March 3, 2023

Washington State Pharmacy Quality Assurance Commission

Commission Business Meeting Materials

SAFETY. QUALITY. INNOVATION.

PROPOSED RULE MAKING

CR-102 (July 2022)
(Implements RCW 34.05.320)
Do **NOT** use for expedited rule making

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OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: January 18, 2023
TIME: 7:56 AM

WSR 23-03-109

Agency: Department of Health – Pharmacy Quality Assurance Commission

☐ **Original Notice**

☒ **Supplemental Notice to WSR** 22-20-100

☐ **Continuance of WSR**

☒ **Preproposal Statement of Inquiry was filed as WSR** 20-17-143**; 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) WAC 246-945-486 (New) Return and reuse of unexpired medications – Department of corrections and WAC 246-945-488 (New) Safe donation of unexpired prescription drugs. The Pharmacy Quality Assurance Commission (commission) is proposing new sections in chapter 246-945 WAC for the implementation of Substitute Senate Bill (SSB) 6526, an act relating to the reuse and donation of unexpired prescription drugs. The supplemental proposal removes a prescriber notification requirement from WAC 246-945-488(2)(h)(i).

Hearing location(s):

Date:	**Time:**	**Location:** (be specific)	**Comment:**
3/3/2023	9:20 a.m.	The Pharmacy Quality Assurance Commission will provide a virtual and a physical location for this hearing to promote social distancing and the safety of the citizens of Washington State. **Physical location:** Capital Region ESD 113 6005 Tyee Dr SW Tumwater, WA 98512 **Virtual:** Please download and import the following iCalendar (.ics) fields to your calendar system. Daily: https://us02web.zoom.us/webinar/tZIsdu2hqzMuHNJhllH4KKYkCjwBU5J0e2Ps/ics?icsToken=98tyKuGurzouE9GdtB-	

		BRpwABYj4LPPwmFxbgo13lBPpK3R4STr9FehVEIcgOojV Topic: PQAC Business Meeting 2022 To access the meeting on March 3, 2023 at 9 a.m., go to https://zoom.us/join or https://us02web.zoom.us/j/86114958466and use the Webinar ID 861 1495 8466 The access options include one tap mobile: US: +12532158782,,86114958466# or +16699009128,,86114958466# Or Telephone: Dial(for higher quality, dial a number based on your current location): US: +1 253 215 8782 or +1 669 900 9128 or +1 346 248 7799 or +1 669 444 9171 or +1 386 347 5053 or +1 564 217 2000 or +1 646 558 8656 or +1 646 931 3860 or +1 301 715 8592 or +1 312 626 6799 Webinar ID: 861 1495 8466 International numbers available: https://us02web.zoom.us/u/kdLNo6unOZ	

Date of intended adoption: 3/3/2023 _(Note: This is **NOT** the **effective** date)

Submit written comments to:	**Assistance for persons with disabilities:**
Name: Joshua Munroe	Contact Joshua Munroe
Address: PO Box 47582 Olympia, WA 98504-7852	Phone: 360-236-2987
Email: https://fortress.wa.gov/doh/policyreview	Fax: 360-236-2901
Fax: 360-236-2901	TTY: 711
Other: N/A	Email: PharmacyRules@doh.wa.gov
By (date) 2/17/2023	Other: N/A
	By (date) 2/24/2023

Purpose of the proposal and its anticipated effects, including any changes in existing rules: The 2020 Washington state legislature passed SSB 6526, an act relating to the reuse and donation of unexpired prescription drugs. SSB 6526 permits the Department of Corrections (DOC) pharmacy to accept returns of unit dose packages. The law also allows the commission to adopt rules to allow the safe donation of prescription drugs under chapter 69.70 RCW including, but not limited to, allowing pharmacy to pharmacy donation of unexpired prescription drug stock.

The proposed WAC 246-945-486 specifically allows the DOC pharmacy to accept for return and reuse noncontrolled unexpired legend drugs in unit dose packages, or full or partial multiple dose medication cards from the facilities it serves. The DOC pharmacy must ensure product integrity by adhering to RCW 69.70.050(1), (2), and (5).

The proposed language in WAC 246-945-488 adopts the required conditions for donated prescription drugs outlined in chapter 69.70 RCW, but also adds a requirement that participating pharmacies must submit an additional form to the commission as notification of participation in the program. They must also notify the commission when terminating

participation in the program. The proposed rule also directs participating pharmacies to develop policies and procedures that facilitate compliance with the statutory requirements. The policies and procedures must also include an additional requirement to notify the prescriber when donated medications are dispensed to a patient.

