Washington State Hospital Association | Washington State Medical Association

July 30, 2018

Daidria Amelia Underwood
Medical Quality Assurance Commission
Washington State Department of Health
P.O. Box 47866
Olympia, WA 98504-7866

Dear Members of the Medical Commission:

Thank you for the opportunity to provide comments on the Medical Commission's CR-102 of opioid prescribing rules required by HB 1427 from the 2017 legislative session.

Physicians and hospitals see firsthand how the opioid crisis is impacting communities across the state. Our associations have joined together to develop community-based solutions, informed by clinician expertise, with the health of our patients of paramount concern. Throughout this rulemaking process, we have submitted 11 comment letters with the aim of making these important rules effective while minimizing unintended consequences.

We applaud improvements made by the Medical Commission to the Department of Health's "conceptual draft". **While the CR-102 is drastically improved over previous iterations, we remain concerned about the volume of administrative burden and liability these rules would place on physicians and other providers and the resulting impact on access to appropriate patient care.** In this communication, we offer specific edits and comments that we believe will make the rules more workable within the limited context of a patient visit. In addition to these comments, we kindly request that you review the attached "HB 1427 opioid prescribing rulemaking guiding principles" document which outlines our thoughts on this complicated issue.

Request for enforcement grace period

Our understanding is the Medical Commission aims to finalize and implement these rules by October or November 2018; in advance of the legislatively mandated date of Jan. 1, 2019. This leaves insufficient time to educate physicians, other providers, and patients on these comprehensive rules.

Should the Commission implement along this timeline, **we request a 6-month enforcement "grace period" to give physicians, health systems, and the public time to understand and adjust clinical workflows to ensure appropriate care delivery under these rules.**

Strike intent and scope section, issue guideline or interpretive statement

Throughout the rulemaking process we have requested the intent section include express assurances to physicians that the rules are not inflexible and recognize the importance of sound clinical judgement.

Language was struck at a rule workshop in late May that would have provided this critical assurance and is therefore not included in the CR-102.

Other boards and commissions tasked with writing these rules have expressed their intent in one or two sentences. The Medical Commission's CR-102's intent section is 814 words. We argue a communication of this kind is not appropriate for this rulemaking and request the Medical Commission to strike its intent section in favor of releasing a guideline or interpretive statement, such as the one released in response to the confusion and ambiguity created by the chronic pain rules in 2012 – reaffirmed in June 2016. For reference, that communication is enclosed.

Should vs. Shall

Earlier in the rulemaking process, we urged rule writers "to focus-in on, and get right, several policies that will have a meaningful contribution to the existing trend of reducing harm associated with opioid drugs in Washington state". Based on our reading of HB 1427, we advocated for clear, easy to follow rules that "shall" be followed when writing every opioid prescription to help minimize confusion and align expectations. However, we believe the CR-102 is not a concise document and does not provide adequate clarity for clinicians seeking to treat pain within both their clinical judgement and the draft's requirements. At the urging of the Department of Health, we submit specific feedback below on which "shalls" should be "should" that will make these rules more workable for physicians and their patients during the limited context of a clinical visit.

Our comments on specific provisions are included below. Please never hesitate to reach out to Jeb Shepard at jeb@wsma.org or Ian Corbridge IanC@wsha.org with any questions you have.

Sincerely,

Members of the WSHA and WSMA joint opioid safe practices task force:
Nathan Schlicher, M.D. emergency physician at St. Joseph's Medical Center in Tacoma
Thomas Schaaf, M.D. family physician and hospitalist at Providence Medical Group in Spokane
Ray Hsiao, M.D. child psychiatrist and addiction specialist at Seattle Children's Hospital
Scott Kennedy, M.D. chief medical officer at Olympic Medical Center in Port Angeles
Sean Dobbin, Pharm.D. pharmacy director at Sacred Heart Medical Center in Spokane
Thomas Staiger, M.D. chief medical officer at UW Medical Center in Seattle

Enclosure:
HB 1427 opioid prescribing rulemaking guiding principles
Medical Commission Interpretive Statement

OPIOID PRESCRIBING – GENERAL PROVISIONS

WAC 246-919-850 Intent and Scope. The rules in WAC 246-919-850 through WAC 246-919-985 govern the prescribing of opioids in the treatment of pain.

Commented [A1]: Per cover letter, please strike this section, align with other boards and commissions, and release guideline or interpretive statement.

The Washington state medical quality assurance commission (commission) recognizes that principles of quality medical practice dictate that the people of the state of Washington have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity, mortality, and costs associated with untreated or inappropriately treated pain. For the purposes of these rules, the inappropriate treatment of pain includes non-treatment, undertreatment, overtreatment, and the continued use of ineffective treatments.

The diagnosis and treatment of pain is integral to the practice of medicine. The commission encourages physicians to view pain management as a part of quality medical practice for all patients with pain including acute, perioperative, subacute, and chronic pain. All physicians should become knowledgeable about assessing patients' pain and effective

methods of pain treatment, as well as become knowledgeable about the statutory requirements for prescribing opioids including co-occurring prescriptions. Accordingly, these rules clarify the commission's position on pain control, particularly as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

Inappropriate pain treatment may result from a physician's lack of knowledge about pain management. Fears of investigation or sanction by federal, state, or local agencies may also result in inappropriate treatment of pain. Appropriate pain management is the treating physician's responsibility. As such, the commission will consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations, recognizing that some types of pain cannot be completely relieved and taking into account whether the treatment is appropriate for the diagnosis.

