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

CONCEPTUAL DRAFT VERSION 5.2.1
OPIOID PRESCRIBING RULES (ESHB 1427)
January 25, 2018

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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.
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GENERAL PROVISIONS

OPPIOID 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 Podiatric Medical Board 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.
- MQAC submission is provided below.

Status:

Task force considered at January 8 meeting; to revisit at later date.

Notes:

- Suggest “collaboratively developed and adopted” instead of “worked together to.”
- Both WSMA and WSPMA have questioned the purpose of this section and whether it could be deleted. They also point out that correctly that this rulemaking is not strictly pursuant to EO 16-09.
- The key question is does this section provide important contextual value (and should be edited and retained), or does it not provide added value. It is not generally enforceable and could have an unintended impact on prescribing.
- If retained, mention of profession specific guidelines may be necessary.

[MQAC submission]:

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 and costs associated with untreated or inappropriately treated pain. For the purposes of these rules, the inappropriate treatment of pain includes non-treatment, under-treatment, overtreatment, and the continued use of ineffective treatments.
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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 pain, perioperative pain, subacute pain and chronic pain. All physicians should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances. Accordingly, these rules have been developed to 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 as defined in the first paragraph may result from a physician's lack of knowledge about pain management. Fears of investigation or sanction by federal, state, and 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 medical management of pain should consider current clinical knowledge and 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 of the pain, and treatment outcomes. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

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 opioid analgesics for other than legitimate medical purposes poses a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, 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 opioid analgesics, for a legitimate medical purpose and in the 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
GENERAL PROVISIONS

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 practitioners in providing appropriate medical care for patients. They are not inflexible rules or rigid practice requirements and are not intended, nor should they be used, to establish a legal standard of care outside the context of the medical quality assurance committee’s jurisdiction.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the practitioner based on all the circumstances presented. Thus, an approach that differs from the rules, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in the rules when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of these rules. However, a practitioner who employs an approach substantially different from these rules is advised to document in the patient record information sufficient to justify the approach taken.

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. Therefore, it should be recognized that adherence to these rules will not assure an accurate diagnosis or a successful outcome. The sole purpose of these rules is to assist practitioners 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.
246-XXX-X02 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.
246-XXX-X03 Definitions
The definitions in this section apply throughout sections XX1 through section X99 unless the context clearly requires otherwise.

[MQAC submission]: **Aberrant Behaviors**: Behavior that indicates misuse, diversion or addiction. This includes, but is not limited to, multiple early refills, obtaining prescriptions for the same or similar drugs from more than one clinician or other health care provider.

(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. Acute pain is considered to be of zero (0) to six (6) weeks in duration.

(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.

[MQAC submission]: **Biological specimen testing** means tests including but not limited to urine, hair or other biological samples for various drugs and metabolites.

(4) **“Chronic pain”** means pain caused by various diseases or abnormal conditions that continue longer than twelve weeks.

[MQAC submission]: **“Chronic pain”** means pain caused by various diseases or abnormal conditions that continue longer than twelve weeks.

[MQAC submission]: **“Chronic non-cancer pain”** means a state in which non-cancer pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

(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.

[MQAC submission]: **“Clinically meaningful improvement in function”** means a numerically measurable improvement in function. A decrease in pain intensity in the absence of improved function is not considered clinically meaningful improvement.
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(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 dose” means ninety (90) milligram MED per day.

(9) “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.

[MQAC submission]: “High-risk” is a category of patient at increased risk of morbidity or mortality, such as from comorbidities, polypharmacy, history of addiction or abuse, aberrant behavior, or the use of any central nervous system depressant.

(10) "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.

[MQAC submission]: "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 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.

(12) “Inpatient” means a person who has been admitted to a hospital for more than twenty-four hours.

(13) “Legacy patient”

[MQAC submission]: “Legacy patients” are chronic pain patients defined later in this document.

(14) “Medication assisted treatment” or “MAT” means the use of FDA-approved opioid agonist and antagonists medications, in combination with counseling and behavioral therapies, to provide a whole-patient approach to the treatment of substance use disorders.
GENERAL PROVISIONS

[MQAC submission]: “Medication Assisted Treatment (MAT)” means the pharmacologic management of opioid use disorder. This may include a treatment program that combines behavioral therapy and medications to treat substance use disorders.

“Morphine equivalent dose” or “MED” means a conversion of various opioids to a morphine equivalent dose by the use of accepted conversion tables.

[MQAC submission]: “Multimodal management of pain” means the application of non-narcotic relief mechanisms, such as anti-inflammatory medications, acetomenophen, nerve blocks, NMDA agonists, and other medications.

“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.

[MQAC submission]: “Opioid Dependence” means physiologic adaptation that is a natural, non-pathologic result of opioid use. It may result in tolerance as well as withdrawal symptoms if the medication is stopped. This is not the same as addiction.

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

[MQAC submission]: “Opioid naïve” means a patient who has not used opioids in the previous thirty days.

Palliative care means care that maintains or improves the quality of life for patients facing serious or life-threatening illness through the identification, assessment, and treatment of pain and other physical, psychosocial, and spiritual problems.

[MQAC submission]: "Palliative" means care that maintains or improves the quality of life of patients and their families facing serious illness.

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

“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.

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

[MQAC submission]: “Perioperative pain” means acute pain that occurs as the result of surgery.

“PMP” means the Washington prescription monitoring program authorized under chapter 70.225 RCW.
(23) “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.

(24) “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.

[MQAC submission]: “Risk assessment tool” means tools appropriate for identifying high risk patients. Examples include, but are not limited to, The Screener and Opioid Assessment for Patients with Pain, and Opioid Risk Tool.

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

[MQAC submission]: Subacute Pain: “Subacute Pain” is considered to be a continuation of pain, of 6 weeks to 12 weeks in duration.

Changes from Previous Draft:

- “Medication assisted treatment,” “high dose,” “palliative care” definitions added/edited per January 8 discussion. “Legacy patient” added as placeholder, if needed.
- MQAC suggested edits to definitions have been incorporated in alphabetical order or below the original proposed language and in red font.

Status:

Additional review needed.

