

Understanding the New Washington State Pain Medication and Opioid Rules

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The state of Washington has recently adopted new rules, or "standards of practice," relating to pain management that apply to all physicians within the state. These new rules are in response to the rising statistics regarding prescription drug abuse involving opioids, the costs of such medications, a belief that the lack of guidance among physicians is contributing to the drug abuse problem in our society, and the belief that there should be a more coherent approach to pain medicine in the non-cancer, non-palliative setting.

Each governing medical board or commission was delegated to create its own rules. The new rules applying to primary care physicians are codified in WAC 246-919-850 through 246-919-863 and are scheduled to become effective January 2, 2012¹. Violation of these rules may lead to charges by the Medical Quality Assurance Commission ("MQAC") for deviation from the standard of care and unprofessional conduct. The rules should be closely read, and protocols and procedures implemented in clinical practice to ensure their observance. It is also important to document instances where the provider elects to deviate from these rules. While the rules state in their preamble that they are not meant to be "inflexible," and that there may be exceptions to the rules based upon "sound clinical judgment," there is no doubt that the rules set forth a standard of care meant to be followed. (WAC 246-919-850)

The following is a synopsis of pertinent aspects of the rules and significant points. I have purposely avoided editorializing upon the rules, or commenting upon their likely efficacy. Such discussion shall await the judgment of those professionals whose duty it will be to follow the rules in their practices, and to thereafter ascribe their effect on pain practice and any results achieved.

Scope

The rules govern the use of opioids for the treatment of chronic pain in the non-cancer setting. They do not apply to palliative, hospice, end-of-life care, or the management of "acute pain" due to injury or surgical procedure. (WAC 246-919-851)

Patient Evaluation

Prior to treating a patient for chronic non-cancer pain, the physician is required to conduct a detailed physical examination of the patient and obtain a detailed health record. The physician is to carefully evaluate the appropriateness of pain treatment, and conduct a detailed risk screening of the patient for drug abuse and diversion. All of this is to be documented in the patient record.

In addition, the patient record should document the presence of "one or more recognized indications for the use of pain medication" before such medication is prescribed, and set forth a "treatment plan." (WAC 246-919-853) The "treatment plan" should document and provide criteria to measure progress made by the patient, reflect any prescription modifications, and provide rationale for any continued course of treatment. (WAC 246-919-854)

¹While this article concerns those rules adopted by MQAC, similar rules were adopted by the remaining boards and commissions, including the Nursing Care Quality Assurance Commission, Dental Quality Assurance Commission, Board of Osteopathic Medicine and Surgery, and Podiatric Medical Board, and are scheduled to become effective July 1, 2011.

Monitoring Patient Conduct

The rules instruct the physician to "include indications for medication use on the prescription and require photo identification of the person picking up the prescription in order to fill." (WAC 246-919-854)

If the patient is at high risk for medication abuse, or has a history of substance abuse or psychiatric comorbidities, the prescribing physician "shall use a written agreement with the patient outlining patient responsibilities." Commonly referred to as a "pain contract," this written agreement shall require the patient to submit to random drug testing, contain a specified protocol for lost prescriptions and early refills, require that all scripts be written by a single practitioner or pain clinic and dispensed by a single pharmacy or chain, contain a written authorization for the physician to release to other practitioners the pain contract, and include authorization for the physician to report to legal authorities any suspected illegal activity by the patient.

The physician is to document any violations of the pain contract and the physician's response to that violation. (WAC 246-919-856)

Detailed Periodic Review

The physician is to conduct a detailed periodic review of the course of treatment of the patient, and to document that review in the patient record. These reviews should occur "at least every six months," unless the patient is stable and receiving a non-escalating daily morphine equivalent dose ("MED") of 40 mg or less, in which case annual review is sufficient. During the periodic review, the physician shall determine the patient's compliance with the medical treatment plan, determine by objective criteria whether the patient's condition has improved, diminished or remained constant, and adjust treatment accordingly. (WAC 246-919-857)