The commission recognizes that controlled substances, including opioids may be essential in the treatment of acute, subacute, perioperative, or chronic pain due to disease, illness, trauma, or surgery. The commission will refer to current clinical practice guidelines and expert review in approaching cases involving management of pain.

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The medical management of pain should consider current clinical knowledge, scientific research, and the use of pharmacologic and non-pharmacologic modalities according to the judgment of the physician. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity, duration, impact of the pain, and treatment outcomes. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioids and are not the same as opioid use disorder.

The commission is obligated under the laws of the state of Washington to protect the public health and safety. The commission recognizes that the use of opioids for other than legitimate medical purposes poses a threat to the individual and society. The inappropriate prescribing of controlled substances, including opioids, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, the commission expects that physicians incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

Physicians should not fear disciplinary action from the commission for ordering, prescribing, dispensing or administering controlled substances, including opioids, for a legitimate medical purpose and in the

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course of professional practice. The commission will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain. To be within the usual course of professional practice, a physician-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of unrelieved pain. Compliance with applicable state or federal law is required.

The commission will judge the validity of the physician's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social, and work-related factors.

These rules are designed to assist physicians in providing appropriate medical care for patients.

The practice of medicine involves not only the science but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment.

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Therefore, it should be recognized that adherence to these rules will not guarantee an accurate diagnosis or a successful outcome. The sole purpose of these rules is to assist physicians in following a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care.

For more specific best practices, the physician may refer to clinical practice guidelines including, but not limited to, those produced by the Agency Medical Directors' Group, the Centers for Disease Control and Prevention, or The Bree Collaborative.

[Statutory Authority: RCW 18.71.450, 18.71A.100, 18.71.017, and 18.71A.020. WSR 11-12-025, § 246-919-850, filed 5/24/11, effective 1/2/12.]

WAC 246-919-851 Exclusions. WAC 246-919-850 through 246-919-985 do not apply to:

(1) The treatment of patients with cancer-related pain;

(2) The provision of palliative, hospice, or other end-of-life care;

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(3) The treatment of admitted inpatient and observation hospital patients ~~who are patients who have been admitted to a hospital for more than twenty-four hours; or~~

(4) The provision of procedural medications.

[Statutory Authority: RCW 18.71.450, 18.71A.100, 18.71.017, and 18.71A.020. WSR 11-12-025, § 246-919-851, filed 5/24/11, effective 1/2/12.]

WAC 246-919-852 Definitions. The following definitions apply to WAC 246-919-850 through 246-919-985 unless the context clearly requires otherwise.

(1) "Aberrant behavior" means behavior that indicates current misuse, diversion, unauthorized use of alcohol or other controlled substances, multiple early refills (renewals), or active opioid use disorder.

(2) "Acute pain" means the normal, predicted physiological response to a noxious chemical, thermal, or mechanical stimulus and typically is associated with invasive procedures, trauma, and disease. Acute pain is of six weeks or less in duration.

Commented [A2]: Applying differing regulatory practice rules to hopitalized patients based on varied hospitlaization time standards (> 24 hrs) is not feasible.

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(3) “Biological specimen test” or “biological specimen testing” means tests of urine, hair, or other biological samples for various drugs and metabolites.

(4) “Cancer-related pain” means pain that is an unpleasant, persistent, subjective sensory and emotional experience associated with actual or potential tissue injury or damage or described in such terms and is related to cancer or cancer treatment that interferes with usual functioning.

(5) "Chronic pain" means a state in which pain persists beyond the usual course of an acute disease or healing of an injury, or which may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years. Chronic pain is considered to be pain that persists for more than twelve weeks.

(6) "Comorbidities" means a preexisting or coexisting physical or psychiatric disease or condition.

(7) "Episodic care" means non-continuing medical or dental care provided by a physician other than the designated primary prescriber for a patient with chronic pain.

(8) “High dose” means ninety milligram morphine equivalent dose (MED), or more, per day.

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(9) "High-risk" is a category of patient at high risk of opioid-induced morbidity or mortality, based on factors and combinations of factors such as medical and behavioral comorbidities, polypharmacy, current substance use disorder or abuse, aberrant behavior, dose of opioids, or the use of any concurrent central nervous system depressant.

(10) "Hospice" means a model of care that focuses on relieving symptoms and supporting patients with a life expectancy of six months or less.

(11) "Hospital" means any health care institution licensed pursuant to chapter 70.41 RCW, 71.12 RCW, and RCW 72.23.020.

(12) "Low-risk" is a category of patient at low risk of opioid-induced morbidity or mortality, based on factors and combinations of factors such as medical and behavioral comorbidities, polypharmacy, and dose of opioids of less than fifty morphine equivalent dose per day.

(13) "Medication assisted treatment" or "MAT" means the use of pharmacologic therapy, often in combination with counseling and behavioral therapies, for the treatment of substance use disorders.

(14) "Moderate-risk" is a category of patient at moderate risk of opioid-induced morbidity or mortality, based on factors and combinations of factors such as medical and behavioral comorbidities, polypharmacy, past history of substance use disorder or abuse, aberrant behavior, and

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dose of opioids between fifty to ninety morphine equivalent doses per day.

