WSR 21-08-048 PROPOSED RULES DEPARTMENT OF HEALTH [Filed April 2, 2021, 12:47 p.m.]

Original Notice.

Preproposal statement of inquiry was filed as WSR 20-03-038. Title of Rule and Other Identifying Information: WAC 246-470-037, adding a new section relating to the prescription monitoring program (PMP). The department of health (department) is proposing a new section in chapter 246-470 WAC to establish a waiver process and criteria for facilities, entities, offices, or provider groups with ten or more prescribers to apply for an exemption from the PMP and electronic health record (EHR) integration required by SSB 5380.

Hearing Location(s): On May 19, 2021, at 1:00. In response to the coronavirus disease 2019 (COVID-19) public health emergency, the department of health 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 join my meeting from your computer, tablet or smartphone https://attendee.gotowebinar.com/register/ 8967228021489391119.

You can also dial in using your phone Dial in: +1 (631) 992-3221, Access code: 441-927-342.

Date of Intended Adoption: May 26, 2021.

Submit Written Comments to: Carly Bartz-Overman, Department of Health, P.O. Box 47850, Olympia, WA 98504-7850, email https:// fortress.wa.gov/doh/policyreview, fax 360-236-2901, carly.bartzoverman@doh.wa.gov, by date May 19, 2021.

Assistance for Persons with Disabilities: Contact Carly Bartz-Overman, phone 360-236-3044, fax 360-236-2901, TTY 711, email carly.bartz-overman@doh.wa.gov, by May 12, 2021.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: The proposed rule is needed in order to meet the department's requirements per SSB 5380, section 22(2)(b), codified as RCW 70.225.090 (2)(b). This section states the department must develop a waiver process for the integration requirements outlined in RCW 70.225.090 (2)(a) due to economic hardship, technological limitations that are not reasonably in the control of the facility, entity, office, or provider group, or other exceptional circumstance demonstrated by the facility, entity, office, or provider group.

The proposed rules create a process for a facility, entity, office, or provider group wishing to receive a waiver from the PMP integration requirement to follow and outlines what constitutes an economic hardship, technological limitations that are not reasonably in the control of the facility, entity, office, or provider group, or other exceptional circumstance. The rule also outlines the number of waivers a facility, entity, office, or provider group may receive with the goal of giving these groups more time to comply with the integration mandate while still ensuring that as many as possible will be able to overcome the hardships and integrate with the PMP.

If a facility, entity, office, or provider group has an economic hardship, technological limitations or other exceptional circumstance, they may attest that they have an economic hardship, technological limitation, or other exceptional circumstance that inhibits their

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ability to integrate their EHR with the PMP. This attestation will grant them a one-year waiver from the integration requirement.

Reasons Supporting Proposal: The proposed rules establish the process by which a facility, entity, office, or provider group may attest to having an economic hardship, technological limitation, or exceptional circumstance in order to have the PMP integration requirement waived. Waiver attestations will give a facility, entity, office, or provider group a simple, streamlined process to follow in order to have the PMP integration mandate waived.

The proposed rules also outline how many waivers will be granted and the length of time a waiver is granted for. This will give a facility, entity, office, or provider group clear direction on how long a waiver is in effect for and how long they have before they must meet the PMP integration mandate.

Additionally, the proposed rules clarify what constitutes an economic hardship, technological limitation, or exception circumstance. This will make the attestation simpler for a facility, entity, office, or provider group as it clearly lays out the waiver criteria so they may quickly review what options they have to request a waiver and determine if they meet any of those criteria.

This clarified, streamlined system will also make the process simpler and more cost-effective for the department as well.

Statutory Authority for Adoption: RCW 70.225.025.

Statute Being Implemented: SSB 5380 (chapter 314, Laws of 2019) as codified as RCW 70.225.090 (2)(b).

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: Washington state department of health, governmental.

Name of Agency Personnel Responsible for Drafting, Implementation, and Enforcement: Carly Bartz-Overman, 111 Israel Road S.E., Tumwater, WA 98501, 360-236-3044.

