



Medical Quality Assurance Commission Allopathic Physicians Allopathic Physician Assistants *CR-103 for chapter 246-919 WAC and chapter 246-918 WAC Opioid Prescribing & Monitoring Rule changes effective January 1, 2019

Following an August 22, 2018 public hearing, the Medical Quality Assurance Commission (commission) adopted new rules in chapter 246-919 WAC (allopathic physicians) and chapter 246-918 (allopathic physician assistants). The commission adopted the rules pursuant to Engrossed Substitute House Bill (ESHB) 1427 which was codified in part as RCW 18.71.800 and 18.71A.800. ESHB 1427 required the commission to develop requirements for prescribing opioid drugs. The commission also amended the current pain management rules to assure alignment with the new opioid prescribing rules, increase consistent rule application, and reduce duplication between existing and new rules. The final rulemaking order was filed with the Office of the Code Reviser on November 16, 2018, as <u>WSR #18-23-061</u>. These changes will become effective on January 1, 2019.

This notification contains three attachments:

- 1. The final rulemaking document (CR-103P) that was filed with the Office of the Code Reviser, which contains the rulemaking order.
- 2. The new rule text.
- 3. A summary of the comments received and the commission's responses to those comments.

The laws and procedures for petitioning the amendment or repeal of an adopted rule are under <u>RCW 34.05.330</u>.

For continued updates on rule development, interested parties are encouraged to subscribe to the commission's <u>Rules email list</u>.

For more information, please contact Daidria Amelia Underwood, Program Manager, at (360) 236-2727 or by email at <u>daidria.underwood@doh.wa.gov</u>.



*CR = Code Reviser

CODE REVISER USE ONLY



RULE-MAKING ORDER PERMANENT RULE ONLY

CR-103P (December 2017) (Implements RCW 34.05.360)

OFFICE OF THE CODE REVISER STATE OF WASHINGTON FILED

DATE: November 16, 2018 TIME: 10:42 AM

WSR 18-23-061

Agency: Department of Health- Medical Quality Assurance Commission Effective date of rule: **Permanent Rules** 31 days after filing. Other (specify) 01/01/2019 (If less than 31 days after filing, a specific finding under RCW 34.05.380(3) is required and \boxtimes should be stated below) Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule? The statute requires the rules to be effective on January 1, 2019. X Yes □ No If Yes, explain: Purpose: Chapters 246-918 WAC - (Allopathic) Physician Assistants and 246-919 WAC - (Allopathic Physicians) Medical Quality Assurance Commission. The Medical Quality Assurance Commission (commission) has adopted new sections, amendments, and repeal of sections to existing rule that establishes requirements and standards for prescribing opioid drugs by allopathic physicians and allopathic physician assistants. The adopted rules provide a necessary framework and structure for safe, consistent opioid prescribing practice consistent with the directives of Engrossed Substitute House Bill (ESHB) 1427. Citation of rules affected by this order: WAC 246-918-815, 246-918-820, 246-918-825, 246-918-830, 246-918-835, 246-918-840, 246-918-845, 246-New: 918-850, 246-918-855, 246-918-860, 246-918-865, 246-918-870, 246-918-875, 246-918-880, 246-918-885, 246-918-890, 246-918-895, 246-918-900, 246-918-905, 246-918-910, 246-918-915, 246-918-920, 246-918-925, 246-918-930, 246-918-935, 246-919-865, 246-919-870, 246-919-875, 246-919-880, 246-919-885, 246-919-890, 246-919-895, 246-919-900, 246-919-905, 246-919-910, 246-919-915, 246-919-920, 246-919-925, 246-919-930, 246-919-935, 246-919-940, 246-919-945, 246-919-950, 246-919-955, 246-919-960, 246-919-965, 246-919-970, 246-919-975, 246-919-980, 246-919-985 WAC 236-918-803, 236-918-804, 236-918-805, 236-918-806, 236-918-807, 236-918-808, 236-918-809, 236-Repealed: 918-810, 236-918-811, 236-918-812, 236-918-813, 246-919-853, 246-919-854, 246-919-855, 246-919-856, 246-919-857, 246-919-858, 246-919-859, 246-919-860, 246-919-861, 246-919-862, 246-919-863 Amended: WAC 246-918-800, 246-918-801, 246-918-802, 246-919-850, 246-919-851, 246-919-852 Suspended: None Statutory authority for adoption: RCW 18.71.017, RCW 18.71.800, and RCW 18.71A.800 Other authority: ESHB 1427 (Chapter 297, Laws of 2017), codified in part as RCW 18.71.800 and 18.71A.800 PERMANENT RULE (Including Expedited Rule Making) Adopted under notice filed as WSR 18-15-055 on 07/16/2018 (date). Describe any changes other than editing from proposed to adopted version: The following non-substantial changes were adopted at the public hearing by the commission that differ from the proposed rules. WAC 246-918-802(7) and 246-919-852(7) - Definitions. Final adopted language: "Designee' means a licensed 1. health care practitioner authorized by a prescriber to request and receive prescription monitoring program (PMP) data on their behalf." As a result of adding this definition, the commission deleted all references to "as defined in WAC 246-470-050" throughout the physician and physician assistant rules. Reasons for this change: A definition for "designee" was added as a new subsection (7). This term is used in rule so a definition is being added for clarification. The subsequent subsections were renumbered to reflect this addition. Adding the definition of designee made the need for the phrase "as defined in WAC 246-470-050" no longer needed in the rest of the sections and was deleted. WAC 246-918-895(2) - (6) - Pain Management Specialist-Chronic Pain. Final adopted language: "(2) If an allopathic 2. physician, in accordance with WAC 246-919-945. (3) If an osteopathic physician, in accordance with WAC 246-853-750. (4) If a dentist, in accordance with WAC 246-817-965, (5) If a podiatric physician, in accordance with WAC 246-922-750.

(6) If an advanced registered nurse practitioner, in accordance with WAC 246-840-493." Reason for this change: The commission determined the MD and PA chapters should be substantially similar. Adding this new language makes them so.

3. WAC 246-918-802(13) and 246-919-852(13) - Definitions. [Formerly subsection (12) in the proposed rules, now adopted as renumbered subsection (13)]. Final adopted language: "Low-risk' is a category of patient at low risk of opioid-induced morbidity or mortality, based on factors and combinations of factors such as medical and behavioral

comorbidities, polypharmacy, and dose of opioids of less than a fifty milligram morphine equivalent dose per day." Reason for this change: The commission determined adding "per day" to the end of the definition was necessary for clarification.

4. WAC 246-918-802 (15) and 246-919-852(15) - Definitions. [Formerly subsection (14) in the proposed rules, now adopted as renumbered subsection (15)]. Final adopted language: "Moderate-risk'" is a category of patient at moderate risk of opioid-induced morbidity or mortality, based on factors and combinations of factors such as medical and behavioral comorbidities, polypharmacy, past history of substance use disorder or abuse, aberrant behavior, and dose of opioids between fifty to ninety milligram morphine equivalent doses per day." Reason for this change: The commission determined adding "per day" to the end of the definition was necessary for clarification.

5. WAC 246-918-802(18) and 246-919-852(18) - Definitions. [Formerly subsection (17) in the proposed rules, now adopted as renumbered subsection (18)]. Final adopted language: "Opioid' means a drug that is either an opiate that is derived from the opium poppy or opiate-like that is a semi-synthetic or synthetic drug. Examples include morphine, codeine, hydrocodone, oxycodone, fentanyl, meperidine, tramadol, buprenorphine, and methadone when used to treat pain." Reason for this change: The commission determined adding "when used to treat pain" to the end of the definition was necessary for clarification.

6. WAC 246-918-820 - Use of alternative modalities for pain treatment. Final adopted language: "The physician assistant shall exercise their professional judgment in selecting appropriate treatment modalities for acute nonoperative, acute perioperative, subacute, or chronic pain including the use of multimodal pharmacologic and nonpharmacologic therapy as an alternative to opioids whenever reasonable, clinically appropriate, evidence-based alternatives exist." WAC 246-919-870 - Use of alternative modalities for pain treatment. Final adopted language: "The physician shall exercise their professional judgment in selecting appropriate treatment modalities for acute nonoperative, subacute, or chronic pain including the use of multimodal pharmacologic therapy as an alternative to opioids whenever reasonable, clinically appropriate treatment modalities for acute nonoperative, acute perioperative, subacute, or chronic pain including the use of multimodal pharmacologic and nonpharmacologic therapy as an alternative to opioids whenever reasonable, clinically appropriate, evidence-based alternatives exist." Reason for change: The commission determined adding "or chronic pain" was necessary for clarification.

7. WAC 246-918-825(1) - Continuing education requirements for opioid prescribing. Final adopted language: "To prescribe an opioid in Washington state, a physician assistant licensed to prescribe opioids shall complete a one-time continuing education requirement regarding best practices in the prescribing of opioids or the opioid prescribing rules in this chapter." WAC 246-919-875(1) - Continuing education requirements for opioid prescribing. Final adopted language: "To prescribe an opioid in Washington state, a physician licensed to prescribe opioids shall complete a one-time continuing education requirement regarding best practices in the prescribe opioids shall complete a one-time continuing education requirement regarding best practices in the prescribing of opioids or the opioid prescribing rules in this chapter." Reason for this change: The commission determined adding "regarding best practices in the prescribing of opioids or" was necessary to add more options for providers to complete this CME requirement.

8. WAC 246-918-845(2)(b) and 246-919-895(2)(b) - Patient evaluation and patient record - subacute pain. Final adopted language: "The observed or reported effect on function or pain control forming the basis to continue prescribing opioids beyond the acute pain episode;" Reason for this change: The commission determined adding "or reported" was necessary for clarification.

9. WAC 246-918-850(2) - Treatment plan - subacute pain. Final adopted rule language: "During the subacute phase the physician assistant shall not prescribe beyond a fourteen-day supply of opioids without clinical documentation to justify the need for such a quantity." WAC 246-919-900(2) - Treatment plan - subacute pain. Final adopted rule language: "During the subacute phase the physician shall not prescribe beyond a fourteen-day supply of opioids without clinical documentation to justify the need for such a quantity." Reason for this change: The commission determined moving "During the subacute phase" to the beginning of the sentence was necessary for clarification.

10. WAC 246-918-855(1)(c) and 246-919-905(1)(c) - Patient evaluation and patient record - chronic pain. Final adopted language: "Current and relevant past treatments for pain, including opioids and other medications and their efficacy;" Reason for this change: The commission determined adding "and relevant" was necessary for clarification.

11. WAC 246-918-870(4) and 246-919-920(4) - Periodic review-Chronic pain [formerly 246-918-865(9) and 246-919-915(9)]. Final adopted language: Subsections (9) in both MD and PA sections 246-918-865 and 246-918-915 were moved to sections -870(4) and -920(4)-Periodic review - Chronic pain. No other changes were made. Reason for this change: WAC 246-918-865(9) and 246-919-915(9) - Written agreement for treatment - chronic pain were moved to WAC 246-918-870(4) and to WAC 246-919-920(4) - Periodic review-Chronic Pain because the commission determined it aligned better with Periodic Review-Chronic Pain section.

12. WAC 246-918-800 through 246-918-935 and WAC 246-919-850 through 246-919-985. Final adopted language: Changed the term "podiatrist" to "podiatric physician" throughout MD and PA chapters. Reason for this change: All references to podiatrist were changed to podiatric physician throughout the pain management sections because this is the proper term for these providers.

13. WAC 246-918-802(1) and 246-919-852(1) - Definitions. Final adopted language: "Aberrant behavior' means behavior that indicates current misuse, diversion, unauthorized use of alcohol or other controlled substances, or multiple early refills (renewals)." Reason for this change: The term "active opioid use disorder" was deleted from this definition because the commission determined opioid use disorder is not an aberrant behavior.

14. WAC 246-918-840(1) - Treatment plan - Acute perioperative pain. Final adopted language: "The physician assistant should consider prescribing nonopioids as the first line of pain control in patients, unless not clinically appropriate, in accordance with the provisions of WAC 246-918-820." WAC 246-919-890(1) - Treatment plan - Acute perioperative pain. Final adopted language: "The physician should consider prescribing nonopioids as the first line of pain control in patients, unless not clinically appropriate, in accordance with the provisions of WAC 246-918-820." WAC 246-919-890(1) - Treatment plan - Acute perioperative pain. Final adopted language: "The physician should consider prescribing nonopioids as the first line of pain control in patients, unless not clinically appropriate, in accordance with the provisions of WAC 246-919-870." Reason for this change: The word "shall" was changed to "should" for clarity and consistency with WAC 246-919-885(1).

15. WAC 246-918-870(2)(c) - Periodic review. Final adopted language: "If continuation or modification of medications for pain management treatment is necessary based on the physician assistant's evaluation of progress towards or maintenance of treatment objectives and compliance with the treatment plan." WAC 246-919-920(2)(c) - Periodic review. Final adopted language: "If continuation or modification of medications for pain management treatment is necessary based on the physician's evaluation of progress towards or maintenance of treatment by based on the physician's evaluation of progress towards or maintenance of treatment objectives and compliance with the treatment plan." Reason for this change: The phrase "or maintenance of" was added for clarity to ensure that the goal for some patients is maintenance of pain level and functional level rather than improvement (progress).

16. 246-918-870(3)(b) and 246-919-920(3)(b) Periodic review - Chronic pain. Final adopted language: "Use of validated tools or patient report from reliable patients to document either maintenance or change in function and pain control;" Reason for this change: The phrase "or patient report from reliable patients" was added because it clarified accepted sources of information.

