1.2. Meeting Minutes Approval - October 19, 2023



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 October 19, 2023 – Minutes

Convene: Chair, Ken Kenyon called the meeting to order on October 19, 2023, 9:05 AM.

Commission Members:

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

Absent:

Matthew Ray, PharmD

Staff:

Marlee O'Neill, Executive Director Lindsay Trant-Sinclair, Deputy Director Shawna Fox, Director, Office of Health Professions Harold Wright, Jr., Deputy Director, Office of **Health Professions** Christopher Gerard, Assistant Attorney General Kseniya Efremova, Policy Analyst Joshua Munroe, Legislative and Rules Consultant Taifa "Nomi" Peaks, Pharmacist Consultant Haleigh Mauldin, Program Consultant Si Bui, Pharmacy Inspector Supervisor Julia Katz, Program Consultant Keith Bond, Operations Manager Irina Tiginyanu, Pharmacy Technician Consultant Amy L Robertson, Communications Coordinator and Program Support

Guests:

Bob Nicoloff, Executive Director of the Chiropractic Quality Assurance Commission.

Kyle Karinen, Executive Director of the Washington Medical Commission

Allison Bradywood, Executive Director of the Washington State Board of Nursing

Karl Hoehn, Assistant Director of Legal Services for the Washington State Board of Nursing

1. Call to Order Ken Kenyon, Chair

1.1 Meeting Agenda Approval – October 19, 2023

MOTION: Hawkins DeFrance moved to amend the agenda: add Section 9.3, CR105 Expedited Rulemaking on Incorporations by Reference and OTC Drug Products; Craig Ritchie, second; Motion carries, 11:0:1. Abstain: Bonnie Bush.

MOTION: Craig Ritchie moved to approve the October 19, 2023, meeting agenda. Uyen Thorstensen, second. Motion carries, 12:0.

1.2 Meeting Minutes Approval – August 24, 2023

MOTION: Craig Ritchie moved to approve the August 24, 2023, meeting minutes. William Hayes, second. Motion carries, 12:0.

1.3 Meeting Minutes Approval – August 25, 2023

MOTION: Craig Ritchie moved to approve the August 25, 2023, meeting minutes as amended by William Hayes. Teri Ferreira, second. Motion carries, 12:0.

2. Consent Agenda

2.1 Correspondence

- 2.1.1 National Precursor Log Exchange Monthly Dashboard August-September 2023
- 2.1.2 Pharmaceutical Firms Application Report

2.2 Ancillary Utilization Plans Approval

- 2.2.1 Moses Lake Pharmacy
- 2.2.2 New Health Programs Association Pharmacy
- 2.2.3 North Olympic Healthcare Network
- 2.2.4 Quynhs Pharmacy
- 2.2.5 Sea Mar
- 2.2.6 Sound Prescriptions dba Custom Prescriptions
- 2.2.7 Tukwila Station Pharmacy
- 2.2.8 Wellfound
- 2.2.9 Bellegrove Pharmacy
- 2.2.10 The Vancouver Clinic

2.3 Pharmacy Technician Training Program Approval

- 2.3.1 Howard's Drug
- 2.3.2 Tick Clock Drug
- 2.3.3 Vashon Pharmacy
- 2.3.4 Vet Ex Animal Supply

MOTION: Craig Ritchie moved to approve 2.1.1, 2.1.2, 2.2.1, 2.2.2, 2.2.5, 2.2.7, 2.2.10, and 2.3.1. Teri Ferreira, second. Motion carries, 12:0.

2.4 Regular Agenda Items Pulled from 2.1, 2.2, or 2.3. The commission will discuss items removed from the consent agenda and placed on the regular agenda for separate discussion.

2.2.3 North Olympic Healthcare Network

MOTION: Teri Ferreira moved to approve contingent on updating the language for vaccine or other medication and device administration per the commission's guidance document. Craig Ritchie, second. Motion carries, 12:0.

2.2.4 Quynhs Pharmacy

MOTION: William Hayes moved to approve contingent staff confirming with licensee to ensure all typographical and grammatical errors are corrected. Craig Ritchie, second. Motion carries, 12:0.

2.2.6 Sound Prescriptions dba Custom Prescriptions

MOTION: Teri Ferreira moved to approve 2.2.6. Craig Ritchie, second. Motion carries, 11:0. (Hawkins DeFrance, recused).

2.2.8 Wellfound

MOTION: Teri Ferreira moved to approve 2.2.8. Craig Ritchie, second. Motion carries, 11:0. (Timothy Lynch, recused).

2.2.9 Bellegrove Pharmacy

MOTION: Timothy Lynch moved to take no action on 2.2.9 pending staff analysis of the AUP submission and a formal agenda item at a future commission meeting for the commission to dedicate the requisite time to discuss technician final product verification. Craig Ritchie, second. Motion carries, 12:0.

2.3.2 Tick Clock Drug

MOTION: Ann Wolken moved to approve the TTP contingent upon staff ensuring the following edits get made: (1) add language to reflect that the TTP will notify the commission in writing or via email prior to any significant changes to the program, including change in the director, course content, and time frames; (2) remove the statement that the pharmacy is a Class A pharmacy; and (3) add language to ensure compounding is done in compliance with USP 795 and 797. Craig Ritchie, second. Motion carries, 12:0.

2.3.3 Vashon Pharmacy

MOTION: Ann Wolken moved to approve contingent upon staff ensuring the following edits get made: (1) add language to reflect that the TTP will notify the commission in writing or via email prior to any significant changes to the program; (2) add language that all student-specific records must either be retained on-site and kept for a minimum of 2 years, as well as be made

available within 72 hours upon request; and (3) add language to ensure compounding is done in compliance with USP 795 and 797. Craig Ritchie, second. Motion carries, 12:0.

3. Rulemaking for the Remote OUD Dispensing Sites

3.1 Public Hearing – WAC 246-945-457. The hearing opened at 9:32 AM.

Joshua Munroe provided an overview of the rules package on SSB6086 – RCW 18.64.600 requiring the commission to adopt rules establishing minimum standards of remote OUD dispensing sites.

Joshua reported that no public comments directly pertaining to the project topic were received during the public comment period. A public comment email was received prior to the hearing, but the commission determined that the subject of inquiry and the requested changes focused on sections of rule (chapter 246-341 WAC) that were neither mentioned in the rulemaking package nor were under the commission's regulatory jurisdiction.

The public rules hearing was opened for public testimony at 9:32 AM. The Commission requested to receive oral testimony from the public, but no oral testimony from the public was received. The public rules hearing was closed at 9:35 AM.

3.2 Approval of Comment Responses and Authorization to file CR-103P (SSB 6086 Rulemaking).

The only suggested change during the commission's discussion of the rules package was to change the term "using this registration" to "holding this registration" in the rule language to more accurately reflect how licensees seeking to extend their licenses to manage a remote OUD dispensing site would interact with the registration.

MOTION: Craig Ritchie moved to approve the draft responses to comments received, ", moved to adopt the rule language including the change to the term "using this registration" to "holding this registration" in the rule language to more accurately reflect how licensees seeking to extend their licenses to manage a remote OUD dispensing site would interact with the registration, and moved to authorize staff to file the CR103p. Patrick Gallaher, second. Motion carries, 12:0.

4. Rulemaking for Health Equity CE Standards

4.1 Public Hearing – CR-102 rules proposal amending WACs 246-945-178 and 246-945-220. Hearing opened at 10:31

Joshua Munroe provided a brief overview on the rules package focused on establishing health equity continuing education standards for pharmacists and pharmacy technicians. Joshua reported that no written comments were received during the public comment period.

The public rules hearing was opened for public testimony at 10:31 AM. The Commission requested to receive oral testimony from the public, but no oral testimony from the public was received. The public rules hearing was closed at 10:34 AM.

4.2 Approval of Comment Responses and Authorization to file CR 103P (Health Equity CE Rulemaking

MOTION: Craig Ritchie moved to adopt the rule language to WACs 246-945-178 and 246-945-220 and authorize staff to file the CR103p. Bonnie Bush, second. Motion carries, 12:0.

5. Old Business.

5.1 Title 21 CFR 1306.08: Transfer of Controlled Substance Prescriptions

MOTION: Craig Ritchie moved to approve the FAQ without edits and to publish it on the commission website. Bonnie Bush, second. 12:0.

5.2 FDA Proposed Rule: Patient Medication Information

MOTION: Craig Ritchie moved to approve the letter with staff updating the commission's phone number. Hawkins DeFrance, second. 12:0

MOTION: Craig Ritchie moved to add the additional language to the approved letter noting that the proposed regulation imposes an unworkable mandate and does not adequately facilitate the availability of PMI to those that are visually impaired, print disabled, or limited English proficiency. Hawkins DeFrance, second. 12:0.

5.3 Policy Statement on Compliance with Revised USP General Chapters <795> and <797>

MOTION: Craig Ritchie moved to approve the policy statement. Teri Ferreira, second. 12:0

6. Informational Session

6.1 Presentation from the Executive Directors for the Chiropractic Commission, Medical Commission, and Board of Nursing for the purpose of future PQAC strategic planning.

Marlee O'Neill introduced guests:

- Bob Nicoloff, Executive Director of the Chiropractic Quality Assurance Commission.
- Kyle Karinen, Executive Director of the Washington Medical Commission
- Allison Bradywood, Executive Director of the Washington State Board of Nursing
- Karl Hoehn, Assistant Director of Legal Services for the Washington State Board of Nursing.

The guests presented information on how their respective boards and commissions operates as partner boards and commissions within the Department of Health.

7. Panel Review.

MOTION: Teri Ferreira moved to delegate the study plan reviews to Panel C (William Hayes, Jerrie Allard, Uyen Thorstensen, Ken Kenyon, and Ann Wolken). Patrick Gallaher, second. Motion carries, 12:0.

7.1 PHRM.PH. 61348645

MOTION: Uyen Thorstensen moved to approve the study plan review Ken Kenyon, second. Motion carries, 5:0.

8. New Business

8.1 RCW 18.130.077 (2SHB 1724, Section 8) and Substantial Equivalency

MOTION: Hawkins DeFrance moved to follow the current procedures for pharmacy assistants and pharmacy interns, respectively, for out-of-state applicants. Craig Ritchie, second. Motion carries, 12:0.

MOTION: Patrick Gallaher moved that the eight hours of guided study are a core licensing requirement, which results in no other state being substantially equivalent for out-of-state pharmacy technician applicants. Uyen Thorstensen, second. Motion carries, 12-0.

MOTION: Craig Ritchie moved that there may be other states that have substantially equivalent standards to Washington, but the Commission is unable to "waive" the Washington MPJE requirement as required by RCW 18.130.077 because of the mandate in RCW 18.64.080(5), and directed staff to proceed with the license transfer application process when applicable for out-of-state pharmacist applicants. Jerrie Allard, second. Motion carries, 12:0.

9. Rules and Legislative Updates.

9.1 CR-103P Authorization: Title 21 CFR Incorporation by Reference (WAC 246-945-040)

MOTION: Craig Ritchie moved to approve the filing of the CR-103p rules adoption for the incorporation by reference of sections Title 21 CFR sections into WAC 246-945-040. Uyen Thorstensen, second. 12:0

9.2 OTC Naloxone Emergency Rule Refile Request

MOTION: Jerrie Allard moved to approve the refiling of the emergency rule language with the updated language. Craig Ritchie, second. 12:0

MOTION: Craig Ritchie moved to also find that there is an opioid public health crisis in the state of Washington and the lifesaving OTC naloxone products proposed in the rule will save lives and aid in addressing this public health emergency. As a result, the Commission findings that refiling the emergency rule is necessary for the preservation of the public health, safety, and 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. William, second. 12:0.

9.3 CR-105: Expedited Rulemaking on Incorporations by Reference and OTC Drug Products

MOTION: Bonnie Bush moved to approve the new language in the CR-105. Craig Ritchie, second. 12:0

10. Open Forum.

Dr. Julie Akers, Washington State University College of Pharmacy and Pharmaceutical Sciences
Dr. Akers asked the commission to consider amending WAC 246-945-155(3) to allow pharmacy
interns to renew their credentials more than twice.

MOTION: Teri Ferreira moved to add Dr. Akers' request to a future agenda. Craig Ritchie, second. 12:0

• **Dr. Gail Elliot, Kaiser Family Foundation of Washington** – Dr. Elliot asked the commission to consider providing clarification on RCW 18.64.450(4).

Marlee O'Neill informed the commission and Dr. Elliot this topic is already in our queue and tentatively on the December business meeting.

