September 2, 2021

Pharmacy Quality Assurance Commission

Meeting Materials

As of August 30, 2021

STATE OF WASHINGTON
Pharmacy Quality Assurance Commission
PO Box 47852 – Olympia, Washington 98504-7852
Tel: 360-236-4030 – 711 Washington Relay Service

Pharmacy Quality Assurance Commission Meeting
July 16, 2021 - Minutes

Convene: Chair, Teri Ferreira called the meeting to order July 16, 2021, 9:03 a.m.

Commission Members:
Teri Ferreira, RPh, Chair
Jerrie Allard, Public Member, Vice Chair
Tim Lynch, PharmD, MS, FABC, FASHP
Craig Ritchie, RPh, JD
Judy Guenther, Public Member
Hawkins DeFrance, Nuclear Pharmacist
Ken Kenyon, PharmD, BCPS
Patrick Gallaher, BS, BPharm, MBA, MPH
William Hayes, PharmD, CCHP
Uyen Thorstensen, CPhT

Commission Member Absent:
Bonnie Bush, Public Member

Staff Members:
Lauren Lyles-Stolz, Executive Director, Pharmacy Commission
Christie Strouse, Deputy Director, Pharmacy Commission
Christopher Gerard, AAG
Marlee O'Neill, Deputy Director, OILS
Hope Kilbourne, Policy Analyst
Lindsay Trant, Rules Program Manager, Pharmacy
Martin Pittioni, Director, OHP
Joanne Miller, Program Manager, Pharmacy
Amy L Robertson, Administrative Assistant, Pharmacy

1. Call to Order Teri Ferreira, Chair

1.1. Meeting Agenda Approval

MOTION: Craig Ritchie moves to approve the July 16, 2021 meeting agenda and move item 5.5 to 1.4; Jerrie Allard, second. Motion carries, 10:0.

1.2. Meeting Minutes Approval, June 3, 2021

MOTION: Craig Ritchie moves to approve the June 3, 2021 meeting minutes; Tim Lynch, second. Motion carries, 10:0.

1.3. Meeting Minutes Approval, June 4, 2021

MOTION: Craig Ritchie moves to approve the June 4, 2021 meeting minutes; Tim Lynch, second. Motion carries, 10:0.

1.4. Chair Recognition Award. Commission presented Tim Lynch with a recognition award for his years of dedication and service to the people of Washington State and PQAC.

2. Executive Session. The Commission convened in executive session between 9:05 am and 10:15 am to discuss with legal counsel representing the Commission matters relating to

Commission enforcement actions, or to discuss with legal counsel representing the Commission litigation or potential litigation to which the Commission is, or is likely to become, a party, when public knowledge regarding the discussion is likely to result in an adverse legal or financial consequence to the Commission pursuant to RCW 42.30.110(1)(i).

10:15 a.m. Roll Call – all present.

3. Consent Agenda

3.1. **MOTION:** Craig Ritchie moves to approve the consent agenda with the exception of 3.3.6, 3.3.3, 3.3.1, 3.4.1, and 3.4.2; Patrick Gallaher, seconds. Motion carries, 10:0.

3.5. Items Pulled

3.3.6 MultiCare Rockwood Clinic Pharmacy – Tim Lynch recused himself from this vote.

MOTION: Jerrie Allard moved to approve 3.3.6 MultiCare Rockwood Clinic Pharmacy; Craig Ritchie, second. Motion carries 9:0.

3.3.3 Geneva Woods Pharmacy

MOTION: Craig Ritchie moves to approve 3.3.3 on the condition of a communication stating "this approval applies only to the update to the pharmacy technician in training AUP (not as indicated in the SBAR)" William Hayes, second; motion carries, 10:0.

3.3.1 CHAS Specialty Pharmacy (multiple locations) – commission consensus to return this application for clarification on the ancillary plan and who can type prescription labels (scope of practice). No motion needed.

3.4.1 Brewster Multiple locations TTP – seems to be missing items. Return to Irina Tiginyanu for clarification. No motion needed.

3.4.2 Charter College TTP – Consensus to return application to Charter College for clarification on accurate course hours needed for law courses. No motion needed.

4. Old Business.

4.1 **Change of Ownership Update/Discussion** – Does stock purchase involving more than 50% of the shares in a pharmacy corporation trigger the commissions "Change of Ownership" process? Commission concurs to send FAQ back to staff for further review at next business meeting.

MOTION: Patrick Gallaher motions that the commission find that a stock sale involving more than 50% of the shares in a pharmacy corporation triggers the commission's change of ownership process based on the applicable laws and rules. Further the staff publish the FAQ to include a list of business model permutations; and DOH team to communicate

this decision internally to the credentialing team, inspectors, and investigators that directly support the commission. Craig Ritchie, second. Motion carries 10:0.

Ronald Friedman, stakeholder, asked that the commission release an FAQ on this specific topic (50%), then address others if needed. Richard Molitor, stakeholder, gave specific examples of when this FAQ would have helped.

5. New Business

5.1. Presentation – PMP Rules

Presenter: Ryan Pistoresi, Assistant Chief Pharmacy Officer, from Health Care Authority (HCA) reviewed the new rules (SUPPORT Act, Section 5042) for PMP and how it impacts Apple Health (Medicaid).

5.2. Presentation – White Bagging of Medications Negative Consequences on Individual and Organizational Patient Safety

Presenters: David Chen, R.Ph., M.B.A, Assistant Vice President for Pharmacy Leadership and Planning, American Society of Health-System Pharmacists (ASHP)

Kyle Robb, Pharm.D., State Policy & Advocacy Associate, American Society of Health-System Pharmacists (ASHP)

David Chen and Kyle Robb presented concerns and case studies on white bagging.

MOTION: Craig Ritchie motions that staff gather other state statutes and rules to report back to the commission; Timothy Lynch, second. Motion carries, 10:0.

(Tim Lynch left the meeting c. 1:00 p.m.)

5.3. Approval 2022 Business Meeting Dates

Commission asked staff to recalculate business meeting dates at eight-week intervals (rather than six as has been done previously). Also, plan post-COVID meetings both inperson and virtual.

5.4. Sunrise Reviews Public Comments Approvals

5.4.1. Anesthesiologist Assistant License – PQAC staff had no public comments on the anesthesiologist sunrise review at this time. Lauren Lyles-Stolz confirmed this will return to the commission if needed.

5.4.2. Midwifery Scope of Practice

MOTION: Craig Ritchie moves to approve the proposed letter regarding the scope of practice for midwifery; Jerrie Allard, second; motion passes 9:0.

5.4.3. Optometrist Scope of Practice

MOTION: Craig Ritchie moves to approve the sunrise review comment letter regarding optometrists; Patrick Gallaher, second; motion passes 9:0.

6. Rules and Legislative Session Updates – Lindsay Trant updated the commission:

6.1. Public Hearing on Fees – the CR-102 rules package was filed on May 28th, 2021 under WSR 21-12-074. Two technical edits were included. The planned completion date for these fee rules and the implementation of the two-year license renewals is December 1, 2021. Any license renewals for pharmacy professions that take place on or after December 1st will be for a two-year license period.

6.2. Retired Pharmacist Emergency Rules Reauthorization - The CR-101 for permanent rulemaking has been filed but the permanent rules will not be complete by the time the emergency rules expire on September 30th. The staff asks the commission to consider reauthorizing staff to file a CR-103E to extend the emergency rules for an additional 120 days.

MOTION: Patrick Gallaher moves to approve authorizing staff to refile the CR-103E emergency rules for the Retired Pharmacist Status; Jerrie Allard, second; motion passes 9:0.

7. Open Forum – none.

8. Commission Member Reports

8.1. Strategic Planning Subcommittee Briefing – Lauren Lyles-Stolz reviewed PQAC sub-committees and priorities.

MOTION: Craig Ritchie motions to approve the committees and subcommittees as captured in the meeting; in addition, accepting the rearranged priorities; Ken Kenyon, second; motion passes 9:0.

MOTION: Jerrie Allard moves to adopt the innovative goals as outlined in the slide presentation; Ken Kenyon, second; motion passes 9:0.

8.2. Budget Subcommittee Briefing – Ken Kenyon updated the commission that the budget looks healthy. However, keep in mind as things ramp up after COVID, there will be additional expenditures we have not had for some time (staffing, HELMS, travel, etc.).

8.3. Commissioners Reports – None

Teri Ferreira informed the commission on August 11, Dr. Lauren Lyles-Stolz will relinquish her position as executive director. Commissioners and staff thanked Lauren for her time with PQAC as well as she will be sorely missed.

8.4. Commissioners Open Discussion

Martin Pittioni (OHP Director) broached the topic of the executive director position not needing to be a pharmacist as legislated in RCW 18.64.310(2). The general consensus of the commission is that the executive director position should continue to be filled by a pharmacist.

Patrick Gallaher request the commission consider having a solid date to open the discussion reviewing the ancillary practice templates. Lauren Lyles-Stolz assured the commission that this issue is slotted for the September meeting.

9. Staff Reports

9.1. Executive Director – Lauren Lyles-Stolz

Review and Approval: FAQ on New Compounding Law going into effect July 25, 2021.

MOTION: Ken Kenyon moves to approve the FAQ as represented; Craig Ritchie, second; motion carries 9:0.

9.2. Deputy Director – Christie Strouse – none.

9.3. Assistant Attorney General – Christopher Gerard

Christopher Gerard informed the commission that PQAC was served with a complaint as part of a lawsuit filed by John Worthington. Mr. Worthington is challenging the denial of his rulemaking petition. The complaint also names the Department of Health and Governor Jay Inslee as defendants in the lawsuit. The complaint also challenges the validity of a number of statutory provisions within the Uniform Controlled Substances Act (RCW 69.50). The Commission will receive updates as this case continues.

10. Summary of Meeting Action Items

- 3 – Consent agenda items 3.4.2, 3.3.1, 3.3.3, and 3.4.1 will be returned to staff to gather more information.
- 4 – Old Business – post change of ownership FAQ to Listserv and our website (with appropriate links); inform credentialing, inspectors, etc. of the same. Adding, "if the licensee has questions not addressed in this FAQ, please contact PQAC."
- 5.2 – White bagging – staff to gather information from other states statutes and rules to be presented at next meeting.
- 5.3 – 2022 Business meeting projection – staff suggest new business meeting schedule for 2022 with eight-week intervals as well as developing a hybrid of in person and virtual meetings.
- 5.4.3 – Optometrists – staff submit to DOH the approved letters
- 6.2 – Emergency rules for retired pharmacists' status
- 8.1 – staff will update the subcommittee list in conjunction with the strategic plan.
- 9.1 – update FAQ on New Compounding Law going into effect July 25, 2021.

Meeting adjourned 3:11 p.m.

Next scheduled business meeting: **September 2, 2021**
9:00 a.m.
Virtual – by Webinar

MONTHLY PROGRAM ADMINISTRATOR'S DASHBOARD

3 Logins - 0 Searches - 0 Report Queries - 32 Active Watches - 0 Active Watch Hits

NEW USERS THIS MONTH	TOP USAGE AGENCIES	TOP AGENCIES BY ACTIVE WATCHES
New Users = 0		1. NW HIDTA (76)
Total Accounts = 139	TOP USERS BY USAGE	2. ICE - King County (10)
Active Users = 2		

TRANSACTION SUMMARY STATISTICS (2021)

	JAN	FEB	MAR	APR	MAY	JUN	JUL	TOTAL
PURCHASES	58,504	51,943	70,640	82,986	78,777	84,242	79,222	**506,314**
BLOCKS	2,433	2,301	2,931	3,933	3,515	3,763	3,233	**22,109**
GRAMS SOLD	130,934	117,632	165,200	197,654	185,979	198,842	181,384	**1,177,625**
BOXES SOLD	66,771	59,470	79,346	92,123	87,787	93,305	88,636	**567,438**
GRAMS BLOCKED	6,569	7,011	8,009	11,356	9,993	10,793	8,922	**62,653**
BOXES BLOCKED	2,700	2,897	3,183	4,360	3,929	4,110	3,617	**24,796**
AVG GRAMS PER BOX BLOCKED	2.43	2.42	2.52	2.60	2.54	2.63	2.47	**2.52**

PHARMACY PARTICIPATION STATISTICS (Jul 2021)

Enabled Pharmacies	999
Pharmacies Submitting a Transaction	944
Pharmacies Logging in Without a Transaction	0
Inactive Pharmacies	55
Pharmacy Participation for Jul	94.49%

Credential #	Status	First Issuance Date	Effective Date	Expiration Date
PHNR.FO.61133896	ACTIVE	07/01/2021	07/01/2021	05/31/2022
PHNR.FO.61171600	ACTIVE	07/02/2021	07/02/2021	05/31/2022
PHNR.FO.61186363	ACTIVE	07/02/2021	07/02/2021	05/31/2022
PHNR.FO.61157112	ACTIVE	07/02/2021	07/02/2021	05/31/2022
PHNR.FO.61189391	ACTIVE	07/06/2021	07/06/2021	05/31/2022
PHNR.FO.61196515	ACTIVE	07/06/2021	07/06/2021	05/31/2022
PHNR.FO.61194981	ACTIVE	07/06/2021	07/06/2021	05/31/2022
PHNR.FO.61195559	ACTIVE	07/06/2021	07/06/2021	05/31/2022
PHNR.FO.61196504	ACTIVE	07/06/2021	07/06/2021	05/31/2022
PHNR.FO.61195015	ACTIVE	07/06/2021	07/06/2021	05/31/2022
PHNR.FO.61195923	ACTIVE	07/06/2021	07/06/2021	05/31/2022
PHHC.FX.61189598	ACTIVE	07/07/2021	07/07/2021	09/30/2022
PHNR.FO.61199126	ACTIVE	07/07/2021	07/07/2021	05/31/2022
PHAR.CF.61097923	ACTIVE	07/12/2021	07/12/2021	05/31/2022
PHAR.CF.61183438	ACTIVE	07/19/2021	07/19/2021	05/31/2022
PHAR.CF.61139039	ACTIVE	07/19/2021	07/19/2021	05/31/2022
PHHC.FX.61162624	ACTIVE	07/19/2021	07/19/2021	09/30/2022
PHHC.FX.61148764	ACTIVE	07/19/2021	07/19/2021	09/30/2022
PHNR.FO.61203072	ACTIVE	07/19/2021	07/19/2021	05/31/2022
PHNR.FO.61171571	ACTIVE	07/29/2021	07/29/2021	05/31/2022
PHHC.FX.61146714	ACTIVE	08/02/2021	08/02/2021	09/30/2022
PHHC.FX.61183375	ACTIVE	08/02/2021	08/02/2021	09/30/2022
PHHC.FX.61200955	ACTIVE	08/02/2021	08/02/2021	09/30/2022
PHAR.CF.61178549	ACTIVE	08/04/2021	08/04/2021	05/31/2022
PHNR.FO.61185541	ACTIVE	08/04/2021	08/04/2021	05/31/2022
PHNR.FO.61210493	ACTIVE	08/05/2021	08/05/2021	05/31/2022
PHNR.FO.61210594	ACTIVE	08/05/2021	08/05/2021	05/31/2022
PHNR.FO.61209473	ACTIVE	08/06/2021	08/06/2021	05/31/2022
PHNR.FO.61209464	ACTIVE	08/06/2021	08/06/2021	05/31/2022
PHNR.FO.61208295	ACTIVE	08/06/2021	08/06/2021	05/31/2022
PHNR.FO.61211824	ACTIVE	08/11/2021	08/11/2021	05/31/2022
PHNR.FO.61211733	ACTIVE	08/11/2021	08/11/2021	05/31/2022
PHAR.CF.61146433	ACTIVE	08/12/2021	08/12/2021	05/31/2022
PHNR.FO.61205364	ACTIVE	08/12/2021	08/12/2021	05/31/2022
PHHC.FX.61202495	ACTIVE	08/23/2021	08/23/2021	09/30/2022
PHNR.FO.61169731	ACTIVE	08/23/2021	08/23/2021	05/31/2022
PHNR.FO.61205343	ACTIVE	08/23/2021	08/23/2021	05/31/2022
PHNR.FO.61213436	ACTIVE	08/24/2021	08/24/2021	05/31/2022

Credential #	Status	First Issuance Date	Effective Date	Expiration Date
PHNR.FO.61199141	CLOSED	07/07/2021	07/07/2021	08/11/2021

3.1

Proposed 2022 Pharmacy Commission

Business Meeting Dates

(Thursday & Friday)

(8 weeks dates)

January 27, 2022
January 28, 2022

March 24, 2022
March 25, 2022

May 12, 2022 (7 weeks)
May 13, 2022
Conflict NABP May 19-20, 2022

July 14, 2022
July 15, 2022

September 22, 2022
September 23, 2022

November 17, 2022
November 18, 2022

2023

January 12, 20023
January 13, 2023

Proposed 2022 PQAC Business Meetings

JANUARY						
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DECEMBER						
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Department of Health
Pharmacy Quality Assurance Commission

Policy Statement

Revised – 10/18/11

Title:	Enforcement of USP Chapters <800> and <825>	*Number: 65.1*
References:	RCW 18.64.270(2); WAC 246-945-016, WAC 246-945-017, WAC 246-945-100, and WAC 246-945-490; United States Pharmacopeia Chapters <795>, <797>, <800>, and <825>; Pharmacy Commission Policy #60.1	
Contact:	Lauren Lyles-Stolz, PharmD, Executive Director	
Phone:	(360) 236-4946	
Email:	wspqac@doh.wa.gov	
Effective Date:	April 1 2021	
Supersedes:	Policy 65 effective October 1, 2020	
Approved By:	Tim Lynch, PharmD, MS, FABC, FASHP, Pharmacy Quality Assurance Commission Chair	

This policy clarifies the Pharmacy Quality Assurance Commission's (commission) approach to United States Pharmacopeia (USP) chapters <800> (USP 800) and <825> (USP 825) as it relates to WAC 246-945-100 and RCW 18.64.270(2).

The commission will not find deficiencies or take enforcement action against its licensees for failure to comply with USP 800 through September 30, 2021.

The commission will not find deficiencies or take enforcement action against its licensees for failure to comply with USP 825 through September 30, 2021.

When appropriate, the commission will revisit its use of enforcement discretion for USP 800 and USP 825. Any decision to modify the commission's use of enforcement discretion for USP 800 and USP 825 will be during an open public meeting before September 30, 2021.

The commission will consider extending its use of enforcement discretion for USP 800 and USP 825 if USP has not made the revised USP chapters <795> (USP 795) and <797> (USP 797) official. In addition, if USP makes the revised USP 795 and USP 797 official prior to September 30, 2021, the commission will consider whether to extend its use of enforcement discretion for an additional period of time. The commission has considered and may revisit the delayed enforcement of USP 800 and USP 825 until the revised USP 795 and USP 797 are made official to avoid licensees being subject to USP standards that conflict with each other. For those licensees who choose to become early adopters of USP 800, the commission's approach to the

discrepancies between USP 797 and USP 800 can be found in a separate policy statement (#60.1), "Regulation of the Handling of Hazardous Drugs" available on the commission's website.