(15) "Morphine equivalent dose" or "MED" means a conversion of various opioids to a morphine equivalent dose using the Agency Medical Directors Group (AMDG) or other conversion table approved by the commission. MED is considered the same as Morphine Milligram Equivalent (MME).

(16) "Multidisciplinary pain clinic" means a health care delivery facility staffed by physicians of different specialties and other non-physician health care providers who specialize in the diagnosis and management of patients with chronic pain

(17) "Opioid" means a drug that is either an opiate that is derived from the opium poppy or opiate-like that is a semi-synthetic or synthetic drug. Examples include morphine, codeine, hydrocodone, oxycodone, fentanyl, meperidine, tramadol, buprenorphine, and methadone.

Commented [A3]: While acknowledging that including these two drugs is technically correct, in that they are opioids, is it really the intent of these rules to apply to drugs that are used to treat addiction?

(18) "Palliative care" means care that maintains or improves the quality of life of patients and their families facing serious, advanced, or life-threatening illness.

(19) "Perioperative pain" means acute pain that occurs surrounding the performance of surgery.

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(20) “Prescription monitoring program” or “PMP” means the Washington state prescription monitoring program authorized under chapter 70.225 RCW. Other jurisdictions may refer to this as the Prescription Drug Monitoring Program or “PDMP”.

(21) “Practitioner” means an advanced registered nurse practitioner licensed under chapter 18.79 RCW, a dentist licensed under chapter 18.32 RCW, a physician licensed under chapters 18.71 or 18.57 RCW, a physician assistant licensed under chapter 18.71A or 18.57A RCW, or a podiatric physician licensed under chapter 18.22 RCW.

(22) “Refill” or “renewal” means a second or subsequent filling of a previously issued prescription.

(23) "Subacute pain" is considered to be a continuation of pain that is six to twelve weeks in duration.

(24) "Substance use disorder” means a primary, chronic, neurobiological disease with genetic, psychosocial, and environmental factors influencing its development and manifestations. Substance use disorder is not the same as physical dependence or tolerance that is a normal physiological consequence of extended opioid therapy for pain. It is characterized by behaviors that include, but are not limited to, impaired control over drug use, craving, compulsive use, or continued use despite harm.

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[Statutory Authority: RCW 18.71.450, 18.71A.100, 18.71.017, and 18.71A.020. WSR 11-12-025, § 246-919-852, filed 5/24/11, effective 1/2/12.]

246-919-865 Patient notification, secure storage, and disposal.

(1) The physician shall ensure the patient is provided the following information at the first issuance of a prescription for opioids and at the transition from acute to subacute, and subacute to chronic:

(a) Risks associated with the use of opioids as appropriate to the medical condition, the type of patient, and the phase of treatment;

(b) The safe and secure storage of opioid prescriptions; and

(c) The proper disposal of unused opioid medications, including but not limited to, the availability of recognized drug take-back programs.

(2) This requirement may be satisfied with a document provided by the Department of Health.

246-919-870 Use of alternative modalities for pain treatment.

The physician shall exercise their professional judgment in selecting appropriate treatment modalities for acute non-operative, acute perioperative, or subacute pain including the use of multimodal pharmacologic and non-pharmacologic therapy as an alternative to opioids whenever reasonable, clinically appropriate, evidence-based alternatives exist.

Commented [A4]: Please change to should.

Commented [A5]: Chronic pain, the phase of pain which alternative modalities might be most appropriate, is not included in this section. Please include.

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246-919-875 Continuing education requirements for opioid prescribing.

(1) To prescribe an opioid in Washington state, a physician licensed to prescribe opioids shall complete a one-time continuing education requirement regarding the opioid prescribing rules in this chapter. The continuing education must be at least one hour in length.

(2) The physician shall complete the one-time continuing education requirement described in subsection (1) of this section by the end of the physician's first full continuing education reporting period after January 1, 2019, or during the first full continuing education reporting period after initial licensure, whichever is later.

(3) The hours spent completing training in prescribing of opioids count toward meeting applicable continuing education requirements in the same category specified in WAC 246-919-460.

Commented [A6]: We appreciate that a physician may meet the CME requirement by learning about these rules, but this reads like the CME must be on the rules, when a different CME, perhaps on general opioid prescribing might be more beneficial to a physician depending on their practice. Please provide for flexibility / both options.

OPIOID PRESCRIBING – ACUTE NON-OPERATIVE PAIN AND ACUTE PERIOPERATIVE PAIN

246-919-880 Patient evaluation and patient record – acute non-operative pain.

Prior to issuing an opioid prescription for acute non-operative pain or acute perioperative pain, the physician shall:

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(1) Conduct and document an appropriate history and physical examination including screening for risk factors for overdose and severe post-operative pain;

(2) Evaluate the nature and intensity of the pain or anticipated pain following surgery; and

(3) Inquire about any other medications the patient is prescribed or is taking.

246-919-885 Treatment plan – acute non-operative pain.

The physician shall comply with the requirements in this section when prescribing opioids for acute non-operative pain.

(1) The physician should consider prescribing non-opioids as the first line of pain control in patients unless not clinically appropriate in accordance with the provisions of WAC 246-919-870.

(2) The physician, or their designee as defined in WAC 246-470-050, shall conduct queries of the PMP in accordance with the provisions of WAC 246-919-985.