11. Commission Member Reports

11.1 Budget

Patrick Gallaher informed the commission that overall the fund balance is healthy. Recent legislation, among other things, is impacting accounting staff but they are making progress on updating items affected. There is a discrepancy between estimated revenue and actual revenue for September 2023. We were able to see that license counts remain steady. This is due to the move to the 2-year renewal cycle that began in December 2021. We anticipate seeing more renewal revenue starting in December 2023. WE noticed a decrease in HCE licenses which may be due to closures or the consolidation of HCEs.

11.2 Open Discussion

- Patrick Gallaher requested staff provide clarification on WAC 246-945-310 and the designated responsible person in USP.
- Jerrie Allard requested the following items be on the December agenda.
 - Debrief of the partner board and commission panel discussion.
 - Update on accessible labeling and significant analysis and small business impact statement

12. Staff Reports

12.1 Executive Director

- Attended the NABP executive officer, compliance officer, and legal counsel forum with Si Bui. There were sessions on artificial intelligence, the DSCSA, and other emerging topics.
- Lindsay, Si, and Marlee will present at the WSPA annual meeting on November 4.
- Marlee will present at the SWPA meeting later in November.

12.2 Deputy Director

- Staffing
 - Joanne Miller's last day was August 31
 - o New Staff: Julia Katz, Program Support
 - O OILS Ashley Maxwell no longer with DOH
 - o Rayne Pearson will take over as deputy director for OILS.
 - Rayne and Judie Mortonwill attend the December business meeting to update the commission on OILS.
- Commissioner Candidates Staff submitted a public packet to the Governor.
- SSB1009 Military Spouse mandatory training NLT December 31. Staff send reminders to commissioners.

12.3 Pharmacist Inspector Supervisor

- New inspector Justin Sisney started on October 1.
- Attended the NABP executive officer, compliance officer, and legal counsel forum in Chicago with Marlee

12.4 Assistant Attorney General

13. Summary of Meeting Action Items.

- 1.3 Meeting Minutes Approval 8/25: Make proposed edit to minutes before posting on the commission's website.
- Consent Agenda
 - Convey the decisions on AUPs and TTPs to the applicants and the Office of Customer
 - Staff will provide an analysis related to the AUP submitted today on technician final product verification and add it as a future agenda item for further discussion.
- 3.2 Approval of Comment Responses and Authorization to file CR-103P: File CR-103P with minor edit to rule language on "holding the registration" rather than "using this registration".
- 4.2 Approval of Comment Responses and Authorization to file CR-103P: File CR-103P on health equity continuing education.
- 5.1 Title 21 CFR 1306.08 Transfer of CS Prescriptions: Replace the commission's FAQ on transfer of controlled substances on its website to the one presented today related to 21 CFR 1306.08
- 5.2 FDA Proposed Rule: Patient Medication Information: Make two minor edits as well as add
 the additional statement revisited today to the letter to the FDA on patient medication
 information discussed today and begin department review process. Will submit to the FDA by
 November 27
- 5.3 Policy Statement on Compliance with Revised USP General Chapters 795 and 797: Post policy statement on Compliance with Revised USP General Chapters 795 and 797 after Department review
- 7.1 PHRM.PH.61345645: Communicate approval to credentialing
- 8.1 Carry out the commission's determinations related to RCW 18.130.077
- 9.1 File CR-103P on the incorporation by reference of Title 21 CFR in WAC 246-945-040.

- 9.2 Refile emergency rule language on designation of OTC naloxone with updated rule language.
- 9.3 File CR-105 on incorporations by reference and designation of OTC drug products with updated language
- Staff will send out instructions on how to complete the military spouse training.

Business Meeting Adjourned, 3:50 PM.

1.3. Special Meeting Minutes



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 Special Meeting November 13, 2023 – Minutes

Convene: Chair, Ken Kenyon called the meeting to order on November 13, 2023, 12:05 p.m.

Commission Members:

Ken Kenyon, PharmD, BCPS, Chair
Hawkins DeFrance, Nuclear Pharmacist, Vice Chair
Bonnie Bush, Public Member
Teri Ferreira, RPh
Judy Guenther, Public Member
William Hayes, PharmD CCHP
Timothy Lynch, PharmD, MS, FABC, FASHP
Craig Ritchie, RPh, JD
Uyen Thorstensen, CPhT
Ann Wolken, PharmD, RPh

Absent:

Jerrie Allard, Public Member Patrick Gallaher, BS, BPharm, MBA, MPH Matthew Ray, PharmD

Staff:

Marlee O'Neill, Executive Director Christopher Gerard, AAG Joshua Munroe, Legislative and Rules Consultant Taifa "Nomi" Peaks, Pharmacist Consultant Julia Katz, Program Consultant Keith Bond, Operations Manager Amy L Robertson, Communications Coordinator and Program Support

Absent:

Lindsay Trant-Sinclair, Deputy Director Kseniya Efremova, Policy Analyst Haleigh Mauldin, Program Consultant Si Bui, Pharmacy Inspector Supervisor Irina Tiginyanu, Pharmacy Technician Consultant

1. Call to Order Ken Kenyon, Chair

1.1 Meeting Agenda Approval – November 13, 2023

MOTION: Craig Ritchie moved to approve the November 13, 2023, meeting agenda. Hawkins DeFrance, second. Motion carries, 10:0.

2. Naturopathic Physician Sunrise Review

Julia Katz, Program Support, provided information about the sunrise review process and the specific sunrise review before the commission.

Commissioners reviewed the sunrise review and accompanying documents, heard feedback from interested parties, and discussed options. At the conclusion, no motion was made, and no further action taken.

Special Meeting Adjourned. Ken Kenyon, Chair, called the meeting adjourned at 1:05 p.m.

2.1.1. National Precursor Log Exchange Monthly Dashboard - October 2023

MONTHLY PROGRAM ADMINISTRATOR'S DASHBOARD

0 Logins - 0 Searches - 0 Report Queries - 21 Active Watches - 0 Active Watch Hits							
NEW USERS THIS MONTH							
New Users = 0	TOP USAGE AGENCIES	TOP AGENCIES BY ACTIVE WATCHES					
Total Accounts = 144	TOP USERS BY USAGE	1. ICE - King County (32)					
Active Users = 0							

TRANSACTION SUMMARY STATISTICS (2023)

	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	ОСТ	TOTAL
PURCHAS ES	71,650	69,842	81,463	75,970	78,412	79,249	64,423	60,350	71,428	70,893	723,680
BLOCKS	3,237	3,382	3,985	3,657	4,049	4,169	3,161	2,720	3,003	3,960	35,323
GRAMS SOLD	149,57	145,51 9	177,06 4	166,66 4	180,07	181,01	147,21	134,30	150,88	147,98	1,580,2 90
BOXES SOLD	81,434	79,115	91,959	86,273	88,279	89,812	73,523	68,692	79,937	79,777	818,801
GRAMS BLOCKED	8,604	8,664	10,706	9,791	11,005	11,827	8,815	7,283	7,872	10,941	95,508
BOXES BLOCKED	3,774	3,863	4,516	4,164	4,507	4,775	3,744	3,122	3,557	4,420	40,442
AVG GRAMS PER BOX BLOCKED	2.28	2.24	2.37	2.35	2.44	2.48	2.35	2.33	2.21	2.48	2.35

PHARMACY PARTICIPATION STATISTICS (Oct 2023)

Enabled Pharmacies	987

Pharmacies Submitting a Transaction	907
Pharmacies Logging in Without a Transaction	0
Inactive Pharmacies	80
Pharmacy Participation for Oct	91.89%

DISCLAIMER: This is an automated report meant to give you a quick snapshot of the NPLEx system in your state. The statistics listed in this report are only meant to be a general overview and not necessarily the exact final numbers. Prior to releasing any statistics mentioned in this report, we highly recommend that you verify the numbers with your NPLEx customer relationship manager. For questions or issues, please contact krista.mccormick@equifax.com.

MONTHLY PROGRAM ADMINISTRATOR'S DASHBOARD

O Logins - 0 Searches - 0 Report Queries - 21 Active Watches - 0 Active Watch HitsNEW USERS THIS MONTH
New Users = 0TOP USAGE AGENCIES
TOP AGENCIES BY ACTIVE WATCHES
1. ICE - King County (32)

TRANSACTION SUMMARY STATISTICS (2023)												
	JAN	JAN FEB MAR APR MAY JUN JUL AUG SEP OCT NOV TOTAL									TOTAL	
PURCHA SES	71,65 0	69,84	81,46	75,97 0	78,41 2	79,24 9	64,42	60,35	71,42 8	70,89	70,04	793,72 3
BLOCKS	3,237	3,382	3,985	3,657	4,049	4,169	3,161	2,720	3,003	3,960	3,090	38,413
GRAMS SOLD	149,5 71	145,5 19	177,0 64	166,6 64	180,0 78	181,0 15	147,2 13	134,3 01	150,8 84	147,9 81	145,2 74	1,725,5 64
BOXES SOLD	81,43 4	79,11 5	91,95 9	86,27	88,27 9	89,81	73,52 3	68,69 2	79,93 7	79,77 7	77,72 5	896,52 6
GRAMS BLOCKED	8,604	8,664	10,70 6	9,791	11,00 5	11,82 7	8,815	7,283	7,872	10,94	8,163	103,67 1
BOXES BLOCKED	3,774	3,863	4,516	4,164	4,507	4,775	3,744	3,122	3,557	4,420	3,446	43,888
AVG GRAMS PER BOX BLOCKED	2.28	2.24	2.37	2.35	2.44	2.48	2.35	2.33	2.21	2.48	2.37	2.36

PHARMACY PARTICIPATION STATISTICS (N	lov 2023)
Enabled Pharmacies	985
Pharmacies Submitting a Transaction	899
Pharmacies Logging in Without a Transaction	0
Inactive Pharmacies	86
Pharmacy Participation for Nov	91.27%

DISCLAIMER: This is an automated report meant to give you a quick snapshot of the NPLEx system in your state. The statistics listed in this report are only meant to be a general overview and not necessarily the exact final numbers. Prior to releasing any statistics mentioned in this report, we highly recommend that you verify the numbers with your NPLEx customer relationship manager. For questions or issues, please contact krista.mccormick@equifax.com.

2.1.2. Pharmaceutical Firms Application Report

Credential #	Status	First Issuance
Orecellual #	Status	Date
PHAR.CF.61476562	ACTIVE	10/03/2023
PHHC.FX.61484037	ACTIVE	10/03/2023
PHHC.FX.61483648	ACTIVE	10/11/2023
PHNR.FO.61494155	ACTIVE	10/11/2023
PHNR.FO.61494938	ACTIVE	10/11/2023
PHWH.FX.61494595	ACTIVE	10/11/2023
PHWH.FX.61247930	ACTIVE	10/11/2023
PHWH.FX.61472917	ACTIVE	10/11/2023
DRCS.FX.61481688	ACTIVE	10/12/2023
DRSD.FX.61491902	ACTIVE	10/12/2023
PHHC.FX.61492835	ACTIVE	10/12/2023
PHWH.FX.61496716	ACTIVE	10/12/2023
PHNR.FO.61480482	ACTIVE	10/16/2023
PHWH.FX.61425372	ACTIVE	10/17/2023
PHNR.FO.61491485	ACTIVE	10/19/2023
PHWH.FX.61296327	ACTIVE	10/19/2023
PHWH.FX.61491916	ACTIVE	10/19/2023
PHNR.FO.61494584	ACTIVE	10/24/2023
PHNR.FO.61412780	ACTIVE	10/24/2023
PHNR.FO.61460038	ACTIVE	10/24/2023
PHNR.FO.61486445	ACTIVE	10/24/2023
PHWH.FX.61494648	ACTIVE	10/24/2023
PHWH.FX.61475069	ACTIVE	10/24/2023
DRSD.FX.61488135	ACTIVE	10/26/2023
PHHC.FX.61482527	ACTIVE	10/26/2023
PHWH.FX.61060810	ACTIVE	10/26/2023
PHWH.FX.61480169	ACTIVE	10/26/2023
PHWH.FX.61496707	ACTIVE	10/26/2023
PHWH.FX.61455226	ACTIVE	10/26/2023
PHWH.FX.61464500	ACTIVE	10/26/2023
PHWH.FX.61501796	ACTIVE	11/01/2023
PHWH.FX.61491518	ACTIVE	11/01/2023
PHHC.FX.61480410	ACTIVE	11/03/2023
PHWH.FX.61356225	ACTIVE	11/03/2023
PHWH.FX.61499254	ACTIVE	11/03/2023
PHWH.FX.61480206	ACTIVE	11/06/2023
PHHC.FX.61464991	ACTIVE	11/09/2023
PHAR.CF.61499243	ACTIVE	11/13/2023
PHAR.CF.61478096	ACTIVE	11/13/2023
PHWH.FX.61393253	ACTIVE	11/13/2023
PHWH.FX.61447825	ACTIVE	11/13/2023
PHWH.FX.61232089	ACTIVE	11/13/2023
PHWH.FX.61450475	ACTIVE	11/13/2023

