STATE OF WASHINGTON

DEPARTMENT OF HEALTH

MEDICAL QUALITY ASSURANCE COMMISSION

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FORM 101B

NOTICE OF ADOPTION OF AN INTERPRETIVE STATEMENT OR POLICY STATEMENT

Title of Interpretive or Policy Statement: Management of Chronic Noncancer Pain

Issuing Entity: Medical Quality Assurance Commission

Subject Matter: Management of chronic noncancer pain

Effective Date: October 5, 2012

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Medical Quality Assurance Commission
Interpretive Statement

Title:	Management of Chronic Noncancer Pain	No: MD2012-01-IS
Reference:	WAC 246-919-850 through 863; and WAC 246-918-800 through 813	
Contact:	Dani Newman, Program Manager	
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Approved:	Mimi Pattison MD	
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Description of the Issues

The Medical Commission (Commission) is aware of some questions and concerns regarding the rules related to the management of chronic noncancer pain (WAC 246-919-850 through 863, and WAC 246-918-800 through 813). These questions and concerns include:

1. Does the presence of "shall" within the rules create inflexible legal mandates, or do the rules in their totality allow for sound clinical judgment that may vary from the rules in some circumstances?

2. Will the Commission apply the rules to a practitioner who, in managing an injury or condition, is secondarily treating pain for longer than the usual course?

3. Will the Commission apply the rules to intermittent prescribing of opioids for a chronic condition?

4. What is episodic care and how does it apply to my practice?

5. In WAC 246-919-862(2) and WAC 246-918-812(2) the rules provide an exemption from the consultation requirement when a practitioner (and the sponsoring physician for a physician assistant) has completed 12 hours of continuing education on chronic pain management in the last two years, but when does this two year period begin and end?

6. Does the rule define the entire standard of care for the management of chronic noncancer pain?

7. Is the 120 mg. (MED) "consultation threshold" a maximum dose under the rules?

8. Is the 120 mg. (MED) "consultation threshold" the *minimum* dosage at which a consultation should be obtained under the rules?

The Commission's Position

Before answering these questions it is important to express and respond to the Commission's concern that misunderstanding of, or over-reaction to, the rules may cause some physicians and physician assistants to refuse, discharge, or fail to treat pain patients. The Commission recognizes that patients in Washington need access to appropriate and effective pain management and does not want to negatively affect the access to care. It is the Commission's goal that the pain management rules provide clarity to an area of previous uncertainty, resulting in better management of chronic noncancer pain. It is the Commission's goal to eliminate some of the misunderstanding and ease some of the concerns through this interpretive statement.

Background Information

The pain management rules satisfy the requirements of Engrossed Substitute House Bill (ESHB) 2876 (Chapter 209, Laws of 2010) which directs the Medical Quality Assurance Commission to repeal existing pain management rules and adopt new rules for the management of chronic noncancer pain. The adopted rules include the mandatory elements for dosing criteria, guidance on specialty consultations, guidance on tracking clinical progress, and guidance on tracking opioid use. The adopted rules also describe practitioner and situational exemptions to the consultation requirement.

In addition the Commission also chose to further clarify its position on chronic pain management by adopting a comprehensive set of rules based upon the "Model Policy for the Use of Controlled Substances for the Treatment of Pain" created by the Federation of State Medical Boards. These rules were adopted in furtherance of the Commission's mission to promote patient safety and quality healthcare, and in direct response to the dramatic increase in opioid related overdoses in Washington.

Response and Analysis

1. Does the presence of "shall" within the rules create inflexible legal mandates, or do the rules in their totality allow for sound clinical judgment that may vary from the rules in some circumstances?

The rules are not inflexible and recognize the importance of sound clinical judgment.

It is important for those concerned about the use of the word "shall" within the rules to consider the Intent Section of the rules. This opening provision describes the purpose of the rules and sets the tone for interpretation and application of the entire rule by the Commission. The intent provision explicitly

states that the rules are not inflexible and repeatedly recognizes the importance of clinical judgment.

The Intent Section of the pain rules, found at WAC 246-919-850 and 246-918-800, makes it clear that while the word "shall" does identify generally necessary elements of care, a practitioner "*may take a course of action different from that specified in the rules*" (emphasis added) when, "in the reasonable judgment of the practitioner" the differing action is indicated by: (a) the patient's condition; (b) limited available resources; or (c) advances in knowledge or technology. This specific statement in the intent section reinforces the Commission's position that the rules "are not inflexible rules or rigid practice requirements." The purpose of the rules is to assist practitioners in providing appropriate medical care for patients.

The word "shall" appears in the rules as a mechanism to communicate what the Commission considers as necessary elements as opposed to recommended or elective elements of pain care. There is no other clear manner to communicate this distinction. However, as made clear by the intent provision, the rules recognize that "[t]he ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the practitioner."

Much of what is contained in the pain management rules is a reiteration of some of the elements already required by the standard of care though previously unarticulated in a manner easily accessible to physicians and physician assistants. As stated in the intent provision, this rule has been developed to clarify the Commission's position in order to alleviate physician uncertainty and to encourage better management of chronic noncancer pain.

2. <u>Will the Commission apply the rules to a practitioner who, in managing an injury or condition, is secondarily treating pain for longer than the usual course?</u>

It is not the intent of the Commission to be either rigid or over-inclusive in its application of the rules. The definition of "chronic noncancer pain" found at WAC 246-919-852(3) and WAC 246-918-802(3) leaves some flexibility in determining when and to whom the rules apply.