(3) If the physician prescribes opioids for effective pain control, such prescription must not be in a greater quantity than needed for the expected duration of pain severe enough to require opioids. A three-day

Commented [A7]: To help with making these rules concise, please combine the acute sections. The only difference is the quantity of pills which could be addressed.

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supply or less will often be sufficient. The physician shall not prescribe beyond a seven-day supply without clinical documentation in the patient record to justify the need for such a quantity.

(4) The physician shall reevaluate the patient who does not follow the expected course of recovery, and reconsider the continued use of opioids or whether tapering or discontinuing opioids is clinically indicated.

(5) Follow-up visits for pain control must include objectives or metrics to be used to determine treatment success if opioids are to be continued. This may include:

(a) Change in pain level;

(b) Change in physical function;

(c) Change in psychosocial function; and

(d) Additional indicated diagnostic evaluations.

(6) If a prescription results in the patient receiving a combination of opioids with a sedative medication listed in WAC 246-919-970, such prescribing must be in accordance with WAC 246-919-970.

(7) Long-acting or extended release opioids are not indicated for acute non-operative pain.

(8) Medication assisted treatment medications must not be discontinued when treating acute pain, except as consistent with the provisions of WAC 246-919-975.

Commented [A8]: This is a guideline, please strike to align with podiatric physician rules.

Commented [A9]: Please change to "should".

Commented [A10]: Unclear as there is a 'may include' – highlighted below. Please change must to should. **246-919-890** below says "should". If the acute sections are not combined, there should be consistency with the should vs shall/must in the two acute sections or it will cause confusion.

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Commented [A11]: Please change to "should" as WAC 246-919-975 provides for situations where it may be appropriate and documented.

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(9) If the physician elects to treat a patient with opioids beyond the six-week time period of acute non-operative pain, the physician shall document in the patient record that the patient is transitioning from acute pain to subacute pain. Rules governing the treatment of subacute pain in WAC 246-919-895 and 246-919-900 shall apply.

246-919-890 Treatment plan - acute perioperative pain.

The physician shall comply with the requirements in this section when prescribing opioids for perioperative pain.

(1) The physician shall consider prescribing non-opioids as the first line of pain control in patients, unless not clinically appropriate, in accordance with the provisions of WAC 246-919-870.

(2) The physician, or their designee as defined in WAC 246-470-050, shall conduct queries of the PMP in accordance with the provisions of WAC 246-919-985.

(3) If the physician prescribes opioids for effective pain control, such prescription must not be in a greater quantity than needed for the expected duration of pain severe enough to require opioids. A three-day supply or less will often be sufficient. The physician shall not prescribe beyond a fourteen-day supply from the time of discharge without clinical documentation in the patient record to justify the need for such a quantity.

Commented [A12]: This is a guideline, please strike to align with podiatric physician rules.

Commented [A13]: Please change to should.

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(4) The physician shall reevaluate a patient who does not follow the expected course of recovery and reconsider the continued use of opioids or whether tapering or discontinuing opioids is clinically indicated.

(5) Follow-up visits for pain control should include objectives or metrics to be used to determine treatment success if opioids are to be continued. This may include:

(a) Change in pain level;

(b) Change in physical function;

(c) Change in psychosocial function; and

(d) Additional indicated diagnostic evaluations or other treatments.

(6) If a prescription results in the patient receiving a combination of opioids with a sedative medication listed in WAC 246-919-970, such prescribing must be in accordance with WAC 246-919-970.

(7) Long-acting or extended release opioids are not indicated for acute perioperative pain.

(8) Medication assisted treatment medications must not be discontinued when treating acute perioperative pain except as consistent with the provisions of WAC 246-919-975.

(9) If the physician elects to treat a patient with opioids beyond the six-week time period of acute perioperative pain, the physician shall

Commented [A14]: This is correct. 246-919-885 sub (5) above says "must". Please change. If the two acute sections are not combined, there should be consistency with the should vs shall/must in the two acute sections or it will cause confusion.

Commented [A15]: Please change to "should" as WAC 246-919-975 provides for situations where it may be appropriate and documented.

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document in the patient record that the patient is transitioning from acute pain to subacute pain. Rules governing the treatment of subacute pain, WAC 246-919-895 and WAC 246-919-900 shall apply unless there is documented improvement in function or pain control and there is a documented plan and timing for discontinuation of all opioid medications.

OPIOID PRESCRIBING – SUBACUTE PAIN

246-919-895 Patient evaluation and patient record – subacute pain.

The physician shall comply with the requirements in this section when prescribing opioids for subacute pain.

(1) Prior to issuing an opioid prescription for subacute pain, the physician shall assess the rationale for continuing opioid therapy as follows:

(a) Conduct an appropriate history and physical examination;

(b) Re-evaluate the nature and intensity of the pain;

(c) Conduct, or cause their designee as defined in WAC 246-470-050 to conduct, a query of the PMP in accordance with the provisions of WAC 246-919-985;

(d) Screen the patient’s level of risk for aberrant behavior and adverse events related to opioid therapy;

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(e) Obtain a biological specimen test if the patient's functional status is deteriorating or if pain is escalating; and

(f) Screen or refer the patient for further consultation for psychosocial factors if the patient's functional status is deteriorating or if pain is escalating.

