



Conceptual Draft Version 6.2
Opioid Prescribing Rules (ESHB 1427)

March 8, 2018

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



Washington State Department of

Health

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Opioid Prescribing Rules (ESHB 1427)

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246-XXX-X83 Co-prescribing of Naloxone

Opioid Prescribing – Prescription Monitoring Program

246-XXX-X91 Prescription Monitoring Program – Required Queries

246-XXX-X92 Prescription Monitoring Program – Recommended Queries

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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OPIOID PRESCRIBING – GENERAL PROVISIONS

246-XXX-X01 Intent and Scope

These rules govern the use of opioids in the treatment of pain.

Notes:

- For the purposes of these conceptual rules, it is recommended that the task force strike the previous –X01 intent section and the previous –X02 scope and applicability section.
- While these sections may provide context to the rules, the language should be carefully considered and may be more appropriately developed and considered by the individual boards and commissions.
- If any reference to a clinical guideline is retained, it is strongly recommended that such reference be made to the publication title, rather than a website link.
- Stakeholder comment from AMDG and WSMA/WSHA:
 - Express support for inclusion of -X01 and -X02 as assurances to providers that clinicians may appropriately treat pain without fear of discipline. However, comments indicate that some passages are substantive in nature and should be amended to make clear the intent section provides only context to the rules and not requirements.
- Stakeholder feedback from WSMA/WSHA and WSPMA:
 - Suggested language as to the application of federal and other state laws: “In addition to these rules, practitioners are required to adhere to applicable state or federal laws such as DEA registration (and then include an example of a state law.)”
- WSPMA comments that reference to adequate training could create a continuing education and training standard.
- Previous WSMA and WSPMA feedback has questioned the purpose of this section and whether it could be deleted. The key question is whether this section provides important contextual value. It is not generally enforceable and could have an unintended impact on prescribing.
- MQAC submission is provided below. Stakeholder comments to the MQAC submission request confirmation that this language is taken from the current Medical Commission chronic pain rules. Comments question whether this section could be simplified.

[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

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pain includes non-treatment, under-treatment, overtreatment, and the continued use of ineffective treatments.

The diagnosis and treatment of pain is integral to the practice of medicine. The commission encourages physicians to view pain management as a part of quality medical practice for all patients with pain, including acute 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 commission recognizes that controlled substances including opioid analgesics may be essential in the treatment of acute pain due to illness, trauma or surgery, subacute pain and chronic pain, whether due to cancer or non-cancer origins. The commission will refer to current clinical practice guidelines and expert review in approaching cases involving management of pain. Examples of current clinical practice guidelines include AMDG guidelines <http://agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf> and CDC guidelines for chronic pain <https://www.cdc.gov/drugoverdose/prescribing/guideline.html>. 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

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

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

These rules are designed to assist 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 commission'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.

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246-XXX-X02 Definitions

The definitions in this section apply throughout sections X01 through section X92 unless the context clearly requires otherwise.

(1) "**Aberrant behaviors**" means behavior that indicates misuse, diversion or **substance use disorder** ~~addiction~~. This includes, but is not limited to, multiple early refills or obtaining prescriptions for the same or similar drugs from more than one clinician or other health care provider.

(2) "**Acute pain**" means the normal, predicted physiological response to a noxious chemical, thermal, or mechanical stimulus and typically is associated with invasive procedures, trauma, and disease. Acute pain is considered to be of zero (0) to six (6) weeks in duration.

(3) "**Biological specimen test**" or "**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 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. ~~Chronic pain means pain caused by various diseases or abnormal conditions that continues longer than twelve weeks.~~

(5) "**Comorbidity**" means a preexisting or coexisting physical or psychiatric disease or condition.

(6) "**Episodic care**" means medical care provided by a practitioner other than the designated primary care practitioner in the acute care setting, for example, urgent care or emergency department.

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

(8) "**High dose**" means ninety (90) milligram MED, or more, per day.

(9) "**High-risk**" is a category of patient at increased risk of morbidity or mortality, such as from comorbidities, polypharmacy, history of substance use disorder ~~addiction~~ or abuse, aberrant behavior, high dose opioid prescription, or the use of any central nervous system (CNS) depressant. ~~means a patient at increased propensity for misuse, abuse, stockpiling, diversion, substance use disorder, 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.~~

(10) "**Hospice**" 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~~

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~~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.~~

(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) **"Medication assisted treatment (MAT)"** ~~for the purposes of this chapter, means the pharmacologic management of opioid use disorder rather than the more traditional definition that would also include a treatment program that combines behavioral therapy and medications to treat substance use disorders.~~ **means the use of FDA-approved opioid agonist and antagonists medications, usually as an adjunct to counseling and behavioral therapies, for the treatment of substance use disorders.**

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

(15) **"Multidisciplinary pain clinic"** means a clinic or office that provides comprehensive pain management and includes care provided by multiple available disciplines, **practitioners** or treatment modalities, ~~for example, medical care through physicians, physician assistants, osteopathic physicians, osteopathic physician assistants, podiatry, dental, advanced registered nurse practitioners, and physical therapists, occupational therapists, and practitioners of other complementary therapies~~ **physical therapy, occupational therapy, or other complementary therapies.**

(16) **"Multimodal management of pain"** means the application of non-narcotic **analgesic** relief mechanisms, such as anti-inflammatory medications, acetaminophen, nerve blocks, N-methyl-D-aspartate (NMDA) **antagonists, or any nonpharmacological pain treatments** ~~and other medications.~~

(17) **"Opioid analgesic"** or **"opioid"** 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.

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

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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.

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

(20) **“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.~~

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

(22) **“Prescription monitoring program”** or **“PMP”** means the Washington state 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 RCW, ~~or 18.22 RCW~~, a physician assistant licensed under chapter 18.71A or 18.57A RCW, or a **podiatric physician licensed under chapter 18.22 RCW**.

(24) **“Risk assessment tools”** ~~for the purposes of this section, means professionally-developed clinically accepted questionnaires appropriate for identifying a patient’s level of risk for substance abuse or misuse. Examples include, but are not limited to, The Screener and Opioid Assessment for Patients with Pain, and Opioid Risk Tool. 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.~~

(25) **“Subacute pain”** ~~is considered to be a continuation of pain, of 6 weeks to 12 weeks in duration means the symptom or illness has passed the acute episode, but is not yet chronic.~~

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

Notes:

- Taskforce and stakeholder suggested revisions are incorporated in red font while proposed deletions are noted in strikethrough.
- Removed terms not used in rule.

