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
June 3, 2021 - Minutes

Convene: Chair, Tim Lynch called the meeting to order June 3, 2021, 9:00 a.m.

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

Staff Members:
Lauren Lyles-Stolz, Executive Director, Pharmacy Commission
Christie Strouse, Deputy Director, Pharmacy Commission
Christopher Gerard, AAG
Marlee O'Neill, Deputy Director, OILS
Lindsay Trant, Rules and Legislative Coordinator
Joanne Miller, Program Manager, Pharmacy Commission
Amy L Robertson, Pharmacy Admin.

1. Call to Order Tim Lynch, Chair

1.1. Meeting Agenda Approval – June 3, 2021

MOTION: Craig Ritchie moves to accept meeting agenda; Hawkins DeFrance, second. Motion carries, 11:0.

2. FDA MOU Update

Lauren Lyles-Stolz updated the commission FDA's responses to questions the commission posed in a letter sent to the FDA on January 8, 2021. Lauren also informed the commission that the National Association of Boards of Pharmacy (NABP) have requested the FDA extend the delay in enforcement of § 503A(b)(3)(B)(ii) of the Federal Food, Drug and Cosmetic Act (FD&C Act). This section of the FD&C Act limits out-of-state distribution of compounded drug products by pharmacists, pharmacies, and physicians, to no more than 5 percent of the total prescription orders dispensed or distributed in States that have not entered into the FDA's memorandum of understanding (MOU). NABP has explained to FDA that the continued delay in enforcement will allow states to engage in relevant rulemaking and legislative activity to approve and implement the MOU.

Lauren explained that based on the FDA's response and NABP's request, commissioners could consider the following action as it relates to the FDA's MOU: (1) approve the MOU, (2) reject the MOU, or (3) direct staff to contact FDA to request delayed enforcement without limitation until more states establish a plan to move forward. PQAC would need to decide whether to sign or not sign the FDA MOU.

MOTION: Craig Ritchie moves the commission direct staff to write to the FDA requesting a two-year delayed enforcement of § 503A(b)(3)(B)(ii) of the FD&C Act, until more states are able to establish a pragmatic plan to move forward with rulemaking and any necessary legislative action/statute changes (option #3). Teri Ferreira, second. Motion carries, 11:0.

3. Old Business- The Commission will discuss, for clarification or decision, ongoing topics and issues from previous meetings. Information/Action

3.1. Guidelines for investigating misfill cases

Lauren Lyles-Stolz updated the commission on the procedure for investigating misfill cases. There are other possible questions the commission might consider in updating these guidelines to understand the environments (trends, patterns vs. isolated events) that may be impacting patient safety.

There is jurisdiction overlap on the rulemaking process with L&I and workplace conditions. The commission has worked with L&I in the past on this overlap. Lauren reached out the L&I prior to this meeting and let them know we were working on this item. They did not have any concerns on this issue at this time.

Taifa Peaks (stakeholder) asked if L&I was considering rulemaking changes regarding professional work hours for pharmacists (and persons with degrees). To the best of our knowledge, no. However, the data PQAC is gathering may open conversations in the future.

MOTION: Craig Ritchie moves we take the following action as discussed:

1. Create a subgroup to formulate questions related to gathering additional data for misfills.
2. Request Dr. Lyles-Stolz to work with American Pharmacists Association (APhA) to better understand when results from their survey will be completed and how we can encourage participation in that survey.
3. Use the data gathered from the additional questions to better understand what issues/factors are impacting patient safety.
4. Consider external guidance for licensees about what questions the commissioners would consider for misfill cases.

Patrick Gallaher, second. Motion carries, 11:0.

3.2. Zero Report and Suspicious Orders

Christie Strouse, Deputy Director, reported PQAC staff has encountered operational challenges related to WAC 246-945-585 specifically as it relates to compliance tracking. We request the commission to consider modification to the rule to mitigate these operational challenges. In addition, consider other potential technical fixes.

MOTION: Teri Ferreira motions to accept Option 1: Zero Report Technical Language Rule Revisions creation language to file CR101 to amend rule and the extend enforcement discretion for zero reports for 12-months from July 3, 2020. Jerrie Allard, second. Motion carries, 11:0.

5. Summary of Meeting Action Items

1. **Suspicious Order Reports** – staff follow thru on action from option 1and develop communication to licensees regarding enforcement discretion.
2. **Guidelines for investigating misfill cases** – commission members were asked to email Lauren Lyles-Stolz (cc: Joanne Miller) if interested in joining the subcommittee.
3. **FDA MOU Update** – Follow up letter to FDA requesting delayed enforcement action on §503a.

