PROPOSED RULE MAKING

CR-102 (June 2024)
(Implements RCW 34.05.320)
Do **NOT** use for expedited rule making

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FILED

DATE: August 30, 2024
TIME: 2:24 PM

WSR 24-18-091

Agency: Department of Health - Washington Medical Commission

☐ **Original Notice**

☒ **Supplemental Notice to WSR** 24-07-106

☐ **Continuance of WSR**

☒ **Preproposal Statement of Inquiry was filed as WSR** 23-17-094 **; or**

☐ **Expedited Rule Making--Proposed notice was filed as WSR _____; or**

☐ **Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1); or**

☐ **Proposal is exempt under RCW _____.**

Title of rule and other identifying information: (describe subject)
General provisions for opioid prescribing and tapering rules for allopathic physicians and physician assistants. The Washington Medical Commission (commission) is proposing amendments to the commission's opioid prescribing rules to exclude patients with sickle cell disease, to clarify tapering considerations, and in this supplemental to clarify the use of biological specimen testing. The proposed rules amend WAC 246-918-801 Exclusions, WAC 246-918-870 Periodic Review—Chronic pain, and WAC 246-918-900 Tapering considerations—Chronic pain for physician assistants, as well as WAC 246-919-851 Exclusions, WAC 246-919-920 Periodic Review—Chronic pain, and WAC 246-919-950 Tapering considerations—Chronic pain for allopathic physicians.

Hearing location(s):

Date:	**Time:**	**Location:** (be specific)	**Comment:**
October 11, 2024	9:45 am	**Virtually:** Register for this virtual meeting to be held via Teams Webinar: https://tinyurl.com/ycxn37ve **In person:** Department of Health 111 Israel Rd SE, Room 166 Tumwater, WA 98501	The public hearing will be hybrid. Participants can attend at the physical location, or virtually by registering on Teams. To join the WMC's Rules interested parties email list, please visit: https://public.govdelivery.com/accounts/WADOH/subscriber/new?topic_id=WADOH_153

Date of intended adoption: October 11, 2024 (Note: This is **NOT** the **effective** date)

Submit written comments to:	**Assistance for persons with disabilities:**
Name: Amelia Boyd, Program Manager	Contact: Amelia Boyd, Program Manager
Address: PO Box 47866, Olympia, WA 98504-7866	Phone: 1 (800) 525-0127
Email: https://fortress.wa.gov/doh/policyreview/	Fax: N/A
Fax: N/A	TTY: 711
Other: medical.rules@wmc.wa.gov	Email: doh.information@doh.wa.gov
Beginning (date and time): Beginning on the date and time of this filing	Other:
By (date and time): October 4, 2024 at 11:59 pm	By (date): October 4, 2024

Purpose of the proposal and its anticipated effects, including any changes in existing rules:
On November 3, 2022, the Center for Disease Control and Prevention (CDC) released the Clinical Practice Guideline for Prescribing Opioids for Chronic Pain (https://www.cdc.gov/opioids/healthcare-professionals/prescribing/guideline/index.html) (Guideline). This Guideline updated the *CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016* (2016

Guideline). Since the release of the 2016 Guideline, new evidence has emerged on the benefits and risks of prescription opioids for both acute and chronic pain as compared to non-opioid treatments, dosing strategies, opioid dose dependent effects, risk mitigation strategies, and opioid tapering and discontinuation. The update expands the 2016 Guideline to provide evidence-based recommendations for prescribing opioid pain medication for acute, subacute, and chronic pain for outpatients aged ≥18 years, excluding pain management related to sickle cell disease, cancer-related pain treatment, palliative care, and end-of-life care. This update leverages new data to expand content on prescription opioids for acute and subacute pain throughout the recommendations.