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- Consider whether the definition of “palliative” is so broad it could be argued to swallow the rule. Recommendation is to maintain the definition used in current chronic rules or consider language from CDC: “Care that provides relief from pain and other symptoms, supports quality of life, and is focused on patients with serious advanced illness.”
- CDC stakeholder feedback cautions that risk assessment tools have not been evaluated to provide sufficient accuracy.
- “Addiction” has been replaced with “substance use disorder” in definitions and throughout rule, as “addiction” is not considered a specific diagnosis in the DSM. Taskforce consideration needed.
- Stakeholder feedback notes that testing of biological specimen beyond urine or blood is very rarely necessary.
- Stakeholder feedback from WSMA/WSHA:
 - (14) “Morphine equivalent dose:” Request accepted conversion table be specified.
 - (16) “Multimodal management of pain:” Used only once in chapter; recommend defining in the appropriate section rather than in definitions.

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246-XXX-X03 Exclusions

- (1) WAC 246-XXX-X01 through 246-XXX-X92 do not apply to:
- (a) The treatment of patients with cancer-related pain;
 - (b) The provision of palliative, hospice, or other end-of-life care; or
 - (c) The treatment of inpatient hospital patients.

Notes:

- Restructured to model the exclusions section of the current chronic rules.

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246-XXX-X04 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 type of patient, and the phase of treatment. The practitioner shall document such notification in the patient 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 a phase of treatment, as follows:

(i) Acute **nonoperative pain or acute perioperative** pain to subacute pain; or

(ii) Subacute pain to chronic pain.

(3) Patient notification must 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.

Notes:

- At this time, the recommendation is that the task force continue its work with the assumption that ESHB 2489 will not pass.
- Stakeholder feedback from WSMA/WSHA and WSPMA: Recommend removing from rule due to expected passage of ESHB 2489. Comment that documentation requirement is an administrative burden. Question whether DOH handout required by ESHB 2489 would meet (3) requirement.
- ESHB 2489 would not address safe storage. It would require that a practitioner providing a prescription for an opioid for the first time during the course of treatment to any patient have a documented in-person discussion that includes: the risks of opioids, including of dependence and overdose; alternatives to opioids, a written copy of the DOH materials required under ESHB 2489, sec. 22. The discussion could be designated to another individual credentialed under RCW 13.130.040. ESHB 2489 would direct DOH to develop a statement warning individuals about the risks of opioid use and abuse and provide information about safe disposal of opioids.
- Stakeholder feedback from AMDG: Patient notification must include information regarding the safety and efficacy of opioids, 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.

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246-XXX-X05 Use of Alternative Modalities for Pain Treatment

(1) The practitioner shall consider multimodal pharmacologic and non-pharmacologic therapy for ~~acute, subacute, or perioperative~~ pain rather than defaulting to the use of opioid therapy alone whenever reasonable, evidence-based, **clinically appropriate**, alternatives exist. A practitioner may combine opioids with other medications and treatments, including, but not limited to, acetaminophen, acupuncture, chiropractic, cognitive behavior therapy, nonsteroidal anti-inflammatory drugs (NSAIDS), osteopathic manipulative treatment, physical therapy, massage, or sleep hygiene.

Notes:

- Taskforce and stakeholder suggested revisions are incorporated in red font while proposed deletions are noted in strikethrough.
- At this time, the recommendation is that the task force continue its work with the assumption that ESHB 2489 will not pass.
- ESHB 2489 would require that a practitioner have an in-person discussion that addresses pain management alternatives to opioids, including nonopioid pharmacological treatments, and nonpharmacological treatments available to the patient, at the discretion of the practitioner and based on the medical condition of the patient. The discussion could be designated to another individual.
- MQAC proposes striking this section.
- Stakeholder comment from WSHPCO: Express continued support for attention to upstream non-pharmacologic pain management
- Stakeholder comment from WSMA/WSHA: Recommend this section be stricken as the topic is addressed by ESHB 2489. Alternatively, suggests revision: "The practitioner shall exercise his or her professional judgment in selecting appropriate treatment modalities for acute, subacute, or perioperative pain, including use of multimodal pharmacologic and non-pharmacologic therapy as alternative to opioids whenever reasonable, clinically appropriate, evidence-based alternatives exist."
- Stakeholder feedback from WSPMA: Recommend this section be stricken as ESHB 2489 addresses the topic or that this language be modified to be consistent with the requirements of ESHB 2489.

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246-XXX-X06 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.

Notes:

- MQAC proposes striking this requirement.
- Stakeholder feedback from WSMA/WSHA and WSPMA: Support that this requirement be stricken. Express concern that protected health information may be released through this mechanism, and that a pharmacist does not need to be provided with this information; perhaps the pharmacist is better served if provided information regarding whether the prescription is for acute, perioperative, subacute, or chronic pain. The administrative burden for some practices of including an ICD code is significant.

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OPIOID PRESCRIBING – ACUTE AND PERIOPERATIVE CARE

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

- (1) **During the preoperative evaluation for elective surgeries** or prior to writing an opioid prescription for acute or perioperative pain **for non-elective surgeries**, the practitioner shall:
- Conduct an appropriate history and physical examination, **including screening for risk factors for overdose and severe postoperative pain**;
 - Evaluate** ~~Identify~~ the nature and intensity of the pain **or anticipated pain following surgery**; and
 - Inquire ~~of the patient~~ about any 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 and WAC 246-XXX-X92 to identify any Class II-IV **or other drugs of concern received by the patient** and document their review and any concerns.~~
- ~~(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:~~
- ~~The presence of one or more recognized diagnoses or indications for the use of opioid pain medication;~~
 - ~~Dates of practitioner queries of the PMP and any relevant findings or impressions of that query;~~
 - ~~All medications the patient is known to be prescribed or taking;~~
 - ~~An appropriate pain treatment plan, including the consideration of, or attempts to use, non-pharmacological and non-opioid therapies; and~~
 - ~~All other required components of the patient record, as set out in statute or rule.~~

Notes:

- Taskforce and stakeholder suggested revisions are incorporated in red font while proposed deletions are noted in strikethrough.
- MQAC proposes striking (2), related to the MQAC proposal of (6) to -X91. MQAC also proposes striking (3).
- If retained, (2) must be consistent with X91 regarding the PMP query at a certain refill.
- Stakeholder feedback from WSMA/WSHA and WSPMA:
 - Request that an authorized designee of the practitioner be permitted to complete any required PMP query.
 - Request any reference to -X92 be stricken as it contains recommendations only; suggest reference may create soft standard.
 - Do not support the requirement of a treatment plan for acute and perioperative care; given the short duration of most acute/perioperative opioid prescriptions, the requirement of considering non-pharmacologic modalities is not warranted; creates administrative burden with little clinical value.