DRSD.FX.61460168	ACTIVE	11/15/2023
PHNR.FO.61500276	ACTIVE	11/15/2023
PHWH.FX.61458861	ACTIVE	11/15/2023
PHWH.FX.61405432	ACTIVE	11/15/2023
PHWH.FX.61500342	ACTIVE	11/15/2023
PHNR.FO.61493059	ACTIVE	11/16/2023
PHNR.FO.61486605	ACTIVE	11/16/2023
PHWH.FX.61428052	ACTIVE	11/16/2023
PHWH.FX.61488371	ACTIVE	11/16/2023
PHAR.CF.61472907	ACTIVE	11/17/2023
PHAR.CF.61470238	ACTIVE	11/17/2023
PHHC.FX.61485247	ACTIVE	11/17/2023
PHWH.FX.61492799	ACTIVE	11/17/2023
DRSD.FX.61430634	ACTIVE	11/27/2023
DRSD.FX.61486690	ACTIVE	11/27/2023
PHAR.CF.61444418	ACTIVE	11/27/2023
PHAR.CF.61499247	ACTIVE	11/27/2023
PHNR.FO.61491513	ACTIVE	11/27/2023
PHNR.FO.61466478	ACTIVE	11/27/2023
PHNR.FO.61489922	ACTIVE	11/27/2023
PHWH.FX.61470382	ACTIVE	11/27/2023
PHWH.FX.61431305	ACTIVE	11/27/2023
PHWH.FX.61508452	ACTIVE	11/27/2023
PHWH.FX.61465672	ACTIVE	11/27/2023
DRSD.FX.61471081	ACTIVE	11/28/2023
PHNR.FO.61453258	ACTIVE	11/28/2023
PHWH.FX.61387285	ACTIVE	11/28/2023
PHWH.FX.61496710	ACTIVE	11/28/2023
PHWH.FX.61471084	ACTIVE	11/28/2023
PHWH.FX.61478743	ACTIVE	11/28/2023
PHNR.FO.61510335	ACTIVE	11/30/2023
PHNR.FO.61143594	ACTIVE	11/30/2023
PHWH.FX.61510278	ACTIVE	11/30/2023
PHWH.FX.61466368	ACTIVE	11/30/2023
PHWH.FX.61469549	ACTIVE	11/30/2023
PHWH.FX.61145636	ACTIVE	11/30/2023
PHWH.FX.61431017	ACTIVE	11/30/2023
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Credential #	Status	Expiration
PHWH.FX.61239051	CLOSED	Date 10/02/2023
PHWH.FX.61019724	CLOSED	10/11/2023
PHWH.FX.60525571	CLOSED	10/11/2023
PHWH.FX.00005150	CLOSED	10/11/2023
PHWH.FX.00057884	CLOSED	10/11/2023
DRSD.FX.00059293	CLOSED	10/12/2023
PHHC.FX.60603650	CLOSED	10/13/2023
PHNR.FO.60932487	CLOSED	10/16/2023
PHAR.CF.60999002	CLOSED	10/17/2023
PHNR.FO.61431216	CLOSED	10/17/2023
PHNR.FO.61431228	CLOSED	10/17/2023
TRNG.TG.61113151-PTEC-O	CLOSED	10/17/2023
DRWL.FF.60628625	CLOSED	10/18/2023
PHWH.FX.00058351	CLOSED	10/18/2023
PHNR.FO.61442489	CLOSED	10/19/2023
PHWH.FX.60007927	CLOSED	10/19/2023
PHNR.FO.60132770	CLOSED	10/20/2023
PHNR.FO.61106572	CLOSED	10/20/2023
PHAR.CF.60180649	CLOSED	10/22/2023
PHNR.FO.61362509	CLOSED	10/24/2023
PHWH.FX.60909560	CLOSED	10/26/2023
PHNR.FO.61393445	CLOSED	10/30/2023
PHWH.FX.61243609	CLOSED	10/30/2023
DRSD.FX.60433075	CLOSED	11/01/2023
PHWH.FX.60540400	CLOSED	11/01/2023
PHWH.FX.61243900	CLOSED	11/01/2023
PHWH.FX.61048708	CLOSED	11/01/2023
PHWH.FX.60543093	CLOSED	11/01/2023
PHWH.FX.60632739	CLOSED	11/01/2023
PHWH.FX.60433076	CLOSED	11/01/2023
PHHC.FX.61173274	CLOSED	11/03/2023
PHWH.FX.61422391	CLOSED	11/06/2023
PHAR.CF.00004319	CLOSED	11/07/2023
PHAR.CF.00000865	CLOSED	11/07/2023
PHAR.CF.00055921	CLOSED	11/07/2023
TRNG.TG.60628254-PTEC-O	CLOSED	11/07/2023
TRNG.TG.60427200-PTEC-O	CLOSED	11/07/2023
PHNR.FO.61428565	CLOSED	11/08/2023
PHAR.CF.60157235	CLOSED	11/09/2023
TRNG.TG.60426997-PTEC-O	CLOSED	11/09/2023
PHAR.CF.61019875	CLOSED	11/13/2023
PHWH.FX.60930078	CLOSED	11/13/2023
PHWH.FX.60916966	CLOSED	11/13/2023
TRNG.TG.61159191-PTEC-O	CLOSED	11/13/2023
PHWH.FX.60981951	CLOSED	11/14/2022

PHAR.CF.60536009	CLOSED	11/14/2023
TRNG.TG.60944488-PTEC-O	CLOSED	11/14/2023
PHNR.FO.60308347	CLOSED	11/15/2023
PHAR.CF.00004844	CLOSED	11/16/2023
PHWH.FX.60888393	CLOSED	11/16/2023
TRNG.TG.60440126-PTEC-O	CLOSED	11/16/2023
PHNR.FO.61132165	CLOSED	11/17/2023
PHAR.CF.00003803	CLOSED	11/19/2023
TRNG.TG.60440090-PTEC-O	CLOSED	11/19/2023
DRSD.FX.61218762	CLOSED	11/27/2023
PHNR.FO.61389494	CLOSED	11/27/2023
PHNR.FO.61213018	CLOSED	11/27/2023
PHAR.CF.00000055	CLOSED	11/28/2023
PHWH.FX.61267114	CLOSED	11/28/2023
TRNG.TG.60440056-PTEC-O	CLOSED	11/28/2023
PHNR.FO.60978072	CLOSED	11/30/2023
PHWH.FX.61031867	CLOSED	11/30/2023

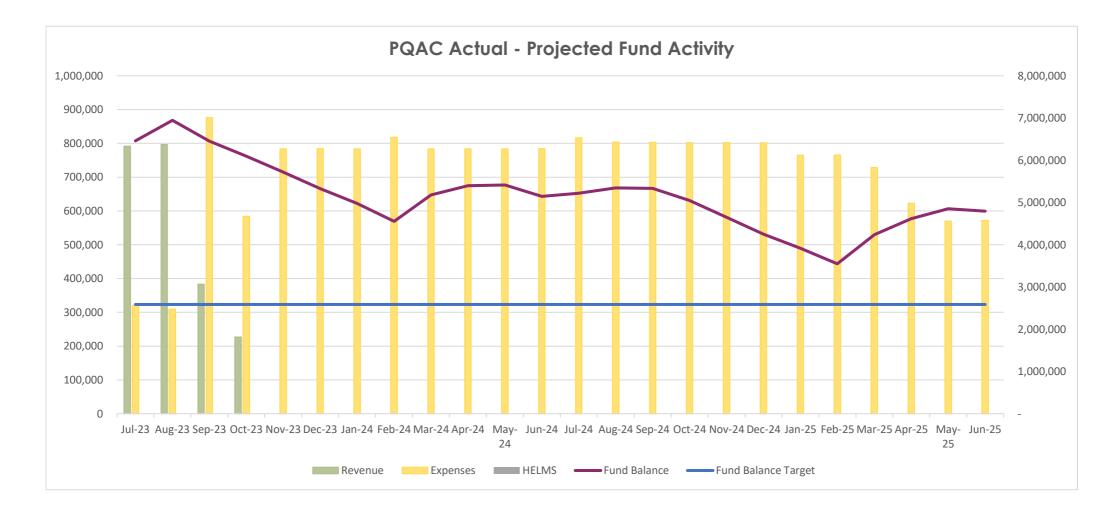
Pharmacy Quality Assurance Commission 2023-25 Budget and Fund Balance Overview

For the period July 1, 2023 through October 31, 2023

Health Professions Account Beginning Fund Balance on July 1, 2023	5,988,767
Revenue To Date	2,198,942
23-25 HELMS Assessment To Date	-
Expenses To Date	2,760,371
Health Professions Account Fund Balance as of October 31, 2023	5,427,338

REVENUE	Est. Revenue	Actual Revenue	Variance	Variance %
To Date	1,816,132	2,198,942	382,810	121.1%
Biennium Total	16,979,058			12.95%

EXPENSES	Biennial Budget	Budget To Date	Expenses To Date	Variance To Date	Variance % To Date
Staff Salaries and Benefits	7,172,992	1,239,244	1,132,087	107,157	8.6%
Commission Pay	97,800	16,300	35,830	(19,530)	-119.8%
Professional Service Contracts	-	-	2,900	(2,900)	-100.0%
Attorney General Support	545,064	90,844	71,618	19,226	21.2%
Goods and Services	62,736	10,456	3,187	7,269	69.5%
Travel	87,816	14,636	14,441	195	1.3%
IT Equipment	20,936	10,468	10,056	412	3.9%
WA Recovery Asst. (WRAPP)	171,024	28,504	13,112	15,392	54.0%
Intra-Agency Charges - Discipline	1,670,330	315,258	232,891	82,367	26.1%
Intra-Agency Charges - Credentialing	3,194,376	584,543	487,304	97,239	16.6%
Intra-Agency Charges - Other	953,933	133,276	88,333	44,943	33.7%
TOTAL DIRECT COSTS	13,977,007	2,443,529	2,091,757	351,772	14.4%
Agency Indirect Costs	2,335,605	408,538	351,025	57,513	14.1%
Division Indirect Costs	1,560,076	272,898	317,589	(44,691)	-16.4%
TOTAL INDIRECT COSTS	3,895,682	681,436	668,614	12,822	1.9%
TOTAL ALL COSTS	17,872,689	3,124,965	2,760,371	364,594	11.7%



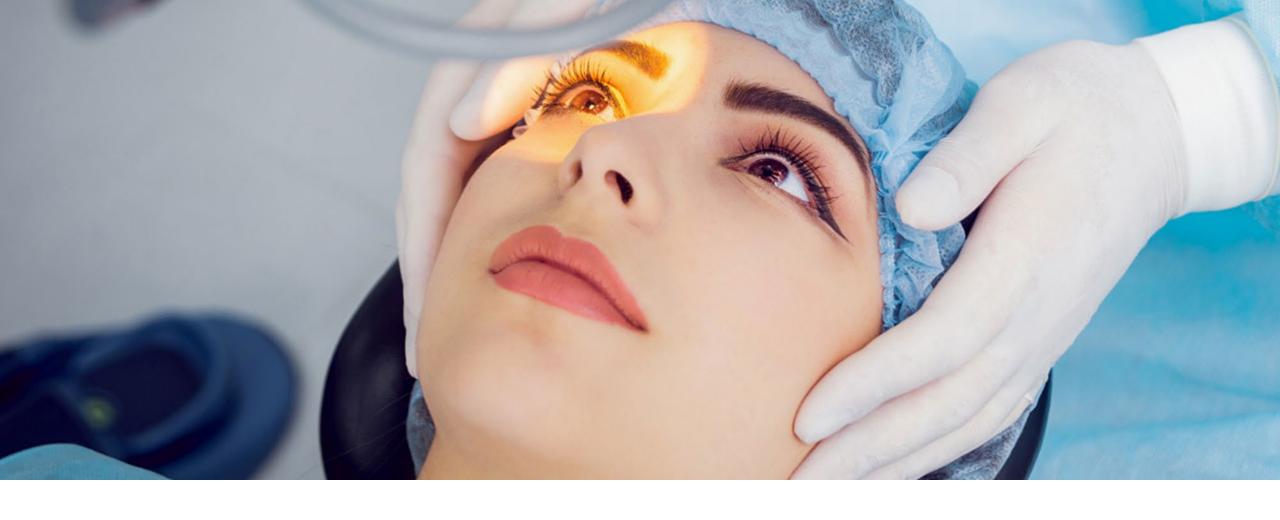




SB 5389 PROPOSED PHARMACOPOEIA CHANGES Board of Optometry

Planned changes to WAC 246-851-580 for consultation and approval between the Board of Optometry and the Pharmacy Commission.

