PAIN MANAGEMENT

Has the Medical Quality Assurance Commission (MQAC) adopted guidelines for the management of pain?

Yes. Effective January 2, 2012, the MQAC has adopted new rules for the management of chronic non-cancer pain. The guidelines specifically address the patient evaluation and treatment plan, informed consent, periodic reviews, use of consultations, and the necessity for maintaining accurate and complete medical records.

Do the pain rules apply to all physicians' practices?

The newly adopted MQAC rules for the management of chronic non-cancer pain (pain rules) apply to physicians who treat patients with opioids for chronic non-cancer pain (as defined in the rules).

The rules do not apply to physicians who provide palliative care, hospice care, or other forms of end-of-life care. The rules also do not apply to the management of acute pain related to an injury or surgical procedure.²

What is chronic non-cancer pain according to the pain rules?

The pain rules define chronic non-cancer pain as a pain not related to cancer which persists beyond the usual course of an acute disease, or the healing of an injury. Chronic non-cancer pain may or may not be associated with a pathologic process (acute or chronic) that causes continuous or intermittent pain over months or years. There is no minimum duration of pain which triggers the definition of chronic non-cancer pain and application of the rules. Of note, however, is that "acute pain" is described as something which is "time limited, often less than three months in duration, and usually less than six months."

What does "MED" mean?

MED is an abbreviation for "morphine equivalent dose," which means a conversion of the dose of various opioids to the equivalent dose of morphine as designated in an accepted conversion table.⁴ One such table may be found on the Washington State Agency Medical Directors Group website at: http://www.agencymeddirectors.wa.gov/opioiddosing.asp#CME, and click on "Dose Calculator." The calculator can be saved on a personal computer for convenience.

¹ WAC 246-919-850 through -863.

² WAC 246-919-851.

³ WAC 246-919-852.

⁴ WAC 246-919-852.

Do the pain rules require physicians to take CME courses in order to treat patients with chronic non-cancer?

In general, taking a CME course is not required to treat patients with chronic non-cancer pain. However, 12 hours of pain-related Category I CME (including at least 2 hours related to long-acting opioids such as methadone) is required if the physician wishes to be exempt from having to send his/her patients for a mandatory consultation with a pain specialist under certain circumstances (see below).⁵

Further, the rules suggest, but do not require, a one-time (lifetime) completion of at least four hours of CME related to long-acting opioids (including methadone) if a physician prescribes those medications.⁶

Are the pain rules guidelines, or do the pain rules impose mandatory requirements on a physician's practice?

The intent section of the rules states that the rules "are not inflexible rules or rigid practice requirements." The section goes on to say that the "ultimate propriety of any specific procedure or course of action must be made by the practitioner based on the circumstances presented." In addition, the intent section clearly states that the rules do not establish a standard of care. A course of treatment which differs from the rules may not be a violation of the rules so long as the physician documents that the variance was based on reasonable judgment, was indicated by the patient's condition, was taken because of limited resources or because of advances in knowledge or technology subsequent to the rules becoming effective. The MQAC has published an interpretive statement regarding the pain rules which is available at: http://www.doh.wa.gov/LicensesPermitsandCertificates/MedicalCommission/MedicalResources/PainManagement.aspx

That being said, most of the rules are nonetheless written as imperatives (i.e. "shall" and "must"). It is unclear how a court might reconcile the apparent conflict between the intent section (rules do not establish a standard of care; rules as guidelines) and the remainder of the pain rules. Until there are clear answers on these points it is safest for physicians to follow the requirements of the rules, unless the physician can provide adequate documentation to support an alternate course of action.

What is inappropriate treatment of pain under the pain rules?

According to the introductory intent section of the pain rules, "inappropriate treatment of pain" includes not only overtreatment and the continuation of ineffective treatments, but also includes non-treatment and under-treatment of chronic non-cancer pain.⁸

⁵ WAC 246-919-862.

⁶ WAC 246-919-858.

⁷ WAC 246-919-850.

[°] Id

The implications of this statement regarding inappropriate treatment of pain are unclear. The pain rules require a defined treatment plan and periodic reviews of the effects of treatment (see below). Therefore it would appear that whatever treatment a physician provides must have a demonstrated positive effect. Otherwise the treatment may have to be modified to avoid having the treatment considered "inappropriate."

What must a physician do before treating a patient with chronic non-cancer pain?