Business Meeting Adjourned, 10:37 a.m.

Next scheduled business meeting: **June 4, 2021**
Business Meetings
9:00 a.m.
Virtual – by Webinar

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Pharmacy Quality Assurance Commission
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Pharmacy Quality Assurance Commission Meeting
June 4, 2021 - Minutes

Convene: Chair, Tim Lynch called the meeting to order June 4, 2021, 9:03 a.m.

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

Staff Members:
Lauren Lyles-Stolz, Executive Director, Pharmacy Commission
Christie Strouse, Deputy Director, Pharmacy Commission
Christopher Gerard, AAG
Martin Pittioni, Director, OHP
Marlee O'Neill, Deputy Director, OILS
Cori Tarzwell, Regulatory Analyst
Christie Spice, Acting Assistant Secretary, HSQA
Tami Thompson, Regulatory Affairs Manager, DOH
Tina Lacey, Pharmacy Inspector
Lindsay Trant, Rules & Legislative Consultant
Joanne Miller, Program Manager, Pharmacy Commission
Amy L Robertson, Pharmacy Admin.

1. Call to Order Tim Lynch, Chair.

1.1 Meeting Agenda Approval – June 4, 2021.

MOTION: Craig Ritchie moves to accept meeting agenda without revisions; Patrick Gallaher, second. Motion carries, 11:0.

1.2 Meeting Minutes Approval – June 4, 2021.

MOTION: Craig Ritchie moves to accept meeting agenda without revisions; Ken Kenyon, second. Motion carries, 11:0.

2. Public Hearing on SSB 5380 – convened: 9:30 a.m.

Lindsay Trant reported that Substitute Senate Bill 5380 (SSB 5380) passed in the 2019 Washington State Legislature. SSB 5380 required prescriptions for controlled substances to be communicated to the pharmacy electronically (among other things) effective January 1, 2021 (due to the COVID-19 public health emergency the Secretary of Health issued a waiver of this requirement until January 1, 2022). The bill also tasked the Department of Health (DOH) to develop a waiver process for practitioners experiencing economic hardship, technological limitations, or other exceptional circumstances limiting their ability to prescribe controlled substances electronically. After the public hearing, the Pharmacy Quality Assurance Commission (PQAC) can consider adopting the rule language as well as authorize filing a CR-103 under joint authority with DOH. (The CR-102 was filed April 5, 2021. PQAC and DOH have 180 days to file CR-103. Once filed, the rule is effective 31 days later.)

Stakeholder's testifying:

Jeb Shephard, Washington State Medical Association, testifying on behalf of Shelby Wiebmann. WSMA submitted written comments for PQAC review. We really appreciate the work of the PQAC staff in accommodating our feedback and concerns of previous iterations. We feel this is a really sound rule for helping physician practices and other providers that simply will not be able to meet the mandate for various reasons. WSMA does have a few suggestions in the final comment letter we submitted and understand where the process is. I want to relay with my testimony gratitude to the staff for working with us on this. Thank you.

WSMA supports these proposed rules.

Greg Lind, nurse practitioner. Established numerous primary care clinics. Have now established Washington State's first firefighter clinic about 10 years ago (c. 200 firefighters wellness). Mr. Lind sees about 200 firefighters on a regular basis and cannot afford electronic medical records at this clinic. Mr. Lind needs to figure out how the waiver affects him Mr. Lind currently handwrites any controlled substance prescriptions.

Mr. Lind supports these proposed rules.

Public Hearing adjourned: 9:40 a.m.

Brief break for staff to prepare response to comments today and return 10:10 a.m. with PQAC response.

10:10 a.m. reconvene.

Lindsay Trant reviewed detailed comments of stakeholders and PQAC responses to the commission (Attachment #1).

MOTION: Craig Ritchie moves to approve the amended language for WAC 246-945-014 and authorize staff to file a CR-103 under joint authority with DOH. In addition, moves to approve PQAC staff responses to public comments. Ken Kenyon, second. Motion carries, 11:0.

3. Consent Agenda.

3.1 National Precursor Log Exchange January

3.2 Pharmaceutical Firms Application Report Approval

- April 1, 2021 thru May 25, 2021– new and closed firms

3.3 Ancillary Utilization Plans Approval

3.3.1 Providence Infusion Service
3.3.2 Credena Health
3.3.3 Hawks Prairie Pharmacy
3.3.4 Marymoor Pharmacy
3.3.5 Thrifty Payless-Rite Adi-Update
3.3.6 Yakima Valley Memorial
3.3.7 Walgreens-Update

3.4 Pharmacy Technician Training Program Approval

3.4.1 Cascade RX
3.4.2 Hawks Prairie Pharmacy
3.4.3 Kussler Compounding Pharmacy
3.4.4 Rankos Stadium Pharmacy
3.4.5 Virginia Mason Medical Center

MOTION: Teri Ferreira moves to approve consent agenda without revisions; Ken Kenyon, second. Motion carries, 11:0.