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- The subject of opioid alternatives is covered in ESHB 2489, requiring the discussion with patients of alternatives to opioids at the discretion of the practitioner based on the medical condition of the patient.
- Other stakeholder feedback suggests PMP query be conducted, if possible, at the initiation for non-operative or perioperative pain.

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246-XXX-X22 Treatment Plan – Acute Nonoperative Pain

The practitioner shall comply with the requirements in this section when prescribing opioid analgesics for acute pain and shall document completion of these requirements in the patient record:

(1) The practitioner shall **prescribe** ~~consider prescribing~~ non-opioid analgesics as the first line of pain control in patients **unless not clinically appropriate** ~~in accordance with the provisions of WAC 246-XXX-X05.~~

(2) The practitioner shall conduct queries of the Washington State PMP in accordance with the provisions of WAC 246-XXX-X91 and WAC 246-XXX-X92 to identify any Class II-IV controlled medications prescribed by other practitioners and document their review and any concerns.

(3) ~~The practitioner shall prescribe opioids for effective pain control and~~ **If the practitioner prescribes opioids for effective pain control, such prescription shall be** 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 **including what evaluations have been undertaken to investigate why a normal course of recovery has not occurred.**

(4) The practitioner shall re-evaluate a patient who does not follow the normal course of recovery. If significant and documented improvement in **function** ~~functional stability~~, pain control, pain relief, or increased function has not occurred, the practitioner shall reconsider the continued use of opioids or whether tapering or discontinuing opioids is clinically indicated.

(5) Follow-up visits **for pain control must** ~~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 **to investigate causes of continued acute nonoperative pain** or other treatments.

(6) Long-acting/**extended release (ER)** opioids are not indicated for acute nonoperative and perioperative pain. Should a practitioner need to use a long-acting opioid for acute pain, that reason must be documented in the patient record.

~~(7) MAT medications shall not be discontinued when treating acute pain, except as consistent with the provisions of WAC 246-XXX-X82.~~

~~(8) If the practitioner elects to treat a patient with opioids beyond the six week time period of acute pain, the practitioner shall **document in the patient record** recognize that the patient is transitioning from acute pain to subacute pain. Rules governing the treatment of subacute pain, WAC 246-XXX-X31 through WAC 246-XXX-X32, shall apply.~~

Notes:

- Taskforce and stakeholder suggested revisions are incorporated in red font while proposed deletions are noted in strikethrough.

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ACUTE AND PERIOPERATIVE CARE

- Consider being specific in sections related to acute “nonoperative” pain versus acute perioperative pain.
- Subsection (8) models X23(6), which was discussed in concept at the February 9 meeting. Purpose is to acknowledge the transition from acute to subacute.
- Stakeholder feedback from WSMA/WSHA and WSPMA:
 - Concerns regarding the administrative burden of a treatment plan in this phase.
 - Suggest that reference to three day recommendation and extra language regarding more than a seven day supply being rarely needed be stricken, leaving only the seven day limit with available documented exception.

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CONCEPTUAL DRAFT VERSION 6.2
ACUTE AND PERIOPERATIVE CARE

246-XXX-X23 Treatment Plan - Acute Perioperative Pain

The practitioner shall comply with the requirements in this section when prescribing opioid analgesics for perioperative pain and shall document completion of these requirements in the patient's record:

(1) The practitioner shall prescribe ~~consider prescribing~~ non-opioid analgesics as the first line of perioperative pain control in patients **unless not clinically appropriate** ~~in accordance with the provisions of WAC 246-XXX-X05.~~

(2) The practitioner shall conduct queries of the Washington State PMP in accordance with the provisions of WAC 246-XXX-X91 and WAC 246-XXX-X92 to identify any Class II-IV controlled medications prescribed by other practitioners and document their review and any concerns.

(3) ~~The practitioner shall prescribe opioids only when clinically appropriate for effective pain control and~~ **If the practitioner prescribes opioids for effective pain control, such prescription shall be** 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 from the time of discharge without clinical documentation in the patient record to justify the need for such a quantity. **For more specific best practices, the practitioner should refer to the AMDG/Bree Collaborative perioperative guidelines.**

(4) The practitioner shall re-evaluate a patient who does not follow the normal course of recovery. If significant and documented improvement in **function** ~~functional stability~~, pain control, pain relief, or increased function has not occurred, the practitioner shall reconsider the continued use of opioids or whether tapering or discontinuing opioids is clinically indicated.

(5) 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.

(6) If the practitioner elects to treat a patient with opioids beyond the six week time period of perioperative pain, the practitioner shall **document in the patient record** ~~recognize~~ that the patient is transitioning from perioperative pain to subacute pain. Rules governing the treatment of subacute pain, WAC 246-XXX-X31 through WAC 246-XXX-X32, shall be followed unless improvement in **function** ~~functional stability~~, pain control, pain relief, or increased function is documented and there is documentation of the timing and plan for discontinuation of all opioid medications.

(7) If the practitioner elects to prescribe a combination of opioids with a Schedule II-IV medication listed in WAC 246-XXX-X81 or to a patient known to be receiving a Schedule II-IV medication listed in WAC 246-XXX-X81 from another practitioner, such prescribing must be in accordance with WAC 246-XXX-X81.