Notes:

- Interest was expressed in waiting until end of task force activity to ensure all necessary terms included.
- If using the MQAC suggested definition: (10) consider including last two sentences of original proposed definition; (24) specify that the tool identifies the risk of the patient, not only whether high risk.
246-XXX-X04 Exclusions

(1) The rules adopted under WAC 246-XXX-XXX through 246-XXX-XXX do not apply to the following:

(a) Patients with cancer-related pain;
(b) Hospice care and end of life patients;
(c) Inpatient hospital patients; and
(d) Palliative care patients.

Changes from Previous Draft:

• Task force discussion and MQAC suggestions incorporated per January 8 meeting.

Status:

Approved at January 8 meeting.

Notes:
246-XXX-X05 Patient Notification, Secure Storage, and Disposal

(1) The practitioner shall provide information to the patient educating them of risks associated with the use of opioids as appropriate to the medical condition, the patient, and the phase of treatment. The practitioner shall document such notification in the patient’s record.

(2) Patient notification must occur, at a minimum, at the following points of treatment:
   - (a) The first issuance of a prescription for an opioid; and
   - (b) The transition between phase of treatment, as follows:
     i. Acute pain to subacute pain; and
     ii. Subacute pain to chronic pain.

(3) Patient notification shall include information regarding the safe and secure storage of opioid prescriptions and the proper disposal of unused opioid medications, including but not limited to the availability of recognized drug take-back programs.

Changes from Previous Draft:
- Combined patient notification with secure storage and disposal.

Status:
Discussed and approved at January 8 meeting.

Notes:
- If passed as written, HB 2447 would direct the Department to create a brief statement warning individuals of the risks of opioid use and abuse. The task force expressed interest in utilization of such a Department-created document, or other approved handout, as compliance with this patient notification requirement. The task force may wish to reference this [CDC factsheet](https://www.cdc.gov) as an example.
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246-XXX-X06 Use of Alternative Modalities for Pain Treatment Encouraged

(1) The practitioner shall utilize multimodal pharmacologic and non-pharmacologic therapy for acute, subacute, or perioperative pain rather than defaulting to the use of opioid therapy alone. A practitioner may combine opioids with other medications, such as but not limited to acetaminophen or non-steroidal anti-inflammatory drugs, or with non-pharmacologic therapies, in order to treat acute, subacute, or perioperative pain.

(2) Long acting opiates are not indicated in the treatment of acute and perioperative pain.

Changes from Previous Draft:

- Amended to reflect task force discussion at the January 8 meeting.

Status:

MQAC suggested language approved at January 8 meeting.

Notes:

- Consider clear language in this section to require documentation of alternative therapies considered/attempted.
This document is a conceptual rules draft, designed for discussion purposes only

CONCEPTUAL DRAFT VERSION 5.1.1
GENERAL PROVISIONS

246-XXX-X07 Diagnosis Identified on Prescriptions
   (1) The practitioner shall include the diagnosis, indications for use, or the International Classification of Diseases (ICD) code on all opioid prescriptions.

<table>
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<th>Changes from Previous Draft:</th>
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<tbody>
<tr>
<td>• Removal of a photo identification requirement on the prescription.</td>
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<tr>
<td>Discussed at January 8 meeting; needs a final decision on February 9.</td>
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<th>Notes:</th>
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<tr>
<td>• Photo ID remains a requirement in chronic pain rules. Recommend moving this section to acute/perioperative/subacute sections or additional language to clarify application if that chronic requirement is maintained.</td>
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CONCEPTUAL DRAFT VERSION 5.1
ACUTE AND PERIOPERATIVE CARE

OPIOID PRESCRIBING – ACUTE AND PERIOPERATIVE CARE

246-XXX-X21 Acute and Perioperative Care – Patient Evaluation and Patient Record

(1) Prior to writing an opioid prescription for acute or perioperative pain, the practitioner shall:

(a) Conduct an appropriate history and physical examination;
(b) Identify the nature and intensity of the pain; and
(c) Inquire regarding other medications the patient is prescribed or is taking, including date, type, dosage and quantity prescribed.

(2) The practitioner shall conduct queries of the Washington State PMP in accordance with the provisions of WAC 246-XXX-X91.

(3) The practitioner treating a patient for acute or perioperative pain with opioids shall ensure that, at a minimum, the following are documented in the patient record:

(a) Documentation of the presence of one or more recognized diagnoses or indications for the use of opioid pain medication;
(b) Documentation of each PMP check;
(c) Documentation of all medications prescribed;
(d) An appropriate pain treatment plan, including the consideration of, or attempts to use, non-pharmacological modalities and non-opioid therapy; and
(e) All other required components of the patient record, as set out in rule.

Changes from Previous Draft:

- Previous general provisions records section combined with acute and perioperative patient evaluation section.
- Removed: diagnostic and lab results; PMP documentation; mention of written agreements; instructions to patient; periodic review of pain or function; biological specimen testing per January 8 meeting discussion.
- Added applicable PMP mandatory checks from section –X91.
- Added subsection (e) as some boards and commissions have recordkeeping rules which may be appropriate to reference here.

Status:

Discussed at January 8 meeting.

Notes:

- Previous stakeholder key questions: 1) What about emergent situations where there may not be time to do all of this before pain meds are administered; and 2) since PMP is just controlled substances, practitioner may not have access to all other medications.

246-XXX-X22 Treatment Plan - Acute

(1) The practitioner shall comply with the following requirements when prescribing opioid analgesics for acute pain. An acute pain episode is no more than six weeks. The practitioner shall document completion of these requirements in the patient record.
CONCEPTUAL DRAFT VERSION 5.1
ACUTE AND PERIOPERATIVE CARE

(2) The practitioner shall consider prescribing non-opioid analgesics as the first line of pain control in patients, unless not clinically appropriate. Examples of such treatments may include, but are not limited to, acetaminophen, acupuncture, chiropractic, cognitive behavior therapy, nonsteroidal anti-inflammatory drugs (NSAIDS), osteopathic manipulative treatment, physical therapy, and sleep hygiene.

(3) The practitioner shall prescribe opioids for effective pain control and in no 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; more than a seven day supply will rarely be needed. The practitioner 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 practitioner shall re-evaluate a patient who does not follow the normal course of recovery.

(5) The practitioner should taper opioids by six (6) weeks if significant and documented improvement in function and or pain has not occurred.

(6) Follow-up visits should 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 planned diagnostic evaluations or other treatments.