Table of PQAC's Enforcement Discretion Timeline	
USP Chapters	Enforcement Discretion
USP 800	October 1, 2020 – September 30, 2021
USP 825	October 1, 2020 – September 30, 2021
Revised USP 795 and 797	N/A; Revised Chapters have not been released
Current USP 795 and 797 **These chapters will continue to be enforced.**	

Note: Please see Pharmacy Commission Policy #60.1 regarding direct conflicts between USP 797 and USP 800.

In 2013, the Washington State Legislature adopted standards set by USP as the standards pharmacies must meet when sterile or non-sterile compounding. RCW 18.64.270(2) states "Any medicinal products that are compounded for patient administration or distribution to a licensed practitioner for patient use or administration shall, at a minimum, meet the standards of the official United States pharmacopeia as it applies to nonsterile products and sterile administered products." As a result, the commission has enforced standards published by USP for sterile and non-sterile compounding since 2014.

The commission's new chapter (chapter 246-945 WAC) went into effect on July 1, 2020. This chapter rewrite took place over two and half years and included extensive collaboration with stakeholders.

The new chapter includes enforcement of USP standards in accordance with RCW 18.64.270(2). Specifically, WAC 246-945-100 Compounding minimum standards requires that licensees comply with USP chapters 795, 797, 800, and 825. There are additional requirements for the labeling of compounded products in WAC 246-945-016 and WAC 246-945-017. WAC 246-945-490(3) and (4) also require nuclear pharmacies to prepare, compound, and dispense radiopharmaceuticals in accordance with the standards in USP 825.

The commission recognizes that there are discrepancies between USP 797 and USP 800 in its current form; however, its approach to these discrepancies is established in a separate policy statement (#60.1), "Regulation of the Handling of Hazardous Drugs" available on the commission's website.

If USP makes the revised USP 795 and USP 797 official prior to September 30, 2021, the commission will consider whether to extend its use for enforcement discretion for an additional period of time to allow licensees to comply with all applicable USP chapters at a future open public meeting.

STATE OF WASHINGTON

DEPARTMENT OF HEALTH

Olympia, Washington 98504

NOTICE OF ADOPTION OF A POLICY STATEMENT

Title of Policy Statement: Enforcement of USP Chapters <800> and <825> | Policy Statement Number: 65.1

Issuing Entity: Pharmacy Quality Assurance Commission

Subject Matter: This policy clarifies the Pharmacy Quality Assurance Commission's approach to United States Pharmacopeia chapters <800> and <825> as it relates to WAC 246-945-100 and RCW 18.64.270(2). Extending the sunset date of the policy to September 30, 2021.

Effective Date: April 1, 2020

Contact Person: Lindsay Trant
Rules & Legislative Consultant
Pharmacy Quality Assurance Commission,
Washington State Department of Health
360-236-2932
PharmacyRules@doh.wa.gov

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: April 02, 2021
TIME: 9:56 AM

WSR 21-08-046

Commission SBAR Communication

Agenda Item/Title: OTC Wholesalers Without a Home State License: OTC Wholesaler Licensure and Inspection Requirement In-State vs Out-of-State

Date SBAR Communication Prepared: May 12, 2021; **Update:** August 20, 2021

Reviewer: Lauren Lyles-Stolz, PharmD, Executive Director

Link to Action Plan:

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

Situation: (Briefly describe the current situation. Give a clear, succinct overview of pertinent issues)

Wholesalers located outside of Washington State that exclusively distribute over-the-counter (OTC) drugs are often not required to hold a wholesaler license and have therefore not received an inspection from the resident state board of pharmacy. WAC 246-945-246(3) requires that a wholesaler applicant located outside of Washington State provide a copy of the resident state license and a copy of a site inspection conducted by the resident regulatory authority or a third-party inspection program recognized by the Pharmacy Quality Assurance Commission (commission). The commission can consider if any adjustments are needed to WAC 246-945-246(3) to accommodate OTC-only wholesalers.

Background: (Briefly state the pertinent history):

While the old rule (WAC 246-879-070) required OTC-only wholesalers to be licensed as a wholesaler, the rule did not require proof of licensure or a copy of an inspection from the resident state for out-of-state applicants. In the new chapter, WAC 246-945-246 (1)(b) requires "In-state and out-of-state pharmaceutical wholesalers" to be licensed by the commission as a wholesaler. This provision applies to wholesalers distributing prescription and OTC drugs. WAC 246-945-246(3) contains additional requirements for wholesaler applicants located outside of Washington State. Specifically, WAC 246-945-246(3) requires that the out-of-state applicant provide:

> (a) A copy of a site inspection conducted by the regulatory authority in the resident U.S. jurisdiction or third-party inspection program recognized by the commission within the last two years and every two years with the distributor's renewal;
> (b) A copy of the resident state license; and
> (c) A list of licenses, registrations, permits or certificates held in other U.S. jurisdictions.

The 2021 NABP Survey of Law indicates that out of the 50 states, 15 require wholesaler distributors of nonprescription drugs to be licensed. Staff have also received feedback from an applicant that their resident state which does not license nonprescription drug

wholesalers does not offer inspections for OTC-only distributors. PQAC inspectors currently inspect all wholesalers in Washington State, including OTC-only distributors.

There are two third-party inspection programs recognized by the commission: NABP Drug Distributor Accreditation (DDA) (formerly VAWD) and, more recently, National Coalition for Drug Quality & Security (NCDQS). NABP DDA does not offer inspections for OTC-only distributors at this time. The program is primarily focused on prescription drugs and devices; however, if issues are observed during their onsite survey that involve OTC drugs, NABP will collect the information and determine if a violation of state or federal law is occurring in that facility. NCDQS also does not currently inspect OTC-only distributors but have indicated to staff that they would be able to.

Finally, at the April 23rd business meeting, the commission voted to accept a proof of license or evidence that the resident state does not require a license or inspections as well as temporarily defer inspections of OTC wholesalers until a method of inspection is established for both in and out of state OTC wholesalers. The commission can now revisit this topic and determine what, if any, adjustments are needed to accommodate OTC-only distributors.

Update: Staff heard back from NABP on July 21, 2021 that they will not expand their inspection program to encompass OTC-only wholesalers at this time.

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

The current rule [specifically WAC 246-945-246(3)(a) and (b)] pose a challenge to out-of-state OTC-only distributors whose resident state does not require licensure or offer inspections.

Since the commission recently recognized NCDQS as a third-party inspection program for wholesalers, commission staff can refer out-of-state OTC-only wholesalers to their services in order to meet the requirements in WAC 246-945-246(3)(a). However, if the resident state does not require OTC-only wholesalers to be licensed they are not able to comply with WAC 246-945-246(3)(b). Additional guidance or rulemaking is needed to accommodate these wholesaler applicants.

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

OPTION 1 (Recommended): Resume the option of in-state OTC wholesaler inspections AND refer people to NCDQS for an out-of-state inspection—especially for those states that require licensure for OTC wholesalers. If a state does not require licensure then the commission may need to develop guidance and future rulemaking to address this gap. This guidance may provide out-of-state applicants with an option to submit a letter in lieu of the inspection report and proof of licensure from their regulatory authority stating that they are not required to be licensed in their resident state. Secondly, the

commission may consider rulemaking to either remove or modify WAC requirements, WAC 246-945-246(3)(a) and (b), for out-of-state OTC-only wholesalers. Finally, Staff can also submit a formal ask to NABP to consider incorporating future OTC wholesaler inspections in their inspection portfolio.

OPTION 2: Continue current decision of deferring inspection of in-state and out-of-state OTC wholesalers AND accept approval or evidence of a state board that does not require a license or inspections.

OPTION 3: Other actions as determined by the commission.

Commission staff will communicate the commission's decision to licensees, credentialing, and other relevant stakeholder and initiate drafting guidance or rulemaking as applicable.

HCE SELF-INSPECTION PUBLIC COMMENTS (2ND ROUND)								
DATE RECEIVED	**TITLE OF INSPECTION SHEET**	**SECTION OF INSPECTION SHEET**	**PAGE NUMBER**	**QUESTION NUMBER**	**ISSUE (wording, clarification, procedure, etc)**	**COMMENTS**	**PQAC TEAM COMMENTS**	**SUBCOMITTEE REVIEW COMMENTS/Approval**
6/3/2021	inspection date	Intro	2	Date inspection was performed	The Commission clarified previously that the self-inspection checklist may be completed by a non-		No changes required. This is addressed in the introductory statement on page 2. "All responsible pharmacy managers	
6/7/2021	wording	Addendum questions around compounding	3	Yes and No questions at top of the page	The questions currently say “Do pharmacy personnel engage in non-sterile compounding of medications?” but this should reflect non-pharmacy staff in a HCE setting. Please consider updating to “Do pharmacy HCE personnel engage in non-sterile compounding of medications?” If changing the first question please also change the second question “Do pharmacy HCE personnel engage in sterile compounding?”		No changes required. This question is specific to pharmacy personnel working within the HCE.	
6/7/2021	wording	General Licensing	7	3	The current HCE application indicates a "pharmacist consultant". Should this align with "pharmacy manager" as indicated in self-inspection and WAC?		No changes required. The question includes the terminology used in the current rule, WAC 246-945-310. The applications are under review for updates and revisions.	
6/3/2021	question order	General Licensing	7	3 and 6	question 3 asks if the RPM is licensed in WA, question 6 asks if there IS an RPM – it seems backwards, so possibly #3 should follow #6 or be included as part a dual question.		No changes required. Question #3 refers to general licensing requirements. Question #6 refers to facility standards.	
6/7/2021	wording	Facility Standards	8	9	Please consider amending question 9 to be similar to question 8. “Are freezers temperatures maintained between -25 & -10C (-13 & 14F)?” Question 8 also includes a comment that **Electronic monitoring is acceptable** Please consider adding that comment to question 9, as well.		Agree to add **Electronic monitoring is acceptable** to question #9.	
6/3/2021	wording	Facility standards	8	8 & 9	Can you add ‘medication’ before refrigerators and freezers in these two questions?		Agree to add "medication" before refrigerators and freezers in question #8 and #9.	
6/7/2021	wording	Facility Standards	8	9	Add "**Electronic monitoring is acceptable.**"		Addressed in previous comment.	
6/7/2021	freezer temps	Facility Standards	8	9	Extend lower range of freezer temperature to -50C. Purpose-built pharmaceutical freezers may be set to -50C. Example, MMR vaccine can be stored down to this low temperature. A consideration is also to do away with providing a temperature range, altogether for both refrigerator and freezer. This is a responsibility of the HCE to know storage conditions.		No changes required. Temperature standards are set by USP. If a drug requires storage outside the of conventional accepted range, personnel must store the drug appropriately to the manufacturer's storage requirements.	
6/7/2021	wording	Facility Standards	8	6	Please consider the following change in order to make it more clear for non-pharmacy HCE staff “Does the facility have a designated responsible manager or pharmacist in charge?”		No changes required. The question includes the terminology used in the current rule, WAC 246-945-410(5).	
6/7/2021	wording	Facility Standards	8	9	Please consider amending question 9 to be similar to question 8. “Are freezers temperatures maintained between -25 & -10C (-13 & 14F)?” Question 8 also includes a comment that **Electronic monitoring is acceptable** Please consider adding that comment to question 9, as well.		Addressed in previous comment.	
6/7/2021	WAC reference	Recordkeeping	11	18	Can WAC 246-945-417(1) be appropriately referenced for this question? 246-945-417(7) maintains subsections (2)-(7) as applicable to HCEs and HPACs		The commission has clarified that this was a technical mistake resulting in the rule rewrite and that subsection (7) is intended to be subsection (1). The commission can authorize rulemaking on this to approve making the technical correction.	
6/7/2021	WAC reference	Recordkeeping	12	20	Can WAC 246-945-417(1) be appropriately referenced for this question? 246-945-417(7) maintains subsections (2)-(7) as applicable to HCEs and HPACs		Addressed in previous comment.	
6/7/2021	wording	Controlled Substances	15	24	Replace "pharmacy" with "HCE" in the question "Does the pharmacy maintain records...?"		Agree to replace "pharmacy" with "HCE" in the question.	
6/7/2021	wording	Controlled Substances	15	24	The questions currently say “Does the pharmacy maintain records of receipt and distribution of all controlled substances?” but this should reflect non-pharmacy staff in a HCE setting. Please consider updating to “Does the pharmacy HCE maintain records of receipt and distribution of all controlled substances?”		Addressed in previous comment.	
6/3/2021	question order	Dispensing	17	31-33	the bolded box at the top of this section says “HCEs that do not dispense for use outside the HCE may skip question numbers 35-47 (please only answer question 34)” – this makes it sound like the only question needing to be answered is #34, however #32 asks if the HCE dispenses. It feels like this should be the first question of this section. If there is no dispensing, there would be no need for a prescription, so I am confused as to why #34 would need to be answered if there is no dispensing.		Agree to move question #34 to the top of this section. This topic was discussed and agreed upon in the previous round of public comments.	
6/7/2021	wording	Dispensing	18	34	Replace "uncontrolled" with "noncontrolled" in the question "Are all uncontrolled legend drugs...?"		Agree to change "uncontrolled" to "noncontrolled" in the question.	
6/7/2021	wording	Facility Standards	18	32	The questions currently say “Does the HCE dispense prescriptions to patients?” but seems disjointed considering question 31. Please consider swapping question 32 to come before question 31.		Addressed in previous comment.	
6/3/2021	numbering	Dispensing	17 - 23	Section header	Can you check the numbering for which questions are required and which may be skipped? It only goes to 42 and looks like you would answer 31-32 and potentially skip the rest if the HCE does not dispense for use outside the location.		Addressed in previous comment.	
6/3/2021	thanks	N/A	N/A	N/A	Thank you for your work on creating and revising the HCE Self-inspection checklist. I can see that my previous comments were received and incorporated in the new revision. I appreciate the opportunity to participate in this process and I value your consideration of my feedback.		Thank you!	

3.4

Read this Page Carefully

Pharmacy Quality Assurance Commission

2021 Health Care Entity (HCE) Self-Inspection Worksheet

Attention: Responsible Pharmacy Manager (or Equivalent Manager)

Washington law holds the responsible pharmacy manager (or equivalent manager) and all pharmacy personnel are responsible for ensuring compliance with all state and federal laws governing the practice of pharmacy. Failure to complete this annual worksheet and applicable self-inspection worksheet addendums within the month of March or within 30 days of becoming responsible pharmacy manager (as required by WAC 246-945-005) may result in disciplinary action.

Following your self-inspection and completion of the worksheet(s), please review it with your staff, correct any deficiencies noted, sign and date the worksheet(s), and file it so it will be readily available to Commission inspectors. DO NOT SEND to the Commission office. You are responsible for ensuring your completed worksheet(s) is available at the time of inspection.

The primary objective of this worksheet, and your self-inspection, is to provide an opportunity to identify and correct areas of non-compliance with state and federal law. (NOTE: Neither the self-inspection nor a Commission inspection evaluates your complete compliance with all laws and rules of the practice of pharmacy.) The inspection worksheet also serves as a necessary document used by Commission inspectors during an inspection to evaluate a HCE's level of compliance.

When a Commission inspector discovers an area of non-compliance, they will issue an Inspection Report with Noted Deficiencies. The responsible pharmacy manager (or equivalent manager) must provide a written response (plan of correction) addressing all areas of non-compliance. Identifying and correcting an area of non-compliance prior to a Commission inspection, or during an inspection, may eliminate that item from being included as a deficiency on an Inspection Report. Do not *assume* compliance with any statement; take the time to personally verify that compliance exists. If you have any questions, please contact your inspector.

A common reason for issuing an Inspection Report with Noted Deficiencies is either not having or not being able to readily retrieve required documents and records. Because Commission inspections are unscheduled, it is common for the responsible manager to be absent or unavailable. For this reason, you are asked to provide a list of the specific locations of required documents. Having all required documents and records maintained in a well-organized and readily retrievable manner (a binder is recommended) reduces the chance that you will receive an Inspection Report with Noted Deficiencies.

By answering the questions and referencing the appropriate laws/rules/CFR provided, you can determine whether you are compliant with many of the rules and regulations. If you have corrected any deficiencies, please write corrected and the date of correction by the appropriate question. Questions highlighted in blue are questions that will be focused on during routine HCE inspections.

2021 Health Care Entity Self-Inspection Worksheet

All responsible pharmacy managers (or equivalent managers) of HCEs MUST complete and sign this self-inspection worksheet within the month of March or within 30 days of becoming responsible pharmacy manager. The form must be available for inspection as required by WAC 246-945-005. Do NOT send to the Commission office.

Date Responsible Pharmacy Manager inspection was performed: _____

Change in Responsible Pharmacy Manager and effective date of change: _____

Print Name of Responsible Pharmacy Manager & License #: _____

Signature of Responsible Pharmacy Manager: _____

Responsible Pharmacy Manager E-mail: _____

Health Care Entity: _____ Telephone: _____ Fax: _____

Address: _____ DEA #: _____

Health Care Entity License #: _____

Endorsements:

☐ Dispense Controlled Substances

In Washington State, compounding is defined in RCW 18.64.011(6) and means "the act of combining two or more ingredients in the preparation of a prescription." If pharmacy personnel adds flavoring to a commercially available product, it is considered compounding and the non-sterile compounding self-inspection worksheets must also be completed.

Yes	No	
☐	☐	Do pharmacy personnel engage in non-sterile compounding of medications? If yes, please complete the 2021 Non-Sterile Compounding Self-Inspection Addendum in addition to the Health Care Entity Self-Inspection Worksheet.
☐	☐	Do pharmacy personnel engage in sterile compounding? If yes, you must also complete the 2021 Sterile Compounding Self-Inspection Addendum.

Document and Record Review

Where are the following items located inside the HCE (be as specific as possible, there can be many filing cabinets and binders)? The documentation listed below are required by rule references to be available during inspection, by listing the location of these documents you are also confirming your compliance with the referenced rule.

	Rule Reference
Responsible Pharmacy Manager Self-Inspection Worksheet for last 2 years Location:	WAC 246-945-005(4)(a) "The responsible pharmacy manager, or equivalent manager, shall sign and date the completed self-inspection worksheet(s), and maintain completed worksheets for two years from the date of completion." WAC 246-945-005(4)(b) "When a change in responsible pharmacy manager, or equivalent manager occurs, the new responsible pharmacy manager, or equivalent manager, shall conduct a self-inspection as required under this section. The new responsible pharmacy manager, or equivalent manager, shall sign and date the self-inspection worksheet(s) within thirty days of becoming responsible pharmacy manager, or equivalent manager, and maintain completed worksheets for two years from the date of completion."