CONCEPTUAL DRAFT VERSION 6.2
ACUTE AND PERIOPERATIVE CARE

Notes:

- It was previously requested to see how the Bree Collaborative perioperative guidelines could be incorporated into rule as part of (3). That concept was provided for stakeholder comment and feedback suggested that inclusion in rule is not recommended. The concept was removed from this conceptual draft V6.2.
- Taskforce and stakeholder suggested revisions are incorporated in red font while proposed deletions are noted in strikethrough.
- Subsection (6) was discussed in concept at the February 9 meeting. Purpose is to acknowledge the transition from acute to subacute.
- Reference to co-prescribing X81 in subsection (7) was discussed at February 9 meeting. Inclusion here is not necessary, as X81 applies generally.
- MQAC proposes reference to AMDG/Bree guidelines in (3).
- Stakeholder comment suggests that requirements of the treatment plan be listed out and moved to the evaluation and record section.
- CDC stakeholder feedback notes CDC recommends a 7 day supply rather than 14.
- Stakeholder feedback from WSMA/WSHA and WSPMA:
 - Suggest that the three day recommendation and extra language regarding more than a fourteen day supply being rarely needed be stricken, leaving only the fourteen day limit with available documented exception.
 - Suggest requirement on non-opioids as first line of defense be removed.

CONCEPTUAL DRAFT VERSION 6.2
SUBACUTE CARE

OPIOID PRESCRIBING – SUBACUTE CARE

246-XXX-X31 Subacute Pain Care

(1) The practitioner should recognize the progression of a patient from the acute or perioperative phases to the subacute phase and take into consideration the risks and benefits of continued opioid prescribing for the patient.

(2) The goal in this phase is to taper opioids. If tapering has not begun prior to the subacute phase, the practitioner shall have observed a patient with significant and documented improvement in functional stability, pain control, pain relief, or increased function in order to have a legitimate basis to continue prescribing opioids beyond the acute pain episode. The practitioner shall make reasonable attempts to discontinue the use of opioids **prescribed for the acute pain event** by no later than the conclusion of the subacute phase.

(3) ~~The practitioner shall prescribe opioids for effective pain control and~~ **If the practitioner prescribes opioids for effective pain control, such prescription shall be** 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~~ **fourteen** day supply of opioids without clinical documentation to justify the need for such a quantity during the subacute phase.

(4) If the practitioner elects to prescribe a combination of opioids with a Schedule II-IV medication listed in WAC 246-XXX-X81 or prescribes opioids to a patient known to be receiving a Schedule II-IV medication listed in WAC 246-XXX-X81 from another practitioner, such prescribing must be in accordance with WAC 246-XXX-X81.

(5) If the practitioner elects to treat patients with opioids beyond **twelve weeks** ~~the subacute phase~~, the practitioner should recognize that the patient is progressing from subacute pain to chronic pain. Rules governing the treatment of chronic pain, WAC 246-XXX-X41 through WAC 246-XXX-X50, shall apply.

[MQAC submission, additional language]: Progression from subacute to Chronic Pain

The progression of subacute to chronic pain is a continuum and must be recognized by the practitioner. 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 prescribe opioids for chronic pain treatment only if function and/or pain control is maintained or if there is sustained meaningful improvement in function and/or pain control, and no serious adverse outcomes 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. See subsequent periodic review section to determine frequency of review.

CONCEPTUAL DRAFT VERSION 6.2
SUBACUTE CARE

Notes:

- Taskforce and stakeholder suggested revisions are incorporated in red font while proposed deletions are noted in strikethrough.
- Subsection (5) was created, modeling subsection (6) of –X23 which was discussed in concept at the February 9 meeting in the context of acute care. Purpose is to acknowledge the transition from subacute to chronic.
- Stakeholder feedback from WSMA/WSHA and WSPMA:
 - Question necessity of this section, generally. Suggests that -X32 is sufficient.
 - Comment that (2) is confusing. Question if intent of (2) is to indicate that a patient in pain, even if no improvement in function is seen, should not receive opioids.
 - WSMA/WSHA acknowledges that (3) language is workable considering public interest in this issue.
- Stakeholder feedback regarding the multiple day limitations of 3 and 7 for acute pain, 10 for subacute pain, 14 for surgery: Operationally, there may be a problem with the 10-day limit in the subacute phase. While the initial opioid prescription is limited to 7 days in the acute phase, there isn't any limit with refills, so there could be 2 more prescriptions for 30-day supply, which take the patient into the subacute phase then the provider would need to reduce it down to 10 day supply. Same thing can apply to perioperative phase.

CONCEPTUAL DRAFT VERSION 6.2
SUBACUTE CARE

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 or review and update the patient's existing history and examination taken during the acute or perioperative phase;
 - (b) ~~Evaluate~~ ~~Identify~~ the nature and intensity of the pain;
 - (c) Inquire regarding other medications the patient is prescribed or taking, including date, type, dosage and quantity prescribed;
 - (d) Conduct queries of the Washington State PMP in accordance with the provisions of WAC 246-XXX-X91 and WAC 246-XXX-X92;
 - (e) Screen and document the patient's ~~potential for high-risk level of risk for aberrant~~ behavior and adverse events related to opioid therapy. If ~~the practitioner determines the patient is determined~~ high risk, consider lower dose therapy, shorter intervals between prescriptions, more frequent visits, increased biological specimen testing, and prescribing rescue naloxone.
 - (f) Obtain a biological specimen test if the patient's function is deteriorating or if pain is escalating;
 - (g) Screen or refer the patient for further consultation for psychosocial factors which may be impairing recovery, including but not limited to depression or anxiety.
- (2) 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 functional stability~~, pain control, pain relief, or increased function forming the basis to continue prescribing opioid analgesics beyond the acute pain episode;
 - (c) Practitioner queries of the PMP;
 - (d) All medications the patient is known to be prescribed or taking;
 - (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) Results of any aberrant biological specimen 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 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 and benzodiazepines or sedative-hypnotics, if applicable; and

CONCEPTUAL DRAFT VERSION 6.2
SUBACUTE CARE

- (k) All other required components of the patient record, as set out in statute or rule.
- (3) Follow-up visits ~~should~~ **must** include objectives or metrics to be used to determine treatment success if opioids are to be continued. This includes, at a minimum:
- (a) Change in pain level;
 - (b) Change in physical function;
 - (c) Change in psychosocial function; and
 - (d) Additional planned diagnostic evaluations or other treatments.

Notes:

- Taskforce and stakeholder suggested revisions are incorporated in red font while proposed deletions are noted in strikethrough.
- Stakeholder feedback from WSMA/WSHA and WSPMA:
 - Note that these rules should not discourage practitioners from treating patients with complex pain or pain that doesn't resolve as anticipated due to administrative burden.
 - Request that an authorized designee of the practitioner be permitted to complete the required PMP query.
 - Request any reference to -X92 be stricken as it contains recommendations only; suggest reference may create soft standard. Any PMP provision should reference X91 only.

