOPLE WHICH DO NEED THESE MEDICATIONS BE MADE TO SUFFER THE CONSEQUESES FOR OTHERS? THIS NEW LAW/RULE HAS ALREADY CAUSED ME TO BE SINGLED OUT WHEN I GO TO THE PHARMACY TO FILL MY PRECRIPTIONS BY REQUIRING A PHOTO ID EACH TIME I HAVE A PRESCRIPTION FILLED. IT HAS ALSO PUT MY NAME AND INFO. INTO A NATION WIDE DATA BASE WHICH ANY PHYSICIAN OR MEDICAL FACILTIY CAN ACCESS IF I REQUIRE TREATMENT (SUCH AS ANY EMERGENCY ROOM FACILITY) WHICH IN MY EXPERIENCE, CAUSES ME TO BE TREATED AS IF I AM A DRUG ADDICT DUE TO THE SMALL MINDS OF THE PEOPLE THAT PROVIDE TREATMENT ON AN EMGERENCY BASIS. I HAVE NEVER TAKEN ANY STREET DRUGS IN MY LIFE AND I PRIDE MYSELF ON BEING A LAW ABIDING CITIZEN YET, DUE TO THOSE THAT ARE DRUG ADDICTS AND THEIR ACTIONS, I AM LOOKED UPON AS THE SAME. SINCE THE STATE AND FEDERAL GOVERNMENT CANNOT SEEM TO GET CONTROL OF THIS SITUATION THIS NEW LAW/RULE HAS BEEN ENACTED AS WELL AS OTHER LAWS/RULES WHICH ARE UNCONSTITUNTIONAL AND SERIOUSLY INFRINGE UPON MY RIGHTS AS A FREE CITIZEN OF AMERICA (I FEEL THIS STRONG ABOUT WHAT AMERICA HAS COME TO BE). PLEASE, DO SOMETHING TO STOP THIS ENACTMENT AS MY VERY WELL BEING DEPENDS UPON IT AS WELL AS MANY OTHERS. I DO NOT KNOW WHAT ELESE I CAN SAY TO YOU TO MAKE YOU UNDERSTAND HOW THIS LAW/RULE WILL AFFECT ME AND SO MANY OTHERS THAT HAVE DONE NOTHING TO DESERVE THIS SORT OF TREATMENT. I AM ONLY ONE OF THE MANY THAT WILL BE EFFECTED BY THIS LAW/RULE. PLEASE, FIND ANOTHER WAY TO STOP THE PILL MILL OR BETTER YET FIND TO PENALIZE THE DOCTORS AND PATIENTS THAT ARE RESPONSIBLE FOR THIS PROBLEM INSTEAD OF PENALIZING GOOD PEOPLE WHO WILL BE GREATLY EFFECTED UNJUSTLY.

SINCERELY,

Wendy K. Morris

WENDY K. MORRIS

December 20, 2012

Anita Barnhouse
Department of Health and Human Resources
Office of Health Facility Licensure and Certification
408 Leon Sullivan Way
Charleston, West Virginia 25301

Re: Proposed Rule—Chronic Pain Management Clinic Licensure

Dear Ms. Barnhouse:

We all want to put a stop to "pill mills" that prescribe enormous quantities of pain pills with little or no medical reason.

Fifteen per cent of Americans suffer from chronic pain. Many of them go untreated or undertreated. Access to care is a serious problem. Even in populated areas around here, there is unmet need.

The proposed rule on Chronic Pain Management Clinic Licensure has been written in a way that could harm many pain patients.

Please see the attachment to this letter for an outline of changes in the proposed rule that would help to avoid unintended consequences affecting many West Virginians.

Without these changes, the new rule will hurt many of us in ways not foreseen by those who drafted this proposed rule.

Without these changes, good doctors will close their practices to people in pain, or even worse, move their offices to nearby states that still value the full range of what these doctors have to offer.

Thank you for your careful consideration of ways to correct what is wrong with a regulation whose core purpose we all agree with.

Sincerely,

Walter Impellizeri Sr.

How to Fix the Pain Clinic Licensure Rule—
Which Facilities Are Pain Clinics?

Pain Clinic Licensure Rule (69-8-3.1.a)

"Where in any one month more than fifty (50) percent of all patients treated at the clinic, facility or office are treated for chronic pain resulting from non-malignant conditions and are prescribed administered or dispensed tramadol, carisoprodol, opioid drugs or other Schedule II or Schedule III controlled substances for such diagnosis. This ratio is calculated by assessing *the total number of patients treated during any one month and then determining the number of patients treated for a diagnosis of chronic pain* and pursuant to such diagnosis were prescribed, administered or dispensed tramadol, carisoprodol, opioid drugs or other Scheduled II or Scheduled III controlled substances."

Comment

The new law defines a pain clinic. The proposed regulation seeks to give a more clear definition, and in the process changes it substantially. Both versions of the definition involve the question, "What proportion of the facility's patients are chronic pain patients?" We are to divide the number of "pain patients" by the number of "all patients". How we get each of these numbers can make a big difference.