Health Care Entity License Location:	RCW 18.64.450(1) “In order for a health care entity to purchase, administer, dispense, and deliver legend drugs, the health care entity must be licensed by the department.”
DEA Registration Location:	WAC 246-945-040(2) “A separate registration is required for each place of business, as defined in 21 C.F.R. Sec. 1301.12, where controlled substances are manufactured, distributed, or dispensed.”
Current Biennial Controlled Substance Inventory Location:	WAC 246-945-420(2) “A facility shall conduct an inventory of controlled substances every two years.” WAC 246-945-420(3)(a) “Within thirty days of designating a responsible pharmacy manager. The incoming responsible pharmacy manager, or designee, shall conduct a complete controlled substance inventory. (b) On the effective date of an addition of a substance to a schedule of controlled substances. Each facility that possesses the substance shall take an inventory of the substance on hand, and thereafter, include the substance in each inventory.” 21 C.F.R. 1304.04(h)(1) "Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all of the records of the registrant; and. (2) Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant.”
Completed CII order forms (DEA Form 222) and/or finalized CSOS documentation for the last 2 years Location:	WAC 246-945-040(6) “A federal order form is required for each distribution of a Schedule I or II controlled substance. Credential holders and pharmaceutical firms must keep and make readily available these forms and other records to the commission or its designee.” 21 C.F.R. 1305.13(e) “The purchaser must record on its copy of the DEA Form 222 the number of commercial or bulk containers furnished on each item and the dates on which the containers are received by the purchaser.” 21 C.F.R. 1305.22(g) “When a purchaser receives a shipment, the purchaser must create a record of the quantity of each item received and the date received. The record must be electronically linked to the original order and archived.”

Schedule II Invoices for the last 2 years Location:	WAC 246-945-040(3)(a) “Every registrant shall keep and maintain inventory records required by 21 C.F.R. Sec. 1304.04. Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug;” WAC 246-945-040(4) “Credential holders and pharmaceutical firms shall maintain records for Schedule II drugs separately from all other records.”
Schedule III-V Invoices for the last 2 years Location:	WAC 246-945-040(3)(a) “Every registrant shall keep and maintain inventory records required by 21 C.F.R. Sec. 1304.04. Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug;” WAC 246-945-040(5) “Credential holders and pharmaceutical firms may maintain records for Schedule III, IV, and V drugs either separately or in a form that is readily retrievable from the business records of the registrant.”
Completed loss by theft or destruction forms (DEA Form 106) for the last 2 years Location:	WAC 246-945-040(3)(c) “In the event of a significant loss or theft, two copies of DEA 106 (report of theft or loss of controlled substances) must be transmitted to the federal authorities and a copy must be sent to the commission.” 21 C.F.R. 1301.76(b) “The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft...”

Power of Attorney for staff authorized to order controlled substances Location:	WAC 246-945-040(1) “The commission adopts 21 C.F.R. as its own.” 21 C.F.R. 1305.05(a) “A registrant may authorize one or more individuals, whether or not located at his or her registered location, to issue orders for Schedule I and II controlled substances on the registrant's behalf by executing a power of attorney for each such individual, if the power of attorney is retained in the files, with executed Forms 222 where applicable, for the same period as any order bearing the signature of the attorney. The power of attorney must be available for inspection together with other order records.”
Change of Responsible Pharmacy Manager forms for the last 2 years Location:	WAC 246-945-480(1) “The outgoing and incoming responsible pharmacy manager must report in writing to the commission a change in a responsible pharmacy manager designation within ten business days of the change.” WAC 246-945-020 (1) “Unless an alternative standard for a specified record type, form, or format is expressly stated a pharmaceutical firm must maintain and retain records required as evidence of compliance with statutes and rules enforced by the commission in a readily retrievable form and location for at least two years from the date the record was created or received, whichever date is later. (2) A pharmaceutical firm must allow the commission, or its designee, access to the pharmaceutical firm's records upon request for the purposes of monitoring compliance with statutes and rules enforced by the commission.”
Prescription Records for the last 2 years Location:	WAC 246-945-410(12) “A facility's paper prescriptions must be maintained in accordance with WAC 246-945-020 and as follows: (a) Paper prescriptions for Schedule II drugs must be maintained as a separate file from other prescriptions. (b) Paper prescriptions for Schedule III, IV, and V drugs must be maintained as a separate file or maintained in a separate file with prescriptions for non-controlled legend drugs as allowed under federal law.”

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
General Licensing						
			1	Does the Health Care Entity (HCE) have a current license?	RCW 18.64.450(1) "In order for a health care entity to purchase, administer, dispense, and deliver legend drugs, the health care entity must be licensed by the department."	
			2	Does the HCE have a current DEA registration?	WAC 246-945-040(2) "A separate registration is required for each place of business, as defined in 21 C.F.R. Sec. 1301.12, where controlled substances are manufactured, distributed, or dispensed."	
			3	Is the responsible pharmacy manager licensed to practice pharmacy in the State of Washington?	WAC 246-945-310 "Responsible pharmacy manager. The responsible pharmacy manager must be licensed to practice pharmacy in the state of Washington. The responsible pharmacy manager designated by a facility as required under WAC 246-945-410 shall have the authority and responsibility to assure that the area(s) within the facility where drugs are stored, compounded, delivered, or dispensed are operated in compliance with all applicable state and federal statutes and regulations."	
Facility Standards						
			4	Is the facility appropriately constructed and equipped to protect equipment, records, drugs/devices and other restricted items from unauthorized access? ***Including samples under the control of the HCE***	RCW 69.45.040(2) "Drug samples shall be maintained in a locked area to which access is limited to persons authorized by the manufacturer." WAC 246-945-410(1) "The facility shall be constructed and equipped with adequate security to protect equipment, records, and supply of drugs, devices, and other restricted sale items from unauthorized access, acquisition, or use."	
			5	Is the facility properly equipped to ensure proper operation, prescription preparation, and product integrity?	WAC 246-945-410(2) "The facility shall be properly equipped to ensure the safe, clean, and sanitary condition necessary for the proper operation, the safe preparation of prescriptions, and to safeguard product integrity."	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
			6	Does the facility have a designated responsible pharmacy manager?	WAC 246-945-410(5) "The facility shall designate a responsible pharmacy manager: (a) By the date of opening; and (b) Within thirty calendar days of a vacancy."	
			7	Are the drug storage areas appropriately secure from unauthorized access and are staff working within their scope of practice?	WAC 246-945-410(10) "Access to the drug storage area located within the facility should be limited to pharmacists unless one of the following applies: (a) A pharmacy intern, or pharmacy ancillary personnel enter under the immediate supervision of a pharmacist; or (b) A pharmacist authorizes temporary access to an individual performing a legitimate nonpharmacy function under the immediate supervision of the pharmacist; or (c) The facility has a policy and procedure restricting access to a health care professional licensed under the chapters specified in RCW 18.130.040, and the actions of the health care professional are within their scope of practice."	
			8	Are refrigerators temperatures maintained between 2- 8°C (36-46°F)? *** Electronic monitoring is acceptable. *****	WAC 246-945-410(2) "The facility shall be properly equipped to ensure the safe, clean, and sanitary condition necessary for the proper operation, the safe preparation of prescriptions, and to safeguard product integrity."	
			9	Are freezers between -25°& -10°C (-13° & 14°F)?	WAC 246-945-410(2) "The facility shall be properly equipped to ensure the safe, clean, and sanitary condition necessary for the proper operation, the safe preparation of prescriptions, and to safeguard product integrity."	
			10	Is drug stock stored under proper conditions (temperature, humidity, light) as recommend by the drug label?	RCW 69.45.040(3) "Drug samples shall be stored and transported in such a manner as to be free of contamination, deterioration, and adulteration.	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
				Including samples under the control of the HCE	(4) Drug samples shall be stored under conditions of temperature, light, moisture, and ventilation so as to meet the label instructions for each drug." WAC 246-945-410(2) "The facility shall be properly equipped to ensure the safe, clean, and sanitary condition necessary for the proper operation, the safe preparation of prescriptions, and to safeguard product integrity."	
			11	Is all drug stock in date? ***Including OTC medications and samples under the control of the HCE*** **It's advised to perform an inventory check for expired medications while filling out this self-inspection worksheet.**	RCW 69.04.100 "Whenever the director shall find in intrastate commerce an article subject to this chapter which is so adulterated or misbranded that it is unfit or unsafe for human use and its immediate condemnation is required to protect the public health, such article is hereby declared to be a nuisance and the director is hereby authorized forthwith to destroy such article or to render it unsalable for human use." RCW 69.45.040(5) "Drug samples which have exceeded the expiration date shall be physically separated from other drug samples until disposed of or returned to the manufacturer." WAC 246-945-410(2) "The facility shall be properly equipped to ensure the safe, clean, and sanitary condition necessary for the proper operation, the safe preparation of prescriptions, and to safeguard product integrity."	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
Policies and Procedures						
			12	Does the HCE have policies and procedures in place for the following: a) Purchasing b) Ordering c) Storing d) Compounding e) Delivering f) Dispensing g) Administration	WAC 246-945-410(6) "The facility shall create and implement policies and procedures related to: (a) Purchasing, ordering, storing, compounding, delivering, dispensing, and administering legend drugs, including controlled substances."	
			13	Does the HCE have policies and procedures addressing administration of patient owned medications?	WAC 246-945-440 "Facilities shall develop written policies and procedures for the administration of patient owned medications."	
			14	Does the HCE accept dispensed drugs or prescription devices for return and reuse appropriately?	WAC 246-945-485(1) "A dispensed drug or prescription device must only be accepted for return and reuse as follows: (a) Noncontrolled legend drugs that have been maintained in the custody and control of the institutional facility, dispensing pharmacy, or their related facilities under common control may be returned and reused if product integrity can be assured. (b) Those that qualify for return under the provisions of chapter 69.70 RCW."	
			15	Does the HCE accept dispensed drugs or prescription devices for return and destruction appropriately?	WAC 246-945-485(2) "A dispensed drug or prescription device may be accepted for return and destruction if: (a) The dispensed drug or prescription device was dispensed in a manner inconsistent with the prescriber's instructions; (b) The return is in compliance with the Washington state safe medication return program laws and rules, chapters 69.48 RCW and 246-480 WAC; or	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					(c) The return and destruction is in compliance with the facility's policies and procedures."	
			16	Does the HCE have policies and procedures addressing computer system downtime?	WAC 246-945-417(7) "HCEs or HPACs that maintain an electronic record system must be done in accordance with subsections (2) through (7) of this section." WAC 246-945-417(4) "The pharmacy shall have policies and procedures in place for system downtime. (a) The procedure shall provide for the maintenance of all patient recordkeeping information as required by this chapter. (b) Upon restoration of operation of the electronic recordkeeping system the information placed in the auxiliary recordkeeping procedure shall be entered in each patient's records within two working days, after which the auxiliary records may be destroyed. (c) This section does not require that a permanent dual recordkeeping system be maintained."	
Recordkeeping						
			17	Are complete patient medical records maintained in either paper or electronic format?	WAC 246-945-418 "If an HPAC or HCE does not maintain an electronic recordkeeping system their manual records must contain all information required in WAC 246-945-417."	
			18	If applicable, does the HCE maintain electronic record system including patient allergies, idiosyncrasies or chronic conditions, and prescription, refill, transfer information, and other information necessary to provide safe and appropriate patient care?	WAC 246-945-417(1) "A pharmacy shall use an electronic recordkeeping system to establish and store patient medication records, including patient allergies, idiosyncrasies or chronic conditions, and prescription, refill, transfer information, and other information necessary to provide safe and appropriate patient care."	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					WAC 246-945-417(7) HCEs or HPACs that maintain an electronic record system must be done in accordance with subsections (2) through (7) of this section.	
			19	Does the electronic recordkeeping system include security features to protect confidentiality and integrity of patient records?	WAC 246-945-417(3) "The electronic recordkeeping system must include security features to protect the confidentiality and integrity of patient records including: (a) Safeguards designed to prevent and detect unauthorized access, modification, or manipulation of prescription information and patient medication records; and (b) Functionality that documents any alteration of prescription information after a prescription is dispensed, including the identification of the individual responsible for the alteration."	
			20	If applicable, does the manual patient medical record system have the capability to store patient medication records e.g. allergies, idiosyncrasies or chronic conditions, and prescription, refill, transfer, and other information as required in WAC 246-945-417?	WAC 246-945-417(7) "HCEs or HPACs that maintain an electronic record system must be done in accordance with subsections (2) through (7) of this section." WAC 246-945-417 "(1) A pharmacy shall use an electronic recordkeeping system to establish and store patient medication records, including patient allergies, idiosyncrasies or chronic conditions, and prescription, refill, transfer information, and other information necessary to provide safe and appropriate patient care. (a) Systems must prevent auto-population of user identification information. (b) Pharmacies that provide off-site pharmacy services without a pharmacist for product fulfillment or prescription processing must track the identity of each individual involved in each step of the off-site pharmacy services. (2) The electronic recordkeeping system must be capable of real-time retrieval of information	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					pertaining to the ordering, verification, and processing of the prescription where possible. (3) The electronic recordkeeping system must include security features to protect the confidentiality and integrity of patient records including: (a) Safeguards designed to prevent and detect unauthorized access, modification, or manipulation of prescription information and patient medication records; and (b) Functionality that documents any alteration of prescription information after a prescription is dispensed, including the identification of the individual responsible for the alteration. (4) The pharmacy shall have policies and procedures in place for system downtime. (a) The procedure shall provide for the maintenance of all patient recordkeeping information as required by this chapter. (b) Upon restoration of operation of the electronic recordkeeping system the information placed in the auxiliary recordkeeping procedure shall be entered in each patient's records within two working days, after which the auxiliary records may be destroyed. (c) This section does not require that a permanent dual recordkeeping system be maintained. (5) The pharmacy shall maintain records in accordance with WAC **246-945-020**. (6) Electronic prescriptions for prescription drugs must be maintained by the pharmacy in a system that meets the requirements of 21 C.F.R. Sec. 1311." WAC 246-945-418 "If an HPAC or HCE does not maintain an electronic recordkeeping system their manual records must contain all information required in WAC 246-945-417. The record system consists of the hard copy of the original prescription and a card	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					or filing procedure that contains all data on new and refill prescriptions for a patient. This data must be organized in such a fashion that information relating to all prescription drugs used by a patient will be reviewed each time a prescription is filled."	
			21	Are suitable record of drugs readily retrievable or maintained separately from all other records? ***Including drug samples under the control of the HCE***	RCW 18.64.470 "Every proprietor or manager of a health care entity shall keep readily available a suitable record of drugs, which shall preserve for a period of not less than two years the record of every drug used at such health care entity. The record shall be maintained either separately from all other records of the health care entity or in such form that the information required is readily retrievable from ordinary business records of the health care entity. All recordkeeping requirements for controlled substances must be complied with."	
			22	Are all records readily retrievable for at least two years from the date the record was created or received, whichever is later?	WAC 246-945-020(1) "Unless an alternative standard for a specified record type, form, or format is expressly stated a pharmaceutical firm must maintain and retain records required as evidence of compliance with statutes and rules enforced by the commission in a readily retrievable form and location for at least two years from the date the record was created or received, whichever date is later." WAC 246-945-001(7) ""Readily retrievable" means a record that is kept by automatic data processing systems or other electronic, mechanized, or written recordkeeping systems in such a manner that it can be separated out from all other records in a reasonable time."	
Controlled Substances						
			23	Are all controlled substances in the HCE locked and secured to prevent unauthorized access?	WAC 246-945-040(1) "The commission adopts 21 C.F.R. as its own."	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					21 C.F.R. 1301.75(a) "Controlled substances listed in Schedule I shall be stored in a securely locked, substantially constructed cabinet. (b) Controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet." WAC 246-945-410(1) "The facility shall be constructed and equipped with adequate security to protect equipment, records, and supply of drugs, devices, and other restricted sale items from unauthorized access, acquisition, or use."	
			24	Does the pharmacy maintain records of receipt and distribution of all controlled substances?	WAC 246-945-040(3) "Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: (a) Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug; (b) Distribution records, including invoices, or any other document regardless of how titled from wholesalers, manufacturers, or any other entity to which the substances were distributed and prescriptions records for dispensers; (d) For transfers of controlled substances from one dispenser to another, a record of the transfer must be made at the time of transfer indicating the drug, quantity, date of transfer, who it was transferred to, and from whom. Records must be retained by both the transferee and the transferor. These transfers can only be made in emergencies pursuant to 21 C.F.R. Sec. 1307.11."	
			25	Are records of Schedule II drugs maintained separately from all other controlled substance records?	WAC 246-945-040(4) "Credential holders and pharmaceutical firms shall maintain records for Schedule II drugs separately from all other records."	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
			26	Does the HCE have completed DEA 222 forms or their electronic equivalent for each acquisition or distribution of Schedule II drugs?	WAC 246-945-040(6) "A federal order form is required for each distribution of a Schedule I or II controlled substance. Credential holders and pharmaceutical firms must keep and make readily available these forms and other records to the commission or its designee."	
			27	Are records of Schedule III-V drugs maintained either separately or in a form that is readily retrievable from other records?	WAC 246-945-040(5) "Credential holders and pharmaceutical firms may maintain records for Schedule III, IV, and V drugs either separately or in a form that is readily retrievable from the business records of the registrant." 21 C.F.R 1304.04(h)(3) "…Inventories and records of Schedules III, IV, and V controlled substances shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy."	
			28	Is an inventory of controlled substances being performed every 2 years? ***Including controlled substance samples under the control of the HCE*** An inventory of controlled substances must be completed within 30 days of a new responsible pharmacy manager or on the effective date of the addition of a substance to a schedule of controlled substances.	WAC 246-945-420(2) "A facility shall conduct an inventory of controlled substances every two years." WAC 246-945-420(3)(a) "Within thirty days of designating a responsible pharmacy manager. The incoming responsible pharmacy manager, or designee, shall conduct a complete controlled substance inventory. (b) On the effective date of an addition of a substance to a schedule of controlled substances. Each facility that possesses the substance shall take an inventory of the substance on hand, and thereafter, include the substance in each inventory." 21 C.F.R. 1304.11(a) "Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written,	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					typewritten, or printed form at the registered location."	
			29	Does the HCE have power of attorney forms for ordering schedule II-controlled substances?	21 C.F.R. 1305.05(a) "A registrant may authorize one or more individuals, whether or not located at his or her registered location, to issue orders for Schedule I and II controlled substances on the registrant's behalf by executing a power of attorney for each such individual, if the power of attorney is retained in the files, with executed Forms 222 where applicable, for the same period as any order bearing the signature of the attorney. The power of attorney must be available for inspection together with other order records."	
			30	Has the HCE reported significant losses or disappearances of controlled substances to PQAC and the DEA in the previous 24 months?	21 CFR 1301.76(b) "The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft." WAC 246-945-040(3)(c) "In the event of a significant loss or theft, two copies of DEA 106 (report of theft or loss of controlled substances) must be transmitted to the federal authorities and a copy must be sent to the commission; …"	
Dispensing **HCEs that do not dispense for use outside the HCE may skip question numbers 35-47 (please only answer question 34)**						
			31	If HCEs dispense medications without a pharmacist's involvement, are they restricting medications dispensed to a seventy-two (72) hour supply?	RCW 18.64.450(4) "…Nothing in this subsection shall prohibit a practitioner, in carrying out his or her licensed responsibilities within a health care entity, from dispensing or delivering to a patient of the health care entity drugs for that patient's personal	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					use in an amount not to exceed seventy-two hours of usage."	
			32	Does the HCE dispense prescriptions to patients?	RCW 18.64.450(4) "A health care entity may only administer, dispense, or deliver legend drugs and controlled substances to patients who receive care within the health care entity and in compliance with rules of the commission…"	
			33	Does the HCE have valid prescription records for all drugs dispensed to patients?	WAC 246-945-410(7) "Prescription drugs must only be dispensed pursuant to a valid prescription as required by WAC 246-945-011." WAC 246-945-011(1) "Prior to dispensing and delivering a prescription, a pharmacist shall verify its validity." (2) A prescription shall be considered invalid if: (a) At the time of presentation, the prescription shows evidence of alteration, erasure, or addition by any person other than the person who wrote it; (b) The prescription does not contain the required information as provided in WAC 246-945-010; (c) The prescription is expired; or (d) The prescription is for a controlled substance and does not comply with the requirements in RCW 69.50.308. (3) A prescription is considered expired when: (a) The prescription is for a controlled substance listed in Schedule II through V and the date of dispensing is more than six months after the prescription's date of issue. (b) The prescription is for a noncontrolled legend drug or OTC's and the date of dispensing is more than twelve months after the prescription's date of issue."	
			34	Are all uncontrolled legend drugs prescribed orally promptly	WAC 246-945-010(8) "A noncontrolled legend drug can only be dispensed pursuant to a valid prescription in accordance with WAC 246-945-011, or	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
				transcribed to a written or electronic prescription?	an oral prescription. An oral prescription for a noncontrolled legend drug must be promptly reduced to a written or electronic prescription that complies with WAC 246-945-011."	
			35	Do all prescriptions for non-controlled legend drugs include all required elements? a) Prescriber's Name b) Name of Patient/Authorized Entity/Animal Name and Species c) Date of Issuance d) Drug Name, Strength, and Quantity e) Directions for Use f) Number of Refills g) Substitution Directions h) Prescribers Signature i) If written, on Tamper-Resistant Paper	WAC 246-945-010(3) "A prescription for a noncontrolled legend drug must include, but is not limited to, the following: (a) Prescriber's name; (b) Name of patient, authorized entity, or animal name and species; (c) Date of issuance; (d) Drug name, strength, and quantity; (e) Directions for use; (f) Number of refills (if any); (g) Instruction on whether or not a therapeutically equivalent generic drug or interchangeable biological product may be substituted, unless substitution is permitted under a prior-consent authorization; (h) Prescriber's manual or electronic signature, or prescriber's authorized agent signature if allowed by law; and (i) If the prescription is written, it must be written on tamper-resistant prescription pad or paper approved by the commission pursuant to RCW 18.64.500"	
			36	Do all prescriptions for controlled substances include additional required elements? a) Elements from Question 38 b) Patient's Address c) Dosage Form d) Prescriber's Address e) Prescriber's DEA Number	WAC 246-945-010(4) "A prescription for a controlled substance must include all the information listed in subsection (1) of this section and the following: (a) Patient's address; (b) Dosage form; (c) Prescriber's address; (d) Prescriber's DEA registration number; and (e) Any other requirements listed in 21 C.F.R., Chapter II."	
			37	Are all prescriptions properly labeled and stored, in accordance with federal and state statutes, rules, and regulations?	RCW 18.64.246(1) "To every box, bottle, jar, tube or other container of a prescription which is dispensed there shall be fixed a label bearing the name and address of the dispensing pharmacy, the prescription number, the name of the prescriber, the prescriber's directions, the name and strength of the medication,	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
				Includes drug samples under the control of the HCE	the name of the patient, the date, and the expiration date." RCW 69.41.050(1) "To every box, bottle, jar, tube or other container of a legend drug, which is dispensed by a practitioner authorized to prescribe legend drugs, there shall be affixed a label bearing the name of the prescriber, complete directions for use, the name of the drug either by the brand or generic name and strength per unit dose, name of patient and date: PROVIDED, That the practitioner may omit the name and dosage of the drug if he or she determines that his or her patient should not have this information and that, if the drug dispensed is a trial sample in its original package and which is labeled in accordance with federal law or regulation, there need be set forth additionally only the name of the issuing practitioner and the name of the patient." WAC 246-945-016(1) and (3) "(1) All licensees of the commission who dispense legend drugs to outpatients shall affix a label to the prescription container that meets the requirements of RCW 69.41.050 and 18.64.246, and shall also include: (a) Drug quantity; (b) The number of refills remaining, if any; (c) The following statement, "Warning: State or federal law prohibits transfer of this drug to any person other than the person for whom it was prescribed.", except when dispensing to an animal, when a warning sufficient to convey "for veterinary use only" may be used; (d) The name and species of the patient, if a veterinary prescription; and (e) The name of the facility or entity authorized by law to possess a legend drug, if patient is the facility or entity. . . (3) For the purposes of determining an expiration date as required in RCW 18.64.246, the	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					dispenser shall take the following factors into account: (a) The nature of the drug; (b) The container in which it was packaged by the manufacturer and the expiration date; (c) The characteristics of the patient's container, if the drug is repackaged for dispensing; (d) The expected conditions to which the drug may be exposed; (e) The expected length of time of the course of therapy; and (f) Any other relevant factors."	
			38	Are all legend drugs dispensed in child-resistant containers, as required by federal law or regulation? *(This includes special packaging used such as customized patient medication packages; blister packs, med-minders, etc.)* *** Please see the FAQ on Commission website. **** *** Best practice: It is recommended that these authorizations are updated annually. **	WAC 246-945-032 (1) "All legend drugs shall be dispensed in a child-resistant container as required by federal law or regulation, including 16 C.F.R., Part 1700, unless: (a) Authorization is received from the prescriber to dispense in a container that is not child-resistant. (b) Authorization is obtained from the patient or a representative of the patient to dispense in a container that is not child-resistant."	
			39	Is supplemental information provided to the patient with each dispensed prescription?	WAC 246-945-410(9) "Each drug dispensed and delivered to a patient must bear a complete and accurate label as required by WAC 246-945-015 through 246-945-018. The information contained on the label shall be supplemented by oral or written information as required by WAC 246-945-325." **WAC 246-945-325** (1) The pharmacist shall offer to counsel:	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					(a) Upon the initial fill of a prescription for a new or change of therapy. (b) When the pharmacist using their professional judgment determines counseling is necessary to promote safe and effective use and to facilitate an appropriate therapeutic outcome for that patient. ***(2) This does not apply to medications that are administered by a licensed health professional acting within their scope of practice.***	
			40	Are electronic prescriptions maintained appropriately?	WAC 246-945-417(6) "Electronic prescriptions for prescription drugs must be maintained by the pharmacy in a system that meets the requirements of 21 C.F.R. Sec. 1311." (7) HCEs or HPACs that maintain an electronic record system must be done in accordance with subsections (2) through (7) of this section.	
Pharmacist Professional Requirements						
			41	***Unless an exception applies***, does the HCE conduct a drug utilization review (DUR) of each prescription before dispensing and delivery? OR If a pharmacist is involved in the dispensing process, is drug utilization review completed?	WAC 246-945-001(29) "'Drug utilization review" includes, but is not limited to, the following activities: (a) Evaluation of prescriptions and patient records for known allergies, rational therapy-contraindications, appropriate dose, and route of administration and appropriate directions for use; (b) Evaluation of prescriptions and patient records for duplication of therapy; (c) Evaluation of prescriptions and patient records for interactions between drug-drug, drug-disease, and adverse drug reactions; and (d) Evaluation of prescriptions and patient records for proper utilization, including over- or under-utilization, and optimum therapeutic outcomes." WAC 246-945-410(8) "A drug utilization review of each prescription before dispensing and delivery shall occur ***except in emergent medical situations, or if***:	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					(a) The drug is a subsequent dose from a previously reviewed prescription; (b) The prescriber is in the immediate vicinity and controls the drug dispensing process; (c) The medication delivery system is being used to provide access to medications on override and only a quantity sufficient to meet the immediate need of the patient is removed; or (d) Twenty-four hour pharmacy services are not available, and a pharmacist will review all prescriptions added to a patient's profile within six hours of the facility opening."	
			42	If a pharmacist is involved in the dispensing process, do pharmacists perform patient counseling?	WAC 246-945-325(1) "The pharmacist shall offer to counsel: (a) Upon the initial fill of a prescription for a new or change of therapy. (b) When the pharmacist using their professional judgment determines counseling is necessary to promote safe and effective use and to facilitate an appropriate therapeutic outcome for that patient."	