CONCEPTUAL DRAFT VERSION 6.2
CHRONIC PAIN MANAGEMENT

OPIOID PRESCRIBING – CHRONIC 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 pain.

- (1) History: The patient's health history must 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, including medications and their efficacy;
 - (d) Review of any significant comorbidities;
 - (e) Any current or historical substance use disorder;
 - (f) Current medications and as related to treatment of the pain, the efficacy of medications tried; and
 - (g) Medication allergies;
- (2) Evaluation: ~~The initial~~ patient evaluation **prior to opioid prescribing** must include:
 - (a) Appropriate physical examination;
 - (b) Chronic pain treatment with opioids must take into consideration the risks and benefits of chronic pain treatment for the patient;
 - (c) 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) Review of the Washington state PMP to identify schedule II-V or other drugs of concern received by the patient in accordance with the provisions of WAC 246-XXX-X91 and WAC 246-XXX-X92.
 - (e) Any available diagnostic, therapeutic, and laboratory results;
 - (f) Use of a risk assessment tool and assignment of the patient to a high, moderate or low risk category. The practitioner should use caution and shall monitor more frequently when prescribing opioid analgesics to a patient identified as high risk;
 - (g) Any available consultations, particularly as related to the patient's pain;
 - (h) Pain related diagnosis, including documentation of the presence of one or more recognized indications for the use of pain medication;
 - (i) Treatment plan and objectives including:
 - (i) Documentation of any medication prescribed;
 - (ii) Biologic specimen testing (urine or other drug screen) ordered; and
 - (iii) Any labs or imaging ordered;
 - (j) Written agreements (also known as "pain contract") for treatment between the patient and the practitioner; and
 - (k) **Patient counseling concerning** ~~Documentation of informed consent, including~~ risks, benefits, and alternatives to chronic opioid therapy.

CONCEPTUAL DRAFT VERSION 6.2
CHRONIC PAIN MANAGEMENT

(3) The health record must be maintained in an accessible manner, readily available for review, and contain documentation of requirements in subsections (1) and (2) of this section, as well as all other required components of the patient record, as set out in rule.

Notes:

- Taskforce and stakeholder suggested revisions are incorporated in red font while proposed deletions are noted in strikethrough.
- CDC stakeholder comment: caution against use of risk assessment tools.
- Stakeholder feedback from WSMA/WSHA and WSPMA: Request any reference to -X92 be stricken as it contains recommendations only; suggest reference may create soft standard. Any PMP provision should reference X91 only.

DRAFT

CONCEPTUAL DRAFT VERSION 6.2
CHRONIC PAIN MANAGEMENT

246-XXX-X42 Treatment Plan

- (1) When the patient enters the chronic stage the patient shall be reevaluated by treating the situation as a new disease.
- (2) The chronic pain treatment plan must state the objectives that will be used to determine treatment success and must include, at a minimum:
 - (a) Any change in pain relief;
 - (b) Any change in physical and psychosocial function; ~~or and~~
 - (c) Additional diagnostic evaluations or other planned treatments.
- (3) After treatment begins the practitioner shall adjust drug therapy to the individual health needs of the patient.
- (4) The practitioner shall **complete patient notification in accordance with the provisions of WAC 246-XXX-X04.** ~~advise the patient that it is the patient's responsibility to safeguard all medications and keep them in a secure location.~~

Notes:

- Taskforce and stakeholder suggested revisions are incorporated in red font while proposed deletions are noted in strikethrough.

CONCEPTUAL DRAFT VERSION 6.2
CHRONIC PAIN MANAGEMENT

246-XXX-X43 Written Agreement for Treatment

The practitioner shall use a written agreement for treatment with the patient who requires long term opioid therapy for chronic pain that outlines the patient's responsibilities. This written agreement for treatment must include:

- (1) The patient's agreement to provide biological samples for biological specimen testing 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~~ **advice** that all chronic pain management prescriptions ~~should be~~ **are** provided by a single prescriber, a single clinic, or a multidisciplinary pain clinic;
- (5) The ~~requirement~~ **advice** that all pain management prescriptions ~~should be~~ **are to be** dispensed by a single pharmacy, pharmacy system, or pharmacy benefits manager whenever possible;
- (6) The patient's agreement to not abuse substances that can put the patient at risk for adverse outcomes;
- (7) A written authorization for:
 - (a) The practitioner to release the agreement for treatment to:
 - (i) Local emergency departments;
 - (ii) Urgent care facilities;
 - (iii) Other practitioners caring for the patient who might prescribe pain medications; and
 - (iv) Pharmacies; and
 - (b) Other practitioners to report violations of the agreement to the practitioner treating the patient's chronic pain and to the PMP;
- (8) A written ~~acknowledgement~~ **authorization** that the practitioner may notify the proper authorities if ~~the practitioner he or she~~ **to the extent such disclosure is permitted under federal and state law;**
- (9) Acknowledgment that it is the patient's responsibility to safeguard all medications and keep them in a secure location; and
- (10) 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.

Notes:

- Taskforce and stakeholder suggested revisions are incorporated in red font while proposed deletions are noted in strikethrough.
- Stakeholder feedback from WSMA/WSHA: Question whether the language of (8) satisfies HIPAA/state law requirements for an authorization to disclose PHI.

CONCEPTUAL DRAFT VERSION 6.2
CHRONIC PAIN MANAGEMENT

246-XXX-X44 Periodic Review

- (1) The practitioner shall periodically review the course of treatment for chronic pain **with the frequency based on risk category. The frequency of visits, biological testing, and PMP queries shall be determined based on the patient's risk category, as follows:**
 - (a) For a high-risk patient, at least quarterly;
 - (b) For a moderate-risk patient, at least semiannually;
 - (c) For a low-risk patient, at least annually; and
 - (d) Immediately upon indication of aberrant behavior.