The law says "Where in any one month more than fifty (50) percent of patients of the prescribers or dispensers". The proposed regulation says "Where in any one month more than fifty (50) percent of all patients treated". The definition in the law is not very clear. The definition in the regulation is not any more clear.

To me, the wording in the law suggests that "all patients" means "all of the prescriber's patient population". Those in the field would usually take that to mean all the patients seen within the last 2 years.

In contrast, the wording in the proposed regulation might mean that "all patients" are "all patients treated during that month". If this unclear wording is allowed to take on that meaning, it drastically reduces the number of "all patients".

Both definitions do make it clear that we are not to look beyond the one month in question when counting "pain patients". It is still unclear inother ways. To make this clear, we should specify "unique patients". That gets rid of double counting in the event that a pain patient was seen more than once in a month.

Putting it all together, here is proposed revised language for the second of two sentences in 3.1.a.:

> "This ratio is calculated by assessing the total number of patients visits (encounters) during a continuous period of 2 years and then determining the number of unique patients seen during one calendar month for a principle diagnosis of chronic pain who, pursuant to such a diagnosis, were prescribed, administered or dispensed tramadol, carisoprodol, opioid medication, or another Schedule II or Schedule III controlled substance."

How to Fix the Pain Clinic Licensure Rule—
Which Facilities Are Pain Clinics?

Pain Clinic Licensure Rule (69-8-3.1.a)

"Where in any one month more than fifty (50) percent of all patients treated at the clinic, facility or office are treated for chronic pain resulting from non-malignant conditions and are prescribed administered or dispensed tramadol, carisoprodol, opioid drugs or other Schedule II or Schedule III controlled substances for such diagnosis. This ratio is calculated by assessing *the total number of patients treated during any one month and then determining the number of patients treated for a diagnosis of chronic pain* and pursuant to such diagnosis were prescribed, administered or dispensed tramadol, carisoprodol, opioid drugs or other Scheduled II or Scheduled III controlled substances."

Comment

The new law defines a pain clinic. The proposed regulation seeks to give a more clear definition, and in the process changes it substantially. Both versions of the definition involve the question, "What proportion of the facility's patients are chronic pain patients?" We are to divide the number of "pain patients" by the number of "all patients". How we get each of these numbers can make a big difference.

The law says "Where in any one month more than fifty (50) percent of patients of the prescribers or dispensers". The proposed regulation says "Where in any one month more than fifty (50) percent of all patients treated". The definition in the law is not very clear. The definition in the regulation is not any more clear.

To me, the wording in the law suggests that "all patients" means "all of the prescriber's patient population". Those in the field would usually take that to mean all the patients seen within the last 2 years.

In contrast, the wording in the proposed regulation might mean that "all patients" are "all patients treated during that month". If this unclear wording is allowed to take on that meaning, it drastically reduces the number of "all patients".

Both definitions do make it clear that we are not to look beyond the one month in question when counting "pain patients". It is still unclear inother ways. To make this clear, we should specify "unique patients". That gets rid of double counting in the event that a pain patient was seen more than once in a month.

Putting it all together, here is proposed revised language for the second of two sentences in 3.1.a.:

> "This ratio is calculated by assessing the total number of patients visits (encounters) during a continuous period of 2 years and then determining the number of unique patients seen during one calendar month for a principle diagnosis of chronic pain who, pursuant to such a diagnosis, were prescribed, administered or dispensed tramadol, carisoprodol, opioid medication, or another Schedule II or Schedule III controlled substance."

December 20, 2012

Anita Barnhouse
Department of Health and Human Resources
Office of Health Facility Licensure and Certification
408 Leon Sullivan Way
Charleston, West Virginia 25301

Re: Proposed Rule—Chronic Pain Management Clinic Licensure

Dear Ms. Barnhouse:

We all want to put a stop to "pill mills" that prescribe enormous quantities of pain pills with little or no medical reason.

Fifteen per cent of Americans suffer from chronic pain. Many of them go untreated or undertreated. Access to care is a serious problem. Even in populated areas around here, there is unmet need.

The proposed rule on Chronic Pain Management Clinic Licensure has been written in a way that could harm many pain patients.

Please see the attachment to this letter for an outline of changes in the proposed rule that would help to avoid unintended consequences affecting many West Virginians.

Without these changes, the new rule will hurt many of us in ways not foreseen by those who drafted this proposed rule.

Without these changes, good doctors will close their practices to people in pain, or even worse, move their offices to nearby states that still value the full range of what these doctors have to offer.

Thank you for your careful consideration of ways to correct what is wrong with a regulation whose core purpose we all agree with.

Sincerely,

Lauren S. Kaznoski

Lauren S. Kaznoski

How to Fix the Pain Clinic Licensure Rule
Which Facilities Are Pain Clinics?

Pain Clinic Licensure Rule (69-8-3.1.a)

"Where in any one month more than fifty (50) percent of all patients treated at the clinic, facility or office are treated for chronic pain resulting from non-malignant conditions and are prescribed administered or dispensed tramadol, carisoprodol, opioid drugs or other Schedule II or Schedule III controlled substances for such diagnosis. This ratio is calculated by assessing *the total number of patients treated during any one month and then determining the number of patients treated for a diagnosis of chronic pain* and pursuant to such diagnosis were prescribed, administered or dispensed tramadol, carisoprodol, opioid drugs or other Scheduled II or Scheduled III controlled substances."