In addition, WAC 246-945-488 contains measures to ensure patient safety and product integrity such as separating the donated drugs from the rest of the pharmacy's drug stock and maintaining a separate inventory. Finally, the rule also adds the clarification that practitioners, pharmacists, medical facilities, manufacturers, wholesalers, or persons to whom a prescription drug was prescribed are not required to obtain a wholesaler license when donating drugs to a pharmacy.

Following the public rules hearing held on November 17, 2022 the commission determined that the proposed rule language required an amendment to WAC 246-945-488(2)(h)(i) to remove a prescriber notification requirement that was deemed unnecessary in order to provide donated prescription drugs to patients with a valid, standing prescription.

Reasons supporting proposal: SSB 6526 requires the commission to adopt rules allowing the DOC pharmacy to accept returns of unit dose packages or full or partial multiple dose medication cards from the facilities it serves and reuse the unexpired medication. The bill also allows the commission to adopt rules allowing the safe donation of prescription drugs under chapter 69.70 RCW including, but not limited to, allowing pharmacy to pharmacy donations of unexpired prescription drug stock. The proposed rules improve accessibility and visibility of the drug donation program under chapter 69.70 RCW while ensuring optimal patient safety and product integrity.

The commission determined during the November 17, 2022 public rules hearing that the prescriber notification requirement found in WAC 246-945-488(2)(h)(i) was superfluous if a patient already has a valid prescription for the drug donated via the prescription donation program. Furthermore, it was decided that any delay caused by notifying prescribers for a prescription they have already issued could be deleterious to the patient's health.

Statutory authority for adoption: RCW 18.64.005; SSB 6526 (chapter 264, Laws of 2020) codified as RCW 18.64.610 and RCW 69.70.110

Statute being implemented: SSB 6526 (chapter 264, Laws of 2020) codified as RCW 18.64.610 and RCW 69.70.110

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

Type of proponent: ☐ Private ☐ Public ☒ Governmental
Name of proponent: (person or organization) Pharmacy Quality Assurance Commission

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting:	Joshua Munroe	111 Israel Rd SE, Tumwater, WA 98501	360-236-2987
Implementation:	Joshua Munroe	111 Israel Rd SE, Tumwater, WA 98501	360-236-2987
Enforcement:	Marlee O'Neill	111 Israel Rd SE, Tumwater, WA 98501	360-480-9108

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: Joshua Munroe

Address: PO Box 47852 Olympia, WA 98504-47852

Phone: 360-236-2987

Fax: 360-236-2901

TTY: 711

Email: PharmacyRules@doh.wa.gov

Other: N/A

☐ 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:

(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.** The proposed rule does not require changes to a licensee's or a pharmacy's existing practices or infrastructure. For pharmacies that choose to participate in the prescription donation program, costs are limited to one-time costs—procuring additional shelving/storage, time taken creating policies and procedures, and time taken to fill out the necessary registration form—and the recurring cost of maintaining a separate inventory for donated items. The agency estimates that the probable one time cost to comply with the optional program could be as high as $733.50 which is significantly less than the minor cost threshold of either 1% of average annual payroll ($6,639.73) or .3% of average annual

gross business income ($53,119.28). The agency determined that the requirements to comply with the optional program did not impose more-than-minor costs on small businesses.

It was further determined that the proposed amendment to WAC 246-945-488(2)(h)(i) to remove the prescriber notification requirement would not affect existing cost estimates.

☐ 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: Joshua Munroe
Address: PO Box 47852 Olympia, WA 98504-7852

Phone: 360-236-2987
Fax: 360-236-2901
TTY: 711
Email: PharmacyRules@doh.wa.gov
Other: N/A

Date: January 17, 2023	**Signature:**
Name: Teri Ferreira, RPh	
Title: Pharmacy Quality Assurance Chair	

Commission SBAR Communication

Agenda Item/Title: Review of Title VI and Other Federal Regulations Related to Accessibility

Date SBAR Communication Prepared: February 24, 2023

Reviewer: PQAC Staff

Link to Action Plan:

☐ **Action** ☒ **Information** ☒**Follow-up** ☐**Report only**

Situation: At the January business meeting, the Pharmacy Quality Assurance Commission (commission) discussed a conceptual draft of the accessible labeling rule. This discussion included identifying a possible intersection between this rulemaking and various federal laws, including Title VI of the Civil Rights Act.