(7) Long-acting opioids are not indicated for acute pain, except in post-operative situations. Should a practitioner need to use a long-acting opioid for acute pain, that reason shall be documented in the patient record.

Changes from Previous Draft:
- Task force approved December 12 language.
- Amended (3) to maintain 3 day recommendation with enforceable 7 day limit.
- Created a separate section for perioperative treatment plan.
- The previous 246-XXX-X09(9)(a)(b)(c)(d) section was added here as subsection (6).
- Utilized “significant and documented improvement in function” rather than “clinically meaningful.”

Status:
Discussed at January 8 meeting.

Notes:
- Recommend specifying “acute non-perioperative.”
CONCEPTUAL DRAFT VERSION 5.1
ACUTE AND PERIOPERATIVE CARE

246-XXX-X23 Treatment Plan - Perioperative

(1) The practitioner shall comply with the following requirements when prescribing opioid analgesics for perioperative pain. Perioperative pain is acute pain that occurs as the result of surgery. The practitioner shall document completion of these requirements in the patient’s record.

(2) The practitioner shall consider prescribing non-opioid analgesics as the first line of pain control in patients, unless not clinically appropriate. Examples of such treatments may include, but are not limited to, acetaminophen, acupuncture, chiropractic, cognitive behavior therapy, nonsteroidal anti-inflammatory drugs (NSAIDS), osteopathic manipulative treatment, physical therapy, and sleep hygiene.

(3) The practitioner shall prescribe opioids for effective pain control and in no 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; more than a fourteen day supply will rarely be needed for perioperative pain. The practitioner shall not prescribe beyond a fourteen day supply without clinical documentation in the patient record to justify the need for such a quantity.

(4) The practitioner shall re-evaluate a patient who does not follow the normal course of recovery.

(5) The practitioner should taper opioids by six (6) weeks if significant and documented improvement in function and or pain has not occurred.

(6) Follow-up visits should 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 planned diagnostic evaluations or other treatments.

Changes from Previous Draft:
• Created a separate section for perioperative from -X22. Amended (3) to a 14 day limit. Task force consideration needed to determine if 3 day recommendation is appropriate in this section.
• The previous 246-XXX-X09(9)(a)(b)(c)(d) section was added here as subsection (6).
• Utilized “significant and documented” rather than “clinically meaningful.”
• Deleted subsection –X22(7) regarding long-acting opioids, as it exempts post-operative situations; task force input needed on whether applicable in perioperative still.

Status:
Creation of section discussed at January 8 meeting, content not considered.

Notes:
• Recommend specifying “acute perioperative.”
OPIOID PRESCRIBING – SUBACUTE CARE

246-XXX-X31 Subacute Pain Episode

(1) The practitioner shall comply with the following requirements when prescribing opioid analgesics for subacute pain. A subacute pain episode is an episode of pain continuing beyond six weeks but less than twelve weeks. The practitioner shall document completion of these requirements in the patient record.

(2) The goal in this phase is to taper opioids. If tapering has not begun prior to the subacute phase, then the following requirements must be met:
   (a) The practitioner must have observed a patient with significant and documented improvement in function and pain in order to have a legitimate basis to continue prescribing opioid analgesics beyond the acute pain episode; and
   (b) Prior to prescribing opioid analgesics for subacute pain, the practitioner shall complete the following:
      (i) Evaluate function and pain using validated instruments to determine whether continued opioid therapy is warranted;
      (ii) Review the Washington state PMP to ensure the patient’s controlled substance history is consistent with the prescribing record and self-report. This review must occur, at a minimum, at the following times:
         (A) The time of transition from acute to subacute pain.
         (B) The time of transition from subacute to chronic pain; and
         (C) The third refill of an opioid prescribed in the subacute phase.
      (iii) If the patient’s function is deteriorating or if pain is escalating, obtain a biological drug screen;
      (iv) Screen or refer the patient for further consultation for psychosocial factors which may be impairing recovery, including but not limited to depression and or anxiety; and
      (v) Screen and document the patient’s level of risk for aberrant behavior and adverse events related to opioid therapy. If high risk, consider lower dose therapy, shorter intervals between prescriptions, more frequent visits, increased biological testing, and prescribing rescue naloxone.

(3) The practitioner shall prescribe opioids for effective pain control and in no greater quantity than needed for the expected duration of pain severe enough to require opioids. The practitioner shall not prescribe beyond a ten day supply without clinical documentation to justify the need for such a quantity.

(4) Any aberrant biological testing results must be addressed and documented in the patient record. If opioids are to be continued in this situation, the risk-benefit analysis must be included in the documentation.

(5) If a patient is prescribed opioid analgesics and benzodiazepines or sedative-hypnotics, the practitioner must ensure these drugs can be co-prescribed safely or should consider
tapering one. If any combination of the above medications are to be continued, the risk-benefit analysis must be included in the documentation.

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<td>• Created per January 8 task force discussion.</td>
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<tr>
<td>• Amended (2)(b)(ii) to specify the time a PMP check is required, in line with -X91.</td>
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<tr>
<td>• Subsection (3) creates a ten day supply limit with available documented exception.</td>
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<tr>
<td>• Utilized “significant and documented” language rather than “clinically meaningful.”</td>
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<td>MQAC suggested language approved at January 8 meeting.</td>
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246-XXX-X32 Subacute Care – Patient Evaluation and Patient Record

(1) Prior to writing an opioid prescription for subacute pain, the practitioner shall:
   (a) Conduct an appropriate history and physical examination;
   (b) Identify the nature and intensity of the pain; and
   (c) Inquire regarding other medications the patient is prescribed or is taking, including date, type, dosage and quantity prescribed.

(2) The practitioner shall conduct a query of the Washington State PMP to ensure the patient’s controlled substance history is consistent with the prescribing record and self-report, at a minimum, at the following times:
   (a) The time of transition from acute to subacute pain;
   (b) The time of transition from subacute to chronic pain; and
   (c) The third refill of an opioid prescribed in the subacute phase.

