



# PROPOSED RULE MAKING

## CR-102 (December 2017) (Implements RCW 34.05.320)

Do NOT use for expedited rule making

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STATE OF WASHINGTON  
FILED

DATE: October 14, 2019

TIME: 1:43 PM

WSR 19-21-083

**Agency:** Department of Health- Board of Osteopathic Medicine and Surgery

**Original Notice**

**Supplemental Notice to WSR**

**Continuance of WSR**

**Preproposal Statement of Inquiry was filed as WSR 19-15-006 ; 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).**

**Proposal is exempt under RCW .**

**Title of rule and other identifying information:** (describe subject) WAC 246-853-675 (osteopathic physicians) Patient notification, secure storage, and disposal and WAC 246-854-255 (osteopathic physician assistants) Patient notification, secure storage, and disposal. The Board of Osteopathic Medicine and Surgery (board) is proposing amendments to establish patient notification, documentation, counseling requirements, and right to refuse an opioid prescription or order for any reason, when prescribing opioid drugs, as directed by Substitute Senate Bill (SSB) 5380 (chapter 314, Laws of 2019), codified as RCW 18.57.810 and RCW 18.57A.810. The board is also proposing clarifications of when notification is not required.

**Hearing location(s):**

Date:	Time:	Location: (be specific)	Comment:
12/06/2019	9:00 a.m.	Department of Health Creekside at Centerpointe Suite 310, Room 309 20425 72nd Avenue South Kent, WA 98032	

**Date of intended adoption:** 12/06/2019 (Note: This is **NOT** the effective date)

**Submit written comments to:**

Name: Tracie Drake

Address: P.O. Box 47852  
Olympia, WA 98504-7852

Email: <https://fortress.wa.gov/doh/policyreview>

Fax: 360-236-2901

Other:

By (date) 11/27/2019

**Assistance for persons with disabilities:**

Contact Tracie Drake

Phone: 360-236-4766

Fax: 360-236-2901

TTY: (360) 833-6388 or 711

Email: [osteopathic@doh.wa.gov](mailto:osteopathic@doh.wa.gov)

Other:

By (date) 11/27/2019

**Purpose of the proposal and its anticipated effects, including any changes in existing rules:** SSB 5380 requires the board, along with the Washington Medical Commission, Dental Quality Assurance Commission, Podiatric Medical Board, and Nursing Care Quality Assurance Commission to adopt or amend rules establishing additional patient notification and right to refuse requirements.

Sections 5 and 6 of SSB 5380, codified as RCW 18.57.810 and RCW 18.57A.810, direct the board to adopt or amend the opioid prescribing rules by January 1, 2020, to establish the requirement for osteopathic physicians and osteopathic physician assistants to notify patients of their right to refuse an opioid prescription or order and to document any refusal.

Section 17 of SSB 5380, codified as RCW 69.50.317, requires the prescribing practitioner, prior to the first opioid prescription, to discuss with the patient risks of opioids, pain management alternatives to opioids, and provide the patient a written copy of the warning language. The proposed rules are amended to include pain management alternatives in the patient notification.

In addition, the proposed rules clarify situations where the notification requirements would not apply. Specifically, notification requirements would not apply to emergent care, situations where pain represents a significant health risk, procedures involving administration of medications, when a patient is unable to grant or revoke consent, or for medication assisted treatment (MAT) for substance use disorders. These exemptions are included because SSB 5380 only applies to prescriptions and these exemptions clarify settings in which direct administration is occurring.

The intent of SSB 5380 is to reduce the number of people who inadvertently become addicted to opioids and, consequently, reduce the burden on opioid treatment programs.

**Reasons supporting proposal:** The proposed rules are necessary to restate patient notification and patient right to refuse related to opioid prescribing requirements for osteopathic physicians and osteopathic physician assistants, and to clarify situations when notification is not required. The proposed rules provide a necessary framework and structure for safe, consistent opioid prescribing practice consistent with the directives of SSB 5380. The goal is to reduce the number of people who inadvertently become addicted to opioids and, consequently, reduce the burden on opioid treatment programs.