Before initiating treatment for a patient with chronic non-cancer pain the physician <u>must</u> perform a thorough history and physical evaluation of the patient.⁹

The history <u>must</u> include:

- Current and past treatments for pain;
- Any co-morbidities; A risk screening for potential co-morbidities, includes a history of:
 - o Addiction;
 - o Abuse of opioid medications or aberrant behavior related to that use;
 - o Psychiatric conditions, including poorly controlled depression or anxiety;
 - Along with use of opioids, any concomitant use of benzodiazepines, alcohol, or other medications which can affect the central nervous system;
 - o Significant adverse events such as falls or fractures (or risk thereof);
 - o Receiving opioids from more than one physician and/or physician group;
 - o Repeated visits to an emergency department seeking opioids;
 - Sleep apnea or other respiratory risk factors;
 - o Possible or current pregnancy; and
 - Allergies or intolerances.
- Any history of substance abuse;
- A review of pain-related issues including:
 - The nature and intensity of the pain;
 - o The effect of the pain on the patient's physical and psychological function; and
 - A list of the patient's medications, including their indications, date, type, dosage, and quantity prescribed

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⁹ WAC 246-919-853.

- A review of any available prescription monitoring program or emergency departmentbased information; and
- Any relevant information a pharmacist has provided to the physician.

The physician must perform a physical examination.

Documentation in the health record <u>must</u> be readily available for review and <u>should</u> include:

- The diagnosis, treatment plan (see below), and objectives of treatment;
- The presence of one or more indications for the use of pain medications;
- Medications prescribed;
- Results of periodic reviews (see below);
- Written agreements for treatment between the physician and the patient (see below); and
- The physician's instructions to the patient.

What is the written treatment plan required in the pain rules?

The written treatment plan <u>must</u> state the objectives which will be used to determine the effectiveness of treatment.¹⁰

The written treatment plan <u>must</u> include at least:

- Any changes in pain relief;
- Any changes in the patient's physical and/or psychosocial function; and
- Any additional diagnostic evaluations or other treatments that are planned.

Are there specific requirements for providing informed consent in the pain rules?

Yes. The physician <u>must</u> obtain informed consent from the patient (or surrogate/guardian with legal decision-making authority for the patient). As with any other informed consent the physician must discuss the nature of the proposed treatment, and the risks and benefits of the treatment, as well as those related to alternative treatments.

¹⁰ WAC 246-919-854.

¹¹ WAC 246-919-855.

What is the written treatment agreement in the pain rules?

For patients the physician feels are at high risk for medication abuse, have a history of substance abuse, or any psychiatric co-morbidities, the physician <u>must</u> use a written treatment agreement which outlines the patient's responsibilities. ¹²

The written treatment agreement must include:

- The patient's agreement to provide suitable samples for urine/serum drug screening when requested by the physician;
- The patient's agreement to comply with the dose and frequency the physician prescribes for their medications, and to comply with a protocol for lost drugs or prescriptions;
- Reasons which the physician states will result in discontinuation of drug therapy, such as violation of the written treatment agreement;
- The patient's agreement to have all prescriptions for medications used to treat the patient's chronic non-cancer pain filled by a single pharmacy or pharmacy system;
- The patient's agreement not to abuse alcohol or use other medically unauthorized substances;
- The patient's written authorization:
 - For the physician to release a copy of the treatment agreement to local emergency departments, urgent care facilities, and pharmacies;
 - For other physicians to report violations of the treatment agreement back to the treating physician; and
 - For the physician to notify the proper authorities if the physician has reason to believe the patient has engaged in illegal activities.
- The patient's acknowledgement:
 - That a violation of the written treatment agreement may result in a tapering or discontinuation of the patients prescriptions for chronic non-cancer pain;
 - o That it is the patient's responsibility to keep all medications safe and secure; and

¹² WAC 246-919-856.

 That if the patient violates the terms of the agreement the physician will document the violation, any change in the patient's treatment plan, and the rationale for those changes.

What is a periodic review, and when is a periodic review required?

The physician <u>must</u> periodically review the course of treatment of his/her patients with chronic non-cancer pain, the patients' state of health, and any new information regarding the etiology of their pain. Such a review must take place at least every six (6) months. However, a periodic review may be performed at least annually for patients whose condition is stable, and whose dose of opioids is not escalating <u>and</u> is less than forty (40) MED per day. In addition, the physician should periodically review any relevant information from any available prescription monitoring program or emergency department-based information exchange, and any information provided by pharmacists about the physician's patients.

