



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: April 05, 2021

TIME: 9:50 AM

WSR 21-08-059

Agency: Department of Health and Pharmacy Quality Assurance Commission

Original Notice

Supplemental Notice to WSR

Continuance of WSR

Preproposal Statement of Inquiry was filed as WSR 21-04-051 ; 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 246-945-014, Electronic prescribing mandate waiver. The Pharmacy Quality Assurance Commission (commission) and the Department of Health (department) are jointly proposing a new section of rule to outline the electronic prescribing mandate, exceptions allowing a waiver, and related waiver process as required by Substitute Senate Bill (SSB) 5380 passed during the 2019 legislative session.

Hearing location(s):

Date:	Time:	Location: (be specific)	Comment:
06/04/2021	9:30 am	In response to the coronavirus disease 2019 (COVID-19) public health emergency, the Department of Health and the Pharmacy Quality Assurance Commission will not provide a physical location for this hearing to promote social distancing and the safety of the citizens of Washington State. A virtual public hearing, without a physical meeting space, will be held instead. To access the meeting: Please register for this meeting and join from your computer, tablet or smartphone. https://attendee.gotowebinar.com/register/3088602240482857744 You can also dial in using your phone. United States: +1 (631) 992-3221 Access Code: 902-027-067 New to GoToMeeting? Get the app now and be ready when your first meeting starts: https://global.gotomeeting.com/in-stall/541045301	N/A

Date of intended adoption: 06/04/2021 (Note: This is **NOT** the effective date)

Submit written comments to:

Name: Cori Tarzwell
Address: PO Box 47990, Olympia, WA 98504
Email: <https://fortress.wa.gov/doh/policyreview>
Fax: N/A
Other: cori.tarzwell@doh.wa.gov
By (date) 05/28/2021

Assistance for persons with disabilities:

Contact Cori Tarzwell
Phone: 360-236-4981
Fax: N/A
TTY: 711
Email: cori.tarzwell@doh.wa.gov
Other:
By (date) 05/28/2021

Purpose of the proposal and its anticipated effects, including any changes in existing rules: SSB 5380, Section 16, requires all providers prescribing controlled substances Schedules II-V, and refills for Schedules III-V, to transmit those prescriptions electronically. The law also provides for exceptions to this mandate and directs the department to create a waiver for practitioners who cannot comply with the mandate due to economic hardship, technological limitations, or other exceptional circumstances. The proposed rules implement the requirements of the bill by creating a waiver and clarifying what qualifies as an economic hardship, technological limitation, or exceptional circumstance.

The intent of the underlying statute is to ensure prescriptions and refills for controlled substances in Schedules II-V are transmitted electronically whenever possible; however, the statute acknowledges challenges to electronic prescribing. The proposed rule clarifies what economic hardships, technological limitations, or exceptional circumstances qualify a provider for a waiver of electronic prescribing.

The requirement to electronically prescribe goes into effect January 1, 2021. However, due to the COVID-19 pandemic, the Secretary of Health (Secretary) issued a waiver for all providers until September 30, 2021. Should it be necessary, the Secretary may consider extending that waiver until such a time that compliance is deemed possible.

Reasons supporting proposal: SSB 5380, Section 16, requires all providers prescribing controlled substances Schedules II-V, and refills for Schedules III-V, to transmit those prescriptions electronically. The law also provides for exceptions to this mandate and directs the department to create a waiver for practitioners who cannot comply with the mandate due to economic hardship, technological limitations, or other exceptional circumstances. Through discussion with stakeholders, it was determined rules are necessary to clarify what is an economic or technological hardship, or exceptional circumstance. The final proposed rules were drafted with stakeholder feedback to create a waiver program that provides necessary guidance to licensees, allows for relatively easy compliance, and results in immediate access to a waiver if a licensee request one.