RCW 18.71.800 and RCW 18.71A.800 directs the commission to consider the guidelines from the CDC when developing opioid prescribing rules. As such, when the new Guideline was released in 2022, the commission contracted with Gregory Terman, MD, to do a comprehensive comparison of the commission's opioid prescribing rules covering physicians (WAC 246-919-850 through 246-919-990) and physician assistants (WAC 246-918-800 through 246-918-835) to the Guideline. Dr. Terman is a former Pro Tempore Commissioner of the commission as well as a Professor of Anesthesiology and Pain Medicine at the University of Washington in Seattle. Dr. Terman was asked to recommend changes to the commission's opioid prescribing rules based on the differences found between the commission's opioid prescribing rules and the Guideline. Dr. Terman provided the commission with a report, titled "Comparing and Contrasting the 2022 CDC Opioid Prescribing Guideline and the 2019 Washington State Prescribing Rules" (Report). Based on the recommendations in the Report, the commission is proposing amending the rules as follows:

1) Exempting patients with Sickle Cell Disease;
2) Stating in rule that not all chronic pain patients need to be tapered off opioids;
3) Stating in rule that decisions regarding patient treatment should not be based solely on one aberrant biological specimen test; and
4) As a result of the previous public rules hearing, reinstating language requiring biological testing at certain intervals for chronic pain patients.

Reasons supporting proposal:
The commission is proposing rules based on the following recommendations from Dr Terman's report:

1. Exempting patients with Sickle Cell Disease: The Guideline exempts Sickle Cell Disease along with cancer and patients receiving palliative or end-of-life care and states that these patients "can be at risk for inadequate pain treatment." The commission's rules already exclude patients with cancer and the provision of palliative, hospice, or other end-of-life care because those patients typically need a different level of care than a patient with chronic pain that is not related to cancer, palliative, or end-of-life care.

2. Stating in rule that not all chronic pain patients need to be tapered off opioids: Since their opioid rules were updated in 2018, the commission has seen a number of complaints from chronic pain patients who have been tapered too rapidly or their opioid regimen has been discontinued completely. The Department of Health released a statement on September 20, 2019, that spoke to this issue:

   "Neither the Washington State opioid prescribing rules nor the CDC opioid prescribing guideline support rapidly tapering or discontinuing opioids for patients on existing opioid doses exceeding 90 mg MME per day under most circumstances. Abruptly tapering or discontinuing opioids in a patient who is physically dependent may cause serious patient harms including severe withdrawal symptoms, uncontrolled pain, psychological distress, and in rare instances, suicide."

   In the Report, Dr. Terman notes: "The CDC states that one of the primary reasons for updating the rules, was 'misapplication of the 2016 CDC Opioid Prescribing Guideline (66), benefits and risks of different tapering strategies and rapid tapering associated with patient harm (68,71–73), challenges in patient access to opioids (6), patient abandonment and abrupt discontinuation of opioids (71)' (page 4). In perhaps the clearest example of the CDC attempting to avoid inflexible interpretations of this version of the Guideline, CDC removed all specific doses and durations from all 12 of the 2022 recommendations – relegating the same doses seen in the 2016 recommendations (based largely on the same data) to the supporting text. The Rules (commission's rules) attempted to avoid dose-focused inflexibility of care by reassuring prescribers that 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" (WAC 246-919-850). Whether this has been successful in avoiding opioid treatment related patient stigma, abandonment and inappropriate discontinuation of opioids is a matter of discussion beyond the scope of this document but the desire to avoid these patient punishments is clearly a similarity between the CDC and the Rules." The commission believes that including in the rule a statement that tapering is not always necessary would be beneficial for achieving this objective.

3. Stating in rule that decisions regarding patient treatment should not be based solely on one aberrant biological specimen test: In the Report, Dr. Terman highlights that both the commission's rules and the Guideline recognize biological specimen testing, such as urine toxicology testing, as an effective risk mitigation strategy for subacute and chronic opioid prescribing. He goes on to say that the Guideline describes the correct utilization of biological specimen testing involves applying it universally to prevent bias, emphasizing discussions over punishment for unexpected results, and integrating results into broader clinical assessments to formulate action plans following unexpected outcomes. The commission's rules do not address how to handle an unexpected result. Additionally, the commission has received reports that physicians and physician assistants have stopped prescribing opioids and, in some cases, dismissed patients solely based on a single abnormal biological specimen test. This abrupt change in a patient's care greatly raises the risk of patient harm. By providing some guidance in rule regarding biological specimen testing, the commission is working toward reducing patient harm.

RCW 18.71.800 and 18.71A.800 require that the commission consider the Agency Medical Directors Group (AMDG) and CDC guidelines when adopting rules regarding opioid prescribing. The proposed rules implement the statute's goals and objectives by:

1) Revising the established rules to be consistent with the CDC's Guideline; and

2) Supporting the overarching goals of RCW 18.71.015 by protecting and promoting public health, safety, and welfare.