(2) The physician treating a patient for subacute pain with opioids shall ensure that, at a minimum, the following is documented in the patient record:

(a) The presence of one or more recognized diagnoses or indications for the use of opioid pain medication;

(b) The observed and/or reported effect on function or pain control forming the basis to continue prescribing opioids beyond the acute pain episode;

(c) Pertinent concerns discovered in the PMP;

(d) An appropriate pain treatment plan including the consideration of, or attempts to use, non-pharmacological modalities and non-opioid therapy;

(e) The action plan for any aberrant biological specimen testing results and the risk-benefit analysis if opioids are to be continued;

(f) Results of psychosocial screening or consultation;

Commented [A16]: These decisions are largely based on patients' reports of pain and function rather than on direct observation by the clinician.

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(g) Results of screening for the patient's level of risk for aberrant behavior and adverse events related to opioid therapy, and mitigation strategies; and

(h) The risk-benefit analysis of any combination of prescribed opioid and benzodiazepines or sedative-hypnotics, if applicable; ~~and~~

(3) Follow-up visits for pain control must include objectives or metrics to be used to determine treatment success if opioids are to be continued. This includes, ~~at a minimum~~:

(a) Change in pain level;

(b) Change in physical function;

(c) Change in psychosocial function; and

(d) Additional indicated diagnostic evaluations or other treatments.

246-919-900 Treatment plan – subacute pain.

The physician, having recognized the progression of a patient from the acute non-operative or acute perioperative phase to the subacute phase shall develop an opioid treatment plan.

(1) If tapering has not begun prior to the six to twelve week subacute phase, the physician shall reevaluate the patient. Based on effect on function or pain control, the physician shall consider whether opioids will be continued, tapered, or discontinued.

Commented [A17]: Please strike. Based on MQAC work group conversations, we don't believe the intent is to require documentation of sub 3. If it is, please consider sub 3 (d): If no other treatments or evaluation are indicated documenting insisting on documenting "No other diagnostic or treatments indicated" will be burdensome and of low value.

Commented [A18]: For consistency with 246-919-890 (5) and requested changes in 246-919-885 (5), please change to "should"

Commented [A19]: For consistency with 246-919-890 (5) and 246-919-885 (5), please insert "may".

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(2) If the physician prescribes opioids for effective pain control, such prescription must not be in a greater quantity than needed for the expected duration of pain that is severe enough to require opioids. ~~The~~ During the subacute phase, the physician shall not prescribe beyond a fourteen-day supply of opioids without clinical documentation to justify the need for such a quantity ~~during the subacute phase.~~

(3) If a prescription results in the patient receiving a combination of opioids with a sedative medication listed in WAC 246-919-970, such prescribing must be in accordance with WAC 246-919-970.

(4) If the physician elects to treat a patient with opioids beyond the six to twelve week subacute phase, the physician shall document in the patient record that the patient is transitioning from subacute pain to chronic pain. Rules governing the treatment of chronic pain, WAC 246-919-905 through WAC 246-919-955, shall apply.

OPIOID PRESCRIBING – CHRONIC PAIN MANAGEMENT

WAC 246-919-905 Patient evaluation and patient record – chronic pain. When the patient enters the chronic pain phase, the patient shall be reevaluated as if presenting with a new disease. The physician ~~shall~~ should include in the patient's record:

Commented [A20]: The patient evaluation and patient record section here is nearly identical to subacute. To help make the rule more concise, please consider combining.

Commented [A21]: Please change this shall to 'should' and move 3 (d) in this section to the 'must document' area under item 4 – "Assessment" in this section. The risk ranking piece has to stay under a 'shall or must' because it is used later to determine the required frequency of the PMP checks.

(1) An appropriate history including:

(a) The nature and intensity of the pain;

(b) The effect of pain on physical and psychosocial function;

(c) Current and relevant past treatments for pain, including opioids and other medications and their efficacy; and

(d) Review of comorbidities with particular attention to psychiatric and substance use.

(2) Appropriate physical examination.

(3) Ancillary information and tools to include:

(a) Review of the PMP to identify any medications received by the patient in accordance with the provisions of WAC 246-919-985;

(b) Any pertinent diagnostic, therapeutic, and laboratory results;

(c) Pertinent consultations; and

(d) Use of a risk assessment tool that is a professionally-developed, clinically recommended questionnaire appropriate for characterizing a patient's level of risk for opioid or other substance use disorders to assign the patient to a high, moderate, or low-risk category.

(4) Assessment. The physician must document medical decision making to include:

(a) Pain related diagnosis, including documentation of the presence of one or more recognized indications for the use of pain medication;

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(b) Consideration of the risks and benefits of chronic opioid treatment for the patient;

(c) The observed effect on function or pain control forming the basis to continue prescribing opioids; and

(d) Pertinent concerns discovered in the PMP;

(5) Treatment plan as provided in WAC 246-919-910.

[Statutory Authority: RCW 18.71.450, 18.71A.100, 18.71.017, and 18.71A.020. WSR 11-12-025, § 246-919-853, filed 5/24/11, effective 1/2/12.]

WAC 246-919-910 Treatment plan – chronic pain.