EXPANDING OPTOMETRY'S PHARMACOPOEIA FOR IMPLEMENTATION OF SB5389.



ANESTHETIC AGENTS

Injectable

- Anesthetics agents, with or without epinephrine and with or without buffer will need to be added to optometry's pharmacopoeia under WAC 246.851.580 Section 3.
- This section now only contains epinephrine. So we could put all new injectable compounds as subsections starting with a.
- Example
 - Lidocaine 2% with epinephrine 1:100,000 and sodium bicarbonate 2 ml by subcutaneous infiltrative injection for removal of benign lid lesion.
 - Partial list of alternate medications bupivacaine, marcaine, prilocaine, mepivacaine, tetracaine, procaine.







ANTIBIOTIC AGENTS

Injectable

- Antibiotic agents will need to be added to optometry's pharmacopoeia under WAC 246.851.580 Section 3.
- This section now only contains epinephrine. So we could put all new injectable compounds as subsections starting with a.
- Example
 - Ceftriaxone sodium reconstitute 500mg vial with 1ml sterile saline. Inject 100mg in 0.2ml subconjunctivally for treatment of bacterial keratitis in patient with severe arthitis making topical treatment impossible. Follow-up in 24 hours.
 - Partial list of alternate medications ceftazidine sodium and amikacin sulfate (gram negative)



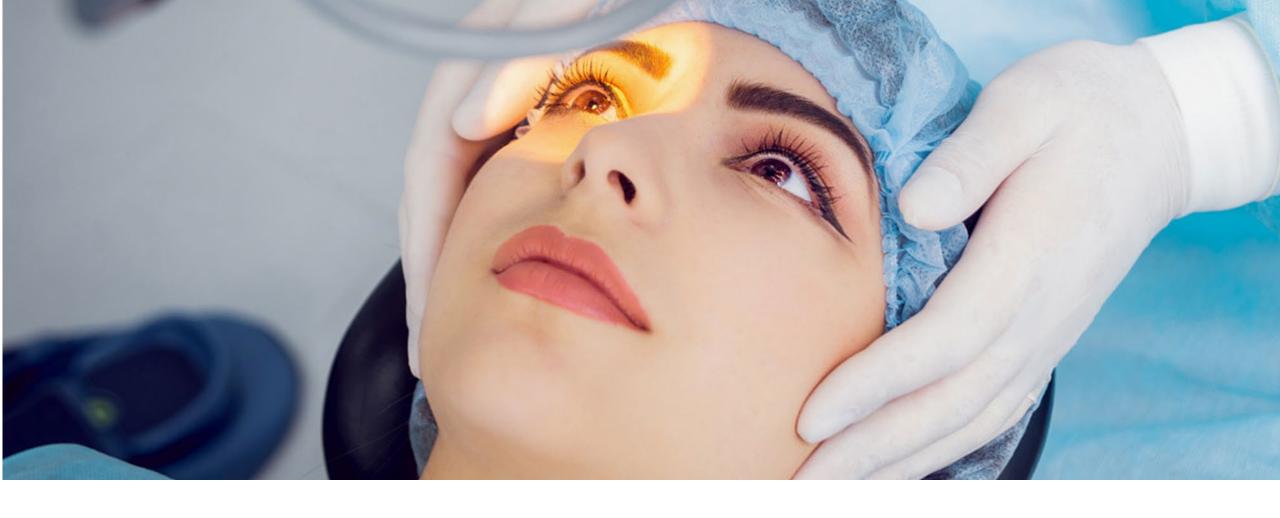
Antifungal Agents



Injectable

- Antifungal agents will need to be added to optometry's pharmacopoeia under WAC 246.851.580 Section 3.
- This section now only contains epinephrine. So we could put all new injectable compounds as subsections starting with a.
- Example
 - Voriconazole 0.5 mcg/0.1 ml sterile water by intrastromal depot injection at site of fungal plaque, for non-responsive filimentary keretitis.
 - Partial list of alternate medications amphotericin B.





Antiparasitic Agents

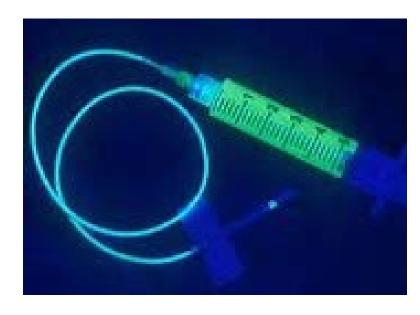
Oral

- Antiparasitic agents will need to be added to the current pharmacopoeia WAC 246.851.580 Section 1. (new subsection)
- Example
 - Ivermectin 200 mcg/kg, one dose per week for two weeks for the treatment of demodex blepharitis.
 - Partial list of alternate medications pyrimethamine, sulfadia, atovaquone, spiramycin.





Diagnostic Dye Agents



Oral

- Diagnostic dye agents will need to be added to the current pharmacopoeia WAC 246.851.580 Section 1. (new subsection)
- Example
 - Fluorescein angiography by oral administration of dye can be used in the pediatric setting. Dose is determined by weight, 7.5mg/kg. The dye is placed in icy lemon drink and is ingested through a straw, to reduce staining of the teeth. Fundus fluorescein imaging is then performed and testing can be completed in approximately 30 minutes.



Injectables

- Diagnostic dye agents will need to be added to optometry's pharmacopoeia under WAC 246.851.580 Section 3.
- This section now only contains epinephrine. So we could put all new injectable compounds as subsections starting with a.
- Example
 - Fluorescence sodium 500mg is administered by IV injection for an adult patient, immediately followed by Fundus fluorescein imaging.
 - Partial list of alternate medications indocyanine green.





Corticosteroid



Oral

- Corticosteroids will need to be added to the current pharmacopoeia WAC 246.851.580 Section 1. (new subsection)
- The current prohibition on oral steroids will need to be removed WAC 246.851.590 Section 11.a
- Example
 - Methylprednisone 4mg dose pack for treatment of poison ivy contact dermatitis of eye lids. Follow dosing instructions on package.
 - Partial list of alternate medications cortisone, prednisone, prednisolone, dexamethasone, betamethasone.



Injectable

- Corticosteroids will need to be added to the current pharmacopoeia WAC 246.851.580 Section 3. (new subsection)
- This section now only contains epinephrine. So we could put all new injectable compounds as subsections starting with a.
- Example
 - Intralesional injection of 0.3 ml of triamcinolone acetonide 40mg/ml for treatment of chalazion.
 - Subcutaneous injection of 0.25 ml of triamcinolone acetonide 10mg/ml for treatment of inflamed sebaceous cyst of the /ocular adnexia.
 - Partial list of alternate medications cortisone, prednisone, prednisolone, dexamethasone, betamethasone.









List of Approved Procedures

Sample list of approved procedures RCW 18.53.010 as updated by SB 5389.

This sample list of approved procedures was developed by the Board of Optometry to aide in the update of the pharmacopoeia. This list is not intended to be an all-inclusive list of allowed procedures.

List of general approved procedures:

Section 1.g.

Ordering necessarily diagnostic lab or imaging tests including, but not limited to, finger-stick testing and collecting samples for culturing.

- Allows for blood workups
- Bacterial, viral, fungal and parasitic cultures
- Radiology testing, CT and MRI
- Fluorescein angiography
- Genetic testing
- Etc.

Section 1.i.

Removal of nonpenetrating foreign body, debridement of tissue, epilation of misaligned eyelashes, placement of punctal or lacrimal plugs, including devices containing pharmaceutical agents implanted in the lacrimal system, dilation and irrigation of the lacrimal system, nonlaser light therapy, and placement of biologic membranes.FB removal (specific tissue not specified, i.e. cornea, conjunctiva, lid)

- Debridement of tissue (i.e. corneal epithelial debridement, conj debridement)
 - Removal of rust rings
 - o Removal of epithelium in abrasions
 - o Removal of band keratopathy
 - Corneal crosslinking
- Epilation
- Placement of punctal/lacrimal plugs including devices containing pharmaceutical agents
- Dilation/irrigation of lacrimal system
- IPL (intense pulsed light therapy) and LLLT (low level light therapy)
- Placement of biologic/amniotic membranes

List of approved advanced procedures

Section 2.a

The practice of optometry may include the following advanced procedures.

Section 2.a.i.

Common complication of the lids, lashes, and lacrimal systems;

- Removal of lid cysts, abscesses, papillomas, skin tags, seborrheic keratosis, molluscum, xanthelasma, nevi (by shave excision, cryotherapy, RF, electrodissection)
- Trichiasis correction by electrolysis, radiofrequency, cryotherapy
- Punctal occlusion cautery by radio frequency, thermal or electrolysis
- See Section 2.a.vii

Section 2.a.ii.

Chalazion management, including injection and excision;

- Incision and curettage of chalazion by blade or radio frequency
- Injection of chalazion with steroid/medication.

Section 2.a.iii.

Injection, including intramuscular injections of epinephrine and subconjunctival and subcutaneous injections of medications;

• Including epinephine, anesthetics and buffers, anti-infectives and anti-inflammatories.

Section 2.a.iv

Management lid lesions, including intralesional injection of medications

- Management of chalazion
- Removal of conjunctival cysts/concretions

Section 2.a.vi

Use of topical and injectable anesthetics; and

• Specific authorization for anesthetics.

Section 2.a.vii

Eyelid surgery, excluding and cosmentic surgery or surgery requiring the use of general anesthesia.

- Removal of lid cysts, abscesses, papillomas, skin tags, seborrheic keratosis, molluscum, xanthelasma, nevi (by shave excision, cryotherapy, RF, electrodissection)
- Trichiasis correction by electrolysis, radiofrequency, cryotherapy

- Punctal occlusion cautery by radio frequency, thermal or electrolysis
- See Section 2.a.i

Other specifically authorized procedures

- Section 3.a Locking in adjustable lens implants.
- Section 3.g Paracentesis of anterior chamber to reduce eye pressure in emergency.
- Section 11 In a public health emergency, the state health officer may authorize licensed optometrists to administer inoculations for systemic health reasons.

Updates needed to the optometry pharmacopoeia.

Oral and injectable agents.

- To be determined by the Board of Optometry in consultation with the Pharmacy Commission.
- Additions required by the update in RCW 18.53.010 caused by SB 5389. See WAC 246-51-580.
 - Anesthetics
 - Anesthetics, Oral. Already authorized as benzodiazepines no change needed.
 - Anesthetics, injectable. To be added
 - Anti-infectives
 - Antibiotics, Oral. Already authorized no change needed
 - Antibiotics, injectable. To be added.
 - Antifungals, oral. Already authorized no change needed.

- Antifungals, injectable. To be added.
- Antiparasitics, oral. To be added.
- Antiparasitics, injectable. None found applicable to eye care.
- Antivirals, oral. Already authorized no change needed.
- Antiviral, injectable. None found applicable to eye care.

Anti-inflammatories

- Corticosteroids oral. To be added.
- Corticosteroids injectable. To be added.
- Non-steroidal anti-inflammatories, oral. Already authorized no change needed.
- Non-steroidal anti-inflammatories, injectable. None found applicable to eye care.
- Diagnostic dyes.
 - Diagnostic dyes, oral. None found applicable to eye care.
 - Diagnostic dyes, injectable. To be added.

Anti-inflammatories

- Corticosteroids oral. To be added.
- Corticosteroids injectable. To be added.
- Non-steroidal anti-inflammatories, oral. Already authorized no change needed.
- Non-steroidal anti-inflammatories, injectable. None found applicable to eye care.

Proposed WAC Updates

WAC 246-851-580

WAC 246-851-590

WAC 246-851-580

Drug list.