4.1

RULE-MAKING ORDER
EMERGENCY RULE ONLY

CR-103E (December 2017)
(Implements RCW 34.05.350 and 34.05.360)

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: July 02, 2021
TIME: 9:22 AM

WSR 21-14-061

Agency: Department of Health- Pharmacy Quality Assurance Commission

Effective date of rule:

Emergency Rules

☒ Immediately upon filing.
☐ Later (specify)

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?

☐ Yes ☒ No If Yes, explain:

Purpose: WAC 246-945-056 Schedule V. The Pharmacy Quality Assurance Commission (commission) is adopting emergency rules to remove Epidiolex from the list of Schedule V controlled substances in Washington state. This adopted emergency rule will extend WSR 21-07-015 filed on March 5, 2021. The emergency which was originally filed on May 20, 2020 under WSR 20-11-078. Epidiolex is an FDA-approved cannabidiol with less than 0.3% tetrahydrocannabinal (THC). De-scheduling the drug from Schedule V will maintain the emergency rule. It also aligns Washington state rule with the federal decision to exclude all hemp products with less than 0.3% THC from the definition of marijuana and the United States drug enforcement agency's (DEA) rulemaking to remove Epidiolex from Schedule V, completed on August 21, 2020.

Citation of rules affected by this order:

New: None
Repealed: None
Amended: WAC 246-945-056
Suspended: None

Statutory authority for adoption: RCW 18.64.005; RCW 69.50.201

Other authority: 21 U.S.C. Â§ 811

EMERGENCY RULE

Under RCW 34.05.350 the agency for good cause finds:

☒ That immediate adoption, amendment, or repeal of a rule is necessary for the preservation of the public health, safety, or general welfare, and that observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the public interest.

☒ That state or federal law or federal rule or a federal deadline for state receipt of federal funds requires immediate adoption of a rule.

Reasons for this finding: The immediate amendment of this existing rule is necessary for the preservation of public health, safety, and general welfare. Epidiolex is an FDA-approved cannabidiol with less than 0.3% THC used to help treat some seizure disorders. The 2018 Agricultural Improvement Act amended the Controlled Substances Act and declassified hemp products with less than 0.3% THC from Schedule I; however, Epidiolex was placed on Schedule V until April 6, 2020 when the DEA announced that it would be de-scheduled as a federally controlled substance. The DEA finalized rulemaking to remove Epidiolex from Schedule V on August 21, 2020. This emergency rule will maintain the emergency rule already in effect and update Washington rule to align with the federal decision. Emergency rules are necessary to reduce burdens on practitioners prescribing Epidiolex and allow patients easier access to the care they need. This rule may also help reduce pressure on the health system during the ongoing COVID-19 pandemic. Observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the public interest. The commission has initiated permanent rulemaking. The CR-101 to permanently de-schedule Epidiolex (WSR 20-23-027) was filed on November 10, 2020.

Note: If any category is left blank, it will be calculated as zero. No descriptive text.

Count by whole WAC sections only, from the WAC number through the history note. A section may be counted in more than one category.

The number of sections adopted in order to comply with:

Federal statute:	New	0	Amended	0	Repealed	0
Federal rules or standards:	New	0	Amended	1	Repealed	0
Recently enacted state statutes:	New	0	Amended	0	Repealed	0

The number of sections adopted at the request of a nongovernmental entity:

	New	0	Amended	0	Repealed	0

The number of sections adopted on the agency's own initiative:

	New	0	Amended	0	Repealed	0

The number of sections adopted in order to clarify, streamline, or reform agency procedures:

	New	0	Amended	0	Repealed	0

The number of sections adopted using:

Negotiated rule making:	New	0	Amended	0	Repealed	0
Pilot rule making:	New	0	Amended	0	Repealed	0
Other alternative rule making:	New	0	Amended	1	Repealed	0

Date Adopted: June 4, 2021	**Signature:** Teri Ferreira
Name: Teri Ferreira, RPh	
Title: Pharmacy Quality Assurance Commission Chair	

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

WAC 246-945-056 Schedule V. The commission finds that the following substances have low potential for abuse relative to substances in Schedule IV under RCW 69.50.210 and WAC 246-945-055 and have currently accepted medical use in treatment in the United States and that the substances have limited physical dependence or psychological dependence liability relative to the substance in Schedule IV. In addition to the substances listed in RCW 69.50.212, the commission places each of the following drugs and substances by whatever official name, common or usual name, chemical name, or brand name in Schedule V.

Depressants. Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts:

(1) Brivaracetam ((2S)-2-[(4R)-2-oxo-4-propylpyrrolidin-1-yl] butanamide); also referred to as BRV; UCB-34714; Briviact;

(2) Ezogabine [N-[2-amino-4-(4-fluorobenzylamino)-phenyl]-carbamic acid ethyl ester].

((~~(3) Approved cannabidiol drugs. A drug product in finished dosage formulation that has been approved by the U.S. Food and Drug Administration that contains cannabidiol (2-[1R-3-methyl-6R-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-benzenediol) derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols, also known as Epidiolex.~~))

4.2

RULE-MAKING ORDER
EMERGENCY RULE ONLY

CR-103E (December 2017)
(Implements RCW 34.05.350 and 34.05.360)

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: July 02, 2021
TIME: 9:12 AM

WSR 21-14-059

Agency: Department of Health- Pharmacy Quality Assurance Commission

Effective date of rule:

Emergency Rules

☒ Immediately upon filing.
☐ Later (specify)

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?

☐ Yes ☒ No If Yes, explain:

Purpose: WAC 246-945-010 Prescription labeling, records, and advertising - Minimum requirements. The Pharmacy Quality Assurance Commission (commission) is adopting emergency rules to reduce burdens on practitioners prescribing Schedule II substances during the coronavirus disease (COVID-19) outbreak. This adopted emergency rule will extend WSR 21-07-016 filed on March 5, 2021.This emergency rule was originally filed on April 21, 2020 under WSR 20-09-133. It was re-filed on July 10, 2020 after the commission's new chapter went into effect under WSR 20-15-058. This emergency rule will continue the existing emergency rule amending WAC 246-945-010 to increase the duration of time a practitioner has to deliver a signed prescription of a Schedule II substance to the pharmacy from seven days to fifteen days when a prescription is dispensed in an emergency. It also defines what a "signed prescription" means and allows for a practitioner to accomplish this requirement through paper, electronic transmission, facsimile, photograph, or scanned copy. These alternative methodologies support patients, practitioners, and pharmacists' efforts to practice social distancing and to help mitigate communal spread.

Citation of rules affected by this order:

New: None
Repealed: None
Amended: WAC 246-945-010
Suspended: None

Statutory authority for adoption: RCW 18.64.005; chapter 69.50 RCW

Other authority:

EMERGENCY RULE

Under RCW 34.05.350 the agency for good cause finds:

☒ That immediate adoption, amendment, or repeal of a rule is necessary for the preservation of the public health, safety, or general welfare, and that observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the public interest.

☐ That state or federal law or federal rule or a federal deadline for state receipt of federal funds requires immediate adoption of a rule.

Reasons for this finding: The immediate amendment of this existing rule is necessary for the preservation of public health, safety, and general welfare. Stakeholders and leaders from the pain community have highlighted this is an immediate need for Washingtonians. This emergency rule has been in effect since April 21, 2020. This emergency rule allows more time and more avenues for complying with the requirements during the ongoing COVID-19 pandemic, reducing burdens on practitioners and pharmacists, and sustaining patient access during this difficult time. The emergency rules follow guidance from the US drug enforcement agency and will help address this problem and reduce barriers for providers and patient populations in need of Schedule II prescriptions throughout this public health emergency. Observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to public interest.

Note: If any category is left blank, it will be calculated as zero. No descriptive text.

Count by whole WAC sections only, from the WAC number through the history note. A section may be counted in more than one category.

The number of sections adopted in order to comply with:

Federal statute:	New	0	Amended	0	Repealed	0
Federal rules or standards:	New	0	Amended	0	Repealed	0
Recently enacted state statutes:	New	0	Amended	0	Repealed	0

The number of sections adopted at the request of a nongovernmental entity:

	New	0	Amended	0	Repealed	0

The number of sections adopted on the agency's own initiative:

	New	0	Amended	1	Repealed	0

The number of sections adopted in order to clarify, streamline, or reform agency procedures:

	New	0	Amended	0	Repealed	0

The number of sections adopted using:

Negotiated rule making:	New	0	Amended	0	Repealed	0
Pilot rule making:	New	0	Amended	0	Repealed	0
Other alternative rule making:	New	0	Amended	1	Repealed	0

Date Adopted: June 4, 2021	**Signature:** 
Name: Teri Ferreira, RPh	
Title: Pharmacy Quality Assurance Commission Chair	

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

WAC 246-945-010 Prescription and chart order—Minimum requirements. (1) For the purposes of this section, prescription does not include chart orders as defined in RCW 18.64.011(3).

(2) For the purposes of WAC 246-945-010 through 246-945-013, prescription includes written and electronic prescriptions.

(3) A prescription for a noncontrolled legend drug must include, but is not limited to, the following:

(a) Prescriber's name;

(b) Name of patient, authorized entity, or animal name and species;

(c) Date of issuance;

(d) Drug name, strength, and quantity;

(e) Directions for use;

(f) Number of refills (if any);

(g) Instruction on whether or not a therapeutically equivalent generic drug or interchangeable biological product may be substituted, unless substitution is permitted under a prior-consent authorization;

(h) Prescriber's manual or electronic signature, or prescriber's authorized agent signature if allowed by law; and

(i) If the prescription is written, it must be written on tamper-resistant prescription pad or paper approved by the commission pursuant to RCW 18.64.500;

(4) A prescription for a controlled substance must include all the information listed in subsection (1) of this section and the following:

(a) Patient's address;

(b) Dosage form;

(c) Prescriber's address;

(d) Prescriber's DEA registration number; and

(e) Any other requirements listed in 21 C.F.R., Chapter II.

(5) A chart order must meet the requirements of RCW 18.64.550 and any other applicable requirements listed in 21 C.F.R., Chapter II.

(6) A controlled substance listed in Schedule II can only be dispensed pursuant to a valid prescription in accordance with WAC 246-945-011 unless there is an "emergency."

(a) For the purposes of this subsection, an "emergency" exists when the immediate administration of the drug is necessary for proper treatment and no alternative treatment is available, and further, it is not possible for the practitioner to provide a written or electronic prescription for the drug at that time.