Background:

Title VI of the Civil Rights Act 1964 (42 U.S.C. 2000d)

- Title VI provides that "[n]o person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance" (42 U.S.C. § 2000d). This includes a prohibition against national origin discrimination affecting limited English proficiency (LEP) persons, *see Lau v. Nichols*, 414 U.S. 563, 94 S. Ct. 786, 39 L. Ed. 2d 1 (1974).
- Title VI applies to "any program or activity receiving Federal financial assistance" (42 U.S.C. § 2000d). HHS has confirmed that this definition of a "program or activity" includes health care providers and facilities who receive Medicaid or Medicare reimbursement are subject to Title VI.
- In 2000, Bill Clinton issued Executive Order 13166: Improving Access to Services for Persons with Limited English Proficiency (recently reaffirmed by Attorney General Merrick Garland on November 12, 2022), which required federal agencies to publish guidelines on how recipients of federal financial assistance can provide meaningful language access under the requirements in Title VI.
- HHS has guidance on its website for federal financial assistance recipients regarding Title VI's prohibition against national origin discrimination affecting LEP persons. The goal of the guidance is to ensure recipients conduct an individualized assessment of their operation to ensure "meaningful access by LEP persons to critical services while not imposing undue burdens on small business, small local governments, or small nonprofits." As a result, what amounts of "meaningful access" has the potential to vary greatly based on the recipient.

- Title VI is enforced by the Department of Justice and the agencies who provide federal financial assistance to recipients. There is no private cause of action for individual persons to enforce disparate impact regulations promulgated under Title VI, such as those related to language accessibility (*Alexander v. Sandoval*, 532 U.S. 275, 121 S. Ct. 1511, 149 L. Ed. 2d 517 (2001)).

Section 504 of the Rehabilitation Act (29 U.S.C. § 794)

- Generally speaking, the Rehabilitation Act protects individuals from discrimination on the basis of disability. In particular, Section 504 of the Rehabilitation Act of 1973 provides that no otherwise qualified individual with a disability in the United States can, solely by reason of his or her disability, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under: (1) any program or activity receiving federal financial assistance; or (2) any program or activity conducted by any executive agency or by the United States Postal Service (29 U.S.C. § 794(a)).
- Similar to Title VI, "program or activity" is defined broadly in the Rehabilitation Act to include all of the operations of "an entire corporation, partnership, or other private organization, or an entire sole proprietorship . . . which is principally engaged in the business of providing education, health care, housing, social services, or parks and recreation."
- Section 504 can be enforced by a private citizen or by the Department of Justice. In order to prevail on a Section 504 claim, a plaintiff must establish that "(1) [they are] an individual with a disability; (2) [they are] otherwise qualified to receive [a certain] benefit; (3) [they were] denied the benefits of [a certain] program solely by reason of [their] disability; and (4) the program receives federal financial assistance" (*Updike v. Multnomah* County, 870 F.3d 939, 949 (9th Cir. 2017)).
- Whether the conduct of a program or activity amounts to a violation of Section 504 is highly fact specific. For example, in *Bax v. Drs. Med. Ctr. of Modesto*, Inc., 48 F.4th 1008 (9th Cir. 2022), the 9th Circuit Court of Appeals considered an appeal related to a Section 504 claim and made clear, on multiple occasions, that whether Section 504 was violated is a fact-intensive exercise (*Bax* at 1016 and 1018) and that ultimately the district court in this matter had engaged in "precisely the sort of fact-intensive exercise our precedent requires" by hearing testimony from nine witnesses and considering 132 exhibits (*Id.* at 1014 and 1018).

Title III of the American with Disabilities Act (42 U.S.C. §§ 12181 to 12189; 28 C.F.R. Pt. 36)

- Title III of the ADA provides that no individual can be discriminated against on the basis of disability in the full and equal enjoyment of the goods, services, facilities, privileges, advantages, or accommodations of any place of public accommodation by any person, or private entity, who owns, leases (or leases to), or operates a place of public accommodation. A place of public accommodation includes a pharmacy (42 U.S.C. § 1281(7)).