17. WAC 246-918-885 - Consultation-Exemptions for exigent and special circumstances. Final rule language: WAC 246-918-885 - "A physician assistant is not required to consult with a pain management specialist as defined in WAC 246-918-895 when the physician assistant has documented adherence to all standards of practice as defined in WAC 246-918-855 through 246-918-875 and when one or more of the following conditions are met:" WAC 246-919-935 - Consultation-Exemptions for exigent and special circumstances. Final rule language: "A physician is not required to consult with a pain management specialist as defined in WAC 246-919-945 when the physician has documented adherence to all standards of practice as defined in WAC 246-919-945 when the physician has documented adherence to all standards of practice as defined in WAC 246-919-945 when the physician has documented adherence to all standards of practice as defined in WAC 246-919-905 through 246-919-940, and when one or more of the following conditions are met:" Reason for this change: Updated the WAC numbers referenced in the first paragraph to align with the new WAC numbers used in the revised Pain Management sections.

18. WAC 246-918-915(2) - Episodic care of chronic opioid patients. Final adopted rule language: "A physician assistant providing episodic care to a patient who the physician assistant knows is being treated with opioids for chronic pain should provide additional analgesics, including opioids when appropriate, to adequately treat acute pain." WAC 246-919-965(2) - Episodic care of chronic opioid patients. Final adopted rule language: "A physician providing episodic care to a patient who the physician depicted rule language: "A physician providing episodic care to a patient who the physician knows is being treated with opioids for chronic pain should provide additional analgesics, including opioids when appropriate, to adequately treat acute pain." Reason for this change: The phrase "when appropriate" was added to clarify that opioids should be prescribed only when appropriate.

19. WAC 246-918-925(1) - Co-prescribing of opioids for patients receiving medication assisted treatment. Final adopted language: "Where practicable, the physician assistant providing acute nonoperative pain or acute perioperative pain treatment to a patient who is known to be receiving MAT medications shall prescribe opioids for pain relief when appropriate for pain relief either in consultation with a MAT prescribing practitioner or a pain specialist." WAC 246-919-975(1) - Co-prescribing of opioids for patients receiving medication assisted treatment. Final adopted language: "Where practicable, the physician providing acute nonoperative pain or acute perioperative pain treatment to a patient who is known to be receiving MAT medications shall prescribe opioids for pain relief either in consultation with a prescribe opioids for pain relief when appropriate for pain relief when appropriate for pain relief either in consultation shall prescribe opioids for pain treatment to a patient who is known to be receiving MAT medications shall prescribe opioids for pain relief of pain relief either in consultation with a MAT prescribing practitioner or a pain specialist." Reason for this change: The phrase "when appropriate" was added to clarify that opioids should be prescribed only when appropriate.

20. WAC 246-918-801 Exclusions. Final adopted language: "WAC 246-918-800 through 246-918-935 do not apply to:

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

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

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

(4) The provision of procedural medications."

Reason for this change: The commission determined the MD and PA chapters should be substantially similar. Adding this new language to the PA sections makes them so.

21. WAC 246-919-895(2)(h). Final adopted language: "The risk-benefit analysis of any combination of prescribed opioid and benzodiazepines or sedative-hypnotics, if applicable." Reason for this change: The "; and" should have been removed as it was inadvertently left in rule after editing subsection (2).

If a preliminary cost-benefit analysis was prepared under RCW 34.05.328, a final cost-benefit analysis is available by contacting:

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Note: If any category is lo No descriptive text		nk, it v	will be calc	ulate	d as zero.	
Count by whole WAC sections onl A section may be c					istory note.	
The number of sections adopted in order to comply	y with:					
Federal statute:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Federal rules or standards:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Recently enacted state statutes:	New	<u>50</u>	Amended	<u>6</u>	Repealed	<u>22</u>
The number of sections adopted at the request of a	a nongo	vernmen	tal entity:			
	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
The number of sections adopted in the agency's o	wn initia	ative:				
	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
The number of sections adopted in order to clarify	, stream	line, or r	eform agency p	procedu	ires:	
	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
The number of sections adopted using:						
Negotiated rule making:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Pilot rule making:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Other alternative rule making:	New	<u>50</u>	Amended	<u>6</u>	Repealed	<u>22</u>
Date Adopted: 08/22/2018		Signatu	re:			
Name: Melanie de Leon		-	$\triangle \bigcirc 0$		delear	1
Title: Executive Director			- i nuca	~~~		

((PAIN MANAGEMENT)) OPIOID PRESCRIBING—GENERAL PROVISIONS

AMENDATORY SECTION (Amending WSR 11-12-025, filed 5/24/11, effective 1/2/12)

WAC 246-919-850 ((Pain management))Intent and scope. ((These)) The rules in WAC 246-919-850 through 246-919-985 govern the ((use)) prescribing of opioids in the treatment of ((patients for chronic noncancer)) pain.

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

The diagnosis and treatment of pain is integral to the practice of medicine. The commission encourages physicians to view pain management as a part of quality medical practice for all patients with pain((τ)) including acute ($(\Theta \tau)$), perioperative, subacute, and chron-ic((τ and it is especially urgent for patients who experience)) pain ($(as \ a \ result \ of \ terminal \ illness)$). All physicians should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as <u>become knowledgeable about the</u> statutory requirements for prescribing ((controlled substances)) <u>opioids including co-occurring prescriptions</u>. Accordingly, ((this rule has been developed to)) these rules clarify the commission's position on pain control, particularly as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

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

The commission recognizes that controlled substances including opioids ((analgesics)) may be essential in the treatment of acute, subacute, perioperative, or chronic pain due to disease, illness, trauma or surgery ((and chronic pain, whether due to cancer or non-cancer origins)). The commission will refer to current clinical prac-

tice guidelines and expert review in approaching cases involving management of pain.

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

The commission is obligated under the laws of the state of Washington to protect the public health and safety. The commission recognizes that the use of opioids ((analgesics)) for other than legitimate medical purposes poses a threat to the individual and society ((and that)). The inappropriate prescribing of controlled substances, including opioids ((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 opioids ((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 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)) physicians 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)) guarantee an accurate diagnosis or a successful outcome. The sole purpose of these rules is to assist ((practitioners)) physicians in following a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care.

For more specific best practices, the physician may refer to clinical practice guidelines including, but not limited to, those produced by the agency medical directors' group, the Centers for Disease Control and Prevention, or the Bree Collaborative.

AMENDATORY SECTION (Amending WSR 11-12-025, filed 5/24/11, effective 1/2/12)

WAC 246-919-851 Exclusions. ((The rules adopted under)) WAC 246-919-850 through ((246-919-863)) 246-919-985 do not apply to:

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

(2) The provision of palliative, hospice, or other end-of-life care; (($\frac{1}{2}$

(2) To the management of acute pain caused by an injury or surgical procedure.))

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

(4) The provision of procedural medications.

<u>AMENDATORY SECTION</u> (Amending WSR 11-12-025, filed 5/24/11, effective 1/2/12)

WAC 246-919-852 Definitions. The <u>following</u> definitions ((in)) <u>apply to</u> WAC 246-919-850 through ((246-919-863 apply)) <u>246-919-985</u> unless the context clearly requires otherwise.

(1) <u>"Aberrant behavior" means behavior that indicates current</u> misuse, diversion, unauthorized use of alcohol or other controlled substances, or multiple early refills (renewals).

(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. ((It is generally time-limited, often less than three months in duration, and usually less than six months.

(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:

(a) Impaired control over drug use;
(b) Craving;

(c) Compulsive use; or

(d) Continued use despite harm.

(3)) Acute pain is six weeks or less in duration.

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

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

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

(((4) "Comorbidity)) <u>(6) "Comorbidities</u>" means a preexisting or coexisting physical or psychiatric disease or condition.

(((5))) <u>(7) "Designee" means a licensed health care practitioner</u> <u>authorized by a prescriber to request and receive prescription moni-</u> <u>toring program (PMP) data on their behalf.</u>

(8) "Episodic care" means <u>noncontinuing</u> medical <u>or dental</u> care provided by a ((practitioner)) <u>physician</u> other than the designated primary ((care practitioner in the acute care setting, for example, urgent care or emergency department.

(6)) prescriber for a patient with chronic pain.

(9) "High dose" means a ninety milligram morphine equivalent dose (MED), or more, per day.

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

(11) "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 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 freestanding hospice facilities, hospitals, nursing homes, or other longterm care facilities)).

(((7))) <u>(12) "Hospital" means any health care institution li-</u> censed pursuant to chapters 70.41 and 71.12 RCW, and RCW 72.23.020.

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

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

(15) "Moderate-risk" is a category of patient at moderate risk of opioid-induced morbidity or mortality, based on factors and combinations of factors such as medical and behavioral comorbidities, polypharmacy, past history of substance use disorder or abuse, aberrant behavior, and dose of opioids between fifty to ninety milligram morphine equivalent doses per day.

(16) "Morphine equivalent dose" or "MED" means a conversion of various opioids to a morphine equivalent dose ((by the use of accepted)) using the agency medical directors' group or other conversion table((s)) approved by the commission. MED is considered the same as morphine milligram equivalent or MME.

(((8))) <u>(17)</u> "Multidisciplinary pain clinic" means a ((clinic or office that provides comprehensive pain management and includes care provided by multiple available disciplines or treatment modalities, for example, medical care through physicians, physician assistants, osteopathic physicians, osteopathic physician assistants, advanced registered nurse practitioners, and physical therapy, occupational therapy, or other complementary therapies.

(9)) health care delivery facility staffed by physicians of different specialties and other nonphysician health care providers who specialize in the diagnosis and management of patients with chronic pain.

(18) "Opioid" means a drug that is either an opiate that is derived from the opium poppy or opiate-like that is a semisynthetic or synthetic drug. Examples include morphine, codeine, hydrocodone, oxycodone, fentanyl, meperidine, tramadol, buprenorphine, and methadone when used to treat pain.

(19) "Palliative <u>care</u>" means care that <u>maintains or</u> improves the quality of life of patients and their families facing <u>serious, ad-</u> <u>vanced, or</u> life-threatening illness. ((With palliative care particular attention is given to the prevention, assessment, and treatment of pain and other symptoms, and to the provision of psychological, spiritual, and emotional support.))

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

(21) "Prescription monitoring program" or "PMP" means the Washington state prescription monitoring program authorized under chapter 70.225 RCW. Other jurisdictions may refer to this as the prescription drug monitoring program or "PDMP."

(22) "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 or 18.57 RCW, a physician assistant licensed under chapter 18.71A or 18.57A RCW, or a podiatric physician licensed under chapter 18.22 RCW.

(23) "Refill" or "renewal" means a second or subsequent filling of a previously issued prescription.

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

(25) "Substance use disorder" means a primary, chronic, neurobiological disease with genetic, psychosocial, and environmental factors influencing its development and manifestations. Substance use disorder is not the same as physical dependence or tolerance that is a normal physiological consequence of extended opioid therapy for pain. It is characterized by behaviors that include, but are not limited to, impaired control over drug use, craving, compulsive use, or continued use despite harm. WAC 246-919-865 Patient notification, secure storage, and disposal. (1) The physician shall ensure the patient is provided the following information at the first issuance of a prescription for opioids and at the transition from acute to subacute, and subacute to chronic:

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

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

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

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

NEW SECTION

WAC 246-919-870 Use of alternative modalities for pain treatment. The physician shall exercise their professional judgment in selecting appropriate treatment modalities for acute nonoperative, acute perioperative, subacute, or chronic pain including the use of multimodal pharmacologic and nonpharmacologic therapy as an alternative to opioids whenever reasonable, clinically appropriate, evidence-based alternatives exist.

NEW SECTION

WAC 246-919-875 Continuing education requirements for opioid prescribing. (1) To prescribe an opioid in Washington state, a physician licensed to prescribe opioids shall complete a one-time continuing education requirement regarding best practices in the prescribing of opioids or the opioid prescribing rules in this chapter. The continuing education must be at least one hour in length.

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

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

OPIOID PRESCRIBING—ACUTE NONOPERATIVE PAIN AND ACUTE PERIOPERATIVE PAIN

NEW SECTION

WAC 246-919-880 Patient evaluation and patient record—Acute nonoperative pain. Prior to issuing an opioid prescription for acute nonoperative pain or acute perioperative pain, the physician shall:

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

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

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

NEW SECTION

WAC 246-919-885 Treatment plan—acute nonoperative pain. The physician shall comply with the requirements in this section when prescribing opioids for acute nonoperative pain.

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

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

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

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

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

- (a) Change in pain level;
- (b) Change in physical function;
- (c) Change in psychosocial function; and
- (d) Additional indicated diagnostic evaluations.

(6) If a prescription results in the patient receiving a combination of opioids with a sedative medication listed in WAC 246-919-970, such prescribing must be in accordance with WAC 246-919-970. (7) Long-acting or extended release opioids are not indicated for acute nonoperative pain.

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

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

<u>NEW SECTION</u>

WAC 246-919-890 Treatment plan—Acute perioperative pain. The physician shall comply with the requirements in this section when prescribing opioids for perioperative pain.

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

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

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

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

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

(a) Change in pain level;

- (b) Change in physical function;
- (c) Change in psychosocial function; and

(d) Additional indicated diagnostic evaluations or other treatments.

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

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

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

(9) If the physician elects to treat a patient with opioids beyond the six-week time period of acute perioperative pain, the physician shall document in the patient record that the patient is transitioning from acute pain to subacute pain. Rules governing the treatment of subacute pain, WAC 246-919-895 and 246-919-900 shall apply unless there is documented improvement in function or pain control and there is a documented plan and timing for discontinuation of all opioid medications.

OPIOID PRESCRIBING-SUBACUTE PAIN

NEW SECTION

WAC 246-919-895 Patient evaluation and patient record—Subacute pain. The physician shall comply with the requirements in this section when prescribing opioids for subacute pain.

