Commission SBAR Communication

Originally presented at the March 2022 business meeting and updated for the June 2023 business meeting (updates are italicized).

Agenda Item/Title: Clarifying Question on the Utilization of Pharmacy Assistants to Replenish Automated Drug Distribution Devices (ADDDs)

Pharmacy Assistants Stocking

Date SBAR Communication Prepared: March 14, 2022

Reviewer: T. Nomi Peaks

Link to Action Plan:

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

Situation:

Pharmacy Quality Assurance Commission (commission) Staff requests the commission's guidance on pharmacy assistants and the replenishment of automated drug distribution devices (ADDDs).

Under the commission's new rules, does the replenishment of an ADDD fall under a pharmacy assistant's scope of practice? Does the act of stocking include stocking an ADDD?

More generally, is a pharmacy assistant's scope of practice limited to "stocking" a shelf?

Background:

- For reference, language specific to the replenishment of ADDDs in the since-repealed WAC 246-874-040(2)(a)(i) only allowed a pharmacist, a pharmacy intern, or a pharmacy technician (under the supervision of a pharmacist) to perform this task. In July 2020, the new rules codified in Chapter 246-945 WAC superseded Chapter 246-874 WAC. The new rules do not distinguish if a pharmacy assistant may or may not replenish an ADDD.

- RCW 18.64A.030(2) states, "'Pharmacy assistants' may perform, under the supervision of a licensed pharmacist, duties including, but not limited to, typing of prescription labels, filing, refiling, bookkeeping, pricing, stocking, delivery, nonprofessional phone inquiries, and documentation of third-party reimbursements and other such duties and subject to such restrictions as the commission may by rule adopt." Historically, the word stocking has been interpreted to refer to the act of stocking pharmacy shelves.

- WAC 246-945-315(3) states, "A pharmacist may delegate to a pharmacy assistant those functions defined in 18.64A.030 and the following: (a) Prepackage and label drugs for subsequent use in prescription dispensing operations; and (b) Count, pour, and label for

individual prescriptions." Customarily, pharmacists or pharmacy technicians retrieve the drugs that pharmacy assistants are tasked with prepackaging, counting, pouring, and labeling.

- *The pharmacy practice subcommittee met several times to discuss whether a pharmacy assistant is limited to stocking a shelf. Subcommittee members and stakeholders shared their thoughts, experiences, and knowledge of different technology and pharmacy settings. Staff had to cancel the most recent pharmacy practice subcommittee meeting and decided it was best to bring this issue to the full commission.*

Assessment:

- The potential benefits of utilizing pharmacy assistants to replenish ADDDs include personnel support for those pharmacies burdened by staffing shortages, the opportunity for assistants to gain professional aptitude and confidence, and improved productivity for high-volume pharmacies. The potential challenges include establishing the appropriate ADDD training for assistants, estimating the impact on pharmacists' duties as they supervise the ADDD replenishment, and determining if that supervision may occur remotely.
- While the new rules delineate tasks that may be assigned to a pharmacy assistant per a supervising pharmacist's discretion, they do not specifically address if the act of stocking encompasses the replenishment of an ADDD.
- *RCW 18.64.030(2) states that "stocking" is within a pharmacy assistant's scope of practice. Neither the legislature nor the commission have defined "stocking."*
- *Pharmacists should ensure pharmacy assistants are supervised in a manner that meets the Pharmacy Commission's definition of "immediate supervision," as found in WAC 246-945-001(44).*
- *While stocking is within the list of tasks that can be completed as part of the pharmacy assistant's scope of practice (see RCW 18.64A.030 and WAC 246-945-315) the delegation of this function is ultimately the responsibility of the supervising pharmacist and must be noted in an ancillary personnel utilization plan (AUP) that has been approved by the Pharmacy Commission (see RCW 18.64A.040, RCW 18.64A.060, WAC 246-945-315, and WAC 246-945-410).*
- *The tenets of the commission's rules rewrite were to provide guardrails and allow for innovation rather than be prescriptive and limiting.*
- *With all of the above in mind, program staff composed the following FAQ for the commission's consideration:*

  Question: Is "stocking" in RCW 18.64A.030 limited to stocking a shelf?