Pursuant to RCW 18.53.010(4)(2)(7), the optometry board adopts the following drug formulary of oral Schedule II hydrocodone combination products, Schedule III through V controlled substances, and legend drugs, and injectable drugs for diagnostic and therapeutic purposes in the practice of optometry. No licensed optometrist may use, prescribe, dispense, purchase, possess, or administer these drugs except as authorized and to the extent permitted by the board. This section includes the approved oral and injectable drug formulary. Optometrists must consult WAC 246-851-590 for specific guidelines on these drugs or drug categories.

- (1) Approved nonscheduled oral drugs include:
- (a) Antibiotic agents excluding those listed in WAC 246-851-590(1).
- (b) Antiviral agents.
- (c) Antifungal agents listed under WAC 246-851-590(2).
- (d) Antihistamine agents.
- (e) Decongestant agents.
- (f) Dry eye agents.
- (g) Anti-emetic agents listed under WAC 246-851-590(3).
- (h) Diuretic agents listed under WAC 246-851-590(4).
- (i) Nonsteroidal anti-inflammatory agents excluding those listed in WAC 246-851-590(5).
- (j) Analgesics and adjuvant analgesics agents.
- (k) Corticosteroid agents.
- (l) Antiparasitic agents.
- (m) Diagnostic dye agents.

Note: a-m should be alphabetized and relabeled

- (2) Approved controlled substances limited to Schedule II hydrocodone combination products and Schedules III, IV, and V.
- (a) Schedule II hydrocodone combination products.
- (b) Schedule III controlled substances.
- (c) Schedule IV controlled substances.

- (d) Schedule IV anti-anxiety/sedative agents.
- (e) Schedule V controlled substances.
- (3) Approved injectable substances.

Administration of epinephrine by injection for the treatment of anaphylactic shock.

- (a) Anesthetic agents, with or without epinephrine, with or without buffer.
- (b) Antibiotic agents excluding those listed in WAC 246-851-590(1).
- (c) Antifungal agents listed under WAC 246-851-590(2).
- (d) Diagnostic dye agents.
- (d) Epinephrine by injection for the treatment of anaphylactic shock.
- (e) Corticosteroid agents.

[Statutory Authority: RCW 18.54.070(2) and 18.53.010(4). WSR 19-04-071, § 246-851-580, filed 2/1/19, effective 3/4/19. Statutory Authority: RCW 18.54.070(2) and 18.53.010. WSR 16-16-017, § 246-851-580, filed 7/21/16, effective 8/21/16. Statutory Authority: 2003 c 142 and RCW 18.54.070(2). WSR 04-12-127, § 246-851-580, filed 6/2/04, effective 7/3/04.]

WAC 246-851-590

Guidelines for the use of oral Schedule II hydrocodone combination products and Schedule III through V controlled substances and legend drugs.

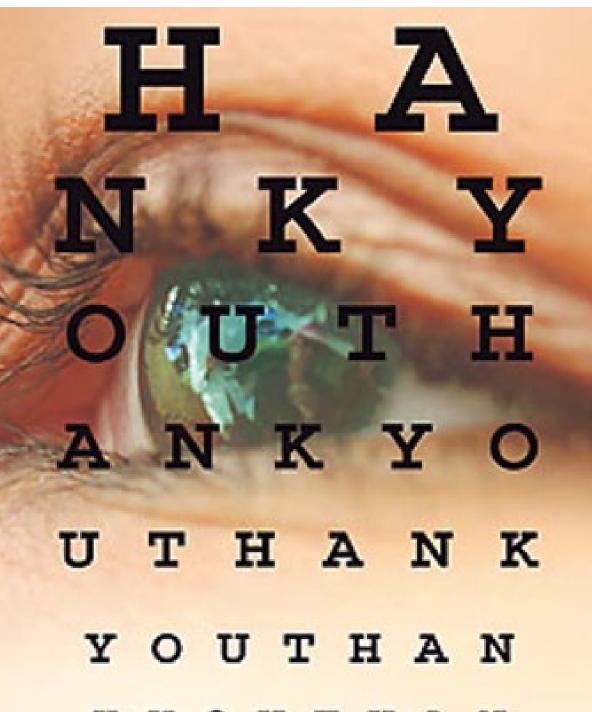
Nothing in these guidelines should be construed to restrict the recommendation of over-the-counter medications, vitamins, or supplements, nor restrict the ordering of any radiologic or laboratory testing necessary to the diagnosis of any eye related disease that is within the scope of practice of optometry.

- (1) All oral forms and dosages of antibiotic agents will be available for use excluding: Vancomycin.
- (2) Antifungal agents used in eye care shall fall into the following categories:
- (a) All oral forms and dosages of polyene antifungals.
- (b) All oral forms and dosages of imidazole antifungals.
- (c) All oral forms and dosages of triazole antifungals.
- (3) Anti-emetic agents used in eye care shall be the following medications:
- (a) All oral forms and dosages of prochlorperazine.
- (b) All oral forms and dosages of metoclopramide.
- (c) All oral forms and dosages of promethazine.
- (4) Diuretic agents used in eye care shall fall into the following categories:
- (a) All oral forms and dosages of carbonic anhydrase inhibitors.
- (b) All oral forms and dosages of osmotic diuretics. Osmotic diuretics shall be used only in the case of acute angle closure glaucoma administered in-office, outpatient, and/or ambulatory procedures only.
- (5) All oral forms and dosages of nonsteroidal anti-inflammatory agents will be available for use excluding: Ketorolac tromethamine.
- (6) Benzodiazepines prescribed, as anti-anxiety agents, shall be used for in-office, outpatient, and/or ambulatory procedures. This family of medications will be utilized as one dosage unit per prescription.
- (7) Schedule II controlled substance will only include hydrocodone combination products.
- (8) Schedules III and IV controlled substances will have a maximum quantity count of thirty dosage units per prescription.
- (9) Specific dosage for use and appropriate duration of treatment of oral medications listed in WAC 246-851-580(1) will be consistent with Food and Drug Administration on- and off-label indications.

- (10) Notation of purpose shall be included on all prescriptions.
- (11) An optometrist may not:
- (a) Use, prescribe, dispense, or administer oral corticosteroids; or
- (b)(a) Prescribe, dispense, or administer a controlled substance for more than seven days in treating a particular patient for a single trauma, episode, or condition or for pain associated with or related to the trauma, episode, or condition; or
- (c)(b) Prescribe an oral drug within ninety days following ophthalmic surgery unless the optometrist consults with the treating ophthalmologist. If treatment exceeding the limitation is indicated, the patient must be referred to a physician licensed under chapter 18.71 RCW.
- (12) To prescribe oral coricosteroids for more than seven days, an optometrist must consult with a licensed physician.
- (12)(13) The prescription or administration of drugs as authorized in this section is specifically limited to those drugs appropriate to treatment of diseases or conditions of the human eye and the adnexa that are within the scope of practice of optometry. The prescription or administration of drugs for any other purpose is not authorized.

 (13)(14) Nothing in this chapter may be construed to authorize the use, prescription, dispensing, purchase, possession, or administration of any Schedule I or II controlled substance with the exception of Schedule II hydrocodone combination products.

[Statutory Authority: RCW 18.54.070(2) and 18.53.010(4). WSR 19-04-071, § 246-851-590, filed 2/1/19, effective 3/4/19. Statutory Authority: RCW 18.54.070(2) and 18.53.010. WSR 16-16-017, § 246-851-590, filed 7/21/16, effective 8/21/16. Statutory Authority: 2003 c 142 and RCW 18.54.070(2). WSR 04-12-127, § 246-851-590, filed 6/2/04, effective 7/3/04.]





Department of Health Pharmacy Quality Assurance Commission Directive

Title:	Nonresident Pharmacy: List of Approved Inspection Programs
Reference:	RCW 18.64.360
Contact:	Marlee B. O'Neill, JD, Executive Director
Effective Date:	May 4, 2023
Supersedes:	Nonresident Pharmacy: Approved List of Recognized States
Approved:	Teri Ferreira, RPh, Pharmacy Quality Assurance Commission Chair

RCW 18.64.360(1)(b) requires a nonresident pharmacy, upon initial licensure and at renewal, to submit a copy of an inspection report that is conducted by an inspection program approved by the Pharmacy Quality Assurance Commission (Commission) as having substantially equivalent standards to those of the Commission, and that was issued within the last two years. This directive identifies those inspection programs the Commission has approved as having substantially equivalent standards to those of the Commission.

The Commission considered multiple factors when choosing whether to approve an inspection program. This includes using the National Association of Boards of Pharmacy (NABP) Multistate Pharmacy Inspection Blueprint Program criteria. The Commission also considered whether the inspection program required nonresident pharmacies who engage in compounding to comply with the minimum standards of the official United States Pharmacopeia (USP).

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Approved Inspection Programs

The Commission has approved the inspection programs of the following state boards of pharmacy (or equivalent state regulatory agency) and two third-party inspection programs as having substantially equivalent standards to those of the Commission:

Alabama	Montana
California	NABP's Verified Pharmacy Program
Connecticut	Nevada
Gates Healthcare Associates	New Hampshire
Georgia	New Jersey
Illinois	North Carolina
lowa	North Dakota
Kentucky	Ohio
Louisiana	Oregon
Maryland	Pennsylvania
Massachusetts	Rhode Island
Michigan	Utah
Minnesota	Virginia

<u>Approved Inspection Programs That Do Not Meet Commission Frequency Standards</u>

The Commission has approved the inspection programs of the following state boards of pharmacy (or equivalent state regulatory agency) as having substantially equivalent standards to those of the Commission. The Commission also understands these inspection programs do not conduct inspections every two years. Nonresident pharmacies are reminded that inspection reports submitted as part of an application or as part of the renewal process must have occurred within the last two years. So while inspection reports conducted by the following state boards of pharmacy (or equivalent state regulatory agency) are acceptable, they must have occurred within the last two years or another inspection report from an approved inspection program will need to be submitted:

Delaware	Nebraska
Maine	New York

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<u>Approved Inspection Programs for Nonresident Pharmacies Who Attest They Do Not Engage in</u> <u>Compounding</u>

The Commission has approved the inspection programs of the following state boards of pharmacy (or equivalent state regulatory agency) as having substantially equivalent standards to those of the Commission <u>but only for</u> nonresident pharmacies who attest that they do not engage in compounding as defined in RCW 18.64.011(6). This is because the following inspection programs do not require nonresident pharmacies to comply with the minimum standards of USP when engaging in compounding.

Arizona	Oklahoma
Arkansas	Pennsylvania
Colorado	South Carolina
Florida	South Dakota
Idaho	Tennessee
Indiana	Texas
Kansas	Vermont
Mississippi	West Virginia
Missouri	Wisconsin
New Mexico	Wyoming

Inspection Programs That Have Not Been Approved by the Commission

The Commission has determined that inspections from the following state board of pharmacy (or equivalent state regulatory agency) are not substantially equivalent to those of the Commission and will not be accepted:

Alaska

The Commission is aware the Hawaii Board of Pharmacy does not conduct inspections. Nonresident pharmacies located in Hawaii are still required to comply with RCW 18.64.360(1)(b) and must provide an inspection report from an approved inspection program as outlined in this Directive.

The Commission will review this Directive on an annual basis.

Need more information? See <u>frequently asked questions</u>.

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Commission SBAR Communication

Agenda Item/Title: Intern Registration Renewal Limits Date SBAR Communication Prepared: November 16, 2023					
Reviewer:	Julia Katz				
Link to Action	Plan:				
★ Action	Information		Report only		
			Quality Assurance Commission cist intern registration renewal limits.		
2020 and repla rules did not sp	Background: The commission's new rules chapter, chapter 246-945 WAC, went into effect on July 1, 2020 and replaced all former requirements, including those of pharmacy intern registrations. The old rules did not specify a time limit for pharmacy intern registrations to be active. The current rule states, 'A pharmacy intern registration can only be renewed twice."				
The old rules made no mention of limits to pharmacy intern registration. This led to occasional instances of applicants retaining their intern licenses for far longer than the commission intended to allow. WAC 246-858-020(2) (now repealed) stated that the intern must continue making satisfactory progress in completing the pharmacy course in order to retain the registration which matches what the legislature set forth in RCW 18.64.080(3).					
WAC 246-858-020 General requirements. (1) RCW 18.64.080(3) states: "Any person enrolled as a student of pharmacy in an accredited college may file with the department an application for registration as a pharmacy intern—." A student of pharmacy shall be defined as any person enrolled in a college or school of pharmacy accredited by the board of pharmacy or any graduate of any accredited college or school of pharmacy					
	retain a certificate as a pharmess in completing the pharmac		nust make continuing satisfactory		

The new rule states that pharmacy intern licenses may be renewed twice following issuance. Issued licenses are valid for two years. Each applicant may therefore hold an active pharmacy intern license for a total of six years. The following states renewal limits for Washington pharmacist intern registrants under current regulation:

WAC <u>246-945-155</u>

Pharmacy interns—Registration requirements.