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- Title III regulations identify three broad principles that underlie the nondiscrimination requirements. These include: (1) equal opportunity to participate; (2) equal opportunity to benefit; and (3) receipt of benefits in the most integrated setting appropriate (28 C.F.R. §§ 36.202-203).
- In addition to these three broad principles, there are also federal requirements that address specific factual situations. For example, 28 C.F.R. § 36.303 addresses the requirement that a public accommodation "shall take those steps that may be necessary to ensure that no individual with a disability is excluded, denied services, segregated or otherwise treated differently than other individuals ***because of the absence of auxiliary aids and services***, unless the public accommodation can demonstrate that taking those steps would fundamentally alter the nature of the goods, services, facilities, privileges, advantages, or accommodations being offered or would result in an undue burden, i.e., significant difficulty or expense." According to the ADA Technical Assistance Manual, "if a specific requirement applies, it controls over the general requirement".
- The ADA can be enforced either by private suits by individuals who are subjected to discrimination or have reasonable grounds for believing they are about to be subjected to discrimination (28 C.F.R. § 36.501); or by the Department of Justice if a person or persons have engaged in a pattern or practice of discrimination or a person has been discriminated against and the discrimination raises an issue of general public importance (28 C.F.R. § 36.503).

Assessment:

In addition to the commission's future accessible labeling rules, there are several federal laws covering the same or similar subject matter that may also be applicable to facilities licensed by the commission.

Recommendation:

Staff recommends ensuring that the commission's rules on accessible labeling make clear that its rules do not in any way restrict the application of the federal laws mentioned here or any other applicable federal laws.

Follow-up Action:

Staff will proceed as directed.

Accessible Labeling Rule Language Draft

PLEASE NOTE: This is a preliminary rule language draft and is not finalized or concrete language. There will be further opportunities to provide comment once the draft rule language is complete.

WAC 246-945-(AAA) Accessible Labeling Definitions

(1) For the purpose of sections WAC 246-945-(AAA) through WAC 246-945-(DDD):

(a) "Accessible labeling" means the act of labeling as defined by RCW 18.64.011(18) in a way that allows any patient to accurately comprehend prescription drug information regardless of visual impairment, print disability, or language barrier.

(b) "Visually impaired" means:

(i) Having a central visual acuity that does not exceed 20/200 in the better eye with corrective lenses, or the widest diameter of the visual field does not exceed twenty degrees; or

(ii) Having a severe loss of visual acuity ranging from 20/70 to 20/200 while retaining some visual function; or

(iii) Having inoperable visual impairments including, but are not limited to: Albinism, aniridia, aphakia, cataracts, glaucoma, macular degeneration, or other similar diagnosed disease or disorder.

(c) "Print disabled" means the inability to effectively read or access printed materials due to a visual, physical, perceptual, or cognitive disability, or other impairment.

(d) "Prescription reader" means a device or other technology that is designed to audibly convey the information contained on the label of a prescription drug.

(e) "QR" means a quick reference code.

(f) "Limited English proficient individual" or "LEP individual" means a person who does not speak

English as their primary language and who has a limited ability to read, speak, write, or understand English.

(g) "Translation" shall mean the conversion of a written text in another language by an individual competent to do so and utilizing all necessary pharmaceutical and health-related terminology.

(h) "Interpretation" shall mean communication in which a person acting as an interpreter comprehends a message and re-expresses that message accurately in another language, utilizing all necessary pharmaceutical and health-related terminology, so as to enable a person to receive all necessary information in the person's preferred primary language. This includes, but is not limited to, interpretation from English to American Sign Language (ASL). message orally from one language into another.

WAC 246-945-(BBB) Accessible Labeling Applicability (placeholder title)

(1) Nothing in WAC 246-945-(BBB) through WAC 246-945-(DDD) shall diminish or impair any requirement that any credential holder of the commission provide any accessibility service, language assistance, interpretation, or translation under any applicable federal or state law, such as, but not limited to, Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d *et seq*), Section 504 of the Rehabilitation Act (29 U.S.C. § 794), and Title III of the American with Disabilities Act (42 U.S.C. §§ 12181 to 12189, 28 C.F.R. Pt. 36).

(2) Facilities must provide accessible labeling accommodations as described in WAC 246-945-(CCC) and WAC-246-945-(DDD) on request from a patient, prescriber, or the patient's agent. If a patient, prescriber, or patient's agent requests accessible labeling accommodations from both WAC 246-945-(CCC) and WAC-246-945-(DDD), the facility must provide both.