Statutory authority for adoption: RCW 69.50.312; SSB 5380 (chapter 314, Laws of 2019)

Statute being implemented: RCW 69.50.312; SSB 5380 (chapter 314, Laws of 2019)

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 Department of Health and the Pharmacy Quality Assurance Commission. Private
 Public
 Governmental

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting:	Cori Tarzwell	111 Israel Rd SE, Olympia, WA 98504	360-236-4981
Implementation:	Lauren Lyles	111 Israel Rd SE, Olympia, WA 98504	360-236-4853
Enforcement:	Lauren Lyles	111 Israel Rd SE, Olympia, WA 98504	360-236-4853

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: Cori Tarzwell

Address: PO Box 47990, Olympia, WA 98504

Phone: 360-236-4981

Fax: N/A

TTY: 711

Email: cori.tarzwell@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:

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. The proposed costs to comply with these rules are minimal and apply directly to health care providers with prescribing authority for controlled substances Schedules II-V and refills for controlled substances Schedules III-V. The only cost is assumed to be completing an attestation and submitting it to the proper disciplining authority at the department. It is assumed that this can be done by staff at any level and would take less than 30 minutes per year.

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: April 5, 2021
Name: Jessica Todorovich for Umair A. Shah, MD, MPH /Tim Lynch
Title: Chief of Staff for Secretary of Health/ Pharmacy Quality Assurance Commission Chair

Signature:
 

NEW SECTION

WAC 246-945-014 Electronic prescribing mandate waiver. (1) A practitioner may submit an attestation to the department for a waiver from the electronic prescribing mandate in RCW 69.50.312, if the practitioner is experiencing an economic hardship, technological limitations not reasonably in the control of the practitioner, or other exceptional circumstance. A practitioner does not need to submit a waiver if exempted from the mandate under RCW 69.50.312 (2)(a) through (j). A practitioner must submit an attestation for the waiver using forms provided by the department. The department shall deem the waiver granted upon submission of an attestation and the practitioner will be deemed exempt under RCW 69.50.312 (2)(k).

(2) A practitioner who has submitted an attestation for a waiver from the mandate in RCW 69.50.312 is exempt from the electronic prescribing mandate for the calendar year in which the attestation is signed, beginning with the effective date of this section.

(a) For economic hardship and technical limitations, a practitioner may attest to the need for a waiver up to three times, giving the practitioner three years to come into compliance with the mandate.

(b) There is no limit on the number of other exceptional circumstance waivers under subsection (3)(c) of this section that a practitioner can submit.

(3) A practitioner required to electronically prescribe under RCW 69.50.312 may submit an attestation for a waiver from this mandate due to:

(a) Economic hardship in the following circumstances:

(i) A bankruptcy in the previous year or submitted an attestation for a waiver under this chapter due to a bankruptcy in the previous year;

(ii) Opening a new practice after January 1, 2020;

(iii) Intent to discontinue operating in Washington prior to December 31, 2021; or

(iv) Operating a low-income clinic, that is defined as a clinic serving a minimum of thirty percent medicaid patients.

(b) Technological limitations outside the control of the practitioner if the practitioner is in the process of transitioning to an electronic prescription system.

(c) Other exceptional circumstances.

(i) The practitioner is providing services at a free clinic;

(ii) The practitioner generates fewer than one hundred prescriptions of Schedules II through V drugs in a one-year period, including both new and refill prescriptions;

(iii) The practitioner is located in an area without sufficient internet access to comply with the e-prescribing mandate; or

(iv) Unforeseen circumstances that stress the practitioner or health care system in such a way that compliance is not possible. Examples may include, but are not limited to, natural disasters, widespread health care emergencies, unforeseeable barriers to electronic prescribing, or unforeseen events that result in a statewide emergency.

(4) The department may audit waiver attestations submitted by a practitioner to determine compliance with this chapter. Submitting a false attestation is grounds for disciplinary action against a practitioner's license by the appropriate disciplinary authority as well as fines pursuant to RCW 69.50.312(5).