(1) Unless otherwise stated, each individual shall register with the commission, as a pharmacy intern before beginning pharmacy practice experiences in Washington state. The commission shall grant a registration to practice pharmacy as a pharmacy intern to an individual who is:



Commission SBAR Communication

- (a) Currently enrolled in a professional degree program of a commission accredited school or college of pharmacy and making satisfactory progress towards meeting the requirements for licensure as a pharmacist;
- (b) A graduate of a commission accredited school or college of pharmacy;
- (c) A graduate of a school or college of pharmacy located outside the United States who has established educational equivalency by obtaining certification by FPGEC;
- (d) Required by the commission to be an intern because the commission has determined the individual needs to complete additional practical experience before a pharmacist license is issued or reissued; or
- (e) An out-of-state pharmacist enrolled in or participating in an established residency program.
- (2) A pharmacy intern shall practice under the immediate supervision of a licensed pharmacist except in accordance with RCW 18.64.253.
- (3) A pharmacy intern registration can only be renewed twice.
- (4) The commission may consider a pharmacy intern registration inoperable or superseded if one of the following occurs:
- (a) A pharmacy intern has not graduated from and is no longer enrolled or in good standing with a commission accredited school or college of pharmacy.
- (b) A pharmacy intern is issued a license to practice as a pharmacist in Washington state or another U.S. jurisdiction.

Assessment: The 6 year time limit (or two renewal limit) for pharmacy intern registrations can pose a challenge for licensees. Interested parties have reported that some students may take longer than 6 years to complete pharmacy school and get a pharmacist license.

Recommendation: The commission is invited to consider one of two options:

- 1. Retain WAC 246-945-155 as currently written; or,
- 2. Open WAC 246-945-155 for possible revision. This option requires authorizing a CR-101 on WAC 246-945-155.

CERTIFICATION OF ENROLLMENT

SECOND SUBSTITUTE HOUSE BILL 1009

Chapter 165, Laws of 2023

68th Legislature 2023 Regular Session

MILITARY SPOUSES-PROFESSIONAL LICENSING AND EMPLOYMENT

EFFECTIVE DATE: July 23, 2023—Except for section 4, which takes effect October 1, 2023.

Passed by the House April 13, 2023 Yeas 97 Nays 0

LAURIE JINKINS

Speaker of the House of Representatives

Passed by the Senate April 10, 2023 Yeas 49 Nays 0

DENNY HECK

President of the Senate

Approved April 25, 2023 3:13 PM

CERTIFICATE

I, Bernard Dean, Chief Clerk of the House of Representatives of the State of Washington, do hereby certify that the attached is **SECOND SUBSTITUTE** HOUSE BILL 1009 as passed by the House of Representatives and the Senate on the dates hereon set forth.

BERNARD DEAN

Chief Clerk

FILED

April 26, 2023

JAY INSLEE

Governor of the State of Washington

Secretary of State State of Washington

SECOND SUBSTITUTE HOUSE BILL 1009

AS AMENDED BY THE SENATE

Passed Legislature - 2023 Regular Session

State of Washington 68th Legislature 2023 Regular Session

By House Appropriations (originally sponsored by Representatives Leavitt, Barkis, Ryu, Paul, Donaghy, Slatter, Simmons, Low, Volz, Schmidt, Christian, Lekanoff, Griffey, Doglio, Robertson, Orwall, Caldier, Reeves, Bronoske, Bergquist, Shavers, Riccelli, and Ormsby)

READ FIRST TIME 02/06/23.

- 1 AN ACT Relating to military spouse employment; amending RCW
- 2 18.340.020 and 73.04.150; adding new sections to chapter 18.340 RCW;
- 3 adding a new section to chapter 28A.410 RCW; adding a new section to
- 4 chapter 43.60A RCW; adding a new section to chapter 38.42 RCW;
- 5 creating new sections; and providing an effective date.
- 6 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:
- 7 <u>NEW SECTION.</u> **Sec. 1.** This act may be known and cited as the
- 8 military spouse employment act.
- 9 <u>NEW SECTION.</u> **Sec. 2.** The legislature finds that the lives of
- 10 military spouses are dominated by frequent deployments and
- 11 relocations, and one-third of military families move each year. Many
- 12 military families depend on two incomes, and military spouses tend to
- 13 be better educated than the civilian population, with approximately
- 14 34 to 50 percent working in fields that require a professional
- 15 license. The length of time to credential after a move is a
- significant employment barrier, with one study finding 20 percent of military spouses waited at least 10 months for a license after moving
- 18 to a new state. This wait contributes to higher rates of unemployment
- 19 or underemployment for military spouses when compared to their
- 20 civilian counterparts. Given the fiscal and economic constraints of

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- 1 military families and the readiness considerations of the department
- 2 of defense, the legislature intends to help alleviate the career
- 3 turmoil military spouses face while serving in our state.
- 4 <u>NEW SECTION.</u> **Sec. 3.** A new section is added to chapter 18.340 5 RCW to read as follows:
- The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.
- 8 (1) "Authority" means any agency, board, commission, or other 9 authority for issuance of a license, certificate, registration, or 10 permit under this title. "Authority" does not include the department 11 of labor and industries, or the department of financial institutions 12 with respect to escrow agent licensure under chapter 18.44 RCW.
- 13 (2) "License" means a license, certificate, registration, or 14 permit to perform professional services.
- 15 **Sec. 4.** RCW 18.340.020 and 2011 2nd sp.s. c 5 s 2 are each 16 amended to read as follows:
- 17 (1) ((For the purposes of this section, "authority" means any board, commission, or other authority for issuance of a license, certificate, registration, or permit under this title.
 - (2) To the extent resources are available:))

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- 21 (a) Each authority shall establish procedures to expedite the 22 issuance of a license((, certificate, registration, or permit to 23 perform professional services)) regulated by each such authority to a 24 person:
 - (i) Who is ((certified or)) licensed, certified, or registered, or has a permit in another state to perform professional services in that state; and
- 28 (ii) Whose spouse is the subject of a military transfer to 29 Washington((; and
- 30 (iii) Who left employment in the other state to accompany the person's spouse to Washington)).
- 32 (b) The procedure must include a process for issuing the person a
 33 license((, certificate, registration, or permit, if, in the opinion
 34 of the authority, the requirements for licensure, certification,
 35 registration, or obtaining a permit of such other state are
 36 substantially equivalent to that required in Washington)) within 30
 37 days of receiving a completed application. A completed application
 38 means that the authority has received all supporting materials,

related application fees, fingerprints, and required documentation associated with a criminal background check.

(((c))) Each authority in this title shall develop a method 3 and adopt rules to authorize a person who meets the criteria in 4 $((\frac{a}{a})(i) + \frac{b}{a})$) this $(\frac{a}{a})$ 5 6 services regulated by the authority in Washington by issuing the 7 person a temporary license((, certificate, registration, or permit)) within 30 days of receiving a completed application. A completed 8 application means that the authority has received a copy of the 9 certificate issued by the other state for a certificated education 10 professional, related application fees, fingerprints, and required 11 documentation associated with a criminal background check. The 12 license may be issued for a limited period of time of no less than 13 180 days to allow the person to perform services regulated by the 14 authority while completing any specific additional requirements in 15 16 Washington that are not related to training or practice standards of 17 the profession that were not required in the other state in which the person is licensed, certified, or registered, or has a permit. 18

((temporary)) license((, certificate, registration, or permit)) if the standards of the other state are substantially unequal to Washington standards.

23 $((\frac{d}{d}))$ An applicant must state in the application that ((he or she)) the applicant:

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 $((\frac{1}{2}))$ (a) Has requested verification from the other state or states that the person is currently licensed, certified, registered, or has a permit; and

(((ii))) <u>(b)</u> Is not subject to any pending investigation, charges, or disciplinary action by the regulatory body of the other state or states.

 $((\frac{(+)}{(+)}))$ <u>(5)</u> If the authority finds reasonable cause to believe that an applicant falsely affirmed or stated either of the requirements under $((\frac{(+)}{(+)}))$ of this subsection $(\frac{(+)}{(+)})$ subsection $(\frac{(+)}{(+)})$ or $(\frac{(+)}{(+)})$ of this section, the authority may summarily suspend the license $((\frac{(+)}{(+)}))$ pending an investigation or further action to discipline or revoke the license $((\frac{(+)}{(+)}))$ registration, or permit).

NEW SECTION. Sec. 5. A new section is added to chapter 18.340 RCW to read as follows:

- 1 (1) Each authority must identify a contact or coordinator within 2 the authority to assist military spouse applicants and licensees.
 - (2) Each authority must provide training to each board or commission member on the culture of military spouses, the military spouse experience, and issues related to military spouse career paths. Board or commission members appointed on or before October 1, 2023, must complete the training by January 1, 2024. Board or commission members appointed after October 1, 2023, must complete the training within 90 days after appointment. The department of veterans affairs shall create an internet-based training that may be used by each authority to satisfy this requirement.
 - (3) Each authority is encouraged to:

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- 13 (a) Appoint a military spouse to serve on its licensing board or 14 commission;
- 15 (b) Conduct a review of the authority's licensing application 16 process for military spouses and identify barriers to military spouse 17 employment; and
- 18 (c) Review licensing fees and related expenses and identify 19 possible ways to reduce costs for military spouses.
- NEW SECTION. Sec. 6. A new section is added to chapter 18.340 RCW to read as follows:
- (1) The employment security department, the department of health, the department of licensing, and the department of veterans affairs shall each maintain a military spouse assistance web page containing, at a minimum:
- 26 (a) Each authority's rules and procedures, including any required 27 fees, related to the licensing of military spouses;
- 28 (b) Contact information for each authority's military spouse 29 contact or coordinator; and
- 30 (c) Links to the military spouse assistance web pages of other 31 agencies.
- 32 (2) A direct link to the agency's military spouse assistance web 33 page must be displayed on the agency's home page.
- NEW SECTION. Sec. 7. A new section is added to chapter 28A.410 RCW to read as follows:
- The agency responsible for educator certification shall, as set forth in chapter 18.340 RCW:

- 1 (1) Adopt rules for expedited professional certification for 2 military spouses;
- (2) Identify a contact or coordinator to assist military spouse 3 applicants and licensees; 4
 - (3) Provide training to each board member on the culture of military spouses, the military spouse experience, and issues related to military spouse career paths; and
 - (4) Maintain a military spouse assistance web page.

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- 9 <u>NEW SECTION.</u> **Sec. 8.** A new section is added to chapter 43.60A RCW to read as follows: 10
- (1) The department, the employment security department, and the department of commerce shall consult local chambers of commerce, associate development organizations, and businesses to initiate a 13 demonstration campaign to increase military spouse employment. This 14 campaign may include partnerships with chambers of commerce that result in business owners sharing, with the local chamber of commerce, information on the number of military spouses employed and the local chambers of commerce providing this information to the department.
- 20 (2) Participants in the campaign are encouraged to work with the 21 Washington state military transition council and county veterans' advisory boards under RCW 73.08.035. 22
- (3) Funding for the campaign shall be established from existing 23 24 resources.
- (4) For the purposes of this section, "military spouse" means any 25 person married or previously married to a military service member, 26 27 irrespective of the length of the marriage, during the military service member's service in any branch of the United States armed 28 29 forces as an active duty service member, reservist, or national guard 30 member.
- <u>NEW SECTION.</u> **Sec. 9.** A new section is added to chapter 38.42 31 RCW to read as follows: 32
- (1) The spouse of a service member may terminate an employment 33 34 contract without penalty at any time after the service member receives military service orders for a permanent change of station 35 36
- 37 (a) The spouse provides written notice, including email, to the employer of the termination under this section; and 38

- (b) The spouse provides written proof to the employer of the official orders showing that the service member has received military orders for a permanent change of station.
- (2) Termination of an employment contract under this section is effective on the day notice is given under subsection (1) of this section or on a date mutually agreed to by the parties to the employment contract.
- (3) An employer may not impose any penalty for termination of an employment contract under this section.
 - (4) For purposes of this section:

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- (a) "Employment contract" means a contract that establishes the terms of employment or other professional relationship with the spouse of a service member. "Employment contract" does not include an independent contractor agreement.
- (b) "Penalty" means any fee or cost or liability for breach of contract or any other adverse consequence imposed by the employer. "Penalty" does not include any requirements established by state or federal law.
- 19 (5) This section applies prospectively only and not 20 retroactively. It applies only to employment contracts entered into 21 on or after the effective date of this section.
- 22 (6) Nothing in this section shall be construed as altering the 23 terms, conditions, or practices contained in any collective 24 bargaining agreement in effect on the effective date of this section 25 until the expiration date of such agreement.
- 26 **Sec. 10.** RCW 73.04.150 and 2017 c 184 s 1 are each amended to read as follows:
 - (1) There is hereby created a joint committee on veterans' and military affairs. The committee shall consist of: (a) Eight members of the senate appointed by the president of the senate, four of whom shall be members of the majority party and four of whom shall be members of the minority party; and (b) eight members of the house of representatives appointed by the speaker, four of whom shall be members of the majority party and four of whom shall be members of the minority party. Members of the committee shall be appointed before the close of the 2005 legislative session, and before the close of each regular session during an odd-numbered year thereafter.
 - (2) Each member's term of office shall run from the close of the session in which he or she was appointed until the close of the next

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regular session held in an odd-numbered year. If a successor is not appointed during a session, the member's term shall continue until the member is reappointed or a successor is appointed. The term of office for a committee member who does not continue as a member of the senate or house of representatives shall cease upon the convening of the next session of the legislature during an odd-numbered year after the member's appointment, or upon the member's resignation, whichever is earlier. Vacancies on the committee shall be filled by appointment in the same manner as described in subsection (1) of this section. All such vacancies shall be filled from the same political party and from the same house as the member whose seat was vacated.