Comment

The new law defines a pain clinic. The proposed regulation seeks to give a more clear definition, and in the process changes it substantially. Both versions of the definition involve the question, "What proportion of the facility's patients are chronic pain patients?" We are to divide the number of "pain patients" by the number of "all patients". How we get each of these numbers can make a big difference.

The law says "Where in any one month more than fifty (50) percent of patients of the prescribers or dispensers". The proposed regulation says "Where in any one month more than fifty (50) percent of all patients treated". The definition in the law is not very clear. The definition in the regulation is not any more clear.

To me, the wording in the law suggests that "all patients" means "all of the prescriber's patient population". Those in the field would usually take that to mean all the patients seen within the last 2 years.

In contrast, the wording in the proposed regulation might mean that "all patients" are "all patients treated during that month". If this unclear wording is allowed to take on that meaning, it drastically reduces the number of "all patients".

Both definitions do make it clear that we are not to look beyond the one month in question when counting "pain patients". It is still unclear inother ways. To make this clear, we should specify "unique patients". That gets rid of double counting in the event that a pain patient was seen more than once in a month.

Putting it all together, here is proposed revised language for the second of two sentences in 3.1.a.:

> "This ratio is calculated by assessing the total number of patients visits (encounters) during a continuous period of 2 years and then determining the number of unique patients seen during one calendar month for a principle diagnosis of chronic pain who, pursuant to such a diagnosis, were prescribed, administered or dispensed tramadol, carisoprodol, opioid medication, or another Schedule II or Schedule III controlled substance."

December 20, 2012

Anita Barnhouse
Department of Health and Human Resources
Office of Health Facility Licensure and Certification
408 Leon Sullivan Way
Charleston, West Virginia 25301

Re: Proposed Rule—Chronic Pain Management Clinic Licensure

Dear Ms. Barnhouse:

We all want to put a stop to "pill mills" that prescribe enormous quantities of pain pills with little or no medical reason.

Fifteen per cent of Americans suffer from chronic pain. Many of them go untreated or undertreated. Access to care is a serious problem. Even in populated areas around here, there is unmet need.

The proposed rule on Chronic Pain Management Clinic Licensure has been written in a way that could harm many pain patients.

Please see the attachment to this letter for an outline of changes in the proposed rule that would help to avoid unintended consequences affecting many West Virginians.

Without these changes, the new rule will hurt many of us in ways not foreseen by those who drafted this proposed rule.

Without these changes, good doctors will close their practices to people in pain, or even worse, move their offices to nearby states that still value the full range of what these doctors have to offer.

Thank you for your careful consideration of ways to correct what is wrong with a regulation whose core purpose we all agree with.

Sincerely,

Joseph Huffman

Joseph Huffman

December 20, 2012

Anita Barnhouse
Department of Health and Human Resources
Office of Health Facility Licensure and Certification
408 Leon Sullivan Way
Charleston, West Virginia 25301

Re: Proposed Rule—Chronic Pain Management Clinic Licensure

Dear Ms. Barnhouse:

We all want to put a stop to "pill mills" that prescribe enormous quantities of pain pills with little or no medical reason.

Fifteen per cent of Americans suffer from chronic pain. Many of them go untreated or undertreated. Access to care is a serious problem. Even in populated areas around here, there is unmet need.

The proposed rule on Chronic Pain Management Clinic Licensure has been written in a way that could harm many pain patients.

Please see the attachment to this letter for an outline of changes in the proposed rule that would help to avoid unintended consequences affecting many West Virginians.

Without these changes, the new rule will hurt many of us in ways not foreseen by those who drafted this proposed rule.

Without these changes, good doctors will close their practices to people in pain, or even worse, move their offices to nearby states that still value the full range of what these doctors have to offer.

Thank you for your careful consideration of ways to correct what is wrong with a regulation whose core purpose we all agree with.

Sincerely,

Leahue L. Morris

I am an 87 year old veteran and retired insurance salesman. I have been receiving prescription pain medications from my primary care physician since I had an aortic aneurysm rupture. They saved my life but, without the pain medication I will suffer tremendously. Please put a stop to this law in order that I can continue to acquire the medication necessary to alleviate the pain I experience daily. If I cannot get this medicine from my primary care physician what will I do?

Thank you.

How to Fix the Pain Clinic Licensure Rule—
Which Facilities Are Pain Clinics?

Pain Clinic Licensure Rule (69-8-3.1.a)

"Where in any one month more than fifty (50) percent of all patients treated at the clinic, facility or office are treated for chronic pain resulting from non-malignant conditions and are prescribed administered or dispensed tramadol, carisoprodol, opioid drugs or other Schedule II or Schedule III controlled substances for such diagnosis. This ratio is calculated by assessing *the total number of patients treated during any one month and then determining the number of patients treated for a diagnosis of chronic pain* and pursuant to such diagnosis were prescribed, administered or dispensed tramadol, carisoprodol, opioid drugs or other Scheduled II or Scheduled III controlled substances."

