CONCEPTUAL DRAFT VERSION 3
OPIOID PRESCRIBING RULES (ESHB 1427)
DECEMBER 21, 2017

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This document is a conceptual rules draft, designed for discussion purposes only

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NOTE: Numbering for the above sections is for illustration purposes only. We recognize that actual numbering will need to take into account existing chronic non-cancer pain rules, which have different section numbers, depending on the chapter.
CONCEPTUAL DRAFT VERSION 3
GENERAL PROVISIONS

OPIOID PRESCRIBING – GENERAL PROVISIONS

246-XXX-X01  Intent

Pursuant to ESHB 1427, chapter 297, sections 2 through 8, Laws of 2017 and Executive Order 16-09, the Dental Quality Assurance Commission, the Nursing Care Quality Assurance Commission, the Medical Quality Assurance Commission, the Board of Osteopathic Medicine and Surgery, and the Board of Podiatric Medicine and Surgery have worked together collaborated to develop and adopt shared professional practice requirements expected of all healthcare practitioners who prescribe opioid analgesics.

The diagnosis and treatment of pain is integral to the practice of (medicine/nursing/osteopathic medicine and surgery/dentistry/podiatric medicine and surgery). Practitioners should not prescribe opioid analgesics by default. Opioid analgesics may be essential in the treatment of acute or subacute pain due to trauma or surgery; however, use for acute or subacute pain can raise the risk of addiction. Use for chronic pain carries significant patient risk.

Changes from Previous Draft:
None

Status:
Scheduled for discussion at January 8 meeting

Notes:
Suggest “collaboratively developed and adopted” instead of “worked together to.”
OPIOID PRESCRIBING – GENERAL PROVISIONS
246-XXX-X01 Scope and Applicability

(1) The variety and complexity of human conditions make it impossible to address in rule all the circumstances the practitioner must consider when treating a patient. As with all health professions regulations, these rules are intended to set minimum standards for professional conduct; these rules do not encompass all of the guidelines recommended by the agency medical directors’ group, the Bree collaborative, centers for disease control guidelines, or other agencies or organizations.

(2) Where these rules do not address specific issues, the (board/commission) will govern based on nationally accepted and evidence-based standard of care and will refer to current clinical practice guidelines and expert review in considering cases involving management of pain. The practitioner should obtain sufficient education and training on current clinical practice guidelines, on an ongoing basis, to ensure competency in safe prescribing of opioids and other analgesics.

(3) These rules establish enforceable standards for practitioners prescribing opioid analgesics under the (board’s/commission’s) jurisdiction. Compliance with applicable state or federal law is required. These rules do not establish a legal standard of care outside the context of the (board’s/commission’s) jurisdiction.

Changes from Previous Draft:
None

Status:
Scheduled for discussion at January 8 meeting

Notes:
Definitions. The definitions in this section apply throughout sections XX1 through section X99 unless the context clearly requires otherwise.

1. "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.

2. "Addiction" means a primary, chronic, neurobiologic disease with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include: impaired control over drug use, craving, compulsive use, or continued use despite harm. Addiction does not mean physical dependence and tolerance that are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

3. "Biological specimen testing" means tests including but not limited to urine, hair or other biological samples for various drugs and metabolites to provide objective documentation of adherence to an opioid treatment plan as well as aid in the diagnosis and treatment of addiction or substance use disorders.

4. "Chronic pain" means pain caused by various diseases or abnormal conditions that continue longer than twelve weeks.

5. "Clinically meaningful improvement in function" means a measurable improvement in function of at least thirty percent as compared to the start of treatment or in response to a dose change. A decrease in pain intensity in the absence of improved function is not considered clinically meaningful improvement in function.

6. "Comorbidity" means a preexisting or coexisting physical or psychiatric disease or condition.

7. "Functional examination" means an examination used to describe an individual’s ability to perform key daily activities and to evaluate changes in the activities of everyday life. It encompasses physical, social, and psychological domains.

8. "High-risk" means a patient at increased propensity for misuse, abuse, stockpiling, diversion, addiction, overdose, or other aberrant behaviors as determined by the patient’s history, and/or the risk assessment tool chosen by the practitioner, or other factors identified by the practitioner.

9. "Hospice care" means a model of care that focuses on relieving symptoms and supporting patients with a life expectancy of six months or less. Hospice involves an interdisciplinary approach to provide health care, pain management, and emotional and spiritual support. The emphasis is on comfort, quality of life, and patient and family support. Hospice can be provided in the patient's home as well as in freestanding hospice facilities, hospitals, nursing homes, or other long-term care facilities.

10. "Hospital" means any institution, place, building, or agency licensed by the department under chapters 70.41 or 71.12 RCW to provide accommodations, facilities, and services over a continuous period of twenty-four hours or more, for observation, diagnosis, or care of two or more individuals not related to the operator who are suffering from illness, injury, deformity, or abnormality, or from any other condition for which obstetrical, medical, or surgical services would be appropriate for care or diagnosis.
(11) “Inpatient” means a person who has been admitted to a hospital for more than twenty-four hours.

(12) "Morphine equivalent dose" or "MED" means a conversion of various opioids to a morphine equivalent dose by the use of accepted conversion tables.

(13) “Opioid analgesic” means a drug that is used to alleviate moderate to severe pain that is either an opiate (derived from the opium poppy) or opiate-like (semi-synthetic or synthetic drugs). Examples include morphine, codeine, hydrocodone, oxycodone, fentanyl, meperidine, and methadone.