(3) The practitioner treating a patient for subacute pain with opioids shall ensure that, at a minimum, the following are 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 significant and documented improvement in function and pain forming the basis to continue prescribing opioid analgesics beyond the acute pain episode;
   (c) Documentation of each PMP check;
   (d) All medications prescribed;
   (e) An appropriate pain treatment plan, including the consideration of, or attempts to use, non-pharmacological modalities and non-opioid therapy;
   (f) Results of evaluations of function and pain using validated instruments;
   (g) The results of any aberrant biological testing results and the risk-benefit analysis if opioids are to be continued;
   (h) Results of screening or referral for further consultation for psychosocial factors which may be impairing recovery, including but not limited to depression and or anxiety;
   (i) Results of screening for the patient’s level of risk for aberrant behavior and adverse events related to opioid therapy;
   (j) The risk-benefit analysis of any combination of prescribed opioid analgesics and benzodiazepines or sedative-hypnotics, if applicable; and
   (k) All other required components of the patient record, as set out in rule.

Changes from Previous Draft:
- Content created based on -X31 and -X91 PMP requirements.
- Utilized “significant and documented” language rather than “clinically meaningful.”
- Added subsection (3)(k) as some boards and commissions have recordkeeping rules.

Status:
Created per January 8 meeting, specific content not yet discussed.
CONCEPTUAL DRAFT VERSION 5.1
SUBACUTE CARE

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<td>• Consider whether this section should also include the content of an evaluation, and what should be included in that.</td>
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OPIOID PRESCRIBING – CHRONIC NON-CANCER PAIN MANAGEMENT

246-XXX-X41 Initial Patient Evaluation and Patient Record
The practitioner shall obtain, evaluate, and document the patient’s health history and physical examination in the patient record prior to treating for chronic non-cancer pain.

(1) The patient's health history shall include:
   (a) The nature and intensity of the pain;
   (b) The effect of pain on physical and psychosocial function;
   (c) Current and past treatments for pain;
   (d) Review of any significant comorbidities; and
   (e) Any current or historical substance use disorder; abuse.
   (f) Current Medications and as related to treatment of the pain, the efficacy of medications tried;
   (g) Medication allergies; and
   (h) Review the Washington state PMP to ensure the patient’s controlled substance history is consistent with the prescribing record and self-reporting.

(2) The patient's health history should include:
   (a) A review of any available prescription monitoring program or emergency department-based information exchange; and
   (b) Any relevant information from a pharmacist provided to the practitioner.

(3) The initial patient evaluation shall include:
   (a) Complete 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, and as related to treatment of the pain, efficacy of medications tried;
   (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) 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.

(4) The initial patient evaluation should include:

(f) Any available diagnostic, therapeutic, and laboratory results;

(g) Use of a risk assessment tool and assign patient to a high, medium or low risk category;

(h) Any available consultations, particularly as related to the patient’s pain;

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

(j) Treatment plan and objectives including documentation of any medication prescribed;

(k) Biologic specimen testing (urine or other drug screen);

(l) Written agreements (also known as “pain contract”) for treatment between the patient and the practitioner; and

(m) Documentation of Informed Consent, including risks, benefits, and alternatives to chronic opioid therapy.

(5) The health record shall be maintained in an accessible manner, readily available for review, and contain documentation of the above as well as all other required components of the patient record, as set out in rule, and should 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.

[MQAC Submission]:
Chronic pain treatment should be a deliberate decision that takes into considerations the risks and benefits of chronic pain treatment for the patient. The practitioner shall comply with the following requirements, in addition to the requirements identified in Section 11, when providing chronic pain treatment for a patient. Chronic pain treatment is for pain lasting greater than twelve weeks. The practitioner shall document completion of these requirements in the patient’s healthcare records.

• The practitioner shall only prescribe chronic pain treatment if function is maintained or if there is sustained meaningful improvement in function and no serious adverse outcome or contraindications.

The practitioner shall periodically review the course of treatment for chronic pain, the patient’s state of health, and any new information about the etiology of the pain.
Warning:
The practitioner should use caution when prescribing opioid analgesics to a patient if the patient has the following relative contraindications:

- Significant respiratory depression, acute or severe asthma in an unmonitored setting or in the absence of resuscitative equipment, non or suspected paralytic ileus or hypersensitivity;
- Current substance use disorder or past opioid use disorder as defined by the current Diagnostic and Statistical Manual of Manual Disorders, except for tobacco, or
- Pattern of aberrant behavior.

It is recognized that opioids may be required for adequate pain control in acute or perioperative situations, but these patients may be at high risk for opioid use disorder.

Changes from Previous Draft:

- This language is from existing chronic non-cancer pain rules.
- This language combines patient evaluation and patient record requirements. This approach is somewhat consistent with how the task force has structured the acute, perioperative, and subacute evaluation and records sections, but it is strongly recommended that this section be restructured to mirror that of –X21 and -X32 (which separate the evaluation, PMP checks, and required documentation) after the content is discussed on February 9.
- MQAC suggested amendments are provided in strikethrough and red font.
- MQAC suggested section regarding the progression to chronic pain and warning language is also provided.
- Additional language in (5) is intended to reference profession specific rules regarding recordkeeping, if applicable.

Status:

Chronic pain was discussed at the October 19 meeting and rules were reviewed at a high level on November 15. Scheduled for discussion and decision on February 9.

Notes:

- The task force may wish to further consider whether to include “history of sexual or physical abuse.” There was discussion about this topic on December 12, but no decision.
- Key stakeholder concerns include availability of information about medications and ER visits, and they are seeking clarification about what “readily accessible” means.
- Need to discuss with task force how we are maximizing consistency in terms of our rules structure. It will make it easier for stakeholders, interested parties and the public to work through the rules if we mimic a structure throughout.
246-XXX-X42 Treatment Plan
(1) The written chronic pain 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.
(3) The practitioner shall advise the patient that it is the patient’s responsibility to
safeguard all medications and keep them in a secure location.
(4) 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.

[MQAC submission]:

WARNING
• The practitioner should use caution and monitor more frequently when prescribing
  opioid analgesics to a patient if the patient has the following risk factors:
  o High risk on the risk assessment tool, such as those referenced in the
definition section and required in the initial evaluation described this section
  o Mental health disorders, including primarily depression, bipolar disorder,
    schizophrenia, attention deficit disorder, obsessive-compulsive disorder,
    anxiety, and PTSD. as defined by the current Diagnostic and Statistical
    Manual of Manual Disorders;
  o Family or personal history of substance use disorder;
  o History of sexual or physical abuse;
  o Medical condition that could increase sensitivity to opioid-related side
effects, (e.g. impaired respiratory function, sleep apnea, high fall risk, altered
drug metabolism, impaired renal, hepatic or cardiac function); or
  o Current use of benzodiazepines, sedative hypnotics, anxiolytics, or central
    nervous system depressants.