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

(a) Conduct an appropriate history and physical examination;

(b) Reevaluate the nature and intensity of the pain;

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

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

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

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

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

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

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

(c) Pertinent concerns discovered in the PMP;

(d) An appropriate pain treatment plan including the consideration of, or attempts to use, nonpharmacological modalities and nonopioid therapy;

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

(f) Results of psychosocial screening or consultation;

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

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

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

- (a) Change in pain level;
- (b) Change in physical function;
- (c) Change in psychosocial function; and

(d) Additional indicated diagnostic evaluations or other treatments.

NEW SECTION

WAC 246-919-900 Treatment plan—Subacute pain. The physician, having recognized the progression of a patient from the acute nonoperative or acute perioperative phase to the subacute phase shall develop an opioid treatment plan.

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

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

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

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

OPIOID PRESCRIBING-CHRONIC PAIN MANAGEMENT

NEW SECTION

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

- (1) An appropriate history including:
- (a) The nature and intensity of the pain;

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

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

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

(2) Appropriate physical examination.

(3) Ancillary information and tools to include:

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

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

(c) Pertinent consultations; and

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

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

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

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

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

(d) Pertinent concerns discovered in the PMP.

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

NEW SECTION

WAC 246-919-910 Treatment plan—Chronic pain. The physician, having recognized the progression of a patient from the subacute phase to the chronic phase, shall develop an opioid treatment plan as follows:

(1) Treatment plan and objectives including:

(a) Documentation of any medication prescribed;

(b) Biologic specimen testing ordered;

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

(d) Other planned treatments; and

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

(2) The physician shall complete patient notification in accordance with the provisions of WAC 246-919-865 or provide this information in the written agreement. WAC 246-919-915 Written agreement for treatment—Chronic pain. The physician shall use a written agreement that outlines the patient's responsibilities for opioid therapy. This written agreement for treatment must include the following provisions:

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

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

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

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

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

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

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

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

NEW SECTION

WAC 246-919-920 Periodic review—Chronic pain. (1) The physician shall periodically review the course of treatment for chronic pain. The frequency of visits, biological testing, and PMP queries in accordance with the provisions of WAC 246-919-985, must be determined based on the patient's risk category:

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

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

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

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

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

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

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

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

(3) Periodic patient evaluations must also include:

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

(b) Use of validated tools or patient report from reliable patients to document either maintenance or change in function and pain control; and (c) Review of the Washington state PMP at a frequency determined by the patient's risk category in accordance with the provisions of WAC 246-919-985 and subsection (1) of this section.

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

NEW SECTION

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

NEW SECTION

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

(2) The mandatory consultation threshold is one hundred twenty milligrams MED. In the event a physician prescribes a dosage amount that meets or exceeds the consultation threshold of one hundred twenty milligrams MED per day, a consultation with a pain management specialist as described in WAC 246-919-945 is required, unless the consultation is exempted under WAC 246-919-935 or 246-919-940.

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

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

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

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

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

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

WAC 246-919-935 Consultation—Exemptions for exigent and special circumstances—Chronic pain. A physician is not required to consult with a pain management specialist as defined in WAC 246-919-945 when the physician has documented adherence to all standards of practice as defined in WAC 246-919-905 through 246-919-925, and when one or more of the following conditions are met:

(1) The patient is following a tapering schedule;

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

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

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

NEW SECTION

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

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

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

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

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

NEW SECTION

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

(1) If an allopathic physician or osteopathic physician:

(a) Is board certified or board eligible by an American Board of Medical Specialties-approved board (ABMS) or by the American Osteo-

pathic Association (AOA) in physical medicine and rehabilitation, neurology, rheumatology, or anesthesiology;

(b) Has a subspecialty certificate in pain medicine by an ABMSapproved board;

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

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

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

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

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

(2) If an allopathic physician assistant, in accordance with WAC 246-918-895.

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

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

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

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

NEW SECTION

WAC 246-919-950 Tapering considerations—Chronic pain. The physician shall consider tapering or referral for a substance use disorder evaluation when:

(1) The patient requests;

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

(3) The patient is noncompliant with the written agreement;

(4) Other treatment modalities are indicated;

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

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

(7) There is unauthorized escalation of doses; or

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

NEW SECTION

WAC 246-919-955 Patients with chronic pain, including those on high doses of opioids, establishing a relationship with a new physician. (1) When a patient receiving chronic opioid pain medications changes to a new physician, it is normally appropriate for the new physician to initially maintain the patient's current opioid doses. Over time, the physician may evaluate if any tapering or other adjustments in the treatment plan can or should be done.

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

(a) The patient was previously being treated with a dosage of opioids in excess of a one hundred twenty milligram MED for chronic pain under an established written agreement for treatment of the same chronic condition or conditions;

(b) The patient's dose is stable and nonescalating;

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

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

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

OPIOID PRESCRIBING—SPECIAL POPULATIONS

NEW SECTION

WAC 246-919-960 Special populations—Children or adolescent patients, pregnant patients, and aging populations. (1) Children or adolescent patients. In the treatment of pain for children or adolescent patients, the physician shall treat pain in a manner equal to that of an adult but must account for the weight of the patient and adjust the dosage prescribed accordingly.

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

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

NEW SECTION

WAC 246-919-965 Episodic care of chronic opioid patients. (1) When providing episodic care for a patient who the physician knows is being treated with opioids for chronic pain, such as for emergency or urgent care, the physician or their designee, shall review the PMP and document their review and any concerns.

(2) A physician providing episodic care to a patient who the physician knows is being treated with opioids for chronic pain should provide additional analgesics, including opioids when appropriate, to adequately treat acute pain. If opioids are provided, the physician shall limit the use of opioids to the minimum amount necessary to control the acute pain until the patient can receive care from the practitioner who is managing the patient's chronic pain.

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

OPIOID PRESCRIBING—COPRESCRIBING

NEW SECTION

WAC 246-919-970 Coprescribing of opioids with certain medications. (1) The physician shall not knowingly prescribe opioids in combination with the following medications without documentation of medical decision making:

- (a) Benzodiazepines;
- (b) Barbiturates;
- (c) Sedatives;
- (d) Carisoprodol; or
- (e) Nonbenzodiazepine hypnotics.

(2) If, because of a prior prescription by another provider, a prescription written by a physician results in a combination of opioids and medications described in subsection (1) of this section, the physician issuing the new prescription shall consult with the other prescriber to establish a patient care plan surrounding these medications. This provision does not apply to emergency care.

NEW SECTION

WAC 246-919-975 Coprescribing of opioids for patients receiving medication assisted treatment. (1) Where practicable, the physician providing acute nonoperative pain or acute perioperative pain treatment to a patient who is known to be receiving MAT medications shall

prescribe opioids when appropriate for pain relief either in consultation with a MAT prescribing practitioner or a pain specialist.

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

NEW SECTION

WAC 246-919-980 Coprescribing of naloxone. The opioid prescribing physician shall confirm or provide a current prescription for naloxone when opioids are prescribed to a high-risk patient.

OPIOID PRESCRIBING—PRESCRIPTION MONITORING PROGRAM

NEW SECTION

WAC 246-919-985 Prescription monitoring program—Required registration, queries, and documentation. (1) The physician shall register to access the PMP or demonstrate proof of having assured access to the PMP if they prescribe Schedule II-V medications in Washington state.

(2) The physician is permitted to delegate performance of a required PMP query to an authorized designee.

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

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

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

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

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

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

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

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

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

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

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

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

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

REPEALER

The following sections of the Washington Administrative Code are repealed:

WAC	246-919-853	Patient evaluation.
WAC	246-919-854	Treatment plan.
WAC	246-919-855	Informed consent.
WAC	246-919-856	Written agreement for treatment.
WAC	246-919-857	Periodic review.
WAC	246-919-858	Long-acting opioids, including methadone.
WAC	246-919-859	Episodic care.
WAC	246-919-860	Consultation—Recommendations and requirements.
WAC	246-919-861	Consultation—Exemptions for exigent and special circumstances.
WAC	246-919-862	Consultation—Exemptions for the physician.
WAC	246-919-863	Pain management specialist.

OPIOID PRESCRIBING—GENERAL PROVISIONS

AMENDATORY SECTION (Amending WSR 11-12-025, filed 5/24/11, effective 1/2/12)

WAC 246-918-800 ((Pain management))Intent and scope. ((These)) The rules in WAC 246-918-800 through 246-918-935 govern the ((use)) prescribing of opioids in the treatment of ((patients for chronic noncancer)) pain.

((Nothing in these rules in any way restricts the current scope of practice of physician assistants as set forth in chapters 18.71A and 18.57A RCW and the working agreements between the physician and physician assistant, which may include pain management.))

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

The diagnosis and treatment of pain is integral to the practice of medicine. The commission encourages physician assistants to view pain management as a part of quality medical practice for all patients with pain, <u>including</u> acute $((\Theta r))$, <u>perioperative</u>, <u>subacute</u>, <u>and</u> chronic((, <u>and it is especially urgent for patients who experience pain as</u> <u>a result of terminal illness</u>)) <u>pain</u>. All physician assistants should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as statutory requirements for prescribing ((<u>controlled substances</u>)) <u>opioids</u>, <u>including co-occurring</u> <u>prescriptions</u>. Accordingly, ((<u>this rule has been developed to</u>)) <u>these</u> <u>rules</u> clarify the commission's position on pain control, particularly as related to the use of controlled substances, to alleviate physician assistant uncertainty and to encourage better pain management.

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

The commission recognizes that controlled substances including opioids ((analgesics)) may be essential in the treatment of acute

<u>subacute</u>, <u>perioperative</u>, <u>or chronic</u> pain due to <u>disease</u>, <u>illness</u>, trauma, or surgery ((and chronic pain, whether due to cancer or noncancer origins)). The commission will refer to current clinical practice guidelines and expert review in approaching cases involving management of pain. The medical management of pain should consider current clinical knowledge and scientific research and the use of pharmacologic and nonpharmacologic modalities according to the judgment of the physician assistant. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity, duration, <u>impact</u> of the pain, and treatment outcomes. Physician assistants should recognize that tolerance and physical dependence are normal consequences of sustained use of opioids ((analgesics)) and are not the same as ((addiction)) <u>opioid use disor-</u> der.

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

Physician assistants should not fear disciplinary action from the commission for ordering, prescribing, dispensing or administering controlled substances, including opioids ((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 be based on clear documentation of unrelieved pain. To be within the usual course of professional practice, a physician assistant-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 assistant'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)) physician assistants 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)) guarantee an accurate diagnosis or a successful outcome. The sole purpose of these rules is to assist ((practitioners)) physician assistants in following a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care.

For more specific best practices, the physician assistant may refer to clinical practice guidelines including, but not limited to, those produced by the agency medical directors' group, the Centers for Disease Control and Prevention, or the Bree Collaborative.

AMENDATORY SECTION (Amending WSR 11-12-025, filed 5/24/11, effective 1/2/12)

WAC 246-918-801 Exclusions. ((The rules adopted under)) WAC 246-918-800 through ((246-918-813)) 246-918-935 do not apply to:

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

(2) The provision of palliative, hospice, or other end-of-life care; (($\frac{1}{2}$

(2) To the management of acute pain caused by an injury or surgical procedure.))

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

(4) The provision of procedural medications.

AMENDATORY SECTION (Amending WSR 11-12-025, filed 5/24/11, effective 1/2/12)

WAC 246-918-802 Definitions. The definitions ((in this section)) apply ((in)) to WAC 246-918-800 through ((246-918-813)) 246-918-935 unless the context clearly requires otherwise.

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

(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. ((It is generally time-limited, often less than three months in duration, and usually less than six months.

(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:

(a) Impaired control over drug use;

(b) Craving;

(c) Compulsive use; or

(d) Continued use despite harm.

(3)) Acute pain is of six weeks or less in duration.

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

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

(5) "Chronic ((noncancer)) pain" means a state in which ((noncancer)) 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 is considered to be pain that persists for more than twelve weeks.

(((4) "Comorbidity)) <u>(6) "Comorbidities</u>" means a preexisting or coexisting physical or psychiatric disease or condition.

(((5))) <u>(7)</u> "Designee" means a licensed health care practitioner authorized by a prescriber to request and receive prescription monitoring program (PMP) data on their behalf.

(8) "Episodic care" means <u>noncontinuing</u> medical <u>or dental</u> care provided by a ((practitioner)) <u>physician assistant</u> other than the designated primary ((care practitioner in the acute care setting, for ex- ample, urgent care or emergency department.

(6))) prescriber for a patient with chronic pain.

(9) "High dose" means a ninety milligram morphine equivalent dose (MED), or more, per day.

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

(11) "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 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 freestanding hospice facilities, hospitals, nursing homes, or other longterm care facilities)).

(((7))) <u>(12)</u> "Hospital" as defined in chapters 70.41, 71.12 RCW, and RCW 72.23.020.

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

(14) "Medication assisted treatment" or "MAT" means the use of pharmacologic therapy, often in combination with counseling and behavioral therapies, for the treatment of substance use disorders. (15) "Moderate-risk" is a category of patient at moderate risk of opioid-induced morbidity or mortality, based on factors and combinations of factors such as medical and behavioral comorbidities, polypharmacy, past history of substance use disorder or abuse, aberrant behavior, and dose of opioids between fifty to ninety milligram morphine equivalent doses per day.

(16) "Morphine equivalent dose" or "MED" means a conversion of various opioids to a morphine equivalent dose ((by the use of accepted)) using the agency medical directors group or other conversion table((s)) approved by the commission. MED is considered the same as morphine milligram equivalent or MME.

(((8))) <u>(17)</u> "Multidisciplinary pain clinic" means a ((clinic or office that provides comprehensive pain management and includes care provided by multiple available disciplines or treatment modalities, for example, medical care through physicians, physician assistants, osteopathic physicians, osteopathic physician assistants, advanced registered nurse practitioners, and physical therapy, occupational therapy, or other complementary therapies.

