



January 13, 2023

Washington State Pharmacy Quality Assurance Commission
ATTN: Joshua Munroe
P.O. Box 47852
Olympia, WA 98504-7852

RE: Prescription Label Accessibility Preliminary Outline

Dear Mr. Munroe,

On behalf of the Washington State Hospital Association (WSHA), we thank you for the opportunity to comment on the Pharmacy Quality Assurance Commission's (PQAC) preliminary outline for prescription label accessibility regulations. WSHA represents more than 100 hospitals and health systems in our state, and our hospital members range from large statewide health care delivery systems to small rural hospitals that are the only health care safety net serving rural, remote communities. We are uniquely interested in these requirements due to their impact on hospital pharmacy operations. We believe that providing visual and linguistically accessible prescription labels is an important patient safety protection that will advance equity in the state's health care system. We appreciate the commission's activities to-date to design these rules and we look forward to future engagement.

WSHA supports the recommendations submitted to PQAC by the Washington State Pharmacy Association (WSPA) on January 10, 2023. WSPA's recommendations were developed through direct engagement between pharmacy leaders and language and visual access advocates. WSHA is proud to have participated in the discussions and we appreciate stakeholders' participation.

We offer the following feedback on the proposed outline:

- Include flexibility in WAC 246-945-BBB (2) for conveying translated label information when doing so on the container or packaging is infeasible;
- Define "container";
- Hospitals support the application of these rules solely to outpatient prescriptions;
- Provide a minimum period of 365 days to prepare for compliance from the date rules are adopted;
- Include a waiver for economic hardship, technological limitations, or other exceptional circumstances;
- Exempt prepackaged emergency medications and opioid reversal medications;
- Add liability protection language to WAC 246-945-AAA;
- Research cost estimates and potential funding sources as part of the rule development process; and
- Pause rulemaking activities until after the 2023 legislative session.

Include flexibility in WAC 246-945-BBB (2) for conveying translated label information when doing so on the container or packaging is infeasible

Hospitals are concerned about the proposed requirement in WAC 246-945-BBB (2) to require English and the non-English translation to appear on the prescription container simultaneously. This may create challenges for printing labels that convey the required information in both languages due to label size limitations. Additionally, we are concerned about the potential lack of available space on containers for attaching a large label or multiple labels. Because of this, we recommend PQAC explore flexible options

for conveying the translated information to ensure the information is provided in a way that satisfies patients' needs and the space limitations posed by labels and various prescription containers. Flexible options could include allowing the patient or their representative to choose which label is on the container, or allowing the information to be conveyed on a separate sheet of paper.

Define "container"

The proposed rule outline uses the term "container" throughout. However, this term is undefined in chapter 246-945 WAC, which could lead to different interpretations of what constitutes a container within the context of these regulations. Defining "container" will provide clarity for these rules.

Hospitals support the application of these rules solely to outpatient prescriptions

Hospitals support the proposed application of these regulations solely to outpatient prescriptions and appreciate PQAC designing the rule outline to do so. The scoped applicability to outpatient prescriptions will prevent delays in care for inpatients due to additional work that may be required under the eventual regulations. Additionally, the applicability to outpatient prescriptions is consistent with the provisions of [ESHB 1852 \(2022\)](#) section 1 (7).

Provide a minimum period of 365 days to prepare for compliance from the date rules are adopted

Pharmacies will need time to comply with the eventual regulations to ensure that new systems work properly and staff are sufficiently trained. Unfortunately, this work cannot begin until there is certainty about what the eventual regulations will require. Hospitals will also need time to evaluate their needs and contract with vendors, in addition to the time required to adjust pharmacy systems and workflow processes. Because of this, we support WSPA's recommendation for PQAC to provide at least 365 days to prepare for compliance from the date the rules are adopted.

Include a waiver for economic hardship, technological limitations, or other exceptional circumstances

The eventual regulations adopted by PQAC are likely to require significant investments of resources and time to implement. The technological aspects are likely to involve products and services from external vendors that need to be integrated into hospitals' existing workflow and systems. Because of this, we support WSPA's recommendation for PQAC to include a waiver for economic hardship, technological limitations, or other exceptional circumstances. This will ensure that hospitals are not penalized if circumstances beyond their control such as finances and vendor challenges prevent on-time compliance.

Exempt prepackaged emergency medications and opioid reversal medications

Hospitals recommend that PQAC exempt prepackaged emergency medications as described in RCW 70.41.480 and opioid reversal medications distributed in accordance with RCW 70.41.485 and RCW 71.24.594. These limited quantity medications are provided to patients through hospital emergency departments, where access to full hospital pharmacy services may not be available during off hours. Additionally, the time necessary to provide the information could create delays in discharging patients from emergency departments. Including this exemption would be consistent with the provisions in [ESHB 1852 \(2022\)](#) section 1 (8).

Add liability protection language to WAC 246-945-AAA

Hospitals support the inclusion of conceptual liability protection language for contracting with third parties in proposed WAC 246-945-BBB (6) for language translation services. However, proposed WAC 246-945-AAA does not contain any liability protection language despite the likelihood that pharmacies

will need to contract with third party vendors to comply with the visual accessibility requirements. Because of this, we recommend adding liability protection language into WAC 246-945-AAA to provide the same level of liability protection for contracting with third parties for visual access services.

Research cost estimates and potential funding sources as part of the rule development process

PQAC’s eventual rules will come with significant implementation costs for hospital pharmacies. The costs are likely to include hardware costs for new printers capable of satisfying the regulatory requirements; software startup and annual subscription costs; software expansion costs to add languages as they are adopted by PQAC; staff training costs to ensure proper use of technological resources; and other costs to ensure that hardware and software remain compliant with future modifications to the rules. Moreover, it is very likely that compliance costs will be incurred simultaneously as hospitals recover from the COVID-19 pandemic. Statewide, hospitals lost \$1.6 billion from operations for January – September of 2022. These losses are not sustainable and are impacting hospitals’ abilities to make important investments in their facilities. Because of this, we recommend PQAC research the costs associated with these rules as they are developed and identify potential funding options to support hospitals’ compliance. WSHA is open to further discussion on cost assistance and finding solutions to ensure hospitals have a smooth path for compliance with these important regulations.

Pause rulemaking activities until after the 2023 legislative session

Hospitals appreciate PQAC moving this important regulatory process forward. However, hospitals are currently focused on multiple pieces of pending legislation and it will be difficult for them to engage in this process until the legislative session concludes. Because of this, we recommend PQAC pause formal accessible label rulemaking activities until the 2023 legislative session concludes.

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Thank you again for the opportunity to comment on PQAC’s preliminary outline for prescription label accessibility regulations. Should you have additional questions on WSHA’s recommendations, please contact WSHA Policy Director Remy Kerr via email at RemyK@WSHA.org.

Sincerely,



David Streeter
Government Affairs
Washington State Hospital Association



Remy Kerr
Policy Director
Washington State Hospital Association