  Answer: No. Stocking is within the list of tasks that can be performed by a licensed pharmacy assistant. RCW 18.664A.030(2). The Pharmacy Commission's rules do not limit "stocking" to a shelf. It should be noted that pharmacy assistants may only perform

this under the immediate supervision of a licensed pharmacist and per that pharmacist's discretion. The performance of this function must also be noted in an ancillary personnel utilization plan (AUP) that has been approved by the Pharmacy Commission. Pharmacy personnel are encouraged to review RCW 18.64A.030, RCW 18.64A.040, RCW 18.64A.060, WAC 246-945-001(44), WAC 246-945-315, WAC 246-945-320, and WAC 246-945-410 in their entirety for further details related to this topic.

Recommendation:

Option 1: Clarify that stocking includes stocking an ADDD. Direct staff to draft FAQ clarifying the commission's interpretation of the word stocking in RCW 18.64A.030(2). The function will need to be included in a commission-approved AUP. The use of an electronic verification system equipped with barcode scanning to stock an ADDD may be noted as a best practice that is subject to the discretion of the responsible pharmacy manager.

Option 2: Clarify that stocking does **not** include stocking an ADDD. Direct staff to draft FAQ, interpretive statement, or conduct rulemaking clarifying the commission's interpretation of the word in RCW 18.64A.030(2).

The PQAC staff members recommend the commission approve the draft FAQ with or without edits and authorize commission staff to publish the FAQ.

Follow-up Action: The PQAC team will implement the commission's decision.

PQAC Rules Tracker

Title	Status	Short Description	Most Recent WSR #
COVID - CII Prescribing (emergency)	Emergency rule will sunset; policy statement will replace	Emergency rules for prescribing Schedule II drugs during COVID-19 pandemic	WSR 23-06-016 (Filed February 17, 2023)
Medication assistance (emergency - filed jointly with DOH)	Under division review	Medication assistance emergency rules in accordance with chapter 69.41 RCW	WSR 23-07-056 (Filed March 9, 2023)
Accessible labeling (visual/print access and translated labels)	Rules workshop conducted on June 15, 2023	Standard/significant rules for setting/improving standards for prescription drug information access/comprehension	WSR 22-09-065 (Filed April 19, 2022)
Medication assistance (standard - will file jointly with DOH)	Draft language under interagency discussion	Medication assistance rules in accordance with chapter 69.41 RCW	WSR 22-02-015 (Filed December 27, 2021)
Remote dispensing OUD medications - SSB 6086 (standard)	CR-102 under internal review prior to division review	SSB 6086 - Implementing remote dispensing of OUD medications	WSR 20-17-123 (Filed August 18, 2020)
Donation of unexpired drugs - SSB 6526 (standard)	CR-103p filed and will go into effect June 17, 2023	SSB 6526 - Implementing the donation and reuse of unexpired drugs	WSR 23-11-088 (Filed May 17, 2023)
Rescind Continuing Education rules	CR-103p under internal review prior to division review	Rescind Continuing Education rules	WSR 23-05-010 (Filed February 2, 2023)
Intramammary Antibiotics	Petition granted and response sent to petitioner; CR-101 to be assembled	Amending chapter 246-945 WAC to add certain intramammary formulations to the list of legend drugs.	Not yet filed
NARCAN	CR-101 and CR-103e being prepared for filing	Reclassifying 4mg of NARCAN as an OTC, amending WAC 246-945-030 and creating a new section of WAC	Not yet filed

PQAC Rules Tracker (cont.)