(b) If a Schedule II drug is dispensed in an emergency, the practitioner must deliver a signed prescription to the dispenser within ((~~seven~~)) fifteen days after authorizing an emergency oral prescription or if delivered by mail it must be postmarked within the ((~~seven~~)) fifteen day period, and further the pharmacist must note on the prescription that it was filled on an emergency basis.

(c) For the purposes of this subsection, a "signed prescription" shall be either:

(i) A paper prescription;

(ii) An electronic prescription;

(iii) A copy of the paper prescription sent via facsimile to the pharmacy; or

(iv) A photograph or scanned copy of the paper prescription sent to the pharmacy.

(7) A controlled substance listed in Schedule III, IV, or V, can only be dispensed pursuant to a valid prescription in accordance with WAC 246-945-011, or an oral prescription. An oral prescription for a controlled substance listed in Schedule III, IV, or V must be promptly reduced to a written or electronic prescription that complies with WAC 246-945-011.

(8) A noncontrolled legend drug can only be dispensed pursuant to a valid prescription in accordance with WAC 246-945-011, or an oral prescription. An oral prescription for a noncontrolled legend drug must be promptly reduced to a written or electronic prescription that complies with WAC 246-945-011.

4.3

RULE-MAKING ORDER
EMERGENCY RULE ONLY

CR-103E (December 2017)
(Implements RCW 34.05.350 and 34.05.360)

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: July 20, 2021
TIME: 1:58 PM

WSR 21-15-108

Agency: Department of Health- Pharmacy Quality Assurance Commission

Effective date of rule:

Emergency Rules

☒ Immediately upon filing.
☐ Later (specify)

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?

☐ Yes ☒ No If Yes, explain:

Purpose: WACs 246-945-710, 246-945-712, 246-945-714, 246-945-716, 246-945-718, 246-945-720, 246-945-722, 246-945-724, 246-945-726, and 246-945-728 - Medication assistance. The Pharmacy Quality Assurance Commission (commission) and Department of Health (department) are filing jointly to reinstate medication assistance rules as permitted under chapter 69.41 RCW. Specifically, this rule establishes criteria for medication assistance in community-based and in-home care settings in accordance with chapter 69.41 RCW. The definition for medication assistance provided in RCW 69.41.010(15) states:

"Medication assistance" means assistance rendered by a nonpractitioner to an individual residing in a community-based care setting or in-home care setting to facilitate the individual's self-administration of a legend drug or controlled substance. It includes reminding or coaching the individual, handing the medication container to the individual, opening the individual's medication container, using an enabler, or placing the medication in the individual's hand, and such other means of medication assistance as defined by rule adopted by the department...

These emergency rules provide further definitions for terms used within this definition such as "enabler" and establish those "other means of medication assistance as defined by rule adopted by the department." These rules help impacted individuals retain their independence and live in the least restrictive setting, such as their own home, longer by providing means and guidance for medication assistance. Also, with the direction provided in RCW 69.41.010(15), the rules are being filed under the joint authority of the commission and the department.

Citation of rules affected by this order:

New: WAC 246-945-710, 246-945-712, 246-945-714, 246-945-716, 246-945-718, 246-945-720, 246-945-722, 246-945-724, 246-945-726, 246-945-728
Repealed: None
Amended: None
Suspended: None

Statutory authority for adoption: RCW 18.64.005; RCW 69.41.010(15); RCW 69.41.075

Other authority:

EMERGENCY RULE

Under RCW 34.05.350 the agency for good cause finds:

☒ That immediate adoption, amendment, or repeal of a rule is necessary for the preservation of the public health, safety, or general welfare, and that observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the public interest.

☐ That state or federal law or federal rule or a federal deadline for state receipt of federal funds requires immediate adoption of a rule.

Reasons for this finding: The commission's new chapter, chapter 246-945 WAC, became effective in July 2020. The old rules, including the former rules on medication assistance (chapter 246-888 WAC), were repealed in March 2021. The commission's repeal of chapter 246-888 WAC has resulted in unintended disruptions for medication assistance in the community-based and in-home care settings permitted under chapter 69.41 RCW. Emergency rulemaking is necessary to immediately restore medication assistance regulations to preserve patient safety and welfare while the commission and the department work on permanent rulemaking.

Note: If any category is left blank, it will be calculated as zero. No descriptive text.

Count by whole WAC sections only, from the WAC number through the history note. A section may be counted in more than one category.

The number of sections adopted in order to comply with:

Federal statute:	New	0	Amended	0	Repealed	0
Federal rules or standards:	New	0	Amended	0	Repealed	0
Recently enacted state statutes:	New	0	Amended	0	Repealed	0

The number of sections adopted at the request of a nongovernmental entity:

	New	0	Amended	0	Repealed	0

The number of sections adopted on the agency's own initiative:

	New	10	Amended	0	Repealed	0

The number of sections adopted in order to clarify, streamline, or reform agency procedures:

	New	0	Amended	0	Repealed	0

The number of sections adopted using:

Negotiated rule making:	New	0	Amended	0	Repealed	0
Pilot rule making:	New	0	Amended	0	Repealed	0
Other alternative rule making:	New	10	Amended	0	Repealed	0

Date Adopted: 04/07/2021	**Signature:** 
Name: Teri Ferreira, RPh and Kristin Peterson, JD	
Title: Pharmacy Quality Assurance Commission Chair and Deputy Secretary, Policy and Planning	

PART 5 - MEDICATION ASSISTANCE

NEW SECTION

WAC 246-945-710 Scope and applicability. (1) This section through WAC 246-945-728 only apply to medication assistance provided in community-based care settings and in-home care settings.

(2) The following definitions apply to this section through WAC 246-945-728 unless the context requires otherwise:

(a) "Medication" means legend drugs and controlled substances; and

(b) "Practitioner" has the same meaning as in RCW 69.41.010(17).

NEW SECTION

WAC 246-945-712 Self-administration with assistance, independent self-administration, and medication administration. (1) Self-administration with assistance means assistance with legend drugs and controlled substances rendered by a nonpractitioner to an individual residing in a community-based care setting or an in-home care setting. It includes reminding or coaching the individual to take their medication, handing the medication container to the individual, opening the medication container, using an enabler, or placing the medication in the hand of the individual/resident. The individual/resident must be able to put the medication into their mouth or apply or instill the medication. The individual/resident does not necessarily need to state the name of the medication, intended effects, side effects, or other details, but must be aware that they are receiving medication. Assistance may be provided by a nonpractitioner with prefilled insulin syringes. Assistance is limited to handing the prefilled insulin syringe to an individual/resident. Assistance with the administration of any other intravenous or injectable medication is specifically excluded. The individual/resident retains the right to refuse medication. Self-administration with assistance shall occur immediately prior to the ingestion or application of a medication.

(2) Independent self-administration occurs when an individual/resident is independently able to directly apply a legend drug or controlled substance by ingestion, inhalation, injection or other means. In licensed assisted living facilities, self-administration may include situations in which an individual cannot physically self-administer medications but can accurately direct others. These regulations do not limit the rights of people with functional disabilities to self-direct care according to chapter 74.39 RCW.

(3) If an individual/resident is not able to physically ingest or apply a medication independently or with assistance, then the medication must be administered to the individual/resident by a person legally authorized to do so (e.g., physician, nurse, pharmacist). All

laws and regulations applicable to medication administration apply. If an individual/resident cannot safely self-administer medication or self-administer with assistance or cannot indicate an awareness that they are taking a medication, then the medication must be administered to the individual/resident by a person legally authorized to do so.

NEW SECTION

WAC 246-945-714 Self-administration with assistance in a community-based care setting or an in-home setting. (1) An individual/resident, or their representative, in a community-based care setting or an in-home setting may request self-administration with assistance.

(2) No additional separate assessment or documentation of the needs of the individual/resident are required in order to initiate self-administration with assistance. It is recommended that providers document their decision-making process in the health record of the individual or resident health record.

(3) A nonpractitioner may help in the preparation of legend drugs and controlled substances for self-administration where a practitioner has determined and communicated orally or by written direction that such medication preparation assistance is necessary and appropriate.

NEW SECTION

WAC 246-945-716 Enabler. (1) Enablers are physical devices used to facilitate an individual's/resident's self-administration of a medication. Physical devices include, but are not limited to, a medicine cup, glass, cup, spoon, bowl, prefilled syringes, syringes used to measure liquids, specially adapted table surface, straw, piece of cloth, or fabric.

(2) An individual's hand may also be an enabler. The practice of "hand-over-hand" administration is not allowed. Medication administration with assistance includes steadying or guiding an individual's hand while he or she applies or instills medications such as ointments, eye, ear, and nasal preparations.

NEW SECTION

WAC 246-945-718 Alteration of medication for self-administration with assistance. Alteration of a medication for self-administration with assistance includes, but is not limited to, crushing tablets, cutting tablets in half, opening capsules, mixing powdered medications with foods or liquids, or mixing tablets or capsules with foods or liquids. Individuals/residents must be aware that the medication is being altered or added to their food.

NEW SECTION

WAC 246-945-720 Medication alteration. A practitioner practicing within their scope of practice must determine that it is safe to alter a legend drug or controlled substance. If the medication is altered, and a practitioner has determined that such medication alteration is necessary and appropriate, the determination shall be communicated orally or by written direction. Documentation of the appropriateness of the alteration must be on the prescription container, or in the individual's/resident's record.

NEW SECTION

WAC 246-945-722 Types of assistance provided by nonpractitioner. A nonpractitioner can transfer a medication from one container to another for the purpose of an individual dose. Examples include: Pouring a liquid medication from the medication container to a calibrated spoon or medication cup.

NEW SECTION

WAC 246-945-724 Oxygen order/prescription requirements. Under state law, oxygen is not a medication and is not covered under this rule. While oxygen is not considered a medication under state law, oxygen does require an order/prescription from a practitioner.

NEW SECTION

WAC 246-945-726 Self-administration with assistance of medication through a gastrostomy or "g-tube." If a prescription is written as an oral medication via "g-tube," and if a practitioner has determined that the medication can be altered, if necessary, for use via "g-tube," the rules as outlined for self-administration with assistance would also apply.

NEW SECTION

WAC 246-945-728 Other medication assistance requirements. A practitioner, nonpractitioner, and an individual/resident or their representative should be familiar with the rules specifically regulating the residential setting. The department of social and health services has adopted rules relating to medication services in assisted living facilities and adult family homes.

PQAC Rules Priority List

Priority Ranking	Status	Title	Short Description	Most Recent WSR #
1	Refile	Removing Epidiolex from Schedule V (emergency)	Emergency rules de-scheduling Epidiolex	WSR 21-14-061 (Filed July 2, 2021)
1	Refile	COVID - CII Prescribing (emergency)	Emergency rules for prescribing Schedule II drugs during COVID-19 pandemic	WSR 21-14-059 (Filed July 2, 2021)
1	Refile	Medication assistance (emergency - filed jointly with DOH)	Medication assistance emergency rules in accordance with chapter 69.41 RCW	WSR 21-15-108 (Filed July 20, 2021)
1	Refiling	Retired pharmacist (emergency)	Emergency rules for retired active pharmacist license status	WSR 21-12-096 (Filed June 2, 2021)
2	Not in PQAC authority	PQAC Fees (standard - not in PQAC authority)	Fee rules for all PQAC licensees and 6086 registration fee	WSR 21-12-074 (CR-102 filed May 28, 2021)
3	CR-102 in review	Remote dispensing OUD medications - SSB 6086 (standard)	SSB 6086 - Implementing remote dispensing of OUD medications	WSR 20-17-123 (Filed August 18, 2020)
4	Pre-review of CR-102	Donation of unexpired drugs - SSB 6526 (standard)	SSB 6526 - Implementing the donation and reuse of unexpired drugs	WSR 20-17-143 (Filed August 19, 2020)
5	Drafting rule language	Retired pharmacist (standard)	Permanent rules for retired active pharmacist license status	WSR 21-09-063 (Filed April 19, 2021)
6	Preparing CR-102	Removing Epidiolex from Schedule V (standard)	Permanent rules to delete Epidiolex from Schedule V	WSR 20-23-027 (Filed November 10, 2020)
7	CR-101 in review	Access to drugs stored outside pharmacy (standard)	Allowing access to drugs stored outside the pharmacy by unlicensed employees of a health care facility	Not yet filed

8	New	Medication assistance (standard - will file jointly with DOH)	Medication assistance rules in accordance with chapter 69.41 RCW	Not yet filed
9	New	Zero Order Reports and Suspicious Orders (standard)	Amending WAC 246-945-001 and WAC 246-945-585 to adjust suspicious order and zero reporting requirement	Not yet filed
10	On hold	Technical fixes to chapter 246-945 WAC (expedited)	Typos and small edits to multiple sections in chapter 246-945 WAC	Not yet filed
11	On hold	AIDS education repeal - ESHB 1551 (expedited)	ESHB 1551 - Repealing AIDS education and training requirements	Not yet filed

Washington State Department of Health

Agency Request Legislation

2021

Enhancing Capacity of Health Profession Boards and Commissions

Z-0216

Health profession boards and commissions protect the public and promote quality care by establishing requirements for professions and taking disciplinary action in cases of misconduct.

Certain boards and commissions are facing challenges related to their size and composition that affect their ability to carry out their regulatory work in an efficient manner.

In addition, boards and commissions are compensated differently for like work, which creates inequities and challenges in recruitment. There are also limitations that do not align with our value of diversity by requiring US citizenship for membership.

This proposal makes the following modifications to board, commission, and committee statutes:

1. It modifies membership and quorum requirements for the following regulatory bodies: the Dental Quality Assurance Commission, the Veterinary Board of Governors, the Board of Physical Therapy, the Board of Massage, and the Board of Nursing Home Administrators
2. It authorizes the Pharmacy Commission to use the same regulatory delegation for facilities enforcement that it currently does for pharmacy professionals.
3. It harmonizes all boards and commissions as Class 5 Groups under Chapter 43.03 RCW.
4. It removes US citizenship as a prerequisite to serve on boards, commissions, or committees.

Background

The laws governing the composition and operation of certain health profession boards and commissions can contain provisions that hinder their ability to carry out their regulatory functions.

For example, members of the Veterinary Board of Governors cannot be reappointed to a consecutive second term, but may be reappointed if there has been a break in service. Members of the Board of Physical Therapy may not have previously served on other health profession boards and commissions. These types of provisions make it challenging to fill vacancies.

Others, such as the Board of Nursing Home Administrators and Board of Massage, lack representation from key segments of their professional communities such as

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administrators of assisted living facilities and massage educators.

In addition, the small size of these boards and commissions, coupled with restrictive quorum requirements, make it difficult for them to make timely decisions about discipline actions and policy work. This leads to delays when quorums cannot be reached and lead to a growing reliance on pro tem members, which is more costly and less efficient.

To address these issues, the department proposes to change quorum requirements to a simple majority, eliminate barriers to member recruitment, and expand the field of expertise by adding professional and public members.

One commission, the Pharmacy Quality Assurance Commission, regulates both health professionals and facilities. While it may delegate its enforcement work for professionals to panels of the Commission or to a health law judge, current statute does not authorize this for facilities enforcement. The bill would provide for this, increasing the commission's efficiency and promoting consistency.

While several boards and commissions are classed as Class 5 Groups (per RCW 43.03.265), others are classed as Class 3 Groups (per RCW 43.03.240). This creates inequities between groups charged with similar regulatory responsibilities. Further, significant differences in member compensation between the two classes can make recruitment more challenging for those groups at Class 3.

Another area of inconsistency between health profession boards, commissions and committees is the requirement that members be US citizens, in addition to any state residency or licensure requirements. It is essential that boards, commissions and committees reflect the makeup of our community. Removing this requirement provides additional opportunities to recruit well qualified individuals to serve.

Benefits

Adding members and revising membership qualifications will provide boards and commissions the capacity needed for timely decisions in matters of discipline and policy. It will also broaden candidate pools for board and commission positions, allowing vacancies to be filled faster.

Increasing board membership brings a wider range of perspectives and promotes informed decision-making. Expanding professionals representing more sub-specialties, practice settings, or sectors of the industry provides a broader base of subject matter expertise.

The bill promotes greater consistency in how boards function, from using similar quorum language to aligning the number of consecutive terms members can serve. It also authorizes the Pharmacy Commission to use the same enforcement methods for regulating facilities as it uses for professionals.

Another benefit of the bill is that it promotes greater participation on boards and commissions. Expanding the number of positions on boards and commissions, changing some qualifications requirements, and eliminating US citizenship requirements—all these measures allow for a broader array of perspectives in licensing, enforcement, rule making and policy decisions. Finally, reclassing boards and commissions also opens up the opportunity for members of the community to serve beyond those for which compensation is not a consideration.

July 2021

BILL REQUEST - CODE REVISER'S OFFICE

BILL REQ. #: Z-0216.4/21 4th draft

ATTY/TYPIST: MW:eab

BRIEF DESCRIPTION: Increasing board and commission capacities.

AN ACT Relating to enhancing the capacity of health profession boards, commissions, and advisory committees; amending RCW 18.32.0351, 18.32.0355, 18.52.040, 18.52.050, 18.74.020, 18.74.027, 18.92.021, 18.92.040, 18.108.020, 18.83.035, 18.83.045, 18.83.051, 18.64.001, 18.64.003, 18.64.005, 18.64.310, 18.59.120, 18.30.050, 18.30.060, 18.36A.150, 18.54.030, 18.54.060, 18.54.130, 18.35.150, 18.57.003, 18.57.003, 18.22.014, 18.200.060, 18.25.0165, 18.79.070, and 18.71.015; adding a new section to chapter 18.64 RCW; adding a new section to chapter 18.59 RCW; providing an effective date; and providing an expiration date.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

Sec. 1. RCW 18.32.0351 and 2007 c 269 s 16 are each amended to read as follows:

The Washington state dental quality assurance commission is established, consisting of ((~~sixteen~~)) seventeen members each appointed by the governor to a four-year term. No member may serve more than two consecutive full terms. ((~~In appointing the initial members of the commission, it is the intent of the legislature that, to the extent possible, members of the previous boards and committees regulating these professions be appointed to the commission.~~)) Members of the commission hold office until their successors are

appointed. ((~~The governor may appoint members of the initial commission to staggered terms of from one to four years. Thereafter, all~~)) All members shall be appointed to full four-year terms. Twelve members of the commission must be dentists, two members must be expanded function dental auxiliaries licensed under chapter 18.260 RCW, and ((~~two~~)) three members must be public members.

Sec. 2. RCW 18.32.0355 and 1994 sp.s. c 9 s 206 are each amended to read as follows:

Members must be ((~~citizens of the United States and~~)) residents of this state. Dentist members must be licensed dentists in the active practice of dentistry for a period of five years before appointment. Of the twelve dentists appointed to the commission, at least four must reside and engage in the active practice of dentistry east of the summit of the Cascade mountain range. Public members of the commission may not be a member of any other health care licensing board or commission, or have a fiduciary obligation to a facility rendering health services regulated by the commission, or have a material or financial interest in the rendering of health services regulated by the commission.