~~the patient's state of health, and any new information about the etiology of the pain. Generally, periodic reviews must take place at least every six months. However, for treatment of stable patients involving non-escalating daily dosages, the practitioner shall determine the periodic review schedule and document the rationale in the patient record.~~
- (2) 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, diminished, or are maintained 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.
- (2) Periodic or subsequent patient evaluations must include:
 - (a) History and physical exam related to the pain;
 - (b) Use of validated tools to document either maintenance of function and pain control or improvement in function and pain level;
 - (c) Review of the Washington State PMP to identify schedule II-IV or other drugs of concern received by the patient at a frequency determined by the patient's risk category, **and otherwise** in accordance with the provisions of WAC 246-XXX-X91 and WAC 246-XXX-X92;
 - (d) Administering a biological specimen test at the frequency determined by the patient's risk category, as follows:
 - (i) For a high risk-patient, at least quarterly;
 - (ii) For a moderate-risk patient, at least semiannually;
 - (iii) For a low-risk patient, at least annually; and
 - (iv) Immediately upon indication of aberrant behavior.
- (3) 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 in accordance with the provisions of WAC 246-XXX-X49.

Notes:

CONCEPTUAL DRAFT VERSION 6.2
CHRONIC PAIN MANAGEMENT

- Taskforce and stakeholder suggested revisions are incorporated in red font while proposed deletions are noted in strikethrough.
- Stakeholder feedback from WSMA/WSHA: Request any reference to -X92 be stricken as it contains recommendations only; suggest reference may create soft standard. Any PMP provision should reference X91 only.

DRAFT

CONCEPTUAL DRAFT VERSION 6.2
CHRONIC PAIN MANAGEMENT

246-XXX-X45 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 pain patients who are under eighteen years of age, or who are **potential high risk patients** ~~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). In the event that the practitioner prescribes a dosage amount that meets or exceeds the consultation threshold of one hundred twenty milligrams MED per day, a consultation with a pain management specialist as described in WAC 246-XXX-X48 is required, unless the consultation is exempted under WAC 246-XXX-X46 or 246-XXX-X47. ~~The practitioner shall use great caution should be used when prescribing opioids to children with chronic pain, and appropriate referral to a specialist is encouraged.~~

(a) The mandatory consultation must 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.**

(3) 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 pain management specialist provides a written record of the consultation to the prescribing practitioner, the practitioner shall maintain it as part of the patient record.

(4) **The practitioner shall use great caution when prescribing opioids to children with chronic pain, and appropriate referral to a specialist is encouraged.**

Notes:

- Taskforce and stakeholder suggested revisions are incorporated in red font while proposed deletions are noted in strikethrough.
- Stakeholder feedback: Is 120 the threshold for all patients, or is there another threshold for kids? Consider moving (3) to X71 pertaining to special populations.

CONCEPTUAL DRAFT VERSION 6.2
CHRONIC PAIN MANAGEMENT

- Consider whether the requirement that a practitioner consult with a pain management specialist, but no further requirement that the high dose be tapered if no improvement in pain control or function continues, is sufficient to address this issue. Currently, X49 only directs the practitioner to consider tapering.

DRAFT

CONCEPTUAL DRAFT VERSION 6.2
CHRONIC PAIN MANAGEMENT

246-XXX-X46 Consultation—Exemptions for Exigent and Special Circumstances

A practitioner is not required to consult with a pain management specialist as defined in WAC 246-XXX-X48 when they have documented adherence to all standards of practice as defined in WAC 246-XXX-X41 through 246-XXX-X50 and when any one or more of the following conditions apply:

- (1) The patient is following a tapering schedule;
- (2) The patient requires treatment for acute pain, which may or may not include hospitalization, requiring a temporary escalation in opioid dosage with expected return to their baseline dosage level or below;
- (3) The practitioner documents reasonable attempts to obtain a consultation with a pain management specialist and the circumstances justifying prescribing above one hundred twenty 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.

Notes:

- Feedback suggests the Task Force provide parameters to what qualifies as a tapering schedule (define/require documentation/etc.). Alternatively, consider whether, or which, exemptions are really needed.

CONCEPTUAL DRAFT VERSION 6.2
CHRONIC PAIN MANAGEMENT

246-XXX-X47 Consultation—Exemptions for the Practitioner

A practitioner is exempt from the consultation requirement in WAC 246-XXX-X45 if one or more of the following qualifications are met:

- (1) The practitioner is a pain management specialist under WAC 246-XXX-X48;
- (2) The practitioner has successfully completed, every four 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 **substance use disorder** ~~addiction~~ medicine;
- (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.

Notes:

- Taskforce and stakeholder suggested revisions are incorporated in red font while proposed deletions are noted in strikethrough.

CONCEPTUAL DRAFT VERSION 6.2
CHRONIC PAIN MANAGEMENT

246-XXX-X48 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 a physician or the Washington state board of osteopathic medicine and surgery for an osteopathic physician; 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 physician assistant or osteopathic physician assistant who has a delegation agreement with a physician or osteopathic physician pain management specialist and meets educational requirements and practice requirements listed below:
 - (a) 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 a physician assistant or the Washington state board of osteopathic medicine and surgery for an osteopathic physician assistant; and
 - (ii) Successful completion of a minimum of at least eighteen continuing education hours in pain management during the past two years; and
 - (iii) At least thirty percent of the physician assistant or osteopathic physician assistant's current practice is the direct provision of pain management care or is in a multidisciplinary pain clinic.
- (3) If a dentist:
 - (a) 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.
- (4) If an advanced registered nurse practitioner (ARNP):
 - (a) A certified registered nurse anesthetist (CRNA) with current certification for anesthesia and/or non-surgical pain management; or

CONCEPTUAL DRAFT VERSION 6.2
CHRONIC PAIN MANAGEMENT

- (b) A minimum of three years of clinical experience in a chronic pain management care setting; and
 - i. Credentialed in pain management by a Washington state nursing care quality assurance commission-approved national professional association, pain association, or other credentialing entity; and
 - ii. Successful completion of a minimum of at least eighteen continuing education hours in pain management during the past two years; and
 - iii. 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.
- (5) 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
 - i. Credentialed in pain management by a Washington state podiatric medical board-approved national professional association, pain association, or other credentialing entity; and
 - ii. Successful completion of a minimum of at least eighteen hours of continuing education in pain management during the past two years; and
 - iii. At least thirty percent of the podiatric physician's current practice is the direct provision of pain management care.

Notes:

- Feedback questions whether qualification as a “pain management specialist” is too easily met.