(14) “Opioid naïve” means a patient who has not used opioids for more than seven consecutive days during the previous thirty days.

(15) "Palliative care" means care that improves the quality of life for patients facing life-threatening illness. With palliative care particular attention is given to the prevention, assessment, and treatment of pain and other symptoms, and to the provision of psychological, spiritual, and emotional support.

(16) “Pain” means an unpleasant sensory or emotional experience associated with actual or potential tissue damage, or described in terms of such damage.

(17) “Pain management clinic” means a publicly or privately owned facility for which a majority of patients are receiving chronic pain treatment which may include opioid analgesics or other care provided by multiple available disciplines or treatment modalities.

(18) “Perioperative pain” means acute pain that occurs as the result of surgery for which opioid analgesics may be prescribed.

(19) “PMP” means the Washington prescription monitoring program authorized under chapter 70.225 RCW.

(20) “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 chapter 18.71, 18.57, or 18.22 RCW, or a physician assistant licensed under chapter 18.71A or 18.57A RCW.

(21) “Risk assessment tools” means utilizing a tool appropriate for the patient, such as but not limited to, the Screener and Opioid Assessment for Patients with Pain, Opioid Risk Tool, or Screening, Brief Intervention and Referral to Treatment, which are designed for predicting the likelihood that a patient will abuse or misuse a prescribed controlled substance based on past behavior, genetic predispositions, social or environmental factors, or other risks.

(22) "Subacute pain" means the symptom or illness has passed the acute episode, but is not yet chronic.

Changes from Previous Draft:
None

Status:
Scheduled for discussion at January 8 meeting

Notes:
• Review definition for “High-risk patient” to see if it needs to be expanded (current context is chronic)
• Insert a definition for “Medication-assisted treatment or ‘MAT’”
• Consider whether inclusion of “milligram morphine equivalent” definition within or in addition to (13) defining morphine equivalent dosing is necessary.
• We will need to consider adding a separate definition for ASF and see where ambulatory surgery facilities need to be incorporated into this rule.
• Should co-prescribing be defined?
246-XXX-X04  Exclusions

Practitioners treating the following patients are exempt from these requirements:
(1) Active cancer treatment patients;
(2) Hospice care patients;
(3) Inpatient hospital patients; or
(4) Palliative care patients.

Changes from Previous Draft:
None

Status:
Scheduled for discussion at January 8 meeting

Notes:
246-XXX-X05  Patient Notification

Changes from Previous Draft:
- Renamed “Patient Notification” from “Informed Consent”
- Established

Status:
Scheduled for discussion at January 8 meeting

Notes:
- Consider whether patient notification is the same as informed consent, and how to make that clear in rule.
- See comments to 246-XXX-X07 below; consider whether -X05 and -X07 should be combined.
Use of Alternative Modalities for Pain Treatment Encouraged

(1) A practitioner shall not treat acute, subacute, or perioperative pain through the singular use of opioid therapy. A practitioner may combine opioids with other medications, such as but not limited to acetaminophen or non-steroidal anti-inflammatory drugs, or with non-drug therapies, in order to treat acute, subacute, or perioperative pain.

(2) A practitioner may prescribe opioids for the treatment of chronic pain but shall consider the use of alternative medications and non-drug therapies when the patient’s pain and function levels are not maintained or improved.

(3) In prescribing alternative modalities for pain control, a practitioner shall exercise their best clinical judgment in selecting evidence-based treatments and document in the patient record why the modality or modalities are the best feasible option for the patient.

Changes from Previous Draft:
None

Status:
Scheduled for discussion at February 9 meeting

Notes:
- Recommend general requirement that opioid therapy should not be a singular first option for the treatment of pain.
- May be prescribed in combination with other non-opioid therapy(ies).
- Evidence-based approach to use of alternative therapies, considering type of care (acute, perioperative, subacute, chronic) and appropriate in responsiveness of therapy to pain.
- Recommend that documentation of use or attempts to use alternative therapy(ies) in patient chart be required.
246-XXX-X07 Security and Disposal of Prescribed Opioids

(1) Where a written agreement between the practitioner and patient for opioid therapy is required, the agreement shall include a requirement for the patient to securely store opioid prescriptions and to dispose of unused medication using a recognized drug take-back program.

(2) For opioid therapy where a written agreement is not required by this chapter, the practitioner shall provide information to the patient at the time of the first opioid prescription explaining proper measures for storing opioids securely and for disposal of opioids.

Changes from Previous Draft:
None

Status:
Matrix discussed at October 19 meeting in Spokane; rule language not yet reviewed

Notes:
- Needs more, especially around “recognized drug take-back program”.
- Consider whether a written agreement will be a requirement of all opioid prescribing, rather than in chronic non-cancer pain management only, and whether that is a feasible requirement. If this section is combined with -X05, patient information/notification of storage and disposal information could address this issue.
246-XXX-X08  Diagnosis identified on prescriptions. Prescriptions for opioids shall include diagnosis, indications for use, or the International Classification of Diseases (ICD) code and shall be written to require photo identification of the person picking up the prescription in order to fill.

Changes from Previous Draft:
Language taken from existing chronic non-cancer pain management rules related to episodic care, subsection (3). Expanded here to apply to all opioid prescribing.

Status:
Discussed at December 12 meeting, raised by PQAC representative.