Sec. 3. RCW 18.52.040 and 2011 c 336 s 488 are each amended to read as follows:

(1) The state board of nursing home administrators shall consist of ((~~nine~~)) eleven members appointed by the governor. ((~~Four~~)) Six members shall be persons licensed under this chapter who have at least four years actual experience in the administration of a licensed nursing home in this state ((~~immediately preceding appointment to the board and who are not employed by the state or federal government~~)). One or two of the six administrator members shall be an administrator of an assisted living facility or a continuing care retirement community.

((~~Four~~)) (2) Three members shall be representatives of ((~~the health care professions~~)) one or more of the following:

(a) Licensed health care professionals providing medical or nursing services in nursing homes who are privately or self-employed; ((~~or shall be persons employed by~~))

(b) Faculty or administrators of educational institutions who have special knowledge ((~~or expertise in the field of health care~~

~~administration, health care education or long-term care or both, or care of the aged and chronically ill.~~

~~One member~~)) of health care education, long-term care, or care of the aged or elderly; or

(c) Persons currently employed in areas related to the long-term care field including, but not limited to, pharmacy, home health, adult family homes, or therapy services.

(3) Two members shall be ((~~a~~)) members of the health care consuming public who are residents of ((~~a~~)) nursing homes or ((~~a~~)) family members of ((~~a resident~~)) nursing home residents or ((~~a~~)) persons eligible for medicare. No member who is a nonadministrator representative shall have any direct or family financial interest in nursing homes while serving as a member of the board. The governor shall consult with and seek the recommendations of the appropriate statewide business and professional organizations and societies primarily concerned with long-term health care facilities in the course of considering his or her appointments to the board. Board members currently serving shall continue to serve until the expiration of their appointments.

Sec. 4. RCW 18.52.050 and 1992 c 53 s 5 are each amended to read as follows:

Members of the board shall be ((~~citizens of the United States and~~)) residents of this state. All administrator members of the board shall be holders of licenses under this chapter. The terms of all members shall be five years. Any board member may be removed for just cause including a finding of fact of unprofessional conduct or impaired practice. The governor may appoint a new member to fill any vacancy on the board for the remainder of the unexpired term. No board member may serve more than two consecutive full terms((~~, whether full or partial~~)). Board members shall serve until their successors are appointed. Board members shall be compensated in accordance with RCW ((~~43.03.240~~)) 43.03.265 and shall be reimbursed for travel expenses as provided in RCW 43.03.050 and 43.03.060. The board is designated as a class five group for purposes of chapter 43.03 RCW. The board may elect annually a chair and vice chair to direct the meetings of the board. The board shall meet at least four times each year and may hold additional meetings as called by the secretary or the chair. A majority of the board members appointed and serving constitutes a quorum for the transaction of board business.

The affirmative vote of a majority of a quorum of the board is required to carry a motion or resolution, to adopt a rule, or to pass a measure.

Sec. 5. RCW 18.74.020 and 2007 c 98 s 2 are each amended to read as follows:

The state board of physical therapy is hereby created. The board shall consist of ((~~six~~)) seven members who shall be appointed by the governor. ((~~Of the initial appointments, two shall be appointed for a term of two years, two for a term of three years, and one for a term of four years. Thereafter, all appointments shall be for terms of four years. Four~~)) Five members of the board shall be physical therapists licensed under this chapter and residing in this state, shall have not less than five years' experience in the practice of physical therapy, and shall be actively engaged in practice within two years of appointment. One member shall be a physical therapist assistant licensed under this chapter and residing in this state, shall not have less than five years' experience in the practice of physical therapy, and shall be actively engaged in practice within two years of appointment. The ((~~sixth~~)) seventh member shall be appointed from the public at large, shall have an interest in the rights of consumers of health services, and shall not be or have been a member of any other licensing board, a licensee of any health occupation board, an employee of any health facility nor derive his or her primary livelihood from the provision of health services at any level of responsibility. In the event that a member of the board for any reason cannot complete his or her term of office, another appointment shall be made by the governor in accordance with the procedure stated in this section to fill the remainder of the term. No member may serve for more than two ((~~successive~~)) consecutive full four-year terms.

The secretary of health shall furnish such secretarial, clerical, and other assistance as the board may require. Each member of the board shall, in addition to travel expenses in accordance with RCW 43.03.050 and 43.03.060, be compensated in accordance with RCW ((~~43.03.240~~)) 43.03.265. The board is designated as a class five group for purposes of chapter 43.03 RCW.

Sec. 6. RCW 18.74.027 and 1983 c 116 s 5 are each amended to read as follows:

The board shall elect from its members a chairperson and vice chairperson-secretary, who shall serve for one year and until their successors are elected. The board shall meet at least once a year and upon the call of the chairperson at such times and places as the chairperson designates. ((~~Three members constitute a quorum of the full board for the transaction of any business.~~)) A majority of the board members appointed and serving constitutes a quorum for the transaction of board business. The affirmative vote of a majority of a quorum of the board is required to carry a motion or resolution, to adopt a rule, or to pass a measure. Meetings of the board shall be open and public, except the board may hold executive sessions to the extent permitted by chapter 42.30 RCW.

Sec. 7. RCW 18.92.021 and 2007 c 235 s 3 are each amended to read as follows:

(1) There is created a Washington state veterinary board of governors ((~~consisting~~)) reflecting the diverse practice of animal medicine, including large animal practice. The board shall consist of ((~~seven~~)) nine members, ((~~five~~)) six of whom shall be licensed veterinarians, one of whom shall be a licensed veterinary technician ((~~trained in both large and small animal medicine~~)), one of whom shall be a licensed veterinarian or a licensed veterinary technician, and one of whom shall be a ((~~lay~~)) member of the public.

(2)(a) The licensed members shall be appointed by the governor. At the time of their appointment the licensed members of the board must be actual residents of the state in active practice as licensed practitioners of veterinary medicine, surgery, and dentistry, or employed as a licensed veterinary technician, as applicable((~~, and must be citizens of the United States~~)). Not more than ((~~one~~)) two licensed veterinary members shall be from the same congressional district. The board shall not be deemed to be unlawfully constituted and a member of the board shall not be deemed ineligible to serve the remainder of the member's unexpired term on the board solely by reason of the establishment of new or revised boundaries for congressional districts.

(b) The terms of the ((~~first licensed~~)) members ((~~of the board~~)) shall be ((~~as follows: One member for five, four, three, two, and one years respectively. Thereafter the terms shall be for~~)) five years and until their successors are appointed and qualified.

(c) ((~~The lay member shall be appointed by the governor for a five year term and until the lay member's successor is appointed.~~

~~(d)~~)) A member may be appointed to serve ((~~a second term, if that term does not run consecutively~~)) two consecutive full terms.

((~~(e)~~)) (d) Vacancies ((~~in~~)) on the board shall be filled by the governor, the appointee to hold office for the remainder of the unexpired term.

(3) ((~~The licensed veterinary technician member is a nonvoting member with respect to board decisions related to the discipline of a veterinarian involving standard of care.~~

~~(4)~~)) Officers of the board shall be a chair and a ((~~secretary-treasurer~~)) vice chair to be chosen by the members of the board from among its members.

((~~(5) Four members of the board shall constitute a quorum at meetings of the board.~~)) (4) A majority of the board members appointed and serving constitutes a quorum for the transaction of board business. The affirmative vote of a majority of a quorum of the board is required to carry a motion or resolution, to adopt a rule, or to pass a measure.

Sec. 8. RCW 18.92.040 and 1991 c 3 s 240 are each amended to read as follows:

Each member of the board shall be compensated in accordance with RCW ((~~43.70.250~~)) 43.03.265 and shall be reimbursed for travel expenses in accordance with RCW 43.03.050 and 43.03.060. The board is designated as a class five group for purposes of chapter 43.03 RCW. No expense may be incurred by members of the board except in connection with board meetings without prior approval of the secretary.

Sec. 9. RCW 18.108.020 and 1991 c 3 s 253 are each amended to read as follows:

The Washington state board of massage is ((~~hereby~~)) created. The board shall consist of ((~~four~~)) seven members who shall be appointed by the governor for a term of four years each. ((~~Members~~)) All members shall be residents of this state ((~~and shall have not less than three years experience in the practice of massage immediately preceding their appointment and shall be licensed under this chapter and actively engaged in the practice of massage during their incumbency.~~

~~In addition to the members specified in this section, the governor shall appoint a consumer member of the board, who shall serve for a term of four years. The consumer member of the board shall be an individual who does not derive his or her livelihood by providing health care services or massage therapy and is not a licensed health professional. The consumer member shall not be an employee of the state nor a present or former member of another licensing board~~)). Five members shall be massage therapists licensed under this chapter with at least three years' experience in the practice of massage immediately preceding their appointment and shall at all times during their terms remain licensed massage therapists.

One member shall be a consumer whose occupation does not include the administration of health activities or the provision of health services and who has no material financial interest in the provision of health care services.

One member shall be a massage educator or massage school owner with at least three years' experience in the teaching or administration of direct student learning of the practice of massage. The educator or school owner member is not required to be a licensed massage therapist. The member shall recuse themselves from any board deliberations or decision making involving the school or educational program with which the member is professionally affiliated.

In the event that a member cannot complete ((~~his or her~~)) their term of office, another appointment shall be made by the governor in accordance with the procedures stated in this section to fill the remainder of the term. No member may serve more than two successive full terms ((~~whether full or partial~~)). The governor may remove any member of the board for neglect of duty, incompetence, or unprofessional or disorderly conduct as determined under chapter 18.130 RCW.

Each member of the board shall be compensated in accordance with RCW ((~~43.03.240~~)) 43.03.265. The board is designated as a class five group for purposes of chapter 43.03 RCW. Members shall be reimbursed for travel expenses incurred in the actual performance of their duties, as provided in RCW 43.03.050 and 43.03.060.

The board may annually elect a chairperson to direct the meetings of the board. The board shall meet as called by the chairperson or the secretary. ((~~Three members of the board shall constitute a quorum of the board.~~)) A majority of the board members appointed and serving constitutes a quorum for the transaction of board business. The

affirmative vote of a majority of a quorum of the board is required to carry a motion or resolution, to adopt a rule, or to pass a measure.

Sec. 10. RCW 18.83.035 and 1989 c 226 s 1 are each amended to read as follows:

There is created the examining board of psychology which shall examine the qualifications of applicants for licensing. The board shall consist of ((~~seven~~)) nine psychologists and two public members, all appointed by the governor. The public members shall not be and have never been psychologists or in training to be psychologists; they may not have any household member who is a psychologist or in training to be a psychologist; they may not participate or ever have participated in a commercial or professional field related to psychology, nor have a household member who has so participated; and they may not have had within two years before appointment a substantial financial interest in a person regulated by the board. Each psychologist member of the board shall ((~~be a citizen of the United States who has~~)) have actively practiced psychology in the state of Washington for at least three years immediately preceding appointment and who is licensed under this chapter. Board members shall be appointed for a term of five years, except that the terms of the existing appointees shall be adjusted by the governor so that no more than two members' terms expire each year with all subsequent appointments for a five-year term. Upon the death, resignation, or removal of a member, the governor shall appoint a successor to serve for the unexpired term. The board shall elect one of its members to serve as chairperson.

Sec. 11. RCW 18.83.045 and 1991 c 3 s 195 are each amended to read as follows:

The board shall meet at least once each year and at such other times as the board deems appropriate to properly discharge its duties. All meetings shall be held in Olympia, Washington, or such other places as may be designated by the secretary. Five members of the board shall constitute a quorum, except that oral examinations may be conducted with only three psychologist members. A majority of the board members appointed and serving constitutes a quorum for the transaction of board business. The affirmative vote of a majority of

a quorum of the board is required to carry a motion or resolution, to adopt a rule, or to pass a measure.

Sec. 12. RCW 18.83.051 and 1984 c 287 s 48 are each amended to read as follows:

Each member of the board shall be compensated in accordance with RCW ((~~43.03.240~~)) 43.03.265 and in addition thereto shall be reimbursed for travel expenses incurred in carrying out the duties of the board in accordance with RCW 43.03.050 and 43.03.060. The board is designated as a class five group for purposes of chapter 43.03 RCW.

Sec. 13. RCW 18.64.001 and 2013 c 19 s 3 are each amended to read as follows:

There shall be a state pharmacy quality assurance commission consisting of fifteen members, to be appointed by the governor by and with the advice and consent of the senate. Ten of the members shall be designated as pharmacist members, four of the members shall be designated a public member, and one member shall be a pharmacy technician.

Each pharmacist member shall be a ((~~citizen of the United States and a~~)) resident of this state, and at the time of his or her appointment shall have been a duly registered pharmacist under the laws of this state for a period of at least five consecutive years immediately preceding his or her appointment and shall at all times during his or her incumbency continue to be a duly licensed pharmacist: PROVIDED, That subject to the availability of qualified candidates the governor shall appoint pharmacist members representative of the areas of practice and geographically representative of the state of Washington.

The public member shall be a ((~~citizen of the United States and a~~)) resident of this state. The public member shall be appointed from the public at large, but shall not be affiliated with any aspect of pharmacy.

Members of the commission shall hold office for a term of four years, and the terms shall be staggered so that the terms of office of not more than two members will expire simultaneously on the third Monday in January of each year.

No person who has been appointed to and served for two four year terms shall be eligible for appointment to the commission.

Each member shall qualify by taking the usual oath of a state officer, which shall be filed with the secretary of state, and each member shall hold office for the term of his or her appointment and until his or her successor is appointed and qualified.

In case of the resignation or disqualification of a member, or a vacancy occurring from any cause, the governor shall appoint a successor for the unexpired term.

Sec. 14. RCW 18.64.003 and 2013 c 19 s 4 are each amended to read as follows:

Members of the commission shall meet at such places and times as it shall determine and as often as necessary to discharge the duties imposed upon it. The commission shall elect a chairperson and a vice chairperson from among its members. A majority of the commission members appointed and serving constitutes a quorum for the transaction of commission business. The affirmative vote of a majority of a quorum of the commission is required to carry a motion or resolution, to adopt a rule, or to pass a measure. The commission is designated as a class five group for purposes of chapter 43.03 RCW. Each member shall be compensated in accordance with RCW ((~~43.03.240~~)) 43.03.265 and shall be reimbursed for travel expenses in accordance with RCW 43.03.050 and 43.03.060.

Sec. 15. RCW 18.64.005 and 2013 c 19 s 5 are each amended to read as follows:

The commission shall:

(1) Regulate the practice of pharmacy and enforce all laws placed under its jurisdiction;

(2) Prepare or determine the nature of, and supervise the grading of, examinations for applicants for pharmacists' licenses;

(3) Establish the qualifications for licensure of pharmacists or pharmacy interns;

(4) Conduct hearings for the revocation or suspension of licenses, permits, registrations, certificates, or any other authority to practice granted by the commission, which hearings may also be conducted by an administrative law judge appointed under chapter 34.12 RCW or a presiding officer designated by the commission. The commission may authorize the secretary, or their designee, to serve as the presiding officer for any disciplinary proceedings of the commission authorized under this chapter. The

presiding officer shall not vote on or make any final decision in cases pertaining to standards of practice or where clinical expertise is necessary. All functions performed by the presiding officer shall be subject to chapter 34.05 RCW;

(5) Issue subpoenas and administer oaths in connection with any hearing, or disciplinary proceeding held under this chapter or any other chapter assigned to the commission;

(6) Assist the regularly constituted enforcement agencies of this state in enforcing all laws pertaining to drugs, controlled substances, and the practice of pharmacy, or any other laws or rules under its jurisdiction;

(7) Promulgate rules for the dispensing, distribution, wholesaling, and manufacturing of drugs and devices and the practice of pharmacy for the protection and promotion of the public health, safety, and welfare. Violation of any such rules shall constitute grounds for refusal, suspension, or revocation of licenses or any other authority to practice issued by the commission;

(8) Adopt rules establishing and governing continuing education requirements for pharmacists and other licensees applying for renewal of licenses under this chapter;

(9) Be immune, collectively and individually, from suit in any action, civil or criminal, based upon any disciplinary proceedings or other official acts performed as members of the commission. Such immunity shall apply to employees of the department when acting in the course of disciplinary proceedings;

(10) Suggest strategies for preventing, reducing, and eliminating drug misuse, diversion, and abuse, including professional and public education, and treatment of persons misusing and abusing drugs;

(11) Conduct or encourage educational programs to be conducted to prevent the misuse, diversion, and abuse of drugs for health care practitioners and licensed or certified health care facilities;

(12) Monitor trends of drug misuse, diversion, and abuse and make periodic reports to disciplinary boards of licensed health care practitioners and education, treatment, and appropriate law enforcement agencies regarding these trends;

(13) Enter into written agreements with all other state and federal agencies with any responsibility for controlling drug misuse, diversion, or abuse and with health maintenance organizations, health care service contractors, and health care providers to assist and promote coordination of agencies responsible for ensuring compliance

with controlled substances laws and to monitor observance of these laws and cooperation between these agencies. The department of social and health services, the department of labor and industries, and any other state agency including licensure disciplinary boards, shall refer all apparent instances of over-prescribing by practitioners and all apparent instances of legend drug overuse to the department. The department shall also encourage such referral by health maintenance organizations, health service contractors, and health care providers.

Sec. 16. RCW 18.64.310 and 2013 c 19 s 21 are each amended to read as follows:

The department shall:

(1) Establish reasonable license and examination fees and fees for services to other agencies in accordance with RCW 43.70.250 and 43.70.280. In cases where there are unanticipated demands for services, the department may request payment for services directly from the agencies for whom the services are performed, to the extent that revenues or other funds are available. Drug-related investigations regarding licensed health care practitioners shall be funded by an appropriation to the department from the health professions account. The payment may be made on either an advance or a reimbursable basis as approved by the director of financial management;

(2) Employ, with confirmation by the commission, an executive officer, who shall be exempt from the provisions of chapter 41.06 RCW ((~~and who~~)). The executive officer shall be a pharmacist licensed in Washington((~~, and~~)) or shall be licensed as a pharmacist in Washington within 180 days of hire. The executive officer shall employ inspectors, investigators, chemists, and other persons as necessary to assist it for any purpose which it may deem necessary;

(3) Investigate and prosecute, at the direction of the commission, including use of subpoena powers, violations of law or regulations under its jurisdiction or the jurisdiction of the commission;

(4) Make, at the direction of the commission, inspections and investigations of pharmacies and other places, including dispensing machines, in which drugs or devices are stored, held, compounded, dispensed, sold, or administered to the ultimate consumer, to take and analyze any drugs or devices and to seize and condemn any drugs or devices which are adulterated, misbranded, stored, held,

dispensed, distributed, administered, or compounded in violation of or contrary to law. The written operating agreement between the department and the commission, as required by RCW 43.70.240 shall include provisions for the department to involve the commission in carrying out its duties required by this section.

NEW SECTION. **Sec. 17.** A new section is added to chapter 18.64 RCW to read as follows:

The commission may appoint members of panels of at least three members. A quorum for transaction of any business by a panel is a minimum of three members. A majority vote of a quorum of the panel is required to transact business delegated to it by the commission including, but not limited to, licensing, disciplinary, and adjudicative actions.