**Statutory authority for adoption:** RCW 18.57.005

**Statute being implemented:** RCW 18.57.810, RCW 18.57A.810, and RCW 69.50.317

**Is rule necessary because of a:**

Federal Law?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Federal Court Decision?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
State Court Decision?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No

If yes, CITATION:

**Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters:** N/A

**Name of proponent:** (person or organization) Washington State Board of Osteopathic Medicine and Surgery  Private  Public  Governmental

**Name of agency personnel responsible for:**

	Name	Office Location	Phone
Drafting:	Tracie Drake	111 Israel Rd SE, Tumwater, WA 98501	360-236-4766
Implementation:	Tracie Drake	111 Israel Rd SE, Tumwater, WA 98501	360-236-4766
Enforcement:	Tracie Drake	111 Israel Rd SE, Tumwater, WA 98501	360-236-4766

**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: Tracie Drake

Address: P.O. Box 47852  
Olympia, WA 98504-7852

Phone: 360-236-4766

Fax: 360-236-2901

TTY: (360) 833-6388 or 711

Email: Osteopathic@doh.wa.gov

Other:

No: Please explain:

**Regulatory Fairness Act Cost Considerations for a Small Business Economic Impact Statement:**

This rule proposal, or portions of the proposal, **may be exempt** from requirements of the Regulatory Fairness Act (see chapter 19.85 RCW). 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)(e)  
(Dictated by statute)

RCW 34.05.310 (4)(c)  
(Incorporation by reference)

RCW 34.05.310 (4)(f)  
(Set or adjust fees)

RCW 34.05.310 (4)(d)  
(Correct or clarify language)

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 .

Explanation of exemptions, if necessary: Except for exemptions in WAC 246-853-675(3)(d) and WAC 246-854-255(3)(d), all proposed changes are dictated by statute.

**COMPLETE THIS SECTION ONLY IF NO EXEMPTION APPLIES**

If 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 analysis showing how costs were calculated. WAC 246-853-675(3)(d) and WAC 246-854-255(3)(d) contain exemptions to the new requirements of law, which are not part of the law, in settings where complying with the law would be overly burdensome or impossible for providers. The board determined the proposed rules do not impose more than minor costs on businesses in the industry. These rules impact providers only.

Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses, and a small business economic impact statement is required. Insert 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:** 10/14/2019

**Signature:**

**Name:** Renee Fullerton



**Title:** Executive Director

**WAC 246-854-255 Patient notification, secure storage, and disposal.** (1) The osteopathic physician assistant shall ~~((provide information to))~~ discuss with the patient educating them of risks associated with the use of opioids, including the risk of dependence and overdose, as appropriate to the medical condition, type of patient, and phase of treatment. The osteopathic physician assistant shall document such notification in the patient record.

(2) Patient notification must occur, at a minimum, at the following points of treatment:

(a) The first issuance of a prescription for an opioid; and

(b) The transition between phases of treatment, as follows:

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

(ii) Subacute pain to chronic pain.

(3) Patient written notification must include information regarding:

(a) Pain management alternatives to opioid medications;

~~(b))~~ (b) The safe and secure storage of opioid prescriptions; ((and  
~~(b))~~ (c) The proper disposal of unused opioid medications including, but not limited to, the availability of recognized drug take-back programs; and

(d) The patient's right to refuse an opioid prescription or order for any reason. If a patient indicates a desire to not receive an opioid, the osteopathic physician assistant shall document the patient's request and avoid prescribing or ordering opioids, unless the request is revoked by the patient.

(4) The requirements in this section do not apply to the administration of an opioid including, but not limited to, the following situations:

(a) Emergent care;

(b) Where patient pain represents a significant health risk;

(c) Procedures involving the actual administration of an opioid or anesthesia;

(d) When the patient is unable to grant or revoke consent; or

(e) MAT for substance use disorders.

(5) If the patient is under eighteen years old or is not competent, the discussion required by subsection (1) of this section must include the patient's parent, guardian, or the person identified in RCW 7.70.065, unless otherwise provided by law.

(6) The requirements of this section may be satisfied with a document provided by the department of health.

(7) The requirements of this section may be satisfied by an osteopathic physician assistant designating any individual who holds a credential issued by a disciplining authority under RCW 18.130.040 to provide the information.

**WAC 246-853-675 Patient notification, secure storage, and disposal.** (1) The osteopathic physician shall ~~((provide information to))~~ discuss with the patient educating them of risks associated with the use of opioids, including the risk of dependence and overdose, as appropriate to the medical condition, type of patient, and phase of treatment. The osteopathic physician shall document such notification in the patient record.

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(a) The first issuance of a prescription for an opioid; and

(b) The transition between phases of treatment, as follows:

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(6) The requirements of this section may be satisfied with a document provided by the department of health.

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