Notes:
246-XXX-X09 Patient Record

A practitioner treating a patient with opioids shall ensure that at a minimum, the following are documented in the patient record:

1. Documentation of the presence of one or more recognized diagnoses or indications for the use of opioid pain medication;
2. Any diagnostic, therapeutic, and laboratory results;
3. Any consultations;
4. Documentation from the PMP;
5. An appropriate pain treatment plan, including consideration of, or attempts to use, non-pharmacological modalities and non-opioid therapy;
6. Any written agreements for treatment between the patient and the practitioner;
7. Documentation of medications prescribed;
8. Practitioner’s instructions to the patient;
9. Results of any periodic reviews of pain or function;
10. Any consequences for failed biological specimen tests or other deviations from the treatment plan, or from a written agreement, if any; and
11. Objectives or metrics to be used to determine treatment success, including, at a minimum:
   a. Change in pain level;
   b. Change in physical and psychosocial function;
   c. Additional planned diagnostic evaluations or other treatments.

Changes from Previous Draft:

New language removed from Section 9 of the previous draft.

Status:

Has not been previously discussed.

Notes:

- This language is an attempt to shorten the provisions of the patient evaluation and treatment plan section of the previous draft. It needs TF review and validation that 1) it is needed beyond existing recordkeeping requirements and 2) that it is crafted as a general requirement.
OPIOID PRESCRIBING – ACUTE AND PERIOPERATIVE CARE
246-XXX-X21 Patient Evaluation

Prior to writing an opioid prescription for acute pain, the practitioner shall:

(1) Conduct a physical examination.

(2) Identify the nature and intensity of the pain.

(3) Determine other medications the patient is prescribed or is taking, including date, type, dosage and quantity prescribed.

Changes from Previous Draft:
New language removed from Section 9 of the previous draft

Status:
Acute prescribing was discussed in the October 19 meeting and draft rules were discussed in the November 15 and December 12 meetings.

Notes:
• TF direction at the December 12 meeting was to limit acute patient evaluation to the above items. The remainder were to be moved to patient evaluation for chronic opioid patients.
• Consider clarifying (3) to make clear what steps are necessary to satisfy this requirement (e.g. run PMP query, document results/prescription decision-making).
246-XXX-X22  Treatment Plan

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CONCEPTUAL DRAFT VERSION 3
ACUTE AND PERIOPERATIVE CARE

246-XXX-X33
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**OPIOID PRESCRIBING – SUBACUTE CARE**
246-XXX-X21
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Patient evaluation.
The practitioner shall obtain, evaluate, and document the patient's health history and physical examination in the health record prior to treating for chronic non-cancer pain.

1. The patient's health history shall include:
   (a) Current and past treatments for pain;
   (b) Comorbidities;
   (c) Any substance abuse;
   (d) A review of any available prescription monitoring program or emergency department-based information exchange; and
   (e) Any relevant information from a pharmacist provided to the practitioner.

2. The initial patient evaluation shall include:
   (a) Physical examination;
   (b) The nature and intensity of the pain;
   (c) Determine other medications the patient is taking including indication(s), date, type, dosage, and quantity prescribed;
   (d) The effect of the pain on physical and psychological function;
   (e) A risk screening of the patient for potential comorbidities and risk factors using an appropriate screening tool. The screening should address:
      (i) Personal or family history of addiction;
      (ii) Abuse or aberrant behavior regarding opioid use;
      (iii) Psychiatric conditions;
      (iv) Regular concomitant use of benzodiazepines, alcohol, or other central nervous system medications;
      (v) Poorly controlled depression or anxiety;
      (vi) Evidence or risk of significant adverse events, including falls or fractures;
      (vii) Receipt of opioids from more than one prescribing practitioner or practitioner group;
      (viii) Repeated visits to emergency departments seeking opioids;
      (ix) History of sleep apnea or other respiratory risk factors;
      (x) Possible or current pregnancy; and
      (xi) History of allergies or intolerances.

3. The initial patient evaluation shall include:
   (a) Any available diagnostic, therapeutic, and laboratory results; and
   (b) Any available consultations.

4. The health record shall be maintained in an accessible manner, readily available for review, and shall include:
   (a) The diagnosis, treatment plan, and objectives;
   (b) Documentation of the presence of one or more recognized indications for the use of pain medication;
(c) Documentation of any medication prescribed;
(d) Results of periodic reviews;
(e) Any written agreements for treatment between the patient and the practitioner; and
(f) The practitioner’s instructions to the patient.

Changes from Previous Draft:

Language is from existing chronic non-cancer pain rules, with the following changes:

- Minor modifications to (2)(c)
- Combined (1) and (2)—it is not clear why they are separate, from a statutory construction standpoint.

I have compared Section 9 of the previous draft (discussed on December 12) side-by-side with the existing rules to identify any items not common to the two.

- The items from the first main point (& five subpoints) are all part of the existing rule
- The item from the second main point, second subpoint:
  “Current substance use disorder as defined by the current Diagnostic and Statistical Manual of Mental Disorders, except for tobacco, or past opioid use disorder”
  is already substantially captured in (2)(e) of the existing rule.
- Modified (2)(e)(i) to say “personal or family history…”

Status:

Chronic pain was discussed in the October 19 meeting and rules were initially reviewed at a high level on November 15.

A universal patient evaluation and treatment plan section was reviewed on December 12 and the TF recommended splitting acute patient evaluation from chronic.

