

WSR 21-08-059

PROPOSED RULES

DEPARTMENT OF HEALTH

(Pharmacy Quality Assurance Commission)

[Filed April 5, 2021, 9:50 a.m.]

Original Notice.

Preproposal statement of inquiry was filed as WSR 21-04-051.

Title of Rule and Other Identifying Information: WAC 246-945-014 Electronic prescribing mandate waiver, the pharmacy quality assurance commission (commission) and the department of health (DOH) 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 SSB 5380 passed during the 2019 legislative session.

Hearing Location(s): On June 4, 2021, at 9:30 a.m. In response to the coronavirus disease 2019 (COVID-19) public health emergency, DOH 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/install/541045301>.

Date of Intended Adoption: June 4, 2021.

Submit Written Comments to: Cori Tarzwell, P.O. Box 47990, Olympia, WA 98504, email <https://fortress.wa.gov/doh/policyreview>, cori.tarzwell@doh.wa.gov, by May 28, 2021.

Assistance for Persons with Disabilities: Contact Cori Tarzwell, phone 360-236-4981, TTY 711, email cori.tarzwell@doh.wa.gov, by May 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[s] 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).

Rule is not necessitated by federal law, federal or state court decision.

Agency Comments or Recommendations, if any, as to Statutory Language, Implementation, Enforcement, and Fiscal Matters: Not applicable.

Name of Proponent: DOH and the pharmacy quality assurance commission, governmental.

Name of Agency Personnel Responsible for Drafting: Cori Tarzwell, 111 Israel Road S.E., Olympia, WA 98504, 360-236-4981; Implementation and Enforcement: Lauren Lyles, 111 Israel Road S.E., Olympia, WA 98504, 360-236-4853.

A school district fiscal impact statement is not required under RCW 28A.305.135.

A cost-benefit analysis is required under RCW 34.05.328. A preliminary cost-benefit analysis may be obtained by contacting Cori Tarzwell, P.O. Box 47990, Olympia, WA 98504, phone 360-236-4981, TTY 711, email cori.tarzwell@doh.wa.gov.

The proposed rule does not impose more-than-minor costs on businesses. Following is a summary of 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 thirty minutes per year.

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

OTS-2896.1

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).

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