(9)) <u>health care delivery facility staffed by physicians of dif</u><u>ferent specialties and other nonphysician health care providers who</u><u>specialize in the diagnosis and management of patients with chronic pain.</u>

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

(19) "Palliative <u>care</u>" means care that <u>maintains or</u> improves the quality of life of patients and their families facing <u>serious, ad-</u> <u>vanced, or</u> life-threatening illness. ((With palliative care particular attention is given to the prevention, assessment, and treatment of pain and other symptoms, and to the provision of psychological, spiritual, and emotional support.))

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

(21) "Prescription monitoring program" or "PMP" means the Washington state prescription monitoring program authorized under chapter 70.225 RCW. Other jurisdictions may refer to this as the prescription drug monitoring program or PDMP.

(22) "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 or 18.57 RCW, a physician assistant licensed under chapter 18.71A or 18.57A RCW, or a podiatric physician licensed under chapter 18.22 RCW.

(23) "Refill" or "renewal" means a second or subsequent filling of a previously issued prescription.

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

(25) "Substance use disorder" means a primary, chronic, neurobiological disease with genetic, psychosocial, and environmental factors influencing its development and manifestations. Substance use disorder is not the same as physical dependence or tolerance that is a normal physiological consequence of extended opioid therapy for pain. It is characterized by behaviors that include, but are not limited to, impaired control over drug use, craving, compulsive use, or continued use despite harm. WAC 246-918-815 Patient notification, secure storage, and disposal. (1) The physician assistant shall ensure the patient is provided the following information at the first issuance of a prescription for opioids and at the transition from acute to subacute, and subacute to chronic:

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

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

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

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

NEW SECTION

WAC 246-918-820 Use of alternative modalities for pain treatment. The physician assistant shall exercise their professional judgment in selecting appropriate treatment modalities for acute nonoperative, acute perioperative, subacute, or chronic pain including the use of multimodal pharmacologic and nonpharmacologic therapy as an alternative to opioids whenever reasonable, clinically appropriate, evidence-based alternatives exist.

NEW SECTION

WAC 246-918-825 Continuing education requirements for opioid prescribing. (1) To prescribe an opioid in Washington state, a physician assistant licensed to prescribe opioids shall complete a one-time continuing education requirement regarding best practices in the prescribing of opioids or the opioid prescribing rules in this chapter. The continuing education must be at least one hour in length.

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

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

OPIOID PRESCRIBING—ACUTE NONOPERATIVE PAIN AND ACUTE PERIOPERATIVE PAIN

NEW SECTION

WAC 246-918-830 Patient evaluation and patient record—Acute nonoperative pain. Prior to issuing an opioid prescription for acute nonoperative pain or acute perioperative pain, the physician assistant shall:

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

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

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

NEW SECTION

WAC 246-918-835 Treatment plan—Acute nonoperative pain. The physician assistant shall comply with the requirements in this section when prescribing opioids for acute nonoperative pain.

(1) The physician assistant should consider prescribing nonopioids as the first line of pain control in patients unless not clinically appropriate in accordance with the provisions of WAC 246-918-820.

(2) The physician assistant, or their designee, shall conduct queries of the PMP in accordance with the provisions of WAC 246-918-935.

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

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

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

- (a) Change in pain level;
- (b) Change in physical function;
- (c) Change in psychosocial function; and

(d) Additional indicated diagnostic evaluations.

(6) If a prescription results in the patient receiving a combination of opioids with a sedative medication listed in WAC 246-918-920, such prescribing must be in accordance with WAC 246-918-920.

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

(8) Medication assisted treatment medications must not be discontinued when treating acute pain, except as consistent with the provisions of WAC 246-918-925.

(9) If the physician assistant elects to treat a patient with opioids beyond the six-week time period of acute nonoperative pain, the physician assistant shall document in the patient record that the patient is transitioning from acute pain to subacute pain. Rules governing the treatment of subacute pain in WAC 246-918-845 and 246-918-850 shall apply.

NEW SECTION

WAC 246-918-840 Treatment plan—Acute perioperative pain. The physician assistant shall comply with the requirements in this section when prescribing opioids for perioperative pain.

(1) The physician assistant should consider prescribing nonopioids as the first line of pain control in patients unless not clinically appropriate in accordance with the provisions of WAC 246-918-820.

(2) The physician assistant, or their designee, shall conduct queries of the PMP in accordance with the provisions of WAC 246-918-935.

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

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

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

(a) Change in pain level;

(b) Change in physical function;

(c) Change in psychosocial function; and

(d) Additional indicated diagnostic evaluations or other treatments.

(6) If a prescription results in the patient receiving a combination of opioids with a sedative medication listed in WAC 246-918-920, such prescribing must be in accordance with WAC 246-918-920.

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

(8) Medication assisted treatment medications must not be discontinued when treating acute perioperative pain, except as consistent with the provisions of WAC 246-918-925.

(9) If the physician assistant elects to treat a patient with opioids beyond the six-week time period of acute perioperative pain, the physician assistant shall document in the patient record that the patient is transitioning from acute pain to subacute pain. Rules governing the treatment of subacute pain, WAC 246-918-845 and 246-918-850, shall apply unless there is documented improvement in function or pain control and there is a documented plan and timing for discontinuation of all opioid medications.

OPIOID PRESCRIBING-SUBACUTE PAIN

NEW SECTION

WAC 246-918-845 Patient evaluation and patient record—Subacute pain. The physician assistant shall comply with the requirements in this section when prescribing opioids for subacute pain.

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

(a) Conduct an appropriate history and physical examination;

(b) Reevaluate the nature and intensity of the pain;

(c) Conduct, or cause their designee to conduct, a query of the PMP in accordance with the provisions of WAC 246-918-935;

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

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

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

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

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

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

(c) Pertinent concerns discovered in the PMP;

(d) An appropriate pain treatment plan including the consideration of, or attempts to use, nonpharmacological modalities and nonopioid therapy;

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

(f) Results of psychosocial screening or consultation;

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

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

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

(a) Change in pain level;

(b) Change in physical function;

(c) Change in psychosocial function; and

(d) Additional indicated diagnostic evaluations or other treatments.

NEW SECTION

WAC 246-918-850 Treatment plan—Subacute pain. The physician assistant, having recognized the progression of a patient from the acute nonoperative or acute perioperative phase to the subacute phase shall develop an opioid treatment plan.

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

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

(3) If a prescription results in the patient receiving a combination of opioids with a sedative medication listed in WAC 246-918-920, such prescribing must be in accordance with WAC 246-918-920.

(4) If the physician assistant elects to treat a patient with opioids beyond the six- to twelve-week subacute phase, the physician assistant shall document in the patient record that the patient is transitioning from subacute pain to chronic pain. Rules governing the treatment of chronic pain, WAC 246-918-855 through 246-918-905, shall apply.

OPIOID PRESCRIBING-CHRONIC PAIN MANAGEMENT

WAC 246-918-855 Patient evaluation and patient record—Chronic pain. When the patient enters the chronic pain phase, the patient shall be reevaluated as if presenting with a new disease. The physician assistant shall include in the patient's record:

(1) An appropriate history including:

(a) The nature and intensity of the pain;

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

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

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

(2) Appropriate physical examination.

(3) Ancillary information and tools to include:

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

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

(c) Pertinent consultations; and

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

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

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

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

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

(d) Pertinent concerns discovered in the PMP.

(5) Treatment plan as provided in WAC 246-918-860.

NEW SECTION

WAC 246-918-860 Treatment plan—Chronic pain. The physician assistant, having recognized the progression of a patient from the subacute phase to the chronic phase, shall develop an opioid treatment plan as follows:

(1) Treatment plan and objectives including:

(a) Documentation of any medication prescribed;

(b) Biologic specimen testing ordered;

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

(d) Other planned treatments; and

(e) Written agreement for treatment as provided in WAC 246-918-865.
(2) The physician assistant shall complete patient notification in accordance with the provisions of WAC 246-918-815 or provide this information in the written agreement.

NEW SECTION

WAC 246-918-865 Written agreement for treatment—Chronic pain. The physician assistant shall use a written agreement that outlines the patient's responsibilities for opioid therapy. This written agreement for treatment must include the following provisions:

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

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

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

(4) The requirement that all opioid prescriptions for chronic pain are provided by a single prescriber or a single clinic, except as provided in WAC 246-918-915 for episodic care;

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

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

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

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

NEW SECTION

WAC 246-918-870 Periodic review—Chronic pain. (1) The physician assistant shall periodically review the course of treatment for chronic pain. The frequency of visits, biological testing, and PMP queries in accordance with the provisions of WAC 246-918-935, must be determined based on the patient's risk category:

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

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

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

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

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

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

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

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

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

(3) Periodic patient evaluations must also include:

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

(b) Use of validated tools or patient report from reliable patients to document either maintenance or change in function and pain control; and

(c) Review of the Washington state PMP at a frequency determined by the patient's risk category in accordance with the provisions of WAC 246-918-935 and subsection (1) of this section.

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

NEW SECTION

WAC 246-918-875 Long-acting opioids—Chronic pain. Long-acting opioids should only be prescribed by a physician assistant who is familiar with its risks and use, and who is prepared to conduct the necessary careful monitoring. Special attention should be given to patients who are initiating such treatment. The physician assistant prescribing long-acting opioids should have a one-time completion of at least four hours of continuing education relating to this topic.

NEW SECTION

WAC 246-918-880 Consultation—Recommendations and requirements— Chronic pain. (1) The physician assistant shall consider referring the patient for additional evaluation and treatment as needed to achieve treatment objectives. Special attention should be given to those chronic pain patients who are under eighteen years of age or who are potential high-risk patients.

(2) The mandatory consultation threshold is one hundred twenty milligrams MED. In the event a physician assistant 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 246-918-895 is required, unless the consultation is exempted under WAC 246-918-885 or 246-918-890.

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

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

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

(c) An audio-visual evaluation conducted by the pain management specialist remotely where the patient is present with either the physician assistant or a licensed health care practitioner designated by the physician assistant or the pain management specialist; or (d) Other chronic pain evaluation services as approved by the commission.

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

NEW SECTION

WAC 246-918-885 Consultation—Exemptions for exigent and special circumstances—Chronic pain. A physician assistant is not required to consult with a pain management specialist as defined in WAC 246-918-895 when the physician assistant has documented adherence to all standards of practice as defined in WAC 246-918-855 through 246-918-875 and when one or more of the following conditions are met:

(1) The patient is following a tapering schedule;

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

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

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

NEW SECTION

WAC 246-918-890 Consultation—Exemptions for the physician assistant—Chronic pain. The physician assistant is exempt from the consultation requirement in WAC 246-918-880 if one or more of the following qualifications are met:

(1) The physician assistant is a pain management specialist under WAC 246-918-895;

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

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

(4) The physician assistant has a minimum of three years of clinical experience in a chronic pain management setting, and at least thirty percent of their current practice is the direct provision of pain management care. WAC 246-918-895 Pain management specialist—Chronic pain. A pain management specialist shall meet one or more of the following qualifications:

(1) If an allopathic physician assistant or osteopathic physician assistant must have a delegation agreement with a physician pain management specialist and meets the educational requirements and practice requirements listed below:

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

(b) Credentialed in pain management by an entity approved by the Washington state medical quality assurance commission for an allopathic physician assistant or the Washington state board of osteopathic medicine and surgery for an osteopathic physician assistant;

(c) Successful completion of a minimum of at least eighteen continuing education hours in pain management during the past two years; and

(d) At least thirty percent of the physician assistant's current practice is the direct provision of pain management care or in a multidisciplinary pain clinic.

(2) If an allopathic physician, in accordance with WAC 246-919-945.

(3) If an osteopathic physician, in accordance with WAC 246-853-750.

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

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

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

NEW SECTION

WAC 246-918-900 Tapering considerations—Chronic pain. The physician assistant shall consider tapering or referral for a substance use disorder evaluation when:

(1) The patient requests;

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

(3) The patient is noncompliant with the written agreement;

(4) Other treatment modalities are indicated;

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

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

(7) There is unauthorized escalation of doses; or

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

WAC 246-918-905 Patients with chronic pain, including those on high doses of opioids, establishing a relationship with a new physician assistant. (1) When a patient receiving chronic opioid pain medications changes to a new physician assistant, it is normally appropriate for the new physician assistant to initially maintain the patient's current opioid doses. Over time, the physician assistant may evaluate if any tapering or other adjustments in the treatment plan can or should be done.

(2) A physician assistant's treatment of a new high dose chronic pain patient is exempt from the mandatory consultation requirements of WAC 246-918-880 if:

(a) The patient was previously being treated with a dosage of opioids in excess of a one hundred twenty milligram MED for chronic pain under an established written agreement for treatment of the same chronic condition or conditions;

(b) The patient's dose is stable and nonescalating;

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

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

(3) With respect to the treatment of a new patient under subsection (1) or (2) of this section, this exemption applies for the first three months of newly established care, after which the requirements of WAC 246-918-880 shall apply.

OPIOID PRESCRIBING-SPECIAL POPULATIONS

NEW SECTION

WAC 246-918-910 Special populations—Children or adolescent patients, pregnant patients, and aging populations. (1) Children or adolescent patients. In the treatment of pain for children or adolescent patients, the physician assistant shall treat pain in a manner equal to that of an adult but must account for the weight of the patient and adjust the dosage prescribed accordingly.

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

(3) Aging populations. As people age, their sensitivities to and metabolizing of opioids may change. The physician assistant shall con-

sider the distinctive needs of patients who are sixty-five years of age or older and who have been on chronic opioid therapy or who are initiating opioid treatment.

NEW SECTION

WAC 246-918-915 Episodic care of chronic opioid patients. (1) When providing episodic care for a patient who the physician assistant knows is being treated with opioids for chronic pain, such as for emergency or urgent care, the physician assistant, or their designee, shall review the PMP and document their review and any concerns.