Title	Status	Short Description	Most Recent WSR #
Health Equity Training – ESSB 5229 (standard)	Significant Analysis form drafted; CR-102 package being assembled	Amend sections in Chapter 246-945 WAC pertaining to continuing education standards and establishing health equity CE requirements per ESSB 5229.	WSR 23-01-113 (Filed December 19, 2022)
Uniform Controlled Substances Act – Title 21 CFR (expedited)	CR-105 drafted; rule language review at March business meeting	Amend language in WAC 246-945-040 to incorporate by reference any changes in Title 21 CFR made after the rule's effective date	Not yet filed
Dialysate and dialysis device manufacturer licensing	CR-101 draft pending; policy statement filed in October 2022 under P008	Determine sections in chapter 246-945 WAC (subsection -090 through -093 at least) to amend to comply with SSB 1675	Not yet filed
Access to drugs stored outside pharmacy (standard)	CR-101 filed December 19, 2022; conducting May rules workshop	Allowing access to drugs stored outside the pharmacy by unlicensed employees of a health care facility	WSR 23-01-111 (Filed December 19, 2022)
Mobile OTP unit licensing	CR-101 draft pending	Amend WAC 246-945-060 to clarify licensing standards for mobile OTP units	Not yet filed
Zero Order Reports and Suspicious Orders (standard)	CR-101 in RMS review	Amending WAC 246-945-001 and WAC 246-945-585 to adjust suspicious order and zero reporting requirement	Not yet filed
Technical fixes to chapter 246-945 WAC (expedited)	CR-105 under internal review prior to division review	Typos and small edits to multiple sections in chapter 246-945 WAC	Not yet filed
Removing Fenfluramine from Schedule IV	Petition granted and response sent to petitioner; CR-101 being assembled	Amending chapter 246-945 WAC to remove fenfluramine from the list of Schedule IV substances	WSR 22-22-092 (Filed November 1, 2022)

Suspicious Orders and Zero Reports Language Draft – June 2023 Rules Workshop

PharmacyRules@doh.wa.gov

WAC 246-945-585 Wholesaler—Suspicious orders and due diligence. (1) For the purposes of this section and WAC 246-945-590, "suspicious order" means an order for drugs of concerns or controlled substances that a wholesaler refuses to supply to a customer located in Washington state after completing due diligence.

(2) Wholesalers shall design and operate a system to identify and report suspicious orders of controlled substances and drugs of concern to the commission.

(a) Suspicious orders shall be submitted electronically ~~through a commission approved system or~~ to the commission~~–~~ in a readable format within five business days of~~ the order being identified as suspicious by the wholesaler~~ refusing to supply the order, and must include, but not necessarily limited to:

(i) Customer name;

(ii) Customer address;

(iii) Customer DEA registration number;

(iv) State license number(s);

(v) Transaction date;

(vi) Drug name;

(vii) NDC number;

(viii) Quantity ordered; and

(ix) ~~Indication of whether the drug was shipped, and if not, t~~The factual basis for the refusal to supply.

(b) Zero reports shall be ~~submitted~~ populated if no suspicious orders have been identified in a calendar month, and such reports shall be ~~submitted within fifteen business days of the end of the calendar month.~~ readily retrievable.

(c) Wholesalers may apply to the commission for an exemption from the reporting requirements if they do not distribute controlled substances or drugs of concern.

(~~2~~3) Except as provided in subsection (~~3~~4) of this section, a wholesaler shall exercise due diligence to identify customers ordering ~~or seeking to order~~ controlled substances or drugs of concern, and establish the normal and expected transactions conducted by those customers, as well as to identify and prevent

the sale of controlled substances or drugs of concern that are likely to be diverted from legitimate channels. ~~Such due diligence measures shall include, but are not limited to, the following, which shall be conducted prior to an initial sale and on a regular basis, as necessary:~~

~~(a) Questionnaires and affirmative steps by the wholesaler to confirm the accuracy and validity of the information provided, it shall be considered illegal for a customer to provide false or misleading information;~~

~~(b) For a customer who is a prescriber, confirmation of prescriber type, specialty practice area, and if the prescriber personally furnishes controlled substances or drugs of concern, the quantity furnished;~~

~~(c) Review of drug utilization reports; and~~

~~(d) Obtaining and conducting a review of the following:~~

~~(i) Methods of payment accepted and in what ratios;~~

~~(ii) The ratio of controlled versus noncontrolled prescriptions and overall sales;~~

~~(iii) Orders for controlled substances or drugs of concern from other wholesalers U.S. DEA's Automation of Reports and Consolidated Orders System (ARCOS); and~~

~~(iv) The ratio of out-of-state patients served compared to in-state patients.~~

(~~3~~4) A wholesaler receiving a request for an initial sale of a controlled substance or drugs of concern may conduct the sale before complying with subsection (~~2~~3) of this section if all of the following apply:

(a) The sale is to a new customer;

(b) The wholesaler documents that the order is to meet an emergent need;

(c) The wholesaler completes the requirements of subsection (~~2~~3) of this section no later than sixty business days from the date of sale.