On April 26, 2024, a rule hearing was held, during which concerns were raised about the proposed removal of "biological testing" from subsection (1) of both the Periodic Review—Chronic pain sections: WAC 246-918-870 and WAC 246-919-920. Due to these concerns, a follow-up workshop was held on June 4, 2024. At this workshop, interested parties, staff and Commissioners worked together to refine the draft language. The revised proposal now includes "biological testing" once again, necessitating this supplemental proposal.

Statutory authority for adoption: RCW 18.71.017, 18.71.800, 18.71A.800, and 18.130.050

Statute being implemented: RCW 18.71.800 and 18.71A.800

Is rule necessary because of a:

Federal Law?	☐ Yes	☒ No
Federal Court Decision?	☐ Yes	☒ No
State Court Decision?	☐ Yes	☒ No

If yes, CITATION:

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters: None

Name of proponent: (person or organization) Washington Medical Commission
Type of proponent: ☐ Private. ☐ Public. ☒ Governmental.

Name of agency personnel responsible for:

Name	Office Location	Phone
Drafting: Amelia Boyd	111 Israel Rd SE, Tumwater, WA 98501	360-918-6336
Implementation: Kyle Karinen	111 Israel Rd SE, Tumwater, WA 98501	360-236-4810
Enforcement: Kyle Karinen	111 Israel Rd SE, Tumwater, WA 98501	360-236-4810

Is a school district fiscal impact statement required under RCW 28A.305.135? ☐ Yes ☒ No
If yes, insert statement here:

The public may obtain a copy of the school district fiscal impact statement by contacting:
Name
Address
Phone
Fax
TTY
Email
Other

Is a cost-benefit analysis required under RCW 34.05.328?

☒ Yes: A preliminary cost-benefit analysis may be obtained by contacting:
Name: Amelia Boyd, Program Manager

Address: PO Box 47866, Olympia, WA 98504-7866
Phone: 360-918-6336
Fax: N/A
TTY: 711
Email: medical.rules@wmc.wa.gov
Other:

☐ No: Please explain:

Regulatory Fairness Act and Small Business Economic Impact Statement
Note: The Governor's Office for Regulatory Innovation and Assistance (ORIA) provides support in completing this part.

(1) Identification of exemptions:
This rule proposal, or portions of the proposal, **may be exempt** from requirements of the Regulatory Fairness Act (see chapter 19.85 RCW). For additional information on exemptions, consult the exemption guide published by ORIA. Please check the box for any applicable exemption(s):

☐ This rule proposal, or portions of the proposal, is exempt under RCW 19.85.061 because this rule making is being adopted solely to conform and/or comply with federal statute or regulations. Please cite the specific federal statute or regulation this rule is being adopted to conform or comply with, and describe the consequences to the state if the rule is not adopted.
Citation and description:

☐ This rule proposal, or portions of the proposal, is exempt because the agency has completed the pilot rule process defined by RCW 34.05.313 before filing the notice of this proposed rule.

☐ This rule proposal, or portions of the proposal, is exempt under the provisions of RCW 15.65.570(2) because it was adopted by a referendum.

☐ This rule proposal, or portions of the proposal, is exempt under RCW 19.85.025(3). Check all that apply:

- ☐ RCW 34.05.310 (4)(b) (Internal government operations)
- ☐ RCW 34.05.310 (4)(c) (Incorporation by reference)
- ☐ RCW 34.05.310 (4)(d) (Correct or clarify language)
- ☐ RCW 34.05.310 (4)(e) (Dictated by statute)
- ☐ RCW 34.05.310 (4)(f) (Set or adjust fees)
- ☐ RCW 34.05.310 (4)(g) ((i) Relating to agency hearings; or (ii) process requirements for applying to an agency for a license or permit)

☒ This rule proposal, or portions of the proposal, is exempt under RCW 19.85.025(4). (Does not affect small businesses).

☐ This rule proposal, or portions of the proposal, is exempt under RCW _____.

Explanation of how the above exemption(s) applies to the proposed rule: The proposed rules do not impact businesses, they only impact providers.

(2) Scope of exemptions: *Check one.*

☒ The rule proposal: Is fully exempt. *(Skip section 3.)* Exemptions identified above apply to all portions of the rule proposal.