NEW SECTION. **Sec. 18.** A new section is added to chapter 18.59 RCW to read as follows:

Each member of the board shall be compensated in accordance with RCW 43.03.265. Members shall be reimbursed for travel expenses incurred in the actual performance of their duties, as provided in RCW 43.03.050 and 43.03.060. The board is designated as a class five group for purposes of chapter 43.03 RCW.

Sec. 19. RCW 18.59.120 and 2011 c 336 s 492 are each amended to read as follows:

(1) There is established a board of occupational therapy practice. The board shall consist of five members appointed by the governor, who may consider the persons who are recommended for appointment by occupational therapy associations of the state. The members of the board shall be residents of the state. Four of the members shall have been engaged in rendering services to the public, teaching, or research in occupational therapy for at least five years immediately preceding their appointment. Three of these four board members shall be occupational therapists who shall at all times be holders of licenses for the practice of occupational therapy in the state, ((~~except for the initial members of the board,~~)) all of whom shall fulfill the requirements for licensure under this chapter. At least one member of the board shall be an occupational therapy assistant licensed to assist in the practice of occupational therapy, except for the initial member appointed to this position, who shall

fulfill the requirements for licensure as a occupational therapy assistant under this chapter. The remaining member of the board shall be a member of the public with an interest in the rights of consumers of health services.

(2) ((~~The governor shall, within sixty days after June 7, 1984, appoint one member for a term of one year, two members for a term of two years, and two members for a term of three years.~~)) Appointments ((~~made thereafter~~)) shall be for three-year terms, but no person shall be appointed to serve more than two consecutive full terms. Terms shall begin on the first day of the calendar year and end on the last day of the calendar year or until successors are appointed, except for the initial appointed members, who shall serve through the last calendar day of the year in which they are appointed before commencing the terms prescribed by this section. The governor shall make appointments for vacancies in unexpired terms within ninety days after the vacancies occur.

(3) The board shall meet during the first month of each calendar year to select a chair and for other purposes. At least one additional meeting shall be held before the end of each calendar year. Further meetings may be convened at the call of the chair or the written request of any two board members. ((~~A majority of members of the board constitutes a quorum for all purposes.~~)) A majority of the board members appointed and serving constitutes a quorum for the transaction of board business. The affirmative vote of a majority of a quorum of the board is required to carry a motion or resolution, to adopt a rule, or to pass a measure. All meetings of the board shall be open to the public, except that the board may hold closed sessions to prepare, approve, grade, or administer examinations or, upon request of an applicant who fails an examination, to prepare a response indicating the reasons for the applicant's failure.

((~~(4) Members of the board shall receive compensation in the amount of fifty dollars for each day's attendance at proper meetings of the committee.~~))

Sec. 20. RCW 18.30.050 and 2002 c 160 s 4 are each amended to read as follows:

(1) The Washington state board of denturists is created. The board shall consist of seven members appointed by the secretary as follows:

(a) Four members of the board must be denturists licensed under this chapter, except initial appointees, who must have five years' experience in the field of denturism or a related field.

(b) Two members shall be selected from persons who are not affiliated with any health care profession or facility, at least one of whom must be over sixty-five years of age representing the elderly.

(c) One member must be a dentist licensed in the state of Washington.

(2) The members of the board shall serve for terms of three years. ((~~The terms of the initial members shall be staggered, with the members appointed under subsection (1)(a) of this section serving two-year and three-year terms initially and the members appointed under subsection (1)(b) and (c) of this section serving one-year, two-year, and three-year terms initially. Vacancies shall be filled in the same manner as the original appointments are made.~~)) Appointments to fill vacancies shall be for the remainder of the unexpired term of the vacant position.

(3) No appointee may serve more than two consecutive terms.

(4) Members of the board shall be reimbursed for travel expenses under RCW 43.03.050 and 43.03.060. Each member of the board shall be compensated in accordance with RCW 43.03.265. The board is designated as a class five group for purposes of chapter 43.03 RCW.

(5) A member of the board may be removed for just cause by the secretary.

Sec. 21. RCW 18.30.060 and 1995 c 1 s 7 are each amended to read as follows:

(1) The board shall elect a chairperson of the board annually. The same person may not hold the office of chairperson for more than three years in succession.

(2) ((~~A majority of the board constitutes a quorum for all purposes, and a majority vote of the members voting governs the decisions of the board.~~)) A majority of the board members appointed and serving constitutes a quorum for the transaction of board business. The affirmative vote of a majority of a quorum of the board is required to carry a motion or resolution, to adopt a rule, or to pass a measure.

Sec. 22. RCW 18.36A.150 and 2011 c 41 s 1 are each amended to read as follows:

(1) There is created the board of naturopathy consisting of seven members appointed by the governor to four-year terms. Five members of the board shall be persons licensed under this chapter and two shall be members of the public. No member may serve more than two consecutive full terms. Members hold office until their successors are appointed. ((~~The governor may appoint the initial members of the board to staggered terms from one to four years. Thereafter, all~~)) All members shall be appointed to full four-year terms.

(2) The public members of the board may not be a member of any other health care licensing board or commission, have a fiduciary obligation to a facility rendering services regulated under this chapter, or have a material or financial interest in the rendering of services regulated under this chapter.

(3) The board shall elect officers each year. The board shall meet at least twice each year and may hold additional meetings as called by the chair. Meetings of the board are open to the public, except that the board may hold executive sessions to the extent permitted by chapter 42.30 RCW. The department shall provide secretarial, clerical, and other assistance as required by the board.

(4) Each member of the board shall be compensated in accordance with RCW ((~~43.03.240~~)) 43.03.265. Members shall be reimbursed for travel expenses incurred in the actual performance of their duties, as provided in RCW 43.03.050 and 43.03.060. The board is designated as a class five group for purposes of chapter 43.03 RCW.

(5) A majority of the board members appointed and serving constitutes a quorum for the transaction of board business. The affirmative vote of a majority of a quorum of the board is required to carry a motion or resolution, to adopt a rule, or to pass a measure.

(6) The board may appoint members to panels of at least three members. A quorum for transaction of any business by a panel is a minimum of three members. A majority vote of a quorum of the panel is required to transact business delegated to it by the board.

(7) The board may adopt such rules as are consistent with this chapter as may be deemed necessary and proper to carry out the purposes of this chapter.

(8) The governor may remove a member of the board for neglect of duty, misconduct, or malfeasance or misfeasance in office. Whenever

the governor is satisfied that a member of the board has been guilty of neglect of duty, misconduct, or malfeasance or misfeasance in office, he or she shall file with the secretary of state a statement of the cause for and the order of removal from office, and the secretary shall immediately send a certified copy of the order of removal and statement of causes by certified mail to the last known post office address of the member. If a vacancy occurs on the board, the governor shall appoint a replacement to fill the remainder of the unexpired term.

Sec. 23. RCW 18.54.030 and 2011 c 336 s 489 are each amended to read as follows:

The initial composition of the optometry board includes the three members of the examining committee for optometry plus two more optometrists to be appointed by the governor.

The governor must make all appointments to the optometry board. Only optometrists who are ((~~citizens of the United States,~~)) residents of this state, having been licensed to practice and practicing optometry in this state for a period of at least four years immediately preceding the effective date of appointment, and who have no connection with any school or college embracing the teaching of optometry or with any optical supply business may be appointed.

((~~The governor may set the terms of office of the initial board at his or her discretion, to establish the following perpetual succession: The terms of the initial board include one position for one year, two for two years, and two for three years; and upon the expiration of the terms of the initial board, all~~)) All appointments are for three years.

In addition to the members specified in this section, the governor shall appoint a consumer member of the board, who shall serve for a term of three years.

In the event that a vacancy occurs on the board in the middle of an appointee's term, the governor must appoint a successor for the unexpired portion of the term only.

Sec. 24. RCW 18.54.060 and 1963 c 25 s 6 are each amended to read as follows:

((~~Three members constitute a quorum for the transaction of business of the board~~)) A majority of the board members appointed and

serving constitutes a quorum for the transaction of board business. The affirmative vote of a majority of a quorum of the board is required to carry a motion or resolution, to adopt a rule, or to pass a measure.

Sec. 25. RCW 18.54.130 and 1984 c 287 s 41 are each amended to read as follows:

Members of the board are entitled to receive their travel expenses in accordance with RCW 43.03.050 and 43.03.060. Each member of the board will also be compensated in accordance with RCW ((~~43.03.240~~)) 43.03.265. The board is designated as a class five group for purposes of chapter 43.03 RCW.

Sec. 26. RCW 18.35.150 and 2014 c 189 s 12 are each amended to read as follows:

(1) There is created hereby the board of hearing and speech to govern the three separate professions: Hearing aid specialist, audiology, and speech-language pathology. The board shall consist of eleven members to be appointed by the governor.

(2) Members of the board shall be residents of this state. Three members shall represent the public and shall have an interest in the rights of consumers of health services, and shall not be or have been a member of, or married to a member of, another licensing board, a licensee of a health occupation board, an employee of a health facility, nor derive his or her primary livelihood from the provision of health services at any level of responsibility. Two members shall be hearing aid specialists who are licensed under this chapter, have at least five years of experience in the practice of hearing instrument fitting and dispensing, and must be actively engaged in fitting and dispensing within two years of appointment. Two members of the board shall be audiologists licensed under this chapter who have at least five years of experience in the practice of audiology and must be actively engaged in practice within two years of appointment. Two members of the board shall be speech-language pathologists licensed under this chapter who have at least five years of experience in the practice of speech-language pathology and must be actively engaged in practice within two years of appointment. One advisory nonvoting member shall be a speech-language pathology assistant certified in Washington. One advisory nonvoting member shall be a medical physician licensed in the state of Washington.

(3) The term of office of a member is three years. ((~~Of the initial appointments, one hearing aid specialist, one speech-language pathologist, one audiologist, and one consumer shall be appointed for a term of two years, and one hearing aid specialist, one speech-language pathologist, one audiologist, and two consumers shall be appointed for a term of three years. Thereafter, all appointments shall be made for expired terms.~~)) No member shall be appointed to serve more than two consecutive terms. A member shall continue to serve until a successor has been appointed. The governor shall either reappoint the member or appoint a successor to assume the member's duties at the expiration of his or her predecessor's term. A vacancy in the office of a member shall be filled by appointment for the unexpired term.

(4) The chair shall rotate annually among the hearing aid specialists, speech-language pathologists, audiologists, and public members serving on the board. In the absence of the chair, the board shall appoint an interim chair. In event of a tie vote, the issue shall be brought to a second vote and the chair shall refrain from voting.

(5) The board shall meet at least once each year, at a place, day and hour determined by the board, unless otherwise directed by a majority of board members. The board shall also meet at such other times and places as are requested by the department or by three members of the board. ((~~A quorum is a majority of the board. A hearing aid specialist, speech-language pathologist, and audiologist must be represented.~~)) A majority of the board members appointed and serving constitutes a quorum for the transaction of board business. The affirmative vote of a majority of a quorum of the board is required to carry a motion or resolution, to adopt a rule, or to pass a measure. Meetings of the board shall be open and public, except the board may hold executive sessions to the extent permitted by chapter 42.30 RCW.

(6) Members of the board shall be compensated in accordance with RCW ((~~43.03.240~~)) 43.03.265 and shall be reimbursed for their travel expenses in accordance with RCW 43.03.050 and 43.03.060. The board is designated as a class five group for purposes of chapter 43.03 RCW.

(7) The governor may remove a member of the board for cause at the recommendation of a majority of the board.

Sec. 27. RCW 18.57.003 and 2017 c 101 s 1 are each amended to read as follows:

There is hereby created an agency of the state of Washington, consisting of eleven individuals appointed by the governor to be known as the Washington state board of osteopathic medicine and surgery.

On expiration of the term of any member, the governor shall appoint for a period of five years a qualified individual to take the place of such member. Each member shall hold office until the expiration of the term for which such member is appointed or until a successor shall have been appointed and shall have qualified. Initial appointments shall be made and vacancies in the membership of the board shall be filled for the unexpired term by appointment by the governor.

Each member of the board shall be ((~~a citizen of the United States and must be~~)) an actual resident of this state. Two members must be consumers who have neither a financial nor a fiduciary relationship to a health care delivery system, one member must have been in active practice as a licensed osteopathic physician assistant in this state for at least five years immediately preceding appointment, and every other member must have been in active practice as a licensed osteopathic physician and surgeon in this state for at least five years immediately preceding appointment.

The board shall elect a chairperson((~~, a secretary,~~)) and a vice chairperson from its members. Meetings of the board shall be held at least four times a year and at such place as the board shall determine and at such other times and places as the board deems necessary.

((~~An affirmative vote of a simple majority of the members present at a meeting or hearing shall be required for the board to take any official action. The board may not take any action without a quorum of the board members present. A simple majority of the board members currently serving constitutes a quorum of the board.~~)) A majority of the board members appointed and serving constitutes a quorum for the transaction of board business. The affirmative vote of a majority of a quorum of the board is required to carry a motion or resolution, to adopt a rule, or to pass a measure.

Each member of the board shall be compensated in accordance with RCW 43.03.265 and shall be reimbursed for travel expenses in

accordance with RCW 43.03.050 and 43.03.060. The board is a class five group for purposes of chapter 43.03 RCW.

Any member of the board may be removed by the governor for neglect of duty, misconduct, malfeasance or misfeasance in office, or upon written request of two-thirds of the physicians licensed under this chapter and in active practice in this state.

Sec. 28. RCW 18.57.003 and 2020 c 80 s 14 are each amended to read as follows:

There is hereby created an agency of the state of Washington, consisting of eleven individuals appointed by the governor to be known as the Washington state board of osteopathic medicine and surgery.

On expiration of the term of any member, the governor shall appoint for a period of five years a qualified individual to take the place of such member. Each member shall hold office until the expiration of the term for which such member is appointed or until a successor shall have been appointed and shall have qualified. Initial appointments shall be made and vacancies in the membership of the board shall be filled for the unexpired term by appointment by the governor.

Each member of the board shall be ((~~a citizen of the United States and must be~~)) an actual resident of this state. Two members must be consumers who have neither a financial nor a fiduciary relationship to a health care delivery system, and every other member must have been in active practice as a licensed osteopathic physician and surgeon in this state for at least five years immediately preceding appointment.

The board shall elect a chairperson((~~, a secretary,~~)) and a vice chairperson from its members. Meetings of the board shall be held at least four times a year and at such place as the board shall determine and at such other times and places as the board deems necessary.

((~~An affirmative vote of a simple majority of the members present at a meeting or hearing shall be required for the board to take any official action. The board may not take any action without a quorum of the board members present. A simple majority of the board members currently serving constitutes a quorum of the board.~~)) A majority of the board members appointed and serving constitutes a quorum for the transaction of board business. The affirmative vote of a majority of

a quorum of the board is required to carry a motion or resolution, to adopt a rule, or to pass a measure.

Each member of the board shall be compensated in accordance with RCW 43.03.265 and shall be reimbursed for travel expenses in accordance with RCW 43.03.050 and 43.03.060. The board is a class five group for purposes of chapter 43.03 RCW.

Any member of the board may be removed by the governor for neglect of duty, misconduct, malfeasance or misfeasance in office, or upon written request of two-thirds of the physicians licensed under this chapter and in active practice in this state.

Sec. 29. RCW 18.22.014 and 2020 c 248 s 2 are each amended to read as follows:

The board shall meet at the places and times it determines and as often as necessary to discharge its duties. The board shall elect a chairperson((~~,~~)) and a vice chairperson((~~, and secretary~~)) from among its members. Members must be compensated in accordance with RCW 43.03.265 in addition to travel expenses provided by RCW 43.03.050 and 43.03.060. The board is a class five group for purposes of chapter 43.03 RCW. ((~~A simple majority of the board members currently serving constitutes a quorum of the board.~~)) A majority of the board members appointed and serving constitutes a quorum for the transaction of board business. The affirmative vote of a majority of a quorum of the board is required to carry a motion or resolution, to adopt a rule, or to pass a measure.

Sec. 30. RCW 18.200.060 and 1997 c 285 s 7 are each amended to read as follows:

(1) The secretary has the authority to appoint an advisory committee to further the purposes of this chapter. The secretary may consider the persons who are recommended for appointment by the orthotic and prosthetic associations of the state. The committee is composed of five members, one member initially appointed for a term of one year, two for a term of two years, and two for a term of three years. Subsequent appointments are for terms of three years. No person may serve as a member of the committee for more than two consecutive terms. Members of the advisory committee must be residents of this state ((~~and citizens of the United States~~)). The committee is composed of three individuals licensed in the category designated and engaged in rendering services to the public. Two

members must at all times be holders of licenses for the practice of either prosthetics or orthotics, or both, in this state, except for the initial members of the advisory committee, all of whom must fulfill the requirements for licensure under this chapter. One member must be a practicing orthotist. One member must be a practicing prosthetist. One member must be licensed by the state as a physician licensed under chapter 18.57 or 18.71 RCW, specializing in orthopedic medicine or surgery or physiatry. Two members must represent the public at large and be unaffiliated directly or indirectly with the profession being credentialed but, to the extent possible, be consumers of orthotic and prosthetic services. The two members appointed to the advisory committee representing the public at large must have an interest in the rights of consumers of health services and must not be or have been a licensee of a health occupation committee or an employee of a health facility, nor derive his or her primary livelihood from the provision of health services at any level of responsibility.

(2) The secretary may remove any member of the advisory committee for cause as specified by rule. In the case of a vacancy, the secretary shall appoint a person to serve for the remainder of the unexpired term.

(3) The advisory committee may provide advice on matters specifically identified and requested by the secretary, such as applications for licenses.

(4) The advisory committee may be requested by the secretary to approve an examination required for licensure under this chapter.

(5) The advisory committee may be requested by the secretary to review and monitor the exemptions to requirements of certain orthoses and prostheses in this chapter and recommend to the secretary any statutory changes that may be needed to properly protect the public.

(6) The advisory committee, at the request of the secretary, may recommend rules in accordance with the administrative procedure act, chapter 34.05 RCW, relating to standards for appropriateness of orthotic and prosthetic care.

(7) The advisory committee shall meet at the times and places designated by the secretary and hold meetings during the year as necessary to provide advice to the secretary. The committee may elect a chair and a vice chair. A majority of the members currently serving constitute a quorum.

(8) Each member of an advisory committee shall be reimbursed for travel expenses as authorized in RCW 43.03.050 and 43.03.060. In addition, members of the committees shall be compensated in accordance with RCW 43.03.240 when engaged in the authorized business of their committees.

(9) The secretary, members of advisory committees, or individuals acting on their behalf are immune from suit in any action, civil or criminal, based on any credentialing or disciplinary proceedings or other official acts performed in the course of their duties.