During the periodic review the physician must:

- Determine the patient's compliance with any medication treatment plan;
- Determine if the patient's pain, function, or quality of life have improved or diminished using objective evidence, and considering input from family members and other caregivers;
- Determine if the patient's pain medications should continue or be modified based on the patient's progress in reaching treatment objectives;
- Assess the appropriateness of the continuation of the current treatment plan if the patient's progress under, or compliance with, the current treatment plan is unsatisfactory.
- Consider tapering, changing, or discontinuing treatment when:
 - The patient's level of function or pain has not improved after a suitable trial period;
 - o There is evidence of significant adverse effects from the current treatment;
 - o The physician determines other treatment modalities would be indicated; or
 - o There is evidence of misuse, addiction, or diversion of prescribed medications.

Do the pain rules specifically address long-acting opioids such as methadone?

Yes. The rules state that if a physician prescribes long-acting opioids, including methadone, the physician should be familiar with the risks and uses of such medications, and

¹³ WAC 246-919-857.

should be prepared to conduct any necessary, careful monitoring.¹⁴ This is especially important for patients who are initiating treatment with such medications. If a physician uses long-acting opioids, including methadone, the rules recommend that the physician should have a one-time (lifetime) completion of at least four (4) hours of CME related to such medications.

What do the pain rules say about treating a patient with chronic non-cancer pain who presents for emergency or urgent care (episodic care)?

The pain rules include recommendations and requirements when a physician evaluates a patient with chronic non-cancer pain for what is termed "episodic care," such as emergency or urgent care. ¹⁵

When providing episodic care for a patient with chronic non-cancer pain a physician should:

- Review any available information from a prescription monitoring program or emergency department-related information exchange or other tracking system regarding the patient;
- Avoid providing opioids for the management of the patient's chronic non-cancer pain;
- Limit the use of opioids for treatment of chronic non-cancer pain to the minimum amount necessary to control the pain or until the patient can receive care from his/her primary care physician if the treating physician feels that prescription of opioids is indicated; and
- Report known violations of a patient's written treatment agreement to the patient's primary care physician <u>if</u> the patient has such an agreement, <u>and</u> has provided a written authorization to release the agreement (see above) to physicians who provide episodic care.

When providing episodic care for a patient with chronic non-cancer pain a physician must:

- Include the indications for use on any prescription for opioids, or include the ICD code related to the patient's diagnosis on the prescription; and
- Write on the prescription that photo identification is required for the prescription to be picked up in order for the prescription to be filled.

What is a "pain management specialist" under the pain rules?

¹⁴ WAC 246-919-858.

¹⁵ WAC 246-919-859.

A pain management specialist is a physician, osteopathic physician, dentist, advanced registered nurse practitioner (ARNP), or podiatrist who has satisfied the minimum criteria for training as established in the pain rules, and may see patients with chronic non-cancer pain in consultation as provided in the pain rules. ¹⁶

What are the requirements for a physician to be considered a pain management specialist under the pain rules?

In order to be considered to be a pain management specialist a physician must:¹⁷

- Be board-certified or eligible by an American Board of Medical Specialties (ABMS)approved board in physical medicine and rehabilitation, rehabilitation medicine,
 neurology, rheumatology, or anesthesiology; or
- Have a subspecialty certificate in pain medicine by an ABMS-approved board; or
- Have a minimum of three (3) years of clinical experience in a chronic pain management care setting, and
 - o Be credentialed in pain management by an entity approved by the MQAC; and
 - O Successfully complete a minimum of at least eighteen (18) CME hours in pain management during the past two (2) years (for physicians); and
 - Have a current practice which consists of at least thirty (30) % direct provision of pain management care, or practice in a multidisciplinary pain clinic.

Note: The criteria for osteopathic physicians to become pain specialists are slightly different than those for medical doctors. Please review the full text of the pain rules for the criteria for osteopathic pain management specialists.

When are consultations with a pain management specialist recommended under the pain rules?

A physician should consider, and document the rationale for, a consultation with a pain management specialist as needed to achieve the treatment objectives the physician has set for patients being treated for chronic non-cancer pain. In particular, special attention, or consultation, is advised for patients with chronic non-cancer pain who:

- Are under eighteen (18) years of age;
- Are at risk for medication abuse or diversion;

17 -

¹⁶ WAC 246-919-863.

¹⁷ *Id*

¹⁸ WAC 246-919-860.

- Have a history of substance abuse; or
- Have co-morbid psychiatric disorders.

Are there mandatory consultation requirements under the pain rules?