Notes:

- Given the current rules separate patient evaluation and treatment plan, I have split them into separate rules both for continuity with current rules and ease of reading.
- Reference is made here to the emergency department information exchange (EDIE) or other databases. My recollection is that this was done in 2010-11 as the PMP was not yet available. Is it sufficient to only list PMP now?
- The task force needs to further consider whether to include “history of sexual or physical abuse” in (2)(e). There was extended discussion about this topic on December 12, but no decision.
246-XXX-X42 Treatment plan.

(1) The written treatment plan shall state the objectives that will be used to determine treatment success and shall include, at a minimum:
   (a) Any change in pain relief;
   (b) Any change in physical and psychosocial function; and
   (c) Additional diagnostic evaluations or other planned treatments.

(2) After treatment begins the practitioner shall adjust drug therapy to the individual health needs of the patient. The practitioner shall include indications for medication use on the prescription and require photo identification of the person picking up the prescription in order to fill. The practitioner shall advise the patient that it is the patient’s responsibility to safeguard all medications and keep them in a secure location.

(3) Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment. Use of alternative treatment modalities shall be consistent with the provisions of WAC 246-XXX-X06.

Changes from Previous Draft:
Language is from existing chronic non-cancer pain rules, with the following changes:
- Added the second sentence to (3) to tie this regulation to general provision on alternative treatments.

Status:
Chronic pain was discussed in the October 19 meeting and rules were initially reviewed at a high level on November 15.

Notes:
- Recommend removing (2) from the rule, with the possible exception of the first sentence. Other items are now covered elsewhere in the rule (general provisions WACs 246-XXX-X08 and –X09); moreover, this section contains several disparate provisions.
Written agreement for treatment. The prescribing practitioner shall use a written agreement for treatment with the patient outlining patient responsibilities. This written agreement for treatment shall include:

1. The patient's agreement to provide biological samples for medical level screening when requested by the practitioner;
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 drug therapy may be discontinued (e.g., violation of agreement);
4. A statement that all chronic pain management prescriptions should be provided by a single prescriber or practice; where patient care necessitates routinely obtaining prescriptions from more than one practitioner or at more than one pharmacy, the written agreement shall document the circumstances for this arrangement.
5. The patient's agreement to not abuse alcohol or use other medically unauthorized substances;
6. A written authorization for:
   a. The practitioner to release the agreement for treatment to local emergency departments, urgent care facilities, and pharmacies; and
   b. Other practitioners to report violations of the agreement back to the practitioner treating the patient’s chronic pain.
7. A written authorization that the practitioner may notify the proper authorities if he or she has reason to believe the patient has engaged in illegal activity;
8. Acknowledgement that the practitioner may check the PMP at any time to ensure the patient is not engaged in behaviors that may violate the written agreement.
9. Acknowledgment that a violation of the agreement may result in a tapering or discontinuation of the prescription;
10. Acknowledgment that it is the patient's responsibility to safeguard all medications and keep them in a secure location; and
11. Acknowledgment that if the patient violates the terms of the agreement, the violation and the practitioner’s response to the violation will be documented, as well as the rationale for changes in the treatment plan.

Changes from Previous Draft:

Language is from existing chronic non-cancer pain rules, with the following changes:
- I removed the first half of the sentence beginning “If a patient is at high risk…” as a written agreement for treatment in the chronic phase of opioid therapy seems to be a minimum standard.
• Removed first sentence in the section, as it is redundant with (4). I changed the verbiage to use one prescriber/pharmacy as a “should” (to reflect what’s in the first sentence) but added language to mandate that the written agreement document circumstances where this standard will not be met.
• Removed “urine/serum” from (2); biological samples could also include hair, so the more general term is sufficient.
• Subsection (8) is a modification of language from the previous draft rule and is not part of the existing rules.

Status:
Chronic pain was discussed in the October 19 meeting and rules were initially reviewed at a high level on November 15.

Notes:
• Need the TF to decide whether a written agreement should be required in other phases of care where a patient is determined to be “high risk”.
• The language in prior drafts of the rule track closely with the content of the existing pain rules.
246-XXX-X44 Periodic review.

The practitioner shall periodically review the course of treatment for chronic non-cancer pain, the patient's state of health, and any new information about the etiology of the pain. Generally, periodic reviews shall take place at least every six months. However, for treatment of stable patients with chronic non-cancer pain involving non-escalating daily dosages of forty milligrams of a morphine equivalent dose (MED) or less, periodic reviews shall take place at least annually.

(1) During the periodic review, the practitioner shall determine:
   (a) Patient's compliance with any medication treatment plan;
   (b) Whether patient may be diverting drugs or taking other drugs through the use of the PMP and biological drug testing;
   (c) If pain, function, or quality of life have improved or diminished using objective evidence, considering any available information from family members or other caregivers; and
   (d) If continuation or modification of medications for pain management treatment is necessary based on the practitioner's evaluation of progress towards treatment objectives.

(2) The practitioner shall assess the appropriateness of continued use of the current treatment plan if the patient's progress or compliance with current treatment plan is unsatisfactory. The practitioner shall consider tapering, changing, or discontinuing treatment when:
   (a) Function or pain does not improve after a trial period;
   (b) There is evidence of significant adverse effects;
   (c) Other treatment modalities are indicated; or
   (d) There is evidence of misuse, addiction, or diversion.

(3) The practitioner shall review information from any available prescription monitoring program or emergency department-based information exchange.

(4) The practitioner shall periodically review any relevant patient information provided by a pharmacist.

