



August 19, 2022

Washington State Pharmacy Quality Assurance Commission
Attn: Marlee O'Neill
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P.O. Box 47877
Olympia, WA 98504-7877

RE: Proposed Uniform Facility Enforcement Framework

Dear Ms. O'Neill

On behalf of the Washington State Hospital Association (WSHA), thank you for the opportunity to provide feedback on the Uniform Facility Enforcement Framework draft bill language. 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 appreciate the Commission's engagement with WSHA staff on the proposed language and are grateful for the Commission's decision to grant additional time for review and feedback. We offer the following recommendations for the draft bill language.

- Amend the definitions in section 14 to clarify the statutory intent.
- Amend section 17 (b)(iii) to establish fines based on license holder type and size.
- Prohibit multiple enforcement actions for the same or similar violations.

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Amend Definitions in Section 14 to Clarify the Statutory Intent

We appreciate Commission staff explaining that this proposed bill is intended to apply solely to facilities and not individual pharmacists covered under the Uniform Disciplinary Act in chapter 18.130 RCW. However, the language in sections 15, 16, and 17, "*[t]his section does not govern actions taken under chapter 18.130 RCW,*" does not feel sufficient to clarify that intent when followed by language such as:

"The commission is authorized to take any of the actions identified in this section against licenses, registrations, permits, or other credentials or approvals issued by the commission under chapters 18.64, 18.64A, 69.38, 69.41, 69.43, 69.45, and 69.50 RCW in any case in which it finds the licensee has failed or refused to comply with any state or federal statute or administrative rule regulating the license in question, including but not limited to title 69 RCW, chapters 18.64 and 18.64A RCW, and administrative rules adopted by the commission."

Because pharmacist and pharmacist assistant licenses are issued under RCW 18.64 and 18.64A, the initial sentence regarding the Uniform Disciplinary Act does not clearly remove individual licensees from the scope of enforcement actions under this bill. These two sentences together create confusion as to the statutory intent.

WSHA recommends amending section 14 to remedy this issue and make clearer which individuals, facilities, or entities regulated by the Commission each statutory section applies to. A clear definition section, with use of well-defined terms throughout the bill, will benefit statutory interpretation in the

future. WSHA's suggestions are as follows:

Edit Section 14 to Define "Licensee" and to Create a New Definition to Encompass Non-Pharmacist License-holders

Section 14 does not contain a definition of "licensee." Instead, "license" is defined as equivalent to a list of other terms. We recommend creating a new definition of "licensee" to be used in cases when the commission is referring to all license holders, including individual pharmacists.

Additionally, the Commission should create a new definition that encompasses pharmacies, health care entities, manufacturers, distributors, and any other license that is not issued to an individual person. This definition would be inserted into bill sections 15, 16, and 17, as well as any other provision that is not intended to apply to individually licensed persons.

WSHA's suggestions for edits to the definition section could fulfill the goal of providing more clarity, but we are open to different changes to the definition section so long as the terms are accurately defined and appropriately integrated throughout the bill.

Amend Section 17 (b)(iii) to Establish Fines Based on License Holder Type and Size

The mandate for the Commission to establish fines in rules in section 17 (b)(iii) appears to treat all licensees the same, regardless of size or type. Hospitals are concerned that the lack of distinction could lead to burdensome fines against smaller pharmacies, such as those within critical access and rural hospitals. The lack of distinction could also lead to hospitals being treated the same as retail pharmacies, manufacturers, and wholesalers despite hospitals' patient-focused missions. Because of this, we recommend amending section 17 (b)(iii) to allow the Commission to adopt differentiated fines in rules instead of a standardized set of fines. We recommend the following language:

(iii) The commission shall adopt in rules under this chapter to establish specific fine amounts in relation to the license holder type, license holder size, and severity of the noncompliance and at an adequate level to be a deterrent to future noncompliance. *(The term "license holder" could/should be replaced when the definition section is updated.)*

Prohibit Multiple Enforcement Actions for the Same or Similar Violations

Since hospitals hold multiple types of licenses, we are concerned that hospitals could be subject to multiple enforcement actions for the same or similar violations. This would be burdensome for hospitals and create duplicative work for state agencies and commissions. Because of this, we recommend adding a new section to chapter 43.70 RCW as follows:

NEW SECTION Sec. X. A new section is added to chapter 43.70 RCW to read as follows:

If the department takes enforcement action against a license holder as authorized under this Act, RCW 70.41.130, or RCW 71.12.710, the department may not impose additional enforcement actions against that license holder based on the same or similar violation under a different chapter of this Act, RCW 70.41.130, or RCW 71.12.710. Nothing in this section shall limit the department from taking enforcement action for separate violations.

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Thank you again for the opportunity to comment on the Commission's proposed bill language. Should you have additional questions on WSHA's recommendations, please contact David Streeter via email at DavidS@wsha.org or Cara Helmer via email at CaraH@wsha.org.

Sincerely,



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