Special Requirements for Opioid Prescribing

Any physician wishing to prescribe long-acting opioids or methadone should complete at least four hours of CME relating to this topic. (WAC 246-919-858)

Requirement of Consultation With a Pain Specialist

In the event that a physician prescribes a daily dose amount equal to or in excess of 120 mg MED (oral) to a patient, consultation with a "pain management specialist" is required and must be documented in the patient file, unless the consultation is exempted by the rules. The mandatory consultation may be satisfied by: (i) an office visit by the patient with a pain management specialist; (ii) a telephone or electronic consultation between the prescribing physician and the pain management specialist; or (iii) an audio-visual evaluation by the pain management specialist where the patient is present with either the physician or a licensed health care practitioner designated by the physician or the pain management specialist. (WAC 246-919-860)

A physician is not required to consult with a pain management specialist when the physician has documented adherence to all standards of practice as defined by the pain management rules and either: (i) the patient is following a tapering schedule; (ii) the patient requires treatment for acute pain requiring a temporary escalation in opioid dosage; (iii) the physician documents reasonable attempts to obtain a consultation with a pain management specialist, and circumstances (unspecified in the rule) justify prescribing above 120 mg without first obtaining a consultation; or (iv) the physician documents that the patient's pain and function is stable, and the patient is on a nonescalating dosage of opioids. This last provision would appear to remove the need for continuing consultations once the 120 mg threshold is met, and the patient remains stable on a nonescalating dose. (WAC 246-919-861)

The rules make clear that "pain management specialists," as defined under the rules, are not required to obtain a consultation. Also exempt from the consultation requirement are: (i) those treating physicians who have successfully completed, within the last two years, a minimum of 12 (Category I) continuing education hours on chronic pain management, with at least two of these hours dedicated to long acting opioids; (ii) physicians who are pain management practitioners working in a multidisciplinary chronic pain treatment center or multidisciplinary academic research facility; and (iii) physicians with a minimum of three years of clinical experience in a chronic pain management setting, with at least 30 percent of that practice devoted to pain management care. (WAC 246-919-862) It is anticipated that most primary care physicians will not meet these requirements and will have to obtain the consultation in order to treat their patients at prescription levels beyond the threshold.

Finally, the rules define "pain management specialist" to include those physicians who are board certified in certain specialties, are credentialed in pain management, or qualify as pain specialists based upon specialized training, certificate and clinical experience. (WAC 246-919-863)

Open Questions

The rules do not portend to tell the treating physician what to do if the physician disagrees with any recommendations made by the pain specialist, other than to observe in its general preamble that the physician is to use "sound clinical judgment."

In addition, the rules do not directly address the question as to what the primary care physicians are to do with their existing patient populations, where the patients are currently receiving 120 mg or more MED, and where the patients are stable and on nonescalating doses. Are those patients now required to have an independent pain consultation under the rules? Or, are they "grandfathered" and subsumed within the category of those patients exempt from the pain consult due to their stable and nonescalating doses?

Conclusion

These rules are meant to add a level of coherence and accountability to the provision of pain medication in the primary care setting. It is hoped that such rules will not serve to chill the provision of pain treatment to those in need of such treatment, stifle necessary innovation among practicing physicians, intimidate practicing physicians, or steer patients suffering from chronic noncancer pain to the practices of pain specialists and away from that of their primary care physician. Such a result is neither warranted nor justified. The answer to these questions will depend, in part, upon the attitude of the regulators in interpreting these rules, bearing in mind that the goal remains the practice of good medicine and ensuring that adequate pain treatment may be provided at all levels of practice.



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Academy of Pain Management Magazine, Summer 2010; "When is a Kickback a Kickback? — Navigating the Perilous Road of Marketing Incentives in the Pharmaceutical Industry," *Contract Pharma Magazine*, May 2010; and "Swallowing the Wrong Pill — Criminal Drug Diversion by Medical Professionals, A Prosecutor's Perspective," *Pain Medicine News Magazine*, May 2009. Ron is a graduate of Harvard Law School. He can be reached at friedmanr@lanepowell.com or 206.223.7032.

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