~~(4) A wholesaler receiving a request from an existing customer to purchase a controlled substance or drug of concern, the size/quantity of which exceeds the established algorithm limitations or quota restrictions for such customer, may sell~~

~~the drug of concern or controlled substance provided the customer submit documentation explaining the request.~~

(5) Any potential customer that ~~is believed to be engaged in potential diversion activity, including those to whom a wholesaler refuses to sell,~~ the wholesaler refuses to onboard due to a concern for diversion of controlled substances or drugs of concern shall be electronically reported to the commission. Such reports shall include:

(a) ~~Customer name~~Name of potential customer;

(b) ~~Customer address~~Address of potential customer;

(c) DEA number;

(d) State license number(s);

(e) A detailed explanation of why the wholesaler identified the potential customer as a possible diversion risk; and

(f) Such reports shall be submitted within thirty days of refusal, cessation, or identification by wholesaler.

~~(6) All licensed wholesalers shall submit all reports to the commission in a DEA ARCOS format where applicable.~~

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470,

18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-585, filed 6/1/20, effective 7/1/20.]

Pharmacy Quality Assurance Commission
Remote OUD Dispensing Site Rule Language Draft – June 15, 2023
PharmacyRules@doh.wa.gov

NEW SECTION

WAC 246-945-457 Remote dispensing sites for opioid use disorder medications. A pharmacy may extend its license to register a remote dispensing site where technology is used to dispense medications ~~indicated by the FDA~~used for treatment of opioid use disorder or its symptoms. A pharmacy using this registration is the supplying pharmacy and must comply with subsections (1) through (5) of this section and all applicable regulations in Title 21 C.F.R.

(1) The supplying pharmacy must separately register each remote dispensing site with the commission by completing and returning an application form supplied by the commission and pay applicable fees established by the secretary.

(2) Medications stored in registered remote dispensing sites shall remain under the control of, and be routinely monitored by, the supplying pharmacy.

(3) The supplying pharmacy shall develop and implement policies and procedures to:

(a) Prevent and detect unauthorized access to the registered remote dispensing site;

(b) Document medications used, returned, and wasted from the registered remote dispensing site;

~~(c)~~(c) Require the supplying pharmacy to perform a perpetual inventory of medications stored at the registered remote dispensing site; and

(d) Ensure that only the supplying pharmacy is stocking medications stored at a registered remote dispensing site.

(4) Access and retrieval of medications from the registered remote dispensing site, other than by the supplying pharmacy, must be:

(a) Pursuant to a valid prescription or chart order; and

(b) Limited to health care professionals licensed under the chapters specified in RCW 18.130.040 who are acting within their scope of practice, and nursing students as provided in WAC 246-945-450.

(5) The supplying pharmacy shall ~~E~~ensure the registered remote dispensing site is appropriately equipped to secure and protect medications from diversion or tampering.

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Pharmacy Quality Assurance Commission
Accessible Labeling Rule Language Draft – June 15, 2023
PharmacyRules@doh.wa.gov

WAC 246-945-AAA Accessible Prescription Information -- Definitions.

Unless the context clearly requires otherwise, the following definitions, as well as the definitions in WAC 246-945-001, apply for the purposes of WAC 246-945-AAA through WAC 246-945-DDD:

(1) "Accessible prescription information" means the provision of prescription information that enables a visually impaired, print disabled, or LEP individual to accurately comprehend prescription information regardless of the individual's visual impairment, print disability, or language barrier.

(2) "Competent oral interpretation" means oral 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 an LEP individual to receive all necessary information in the LEP individual's preferred language.

(3) "Complete directions for use" means instructions intended for the individual patient to use in order to understand the intended administration of the dispensed prescription. Elements include the verb (such as, but not limited to take, place, instill), the dosage form (such as, but not limited to tablet, capsule, drops), quantity of the medication, strength of the medication, route of administration, frequency of administration, additional contextual information for administration (such as, but not limited to "as needed," "when tired"), and the reason or indication of the prescription (such as, but not limited to for insomnia, for blood pressure, for anxiety).

~~(3)~~(4) “Dispensing facility” or “dispensing facilities” means a pharmacy, nonresident pharmacy, health care entity, or hospital pharmacy associated clinic that dispenses and delivers medications to the ultimate user or the ultimate user’s authorized representative. It does not include medications dispensed by a pharmacy, nonresident pharmacy, health care entity, and hospital pharmacy associated clinic that are administered by a licensed health care professional.