The rules apply to the use of opioids in the treatment of patients for chronic noncancer pain. WAC 246-919-850 and WAC 246-919-800 (first paragraph). The definition of chronic noncancer pain" is significant in determining if the rules apply in a specific situation. The definition of chronic noncancer pain, WAC 246-919-852(3) and WAC 246-918-802(3), provides some flexibility in that it references pain that persists beyond the "*usual course*" of an acute disease, injury, or pathologic process, and continues for "*months or years.*" (Emphasis added.)

The Commission intends to use a reasonable approach in determining how to enforce the rules. The Commission may determine the following sample situations are exempt circumstances:

A. A practitioner treating a patient for an acute injury or condition that improves, but is a source of pain that continues for a few months beyond the usual course for that injury or condition, if the following are true: (a) the treatment being provided is specific in scope and duration; (b) the treatment for pain is secondary to treating the condition or injury, meaning that pain management is not the primary focus of treatment; and (c) the opioid medication used to treat the pain is prescribed at a low, stable, non-escalating dose.

B. A specialist, for example an orthopedic surgeon, treating a patient's pain using a low, stable, non-escalating dose of opioid medication as part of a conservative management or rehabilitation approach when the approach and time period are within the standard of care for the practitioner's specialty or sub-specialty.

The interpretation that the rules may not apply to these situations is supported by the following: (1) there may be circumstances that extend the "usual course" of pain following an acute injury or condition; (2) the number of months of resulting pain is not specified in the rules, and the Commission intends to use a reasonable standard in applying these rules; and (3) the substance of the requirements under the rules regarding evaluation, treatment plans, informed consent, treatment agreements, and periodic review, do not squarely apply to situations where the treatment of pain is secondary to treatment of an injury or condition, or is part of a specialty's conservative management or rehabilitation approach, given the conditions described above.

3. Will the Commission apply the rules to intermittent prescribing of opioids for a chronic condition?

No. The rules apply to continuous prescribing of opioids for chronic noncancer pain, not the intermittent prescribing of opioids for a chronic condition.

4. What is episodic care and how does it apply to my practice?

For the purpose of this rule, episodic care usually includes patients seen in an emergency department or urgent care facility for chronic pain, when complete medical records are not available. Patients seen in an ambulatory care setting, with complaints associated with chronic pain, when complete medical records are not available would also be covered by this rule. Some healthcare systems and clinics may have an associated urgent care facility with complete availability of medical records. These facilities would be excluded from the definition of episodic care for the purposes of these rules.

5. The Consultation Exemptions Section of the rules, WAC 246-919-862(2) and 246-918-812(2), provides an exemption from the consultation requirement when a practitioner (and the sponsoring physician for a physician assistant) has completed 12 hours of continuing education on chronic pain management in the last two years, but when does this two year period begin and end?

The two year CME exemption is measured by the date a practitioner provides chronic pain care to a patient who meets or exceeds the 120 mg. (MED). For example, a practitioner providing chronic pain management to a patient who meets or exceeds 120 mg. (MED) on January 2, 2012, when the rules become effective, must have successfully completed all 12 hours of Category I continuing medical education on chronic pain management, since January 2, 2010 to qualify for an exemption. If four of the hours were completed in October 2009, for example, the sample practitioner would be four hours short of qualifying for the exemption.

However, if the patient is at or above 120 mg. (MED) on January 2, 2012, there may also be situational exemptions that apply. In WAC 246-919-861 ("Consultation--Exemptions for exigent and special circumstances"), the rules provide an exemption to the consultation requirement when the treating practitioner has otherwise followed the requirements of the rules, and: (a) the patient is following a tapering schedule; (b) the patient requires treatment for acute pain that requires a temporary escalation in dose; (c) the practitioner documents that they were unsuccessful in obtaining a consultation after reasonable attempts, and documents the circumstances justifying the dosage at or above 120 mg. (MED); or (d) the patient is on a non-escalating dose and the patient's pain and function are stable.

6. Does the rule define the entire standard of care for the management of chronic noncancer pain?

No. The contents of the rules do address some important elements of the standard of care for chronic pain management, but they do not define the entire standard of care. The rules are not exhaustive. The standard of care (current practice guidelines articulated by expert review) will continue to control circumstances and issues not addressed by the rule.

7. Is the 120 mg. (MED) "consultation threshold" a maximum dose under the rules?

No. The 120 mg. (MED) threshold is a triggering dose, intended to alert the practitioner to the fact that prescribing at this dose or higher significantly increases morbidity and mortality, and requiring a consultation with a pain specialist unless the physician or circumstances are exempted under the rules. The articulation of this dose in the rules is consistent with the legislature's requirement in ESHB 2876 to adopt rules that contain a dosage amount that must not be exceeded without pain specialist consultation.

Some have referred to the 120 mg. (MED) threshold (or "triggering") dose as a "maximum dose." The rules do not provide a maximum dose. They simply require, absent an exemption, that the practitioner obtain a pain specialist consultation before continuing on to prescribe opioids at a level that is associated with significant increases in opioid-related overdoses and deaths.

CAUTION: Dosage conversion tables (or calculators) are intended *only* to determine if the consultation requirement threshold has been met, NOT as a tool to convert between opioids.

8. Is the 120 mg. (MED) "consultation threshold" the *minimum* dosage at which a consultation should be obtained under the rules?

No. A physician or physician assistant should obtain a consultation when warranted. In WAC 246-919-860(2) and WAC 246-918-810(2) the threshold for mandatory consultation is set at 120 mg. (MED) for adult patients. However, WAC 246-919-860(1) and WAC 246-918-810(1) reference, more generally, additional evaluation that *may* be needed to meet treatment objectives. This provision makes specific reference to evaluation of patients under 18 who are at risk, and patients with co-morbid psychiatric disorders. However, other circumstances may call for a consultation with a pain management specialist for patients who have not met the threshold dose.

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