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 Carly Bartz-Overman, P.O. Box 47850, Olympia, WA 98504-7850, phone 360-236-3044, fax 360-236-2901, TTY 711, email carly.bartzoverman@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 policies in this proposed rule create little additional cost to a facility, entity, office, or provider group seeking to submit a waiver for the PMP integration requirement. Any costs would be related to the amount of time a staff member must spend completing a form and submitting it to the department attesting that they meet one or more of the waiver criteria.

Cost estimates: The department estimates this would take no more than thirty minutes per year to complete and could be done by any member of staff. The department assumes that an office manager would be the staff person to fill out the form and, based on average salaries in Washington, clinic office managers make about \$21 an hour. For thirty minutes of work on an annual basis, the calculated cost to a facility, entity, office, or provider group is \$10.50 annually. This falls well below the minor-cost-threshold for any of the identified businesses in the industry. 2017 Industry NAICS Code - Threshold calculated based on 0.3% of Average Annual Gross Business Income: 62133 Offices of Mental Health Practitioners (except Physicians) - \$519.90 621399 Offices of All Other Miscellaneous Health Practitioners -\$826.66 62139 Offices of All Other Health Practitioners - \$844.48 621391 Offices of Podiatrists - \$1,674.73 62132 Offices of Optometrists - \$2,690.05 62142 Outpatient Mental Health and Substance Abuse Centers -\$3,444.05 62121 Offices of Dentist - \$3,551.76 62141 Family Planning Centers - \$4,347.88 62111 Offices of Physicians - \$8,994.55 621610 Home Health Care Services - \$9,631.09 62221 Psychiatric and Substance Abuse Hospitals - \$28,916.57 62149 Other Outpatient Care Centers - \$31,975.74 62211 General Medical and Surgical Hospitals - \$585,843.60 April 1, 2021 Jessica Todorovich Chief of Staff for Umair A. Shah, MD, MPH Secretary

OTS-2913.1

NEW SECTION

WAC 246-470-037 Waiver for integrating electronic health record system with the prescription monitoring program. (1) A facility, entity, office, or provider group that is subject to the prescription monitoring program integration mandate requirement in RCW 70.225.090 (2) (a), and is experiencing an economic hardship, technological limitation, or other exceptional circumstances as stated in RCW 70.225.090 (2) (b), may submit an attestation to the department for a waiver from the integration mandate. The attestation must be submitted on forms provided by the department. The waiver is deemed granted upon submission.

(2) A facility, entity, office, or provider group that has been granted a waiver from the mandate in RCW 70.225.090 (2)(a) shall be exempt from the prescription monitoring program integration mandate for the calendar year in which the attestation is received by the department beginning with the effective date of this section.

(a) For economic hardship and technical limitation, a facility, entity, office, or provider group may submit up to three annual attestations, giving the facility, entity, office, or provider group up to three years to integrate its electronic health record with the prescription monitoring program.

(b) There is no limit on the number of other exceptional circumstance waivers under subsection (3)(c) of this section that a facility, entity, office, or provider group may submit.

(3) A facility, entity, office, or provider group may submit an attestation for a waiver from the mandate due to:

(a) Economic hardship in the following circumstances:

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

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

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

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

(b) Technological limitations outside the control of the facility, entity, office, or provider group in the following circumstance: Integration of electronic health records system with the PMP through a method approved by the department is in process but has not yet been completed;

(c) Other exceptional circumstances:

(i) Providing services as a free clinic;

(ii) The internet speed or bandwidth required to integrate an electronic health record with the prescription monitoring program through a method approved by the department is not available;

(iii) The technology to connect the electronic health record of the entity requesting the waiver to the prescription monitoring program through a method approved by the department does not exist;

(iv) Fewer than one hundred prescriptions for Schedule II-V drugs are generated in a calendar year; or

(v) 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, unforeseen barriers to integration, or unforeseen events that result in a statewide emergency.

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