☐ The rule proposal: Is partially exempt. *(Complete section 3.)* The exemptions identified above apply to portions of the rule proposal, but less than the entire rule proposal. Provide details here (consider using this template from ORIA):

☐ The rule proposal: Is not exempt. *(Complete section 3.)* No exemptions were identified above.

(3) Small business economic impact statement: *Complete this section if any portion is not exempt.*

If any portion of the proposed rule is **not exempt**, does it impose more-than-minor costs (as defined by RCW 19.85.020(2)) on businesses?

☐ No Briefly summarize the agency's minor cost analysis and how the agency determined the proposed rule did not impose more-than-minor costs.

☐ Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses and a small business economic impact statement is required. Insert the required small business economic impact statement here:

The public may obtain a copy of the small business economic impact statement or the detailed cost calculations by contacting:

Name
Address
Phone
Fax

TTY
Email
Other

Date: August 29, 2024 **Name:** Kyle Karinen **Title:** Executive Director, Washington Medical Commission	**Signature:** Signature on file

AMENDATORY SECTION (Amending WSR 22-22-039, filed 10/25/22, effective 11/25/22)

WAC 246-918-801 Exclusions. WAC 246-918-800 through 246-918-935 do not apply to:

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

(2) The treatment of patients with sickle cell disease;

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

((~~(3)~~)) (4) The provision of procedural medications;

((~~(4)~~)) (5) The treatment of patients who have been admitted to any of the following facilities for more than 24 hours:

(a) Acute care hospitals licensed under chapter 70.41 RCW;

(b) Psychiatric hospitals licensed under chapter 71.12 RCW;

(c) Nursing homes licensed under chapter 18.51 RCW and nursing facilities as defined in WAC 388-97-0001;

(d) Long-term acute care hospitals as defined in RCW 74.60.010; or

(e) Residential treatment facilities as defined in RCW 71.12.455; or

((~~(5)~~)) (6) The treatment of patients in residential habilitation centers as defined in WAC 388-825-089 when the patient has been transferred directly from a facility listed in subsection ((~~(4)~~)) (5) of this section.

AMENDATORY SECTION (Amending WSR 18-23-061, filed 11/16/18, effective 1/1/19)

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.

(5) Biological specimen testing should not be used in a punitive manner but should be used in the context of other clinical information to inform and improve patient care. Physician assistants should not dismiss patients from care on the basis of a biological specimen test result alone.

AMENDATORY SECTION (Amending WSR 18-23-061, filed 11/16/18, effective 1/1/19)

WAC 246-918-900 Tapering considerations—Chronic pain. Not all chronic pain patients will need their opioid prescriptions tapered. Relying on medical decision making and patient-centered treatment, 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.

AMENDATORY SECTION (Amending WSR 22-22-039, filed 10/25/22, effective 11/25/22)

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

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

(2) The treatment of patients with sickle cell disease;

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

((~~(3)~~)) (4) The provision of procedural medications;

((~~(4)~~)) (5) The treatment of patients who have been admitted to any of the following facilities for more than 24 hours:

(a) Acute care hospitals licensed under chapter 70.41 RCW;

(b) Psychiatric hospitals licensed under chapter 71.12 RCW;

(c) Nursing homes licensed under chapter 18.51 RCW and nursing facilities as defined in WAC 388-97-0001;

(d) Long-term acute care hospitals as defined in RCW 74.60.010; or

(e) Residential treatment facilities as defined in RCW 71.12.455; or

((~~(5)~~)) (6) The treatment of patients in residential habilitation centers as defined in WAC 388-825-089 when the patient has been transferred directly from a facility listed in subsection ((~~(4)~~)) (5) of this section.

AMENDATORY SECTION (Amending WSR 18-23-061, filed 11/16/18, effective 1/1/19)

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.

(5) Biological specimen testing should not be used in a punitive manner but should be used in the context of other clinical information to inform and improve patient care. Physicians should not dismiss patients from care on the basis of a biological specimen test result alone.

AMENDATORY SECTION (Amending WSR 18-23-061, filed 11/16/18, effective 1/1/19)

WAC 246-919-950 Tapering considerations—Chronic pain. Not all chronic pain patients will need their opioid prescriptions tapered. Relying on medical decision making and patient-centered treatment, 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.