Changes from Previous Draft:

Language is from existing chronic non-cancer pain rules, with the following changes:

- Added the following under (1): “Whether patient may be diverting drugs or taking other drugs through the use of the PMP and biological drug testing”.

I have compared Section 9, 4th point and subpoints, of the previous draft (discussed on December 12) side-by-side with the existing rules to identify any items not common to the two.

- Made slight editorial changes to (4).

Status:

Chronic pain was discussed in the October 19 meeting and rules were initially reviewed at a high level on November 15.
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CONCEPTUAL DRAFT VERSION 3
CHRONIC NON-CANCER PAIN MANAGEMENT

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<td>• Recommend striking (3) as redundant, based on new language added to (1)(b).</td>
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<td>• Recommend moving (2) to WAC 246-XXX-X61 on tapering requirements.</td>
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Clinically Meaningful Improvement.

Changes from Previous Draft:

Status:

Notes:
246-XXX-X46 Long acting opioids, including methadone.

(1) Long-acting opioids, including methadone, should only be prescribed by a practitioner 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. A practitioner prescribing long-acting opioids or methadone shall have a one-time (lifetime) completion of at least four hours of continuing education relating to this topic.

(2) The use of methadone, as part of medication-assisted treatment, must also comply with the provisions of WAC 246-XXX-X82.

Changes from Previous Draft:
Language is from existing chronic non-cancer pain rules, with the following changes:
- In (1), changed the 4-hour CE requirement from “should” to “shall”
- Added (2) to reference the new WAC on MAT, WAC 246-XXX-X82.

Status:
Has not yet been reviewed;

Notes:
- Recommend either
  - Changing the first sentence in (1) to “shall”, then strike the second sentence.
  - Revise the two sentences into one, something like “A practitioner prescribing methadone or other long-acting opioids shall be familiar with their risks and use and shall conduct the necessary careful monitoring, particularly with patients initiating treatment, to ensure patient safety.”
  - Delete the first two sentences of (1).
- A question—my sense is that, while methadone is generally used for MAT, it may also be prescribed generally for chronic pain treatment. If this is true, then does this still belong in the chronic pain rules with a reference to MAT? Or if not, then should this be moved entirely to co-prescribing/MAT?
246-XXX-X47  Consultation—Recommendations and requirements.

(1) The practitioner shall consider referring the patient for additional evaluation and treatment as needed to achieve treatment objectives. Special attention should be given to those chronic non-cancer pain patients who are under eighteen years of age, or who are at risk for medication misuse, abuse, or diversion. The management of pain in patients with a history of substance abuse or with comorbid psychiatric disorders may require extra care, monitoring, documentation, and consultation with, or referral to, an expert in the management of such patients.

(2) The mandatory consultation threshold for adults is one hundred twenty milligrams morphine equivalent dose (MED) (oral). In the event practitioner prescribes a dosage amount that meets or exceeds the consultation threshold of one hundred twenty milligrams MED (orally) per day, a consultation with a pain management specialist as described in WAC 246-XXX-X50 is required, unless the consultation is exempted under WAC 246-XXX-X48 or 246-XXX-X49. Great caution should be used when prescribing opioids to children with chronic non-cancer pain, and appropriate referral to a specialist is encouraged.

(a) The mandatory consultation shall consist of at least one of the following:
   (i) An office visit with the patient and the pain management specialist;
   (ii) A telephone consultation between the pain management specialist and the practitioner;
   (iii) An electronic consultation between the pain management specialist and the prescribing practitioner; or
   (iv) An audio-visual evaluation conducted by the pain management specialist remotely, where the patient is present with either the prescribing practitioner or with a licensed health care practitioner designated by the prescribing practitioner or the pain management specialist.

(b) The practitioner shall document each mandatory consultation with the pain management specialist. Any written record of the consultation by the pain management specialist shall be maintained as a patient record by the specialist. If the specialist provides a written record of the consultation to the prescribing practitioner, the practitioner shall maintain it as part of the patient record.

(3) Nothing in this chapter shall limit any person's ability to contractually require, as part of a written agreement, a consultation with a pain management specialist at any time. For the purposes of WAC 246-853-660 through 246-853-673, "person" means an individual, a trust or estate, a firm, a partnership, a corporation (including associations, joint stock companies, and insurance companies), the state, or a political subdivision or instrumentality of the state, including a municipal corporation or a hospital district.

Changes from Previous Draft:
Language is from existing chronic non-cancer pain rules, with the following changes:
### Status:

Chronic pain treatment was discussed in the October 19 meeting. This section was not specifically discussed in the November 15 meeting in Yakima. The TF has expressed interest in removing the mandatory consultation requirement from the rules, but existing law from 2010 HB 1876 is still codified and controls.

### Notes:

- The first sentence in (1) is a “soft” requirement, but is non-specific. It implies that any and all patients should potentially be referred. Given that it provides little practical direction for prescribers, it could be deleted.
- The remainder of (1) seems better suited to the special populations section. I would recommend we consider using it there.
- The sentence in (2) “Great caution should be used when prescribing opioids to children...” should be moved to the rules part on special populations.
- After the first sentence of (3), the remainder, I would suggest, needs a legal review. If it is to be kept, since it currently applies to all of the chronic non-cancer pain rules, I would recommend that it be moved to definitions.

- In (3), I changed the word “contractually” to “require, as part of a written agreement,“
246-XXX-X48  Consultation—Exemptions for exigent and special circumstances.