(3) If an accessible labeling accommodation is provided on the label of a drug container, the label on the prescription drug container dispensed to a patient for patient administration under WAC 246-945-CCC or WAC 246-945-DDD must at least be in non-Braille English and contain all of the information required by WAC 246-945-016, RCW 18.64.246, and RCW 69.41.050.

(a) If a separate information sheet is used to provide prescription information, that sheet must contain all information required by WAC 246-945-016, RCW 18.64.246, and RCW 69.41.050.

(4) The following are exempt from WAC 246-945-BBB and WAC 246-945-CCC:

(a) Pre-packaged emergency medications;

(b) Opioid reversal medications;

(c) Bubble packs; and,

(d) Medication packs dispensed in strip machines.

(5) Compliance with WAC 246-945-AAA through WAC 246-945-DDD does not eliminate the need for

patient counseling or any other requirement in any applicable law or rule. Patient counseling must be provided in a visual or language accessible manner in accordance with patient circumstances.

[]

WAC 246-945-(CCC) Visual Accessibility Requirements for Prescription Information and Prescription Labeling and Written Counseling

(1) Each facility that dispenses and delivers to patients shall, upon the request of a prescriber, a patient, or the patient's agent, provide at least the following accessible labeling accommodations in a timely manner at no additional cost to the patient. Nothing in this section shall prevent a facility from providing additional options to promote visual accessibility.

(a) A minimum 12-point font size;

(b) Braille; or,

(c) A QR reference code, device, or other technology that can direct the patient to a separate print or digital resource that provides all required information for the dispensed prescription; or,

(d) A prescription reader provided as a device or other technology. The facility must provide a device that can be used as a prescription reader, but the patient may elect to use their own device or technology in place of that device.

(i) If a prescription reader is provided through a device supplied by the pharmacy, it must be provided for at least the duration of the drug therapy. The device or other technology used must be capable of conveying all required information in WAC 246-945-016, RCW 18.64.246, and RCW 69.41.050. The pharmacy must also provide directions for using the prescription reader appropriate to the patient's visual or print impairment.

(e) Additional information relevant to the patient's intended use of the prescription but not required in WAC 246-945-016, RCW 18.64.246, and RCW 69.41.050 must be provided in an accessible format on a separate print or digital resource accessible through a device or

other technology.

(2) A pharmacy shall notify each patient to whom a drug is dispensed in a manner that fits the patient's needs and circumstances of the availability of accessibility accommodations as defined by subsection 1 of this section.

(a) Pharmacies shall make a good faith effort to communicate the availability of visually impaired and print disabled services to their community.

(b) Good faith communication efforts include but are not limited to signage, phone notification and messaging, inserts, advertisements, and websites.

(3) Pharmacies must comply with the requirements of this section by [12 months after the rule goes into effect].

[]

WAC 246-945-(DDD) Translation and interpretation requirements for prescription drug information and standardized medication labeling.

(1) Each facility that dispenses to patients for patient administration shall, upon the request of an LEP individual, their agent or their prescriber, provide free translation services and interpretation of prescription information as described in WAC 246-945-016, RCW 18.64.246, and RCW 69.41.050 to each LEP individual.

(2) Facilities that dispense and deliver to patients must provide translation services and interpretation services in a minimum of [XX] languages that address the needs of the community around the facility in addition to English.

(a) The facility shall choose languages to make available for translation by the identified needs of the community that facility serves.

(3) Each facility that dispenses and delivers to patients shall provide conspicuously posted notices to inform LEP individuals of their rights to free, competent oral interpretation services and translation services of prescription information as described in WAC 246-945-016, RCW 18.64.246, and RCW 69.41.050.

(a) The commission will make available a free downloadable notice for facilities to print and display.

(b) The printed notice shall include the following statement in English and in each language provided by the pharmacy: "Point to your language. Language assistance will be provided at no cost to you."

(4) Pharmacies must comply with the requirements of this section by [12 months after the rule goes into effect].

[]

Commission SBAR Communication

Originally presented at the September 2022 business meeting

Agenda Item/Title: Monitoring of Drug Therapy: Pharmacists Conducting Health Screenings and Point-of-Care Testing

Date SBAR Communication Prepared: 9/7/2022

Reviewer: Commission Staff

Link to Action Plan:

☐ **Action** ☒ **Information** ☐ **Follow-up** ☐ **Report only**

Situation: (Brief Description)

Over the last two years, Pharmacy Quality Assurance Commission (commission) staff have received questions related to the ability of pharmacists to conduct point-of-care (POC) testing and perform health screenings. Specifically, whether it is within the scope of practice for a pharmacist to conduct POC testing and perform health screenings related to a condition the individual has not received a diagnosis for and has not been prescribed any medication to treat.