Changes from Previous Draft:
• Language is from existing chronic non-cancer pain rules.
• MQAC suggested amendments noted in strikethrough and red font.

Status:
Chronic pain was discussed at the October 19 meeting and rules were reviewed at a high
level on November 15. Scheduled for discussion and decision on February 9.

Notes:
Discussion of photo ID requirement in chronic rules needed.
Stakeholder concerns: Indication information on prescriptions and requirement of photo ID.
Task force may wish to consider retaining subsection (4), as it relates to other programs and policies being put forward at this time.
Chronic non-cancer pain patients should receive all chronic pain management prescriptions from one practitioner and one pharmacy whenever possible. If the patient is at high risk for medication abuse, or has a history of substance abuse, or psychiatric comorbidities, the prescribing practitioner shall use a written agreement for treatment with the patient outlining patient responsibilities. The practitioner shall use a written agreement for treatment with the patient outlining patient responsibilities for patients receiving chronic pain treatment. This written agreement for treatment shall include:

1. The patient’s agreement to provide biological samples for urine/serum 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. The requirement that all chronic pain management prescriptions are provided by a single prescriber or multidisciplinary pain clinic and dispensed by a single pharmacy or pharmacy system, whenever possible;
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, other practitioners caring for the patient who might prescribe pain medications, 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. Acknowledgement 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.
- Suggested amendments from MQAC have been noted in strikethrough and red font.

Status:

January 25, 2018
Chronic pain was discussed in the October 19 meeting and rules were initially reviewed at a high level on November 15.

Notes:

- In the existing chronic non-cancer pain rules, there is an informed consent section that requires the practitioner to inform the patient of the risks and benefits of COAT with the patient or surrogate. The task force needs to consider whether this should be included here, as part of the written treatment, or whether it belongs in patient notification in X05.
- Key question came up in feedback about existing language and whether the authorization to share information with law enforcement is problematic.
- MQAC suggested amendments would require a written agreement for all chronic pain patients, not just high risk.
- Consider whether subsection (8) and (9) provide important notice to the patient and thus are an important piece of the written agreement, though they are not necessary in terms of enforcement of the agreement or the practitioner’s decision to check the PMP or dismiss a patient from care.
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 to fifty 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. The patient's compliance with any medication treatment plan;
   b. 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
   c. If continuation or modification of medications for pain management treatment is necessary based on the practitioner's evaluation of progress towards treatment objectives.

[MQAC submission, additional subsection]: Subsequent patient evaluations shall include:
   a. History and physical exam related to the pain;
   b. Using validated tools to document either maintenance of function and pain control or clinically meaningful improvement in function and pain level;
   c. Review the Washington state PMP to ensure the patient's controlled substance history is consistent with the prescribing record and self-reporting at the frequency determined by the patient's risk category, as follows:
      i. For a high risk patient, a PMP query shall be completed at least quarterly.
      ii. For a medium risk patient, a PMP query shall be completed at least semiannually.
      iii. For a low risk patient, a PMP query shall be completed at least annually; and
      iv. Immediately upon identification of aberrant behavior.
   d. Conducting a re-examination for patients whose clinical condition worsens.
   e. Administering a drug screen at the frequency determined by the patient's risk category: High risk shall be tested quarterly, mid risk biannually, low risk annually, and aberrant behavior at the time of visit.
   f. Excessive testing utilizing high cost testing procedures is not appropriate unless justified in the medical record. Point of care testing can be used as a screening tool.

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; Clinical condition worsens;
CONCEPTUAL DRAFT VERSION 5.1
CHRONIC NON-CANCER PAIN MANAGEMENT

(b) When opioid dose continues to escalate with no improvement in pain or function;
(c) There is evidence of significant adverse effects;
(d) Other treatment modalities are indicated; or
(e) 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 should periodically review any relevant patient information provided by a pharmacist.

Changes from Previous Draft:
- Language is from existing chronic non-cancer pain rules.
- Suggested amendments from MQAC have been noted in strikethrough and red font.

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

Notes:
- Recommend moving (2) to WAC 246-XXX-X63 on tapering requirements, combining sections, or incorporating by reference.
- Recommend amending (4) to “shall,” if maintained in rule.
- Recommend restructuring rule to clarify the frequency of review depending on stability of patient (see second and third sentence of section).
CONCEPTUAL DRAFT VERSION 5.1
CHRONIC NON-CANCER PAIN MANAGEMENT

246-XXX-X45 Clinically Meaningful Improvement

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<td>Necessity of this section has not yet been reviewed.</td>
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<td><strong>Notes:</strong></td>
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<tr>
<td>• At this time, the term “significant and documented improvement” has been utilized rather than “clinically meaningful improvement” throughout these conceptual rules. This is intended to allow practitioners latitude in treatment goals rather than require a strict quantitatively measured improvement goal.</td>
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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:
- Added (2) to reference the new WAC on MAT, WAC 246-XXX-X82.

Status:
Has not yet been reviewed.

Notes:
- Considered whether the content of (1) is a requirement, in which case amend to “shall” language.
- Consider whether 4-hours of CE is a requirement or not; MQAC suggestion is “should.”
- Consider the following question: 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; or
   (v) Other chronic pain evaluation services as approved by the regulatory authority.

(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.
Chronic pain treatment was discussed at the October 19 meeting. This section was not specifically discussed on the November 15. The task force has expressed interest in removing the mandatory consultation requirement from the rules, but existing law from 2010 HB 2876 is still codified and controls.

Notes:

- The first sentence in (1) is a “soft” requirement. It implies that any and all patients should potentially be referred.
- Consider overlap with special populations sections, recommend either combining those subsections or incorporate by reference.
- Stakeholder feedback suggests a consistent review of the terms “oral” and “orally.”
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; 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.
- Suggested amendments from MQAC have been noted in strikethrough and red font.

Status:
Chronic pain treatment was discussed at the October 19 meeting. This section was not specifically discussed on November 15. The task force has expressed interest in removing the mandatory consultation requirement from the rules, but existing law from 2010 HB 2876 is still codified and controls.