Sec. 31. RCW 18.25.0165 and 1994 sp.s. c 9 s 106 are each amended to read as follows:

Members must be ((~~citizens of the United States and~~)) residents of this state. Members must be licensed chiropractors for a period of five years before appointment. Public members of the commission may not be a member of any other health care licensing board or commission, or have a fiduciary obligation to a facility rendering health services regulated by the commission, or have a material or financial interest in the rendering of health services regulated by the commission.

Sec. 32. RCW 18.79.070 and 2005 c 17 s 1 are each amended to read as follows:

(1) The state nursing care quality assurance commission is established, consisting of fifteen members to be appointed by the governor to four-year terms. The governor shall consider nursing members who are recommended for appointment by the appropriate professional associations in the state. No person may serve as a member of the commission for more than two consecutive full terms.

(2) There must be seven registered nurse members, two advanced registered nurse practitioner members, three licensed practical nurse members, and three public members on the commission. Each member of the commission must be a ((~~citizen of the United States and a~~)) resident of this state.

(3)(a) Registered nurse members of the commission must:

(i) Be licensed as registered nurses under this chapter; and

(ii) Have had at least three years' experience in the active practice of nursing and have been engaged in that practice within two years of appointment.

(b) In addition:

(i) At least one member must be on the faculty at a four-year university nursing program;

(ii) At least one member must be on the faculty at a two-year community college nursing program;

(iii) At least two members must be staff nurses providing direct patient care; and

(iv) At least one member must be a nurse manager or a nurse executive.

(4) Advanced registered nurse practitioner members of the commission must:

(a) Be licensed as advanced registered nurse practitioners under this chapter; and

(b) Have had at least three years' experience in the active practice of advanced registered nursing and have been engaged in that practice within two years of appointment.

(5) Licensed practical nurse members of the commission must:

(a) Be licensed as licensed practical nurses under this chapter; and

(b) Have had at least three years' actual experience as a licensed practical nurse and have been engaged in practice as a practical nurse within two years of appointment.

(6) Public members of the commission may not be a member of any other health care licensing board or commission, or have a fiduciary obligation to a facility rendering health services regulated by the commission, or have a material or financial interest in the rendering of health services regulated by the commission.

In appointing the initial members of the commission, it is the intent of the legislature that, to the extent possible, the governor appoint the existing members of the board of nursing and the board of practical nursing repealed under chapter 9, Laws of 1994 sp. sess. The governor may appoint initial members of the commission to staggered terms of from one to four years. Thereafter, all members shall be appointed to full four-year terms. Members of the commission hold office until their successors are appointed.

When the secretary appoints pro tem members, reasonable efforts shall be made to ensure that at least one pro tem member is a registered nurse who is currently practicing and, in addition to meeting other minimum qualifications, has graduated from an associate or baccalaureate nursing program within three years of appointment.

Sec. 33. RCW 18.71.015 and 2019 c 55 s 4 are each amended to read as follows:

The Washington medical commission is established, consisting of thirteen individuals licensed to practice medicine in the state of Washington under this chapter, two individuals who are licensed in the state of Washington as physician assistants under chapter 18.71A RCW, and six individuals who are members of the public. At least two of the public members shall not be from the health care industry. Each congressional district now existing or hereafter created in the state must be represented by at least one physician member of the commission. The terms of office of members of the commission are not affected by changes in congressional district boundaries. Public members of the commission may not be a member of any other health care licensing board or commission, or have a fiduciary obligation to a facility rendering health services regulated by the commission, or have a material or financial interest in the rendering of health services regulated by the commission.

The members of the commission shall be appointed by the governor((~~. Members of the initial commission may be appointed to staggered terms of one to four years~~)), and ((~~thereafter~~)) all terms of appointment shall be for four years. The governor shall consider such physician and physician assistant members who are recommended for appointment by the appropriate professional associations in the state. ((~~In appointing the initial members of the commission, it is the intent of the legislature that, to the extent possible, the existing members of the board of medical examiners and medical disciplinary board repealed under section 336, chapter 9, Laws of 1994 sp. sess. be appointed to the commission.~~)) No member may serve more than two consecutive full terms. Each member shall hold office until a successor is appointed.

Each member of the commission must be ((~~a citizen of the United States, must be~~)) an actual resident of this state, and, if a physician or physician assistant, must have been licensed to practice medicine in this state for at least five years.

The commission shall meet as soon as practicable after appointment and elect officers each year. Meetings shall be held at least four times a year and at such place as the commission determines and at such other times and places as the commission deems necessary. A majority of the commission members appointed and serving constitutes a quorum for the transaction of commission business.

The affirmative vote of a majority of a quorum of the commission is required to carry any motion or resolution, to adopt any rule, or to pass any measure. The commission may appoint panels consisting of at least three members. A quorum for the transaction of any business by a panel is a minimum of three members. A majority vote of a quorum of the panel is required to transact business delegated to it by the commission.

Each member of the commission shall be compensated in accordance with RCW 43.03.265 and in addition thereto shall be reimbursed for travel expenses incurred in carrying out the duties of the commission in accordance with RCW 43.03.050 and 43.03.060. Any such expenses shall be paid from funds appropriated to the department of health.

Whenever the governor is satisfied that a member of a commission has been guilty of neglect of duty, misconduct, or malfeasance or misfeasance in office, the governor shall file with the secretary of state a statement of the causes for and the order of removal from office, and the secretary shall forthwith send a certified copy of the statement of causes and order of removal to the last known post office address of the member.

Vacancies in the membership of the commission shall be filled for the unexpired term by appointment by the governor.

The members of the commission are immune from suit in an action, civil or criminal, based on its disciplinary proceedings or other official acts performed in good faith as members of the commission.

Whenever the workload of the commission requires, the commission may request that the secretary appoint pro tempore members of the commission. When serving, pro tempore members of the commission have all of the powers, duties, and immunities, and are entitled to all of the emoluments, including travel expenses, of regularly appointed members of the commission.

NEW SECTION. **Sec. 34.** Section 27 of this act expires July 1, 2022.

NEW SECTION. **Sec. 35.** Section 28 of this act takes effect July 1, 2022.

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Commission SBAR Communication

Agenda Item/Title: Uniform Facility Enforcement Workgroup Recommendations

Date SBAR Communication Prepared: August 25, 2021

Reviewer: Trina Crawford, Interim Executive Director

Link to Action Plan:

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

Situation: (Briefly describe the current situation. Give a clear, succinct overview of pertinent issues)

HB 2426 (chapter 115, Laws of 2020) directed the Department of Health (department) to make recommendations for a uniform health care facility enforcement act in collaboration with stakeholders and the Washington State Legislature. As such, the department assembled a workgroup in the summer of 2020. Staff have participated in this workgroup and developed recommendations relevant to pharmaceutical firms with guidance from the Pharmacy Quality Assurance Commission's (commission) Facility Subcommittee.

The commission can now review these preliminary recommendations and provide the department with feedback on the proposal as it relates to pharmaceutical firms to incorporate into its report to the legislature.

Background: (Briefly state the pertinent history):

In 2020, HB 2426 passed requiring the department to conduct a review of the statutes for health care facilities licensed by the department, and to identify opportunities to consolidate and standardize licensing and enforcement requirements. The bill also directed the department to work with stakeholders and the Washington State Legislature to create a uniform health care facility enforcement act. HB 2426 also established new enforcement tools for psychiatric hospitals.

During the 2021 session, the legislature chose to pass a second bill establishing new enforcement tools for acute care hospitals, HB 1148. This bill was closely modeled on the psychiatric hospital bill and has now provided the department with two bills to consider as a framework when establishing enforcement recommendations for other facility types. Using that framework, the department's workgroup determined which facility laws have limited options for taking action, short of revocation or suspension of a license, and are proposing recommendations for adding options that would allow more flexibility in working with facilities to resolve compliance issues.

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

Through participation in the workgroup and some guidance from the Facility Subcommittee, staff have identified the following for the commission to consider. The department is seeking feedback from the commission on these preliminary recommendations, which will be incorporated into the department's report to the legislature. The commission will have future opportunities to weigh in on work related to the uniform facilities enforcement act.

Current state: The current enforcement options for pharmaceutical firms are:

Pharmaceutical firms: Refuse, Suspend, and Revoke the license. The commission can also issue a summary restriction to limit certain "services" in a pharmacy or facility under the commission's jurisdiction. These services may include limiting intake of controlled substance prescriptions, compounding, or vaccination services to name a few.

Nonresident pharmacies: Refuse, Suspend, and Revoke. Summary suspension is available for pharmaceutical firms with deficiencies that represent an imminent or immediate risk or threat to public health, safety, or welfare. The commission may impose a fine not to exceed $1,000 per violation for conduct that causes serious bodily or psychological injury to a resident of this state if the secretary has referred the matter to the regulatory or licensing agency in the state in which the pharmacy is located and that regulatory or licensing agency fails to initiate an investigation within forty-five days of the referral under this subsection or fails to make a determination on the referral.

Challenges: With current enforcement options, the commission faces several challenges in relation to the discipline of pharmaceutical firms. The commission may deny an applicant, revoke, or suspend an existing credential. There are many instances where the conduct is not severe enough to warrant suspension or revocation and these sanctions may have an impact on access to pharmaceutical services and patient care. While suspension or revocation may be necessary in some cases, they aren't necessary in most cases. The commission needs a wider array of options to maintain patient safety and correct deficiencies or violations, while not negatively impacting patient access to care. For example, a pharmacy may not be following the proper regulations when compounding. Rather than suspend the licensee, the commission may prefer progressive enforcement steps such as fining authority, the ability to place the entity's credential on probation, requiring training for all staff, or requiring audits to ensure compliance. The use of this enforcement tool would be highly specific to the facts of the case (e.g., infection control, compounding, or other compliance issues).

Recommendations: Due to the challenges identified above, the recommendations related to pharmaceutical firms in the uniform facility enforcement are to include

progressive enforcement steps, such as fining authority, the ability to place conditions on a license, and ability to issue statements of deficiency.

- Some conditions on a license may include: the ability to place the entity's credential on probation, requiring training for all staff, or requiring audits to ensure compliance.
- Fining limits
  - Upper fine limit of a specified dollar amount per violation (Note: North Carolina also has a comparable fine of ***up to*** $10,000.00)
  - Recommend this upper limit to further align with other facility types in WA state.
- Use of Severity Matrix if granted fining authority (see example Severity Matrix)
  - PQAC prefers to keep the statute broad with a fining authority of up to a specified dollar amount per violation. We also plan to explore additional options in policy and/or rule to determine the level of severity per violation.
  - PQAC could use the nursing severity grid or the behavioral health matrix as a reference point (CR-101 phase).
- Facility fines would be based on specific factors and assessed on a case-by-case basis
- PQAC also encourages consideration for PQAC to adopt a SOD/POC process for discipline cases similar to Behavioral Health.

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

The commission can consider the above recommendations and provide feedback for the department to incorporate into its report to the legislature. Commission staff will relay any feedback provided to the department. The commission will have future opportunities to weigh in on work related to the uniform facilities enforcement act.

Commission SBAR Communication

Agenda Item/Title: FDA Memorandum of Understanding Update

Date SBAR Communication Prepared: May 27, 2021; **Update: August 26, 2021**

Reviewer: Lauren Lyles-Stolz, PharmD, Executive Director

Link to Action Plan:

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

Situation: (Briefly describe the current situation. Give a clear, succinct overview of pertinent issues)

The commission should decide whether to approve, reject, or continue to evaluate next steps regarding the FDA's Memorandum of Understanding (MOU). The commission has until October 27, 2021 before the FDA limits interstate distribution of compounded human drug products to 5 percent of the total prescription orders dispensed or distributed by a pharmacy. If the FDA MOU is signed then this limit is not applicable.

Commission staff distributed a survey to compounding pharmacies in Washington State to assess the perceived impact.

Update: The FDA has extended the deadline to sign the MOU until October 27, **2022**.

Background: (Briefly state the pertinent history):

While the commission has several rules in place to ensure the safety of compounded drug products (see WAC 246-945-100, WAC 246-945-410, WAC 246-945-490, and RCW 18.64.270), compounded drug products are not approved by the FDA for quality and safety. As such, the FDA issues an MOU as an agreement which states may enter regarding the distribution of inordinate amounts of compounded human drug products and the investigation of complaints related to human compounded drug products. As described in the Federal Food, Drug, and Cosmetic Act, the FDA works with the National Association of Boards of Pharmacy (NABP) in developing the MOU. The MOU does not apply to "veterinary drug products, biological products subject to licensure under section 351 of the Public Health Service Act (42 U.S.C. 262), and drugs that are compounded by outsourcing facilities under section 503B of the FD&C Act" (MOU, Sec. I).

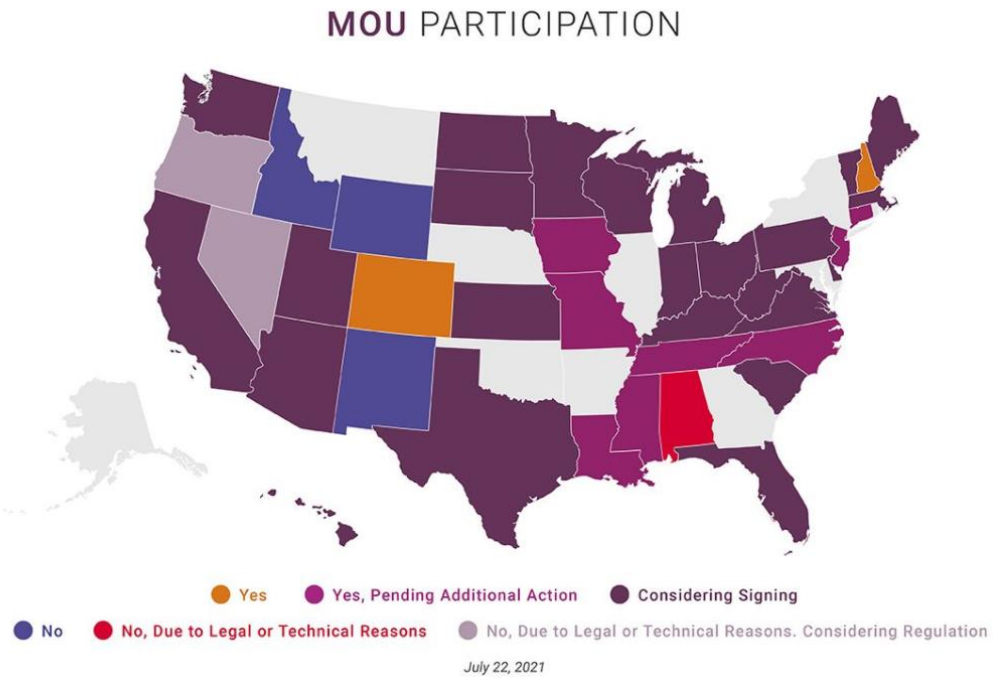
The FDA defines "inordinate amounts" if "the number of prescription orders for compounded human drug products that the pharmacy distributed interstate during any calendar year is greater than 50 percent of the sum of: (i) the number of prescription orders for compounded human drug products that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year; plus (ii) the number of prescription orders for compounded human

drug products that were dispensed (e.g., picked up by a patient) at the facility in which they were compounded during that same calendar year" (MOU, Appendix A).

Further, the FDA clarifies that "interstate distribution" means that a pharmacy or physician has sent (or caused to be sent) a compounded drug product out of the State in which the drug was compounded" (MOU, Appendix A).

In a more recent letter from NABP as well as discussed during this year's annual conference, NABP is also requesting that FDA delay enforcement of Section 503A(b)(3)(B)(ii) of the Federal Food, Drug, and Cosmetic Act. According to NABP, they anticipate that an enforcement delay will give many states the time needed to take the necessary actions to sign the MOU. Additionally, they noted that some boards also cited issues beyond those related to COVID-19. Several states have indicated that regulatory changes, which involve lengthy processes and require extensive public comment periods, are needed. Others have indicated that statutory amendments are necessary, and these legislatures are placing a great deal of focus on COVID-19-related legislation. In addition, states where legislatures only meet biennially (e.g., Montana, Nevada, North Dakota, Texas) may not have appropriate changes in place until 2022 or even 2023.

While NABP is waiting on a response from the FDA, they continue to work on developing the Information Sharing Network in order to onboard states that have decided to sign the MOU. They also have a map available on their website where you can view the status of other states' current thinking of signing the FDA MOU. Currently **(updated August 26, 2021)**, 10 states have stated they are signing or signed the FDA MOU while 23 are still considering signing (including WA). Six states have stated they are not signing the FDA MOU (some for legal or technical reasons) and there is currently no data available for the other states.



There are several considerations for the commission to consider regarding the MOU. Rejecting to adopt the MOU would limit interstate distribution of compounded drug products to 5 percent of the total prescription orders dispensed or distributed by a compounding pharmacy (MOU, Sec. II.b.2). Limiting distribution may come with operational costs and barriers to pharmacies for the commission to consider.

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

Commission staff distributed a survey (see SBAR Appendix 1) to compounding pharmacies in Washington to assess the perceived impact of not signing the FDA MOU. Out of the 116 respondents who completed the survey in total, 75 reported that they were affiliated with 503A compounding facilities that also distribute compounded drug products outside of Washington State. The below table shows the results based on those 75 respondents. Based on the FDA MOU Survey results, 98.3% of compounding pharmacies (59 out of 60 respondents) that distribute 5% or more human compounded drug products reported that not signing the FDA MOU would have a negative impact on patient care and their pharmacy practice. Respondents also provided comments for the commission to consider elaborating on their responses (see SBAR Appendix 2, Appendix 3). Notably, 100% of respondents who reported distributing more than 50% human compounded drug products stated not signing would have a negative impact. Only 33.3% of those who reported distributing less than 5% felt that not signing the FDA MOU would result in a negative impact.

Table: Perceived Impact of Not Signing FDA MOU on Compounding Pharmacies in WA

Percent Compounded Product Dist. Outside WA	Number Who Responded "Yes" to Negative Impact	Total in Subgroups	Percentage in Subgroups Who Responded "Yes" to Negative Impact
<5% Distributed	5	15	33.3%
5-50% Distributed	48	49	98%
>50% Distributed	11	11	100%
Grand Total	***64***	***75***	***85.3%***

Note: Table only includes those who are affiliated with a 503A compounding facility that distribute product outside of WA State

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

After discussing the MOU, the commission may choose to adopt the following options in part or in whole. It is recommended that the commission come to a decision within 365 days of the MOU's publication.

OPTION 1: Approve the MOU.

OPTION 2: Reject the MOU. This determination would limit interstate distribution of compounded drug products to 5 percent of the total prescription orders dispensed or distributed by a pharmacy.

OPTION 3: The commission can direct PQAC staff to write to the FDA requesting delayed enforcement of Section 503A(b)(3)(B)(ii) of the Federal Food, Drug, and Cosmetic Act until more states are able to establish a pragmatic path forward (e.g., rulemaking, guidance, etc.) to uphold the FDA MOU.

Update: The letter to the FDA was sent on August 11, 2021 requesting a two-year extension to sign the MOU.

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.).

Depending on the options identified above, the PQAC team will proceed as directed and communicate to licensees through GovDelivery.