Yes. Unless a physician qualifies for an exemption (see below), the physician <u>must</u> obtain a consultation from a pain management specialist if the physician prescribes a dose of opioids which exceeds one hundred twenty (120) mg MED per day.¹⁹

The mandatory consultation <u>must</u> consist of at least:

- An office visit with the patient and a pain management specialist; or
- A telephone consultation between the treating physician and the pain management specialist; or
- An electronic consultation between the treating physician and the pain management specialist; or
- An audio-visual evaluation conducted by the pain management specialist remotely, where
 the patient is present with the treating physician or another licensed health care
 practitioner the treating physician has designated or who has been designated by the pain
 management specialist.

The physician <u>must</u> document each mandatory consultation, and the physician <u>must</u> maintain any written consultation report as part of the patient's medical record. The pain management specialist must also maintain a record of each consultation report as a patient medical record.

A consultation with a pain management specialist may also be required as part of a contract with an individual, insurance companies, or other entities.

Are there special circumstances where a physician is exempt from the mandatory consultation requirement under the pain rules?

Yes. A physician may be exempt from the mandatory consultation requirement of the pain rules under certain exigent and special circumstances when the physician has otherwise documented adherence to all other applicable standards as set forth in the pain rules.²⁰

¹⁹ WAC 246-919-860.

²⁰ WAC 246-919-861.

Exigent and special circumstances in which a physician may be exempt from the mandatory consultation requirement include situations when:

- The patient is taking more than 120 mg MED per day of opioids but is following a tapering schedule; or
- The patient requires a temporary augmentation of the dose of opioids for treatment of acute pain which exceeds the 120 mg MED per day threshold (which may or may not include hospitalization), and when the physician expects the dose of opioids to return to, or below, the patient's baseline dosage level; or
- The physician documents reasonable attempts to obtain a consultation from a pain management specialist which have been unsuccessful, and in the physician's clinical judgment the circumstances justify prescribing more than 120 mg MED per day without first obtaining the consult; or
- The physician documents that the patient's pain and function are stable and the patient's dose of opioids in not escalating.

Is there any way a physician can become personally exempt from the mandatory consultation requirement of the pain rules?

Yes. The pain rules provide four (4) specific ways a physician can become exempt personally from the mandatory consultation requirement of the pain rules.²¹ A physician may become exempt from the mandatory consultation requirement if the physician:

- Is a pain management specialist; or
- Has successfully completed a minimum of twelve (12) hours of Category I CME on chronic pain management, which must include at least two (2) hours related to longacting opioids, within the last two (2) years; or
- Is a pain management practitioner working in a multidisciplinary pain treatment center, or a multidisciplinary academic research facility; or
- Has a minimum of three (3) years of clinical experience in a chronic pain management facility where at least thirty (30) % of the physician's practice has been the direct provision of pain management care.

W	hat i	s the	prescrip	tion	monit	oring	program	
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²¹ WAC 246-919-862.

The prescription monitoring program (PMP) is a patient safety toll which allows physicians to access information about the schedule II, III, IV, and V controlled substances their patients have been prescribed previously before the physician prescribes any new medications.²²

What information is entered into the prescription monitoring program?

All dispensers of controlled substances (i.e. the practitioner or pharmacist that delivers the controlled substance to the ultimate user)²³ must report to the Department of Health the patient's identity, drug dispensed, date of prescription, date of dispensing, quantity dispensed, refill information, prescriber, dispenser, and source of payment.²⁴

Who can access the data in the prescription monitoring program?

The PMP data may be provided to a physician for the purpose of providing medical care, ²⁵ pharmacists, ²⁶ the patient, ²⁷ health professional licensing, certification, or regulatory agency, law enforcement officials engaged in a specific investigation, state Medicaid officials, the director of Labor & Industries, the director of the Department of Corrections, pursuant to a grand jury subpoena, and Department of Health personnel. ²⁸

What must a physician do in order to access the prescription monitoring program data?'

Physicians and other dispensers must be registered with the Department of Health before being able to access data in the PMP.²⁹ Physicians may register at http://www.wapmp.org/practitioner/pharmacist/.

Where can a physician find out more information about the prescription monitoring program?

More information about the PMP may be found at: $\frac{http://www.doh.wa.gov/PublicHealthandHealthcareProviders/HealthcareProfessionsandFacilities}{/PrescriptionMonitoringProgramPMP.aspx}.$

²⁷ WAC 246-470-040.

²² RCW 70.225.020; WAC 246-470-001.

²³ WAC 246-470-010(4).

²⁴ RCW 70.225.020(2).

²⁵ WAC 246-470-050.

²⁶ *Id*.

²⁸ RCW 70.225.040(3); WAC 246-470-030.

²⁹ WAC 246-470-050.