Notes:
- Consider moving (4) to WAC 246-XXX-X51 to be incorporated into rule dealing with “legacy” patients, or incorporate by reference.
- Consider amending (2) to include reference to WAC 246-XXX-X77, which is the special populations section on chronic patients with episodic acute pain needs.
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.
- Suggested amendments from MQAC have been noted in strikethrough and red font.

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 task force has expressed interest in removing the mandatory consultation requirement from the rules, but existing law from 2010 HB 2876 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:
   - 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
   - Has a subspecialty certificate in pain medicine by an ABMS-approved board; or
   - Has a certification of added qualification in pain management by the AOA; or
   - A minimum of three years of clinical experience in a chronic pain management care setting; and
     - Credentialed in pain management by an entity approved by the Washington state medical quality assurance commission for physicians and PA-C’s or the Washington state board of osteopathic medicine and surgery for osteopathic physicians; and
     - 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
     - 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 minimum of three years of clinical experience in a chronic pain management care setting; and
   - Successful completion of a minimum of at least eighteen continuing education hours in pain management during the past two years; and
   - At least thirty percent of the PA-C’s current practice is the direct provision of pain management care or is in a multidisciplinary pain clinic.
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;

   (5) [MQAC submission, move from podiatric physician to new subsection]: A practitioner with the following qualifications:
      
      (a) A minimum of three years of clinical experience in a chronic pain management care setting; and
      
      (b) Credentialed in pain management by a Washington state podiatric medical board-approved national professional association, pain association, or other credentialing entity; and
      
      (c) 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.

Changes from Previous Draft:

- Language is from existing chronic non-cancer pain rules.
- Suggested amendments from MQAC have been noted in strikethrough and red font.

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 task force has expressed interest in removing the mandatory consultation requirement from the rules, but existing law from 2010 HB 2876 is still codified and controls.

Notes:

- Any additions with respect to PA-Cs should apply both to allopathic and osteopathic PAs.
- The understood intent of the proposed amendment creating (5) is to allow any practitioner with certain qualifications to be deemed a pain management specialist. If embraced by the task force, (5)(b) and (c) must be amended to reflect the profession specific board/commission.
246-XXX-X51 Legacy and High Dose Chronic Opioid Therapy Patients

(1) A patient with an established written agreement for chronic opioid therapy who meets all of the following criteria may be exempted from the provisions of WAC 246-XXX-X47 and from any dosage limitations imposed in this chapter:
   (a) The patient has been on a dose of opioids exceeding ninety (90) milligrams MED per day;
   (b) The patient’s dose is stable and non-escalating;
   (c) The patient has a demonstrated history in their record of compliance with treatment plans and written agreements; and
   (d) The patient has documented functional stability and or pain control, or has documented improvements in pain relief and increased function at the exceptional dose.

(2) When a patient with an established written agreement for chronic opioid therapy who meets the requirements of subsection (1) of this section changes to a new practitioner, the new practitioner is encouraged to maintain the patient’s current dose initially unless, in the practitioner’s judgement, the current dose poses an imminent health risk to the patient. Over time, the practitioner may evaluate if any tapering can be achieved.

Changes from Previous Draft:
- “High risk” definition added to definitions section and changed to 90 milligram MED here.
- Amended to remove “legacy patient” and instead use “established written agreement” language in (1) and (2).

Status:
- MQAC suggestion discussed and approved at January 8 meeting.

Notes:
- Remove “legacy patient” from definitions section and “legacy” from section title if not used in rule.
246-XXX-X52 Tapering Requirements

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

(a) The patient requests tapering;
(b) The patient experiences a deterioration in function or pain;
(c) There is patient non-compliance with the written agreement;
(d) There is evidence of significant adverse events or overdose;
(e) Other treatment modalities are indicated; or
(f) There is evidence of misuse, abuse, addiction, or diversion.

Changes from Previous Draft:
- Moved from previous tapering section (-X63)

Status:
Approved at January 8 meeting.

Notes:
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.

[MQAC submission]: Adolescents from 12-24 years old: This group is at increased lifetime risk of opioid use disorder with any opioid therapy. If opioids must be used, duration should be minimized, with the minimum number of pills necessary to achieve pain relief. Unused opioids should be discarded.

The following are AMDG recommendations; they are only recommendations:

1. Prescribe opioids for acute pain in infants and children only if knowledgeable in pediatric medicine, developmental elements of pain systems, and differences in pharmacokinetics and pharmacodynamics in young children.

2. Avoid opioids in the vast majority of chronic non-cancer pain problems in children and adolescents (e.g. abdominal pain, headache, pervasive musculoskeletal pain), as evidence of safety and efficacy is lacking.

3. Opioids are indicated for a small number of persistent painful conditions, including those with clear pathophysiology and when an endpoint to usage may be defined, such as pain associated with most surgical procedures, trauma (including burns), and major reconstructive surgery.

4. Opioids may be indicated for some chronic pain conditions in children and adolescents when there is clear pathophysiology and no definable endpoint. This may include treatment at the end of life or for certain ongoing nociceptive mediated painful conditions, such as osteogenesis imperfecta or epidermolysis bullosa.

5. Put safety first when prescribing opioids to younger patients: limit the total dispensed and educate parents about dosing, administration, storage and disposal to minimize risks of diversion or accidental ingestion. Adolescents should undergo similar screening for risk of substance use disorder that one would conduct with adults.

6. Consult or refer to a pediatric pain specialist when chronic pain problems in children and adolescents are complicated or persistent, given the developmental complexities and potential for ongoing pain problems in the future. These problems are best treated by those with specialty training in the area.

Changes from Previous Draft:
- Suggested language from MQAC is included in the red font.

Status:
- This section has not yet been reviewed by task force.

Notes:
CONCEPTUAL DRAFT VERSION 5.1
SPECIAL POPULATIONS

- The MQAC suggested language, as written, cannot be enforced. It is strongly recommended that these recommendations be provided to practitioners through educational materials, rather than in rule.
- The original language is based on feedback from Gary Walco, technical expert for this discussion.
- Stakeholder feedback suggests a consistent usage of the terms “opioid therapy” (in relation to chronic) and “prescribing of opioids” (other phases).
- Recommend the existing language be made a subsection (1), and incorporate the first two sentences of the MQAC submission as subsection (2).
- Information regarding disposal of unused opioids is addressed in patient notification.
246-XXX-X72 Pregnancy

[MQAC submission]: Pregnancy: Pregnancy in patients on chronic opioid therapy or have a history of opioid use disorder (use Part VII Chronic Management in Special Populations. should be managed with specialty oversight.)