The physician, having recognized the progression of a patient from the subacute phase to the chronic phase, shall develop an opioid treatment plan as follows:

(1) Treatment plan and objectives including:

(a) Documentation of any medication prescribed;

(b) Biologic specimen testing ordered;

(c) Any labs, diagnostic evaluations, referrals, or imaging ordered;

(d) Other planned treatments; and

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(e) Written agreement for treatment as provided in WAC 246-919-915.

(2) The physician shall complete patient notification in accordance with the provisions of WAC 246-919-865 or provide this information in the written agreement.

WAC 246-919-915 Written agreement for treatment – chronic pain.

The physician shall use a written agreement that outlines the patient's responsibilities for opioid therapy. This written agreement for treatment must include the following provisions:

(1) The patient's agreement to provide samples for biological specimen testing when requested by the physician;

(2) The patient's agreement to take medications at the dose and frequency prescribed with a specific protocol for lost prescriptions and early refills;

(3) Reasons for which opioid therapy may be discontinued;

(4) The requirement that all opioid prescriptions for chronic pain are provided by a single prescriber or a single clinic, except as provided in WAC 246-919-965 for episodic care;

(5) The requirement that all opioid prescriptions for chronic pain are to be dispensed by a single pharmacy or pharmacy system whenever possible;

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(6) The patient's agreement to not abuse alcohol or use other medically unauthorized substances;

(7) A violation of the agreement may result in a tapering or discontinuation of the prescription;

(8) The patient's responsibility to safeguard all medications and keep them in a secure location; and

(9) If the patient violates the terms of the agreement, the violation and the physician's response to the violation will be documented, as well as the rationale for changes in the treatment plan.

[Statutory Authority: RCW 18.71.450, 18.71A.100, 18.71.017, and 18.71A.020. WSR 11-12-025, § 246-919-856, filed 5/24/11, effective 1/2/12.]

Commented [A22]: This would make more sense in the "periodic review" section below, not the written agreement section.

WAC 246-919-920 Periodic review – chronic pain.

(1) The physician shall periodically review the course of treatment for chronic pain. The frequency of visits, biological testing, and PMP queries in accordance with the provisions of WAC 246-919-985, must be determined based on the patient's risk category:

(a) For a high-risk patient, at least quarterly;

(b) For a moderate-risk patient, at least semiannually;

(c) For a low-risk patient, at least annually;

(d) Immediately upon indication of concerning aberrant behavior; and

~~(e) More frequently at the physician's discretion.~~

Commented [A23]: This can already occur as needed.

(2) During the periodic review, the physician shall determine:

(a) The patient's compliance with any medication treatment plan;

(b) If pain, function, and quality of life have improved, diminished, or are maintained; and

(c) If continuation or modification of medications for pain management treatment is necessary based on the physician's evaluation of progress towards treatment objectives and compliance with the treatment plan.

(3) Periodic patient evaluations must also include:

(a) History and physical examination related to the pain;

(b) Use of validated tools to document either maintenance or change in function and pain control; and

(c) Review of the Washington state PMP at a frequency determined by the patient's risk category in accordance with the provisions of WAC 246-919-985 and section (1) of this subsection.

[Statutory Authority: RCW 18.71.450, 18.71A.100, 18.71.017, and 18.71A.020. WSR 11-12-025, § 246-919-857, filed 5/24/11, effective 1/2/12.]

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WAC 246-919-925 Long-acting opioids – chronic pain. Long-acting opioids should only be prescribed by a physician who is familiar with its risks and use, and who is prepared to conduct the necessary careful monitoring. Special attention should be given to patients who are initiating such treatment. The physician prescribing long-acting opioids should have a one-time completion of at least four hours of continuing education relating to this topic.

[Statutory Authority: RCW 18.71.450, 18.71A.100, 18.71.017, and 18.71A.020. WSR 11-12-025, § 246-919-858, filed 5/24/11, effective 1/2/12.]

WAC 246-919-930 Consultation—Recommendations and requirements – chronic pain. (1) The physician shall consider referring the patient for additional evaluation and treatment as needed to achieve treatment objectives. Special attention should be given to those chronic pain patients who are under eighteen years of age or who are potential high-risk patients.

(2) The mandatory consultation threshold is one hundred twenty milligrams MED. In the event a physician prescribes a dosage amount that meets or exceeds the consultation threshold of one hundred twenty milligrams MED per day, a consultation with a pain management specialist

Commented [A24]: There is no CME requirement in the other sets of rules for other professions, including nurses, DOs, and podiatric physicians. Please strike.

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as described in WAC 246-919-945 is required, unless the consultation is exempted under WAC 246-919-935 or 246-919-940.

(3) The mandatory consultation must consist of at least one of the following:

(a) An office visit with the patient and the pain management specialist;

(b) A telephone, electronic, or in-person consultation between the pain management specialist and the physician;

(c) An audio-visual evaluation conducted by the pain management specialist remotely where the patient is present with either the physician or a licensed health care practitioner designated by the physician or the pain management specialist; or

(d) Other chronic pain evaluation services as approved by the commission.

(4) A physician shall document each consultation with the pain management specialist.

[Statutory Authority: RCW 18.71.450, 18.71A.100, 18.71.017, and 18.71A.020. WSR 11-12-025, § 246-919-860, filed 5/24/11, effective 1/2/12.]