A practitioner is not required to consult with a pain management specialist as described in WAC 246-XXX-X50 when they have documented adherence to all standards of practice as defined in WAC 246-X01 through 246-XXX-X92 and when any one or more of the following conditions apply:

1. The patient is following a tapering schedule; or

2. The patient requires treatment for acute pain, which may or may not include hospitalization, requiring a temporary escalation in opioid dosage with expected return to their baseline dosage level or below, in accordance with WAC 246-XXX-X77; or

3. The practitioner 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 practitioner documents the patient's pain and function is stable and the patient is on a non-escalating dosage of opioids.

Changes from Previous Draft:

Language is from existing chronic non-cancer pain rules, with the following changes:

- In (2), I added “in accordance with WAC 246-XXX-X77”, which is the special populations section on chronic patients with episodic acute pain needs.

Status:

Chronic pain treatment was discussed in the October 19 meeting. This section was not specifically discussed in the November 15 meeting in Yakima. The TF has expressed interest in removing the mandatory consultation requirement from the rules, but existing law from 2010 HB 1876 is still codified and controls.

Notes:

- I recommend that (4) be moved to WAC 246-XXX-X51 and be incorporated into a section of rule dealing with “legacy” patients.
246-XXX-X49 Consultation—Exemptions for the practitioner.

A practitioner is exempt from the consultation requirement in WAC 246-XXX-X47 if one or more of the following qualifications are met:

(1) The practitioner is a pain management specialist under WAC 246-XXX-X50; or

(2) The practitioner has successfully completed, within the last two years, a minimum of twelve continuing education hours on chronic pain management approved by the profession's continuing education accrediting organization, with at least two of these hours dedicated to long-acting opioids, to include methadone, or within the last three years a minimum of eighteen continuing education hours on chronic pain management approved by the profession's continuing education accrediting organization, with at least three of these hours dedicated to long-acting opioids, to include methadone; or

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

(4) The practitioner has a minimum 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.

Changes from Previous Draft:
Language is from existing chronic non-cancer pain rules, with the following changes:

Status:
Chronic pain treatment was discussed in the October 19 meeting. This section was not specifically discussed in the November 15 meeting in Yakima. The TF has expressed interest in removing the mandatory consultation requirement from the rules, but existing law from 2010 HB 1876 is still codified and controls.

Notes:
246-XXX-X50  Pain management specialist.
A pain management specialist shall meet one or more of the following qualifications:

(1) If a physician or osteopathic physician:
   (a) 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, rehabilitation medicine, neurology, rheumatology, or anesthesiology; or
   (b) Has a subspecialty certificate in pain medicine by an ABMS-approved board; or
   (c) Has a certification of added qualification in pain management by the AOA; or
   (d) A minimum of three years of clinical experience in a chronic pain management care setting; and
      (i) Credentialed in pain management by an entity approved by the Washington state medical quality assurance commission for physicians or the Washington state board of osteopathic medicine and surgery for osteopathic physicians; and
      (ii) Successful completion of a minimum of at least eighteen continuing education hours in pain management during the past two years for a physician or three years for an osteopathic physician; and
      (iii) At least thirty percent of the physician's or osteopathic physician's current practice is the direct provision of pain management care or in a multidisciplinary pain clinic.

(2) If a dentist: Board certified or board eligible in oral medicine or orofacial pain by the American Board of Oral Medicine or the American Board of Orofacial Pain.

(3) If an advanced registered nurse practitioner (ARNP):
   (a) A minimum of three years of clinical experience in a chronic pain management care setting;
   (b) Credentialed in pain management by a Washington state nursing care quality assurance commission-approved national professional association, pain association, or other credentialing entity;
   (c) Successful completion of a minimum of at least eighteen continuing education hours in pain management during the past two years; and
   (d) At least thirty percent of the ARNP's current practice is the direct provision of pain management care or is in a multidisciplinary pain clinic.

(4) If a podiatric physician:
   (a) Board certified or board eligible in a specialty that includes a focus on pain management by the American Board of Podiatric Surgery, the American Board of Podiatric Orthopedics and Primary Podiatric Medicine, or other accredited certifying board as approved by the Washington state podiatric medical board; or
   (b) A minimum of three years of clinical experience in a chronic pain management care setting; and
(c) Credentialed in pain management by a Washington state podiatric medical board-approved national professional association, pain association, or other credentialing entity; and
(d) Successful completion of a minimum of at least eighteen hours of continuing education in pain management during the past two years, and at least thirty percent of the podiatric physician's current practice is the direct provision of pain management care.

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<td>Language is from existing chronic non-cancer pain rules, with the following changes:</td>
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| Status: |
| Chronic pain treatment was discussed in the October 19 meeting. This section was not specifically discussed in the November 15 meeting in Yakima. The TF has expressed interest in removing the mandatory consultation requirement from the rules, but existing law from 2010 HB 1876 is still codified and controls. |

| Notes: |
Legacy chronic opioid therapy patients.

(1) A patient with an established written agreement for chronic opioid therapy prior to January 1, 2016 who meets all of the following criteria may be exempted from the provisions of WAC 246-XXX-X45 and from any dosage limitations imposed in this chapter:
   (a) The patient has been on a dose of opioids exceeding one hundred twenty milligrams MED per day;
   (b) The patient has a demonstrated history in their record of compliance with treatment plans and written agreements;
   (c) The patient’s dose is stable and non-escalating;
   (d) The patient has documented improvements in pain relief and increased function at the exceptional dose; and
   (e) The patient has experienced documented decreases in pain relief and function in any attempts to taper their dosages from the exceptional dose.