The following are AMDG recommendations; they are recommendations ONLY.

1. Recommend counseling before (preconception) and during pregnancy for women on COAT to assess and educate about potential maternal, fetal, and neonatal risks.

2. Address underlying contributors to pain syndromes such as stress and anxiety and use non-pharmacologic therapies as appropriate, including stress reduction, exercise, mechanical therapies, activity modification, and complementary and alternative medicine approaches. If appropriate, refer for mental health services (Non-opioid Options).

3. Use acetaminophen during pregnancy for treatment of pain. Consider NSAIDs in consultation with an obstetrical provider for short duration of therapy (<48 hours) prior to the third trimester.

4. Use caution when initiating short-acting opioids for treatment of pain during pregnancy and limit it to women with severe pain for whom other medical treatments have failed.

5. Assess pregnant women taking opioids for opioid use disorder. If present, refer to a qualified specialist for methadone or buprenorphine treatment for pregnant women. Buprenorphine may have improved neonatal outcomes, but availability may be limited due to provider or geographic access (Appendix H: Clinical Tools and Resources).

6. Monitor fetal growth for women on opioids, using fundal height or ultrasound surveillance, given the risk of intrauterine growth restriction.

7. Consider a perinatal pediatric consultation for pregnant women on opioids to better prepare them for risks of NAS and possible increased hospital stay for the newborn.

8. Use the Finnegan score to assess neonates during the immediate postnatal period if they were exposed to opioids in utero.

9. Weigh carefully the risks/benefits of opioid detoxification during pregnancy, when making the decision to go forward with treatment; and closely monitor the treatment plan for symptoms of withdrawal and risk of relapse.

10. Assess availability of social and community support for women with opioid use disorder or escalating pain symptoms during pregnancy to help meet any needs for education and services.

Changes from Previous Draft:

- Suggested language from MQAC is included in the red font.

Status:

This section has not yet been reviewed by task force.

Notes:
CONCEPTUAL DRAFT VERSION 5.1
SPECIAL POPULATIONS

- The MQAC suggested language, as written, cannot be enforced. It is strongly recommended that these recommendations be provided to practitioners through educational materials, rather than in rule.
CONCEPTUAL DRAFT VERSION 5.1
SPECIAL POPULATIONS

246-XXX-X73 Aging Populations

[MQAC submission]: Aging Population: As people age, their tolerance of opioids may change. This requires special attention particularly for individuals who are over 65 years of age and have been on opioids for a long time as well as for initiating opioids in an older population.

The following are clinical recommendations from the AMDG guidelines. They are ONLY recommendations:

1. Use opioids with short half-lives, as they are usually the best choices for older adults. Drugs with a long half-life can readily accumulate in older adults and result in toxicity (e.g. respiratory depression, sedation).
2. Weigh the individual patient’s needs and clinical presentation with known risk factors when deciding whether short or long acting opioids are best.
3. Avoid the use of agonist-antagonist opioids in older adults as their psychomimetic side effects can be pronounced.
4. Be vigilant when treating patients over 65 to adequately relieve pain while minimizing the risk of delirium and other opioid-related adverse drug events.
5. Use the least invasive method of drug administration (e.g. oral).
6. Initiate opioid therapy at a 25% to 50% lower dose than that recommended for younger adults, and slowly and carefully titrate dosage by 25% increments on an individual basis, balancing pain relief, physical function, and side effects.
7. Have a plan for addressing constipation from the start of opioid therapy. Prophylaxis and/or treatment can include hydration, bulk fiber (only if hydration is maintained), activity, senna, and sorbitol (20 ml of 70% taken twice daily for 3 days per week)
8. Recognize and manage all potential causes of side effects, taking into consideration medications that potentiate opioid side effects:
   a. Sedatives, tranquilizers, and anti-emetics can cause sedation.
   b. Antihypertensives and tricyclics can cause postural hypotension.
   c. Antihistamines, phenothiazines, tricyclics, and anticholinergics can cause confusion and urinary retention.
9. Avoid using more than one opioid at the same time. This makes it is easier to identify the cause of an adverse effect or toxic reaction. The incidence of delirium and other adverse reactions increases with the number of prescription drugs taken.
10. Avoid the following drugs:
    a. Codeine: the doses required for effective pain relief in older adults are associated with an increased incidence of side effects (e.g. constipation, nausea and sedation).
    b. Meperidine: the metabolite, normeperidine, is toxic to the central nervous system and can cause seizures, mood alterations and confusion; more so in older patients, especially if the patient has renal impairment.
    c. Methadone: has a high drug-drug interaction potential and is associated with prolongation of the QT interval and a potential risk of accumulation due to a long
elimination half-life. In addition, methadone is difficult to titrate because of its large inter-individual variability in pharmacokinetics, particularly in the frail elderly.

Changes from Previous Draft:
- Suggested language from MQAC is provided in red font.

Status:
This section has not yet been reviewed by task force.

Notes:
- The MQAC suggested language, as written, cannot be enforced. It is strongly recommended that these recommendations be provided to practitioners through educational materials, rather than in rule.
### Changes from Previous Draft:
- Sections for special populations were combined here for task force consideration.
  - Patients with mental/behavioral health conditions.
  - Patients with cognitive limitations.
  - Acute opioid prescribing to patients with past history of opioid misuse/abuse.

### Status:
The section has not yet been reviewed by task force.

### Notes:
- A key question is whether a rule is needed here. Stakeholder feedback questions how a practitioner would obtain the information.
246-XXX-X75 Episodic Care of Chronic Opioid Patients

(1) When evaluating chronic pain patients for episodic care, such as emergency or urgent care, the practitioner shall review any available prescription monitoring program, emergency department-based information exchange, or other tracking system to review the Washington state PMP to ensure the patient’s controlled substance history is consistent with the prescribing record and self-reporting or any other appropriate, available prescription monitoring program.

(2) Episodic care practitioners should avoid providing opioids for chronic pain patients management. However, if opioids are provided, the practitioner should limit the use of opioids for a chronic non-cancer pain patient to the minimum amount necessary to control the acute, perioperative, or similar breakthrough pain until the patient can receive care from a primary care practitioner—the practitioner who is managing the patient’s chronic pain.