~~(4)~~(5) “Dispensing practitioner” or “dispensing practitioners” means a practitioner authorized to prescribe legend drugs and who dispenses and delivers medications directly to the ultimate user or the ultimate user’s authorized representative.

~~(5)~~(6) "External accessible device" means a commercially available computer, mobile phone, or other communications device that is able to receive electronic information transmitted from an external source and provide the electronic information in a form and format accessible to the individual.

~~(6)~~(7) “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.

(8) “Means of access” means providing a mechanism to enable a visually impaired or print disabled individual to accurately comprehend prescription information.

(9) “Prescription information” means drug name, patient name/species, complete directions of use, and drug quantity.

~~“Prescription information” means:~~

~~( ) All information required to be affixed to a label pursuant to either WAC 246-945-015 for dispensing practitioners or WAC 246-945-016 for dispensing facilities;~~

~~( ) Written counseling and oral counseling documentation provided with a prescription medication to meet the patient counseling requirement in WAC 246-945-325; and~~

~~( ) Any other such information that a dispensing practitioner or dispensing facility would routinely affix to a prescription container including, but not limited to, pharmacy auxiliary labels.~~

~~Prescription information does not include any packaging or material that has been approved by the FDA.~~

~~(13)~~(10) "Prescription drug reader" means a dedicated electronic device that is able to obtain information from a QR code, or equivalent, affixed to a prescription drug container and provide the information in an audio format accessible to the individual.

~~(14)~~(11) "Print disabled" means the inability to effectively read or access prescription information due to a visual, physical, perceptual, cognitive disability, or other impairment.

~~(15)~~(12) "QR Code" means a two-dimensional barcode printed as a square pattern of black and white squares that encodes data.

~~(16)~~(13) "Translation" shall mean the conversion of a written text from one language into an equivalent written text in another language by an individual competent to do so and utilizing all necessary pharmaceutical and health-related terminology. Such translation may occur, where appropriate, in a separate document provided to an LEP individual or authorized representative that accompanies the prescribed medication.

~~(17)~~(14) "Visually impaired" means:

(a) 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;

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

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

WAC 246-945-BBB Accessible Prescription Information.

(1) Dispensing facilities and dispensing practitioners shall comply with the requirements in WAC 246-945-BBB through WAC 246-945-DDD to provide accessible prescription information unless the prescribed medication is:

(a) A prepackaged medication delivered pursuant to WAC 246-945-435; or

(b) An opioid overdose reversal medication as defined in RCW 69.41.095.

(2) Dispensing facilities and dispensing practitioners shall develop and implement policies and procedures to implement the requirements in WAC 246-945-BBB through WAC 246-945-DDD to provide accessible prescription information.

(3) Dispensing facilities and dispensing practitioners shall provide accessible prescription information as required in WAC 246-945-BBB through WAC 246-945-DDD at no additional cost.

(4) The accessible labeling services required by WAC 246-945-BBB through WAC 246-945-DDD may be provided by an employee of the dispensing facility or dispensing practitioner, the dispensing practitioner, or an independent contractor of the dispensing facility or dispensing practitioner. The use of an independent contractor does not diminish the responsibility of the dispensing facility or dispensing practitioner ~~or employee of the dispensing facility or dispensing practitioner, the dispensing practitioner~~ to comply with this subsection.

(5) The provision of accessible labeling services required by WAC 246-945-BBB through WAC 246-945-DDD shall be provided immediately but need not be provided in-person.

(6) Nothing in this section shall diminish or impair any requirement that a dispensing facility or dispensing practitioner provide any accessibility service, language assistance, interpretation, or translation under 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).

WAC 246-945-CCC Accessibility of Prescription Information for Visually Impaired or Print Disabled Individuals.

(1) Every dispensing facility and dispensing practitioner shall provide means of access to prescription information to visually impaired or print disabled individuals upon the request of the visually impaired or print disabled individual, their prescriber, or their authorized representative.

(2) Every dispensing facility and dispensing practitioner shall offer to provide means of access to prescription information to visually impaired or print disabled individuals when it is self-evident the person to whom the prescription is being prescribed and delivered is visually impaired or print disabled.