(2) A physician assistant providing episodic care to a patient who the physician assistant knows is being treated with opioids for chronic pain should provide additional analgesics, including opioids when appropriate, to adequately treat acute pain. If opioids are provided, the physician assistant shall limit the use of opioids to the minimum amount necessary to control the acute pain until the patient can receive care from the practitioner who is managing the patient's chronic pain.

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

OPIOID PRESCRIBING—COPRESCRIBING

NEW SECTION

WAC 246-918-920 Coprescribing of opioids with certain medications. (1) The physician assistant shall not knowingly prescribe opioids in combination with the following medications without documentation of medical decision making:

- (a) Benzodiazepines;
- (b) Barbiturates;
- (c) Sedatives;
- (d) Carisoprodol; or
- (e) Nonbenzodiazepine hypnotics.

(2) If, because of a prior prescription by another provider, a prescription written by a physician assistant results in a combination of opioids and medications described in subsection (1) of this section, the physician assistant issuing the new prescription shall consult with the other prescriber to establish a patient care plan surrounding these medications. This provision does not apply to emergency care.

WAC 246-918-925 Coprescribing of opioids for patients receiving medication assisted treatment. (1) Where practicable, the physician assistant providing acute nonoperative pain or acute perioperative pain treatment to a patient who is known to be receiving MAT medications shall prescribe opioids when appropriate for pain relief either in consultation with a MAT prescribing practitioner or a pain specialist.

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

<u>NEW SECTION</u>

WAC 246-918-930 Coprescribing of naloxone. The opioid prescribing physician assistant shall confirm or provide a current prescription for naloxone when opioids are prescribed to a high-risk patient.

OPIOID PRESCRIBING—PRESCRIPTION MONITORING PROGRAM

NEW SECTION

WAC 246-918-935 Prescription monitoring program—Required registration, queries, and documentation. (1) The physician assistant shall register to access the PMP or demonstrate proof of having assured access to the PMP if they prescribe Schedule II-V medications in Washington state.

(2) The physician assistant is permitted to delegate performance of a required PMP query to an authorized designee.

(3) At a minimum, the physician assistant shall ensure a PMP query is performed prior to the prescription of an opioid or of a medication listed in WAC 246-918-920 at the following times:

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

- (b) The time of transition from acute to subacute pain; and
- (c) The time of transition from subacute to chronic pain.

(4) For chronic pain management, the physician assistant shall ensure a PMP query is performed at a minimum frequency determined by the patient's risk assessment, as follows: (a) For a high-risk patient, a PMP query shall be completed at least quarterly;

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

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

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

(6) The physician assistant shall ensure a PMP query is performed when providing episodic care to a patient who the physician assistant knows to be receiving opioids for chronic pain, in accordance with WAC 246-918-915.

(7) If the physician assistant is using an electronic medical record (EMR) that integrates access to the PMP into the workflow of the EMR, the physician assistant shall ensure a PMP query is performed for all prescriptions of opioids and medications listed in WAC 246-918-920.

(8) For the purposes of this section, the requirement to consult the PMP does not apply when the PMP or the EMR cannot be accessed by the physician assistant or their designee due to a temporary technological or electrical failure.

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

REPEALER

The following sections of the Washington Administrative Code are repealed:

WAC 246	5-918-803	Patient evaluation.
WAC 246	5-918-804	Treatment plan.
WAC 246	5-918-805	Informed consent.
WAC 246	5-918-806	Written agreement for treatment.
WAC 246	5-918-807	Periodic review.
WAC 246	5-918-808	Long-acting opioids, including methadone.
WAC 246	5-918-809	Episodic care.
WAC 246	5-918-810	Consultation—Recommendations and requirements.
WAC 246	5-918-811	Consultation—Exemptions for exigent and special circumstances.
WAC 246	5-918-812	Consultation—Exemptions for the physician assistant.
WAC 246	5-918-813	Pain management specialist.

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The Medical Quality Assurance Commission (commission) adopted new, repealed, and amended rule sections to implement sections 4 and 5 of Engrossed Substitute House Bill (ESHB) 1427, (Chapter 297, Laws of 2017), codified as RCW 18.57.800 and 18.57A.800. The adopted rules provide a framework, structure, and guidance for safe, consistent opioid prescribing practice for osteopathic physicians and osteopathic physician assistants that align with the directives of ESHB 1427, and reduce the risks associated with opioid use in the management of pain, while increasing public health and safety.

The commission adopted these opioid prescribing rules at a public rules hearing held on August 22, 2018 in Olympia, Washington. The commission thanks everyone who participated in this rulemaking process.

Table 1 describes the non-substantive changes made to the proposed rule at the hearing. Table 2 summarizes comments submitted to the commission and the commission's responses to those comments.

WAC	Edit/Change	Reason
246-918-802(7) and 246-919-852(7) - Definitions	"Designee" means a licensed health care practitioner authorized by a prescriber to request and receive prescription monitoring program (PMP) data on their behalf.	A definition for "designee" was added as a new subsection (7). This term is used in rule so a definition is being added for clarification.
	As a result of adding this definition, the commission deleted all references to "as defined in WAC 246-470-050" throughout the physician and physician assistant rules.	The subsequent subsections were renumbered to reflect this addition. Adding the definition of designee made the need for the phrase "as defined in WAC 246-470-050" no longer needed in the rest of the sections and was deleted.

Table 1: Non-substantial Changes Made at Hearing

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WAC	Edit/Change	Reason
246-918-895(2) - (6)	(2) If an allopathic physician, <u>in accordance with</u>	The commission determined the MD and PA
– Pain Management	<u>WAC 246-919-945</u> .	chapters should be substantially similar. Adding this
Specialist—Chronic Pain	 (3) If an osteopathic physician, <u>in accordance with WAC 246-853-750.</u> (4) If a dentist, <u>in accordance with WAC 246-817-965.</u> (5) If a podiatric physician, <u>in accordance with WAC 246-922-750.</u> (6) If an advanced registered nurse practitioner, <u>in accordance with WAC 246-840-493.</u> 	new language makes them so.
246-918-802(13) and 246-919-852(13) – Definitions [formerly subsection (12) in the proposed rules, now adopted as renumbered subsection (13)]	"Low-risk" is a category of patient at low risk of opioid-induced morbidity or mortality, based on factors and combinations of factors such as medical and behavioral comorbidities, polypharmacy, and dose of opioids of less than a fifty milligram morphine equivalent dose <u>per day</u> .	The commission determined adding "per day" to the end of the definition was necessary for clarification.

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WAC	Edit/Change	Reason
246-918-802 (15) and 246-919-852(15) – Definitions [formerly subsection (14) in the proposed rules, now adopted as renumbered subsection (15)]	"Moderate-risk" is a category of patient at moderate risk of opioid-induced morbidity or mortality, based on factors and combinations of factors such as medical and behavioral comorbidities, polypharmacy, past history of substance use disorder or abuse, aberrant behavior, and dose of opioids between fifty to ninety milligram morphine equivalent doses <u>per</u> <u>day</u> .	The commission determined adding "per day" to the end of the definition was necessary for clarification.
246-918-802(18) and 246-919-852(18) – Definitions [formerly subsection (17) in the proposed rules, now adopted as renumbered subsection (18)]	"Opioid" means a drug that is either an opiate that is derived from the opium poppy or opiate-like that is a semi-synthetic or synthetic drug. Examples include morphine, codeine, hydrocodone, oxycodone, fentanyl, meperidine, tramadol, buprenorphine, and methadone <u>when used to treat pain.</u>	The commission determined adding "when used to treat pain" to the end of the definition was necessary for clarification.
246-918-820 and 246- 919-870 – Use of alternative modalities for pain treatment	246-918-820: The physician assistant/physician shall exercise their professional judgment in selecting appropriate treatment modalities for acute nonoperative, acute perioperative, subacute, <u>or</u> <u>chronic pain</u> including the use of multimodal pharmacologic and nonpharmacologic therapy as an	The commission determined adding "or chronic pain" was necessary for clarification.

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WAC	Edit/Change	Reason
	alternative to opioids whenever reasonable, clinically appropriate, evidence-based alternatives exist. 246-919-870: The physician shall exercise their professional judgment in selecting appropriate treatment modalities for acute nonoperative, acute perioperative, subacute, or chronic pain including the use of multimodal pharmacologic and nonpharmacologic therapy as an alternative to opioids whenever reasonable, clinically appropriate, evidence- based alternatives exist.	
246-918-825(1) and 246-919-875(1) – Continuing education requirements for opioid prescribing	 246-918-825(1): To prescribe an opioid in Washington state, a physician assistant licensed to prescribe opioids shall complete a one-time continuing education requirement <u>regarding best</u> practices in the prescribing of opioids or the opioid prescribing rules in this chapter. 246-919-875(1): To prescribe an opioid in Washington state, a physician licensed to prescribe opioids shall complete a one-time continuing education requirement <u>regarding best practices in the prescribe opioids</u> or the opioid in the prescribing of opioids or the opioid prescribe opioids shall complete a one-time continuing education requirement <u>regarding best practices in the prescribing of opioids</u> or the opioid prescribing rules in this chapter. 	The commission determined adding "regarding best practices in the prescribing of opioids or" was necessary to add more options for providers to complete this CME requirement.

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WAC	Edit/Change	Reason
246-918-845(2)(b) and 246-919- 895(2)(b) – Patient evaluation and patient record – subacute pain	The observed <u>or reported</u> effect on function or pain control forming the basis to continue prescribing opioids beyond the acute pain episode;	The commission determined adding "or reported" was necessary for clarification.
246-918-850(2) and 246-919-900(2) – Treatment plan – subacute pain	 246-918-850(2): During the subacute phase the physician assistant shall not prescribe beyond a fourteen-day supply of opioids without clinical documentation to justify the need for such a quantity during the subacute phase. 246-919-900(2): During the subacute phase the physician assistant shall not prescribe beyond a fourteen-day supply of opioids without clinical documentation to justify the need for such a quantity during the subacute phase. 	The commission determined moving "During the subacute phase" to the beginning of the sentence was necessary for clarification.
246-918-855(1)(c) and 246-919- 905(1)(c) – Patient evaluation and patient record – chronic pain	Current <u>and relevant past treatments for pain</u> , including opioids and other medications and their efficacy;	The commission determined adding "and relevant" was necessary for clarification.
246-918-870(4) and 246-919-920(4) –	Subsections (9) in both MD and PA sections 246-918- 865 and 246-918-915 were moved to sections -870(4)	WAC 246-918-865(9) and 246-919-915(9) – Written agreement for treatment – chronic pain were

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WAC	Edit/Change	Reason
Periodic review- Chronic pain [formerly 246-918- 865(9) and 246-919- 915(9)]	and -92(4)—Periodic review – Chronic pain. No other changes were made.	moved to WAC 246-918-870(4) and to WAC 246- 919-920(4) – Periodic review-Chronic Pain because the Commission determined it aligned better with Periodic Review-Chronic Pain section.
246-918-800 through 246-918-935 and WAC 246-919-850 through 246-919-985	Changed the term "podiatrist" to "podiatric physician" throughout MD and PA chapters.	All references to podiatrist were changed to podiatric physician throughout the pain management sections because this is the proper term for these providers.
246-918-802(1) and 246-919-852(1) – Definitions	"Aberrant behavior" means behavior that indicates current misuse, diversion, unauthorized use of alcohol or other controlled substances, <u>or</u> multiple early refills (renewals)., <u>or active opioid use disorder.</u>	The term "active opioid use disorder" was deleted from this definition because the commission determined opioid use disorder is not an aberrant behavior.
246-918-840(1) and 246-919-890(1) – Treatment plan – Acute perioperative pain	246-918-840(1): The physician assistant shall should consider prescribing nonopioids as the first line of pain control in patients, unless not clinically appropriate, in accordance with the provisions of WAC 246-918-820.	The word "shall" was changed to "should" for clarity and consistency with WAC 246-919-885(1).
	246-919-890(1): The physician shall should consider prescribing nonopioids as the first line of pain control in patients, unless not clinically appropriate, in accordance with the provisions of WAC 246-919-870.	

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WAC	Edit/Change	Reason
246-918-870(2)(c) and 246-919- 920(2)(c) – Periodic review	 246-918-870(2)(c): If continuation or modification of medications for pain management treatment is necessary based on the physician assistant's evaluation of progress towards or maintenance of treatment objectives and compliance with the treatment plan. 246-919-920(2)(c): If continuation or modification of medications for pain management treatment is necessary based on the physician's evaluation of progress towards <u>or maintenance of treatment</u> is necessary based on the physician's evaluation of progress towards <u>or maintenance of treatment</u> objectives and compliance with the treatment plan. 	The phrase "or maintenance of" was added for clarity to ensure that the goal for some patients is maintenance of pain level and functional level rather than improvement (progress).
246-918-870(3)(b) and 246-919- 920(3)(b) Periodic review – Chronic pain	Use of validated tools <u>or patient report from reliable</u> <u>patients</u> to document either maintenance or change in function and pain control;	The phrase "or patient report from reliable patients" was added because the commission determined it clarified accepted sources of information.
246-918-885 and 246- 919-935 – Consultation- Exemptions for exigent and special circumstances	246-918-885: A physician assistant is not required to consult with a pain management specialist as defined in WAC 246-918-895 when the physician assistant has documented adherence to all standards of practice as defined in WAC 246-918-855 through 246-918- 8795 and when one or more of the following conditions are met:	Updated the WAC numbers referenced in the first paragraph to align with the new WAC numbers used in the revised Pain Management sections.
	246-919-935: A physician is not required to consult with a pain management specialist as defined in WAC	

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WAC	Edit/Change	Reason
	246-919-945 when the physician has documented adherence to all standards of practice as defined in WAC 246-919-905 through 246-919-9450, and when one or more of the following conditions are met:	
246-918-915(2) and 246-919-965(2) – Episodic care of chronic opioid patients	 246-918-915(2): A physician assistant providing episodic care to a patient who the physician assistant knows is being treated with opioids for chronic pain should provide additional analgesics, including opioids when appropriate, to adequately treat acute pain. 246-919-965(2); A physician providing episodic care to a patient who the physician knows is being treated with opioids for chronic pain should provide additional analgesics, including episodic care to a patient who the physician knows is being treated with opioids for chronic pain should provide additional analgesics, including opioids when appropriate, to adequately treat acute pain. 	The phrase "when appropriate" was added to clarify that opioids should be prescribed only when appropriate.
246-918-925(1) and 246-919-975(1) – Co- prescribing of opioids for patients receiving medication assisted treatment	246-918-925(1): Where practicable, the physician assistant providing acute nonoperative pain or acute perioperative pain treatment to a patient who is known to be receiving MAT medications shall prescribe opioids for pain relief when appropriate for pain relief either in consultation with a MAT prescribing practitioner or a pain specialist.	The phrase "when appropriate" was added to clarify that opioids should be prescribed only when appropriate.