Comment

The new law defines a pain clinic. The proposed regulation seeks to give a more clear definition, and in the process changes it substantially. Both versions of the definition involve the question, "What proportion of the facility's patients are chronic pain patients?" We are to divide the number of "pain patients" by the number of "all patients". How we get each of these numbers can make a big difference.

The law says "Where in any one month more than fifty (50) percent of patients of the prescribers or dispensers". The proposed regulation says "Where in any one month more than fifty (50) percent of all patients treated". The definition in the law is not very clear. The definition in the regulation is not any more clear.

To me, the wording in the law suggests that "all patients" means "all of the prescriber's patient population". Those in the field would usually take that to mean all the patients seen within the last 2 years.

In contrast, the wording in the proposed regulation might mean that "all patients" are "all patients treated during that month". If this unclear wording is allowed to take on that meaning, it drastically reduces the number of "all patients".

Both definitions do make it clear that we are not to look beyond the one month in question when counting "pain patients". It is still unclear inother ways. To make this clear, we should specify "unique patients". That gets rid of double counting in the event that a pain patient was seen more than once in a month.

Putting it all together, here is proposed revised language for the second of two sentences in 3.1.a.:

> "This ratio is calculated by assessing the total number of patients visits (encounters) during a continuous period of 2 years and then determining the number of unique patients seen during one calendar month for a principle diagnosis of chronic pain who, pursuant to such a diagnosis, were prescribed, administered or dispensed tramadol, carisoprodol, opioid medication, or another Schedule II or Schedule III controlled substance."

December 20, 2012

Anita Barnhouse
Department of Health and Human Resources
Office of Health Facility Licensure and Certification
408 Leon Sullivan Way
Charleston, West Virginia 25301

Re: Proposed Rule—Chronic Pain Management Clinic Licensure

Dear Ms. Barnhouse:

We all want to put a stop to "pill mills" that prescribe enormous quantities of pain pills with little or no medical reason.

Fifteen per cent of Americans suffer from chronic pain. Many of them go untreated or undertreated. Access to care is a serious problem. Even in populated areas around here, there is unmet need.

The proposed rule on Chronic Pain Management Clinic Licensure has been written in a way that could harm many pain patients.

Please see the attachment to this letter for an outline of changes in the proposed rule that would help to avoid unintended consequences affecting many West Virginians.

Without these changes, the new rule will hurt many of us in ways not foreseen by those who drafted this proposed rule.

Without these changes, good doctors will close their practices to people in pain, or even worse, move their offices to nearby states that still value the full range of what these doctors have to offer.

Thank you for your careful consideration of ways to correct what is wrong with a regulation whose core purpose we all agree with.

Sincerely, Mr & Mrs David Kerns

We are concerned about the new pain rule and would like you to consider the included proposed revised language

Thank You.

December 20, 2012

Anita Barnhouse
Department of Health and Human Resources
Office of Health Facility Licensure and Certification
408 Leon Sullivan Way
Charleston, West Virginia 25301

Re: Proposed Rule—Chronic Pain Management Clinic Licensure

Dear Ms. Barnhouse:

We all want to put a stop to "pill mills" that prescribe enormous quantities of pain pills with little or no medical reason.

Fifteen per cent of Americans suffer from chronic pain. Many of them go untreated or undertreated. Access to care is a serious problem. Even in populated areas around here, there is unmet need.

The proposed rule on Chronic Pain Management Clinic Licensure has been written in a way that could harm many pain patients.

Please see the attachment to this letter for an outline of changes in the proposed rule that would help to avoid unintended consequences affecting many West Virginians.

Without these changes, the new rule will hurt many of us in ways not foreseen by those who drafted this proposed rule.

Without these changes, good doctors will close their practices to people in pain, or even worse, move their offices to nearby states that still value the full range of what these doctors have to offer.

Thank you for your careful consideration of ways to correct what is wrong with a regulation whose core purpose we all agree with.

Sincerely,

Melissa D. Rutter

How to Fix the Pain Clinic Licensure Rule—
Which Facilities Are Pain Clinics?

Pain Clinic Licensure Rule (69-8-3.1.a)

"Where in any one month more than fifty (50) percent of all patients treated at the clinic, facility or office are treated for chronic pain resulting from non-malignant conditions and are prescribed administered or dispensed tramadol, carisoprodol, opioid drugs or other Schedule II or Schedule III controlled substances for such diagnosis. This ratio is calculated by assessing *the total number of patients treated during any one month and then determining the number of patients treated for a diagnosis of chronic pain* and pursuant to such diagnosis were prescribed, administered or dispensed tramadol, carisoprodol, opioid drugs or other Scheduled II or Scheduled III controlled substances."

Comment

The new law defines a pain clinic. The proposed regulation seeks to give a more clear definition, and in the process changes it substantially. Both versions of the definition involve the question, "What proportion of the facility's patients are chronic pain patients?" We are to divide the number of "pain patients" by the number of "all patients". How we get each of these numbers can make a big difference.