- (3) The committee shall establish an executive committee of four members, two of whom are members of the senate and two of whom are members of the house of representatives. The executive committee shall appoint one cochair from the two executive committee members who are senators and one cochair from the two executive committee members who are representatives. The two cochairs shall be from different political parties and their terms of office shall run from the close of the session in which they are appointed until the close of the next regular session in an odd-numbered year. The executive committee is responsible for performing all general administrative and personnel duties assigned to it in the rules and procedures adopted by the joint committee, as well as other duties delegated to it by the joint committee.
- (4) The joint committee on veterans' and military affairs has the following powers and duties:
- (a) To study veterans' issues, active military forces issues, and national guard and reserve component issues, and make recommendations to the legislature; and
- (b) To study structure and administration of the department of veterans affairs and the military department, and make recommendations to the legislature.
 - (5) The joint committee shall adopt rules and procedures for its orderly operation. The joint committee may create subcommittees to perform duties under this section.
- (6) The regulating authorities for the department of licensing ((and)), the department of health, and the professional educator standards board shall file reports to the legislature ((biennially and the Washington state military transition council)) annually beginning January 1, ((2018)) 2024, and appear annually before the

- joint committee on veterans' and military affairs, to provide updates 1 on progress in their efforts to implement the requirements of chapter 2 18.340 RCW, chapter 32, Laws of 2011, ((and)) chapter 351, Laws of 3 2011((. By January 1, 2018, the department of labor and industries 4 and the professional educator standards board must each submit a 5 6 report to the legislature, including an assessment on how its licensing, certification, and apprenticeship programs apply training 7 and experience acquired by military members and their spouses outside 8 of Washington, and recommendations about whether such programs should 9
- 10 be included in the reporting schedule within this subsection)), and
- 11 <u>section 6 of this act</u>.
- NEW SECTION. Sec. 11. Section 4 of this act takes effect 13 October 1, 2023.
 - Passed by the House April 13, 2023. Passed by the Senate April 10, 2023. Approved by the Governor April 25, 2023. Filed in Office of Secretary of State April 26, 2023.

--- END ---

Accessible Labeling Rulemaking Update

Dr. Joshua Munroe, PhD
Rules and Legislative Consultant
Pharmacy Quality Assurance Commission

December 14, 2023

Standard Rulemaking

- Inquiry Phase (RCW 34.05.310)
 - CR-101
- Proposal Phase (RCW 34.05.320)
 - CR-102
- Adoption Phase (RCW 34.05.360)
 - CR-103p



Post-Inquiry Phase (CR-101 → CR-102)

- Preliminary research
 - Other states?
 - Licensee survey
- Drafting rule language
 - Outline drafts
 - Rule language drafts
 - Rules workshops
- Determining costs (required by statute)
 - Significant Analysis (CBA)
 - Is an SBEIS needed?
- SBEIS = Small Business Economic Impact Statement
 - Minor cost thresholds and NAICS codes



Rule Proposal Phase (CR-102)

- The CR-102 form
 - Base form
 - OTS form (rule language)
 - Significant analysis (and SBEIS if necessary)
- Department review of CR-102 package
- Post-filing
 - Public comment period
 - Public hearing

Accessible Labeling Rule Language

- WAC 246-945-026: Accessible Prescription Information Definitions
 - Accessible prescription information, complete directions for use, LEP, etc.
- WAC 246-945-027: Accessible Prescription Information
 - Exemptions, general compliance directives, P&P, third party servicers
- WAC 246-945-028: Accessibility of Prescription Information for Visually Impaired or Print Disabled Individuals
 - "Self-evident," means of access (minimum one of four options, based on patient request)
- WAC 246-945-029: Translation and Interpretation for Prescription Information for LEP Individuals
 - "Self-evident," translation and interpretation, signage (minimum languages on sign)

Significant Analysis

- Section 1: Describe topic and history of issue
- Section 2: Significant analysis requirement
 - What sections of rule do not require significant analysis? WAC 246-945-026
- Section 3: Goals and objectives
 - Two methods to achieve this goal:
 - 1. Provide the complete directions for use for the prescription medication on the container label in the language with which the patient is most comfortable.
 - 2. Provide the complete directions for use, patient name, patient species (for veterinary prescriptions), drug name, and drug quantity for the prescription medication on the container label in at least one visually accessible format. These formats are large print, Braille, a QR code or equivalent tool, and a prescription reader that delivers the necessary information in an audible format.

Significant Analysis (cont.)

- Section 4: Why is rulemaking needed? Which alternatives were considered?
- Section 5: Probable costs and benefits (quantitative and qualitative)
 - Latter three rule sections represent costs incurred
 - Costs
 - One-time, ongoing
 - Dispensing practitioners, dispensing facilities
 - Benefits
 - More qualitative
 - Focused more on public health outcomes (preventing medication error resulting in injury/death)

Significant Analysis (cont.)

- Section 6: Describe alternative versions of the rule that were considered
 - HB 1852 (2022)
 - Other state models (Oregon, California)
- Section 7: Does it violate other federal or state laws?
- Section 8: More stringent performance requirements on private entities than on public entities (unless required by state/federal law)?
- Section 9: How does the rule differ from federal regulation?
 - Title VI of CRA, Section 504 of Rehabilitation Act, Title III of ADA
 - Explain why any differences are necessary
- Section 10: Explain how the rule was coordinated "to the maximum extent practicable" with other federal, state, or local laws on the same topic

Preparing for the SBEIS and CR-102

- Minor cost calculator
 - North American Industry Classification System (NAICS) code
 - Updated November 2023
- Additional staff feedback (if needed)
- CR-102 materials
 - 102 form
 - OTS (rule language) files
 - SA and SBEIS
- Department review and filing
- Public comment period and public hearing

7.3. Implementation for Health Equity Continuing Education



Commission SBAR Communication

Agenda Item	/Title: Health Equity Cont	inuing Education	Rule Effective Date	
Date SBAR C	communication Prepared: De	ecember 4, 2023		
Reviewer:	Joshua Munroe			
Link to Action	n Plan:			
	Information	☐Follow-up	Report only	
Pharmacy Qua The effective of Reviser. Since	ality Assurance Commission's (late for the CR-103p Rules Ad- continuing education is retrosp	(commission) health of option package is 31 poetive, staff are asking	hey must begin complying with the equity continuing education (CE) rule. days after it is filed with the Code ng the commission to consider ortly after the effective date of these	
2021), the comeducation (CE)	nmission conducted standard ru) requirements for pharmacists ge in WAC 246-945-178 and 24	lemaking to establish and pharmacy techni	ate Bill 5229 (chapter 276, Laws of a minimum health equity continuing cians. The commission decided to nent ESSB 5229 and comply with	
followed by a	public comment period. A publ	lic hearing was held a	aly 27, 2023 under WSR 23-16-070, at the October 19, 2023 business cCR-103p package and submitting it	
Assessment: In August 2022, the commission voted that it will not take enforcement action and the department will not conduct continuing education audits until one full renewal cycle after October 27, 2022 (Reinstituting CE for Pharmacists and Pharmacy Technicians (govdelivery.com)). Even though the commission is not conducting continuing education audits, the commission does expect its licensees to comply with its continuing education rules. As a reminder, the department does have a list of free health equity continuing education trainings (Health Equity Continuing Education Washington State Department of Health).				
	tion: It is recommended that the be maintained.	ne current effective da	ate—31 days after the filing of the CR	
Follow-up Ac	tion: Staff will carry out the o	commission's decisio	on.	

PQAC Rules Tracker

Title	Status	Short Description	Most Recent WSR #
Naloxone OTC status (emergency)		Emergency rule for reclassifying 4mg of NARCAN as an OTC, amending WAC 246-945-030 and creating a new section of WAC	WSR 23-17-059 (Filed August 11, 2023)
Medication assistance (emergency - filed jointly with DOH)		Medication assistance emergency rule in accordance with chapter 69.41 RCW	WSR 23-23-032 (Filed November 3, 2023)
Accessible labeling (visual/print access and translated labels)	Draft Significant Analysis form (and SBEIS if necessary)	Standard/significant rules for establishing standards for prescription drug information access and comprehension	WSR 22-09-065 (Filed June 12, 2023)
Medication assistance (standard - will file jointly with DOH)	·	Medication assistance rules in accordance with chapter 69.41 RCW	WSR 22-02-015 (Filed December 27, 2021)
Remote dispensing OUD medications - SSB 6086 (standard)	·	SSB 6086 - Implementing remote dispensing of OUD medications	WSR 23-16-071 (Filed July 27, 2023)
Health Equity Training – ESSB 5229 (standard)		Amend sections in Chapter 246-945 WAC pertaining to continuing education standards and establishing health equity CE requirements per ESSB 5229.	WSR 23-16-070 (Filed July 27, 2023)
Uniform Controlled Substances Act – Title 21 CFR (expedited)	review	Amend language in WAC 246-945-040 to incorporate by reference any changes in Title 21 CFR made after the rule's effective date	WSR 23-15-015 (Filed July 7, 2023)
White Bagging and Brown Bagging	Drafting rule language	Establishing standards around the practice of white bagging and brown bagging	WSR 23-20-115 (Filed October 3, 2023)
Technical fixes to chapter 246-945 WAC (expedited)	Public comment period ends January 22, 2024	Typos and small edits to multiple sections in chapter 246-945 WAC	WSR 23-23-153 (Filed November 20, 2023)

PQAC Rules Tracker (cont.)

Title	Status	Short Description	Most Recent WSR#
Incorporations by Reference	CR-105 under division review	Updating incorporations by reference and reclassifying 4mg of NARCAN as an OTC, amending WAC 246-945-030, and creating a new section of WAC permanently	Not yet filed
USP 795 and 797 Incorporation (expedited)	•	Amend WAC 246-945-100 to incorporate by reference changes in USP <795> and <797> with a November 1, 2023 effective date	WSR 23-22-035 (Filed October 23, 2023)
Mobile OTP unit licensing	Drafting rule language	Amend WAC 246-945-060 to clarify licensing standards for mobile OTP units	WSR 23-18-046 (Filed August 30, 2023)
Access to drugs stored outside pharmacy (standard)	Draft Significant Analysis form (and SBEIS if necessary)	Allowing access to drugs stored outside the pharmacy by unlicensed employees of a health care facility	WSR 23-01-111 (Filed December 19, 2022)
Zero Order Reports and Suspicious Orders (standard)	Drafting rule language	Amending WAC 246-945-001 and WAC 246-945-585 to adjust suspicious order and zero reporting requirement	WSR 23-10-012 (Filed April 24, 2023)
Removing Fenfluramine from Schedule IV	Petition granted and response sent to petitioner; CR-101 being assembled	Amending chapter 246-945 WAC to remove fenfluramine from the list of Schedule IV substances	WSR 23-20-119 (Filed October 3, 2023)
Wildlife Capture Drugs	Rules Workshop	Amending chapter 246-945 WAC to add certain intramammary antibiotic formulations to the list of legend drugs.	WSR 23-21-011 (Filed October 5, 2023)
Dialysate and dialysis device manufacturer licensing	Drafting rule language	Determine sections in chapter 246-945 WAC (subsection -090 through -093 at least) to amend to comply with SSB 1675	WSR 23-21-010 (Filed October 5, 2023)
Prescription Transfers	Drafting rule language	Amend WAC 246-945-345(2) to change "may transfer" to "shall transfer"	WSR 23-23-051 (Filed November 7, 2023)

9.1. CR-103E: Refile Request for Medication Assistance



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: November 03, 2023

TIME: 10:33 AM

WSR 23-23-032

Agency: Department of Health - Pharmacy Quality Assurance Commission
Effective date of rule:
Emergency Rules
☐ 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: Medication assistance in community-based and in-home care settings. As provided in RCW 69.41.010 (15) 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 by adopting new rules in 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. This adopted emergency rule will extend WSR 23-15-017 filed on July 7, 2023 without change.
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.
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, 69.41.010(15), and 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

rulemaking was originally delayed due to the novel coronavirus COVID-19 pandemic but is still in progress. Commission staff and the Department of Social and Health Services (DSHS) met for preliminary discussions regarding draft language. Drafts of the amended rule language were written by commission staff and shared with DSHS personnel for interagency review. The commission will distribute draft language to the public leading up to the planned workshops in early winter of 2023.