CONCEPTUAL DRAFT VERSION 6.2
CHRONIC PAIN MANAGEMENT

246-XXX-X49 Tapering Requirements

(1) The practitioner shall assess and document the appropriateness of continued use of the current treatment plan if the patient's **response to or** 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) The patient is non-compliant with the written agreement;
- (d) Other treatment modalities are indicated;
- (e) There is evidence of misuse, abuse, **substance use disorder** ~~addiction~~, or diversion;
- (f) **There is evidence of significant adverse effects;**
- (g) **The patient experiences a severe adverse event or overdose;**
- (h) **There is unauthorized escalation of doses; or**
- (i) **When the opioid dose continues to escalate with no improvement in pain, function or quality of life.**

Notes:

- Taskforce and stakeholder suggested revisions are incorporated in red font while proposed deletions are noted in strikethrough.
- Consider whether the requirement that the practitioner consider tapering, but no requirement that the practitioner actually taper the dose even if there is no improvement in pain control or function, is sufficient.

CONCEPTUAL DRAFT VERSION 6.2
CHRONIC PAIN MANAGEMENT

246-XXX-X50 High Dose Pain Patients Establishing a Relationship with a New Practitioner

(1) When a patient is already on a high dose of opioid pain medications and changes to a new practitioner, it is normally appropriate for that practitioner to maintain their current opioid doses initially. Over time, the practitioner may evaluate if any tapering or other adjustments in the treatment plan can or should be done.

(2) A practitioner's treatment of a new chronic pain patient is exempt from the mandatory consultation requirements of WAC 246-XXX-X45 and the tapering requirements of WAC 246-XXX-X49 if: ~~To ensure a safe transfer of care, the new practitioner must ensure that the following requirements are met in order for this exemption to apply must be met:~~

- (a) The patient was previously being treated with a dosage of opioids in excess of one hundred twenty milligram MED for chronic pain under an established written agreement for treatment of the same chronic condition;
- (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 as documented by medical records and PMP queries; and
- (d) The patient has documented functional stability or pain control, or has documented improvements in pain relief and increased function at the exceptional dose.

(3) With respect to the treatment of a new patient, this exemption applies for the first three months of that new care, after which the requirements of WAC 246-XXX-X45 and WAC 246-XXX-X49 shall apply.

Notes:

- Taskforce and stakeholder suggested revisions are incorporated in red font while proposed deletions are noted in strikethrough.
- There was extensive discussion on this section at the February 9 meeting. Multiple edits were discussed, however discussion was tabled without a final resolution due to time constraints.
- Clarity is needed regarding which provisions a high dose patient is exempt from (consultation, tapering, etc.) and for what period of time. An alternative suggestion is provided below for consideration by the task force.

CONCEPTUAL DRAFT VERSION 6.2
SPECIAL POPULATIONS

OPIOID PRESCRIBING – SPECIAL POPULATIONS

246-XXX-X71 Special Populations: Patients Under 25 Years of Age, Pregnant Patients, and Aging Populations

(1) **Patients 25 years of age or under:** In the treatment of pain for patients 25 years of age or under, the practitioner shall treat pain in a manner commensurate with that of an adult but must account for the weight of the patient and reduce the dosage prescribed accordingly.

(2) **Pregnant patients:** Use of medication assisted treatment (MAT) opioids, such as methadone or buprenorphine, by a pregnant patient shall not be discontinued without oversight by the MAT prescribing practitioner.

(3) **Aging Populations:** As people age, their tolerance and metabolizing of opioids may change. The practitioner shall consider the distinctive needs of patients who are 65 years of age or older and who have been on chronic opioid therapy or who are initiating opioid treatment.

Notes:

- All special populations have been condensed into one section. The task force will need to consider this approach in its discussions on March 14 and whether the current version of X71 is appropriate for rule, or if it is better suited for guidelines or educational outreach efforts.
- Reference to the AMDG guidelines was removed due to concern that any change in name or content of the guidelines could necessitate a change in rule. Rather than referring to these sources in rule, it is recommended these be provided to practitioners as educational materials.
- Stakeholder feedback questions whether the under 25 population includes young children or is intended to apply to adults under 25.
- Stakeholder feedback from WSMA/WSHA and WSPMA: Request this section be stricken as it is a recommendation only.

CONCEPTUAL DRAFT VERSION 6.2
SPECIAL POPULATIONS

246-XXX-X72 Episodic Care of Chronic Opioid Patients

(1) When providing episodic care for a patient **who the practitioner knows is** being treated with opioids for chronic pain, such as for emergency or urgent care, the practitioner shall review the Washington state PMP to identify schedule II-IV or other drugs of concern received by the patient and document their review and any concerns.

(2) A practitioner providing episodic care to a patient **who the practitioner knows is** being treated with opioids for chronic pain should avoid providing additional opioids. ~~However,~~ if opioids are provided, the practitioner shall limit the use of opioids for a chronic pain patient to the minimum amount necessary to control the acute, perioperative, or similar **acute exacerbation of breakthrough** pain until the patient can receive care from the practitioner who is managing the patient's chronic pain treatment.

(3) The episodic care practitioner shall report known violations of the patient's written agreement to the patient's treatment practitioner who provided the agreement for treatment.

(4) The episodic care practitioner shall coordinate care with the patient's treatment practitioner **if that person is known to the episodic care practitioner**, when practicable.

Notes:

- Taskforce and stakeholder suggested revisions are incorporated in red font while proposed deletions are noted in strikethrough.
- Suggested provision requiring a check of other state PMPs was moved for consideration as part of X91.
- Final task force decision on whether subsection (2) will be "shall" or "should" needed.
- Stakeholder feedback from WSMA/WSHA and WSPMA: Question how a practitioner would know if a patient is under a written agreement, as this may not be known if the practitioner is not in an integrated or affiliated practice. Requests this section be stricken as it is a recommendation only.

CONCEPTUAL DRAFT VERSION 6.2
CO-PRESCRIBING AND MEDICATION-ASSISTED TREATMENT

OPIOID PRESCRIBING – CO-PRESCRIBING AND MEDICATION-ASSISTED TREATMENT

246-XXX-X81 Co-prescribing with Certain Medications

(1) A practitioner shall not **knowingly** prescribe opioids in combination 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 **known to be** concurrently prescribed one or more of the medications listed in subsection (1) of this section, the practitioner prescribing opioids shall consult with the other prescriber(s) to establish a patient care plan for the use of the medications concurrently **or whether one or the other medication(s) should be tapered**.