Background: (Briefly state the pertinent history):

Commission staff have heard that conducting POC testing and performing health screenings on individuals related to a condition the individual has not received a diagnosis for and has not been prescribed any medication to treat is within the scope of practice for a pharmacist because it amounts to the "monitoring of drug therapy."

The scope of practice of a pharmacist is delineated in statute. A pharmacist is permitted to engage in the "practice of pharmacy" (RCW 18.64.011(25)). The Legislature has defined the "practice of pharmacy" to include:

> the practice of and responsibility for: Interpreting prescription orders; the compounding, dispensing, labeling, administering, and distributing of drugs and devices; the monitoring of drug therapy and use; the initiating or modifying of drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs; the participating in drug utilization reviews and drug product selection; the proper and safe storing and distributing of drugs and devices and maintenance of proper records thereof; the providing of information on legend drugs which may include, but is not limited to, the advising of therapeutic values, hazards, and the uses of drugs and devices.

RCW 18.64.011(28).

The Commission has further explained in rule that, in the absence of a collaborative drug therapy agreement (CDTA), "monitoring of drug therapy and use" shall mean:

a review of the drug therapy regimen of patients by a pharmacist for the purpose of evaluating or rendering advice to the prescribing practitioner or patient regarding the patients drug therapy. Monitoring of drug therapy includes, but is not limited to, the evaluation of the patient through history taking, physical examination, ordering, administering or reviewing laboratory tests, imaging, and social evaluation related to an existing diagnosis and drug therapies for optimization of drug therapy.

WAC 246-945-355.

Taken in aggregate, the Commission's statute and rule does not permit pharmacists from independently engaging in POC testing and health screenings related to a condition an individual has not received a diagnosis for and has not been prescribed any medication to treat, unless the pharmacist is acting pursuant to the terms of a CDTA or other standing order or protocol developed by an interdisciplinary team that includes a prescribing practitioner.

Assessment: (Summarize the facts and give your best assessment. What is going on? Use your best judgment)

Commission staff have concluded that based on current law, pharmacists are authorized to engage in POC testing and health screenings as part of their scope without a CDTA or protocol; however, it must be related to an existing diagnosis and drug therapy as stated in WAC 246-945-355.

Recommendation: (What actions are you asking the commission to take? What do you want to happen next?)

The commission can reaffirm its rule (WAC 246-945-355) as being in line with the parameters placed in statute and provide licensees with the following clarification:

Pursuant to the terms of a collaborative drug therapy agreement (CDTA), or other standing order or protocol developed by an interdisciplinary team that includes a prescribing practitioner, a pharmacist can:

- Screen individuals for previously undiagnosed acute and chronic conditions and provide a report of the results to the individual;
- Monitor an individual's diagnosed condition, regardless of whether the individual takes medication to treat the diagnosed condition, and report the outcome of monitoring to the patient; and
- Perform CLIA-waived point-of-care testing, interpret the results of this testing, and make recommendations for care to the patient.

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In the absence of a CDTA, or other standing order or protocol, a pharmacist can:

- Monitor an individual's diagnosed condition and report the outcome of the monitoring to the individual or prescribing practitioner so long as the individual takes medication to treat their diagnosed condition; and
- Perform CLIA-waived point-of-care testing, interpret the results of this testing, and make recommendations for care to the patient or prescribing practitioner if the individual has received a diagnosis and been prescribed medication to treat the diagnosed condition and the pharmacist is monitoring the individual's drug therapy.

In the absence of a CDTA, or other standing order or protocol, a pharmacist cannot:

- Screen individuals for previously undiagnosed acute and chronic conditions and provide the individual with a report;
- Monitor an individual's diagnosed condition if they have not been prescribed medication to treat the diagnosed condition; and
- Perform CLIA-waived point-of-care testing, interpret the results of this testing, and make recommendations for care to the individual if they do not have a related diagnosis and prescribed medication.

Follow-up Action: (Next Steps After the meeting – Document the commission's decision and/or any additional steps or follow-up requested; such as, report back in 6- months, etc.)

- Staff will follow-up as determined by the commission.