(2) A patient shall not be exempted from tapering requirements, as set forth in WAC 246-XXX-X63, or from written agreement requirements in WAC 246-XXX-X43, if there is evidence of patient addiction, misuse, or diversion.

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<td>This topic has not been specifically discussed, nor has language been reviewed.</td>
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<tr>
<td>• Current rule (here listed as WAC 246-XXX-X48) already provides for patients who are on a stable non-escalating dose of opioids and have achieved reasonable pain relief and function to be exempted from specialist consultation requirements.</td>
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<tr>
<td>• Given the greater emphasis on clinically meaningful improvement in function (defined as sustaining a 30 percent increase in function), there has been discussion about whether a rule is needed to address “legacy” patients, who are long-term, high-dose opioid patients.</td>
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<tr>
<td>• “Legacy patient”, if a rule is added, should be added to definitions. One definition states: “Legacy patient means a person who has been on chronic opioid therapy prior to the implementation of the AMDG guidelines in 2015.”</td>
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<td>• (1) needs additional work to ensure the language only exempts the patients to stay at their current dosages and are not subject to forced tapering.</td>
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OPIOID PRESCRIBING – TAPERING REQUIREMENTS
246-XXX-X61  Tapering requirements – acute and subacute opioid therapy

(1) Where the patient’s condition is progressing normally toward resolution, the practitioner shall taper the patient’s use of opioids by six weeks after the acute or subacute episode.

(2) Where the patient does not follow the normal course of recovery, the practitioner shall reassess the patient’s progress toward recovery and whether continued opioid pain management is required beyond the acute phase of treatment.

Changes from Previous Draft:
Language in (1) and (2) are from Section 10, third and fourth points of the previous draft, with minor modifications.

Status:
This language has not yet been reviewed

Notes:
Could this section be eliminated and added to each respective category, Acute, subacute, perioperative, and chronic?
246-XXX-X62  Tapering requirements – perioperative opioid therapy

(1) The provisions of WAC 246-XXX-X61 shall generally apply to surgical interventions. However, given the wide range of recovery times for planned and unplanned surgical interventions, the practitioner may document that opioid therapy is medically necessary for a period beyond six weeks.

(2) Where perioperative opioid therapy is indicated for a patient, the practitioner shall document in the patient record the expected time period for recovery and establish an appropriate tapering schedule to eliminate opioids by the date of recovery.

(3) If the patient’s rate of recovery is slower than expected, or if the recovery period is expected to exceed six weeks, the practitioner shall reassess the patient’s progress at not later than six weeks post-surgery to determine:

   (a) Whether continued opioid therapy is warranted;

   (b) If so, when the patient can reasonably be tapered off of opioid therapy; and

   (c) Whether concurrent alternative treatments for pain can be used to assist in disengaging the patient from opioid therapy.

Changes from Previous Draft:
N/A

Status:
Perioperative prescribing was discussed on November 15; rules have not been discussed at the Task Force meetings.

Notes:

• (1) may need to be revised to more explicitly build an exception to X61, with documentation.
• I recommend that the Task Force review this section carefully, and that technical expert guidance be sought in whether the proposed is both accurate and sufficient.
CONCEPTUAL DRAFT VERSION 3
TAPERING REQUIREMENTS

246-XXX-X63  Tapering requirements – chronic opioid therapy

The practitioner shall assess the appropriateness of continued use of the current treatment plan if the patient's progress or compliance with current treatment plan is unsatisfactory. The practitioner shall consider tapering, changing, or discontinuing treatment when:

1. Function or pain does not improve after a trial period;
2. There is evidence of significant adverse effects;
3. Other treatment modalities are indicated; or
4. There is evidence of misuse, addiction, or diversion.

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<tr>
<td>This language is cross-referenced to existing chronic non-cancer pain rule language in WAC 246-XXX-X44  Periodic Review.</td>
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<td>Recommend the TF consider whether it wants to identify tapering in separate rules. If so, then the redundant language in WAC 246-XXX-X44 should be stricken.</td>
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OPIOID PRESCRIBING – SPECIAL POPULATIONS
246-XXX-X71   Minors

In the treatment of pain in minors, the practitioner shall treat pain in a manner commensurate with that of an adult, but will account for the weight of the minor and reduce the dosage prescribed accordingly.

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<td>The topic was discussed in the November 15 Task Force meeting; rule language has not been reviewed.</td>
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<td>Notes:</td>
<td>• This language is based on feedback from Gary Walco, our technical expert for this discussion.</td>
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CONCEPTUAL DRAFT VERSION 3
SPECIAL POPULATIONS

246-XXX-X72  Pregnant Women

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246-XXX-X74  Patients with mental/behavioral health conditions
246-XXX-X75  Patients with cognitive limitations

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CONCEPTUAL DRAFT VERSION 3
SPECIAL POPULATIONS

246-XXX-X76  Acute opioid prescribing – patients with past history of opioid misuse/abuse

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246-XXX-X77  Episodic care of chronic opioid patients

(1) When evaluating patients for episodic care, such as emergency or urgent care, the practitioner shall review the PMP, emergency department-based information exchange, or other tracking system.

(2) Episodic care practitioners shall avoid providing opioids for chronic pain management. However, if opioids are provided, the practitioner shall limit the use of opioids for a chronic non-cancer pain patient to the minimum amount necessary to control the pain until the patient can receive care from a primary care practitioner.