Notes:

- Taskforce and stakeholder suggested revisions are incorporated in red font while proposed deletions are noted in strikethrough.
- Stakeholder feedback from WSMA/WSHA and WSPMA: Members have reported problems with other physicians not responding to requests for consultation. Requests additional language be included such as “shall consult or shall make reasonable effort to consult with...”

CONCEPTUAL DRAFT VERSION 6.2
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 **nonoperative** or perioperative episode, the practitioner prescribing opioids shall coordinate their prescribing with the MAT practitioner. This coordination must occur as soon as is practicable to appropriately treat episodic pain while maintaining the patient's MAT. **[Alternative submission]: Where practicable, clinicians providing care to acute nonoperative ~~pain~~ or perioperative pain patients known to be engaged in MAT shall prescribe pain relief either in consultation with a pain specialist or with the MAT prescribing clinician.**

(2) **MAT medications shall not be discontinued when treating acute or perioperative pain without ~~clear and convincing~~ documentation of the reason for doing ~~necessity to do~~ so, nor shall use of these medications be used to deny necessary operative intervention.**

Notes:

- Taskforce and stakeholder suggested revisions are incorporated in red font while proposed deletions are noted in strikethrough.
- 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?
- MQAC prefers the following language: "MAT medications should not be discontinued when treating acute or perioperative pain without clear and convincing documentation of the necessity to do so, nor should use of these medications be used to deny necessary operative intervention. Whenever possible, clinicians providing care to acute pain or perioperative pain patients should prescribe pain relief either in consultation with a pain specialist or with the prescribing clinician."
- Stakeholder feedback from WSMA/WSHA and WSPMA: What if MAT practitioner cannot be reached or is unresponsive? Express concern with use of "clear and convincing" as it may be interpreted as setting a standard of proof.

CONCEPTUAL DRAFT VERSION 6.2
CO-PRESCRIBING AND MEDICATION-ASSISTED TREATMENT

246-XXX-X83 Co-prescribing of Naloxone

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

Notes:

- Taskforce and stakeholder suggested revisions are incorporated in red font while proposed deletions are noted in strikethrough.
- Stakeholder feedback from WSMA/WSHA and WSPMA: Request this section be stricken if it is a recommendation only.

DRAFT

CONCEPTUAL DRAFT VERSION 6.2
PRESCRIPTION MONITORING PROGRAM

OPIOID PRESCRIBING – PRESCRIPTION MONITORING PROGRAM

246-XXX-X91 Prescription Monitoring Program – Required Queries

(1) **At a minimum**, The practitioner shall ensure a PMP query is performed prior to the prescription of an opioid or **a Schedule II-IV medication listed in WAC 246-XXX-X81** ~~sedative hypnotic~~ at the following times:

- (a) Upon the **second** ~~third~~ refill, **which is the third prescription**, of an ~~acute~~ opioid prescription **for acute or perioperative pain**;
- (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 practitioner shall ensure a PMP query is performed at a minimum frequency determined by the patient’s risk assessment, as follows:

- (a) For a high risk patient, a PMP query shall be completed at least quarterly.
- (b) For a moderate risk patient, a PMP query shall be completed at least semiannually.
- (c) For a low risk patient, a PMP query shall be completed at least annually.

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

(4) The practitioner shall ensure a PMP query is performed in conjunction with episodic care **provided to a patient who is being treated with opioids for chronic pain, when that information is known to the practitioner**, for a chronic pain patient, in accordance with WAC 246-XXX-X72.

(5) **A practitioner treating a patient known to be concurrently receiving care outside of Washington State shall also consider reviewing any other appropriate, available and appropriate prescription monitoring program in accordance with the requirements of subsections (1) through (4) of this section.**

(6) **Aberrant behavior discovered in the PMP shall be documented in the patient record.**

Notes:

- Taskforce and stakeholder suggested revisions are incorporated in red font while proposed deletions are noted in strikethrough.
- Two additional proposals have been suggested and will be provided to the task force and stakeholders for review. These proposals have not been incorporated into this section.
- Stakeholder feedback strongly suggests inclusion of a PMP check at the first prescription for an opioid.
- Stakeholder feedback suggests a PMP check before surgery or before prescribing opioids upon discharge from hospital postoperatively.
- Subsection (5) was created from a MQAC suggestion to X72. It was moved to this section for consideration as a general requirement of PMP checks.
- Stakeholder concern with the practicability of required checks of other state PMP systems at this time.
- Stakeholder feedback from WSMA/WSHA and WSPMA:

CONCEPTUAL DRAFT VERSION 6.2
PRESCRIPTION MONITORING PROGRAM

- What if a check is unable to be completed due to an unforeseen circumstance?
- Concern regarding check of other state PMP systems, as a WA practitioner may not have access, and it could be unclear in what circumstances a practitioner would be required to check other state PMP systems.
- Request that an authorized designee of the practitioner be permitted to complete the required PMP query.
- Consider whether the PMP check at any indication of aberrant behavior applies to all patients, not just chronic.

DRAFT

CONCEPTUAL DRAFT VERSION 6.2
PRESCRIPTION MONITORING PROGRAM

246-XXX-X92 Prescription Monitoring Program – Recommended Queries

(1) For acute **nonoperative, acute** perioperative, and subacute pain **opioid prescribing care**, it is strongly recommended that a PMP query be performed prior to any prescription for an opioid or **a Schedule II-IV medication listed in WAC 246-XXX-X81** ~~sedative hypnotic~~ to identify ~~schedule II-V~~ or other drugs of concern received by the patient.

(2) For chronic pain management, it is strongly recommended that a PMP query be performed quarterly and prior to prescribing any opioid or sedative hypnotic to identify schedule II-V or other drugs of concern received by the patient **for all patients, regardless of risk level**.

Notes:

- Taskforce and stakeholder suggested revisions are incorporated in red font while proposed deletions are noted in strikethrough.
- Stakeholder feedback suggests recommending a PMP check be conducted prior to every prescription, rather than quarterly for chronic pain.
- Stakeholder feedback suggests including recommendations in X91 as separate subsection of recommendations so there is only one section related to the PMP.
- Stakeholder feedback from WSMA/WSHA and WSPMA: Request section be stricken as they are recommendations only. Acknowledge that these are good clinical practices, but inclusion in rule, even as a recommendation, may create a soft standard.
- Consider providing additional language to clarify that these provisions represent best practices, rather than requirements.