(3) If the dispensing facility or dispensing practitioner offers to provide a means of access to prescription information pursuant to subsection (2) of this section but the visually impaired or print disabled individual refuses that service, then the dispensing facility or dispensing practitioner shall document this refusal in the individual's health record.

(4) A dispensing facility or dispensing practitioner shall provide one, or a combination, of the following means of access for visually impaired or print disabled individuals upon the request of the visually impaired or print disabled individual, their prescriber, or their authorized representative:

(a) Printed prescription information in a minimum of 12-point font size, including the ability to affix ~~all~~ the printed prescription information ~~required by WAC 246-945-015 for dispensing practitioners or WAC 246-945-016 for dispensing facilities~~ to the prescription drug container in a minimum of 12-point font size;

(b) Prescription information in Braille;

(c) A QR code, or equivalent, affixed to the prescription drug container that transmits prescription information to an individual's external accessible device; or

(d) A prescription drug reader that is able to obtain prescription information from the label affixed to the prescription drug container and provide the prescription information in an audio format accessible to the individual.

(5) When dispensing facilities or dispensing practitioners provide prescription information in one or more accessible means to visually impaired or print disabled individuals the dispensing facility or dispensing practitioner must still affix their standard label to the prescription drug container that meets the requirements of WAC 246-945-015 for dispensing practitioners or WAC 246-945-016 for dispensing facilities~~, unless the only modification to the standard label is font size~~.

WAC 246-945-DDD Translation and Interpretation for Prescription Information for LEP individuals.

(1) Every dispensing facility and dispensing practitioner shall provide competent oral interpretation and translation services of ~~prescription information~~the complete directions of use ~~a prescribed medication~~ to LEP individuals upon the request of the LEP individual, their prescriber, or their authorized representative.

(2) Every dispensing facility and dispensing practitioner shall offer to provide competent oral interpretation and translation services of ~~prescription information~~the complete

directions of use ~~a prescribed medication dispensed prescriptions~~ to LEP individuals when it is self-evident the person to whom the prescription is being prescribed or delivered is an LEP individual.

(3) If the dispensing facility or dispensing practitioner offers to provide competent oral interpretation and translation services of ~~prescription information~~the complete directions of use ~~a prescribed medication dispensed prescriptions~~ pursuant to subsection (2) of this section but the LEP individual refuses those services, then the dispensing facility or dispensing practitioner shall document this refusal in the individual's health record.

(4) Dispensing facilities and dispensing practitioners who dispense and deliver medications at a fixed physical location shall conspicuously post~~,~~ at, or adjacent to each counter over which prescription drugs are sold, a notification of an individual's right to competent oral interpretation and translation services of ~~prescription information~~the complete directions of use ~~a prescribed medicationdispensed prescriptions~~. The notification shall:

(a) Identify that competent oral interpretation and translation services of ~~prescription information~~the complete directions of use ~~a prescribed medication dispensed prescriptions~~ will be provided at no additional cost upon request;

(b) Be in at least 20-point bold face font;

(c) Be in a color that sharply contrasts with the background color of the sign; and

(d) Be in each language spoken by at least one percent of the population in Washington as determined by the most recent decennial census conducted by the Bureau of the Census of the United States Department of Commerce.

(5) Dispensing facilities and dispensing practitioners who dispense and deliver medications through the mail shall notify individuals of the individual's right to competent oral interpretation and translation services of ~~prescription information~~the complete directions of use ~~a~~

~~prescribed medication dispensed prescriptions~~ when delivering the individual's medication. The notification shall:

(a) Identify that competent oral interpretation and translation services of ~~prescription information~~the complete directions of use ~~a prescribed drug dispensed prescriptions~~ will be provided at no additional cost upon request;

(b) Be in at least 20-point bold face font;

(c) Be in a color that sharply contrasts with the background color of the notification; and

(d) Be in each language spoken by at least one percent of the population in Washington as determined by the most recent decennial census conducted by the Bureau of the Census of the United States Department of Commerce.

(6) Dispensing practitioners and dispensing facilities must still affix a label that meets the requirements of WAC 246-945-015 for dispensing practitioners or WAC 246-945-016 for dispensing facilities in English when providing translation services of ~~prescription information~~the complete directions of use ~~a prescribed drug dispensed prescriptions~~ to LEP individuals.