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

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: Ne	v 0	Amended	0	Repealed	0		
Federal rules or standards: Ne	v 0	Amended	0	Repealed	0		
Recently enacted state statutes: Ne	v 0	Amended	0	Repealed	0		
The number of sections adopted at the request of a non-	governmen	tal entity:					
Ne	v 0	Amended	0	Repealed	0		
The number of sections adopted on the agency's own in	itiative:						
Ne	v 10	Amended	0	Repealed	0		
The number of sections adopted in order to clarify, stream	mline, or re	eform agency	procedure	es:			
Ne	w 0	Amended	0	Repealed	0		
The number of sections adopted using:							
Negotiated rule making: Ne	v 0	Amended	0	Repealed	0		
Pilot rule making: Ne	v 0	Amended	0	Repealed	0		
Other alternative rule making: Ne	v 10	Amended	0	Repealed	0		
Date Adopted: 10/3/2023	Signatur	e:	<u> </u>				
Name: Kenneth Kenyon, PharmD, MBA Kristin Peterson, of Umair A. Shah MD, MPH	D	¥	Len K	Myn	L		
Title: Pharmacy Quality Assurance Commission Chair Chi of Policy for Secretary of Health	ef Kisti	n fuliso	,				

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. Selfadministration 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

[1] OTS-2998.2

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.

[2] OTS-2998.2

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.

[3] OTS-2998.2



Name: Joshua Munroe

PREPROPOSAL STATEMENT OF INQUIRY

CR-101 (October 2017) (Implements RCW 34.05.310)

Do **NOT** use for expedited rule making

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER STATE OF WASHINGTON FILED

DATE: December 27, 2021

TIME: 12:56 PM

WSR 22-02-015

Agency: Department of Health- Pharmacy Quality Assurance Commission
Subject of possible rule making: Chapter 246-945 WAC, rules pertaining to medication assistance and the settings in which medication assistance occurs. The Pharmacy Quality Assurance Commission (commission) and Department of Health (department) are filing jointly to consider adopting new rules to reinstate rules on medication assistance as permitted under chapter 69.41 RCW.
Statutes authorizing the agency to adopt rules on this subject: RCW 18.64.005; RCW 69.41.010(15); and RCW 69.41.075
Reasons why rules on this subject may be needed and what they might accomplish: The Pharmacy Quality Assurance Commission (commission) completed a nearly 3-year process in July 2020 to update and consolidate all rules under its authority, resulting in the creation of chapter 246-945 WAC. Although this process included extensive work with interested parties, it was brought to the commission's attentiononce the new chapter was publishedthat the repeal of chapter 246-888 WAC resulted in unintended disruptions for medication assistance in the community-based and in-home care settings permitted under chapter 69.41 RCW.
Medication assistance under chapter 69.41 RCW lacks the detail needed to develop and implement training, policies, procedures and regulations. RCW 69.41.010(15) does not provide the level of specificity needed by the broad range of entities charged with implementation and oversight of community-based or in-home care settings and requires that "such other means" of medication assistance are established in rule by the department. The commission also has rules on patient-owned medications (WAC 246-945-440), but they do not apply to community-based and in-home care settings and do not adequately cover the concerns communicated to the commission by the impacted parties.
The commission and the department will consider adopting rules to provide further definitions for terms used such as "enabler," and establish those "other means of medication assistance as defined by rule adopted by the department." These rules are intended to 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.
Emergency rules pertaining to this issue are currently in effect under WSR 21-23-098, filed November 17, 2021. The emergency rules have been in effect since July 20, 2021 with the filing of WSR 21-15-108. The commission and the department intend to keep emergency rules in effect until permanent rules are formalized as necessary.
Identify other federal and state agencies that regulate this subject and the process coordinating the rule with these agencies: The Washington State Department of Social and Health Services believes additional specificity is needed by the entities that are charged with implementation and oversight. Medication assistance under chapter 69.41 RCW lacks the detail needed to develop and implement training, policies, procedures and regulations.
Process for developing new rule (check all that apply): Negotiated rule making Pilot rule making Agency study Other (describe) Collaborative
Interested parties can participate in the decision to adopt the new rule and formulation of the proposed rule before
publication by contacting:
(If necessary)

Name:

Address: PO Box 47852, Olympia, WA 98504-7852 Address: Phone: 360-236-2987 Phone: Fax: 360-236-2321 Fax: TTY: 711 TTY: Email: PharmacyRules@doh.wa.gov Email: Web site: Web site: Other: Other: Additional comments: Rule development takes place in open public meetings prior to a formal rule proposal and comment period. All rulemaking notices are mailed via GovDelivery. To receive notices, interested persons may sign up by going to: https://public.govdelivery.com/accounts/WADOH/subscriber/new. After signing up, please click open the box labeled "Health Systems Quality Assurance." Next, click open the box labeled "Health Professions," then check the boxes next to either "Pharmacy Commission Meeting and Agenda" and/or "Pharmacy Commission Newsletter." Signature: Date: 12/27/2021 Vin Jemua Name: Teri Ferreira, RPh and Kristin Peterson, JD Title: Pharmacy Quality Assurance Chair and Deputy

Secretary, Policy and Planning

9.2. Medication Assistance Rules Workshop

PART 5 - MEDICATION ASSISTANCE

NEW SECTION

WAC 246-945-710 Scope and applicability. WAC 246-945-710 through WAC 246-945-718 only apply to medication assistance or medication preparation assistance rendered by a nonpractitioner to an individual residing in a community-based care setting or an in-home care setting.

[]

NEW SECTION

WAC 246-945-712 **Definitions.** The following definitions apply to WAC 246-945-710 through WAC 246-945-718:

residential programs for persons with developmental disabilities,

certified by the department of social and health services under

chapter 71A.12 RCW; adult family homes licensed under

chapter 70.128 RCW; and assisted living facilities licensed under

chapter 18.20 RCW. Community-based care settings do not include acute care or skilled nursing facilities.

- (2) "Enabler" means a physical device or devices used to facilitate an individual's self-administration of a medication including but not limited to a medicine cup, glass, cup, spoon, bowl, prefilled syringes for insulin, syringes used to measure liquids, a specially adapted table surface, straw, piece of cloth, fabric, or the individual's hand;
- (23) "'Hand-over-hand' administration" means a nonpractitioner is providing total physical assistance to an individual when administering the individual's medication;
- $(\frac{34}{2})$ "Individual" means a person residing in a community based setting or in-home care setting.
- (45) "Medication" means legend drugs, including controlled substances, prescribed to an individual residing in a community-based care setting and an in-home care setting;
- ($\frac{5}{6}$) "Practitioner" has the same meaning as RCW 69.41.010(17).

NEW SECTION

- WAC 246-945-714 Medication Assistance by Nonpractitioners. (1)

 Individuals may receive medication assistance from nonpractitioners.

 Medication assistance includes:
- (a) reminding or coaching the individual to take their medication;
 - (b) handing the medication container to the individual;
 - (c) opening the individual's medication container;
- (d) using an enabler, except if a nonpractitioner uses an individual's hand as an enabler, the nonpractitioner may only steady or guide an individual's hand while the individual administers a medication to themselves and may not engage in "hand-over-hand" administration;
 - (e) placing the medication in the individual's hand; or
 - (f) handing a prefilled insulin syringe to an individual.
- (2) Nonpractitioners shall not provide medication assistance to individuals that involves intravenous medications or injectable medications, except as provided in WAC 246-945-712(5).

[]

NEW SECTION

WAC 246-945-716 Medication Preparation by Nonpractitioners.

- (1) Nonpractitioners may help individuals in the preparation of medications for self-administration where a practitioner has determined and communicated orally or by written direction that such medication preparation assistance is necessary and appropriate. This includes, but is not limited to, the transfer of a medication from one container to another container for the purpose of preparing an individual dose.
- (2) 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.

[]

NEW SECTION

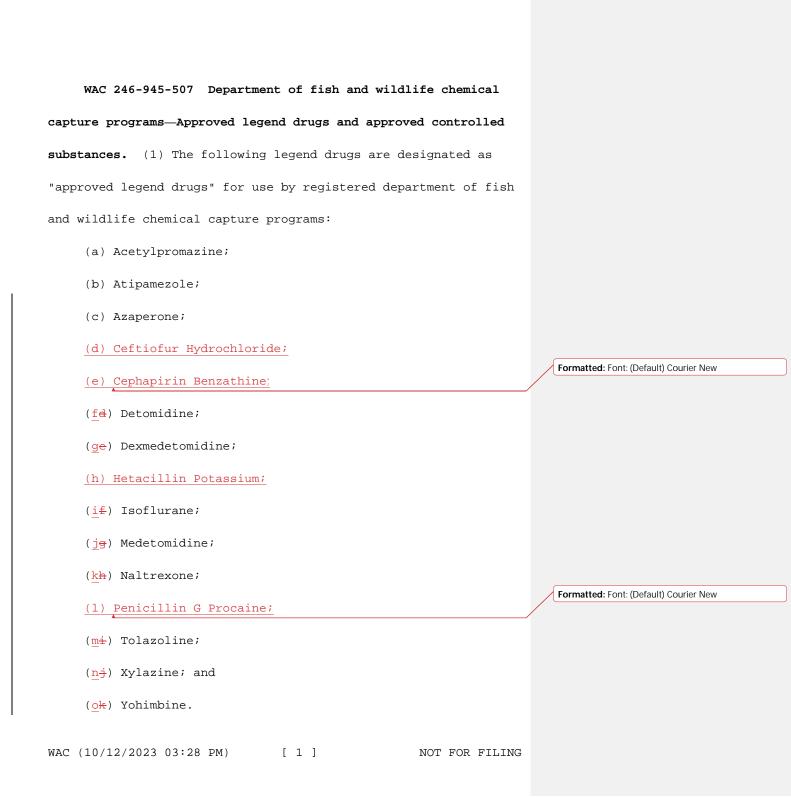
WAC 246-945-718 Medication alteration. (1) Alteration of a medication by a nonpractitioner for medication assistance includes, but is not limited to, crushing tablets, cutting tablets in half,

opening capsules, mixing powdered medications with foods or liquids, or mixing tablets or capsules with foods or liquids. Individuals must be aware that the medication is being altered or added to their food.

(2) 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 record.

[]

9.3. Rules Workshop: Adding Certain Intramammary Antibiotics (WAC 246-945-507)



- (2) The following controlled substances are controlled substances approved for use by registered department of fish and wildlife chemical capture programs:
 - (a) Butorphanol;
 - (b) Carfentanil;
 - (<u>c</u>b) Diazepam;
 - (de) Diprenorphine;
 - (d) Carfentanil;
 - (e) Fentanyl;
 - (f) Ketamine;
 - (g) Midazolam;
 - (h) Tiletamine; and
 - (i) Zolazepam.
- (3) Staff of registered department of fish and wildlife chemical capture programs may administer legend drugs and controlled substances which have been prescribed by a licensed veterinarian for a specific animal or management group of animals, which have been dispensed by a pharmacy or a veterinarian and are properly labeled in accordance with either

RCW 18.64.246 or 69.41.050 and WAC 246-945-015 through 246-945-017 or 246-933-340 (5)(a) and (b). [Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-507, filed 6/1/20, effective 7/1/20.]