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WAC	Edit/Change	Reason
246-918-801 Exclusions	 246-919-975(1): Where practicable, the physician providing acute nonoperative pain or acute perioperative pain treatment to a patient who is known to be receiving MAT medications shall prescribe opioids for pain relief when appropriate for pain relief either in consultation with a MAT prescribing practitioner or a pain specialist. Exclusions. WAC 246-918-800 through 246-918-935 do not apply to: 	The commission determined the MD and PA chapters should be substantially similar. Adding this
	 (1) The treatment of patients with cancer-related pain; (2) The provision of palliative, hospice, or other end-of-life care; (3) The treatment of inpatient hospital patients who are patients who have been admitted to a hospital for more than twenty-four hours; or (4) The provision of procedural medications. 	new language to the PA sections makes them so.
246-919-895(2)(h)	The risk-benefit analysis of any combination of prescribed opioid and benzodiazepines or sedative-hypnotics, if applicable ; and .	The "; and" should have been removed as it was inadvertently left in rule after editing subsection (2).

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Applicable WAC as	Comment/recommended change to proposed rule	Commission response
filed under WSR 18-		
15-055		
246-918-802(7) and	Add a definition for "designee"	The rule was changed as a result of this comment. A
246-919-852(7) -	Add a definition for designee	definition for "designee" was added as a new
Definitions		subsection (7). This term is used in rule so a
Definitions		definition is being added for clarification.
		demittion is being added for clarification.
		The subsequent subsections were renumbered to
		reflect this addition. Adding the definition of
		designee made the need for the phrase "as defined in
		WAC 246-470-050" no longer needed in the rest of
		the sections and was deleted.
246-918-895(2) - (6)	The language in the Pain Management Specialist	The rule was changed as a result of this comment.
– Pain Management	section is different in the PA rules. The language	The commission determined the MD and PA
Specialist—Chronic	should be substantially similar to the MD rules.	chapters should be substantially similar. Adding this
Pain		new language makes them so.
246-918-802(13) and	Add "per day" at the end of the "low-risk" definition.	The rule was changed as a result of this comment.
246-919-852(13) -		The commission determined adding "per day" to the
Definitions		end of the definition was necessary for clarification.
[formerly subsection		
(12) in the proposed		
rules, now adopted as		

 Table 2: Summary of Written and Oral Comments Received and Commission Response

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Applicable WAC as filed under WSR 18- 15-055	Comment/recommended change to proposed rule	Commission response
renumbered subsection (13)]		
246-918-802 (15) and 246-919-852(15) – Definitions [formerly subsection (14) in the proposed rules, now adopted as renumbered subsection (15)]	Add "per day" at the end of the "high-risk" definition.	The rule was changed as a result of this comment. The commission determined adding "per day" to the end of the definition was necessary for clarification.
246-918-802(18) and 246-919-852(18) – Definitions [formerly subsection (17) in the proposed rules, now adopted as renumbered subsection (18)]	Change the definition of "opioid" regarding buprenorphine and methadone to clarify the definition applies to those two medications only when they are used to treat pain and not addiction.	The rule was changed as a result of this comment. The commission determined adding "when used to treat pain" to the end of the definition would add clarification.

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Applicable WAC as filed under WSR 18- 15-055	Comment/recommended change to proposed rule	Commission response
246-918-820 and 246-919-870 – Use of alternative modalities for pain treatment	Add "chronic pain" to the list of pain phases in the first paragraph.	The rule was changed as a result of this comment. The commission determined adding "or chronic pain" was necessary for clarification.
246-918-825(1) and 246-919-875(1) – Continuing education requirements for opioid prescribing	 "We appreciate that a physician may meet the CME requirement by learning about these rules, but this reads like the CME must be on the rules, when a different CME, perhaps on general opioid prescribing might be more beneficial to a physician depending on their practice. Please provide for flexibility / both options." 	The rule was changed as a result of this comment. The commission determined adding "regarding best practices in the prescribing of opioids or" was necessary to add more options for providers to complete this CME requirement.
246-918-845(2)(b) and 246-919- 895(2)(b) – Patient evaluation and patient record – subacute pain	Change (2)(b) to "The observed <u>and/or reported</u> effect on function"	The rule was changed as a result of this comment. The commission determined adding "or reported" was necessary for clarification.

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Applicable WAC as filed under WSR 18- 15-055	Comment/recommended change to proposed rule	Commission response
246-918-850(2) and 246-919-900(2) – Treatment plan – subacute pain 246-918-870(4) and 246-919-920(4) – Periodic review- Chronic pain [formerly 246-918- 865(9) and 246-919- 915(9)]	"During the subacute phase the physician assistant shall not prescribe beyond a fourteen-day supply of opioids without clinical documentation to justify the need for such a quantity during the subacute phase." Move (4) of the Written agreement for treatment – Chronic pain section to the Periodic review – chronic pain section.	The rule was changed as a result of this comment. The commission determined moving "During the subacute phase" to the beginning of the sentence was necessary for clarification. The rule was changed as a result of this comment. WAC 246-918-865(9) and 246-919-915(9) – Written agreement for treatment – chronic pain were moved to WAC 246-918-870(4) and to WAC 246- 919-920(4) – Periodic review-Chronic Pain because the Commission determined it aligned better with Periodic Review-Chronic Pain section.
246-918-800 through 246-918-935 and WAC 246-919-850 through 246-919-985	Change the term "podiatrist" to "podiatric physician" throughout MD and PA chapters.	The rule was changed as a result of this comment. All references to podiatrist were changed to podiatric physician throughout the pain management sections because this is the proper term for these providers.
246-918-802(1) and 246-919-852(1) – Definitions	"Delete 'active opioid use disorder.' Modify the definition as follows: 'behavior that indicates current misuse, diversion, or unauthorized use of alcohol or other controlled substances, such as multiple early refills	The rule was changed as a result of this comment. The term "active opioid use disorder" was deleted from this definition because the commission determined opioid use disorder is not an aberrant behavior.

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Applicable WAC as filed under WSR 18- 15-055	Comment/recommended change to proposed rule	Commission response
	(renewals), repeated non-compliance with prescription directions, use of non-prescribed medications, obtaining controlled medications from multiple prescribers."	
246-918-840(1) and 246-919-890(1) – Treatment plan – Acute perioperative pain	Change the word "shall" to "should".	The rule was changed as a result of this comment. The word "shall" was changed to "should" for clarity and consistency with WAC 246-919-885(1).
246-918-870(2)(c) and 246-919- 920(2)(c) – Periodic review	"Modify the phrase 'based on the physician's evaluation of progress towards treatment objectives' to 'based on the physician's evaluation of progress towards or <u>maintenance of</u> treatment objectives"	The rule was changed as a result of this comment. The phrase "or maintenance of" was added for clarity to ensure that the goal for some patients is maintenance of pain level and functional level rather than improvement (progress).
246-918-870(3)(b) and 246-919- 920(3)(b) Periodic review – Chronic pain	"Modify the phrase 'Use of validated tools' to 'Use of validated tools or patient report from reliable patients"	The rule was changed as a result of this comment. The phrase "or patient report from reliable patients" was added because the commission determined it clarified accepted sources of information.

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Applicable WAC as filed under WSR 18- 15-055	Comment/recommended change to proposed rule	Commission response
246-918-885 and 246-919-935 – Consultation- Exemptions for exigent and special circumstances	Update the WAC numbers in the first paragraph to the new WAC numbers.	The rule was changed as a result of this comment. The WAC numbers referenced in the first paragraph were updated to align with the new WAC numbers used in the revised Pain Management sections.
246-918-915(2) and 246-919-965(2) – Episodic care of chronic opioid patients	"Modify the phrase 'should provide additional analgesics, including opioids' to 'should provide additional analgesics, including opioids when appropriate'"	The rule was changed as a result of this comment. The phrase "when appropriate" was added to clarify that opioids should be prescribed only when appropriate.
246-918-925(1) and 246-919-975(1) – Co- prescribing of opioids for patients receiving medication assisted treatment	"Modify the phrase 'shall prescribe opioids for pain relief' to 'shall prescribe opioids <u>when appropriate</u> for pain relief"	The rule was changed as a result of this comment. The phrase "when appropriate" was added to clarify that opioids should be prescribed only when appropriate.
246-918-801 Exclusions	The language in the Exclusions section is different in the PA rules. The language should be substantially similar to the MD rules.	The rule was changed as a result of this comment. The commission determined the MD and PA chapters should be substantially similar. Adding this new language to the PA sections makes them so.

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246-919-895(2)(h)	Remove ";and" at the end of WAC 246-919- 895(2)(h).	The rule was changed as a result of this comment. The "; and" should have been removed as it was inadvertently left in rule after editing subsection (2).
246-918-935 and 246-919-985	There were several requests to adopt a more protective PMP check requirement than on first refill of an opioid prescription and to align with the Agency Medical Director's Group's (AMDG) recommendations.	The rule was not changed as a result of this comment. The commission acknowledged, and committed to, future rulemaking as necessary to address harmonization between the rules promulgated by the commissions and other boards, including at least, but not limited to, the frequency and timing of PMP checks.
246-918-835, 246- 918-840, 246-919- 885, 246-919-890	Requests that the rule align closer to the Bree Collaborative and AMDG supplemental guidance on prescribing opioids for postoperative pain for day supply limits. The comments recommended that the commission establish a seven-day limit for acute perioperative pain unless clinically justified; or a hard limit of 14 days for acute perioperative pain as recommended by the AMDG and the Bree Collaborative. The comments also recommended a three-day limit for youth prescriptions for acute nonoperative pain and perioperative pain.	The rule was not changed as a result of these comments. The commission agreed that the rules need to leave room for exceptions based on the clinical judgment of the practitioner and on specific patient circumstances. The commission also agreed, based on information provided by experts during the rule development process, that day supply or pill limits should not be set based only on the age of the patient.

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246-918-845, 246- 918-855, 246-918- 865, 246-918-870, 246-919-895, 246- 919-905, 246-919- 915, and 246-919- 920	Offered alternative language for several rule sections to request emphasis on specific requirements for biological specimen drug testing.	The rule was not changed as a result of these comments. The commission agreed that room should be left for practitioner judgment regarding the frequency and type of biological specimen testing necessary when treating pain with opioid medications.
246-918-815 and 246-919-925, 246- 919-851	Expressed concerns regarding a four-hour CME on long acting opiates not equally applied to other licensed independent providers; the need for CME on opiate prescribing to include information on long- acting options; proposed exclusion rules not including long term care settings and patients; the potentially high complaints providers will receive for adhering to the new rules; lack of consistency with the Bree Collaborative Guidelines; and lack of patient handout information on opioid prescribing to be reviewed with proposed rules.	The rules were not changed as a result of these comments. The commission noted that WAC 246- 919-925 is guidance only and is similar to existing rules; that exclusion of opioid prescribing requirements for long term care of special patient populations will be tabled for later consideration when more research has been completed; a complaint can be made against a physician or physician assistant at any time, for any reason and the commission must review each complaint; and the rules are not intended to align with the Bree Collaborative since they are minimum requirements rather than best practice.

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246-918-801 and 246-919-851	Requests exclusions for post-acute care, LTAC, long term care, and/or skilled nursing facilities.	The rule was not changed as a result of these comments. The commission felt more research is needed before additional exclusions are added to rule. The commission recognizes that future harmonization of rule language may potentially be required and the rules may need to be opened for necessary amendments.
246-918-800 through 246-918-935 and 246-919-850 through 246-919-985	"Provider Protection: One thing this document does not address is the offering of protection from the high rates of MQAC complaints against providers who abide by the rules, and as a result, are investigated for allegedly inadequately treating/controlling pain. As a victim of this myself by a patient who was being weaned for failure to comply with a contract and retaliated by making a series of complaints, I feel it is of utmost importance that the DOH and MQAC address this concern to ensure a just environment and protection for providers following recommended guidelines."	The rule was not changed as a result of this comment. A complaint can be made against a physician or physician assistant at any time for any reason and the commission must review each complaint.
246-918-800 through 246-918-935 and	"Lack of consistency with some of the Bree Collaborative Guidelines: examples include that	The rule was not changed as a result of these comments. The commission agreed that the rules need to leave room for exceptions based on the

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246-919-850 through 246-919-985	the Bree Collaborative advises referral to chronic pain management if >90 MED"	clinical judgment of the practitioner and on specific patient circumstances.
246-918-815 and 246-919-865	"Patient Education: WAC 246-918-815 indicates a handout provided by the DOH will suffice, that document is not included for review. Additionally, the Bree Collaborative also has a patient education handout, will that meet requirements? There needs to be more detail in this respect in order to reduce ambiguity and ensure compliance."	The rule was not changed as a result of these comments. The rule language does list what should be included in the patient notification.
246-918-801 and 246-919-851	"I recommend the following additional clarifying language: 'While palliative care consultation and/or enrollment in a hospice program is often recommended for patients receiving end-of-life care, such consultation and/or enrollment is not required in order for the treatment of patients with terminal illness with opioids to be excluded from the rules.""	The rule was not changed as a result of these comments. The commission felt more research is needed before additional exclusions are added to rule.
246-919-850 through 246-919-985	Expressed concerns with the rules mandating requirements with the term "shall" as opposed to using the term "should" throughout both chapters. Also concerned with administrative burden physicians will face in managing patients in pain, especially among	The rules were not changed as a result of these comments. The commission considered the liability of each shall within the adopted rule. They determined each shall that remains was necessary. The other comments were not acted upon since no

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	primary care providers. Expressed concerns that the proposed rules were too long and cumbersome to read and understand.	specific rule sections of the proposal were identified by the commenter to be amended.
246-919-970 and 246-919-975	"I find the use of the phrase "medication assisted treatment" (definitions, section 12; section22 (7); co-prescribing, sections 970 and 975) more confusing than helpful. MAT refers to the treatment of substance use disorders but then section 81 does not mention either methadone or buprenorphine. I tried to get away from using MAT entirely as well as the limited listing of scheduled medications and still address the co-prescribing issue. I combined sections - 970 and -975. Section -970: Opioid Prescribing – Simultaneous scheduled medications (1) A practitioner who chooses to provide an opioid to an acute non-operative or perioperative pain patient who is already on one or more scheduled medications must document a clinical care plan justifying the simultaneous use of scheduled medications. A decision whether or not to taper established scheduled	The rule was not changed as a result of these comments. The commission felt the language in the adopted rule was adequate.