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WAC 246-919-935 Consultation—Exemptions for exigent and special circumstances – chronic pain. A physician is not required to consult with a pain management specialist as defined in WAC 246-919-945 when the physician has documented adherence to all standards of practice as defined in WAC 246-919-905 through 246-919-945, and when one or more of the following conditions are met:

(1) The patient is following a tapering schedule;

(2) The patient requires treatment for acute pain, which may or may not include hospitalization, requiring a temporary escalation in opioid dosage, with an expected return to their baseline dosage level or below;

(3) The physician documents reasonable attempts to obtain a consultation with a pain management specialist and the circumstances justifying prescribing above one hundred twenty milligrams morphine equivalent dose (MED) per day without first obtaining a consultation; or

(4) The physician documents the patient's pain and function are stable and the patient is on a non-escalating dosage of opioids.

[Statutory Authority: RCW 18.71.450, 18.71A.100, 18.71.017, and 18.71A.020. WSR 11-12-025, § 246-919-861, filed 5/24/11, effective 1/2/12.]

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WAC 246-919-940 Consultation—Exemptions for the physician – chronic pain. The physician is exempt from the consultation requirement in WAC 246-919-930 if one or more of the following qualifications is met:

(1) The physician is a pain management specialist under WAC 246-919-945;

(2) The physician has successfully completed a minimum of twelve Category I continuing education hours on chronic pain management within the previous four years. At least two of these hours must be dedicated to substance use disorders;

(3) The physician is a pain management physician working in a multidisciplinary chronic pain treatment center or a multidisciplinary academic research facility; or

(4) The physician has a minimum of three years of clinical experience in a chronic pain management setting, and at least thirty percent of their current practice is the direct provision of pain management care.

[Statutory Authority: RCW 18.71.450, 18.71A.100, 18.71.017, and 18.71A.020. WSR 11-12-025, § 246-919-862, filed 5/24/11, effective 1/2/12.]

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WAC 246-919-945 Pain management specialist – chronic pain. A pain management specialist shall meet one or more of the following qualifications:

(1) If an allopathic physician or osteopathic physician:

(a) Is board certified or board eligible by an American Board of Medical Specialties-approved board (ABMS) or by the American Osteopathic Association (AOA) in physical medicine and rehabilitation, neurology, rheumatology, or anesthesiology;

(b) Has a subspecialty certificate in pain medicine by an ABMS-approved board;

(c) Has a certification of added qualification in pain management by the AOA;

(d) Is credentialed in pain management by an entity approved by the commission for an allopathic physician or the Washington state board of osteopathic medicine and surgery for an osteopathic physician;

(e) Has a minimum of three years of clinical experience in a chronic pain management care setting; and

(i) Has successful completion of a minimum of at least eighteen continuing education hours in pain management during the past two years for an allopathic physician or three years for an osteopathic physician; and

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(ii) Has at least thirty percent of the allopathic physician's or osteopathic physician's current practice is the direct provision of pain management care or is in a multidisciplinary pain clinic.

(2) If an allopathic physician assistant, in accordance with WAC 246-918-885.

(3) If an osteopathic physician assistant, in accordance with WAC 246-854-330.

(4) If a dentist, in accordance with WAC 246-817-965.

(5) If a podiatrist, in accordance with WAC 246-922-750.

Commented [A25]: Please change to the correct terminology, "podiatric physician", as utilized on page 10 under definition of "provider".

(6) If an advanced registered nurse practitioner in accordance with WAC 246-840-493.

[Statutory Authority: RCW 18.71.450, 18.71A.100, 18.71.017, and 18.71A.020. WSR 11-12-025, § 246-919-863, filed 5/24/11, effective 1/2/12.]

246-919-950 Tapering considerations – chronic pain.

(1) The physician shall consider tapering or referral for a substance use disorder evaluation when:

(a) The patient requests;

(b) The patient experiences a deterioration in function or pain;

(c) The patient is non-compliant with the written agreement;

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(d) Other treatment modalities are indicated;

(e) There is evidence of misuse, abuse, substance use disorder, or diversion;

(f) The patient experiences a severe adverse event or overdose;

(g) There is unauthorized escalation of doses; or

(h) The patient is receiving an escalation in opioid dosage with no improvement in their pain or function.

246-919-955 Patients with chronic pain, including those on high doses of opioids, establishing a relationship with a new physician.

(1) When a patient receiving chronic opioid pain medications changes to a new physician, it is normally appropriate for the new physician to initially maintain the patient's current opioid doses. Over time, the physician may evaluate if any tapering or other adjustments in the treatment plan can or should be done.

(2) A physician's treatment of a new high dose chronic pain patient is exempt from the mandatory consultation requirements of WAC 246-919-930 if:

(a) The patient was previously being treated with a dosage of opioids in excess of one hundred twenty milligram MED for chronic

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pain under an established written agreement for treatment of the same chronic condition or conditions;

(b) The patient's dose is stable and non-escalating;

(c) The patient has a history of compliance with treatment plans and written agreements documented by medical records and PMP queries; and

(d) The patient has documented functional stability, pain control, or improvements in function or pain control at the presenting opioid dose.

(3) With respect to the treatment of a new patient under subsection (1) or (2) of this section, this exemption applies for the first three months of newly established care, after which the requirements of WAC 246-919-930 shall apply.

OPIOID PRESCRIBING – SPECIAL POPULATIONS

246-919-960 Special populations – Children or adolescent patients, pregnant patients, and aging populations.