(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 should report known violations of the agreement back to the patient's treatment practitioner who initiated the agreement for treatment.

Changes from Previous Draft:
- Language is from existing chronic non-cancer pain rules.
- Suggested amendments from MQAC have been noted in strikethrough and red font.
- Added “acute, perioperative, or similar breakthrough pain” for clarification.

Status:
This section has not yet been reviewed by the task force

Notes:
- Some concern has been expressed regarding the language “ensure the patient’s controlled substance history is consistent with the prescribing record and self-reporting or any other appropriate, available prescription monitoring program.” It is recommended that the language is consistent throughout the rules.
  - Suggested amendment: “review the PMP to determine the patient’s prior controlled substances prescription history.”
- Consider defining episodic care in XX3, so that the “such as” in (1) is not needed.
- Resolve whether subsection 2 should be “shall” or “should.”
- Key questions: 1) is there a way for practitioners to know, especially in acute/perioperative/emergent prescribing, whether the person is on COAT; 2) earlier concern about adding ICD code on prescriptions.
- Recommend language to clarify patients known to be a chronic pain patient (continued)
CONCEPTUAL DRAFT VERSION 5.1
SPECIAL POPULATIONS

- Consider whether this episodic care section is needed, given the specific acute and perioperative requirements.
CO-PRESCRIBING AND MEDICATION-ASSISTED TREATMENT

246-XXX-X81 Co-prescribing with Certain Medications

(1) A practitioner shall not prescribe a combination of opioids with the following Schedule II-IV medications without documentation of clinical judgment:
   a. Benzodiazepines;
   b. Barbiturates;
   c. Sedatives;
   d. Carisoprodol; or
   e. Sleeping medications (Z drugs).

(2) If a patient receiving an opioid prescription is concurrently prescribed one or more of the medications listed in subsection (1), the opioid prescribing practitioner shall consult with the other prescriber(s) to establish a patient care plan for the use of the medications concurrently.

Changes from Previous Draft:
- The trade name Soma was replaced with the generic drug name.

Status:
Approved, with edits, at January 8 meeting.

Notes:
- It is strongly recommended that the task force consider whether one or more catch-all categories such as “sedative hypnotics” would capture some or all of these listed medications. This would be beneficial as it would address the concern that future medications may not be contained by this list.
CONCEPTUAL DRAFT VERSION 5.1
CO-PRESCRIBING AND MEDICATION-ASSISTED TREATMENT

246-XXX-X82 Co-prescribing of Opioid Agonists for Medication-Assisted Treatment

(1) If a practitioner prescribes opioids to a patient known to be engaged in medication-assisted treatment (MAT) for events such as an acute or perioperative episode, the opioid-prescribing practitioner shall coordinate their prescribing with the MAT practitioner. This coordination shall occur as soon as is practicable to appropriately treat episodic pain while maintaining the patient’s MAT.

(2) The provision of MAT medications should not be discontinued during acute or perioperative treatment unless clinically indicated.

(3) A patient’s use of MAT medications should not be a basis of denial of treatment.

Changes from Previous Draft:
- Slight changes to language of section for clarity.

Status:
Approved at January 8 meeting.

Notes:
- Does the task force want to require that those performing MAT have a buprenorphine waiver from SAMHSA?
- Does the task force want to establish any special education/training requirements for those performing MAT?
246-XXX-X83 Co-prescribing of Naloxone

(1) The practitioner shall confirm or provide a current prescription for Naloxone when opioids are prescribed to a high-risk patient.

(2) The practitioner should confirm or provide a current prescription for Naloxone when opioids are prescribed at 50 med or higher.

Changes from Previous Draft:
- Subsection (1) amended to “shall.”

Status:
Approved at January 8 meeting.

Notes:
(1) A PMP query shall be performed prior to the prescription of an opioid or sedative hypnotic at the following times:
   (a) Upon the third refill of an acute opioid prescription;*
   (b) The time of transition from acute to subacute pain; and
   (c) The time of transition from subacute to chronic pain.
(2) For chronic opioid therapy, the PMP shall be checked 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 medium risk patient, a PMP query shall be completed at least semiannually.
   (c) For a low risk patient, a PMP query shall be completed at least annually.
(3) A PMP check shall be completed for any chronic pain patient immediately upon identification of aberrant behavior.
(4) A PMP check is required in conjunction with episodic care, in accordance with WAC 246-XXX-X75.

*NOTE: The Task Force discussed and voted on this part of the rules at the November 15 and January 8 meetings. It appears that the requirement to check the PMP at the initial prescription does not have full consensus. The language above reflects where consensus does exist. The Task Force will revisit this issue at its February 9 meeting in Everett.

Changes from Previous Draft and Follow-ups:
- PMP requirements were discussed at the January 8 meeting; the task force approved differentiating between various phases of care and patients based on risk level.
- The group needs to further discuss the requirement to check the PMP for the initial prescription.
- The group needs to discuss whether or when PMP checks are mandated for perioperative care.
- At the Kent task force meeting, the group supported in concept requiring PMP checks when co-prescribing benzodiazepines or sleep aids. The TF needs to reconfirm this on February 9 and consider specific language to be developed by staff on this issue.

Status:
Discussed and approved at the January 8 meeting, and for revisit on February 9.

Notes:
- It was proposed that PMP requirement language should be embedded in rules for each type of care (acute, perioperative, subacute, chronic). In the current draft, these requirements were incorporated in the acute/perioperative/subacute/chronic sections as well as here in a separate PMP section.
The task force discussed stating the rule in only one section; given the broad audience for the task force work and need for clarity, this draft clearly segregates what is required from what is recommended in two distinct sections.

OPIOID PRESCRIBING – PRESCRIPTION MONITORING PROGRAM
246-XXX-X92 Prescription Monitoring Program – Recommended Queries

(1) For acute, perioperative, and subacute care, it is strongly recommended that a PMP query be performed prior to any prescription for an opioid or sedative hypnotic.

(2) For chronic pain management, it is strongly recommended that a PMP query be performed quarterly, prior to prescribing any opioid or sedative hypnotic. It is also strongly recommended that the practitioner review the PMP on a more frequent basis to ensure the patient’s controlled substance history is consistent with the prescribing record and self-reporting.