(3) Prescriptions for opioids written by an episodic care practitioner shall include indications for use or the International Classification of Diseases (ICD) code and shall be written to require photo identification of the person picking up the prescription in order to fill.

(4) If a patient has signed a written agreement for treatment and has provided a written authorization to release the agreement under WAC 246-XXX-X43 to episodic care practitioners, then the episodic care practitioner shall report known violations of the agreement back to the patient’s treatment practitioner who provided the agreement for treatment.

Changes from Previous Draft:

Language is from existing chronic non-cancer pain rules, with the following changes:
- Changed “should” to shall in (1)
- Changed “should” to “shall” in (2), as this is consistent with other conversations the TF has had about division of responsibility for acute/perioperative prescribing for COAT patients.

Status:

Notes:

- Consider defining episodic care in XX3, so that the “such as” in (1) is not needed.
- (3) partially addresses concerns raised by PQAC representatives and is already in WAC. I have repeated this language in WAC 246-XXX-X08 in an attempt to apply to opioid prescribing generally. This was discussed at the December 12 meeting but needs formal TF consideration.
(1) A practitioner shall not initiate opioid therapy for a patient where the patient is concurrently receiving one or more of the following Schedule II-IV medications:
   a. Benzodiazepines
   b. Barbiturates
   c. Sedatives
   d. Soma and sleeping medications
   e. Anxiolytics

(2) If a practitioner who has prescribed opioids for a patient determines that the patient is concurrently prescribed one or more of the medications listed in subsection (1) of this section, they shall consult with the other prescriber(s) to establish a patient care plan for the use of the medications concurrently.

(3) The patient care plan established in subsection (2) of this section shall be documented in the patient record.

Changes from Previous Draft:
N/A

Status:
New issue matrix discussed at the December 12 meeting.

Notes:
• Consider whether (1) is a “shall not” or a “should not”—are there situations where a patient can be managed on both?
Co-prescribing of opioid agonists for medication-assisted treatment

If a practitioner prescribes opioids to a patient, for events such as, but not limited to, an acute or surgical episode, who is already engaged in medication-assisted treatment (MAT), the opioid-prescribing practitioner shall coordinate their prescribing with the MAT practitioner, as soon as is practicable, to appropriately treat episodic pain while maintaining the patient’s MAT.

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<td>New issue matrix discussed at the December 12 meeting.</td>
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<tr>
<td>• Check to see if we have a definition of “Medication-assisted treatment”</td>
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<tr>
<td>• Does the TF want to require that those performing MAT have a buprenorphine waiver from SAMHSA?</td>
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<tr>
<td>• Does the TF want to establish any special education/training requirements for those performing MAT?</td>
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246-XXX-X83  Co-prescribing of naloxone

The practitioner should make Naloxone available when opioids are prescribed to a patient that is assessed as high-risk.

Changes from Previous Draft:
The previous draft language read: “The practitioner should consider issuing a prescription for naloxone for any patient when the doses are in excess of 120 MED, there are risk factors for overdose, or the patient is also prescribed concomitant benzodiazepines, sedative-hypnotics, anxiolytics, or CNS depressants.”

Status:
Discussed at the December 12 meeting.

Notes:
• Dr. Roberts recommended the above language, with the group’s informal agreement.
• The group agreed that this is an appropriate situation for the use of “should”.
• My notes suggest the group intended this to be for subacute and chronic phases only, but should this be specified, or is better simply to leave it to high-risk patients?
• The term “high-risk” is used. I thought the taskforce had a discussion about what constitutes “high-risk”, and it may be inappropriate to indicate “high-risk”.
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OPIOID PRESCRIBING – PRESCRIPTION MONITORING PROGRAM
246-XXX-X91  Prescription Monitoring Program – Registration and Queries

(1) Prior to writing any prescription for opioid analgesics or sedative hypnotics, the practitioner shall review the Washington state PMP to ensure the patient’s controlled substance history is consistent with the prescribing record and self-report.

(2) If the patient is prescribed a drug by another prescriber which could interact with opioid analgesics (e.g. benzodiazepines, sedative-hypnotics, anxiolytics, or CNS depressants) or other opioid analgesics, the practitioner shall consult with the other practitioner. If the other practitioner is not available, the practitioner will document attempts to contact the other practitioner in the patient’s healthcare record.

(3) If the practitioner identifies aberrancies in the PMP, the practitioner shall consider tapering based on the requirements of these rules. The practitioner shall document completion of these requirements in the patient’s healthcare records.

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<td>Scheduled for discussion at January 8 meeting</td>
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<tr>
<td>• Recommend that (2) be moved to X71 in Co-Prescribing</td>
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<tr>
<td>• Dr. Ludwig proposed that PMP requirement language should be embedded in rules for each type of care (acute, perioperative, subacute, chronic).</td>
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<tr>
<td>• Alternatively, I recommend serious consideration of the marginal value of checking PMP at every prescription versus the technical and administrative costs. A proposal of</td>
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<td>o checking at initiation of opioid therapy,</td>
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<td>o at every 3 weeks during the acute, perioperative and subacute phases,</td>
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<td>o at the change of phase (e.g. acute to subacute, subacute to chronic) and,</td>
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<td>o no less than every three months during chronic therapy</td>
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<td>may have nearly the same benefit, but with less administrative and technical burden.</td>
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