The law says "Where in any one month more than fifty (50) percent of patients of the prescribers or dispensers". The proposed regulation says "Where in any one month more than fifty (50) percent of all patients treated". The definition in the law is not very clear. The definition in the regulation is not any more clear.

To me, the wording in the law suggests that "all patients" means "all of the prescriber's patient population". Those in the field would usually take that to mean all the patients seen within the last 2 years.

In contrast, the wording in the proposed regulation might mean that "all patients" are "all patients treated during that month". If this unclear wording is allowed to take on that meaning, it drastically reduces the number of "all patients".

Both definitions do make it clear that we are not to look beyond the one month in question when counting "pain patients". It is still unclear inother ways. To make this clear, we should specify "unique patients". That gets rid of double counting in the event that a pain patient was seen more than once in a month.

Putting it all together, here is proposed revised language for the second of two sentences in 3.1.a.:

> "This ratio is calculated by assessing the total number of patients visits (encounters) during a continuous period of 2 years and then determining the number of unique patients seen during one calendar month for a principle diagnosis of chronic pain who, pursuant to such a diagnosis, were prescribed, administered or dispensed tramadol, carisoprodol, opioid medication, or another Schedule II or Schedule III controlled substance."

Barnhouse, Anita L

From: Evan Jenkins [evan@wvsma.org]
Sent: Friday, January 04, 2013 3:41 PM
To: Barnhouse, Anita L
Subject: pain clinic definition suggestion

Anita...thanks again for the opportunity to talk on Wednesday.

I've taken a stab at a modified definition relating to the 50% threshold in the pain clinic rule that is giving us all some difficulty in nailing down. See if the following might be workable.

The intent is to modify the calculation of the denominator in the equation. The initial proposed language generated a lot of concern that it was two restrictive because appropriate clinical management of a patient being treated for chronic pain necessitates that that patient be seen more often and if (as in the initial draft) the period for determining all patients was just one month the number would skew the true profile of the practice. The following allows for a 'smoothing' by defining the total patients (denominator) as those seen over the course of a year then taking that total and dividing it by 12 to get a monthly average that will be used as the denominator in the ratio. Thanks!

§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 and:

3.1.a. Where in any one month more than fifty (50) percent of all patients of the clinic, facility or office are treated for chronic pain resulting from non-malignant conditions and are prescribed, administered or dispensed tramadol, carisoprodol, opioid drugs or other Schedule II or Schedule III controlled substances for such diagnosis. This ratio is calculated by dividing the average monthly total of all patient encounters at the clinic, facility or office over a twelve (12) month calendar period by the number of unique patient encounters at the clinic, facility or office during any one month for a diagnosis of chronic pain and pursuant to such diagnosis were prescribed, administered or dispensed tramadol, carisoprodol, opioid drugs or other Scheduled II or Scheduled III controlled substances.

Evan H. Jenkins
Executive Director, West Virginia State Medical Association

WVSMA
PO Box 4106
Charleston, WV 25364
(304) 925-0342 ext. 15
evan@wvsma.org

PPPFD, Inc.
213 Pinewood Drive
Shady Spring, WV 25918

Comments on Proposed Rules: Chronic Pain Management Clinic Licensure

To: Anita Barnhouse, Department of Health and Human Resources

Dear Ms. Barnhouse, January 2, 2013

First and foremost, please accept our compliments on a great start in addressing a HUGE problem!

However we have major concerns over segments of these proposed rules that will likely serve only to make it **more difficult for us law-abiding patients** to get the pain medicine we legitimately need. Concerns:

1. CONFLICT OF INTEREST: A member of our organization heard Doctor Paul Skaff boast that he "helped" Delegate Doug Skaff "write the pain law." Doctor Skaff is certified by the American Board of Anesthesiology (ABA) as an anesthesiologist. His influence apparently resulted in the pain law requiring interventional specialty credentialing as a training requirement for Designated Physician Owners. Why? What do "needle jockeys" know about appropriate **oral** opiate pharmacotherapy? Many, if not most, interventional pain specialists refuse to prescribe oral opiate pain meds! The few who do, know that they can **require** patients to receive expensive, painful, yet frequently ineffective injections BEFORE agreeing to prescribe an oral opiate analgesic. Many chronic pain patients report having to endure **painful** injections that "don't help relieve my pain" in order to receive their pain meds. Doesn't that qualify as a fraudulent practice costing the state and private insurances millions?
2. WHY NOT SIMPLY ENFORCE THE PAIN MEDICINE GUIDELINES? The American Pain Society (APS) and the American Academy of Pain Medicine (AAPM) published the first comprehensive, evidence-based clinical practice guideline to assist clinicians in prescribing potent opiate pain medications for patients with chronic non-cancer pain. The guideline was published in the February 2009 issue of *The Journal of Pain*. Why not require ALL pain management clinic physicians (owners and prescribers) to be certified and **tested periodically by the Licensure Office** on this guideline?
3. WHY NOT REQUIRE A CHRONIC PAIN DIAGNOSIS CODE ON THE PRESCRIPTION before the pharmacist is permitted to dispense the opiate pain medicine for chronic pain? Why not track the chronic pain diagnosis codes along with the pain medicine in the Board of Pharmacy database?
4. PHARMACOVIGILANCE GUIDELINES: The Pain Medicine Guidelines also detail techniques for stratifying patients into diversion risk categories of Low, Moderate, or High Risk. For example, the frequency of random urine drug tests and pill counts can be established systematically based on patient histories. It is also important to recognize that fraudulent patients will borrow or rent pills from friends, family, or co-conspirators in order to pass random pill counts. Drugs.com has an excellent pill identifier tool that can help pain clinic staff identify "street pills" brought into the clinic for random pill counts.
5. SHOULDN'T ALL TOXICOLOGY RESULTS BE CONFIRMED? For example, if a patient is prescribed oxycodone on a chronic basis and their point of care drug screen shows a "positive" for oxycodone, the urine may in fact be "negative" for oxymorphone (primary analgesic metabolite of oxycodone). Therefore, shouldn't that toxicology test result be confirmed by LCMS technology?