(1) Children or adolescent patients. In the treatment of pain for children or adolescent patients, the physician shall treat pain in a manner equal to that of an adult but must account for the weight of the patient and adjust the dosage prescribed accordingly.

Commented [A26]: What is the definition of "adolescent". There is a definition for "aging" below.

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(2) Pregnant patients. The physician shall not initiate opioid detoxification without consultation with a provider with expertise in addiction medicine. Medication assisted treatment for opioids, such as methadone or buprenorphine, must not be discontinued during pregnancy without consultation with a MAT prescribing practitioner.

(3) Aging populations. As people age, their sensitivities to and metabolizing of opioids may change. The physician shall consider the distinctive needs of patients who are sixty-five years of age or older and who have been on chronic opioid therapy or who are initiating opioid treatment.

246-919-965 Episodic care of chronic opioid patients.

(1) When providing episodic care for a patient who the physician knows is being treated with opioids for chronic pain, such as for emergency or urgent care, the physician or their designee as defined in WAC 246-470-050, shall review the PMP and document their review and any concerns.

(2) A physician providing episodic care to a patient who the physician knows is being treated with opioids for chronic pain should provide additional analgesics, including opioids, to adequately treat acute pain. If opioids are provided, the physician

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shall limit the use of opioids to the minimum amount necessary to control the acute pain until the patient can receive care from the practitioner who is managing the patient's chronic pain.

(3) The episodic care physician shall coordinate care with the patient's chronic pain treatment practitioner, if possible.

OPIOID PRESCRIBING – CO-PRESCRIBING

246-919-970 Co-prescribing of opioids with certain medications.

(1) The physician shall not knowingly prescribe opioids in combination with the following medications without documentation of medical decision making:

(a) Benzodiazepines;

(b) Barbiturates;

(c) Sedatives;

(d) Carisoprodol; or

(e) Non-benzodiazepine hypnotics.

(2) If, because of a prior prescription by another provider, a prescription written by a physician knowingly results in a combination of opioids and medications described in subsection (1) of this section, the physician issuing the new prescription shall consult with the other prescriber to establish a patient care plan

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surrounding these medications. This provision does not apply to emergency care.

246-919-975 Co-prescribing of opioids for patients receiving medication assisted treatment.

(1) Where practicable, the physician providing acute non-operative pain or acute perioperative pain treatment to a patient who is known to be receiving MAT medications shall prescribe appropriate opioids for pain relief either in consultation with a MAT prescribing practitioner or a pain specialist.

Commented [A27]: Without 'appropraite' added, the rule would require opioid for 'pain relief'

(2) The physician providing acute non-operative pain or acute perioperative pain treatment shall not discontinue MAT medications without documentation of the reason for doing so, nor shall the use of these medications be used to deny necessary operative intervention.

246-919-980 Co-prescribing of naloxone.

The opioid prescribing physician shall confirm or provide a current prescription for naloxone when opioids are prescribed to a ~~high risk~~ patient who is known to be high-risk for opioid overdose.

OPIOID PRESCRIBING – PRESCRIPTION MONITORING PROGRAM

246-919-985 Prescription monitoring program – Required registration, queries, and documentation.

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(1) The physician shall register to access the PMP or demonstrate proof of having assured access to the PMP if they prescribe schedule II-V medications in Washington state.

(2) The physician is permitted to delegate performance of a required PMP query to an authorized designee as defined in WAC 246-470-050.

(3) At a minimum, the physician shall ensure a PMP query is performed prior to the prescription of an opioid ~~or of a medication listed in WAC 246-919-970~~ at the following times:

(a) Upon the first refill or renewal of an opioid prescription for acute non-operative pain or acute perioperative pain;

(b) The time of transition from acute to subacute pain; and

(c) The time of transition from subacute to chronic pain.

(4) For chronic pain management, the physician shall ensure a PMP query is performed at a minimum frequency determined by the patient's risk assessment, as follows:

(a) For a high-risk patient, a PMP query shall be completed at least quarterly;

(b) For a moderate-risk patient, a PMP query shall be completed at least semiannually; and

Commented [A28]: Please align with other boards and commissions, which don't require a check on all substances listed in WAC 246-919-970. This should not be a more stringent requirement for medical doctors.

Ex. Podiatry: "At a minimum, the podiatric physician shall ensure a PMP query is performed prior to the prescription of an opioid at the following times:"

Ex. Nursing: "At a minimum, the advanced registered nurse practitioner shall ensure a PMP query is performed prior to the prescription of an opioid at the following times:"

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(c) For a low-risk patient, a PMP query shall be completed at least annually.

(5) The physician shall ensure a PMP query is performed for any chronic pain patient immediately upon identification of aberrant behavior.

(6) The physician shall ensure a PMP query is performed when providing episodic care to a patient who the physician knows to be receiving opioids for chronic pain, in accordance with WAC 246-919-965.

(7) If the physician is using an electronic medical record (EMR) that integrates access to the PMP into the workflow of the EMR, the physician shall ensure a PMP query is performed for all prescriptions of opioids and medications listed in WAC 246-919-970.

(8) For the purposes of this section, the requirement to consult the PMP does not apply when the PMP or the EMR cannot be accessed by the physician or their designee, as defined in WAC 246-470-050, due to a temporary technological or electrical failure.

(9) Pertinent concerns discovered in the PMP shall be documented in the patient record.

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