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	medications when adding opioids may require input from a previous prescriber or a pain specialist.	
246-918-800 through 246-918-935 and 246-919-850 through 246-919-985	Request for a six month grace period before rules are effective.	The commission's rule will be effective January 1, 2019. The commission plans to start their education on these rules in October 2018. The education will be ongoing.
246-919-850	Strike intent and scope section.	The rule was not changed as a result of this comment. The commission feels the intent and scope section is necessary and contains important information. The intent and scope section does not have requirements so it does not create a burden for providers.
246-919-851(3)	Update the definition of "inpatient".	The rule was not changed as a result of this comment. The commission felt the language in the adopted rule was clear.
246-919-865(1)	Change the word "shall" to "should" in WAC 246- 919-865(1) to read: "The physician shall-should ensure the patient is provided the following information at the first issuance of a prescription for	The rule was not changed as a result of this comment. The items laid out in (1) are requirements so shall is appropriate.

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	opioids and at the transition from acute to subacute, and subacute to chronic:"	
246-919-885 through 246-919-890	Combine acute non-operative and acute perioperative treatment plan sections to help with making the rules concise since the only difference is the quantity of pills that could be addressed.	The rule was not changed as a result of this comment. The commission felt there was enough difference between the two sections to keep them separated.
246-919-885(3)	Strike "a three day supply or less will often be sufficient" as it is a guideline.	The rule was not changed as a result of this comment. The commission felt including this information was important.
246-919-885(3)	Change "shall" to "should" in WAC 246-919-885(3) to read: "The physician shall should not prescribe beyond a seven-day supply without clinical documentation in the patient record to justify the need for such a quantity."	The rule was not changed as a result of this comment. It is a requirement that the physician not prescribe beyond a seven-day supply without clinical documentation which makes "shall" appropriate.
246-919-885(5)	Change "must" to "should" in 246-919-885(4) to read: "Follow-up visits for pain control must <u>should</u> include objectives or metrics to be used to determine treatment success if opioids are to be continued."	The rule was not changed as a result of this comment. The commission felt the "follow-up visit must include objective or metrics to be used to determine treatment success if opioids are to be continued." The rule then provides a list of what those objectives or metrics could be.

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		The commission recognizes that future harmonization of rule language may potentially be required and the rules may need to be opened for necessary amendments.
246-919-885(8)	Change "must" to "should" in WAC 246-919-885(8) to read: "Medication assisted treatment medications must should not be discontinued when treating acute pain"	The rule was not changed as a result of this comment. This commission determined that this is a requirement.
246-919-890(3)	Strike "a three day supply or less will often be sufficient" as it is a guideline.	The rule was not changed as a result of this comment. The commission felt including this information was important.
246-919-890(3)	Change "shall to "should" in WAC 246-919-890(3) to read: "The physician shall should 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."	The rule was not changed as a result of this comment. It is a requirement that the physician not prescribe beyond a fourteen-day supply without clinical documentation which makes "shall" appropriate.
246-919-851(3)	WAC 246-919-851 – Exclusions. Section (3) – We support the WSHA-WSMA joint task force's recommendation to change this language to avoid implementation of rules that vary based on	The rule was not changed as a result of this comment. However, the commission acknowledged that this issue may be reconsidered if the rules are reopened.

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	hospitalization times. We agree with their assessment that the language as proposed in the CR-102 would not be feasible to implement.	
246-919-890(8)	Change "must" to "should" in WAC 246-919-890(8) to read: "Medication assisted treatment medications <u>must should</u> not be discontinued when treating acute perioperative pain except as consistent with the provisions of WAC 246-919-975."	The rule was not changed as a result of this comment. This commission determined that this is a requirement.
246-919-895(3)	Change "must" to "should" in WAC 246-919-895(3) to read: "Follow-up visit for pain control must should include objectives or metrics to be used to determine treatment success if opioids are to be continued." This change would make it consistent with 246-919-890(5) and other requested changes.	The rule was not changed as a result of this comment. The commission felt the "follow-up visit must include objective or metrics to be used to determine treatment success if opioids are to be continued." The rule then provides a list of what those objectives or metrics could be.
246-919-895(3)	Suggestion to revise a proposed requirement to guidance language with the following suggested change for WAC 246-919-895(3) to read: "Follow-up visits for pain control must include objectives or metrics to be used to determine treatment success if opioids are to be continued. This includes, at a minimum: may include:"	The rule was not changed as a result of this comment. The commission recognizes that future harmonization of rule language may potentially be required and the rules may need to be opened for necessary amendments.

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246-919-895 and 246-919-905	Combine subacute and chronic patient evaluation and patient record sections, -895 and -905, to help make the rule more concise since they are nearly identical.	The rule was not changed as a result of this comment. The commission felt there was enough difference between the two sections to keep them separated.
246-919-905	Change "shall" to "should" in WAC 246-919-905 to read: "When the patient enters the chronic pain phase, the patient shall be reevaluated as if presenting with a new disease. The physician shall should include in the patient's record:" Also move -905(3)(d) to the 'must document' area under item 4 – "Assessment" in this section. The risk ranking piece has to stay under a 'shall' or 'must'.	The rule was not changed as a result of this comment. This is a requirement and so must be a "shall".
	Concern that the proposed rules would place a large administrative burden and liability on physicians, other providers and their health care organizations with negative impact on appropriate patient care. Additional concern registered regarding lack of alignment with other professions required to adhere to ESHB 1427.	The rules were not changed as a result of this comment. The commission felt the rules were complying with the requirements of ESHB 1427 sufficiently.

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246-919-920(1)(e)	Strike (1)(e) that reads: "More frequently at the physician's discretion," as this can already occur as needed.	The rule was not changed as a result of this comment. The commission felt including this information was important.
246-919-925	"There is no CME requirement in the other sets of rules for other professions, including nurses, DOs, and podiatric physicians. Please strike 'The physician prescribing long-acting opioids should have a one-time completion of at least four hours of continuing education relating to this topic.""	The rule was not changed as a result of this comment. This is not a requirement – it is optional. This section was unchanged from the previous rule.
246-919-960	What is the definition of "adolescent"?	The rule was not changed as a result of this comment. The commission felt they could not define adolescent and that the rule requires the prescriber base their prescription on the patient's weight as opposed to their age. The commission acknowledged more science-based research on this subject is needed.
246-919-970(2)	Add the term "knowingly" to WAC 246-919-970(2) to read: "If, because of a prior prescription by another provider, a prescription written by a physician <u>knowingly</u> results in a combination of opioids and	The rule was not changed as a result of this comment. The commission felt the "knowingly" was implied.

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	medications described in subsection (1) of this section"	
246-919-980	Change WAC 246-919-980 to read: "The opioid prescribing physician shall confirm or provide a current prescription for naloxone when opioids are prescribed to a high-risk patient who is known to be high-risk for opioid overdose".	The rule was not changed as a result of this comment. "High-risk" is defined in the definitions section.
246-919-985(3)	Modify this subsection to make it clear the PMP check should be only when a medication listed in WAC 246- 919-970 is prescribed in conjunction with an opioid.	The rule was not changed as a result of this comment. The intent of this sentence is related to co- prescribing of medications listed in WAC 246-919- 970 with opioids. The commission felt that since these rules are specifically for prescribing opioids the co-prescribing is implied.
246-919-850	 "You should probably add a line about appropriate pain management doesn't necessarily mean opiates, but can include conservative care options, OTC medications, NSAIDS, muscle relaxers, antidepressants, interventional treatments options, psychiatric care, etc. With the wording left as is, 	The rule was not changed as a result of this comment. The commission will include this information in its education materials on opioid prescribing.

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	physicians will be damned if they do and damned if they don't so to speak. This whole paragraph contradicts the entire proposed rules. We should be encouraged to find alternatives and take people off opiates, although you recognize that some patients will never get off opiates or this transition will be difficult."	
246-919-980	All patients with an active prescription for opioids should have a naloxone prescription.	The rule was not changed as a result of this comment. The commission felt that, at this time, requiring prescribers to also prescribe naloxone to high-risk patients was necessary.
246-918-845, 246- 918-860, 246-918- 865, 246-918-870	Add "drug" in references to "biological specimen test".	The rule was not changed as a result of this comment. The commission felt the adopted language was appropriate.
246-919-850	"We believe the CR-102 is not a concise document and does not provide adequate clarity for clinicians seeking to treat pain within both their clinical judgement and the draft's requirements. We specifically request that the intent section include express assurances to physicians that the rules are not	The rule was not changed as a result of this comment. The commission feels the intent and scope section addresses these concerns adequately. In addition, the commenters did not provide recommendations to specific sections in order for the commission to respond to and take action.
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	inflexible and recognize the importance of sound clinical judgement."	
New section & new definition	Recommended that the commission add a new section concerning chronic and high dose patients with established provider relationships and add a definition of "nonconsensual tapering" to the definitions section.	The rule was not changed as a result of this comment. The commission agreed that the decision whether or not to taper or continue current levels of opioid treatment is dependent on the clinical judgment of the practitioner and is patient specific.
	"Keep acute pain and post-operative pain separate. The Bree Collaborative supplement to the AMDG guidelines was created in order to embrace the nuances and differences in approach. By defining categories of surgical procedures based on invasiveness, one can match the duration of opioid treatment to specific procedures. That is not the case for most acute painwhich is why we continue to urge to keep these separate."	The rule was not changed as a result of this comment. These phases of pain are considered by the commission to be separate.
246-919-890(3)	"Modify the statement that a 3 day supply or less will often be sufficient as follows: "A three day supply or less will often be sufficient for some types of surgery." Why: The Bree	The rule was not changed as a result of this comment. The commission felt more research should be done before considering this change.

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	Collaborative's very recently released document on prescribing opioids for post-op pain categorizes almost 30 surgeries into 3 types, and suggests that a supply of up to 3 days is typical for so-called Type I, a supply of up to 7 days is typical for so-called Type II, and up to 14 days for Type III. So a 3 day supply or less is only "often sufficient" for so-called Type I surgeries.	
246-919-890(5)	Change "should" to "must" in WAC 246-919-890(5) to read: "Follow-up visits for pain control should <u>must</u> include" to be consistent with WAC 246-919-885 and 246-919-895.	The rule was not changed as a result of this comment. The commission felt the adopted language was clear.
246-919-985(7)	Modify this subsection to make it clear the PMP check should be only when a medication listed in WAC 246- 919-970 is prescribed in conjunction with an opioid.	The rule was not changed as a result of this comment. The intent of this sentence is related to co- prescribing of medications listed in WAC 246-919- 970 with opioids. The commission felt that since these rules are specifically for prescribing opioids the co-prescribing is implied.
246-918-800 through 246-918-935 and	"Similarly, three Boards and Commissions (osteopathic, medical, and podiatric) removed	The rule was not changed as a result of this comment. However, the commission agreed to move this language to the Intent and Scope section.

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246-919-850 through	language recommended by the Task Force under the	
246-919-985	perioperative section, 'For more	
	specific best practices, the (osteopath, physician,	
	podiatrist) may refer to clinical practice	
	guidelines including, but not limited to, those	
	produced by the Agency Medical Directors' Group,	
	the Centers for Disease Control and Prevention, or the	
	Bree Collaborative.' I recommend that you restore this	
	language as being consistent with the legislative	
	intent."	
246-918-935 and	"Additionally, as I have previously communicated in	The rule was not changed as a result of this
246-919-985	my letter co-signed by Attorney General Ferguson, I	comment. The commission discussed this issue at
	am concerned about the Commission's decision to	length. The decision to require the PMP check at
	only require a check of the Prescription Monitoring	first refill/renewal was based on comments from
	Program (PMP) upon the first refill of an opioid	stakeholders and prescribers. The commission felt
	prescription. While that is an important improvement	first refill/renewal along with the periodic checks
	over the recommendation of the Opioid Prescribing	based on the patient's risk level was adequate
	Task Force, this standard still falls short of the AMDG	protection. In the adopted rule, PMP checks are
	recommendation to require a PMP check before initial	required for every opioid prescription if the
	opioid prescriptions. Of note, preliminary state	prescriber's EHR has the PMP integrated (WAC
	performance metrics show improvement in every	246-918-935(7) and WAC 246-919-985(7)).
	opioid prescription standard except the duration of	

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	first fill. I urge you to adopt a more protective requirement that is at least in line with the AMDG's recommendation."	
246-918-910 and 246-919-960	"because youth are particularly vulnerable to opioid misuse, even when initial use is for a legitimate medical purpose, I renew my previous request that you revise the rules to establish a three- day limit for youth prescriptions for acute pain and perioperative pain following surgical procedures with expected rapid recovery."	The rule was not changed as a result of this comment. The commission heard from experts on this issue and felt the best practice regarding prescribing opioids to youth was to base the prescription on the patient's weight as opposed to their age. The commission recognizes that future harmonization of rule language may potentially be required and the rules may need to be opened for necessary amendments.
246-919-875	"Providence supports the Commission's requirement for all prescribing physicians to complete the CME as outlined. We believe that taken in conjunction with the additional four-hour requirement for those prescribing long-acting opioids, the provision included here focusing on opioid prescribing rules makes sense. We do however urge the Commission to consider making this training as easy to complete as possible for all prescribing physicians, so as not to discourage or further stigmatize opioid prescribing. The training	The rule was not changed as a result of this comment. The commission does plan to create a webinar regarding these rules and opioid prescribing. The webinar will be at least one hour in length, will be approved for CME, and will be free of charge.