Law-abiding chronic pain patients want to help STOP law-breaking chronic pain patients! Thank You!

Mark Radcliffe, PPPFD President
mark@protectpaincare.org
304-860-8825

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. - _____, 2012.

1.4. Effective Date. - _____, 2013.

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

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

§ 69-8-2. Definitions.

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

2.2. 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.

2.3. 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.

2.4. 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.

2.5. 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.

2.6. 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 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.

2.7. 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 pharmacies in West Virginia.

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

2.9. 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.

2.10. Dispense - The preparation and delivery of any medication, including a controlled substance, 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.

2.11. Informed Consent - Written acknowledgment 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.

2.12. 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.

2.13. 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.

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

2.15. 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.

2.16. 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.*

2.17. Plan of Care - A written plan of treatment and care 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.

2.18. 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.

2.19. 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.

2.20. 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.

2.21. Secretary - The secretary of the West Virginia Department of Health and Human Resources or his or her designee.

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

§ 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, and;

3.1.a. Where in any one month more than fifty (50) percent of all patients of the clinic, facility or office are treated for chronic pain resulting from non-malignant conditions and are prescribed, administered or dispensed tramadol, carisoprodol, opioid drugs or other Schedule II or Schedule III controlled substances for such diagnosis. This ratio is calculated by dividing the average monthly total of all patient encounters at the clinic, facility or office over a twelve (12) month calendar period by the number of unique patient encounters at the clinic, facility or office during any one month for a diagnosis of chronic pain and pursuant to such diagnosis were prescribed, administered or dispensed tramadol, carisoprodol, opioid drugs or other Scheduled II or Scheduled III controlled substances.

3.1.b. Where at least one owner is a physician, as required by this rule;

3.1.c. Where the designated physician owner is responsible for overseeing practices within the clinic, as required by this rule; and

3.1.d. Where the staffing, training, education and supervision requirements of this rule are satisfied.

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

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

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

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

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

3.2.h. 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. Any other facility granted an exemption by the secretary.

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. 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. A license is valid only for the location and persons named and described in the application.

4.1.c. 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. Each licensed clinic location shall designate a physician owner unique to that clinic. The 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. A license is not transferable or assignable.

4.1.f. If the ownership of a pain management clinic changes, the new owner shall notify the secretary within ten (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 (3) months from the date the application is received by the director.

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

4.1.h. If there is a change in the designated physician owner, the pain management clinic must comply with the provisions of 6.5.c. of this rule.

4.1.i. All licenses shall expire one (1) year from issuance.

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

4.1.k. 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.l. 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.m. 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 ten (10) days.

4.1.n. A pain management clinic that fails to apply for a license is subject to the penalties established by Sections seventeen (17) and eighteen (18) of this rule.

4.1.o. 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. An applicant shall submit a completed application to the secretary, on a form prescribed by the secretary, not less than thirty (30) days and not more than sixty (60) days prior to the date proposed for commencement of operation for a pain management clinic. 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 ninety(90)days of the effective date of this rule.

4.2.b. The application shall include:

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

4.2.b.2. The name, address, principal occupation and official position for each owner. At least one (1) owner shall be a physician with an active license in West Virginia;

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

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

4.2.b.5. 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. A list of the owners' and physicians' names, medical licenses, drug enforcement agency numbers and any pain management specialty certifications;

4.2.b.7. 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. Days and times of operation;

4.2.b.9. 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 (5) years preceding the date of application;

4.2.b.10. Verification that a criminal records background check for each anticipated owner, physician, employee, volunteer, associate or contracted agent has been completed; and

4.2.b.11. A description of services provided.

4.2.c. 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. If, at the initial licensing survey, a pain management clinic has more than five (5) 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 until the clinic is found to be in substantial compliance with this rule.

4.3. Renewal license

4.3.a. An applicant shall submit a completed application to the secretary, on a form prescribed by the secretary, sixty (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. 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. 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. Initial license fee - $250;

4.4.a.2. Renewal fee - fewer than 500 patients - $250 plus adjustment;

4.4.a.3. Renewal fee - 500 to 1,000 patients - $500 plus adjustment;

4.4.a.4. Renewal fee - more than 1,000 patients - $750 plus adjustment.

4.4.b. 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. The secretary may deny an application for an initial or renewal license if:

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

4.5.a.2. 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. 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. The pain management clinic has made misrepresentations in obtaining licensure;

4.5.a.5. 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; or

4.5.a.6. The pain management clinic fails to have a designated physician owner practicing at the clinic location.

4.5.b. 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.

§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 annual inspections, follow-up inspections, complaint investigations and periodic inspections.

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

5.3. Within ten (10) working days of the exit date of an 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.

5.4 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 ten (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.

5.5. 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.

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

5.7. 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.

5.8. 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.

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

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

5.11. 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.

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

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

6.3.b. Whose application for a license to prescribe, dispense or administer a controlled substance has been denied by any jurisdiction; or

6.3.c. 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.

6.4. Owner

6.4.a. 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. 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. 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. The owner(s) and administrator shall meet at least annually to review the pain management clinics 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. Designated physician owner

6.5.a. 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.

6.5.b. The designated physician owner shall:

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

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

6.5.b.2.A. 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. 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; or hold current board certification from such other program as may be approved by the secretary;

6.5.b.3. Practice a minimum of thirty two (32) hours per week at the licensed pain management clinic for which the physician has assumed responsibility;

6.5.b.4. 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. Develop operation and clinical policies and procedures;

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

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

6.5.b.8. 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. Periodically conduct appraisals of the medical staff as defined by clinic policy;

6.5.b.10. Periodically examine credentials of candidates for medical staff membership; and

6.5.b.11. Supervise all clinical quality assessment and performance improvement activities.

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

6.5.c. Within ten (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, 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. Administrator

6.6.a. The administrator is responsible for the day to day operation of the pain management clinic.

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

6.6.c. Duties of the administrator include:

6.6.c.1. Maintenance and security of the clinic;

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

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

6.6.c.4. Protection of patient rights as outlined in section nine (9) of this rule;

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

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

6.6.c.7. 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. 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. Clean, safe and well-maintained patient and staff areas;

7.1.c. A secure room and lockable equipment for patient records;

7.1.d. A double locked area to prevent access to controlled substances by any unauthorized personnel;

7.1.e. Sanitary and secure dosing areas;

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

7.1.g. Adequate parking areas for the expected flow of traffic; and

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

7.1.i. 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 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. 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. All physicians and licensed health care professionals employed by the pain management clinic shall be actively licensed in West Virginia and shall have:

8.2.b.1. A minimum of one (1) year experience in chronic pain management; or

8.2.b.2. 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. 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. 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. 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. A pain management clinic may employ or utilize unlicensed staff and volunteers to assist in the operation of the clinic.

8.3.b. The clinic shall develop policies and procedures that specify the job descriptions and responsibilities of unlicensed employees and volunteers. Documentation of the responsibilities,

training and other obligations of unlicensed employees or volunteers shall be included in the personnel file of the employees or volunteers.

8.3.c. All unlicensed staff 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. The pain management clinic shall ensure that all physicians, physician assistants, advanced practice registered nurses, 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. All clinic staff members 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. The pain management clinic shall develop detailed job descriptions for each staff member that clearly define the education, training, qualifications and competencies needed to provide specific services; Provided that additional job duties for a Physician Assistant beyond those delineated in 11-1B-13.2 are submitted for the consideration and approval of the Board of Medicine.

8.4.d. Upon hire of any new clinical staff member, the pain management clinic shall provide the staff member with an orientation as to the person's primary job responsibilities, including 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. The pain management clinic shall maintain confidential individual personnel files for every staff member. Personnel files shall contain, at a minimum:

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

8.4.e.2. Documentation of the date of employment;

8.4.e.3. Identifying information and emergency contacts;

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

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

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

8.4.e.7. Detailed job descriptions; and

8.4.e.8. Evidence that the pain management clinic has determined that the employee, independent contractor or volunteer has never been convicted of a felony.

§ 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. 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. 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. 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 at least every ninety (90) days by the patient's physician and shall be maintained in the patient's chart;

9.1.d. 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 ninety (90) days during the course of ongoing treatment;

9.1.e. 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. 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. 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. 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. Who to contact to file a grievance;

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

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

9.2.e. 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, inappropriate behavior or other escalating and potentially dangerous situations, with emphasis on when security guards or police need to be summoned. In regards 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. 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. The initial assessment shall include documentation of:

10.2.b.1. A physical examination;

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

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

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

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

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

10.2.b.7. Laboratory tests as deemed necessary;

10.2.b.8. A full toxicology screen as deemed necessary;

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

10.2.b.10. The diagnosis of all conditions, including a

diagnosis of chronic pain, if applicable, including signs, symptoms and causes;

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

10.2.b.12. The dates, amounts and dosage forms for any drugs prescribed, dispensed and administered.

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

10.2.c.1 Follow-up physical examinations;

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

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

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

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

10.2.d. A physician, physician assistant, certified registered nurse anesthetist or advanced 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 (4) times, or every ninety (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. The treating physician and other health care professionals directly involved in the care of the patient shall develop a written individualized plan of care for every patient.