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	should be available online, and the Commission should consider including information on their website for where physicians can receive the training free of charge when available."	
246-919-925	"According to the latest FDA requirements regarding opioid training, we believe the designation of separate requirements for the use of 'long-acting' vs. 'short- acting' opioids is outdated terminology. We recommend instead that there be the same set of standards for physicians prescribing opioids, and agree with the Commission's proposed rule for a four-hour continuing education component on this topic."	The rule was not changed as a result of this comment. The commission felt more research should be done before considering this change.
246-919-940	"In addition to the exemptions currently listed, our internal experts agree that there should be an exemption from the consultation requirement for physicians boarded in addiction psychiatry and in addiction medicine. These physicians have specialized training in high risk populations and should be exempt from the consultation requirements in order to ensure that we are not creating additional barriers to care for patients, knowing that there is a significant shortage at	The rule was not changed as a result of this comment. The commission felt more research should be done before considering this change.

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	the state and national levels for pain specialists and addiction medicine specialists."	
246-918-835, 246- 918-840, 246-919- 885, and 246-919- 890	 "To further protect public health and safety, I also urge you to reduce the amount of opioids allowed to be prescribed after surgery. This will make fewer unnecessary pills available for misuse and decrease the chances that youth and adults become dependent. I understand that the Bree Collaborative and AMDG Supplemental Guidance on Prescribing Opioids for Postoperative Pain was not finalized when the Opioid Prescribing Task Force convened. However, since it is now available, I request that you incorporate the latest scientific evidence before finalizing the rule. According to Bree/AMDG, more than a seven-day supply will rarely be needed following surgery; fourteen days is only warranted for major procedures. Please consider, in order of preference: Establishing a seven-day limit for acute perioperative pain, as you have proposed for acute non-operative pain, while permitting prescribers to exercise discretion to prescribe more opioids with clinical documentation to 	The rule was not changed as a result of this comment. The commission felt that the adopted language, which requires documentation when prescribing beyond the 7 or 14 day limit, is best practice.

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	 justify the need for such a quantity; or failing that, Establishing a hard limit of fourteen days for acute perioperative pain, as recommended by AMDG and the Bree Collaborative (i.e., "The initial prescription at discharge shall not exceed fourteen days"). 	
246-918-910 and 246-919-960	"Because youth are particularly vulnerable to opioid misuse, even when initial use is for a legitimate medical purpose, I also request that you revise the rules to establish a three-day limit for youth prescriptions for acute pain and perioperative pain following surgical procedures with expected rapid recovery."	The rule was not changed as a result of this comment. The commission heard from experts on this issue and felt the best practice regarding prescribing opioids to youth was to base the prescription on the patient's weight as opposed to their age.
246-919-865	"Drugs are not controlled by patients, so we question whether the patient notification provisions are relevant or helpful."	The rule was not changed as a result of this comment. The commission, along with the other boards and commissions, felt patient notification is an important part of opioid prescribing and that requiring notification of risks and disposal is a best practice for opioid prescribing.
	"It is imperatively to incorporate into the rules making on Opiate Prescribing, language and statements for any prescription of narcotics to have a conversation	The rule was not changed as a result of this comment. The rule does include requirements to

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	with their patients around the importance of secure medicine return and locking up medication while it is in the house. This simple conversation of 15-30 seconds will help keep prescriptions from falling into persons hands inappropriately. According to the American Society of Addiction Medicine 80% of new heroin users start with inappropriate use of narcotic medication, locking up medication when it is in the home, and getting rid of unused medication is so very important. With the new statewide rollout of secure medicine return, having a one-stop resource such as ttp://www.takebackyourmeds.org/ is vital to cross promote at that crucial moment from a prescriber.	notify patients of the risks, secure storage, and disposal of opioids in WAC 246-919-865.
	"I would like to weigh in on my plight as a user of opioids for over 10 years. My Doctor, Roy Gondo, in Yakima, is a very good doctor and wants to treat his patients and HE sees fit with all of his training, and not you idiot politicians deciding what they can and cannot prescribe to their patients. I have a neck fusion of 5 vertebra in my neck and a back fusion in 2008 when I was 52 years old, then another back fusion in 2010, and another in 2012. I refuse to have any more and although it's hard to say how I would be doing	The rule was not changed as a result of this comment. The commenter did not provide recommendations to specific sections in order for the commission to respond to and take action.

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	 without these, I don't feel like they were all that successful. My back has been very painful since the first symptoms and Dr. Gondo has treated me fairly and got me working, with the help of opioids. I have a very physically demanding job and would be almost impossible to get even 5-6 hours a day in without the help of opioids, and yes, I have tried all the others and nothing helps at all with the exception of Ibuprofen. I have never abused them, have had 4 or 5 tests to make sure I am taking them, never had kids or grandkids steal them, etc. Furthermore, I would like to refer you to some research, (if you know what that is) Greg Gutfeld did a lot of research and has findings that are almost completely ignored. Why don't they "RESEARCH" stuff? They are killing people with these ignorant policies and depriving millions of people like me that depend on these to get by, even work some. I only take 3 10 MG per day, cut back drastically and still hurts pretty bad, but if these policies go through, even those will be in jeopardy. Please reconsider and 	

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	"RESEARCH""!!! Opioids play a very important role in many peoples lives and your policies put them at risk while the real problem is heroin abusers."	
	Concerns regarding the increased regulatory work, administrative burden for prescribers. Indicated the rules should be workable within the limited context of a patient encounter. Documentation and care plan requirements should not be so onerous as to make addressing the patient's medical condition impossible in that amount of time.	The rule was not changed as a result of this comment. The commission considered this during the rulemaking process and determined that the new rules that will provide clear guidance, compliance with statutory requirements, and will achieve the statutorily identified general goals and specific objectives described in chapter 18.71 RCW, chapter 18.71A RCW, and ESHB 1427.
	"The rules must permit physicians to exercise their professional judgement by providing the necessary flexibility to ensure patients will receive appropriate treatment for their pain. Blunt mechanisms intended to lower the number of opioid prescriptions in the community would be successful in that goal but would also prevent some patients from accessing clinically appropriate treatments. Unlike blood pressure or temperature, the unpleasant reaction to pain is difficult to quantify or predict. Pain is both a sensory and emotional state and varies3 greatly from person to person; individuals each have different expressions of	The rule was not changed as a result of this comment. The commenter did not provide recommendations to specific sections in order for the commission to respond to and take action.

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	the receptors that respond to pain stimuli. Patient's past experiences, fear, personal expectations, genetics, hormones, sleep patterns, other medications, and societal norms all contribute to the complexity of treating pain. We appreciate the documented exception present in the CR-102 that permits physicians to exercise their professional judgment when treating unique patient conditions. We believe this kind of policy strikes an effective balance by holding physicians and other prescribers to limits while not prohibiting access to appropriate care."	
	"The rules must consider that Washington state has been a leader in addressing the opioid epidemic and has seen sustained reduction in the number of opioids prescribed and associated harm. This reduction was the result, in part, of publication of the first opioid prescribing guideline (2007, 2015), repeal of permissive intractable pain laws (2010), and promulgation of new standards for all prescribers, including chronic pain rules (2010). These efforts have led to a sustained reduction in the number of opioids prescribed and associated harms; including a	The rule was not changed as a result of this comment. The commenter did not provide recommendations to specific sections in order for the commission to respond to and take action.

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	44% decline in the number of unintentional	
	prescription opioid deaths in Washington."	
	"The rules must consider the opioid epidemic is	The rule was not changed as a result of this
	evolving. Emerging data is starting to challenge the	comment. The commenter did not provide
	long held popular narrative that people start on	recommendations to specific sections in order for
	prescription drugs and then move to heroin. According	the commission to respond to and take action.
	to a	
	study released by Addictive Behaviors9 in Nov. 2017,	
	in 2005, only 8.7% of opioid initiators started with	
	heroin, but this sharply increased to 33.3% (p<0.001)	
	in 2015, with no evidence of stabilization. The use	
	of commonly prescribed opioids, oxycodone and	
	hydrocodone, dropped from 42.4% and 42.3% of	
	opioid initiators, respectively, to 24.1% and 27.8% in	
	2015, such that heroin as an initiating opioid was now	
	more frequently endorsed than prescription opioid	
	analgesics. The authors conclude as the most	
	commonly prescribed opioids - hydrocodone and	
	oxycodone - became less accessible due to supply-side	
	interventions, the use of heroin as an initiating opioid	
	has grown at an alarming rate. Given that opioid	

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	novices have limited tolerance to opioids, a slight imprecision in dosing inherent in heroin use is likely to be an important factor contributing to the growth in heroin-related over dose fatalities in recent years. Inappropriate prescribing of opioid drugs continues to be a contributing factor to the epidemic that must be addressed, but interventions must consider recent trends and acknowledge that the United States and Washington are facing two opioid epidemics; one prescription, the other from illicit drugs." Concerns expressed that the PMP is database is difficult to access and cumbersome to navigate in the limited context of a patient encounter.	The rule was not changed as a result of this comment. The commission acknowledged that the legislature can do more to ensure the PMP database if more accessible and user friendly to physicians and other prescribing professions.
	Concern that the rules do not have a "freezing effect" on the treatment of painthat opioids are a very effective drug for relief from human pain and suffering. Requested that the authors of the rule language not swing the pendulum from 'overtreatment	The rules were not changed as a result of this comment. The comments did not reference specific sections to amend and as a result, no action was taken by the commission.

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	with opioids, to under-treatment in clinically appropriate circumstances.	
	Requested the ability to use MS Contin (morphine) as needed for high-risk patients.	The rule was not changed as a result of this comment. The commission considered this alternative language but felt the proposed rule was clearer and more responsive to the mandate of ESHB 1427
	A general concern from a citizen.	The rules were not changed as a result of this comment. The commenter did not request a specific change to the proposed rules.
	A general concern from an MD.	The rules were not changed as a result of this comment. The commenter did not request a specific change to the proposed rules.
	General concerns about legislating the prescribing of opioids as well as comments regarding tapering requirements.	The rule was not changed as a result of these comments. The commenter did not identify specific sections of the rule that they would like changed regarding their concern about legislating the specifics of proper medical care.

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	Concerned about time/costs of a 3-minute query to the PMP and asked that all providers be on electronic medical records (EMRs). Until they are, requested that the PMP checks that are required be limited to a reasonable threshold.	The rules were not changed as a result of this comment. The commission acknowledges that improvements in the state's PMP database are needed to assist providers in complying with the proposed rules. However, until legislation is introduced to modify the state's current system to allow for EMRs statewide, the commission feels the proposed rules are responsive to ESHB 1427's mandate and the frequency and timing of PMP checks that equate to three minutes per query are not overly burdensome.
	General concerns were expressed regarding the increasing regulatory work proposed and resulting decrease in appropriate and effective pain medications in many, if not most, situations. Concerns about unintended consequences of the opioid prescribing rules.	The rule was not changed as a result of these comments. The commenter did not identify specific sections of the rule that they would like changed.
	A general concern from a citizen.	The rules were not changed as a result of this comment. The commenter did not request a specific change to the proposed rules.

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	Commenter expressed concerns about restricting opioids for chronic pain patients.	The rules were not changed as a result of this comment. The commenter did not request a specific change to the proposed rules.
	General concerns about the proposed rules making the current epidemic worse.	The rules were not changed as a result of these comments. The commenter did not request any specific changes to the proposed rules.
	General concerns from a chronic pain patient.	The rule was not changed as a result of this comment. The commenter did not request a specific change to the proposed rules.
	General concerns from a chronic pain patient.	The rule was not changed as a result of this comment. The commenter did not request a specific change to the proposed rules.
	General concerns from a chronic pain patient.	The rule was not changed as a result of this comment. The commenter did not request a specific change to the proposed rules.
	General concerns from a chronic pain patient.	The rule was not changed as a result of this comment. The commenter did not request a specific change to the proposed rules.

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	General concerns from a chronic pain patient.	The rule was not changed as a result of this comment. The commenter did not request a specific change to the proposed rules.
	General concern from a chronic pain patient.	The rule was not changed as a result of this comment. The commenter did not request a specific change to the proposed rules.
	Concerns about a dose ceiling.	The rule was not changed as a result of this comment. The commenter did not request a specific change to the proposed rules.
	Multiple comments were received in writing and were presented orally at the public hearing regarding concerns about regulating the practice of medical care and of limiting opioid prescribing and dose ceilings for chronic pain patients.	The rules were not changed as a result of these comments. These comments did not request a change or changes to specific proposed rules.

Please direct any questions regarding this rule adoption to Daidria Amelia Underwood at 360-236-2727 or medical.rules@doh.wa.gov.