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

10.3.b.1. Information required for the initial assessment;

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

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

10.3.b.4. Laboratory test results;

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

10.3.b.6. 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; and

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

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

10.3.d. 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 ninety (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.

10.3.e. 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. 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 seventy two (72) hour supply of any controlled substance.

10.4.b. 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. At the patient's intake;

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

10.4.b.3. At each ninety-day (90) examination;

10.4.b.4. After any positive drug test; and

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

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

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

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

10.4.d. 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. 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. 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. The signature or initials of the qualified person administering or dispensing medication;

10.4.f.2. The date and time of dispensing;

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

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

10.4.f.5. 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. Each medication order and dosage change shall be written on an acceptable order sheet and signed and dated by only the treating physician. If 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.

10.4.f.7. 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. 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. 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. Each physician shall comply with all state and federal requirements for tamper-resistant prescription paper.

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

§ 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. Patient records shall include, at a minimum:

11.5.a. Patient identification and demographic data;

11.5.b. Properly executed informed consent forms for procedures and treatments;

11.5.c. Copy of signed patient rights;

11.5.d. Patient history and physical examination, including any history of drug abuse or dependence;

11.5.e. Patient assessments and plans of care;

11.5.f. Progress notes and practitioners orders;

11.5.g. Diagnostic, therapeutic and laboratory results, including drug testing results;

11.5.h. Reports of evaluations, consultations, and hospitalizations;

11.5.i. Treatment objectives, including discussion of risks and benefits;

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

11.5.k. Treatments;

11.5.l. Receipt and assessment of drug database or prescription monitoring program reports; and

11.5.m. 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.

11.6. All patient records shall be maintained for a minimum of five (5) 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 eighteen (18) years.

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

11.8. Each entry in the medical record shall be completed within twenty-four (24) hours of the patient contact and shall be dated and signed by the medical staff person involved.

11.9. 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 polices and areas of measurement shall include, but not be limited to:

13.4.a. Staff, administrative and practitioner performance;

13.4.b. Grievance findings;

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

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

13.4.e. Drug therapy and adverse drug reactions;

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

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

13.4.h. Review of clinic policies and procedures;

13.4.i. Review of patient satisfaction of services;

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

13.4.k. 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 officer to develop and implement policies 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. Medication errors;

15.2.b. Patient suicide attempts;

15.2.c Patient deaths;

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

15.2.e. Selling drugs on the premises;

15.2.f. Medication diversion;

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

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

15.2.i. 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. Fully document the event or incident and report the matter to the applicable state agencies within twenty-four (24) hours according to procedures established by the secretary;

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

15.4.c. Take corrective action within ten (10) days, unless an extension is requested and granted;

15.4.d. 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 forty-eight (48) hours of any person at the clinic receiving notification of the mortality.

§ 69-8-16. Advertisement disclosure.

16.1. 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. License Revocations and Suspensions.

17.1. Grounds for Suspension or Revocation.

17.1.a. The secretary may revoke or suspend 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 (1) year.

17.1.b. The secretary may revoke or suspend a pain management clinic license for one (1) or more of the following reasons:

17.1.b.1. 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. 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. The pain management clinic engages in practices that jeopardize the health, safety, welfare or clinical treatment of a patient;

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

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

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

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

17.1.b.8. 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. 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. 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. The pain management clinic fails to have a licensed designated physician owner practicing at the location as required by this rule.

17.2. Effect of Suspension or Revocation.

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

17.2.c. Upon the effective date of the suspension or revocation, 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.d. If the license of a pain management clinic is suspended or revoked, no person named in the licensing documents of the clinic, including persons owning or operating the pain management clinic, may apply to own, license or operate another pain management clinic for five (5) years after the date of

suspension or revocation, either individually or as part of a group practice, firm, association or corporation.

17.2.e. If a pain management clinic license is revoked, a new application for a license shall be considered by the secretary if, when and after the conditions upon which revocation 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. Penalties and Equitable Relief.

18.1. Grounds for Penalties and Injunctions.

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

18.1.c. 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 ten thousand dollars ($10,000) and revoke or deny the pain management clinic's license.

18.1.d. If an owner or designated physician owner of a 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 five thousand dollars ($5,000) per day.

18.1.e. 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 five thousand dollars ($5,000).

18.1.f. 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 through misrepresentation or fraud; 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, the secretary may assess a civil money penalty of not more than twenty thousand dollars ($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. 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. 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. 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. 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. What actions, if any, the designated physician owner or treating physician took to correct the violations;

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

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

18.3. 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. Administrative Due Process.

19.1. Before any pain management clinic license is suspended or revoked, written notice shall be given to the owner(s) 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 thirty days from the time the notice is given.

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

19.1.b. Nothing prohibits the parties from engaging 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.

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

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

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

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

20.1. Any owner of a pain management clinic who disagrees with the decision of the secretary as a result of the hearing may, within thirty (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.

20.1.a. The Circuit Court may affirm, modify or reverse the decision of the secretary. The owner(s) or the secretary may appeal the court's decision to the Supreme Court of Appeals.