4. Old Business.

4.1 **HCE Self-Inspection Worksheet Update** (information) – Christie Strouse updated PQAC on status of these worksheets. The deadline to submit comments is June 7, 2021.

4.2 **Self-Inspection Worksheets and Updates Regarding New Compounding Law**

Tina Lacey updated the commission on Substitute Senate Bill 1445 (SSB 1445) that passed the legislature this session (effective July 25, 2021). SSB 1445 changed the definition of compounding to exclude reconstitution by specifically excluding for both sterile and non-sterile reconstituted drug products. Self-inspection worksheets affected: General, Hospital/Pharmacy HPAC, and (future) Health Care Entity.

MOTION: Ken Kenyon moves to accept the language for the revised General, Hospital and HPAC self-inspection worksheets with the suggested staff edits. Also move we

utilize enforcement discretion to waive the requirements to complete the sterile and non-sterile self-inspection addendums for those entities only if engaging in reconstitution until August 1, 2021. Craig Ritchie, second. Motion carries, 11:0.

4.3 HPAC Subcommittee Update.

Christopher Gerard, AAG, informed the commission many of the issues on this have been resolved. The subcommittee is ready to move forward with a detailed report for the July 2021 business meeting.

5. New Business –The Commission will review items of interest related to pharmacy practice for discussion, clarification, information or action by or on behalf of the commission. ***Information/Action.***

5.1 OTC wholesalers without license in home state.

Lindsay Trant reminded PQAC that at the April 23rd business meeting, PQAC voted to accept a proof of license or evidence that the resident state does not require a license or inspections as well as temporarily defer inspections of OTC wholesalers until a method of inspection is established for both in and out-of-state OTC wholesalers. After research, staff found it may be difficult for an out-of-state applicant to meet the requirements of WAC 246-945-246(3). The question before the commission is to determine what, if any, adjustments are needed to accommodate OTC-only distributors.

Lauren Lyles-Stolz did reach out to NABP regarding the process of adding OTC wholesalers to the DDA portfolio. Still waiting on a response.

MOTION: Craig Ritchie moves to continue current decision of deferring in and out-of-state OTC wholesalers and accept approval of evidence of a state board not requiring license or inspection for 90 days and request staff to follow-up with NABP and review this at the next business meeting after receiving the information from NABP. Patrick Gallaher, second. Motion carries, 11:0.

5.2 Delegation of Signature Authority.
Delegation of Decision Making.
Delegation of Appointment of a Brief Adjudicative Proceeding (BAP) Officer.

MOTION: Craig Ritchie moves to approve modifications to **Delegation of Signature Authority** as made during the meeting. Hawkins DeFrance, seconds. Motion carries, 11:0.

PQAC reviewed the **Delegation of Decision Making** and **Delegation of Appointment of a Brief Adjudicative Proceeding (BAP) Officer** and did not have any recommended amendments

5.3 Election of Officers.

PQAC Officers July 2021 – June 2022:

Teri Ferreira was elected Chair and Jerrie Allard was elected Vice-Chair and that their terms will run from July 2021 to June 2022

5.4 Review of Joint Operating Agreement (JOA)

The commission reviewed the JOA and did not identify issues requiring amendment.

6. Rules and Legislative Session Updates

6.1 Reauthorizing Filing of Epidiolex emergency rules.

MOTION: Ken Kenyon moves to refile the Epidiolex emergency rules as is. Jeri Allard, second. Motion carries, 11:0.

Reauthorizing Filing of the COVID Schedule II prescribing emergency rules.

MOTION: Ken Kenyon moves to refile the COVID Schedule II emergency rules as is. Hawkins DeFrance, second. Motion carries, 11:0.

Note: These rules will last 120 days.

6.2 Legislative Proposal Update

Guests:

- Martin Pittioni, Director, OHP
- Christie Spice, Acting Assistant Secretary, HSQA

Martin Pittioni updated the commission on a proposal moving through the department that includes pharmacy specific items. Division leadership has endorsed both of these 2022 legislative requests and are now at the agency level.

1. Technical enhancements to PQAC operations by granting authority to delegate to a health law judge or panel for facility related cases.

2. Commission compensation – changing all boards/commissions from Class 3 to Class 5 (payroll from $50 to $250/day).

Board members thanked Martin for his collaboration and strong advocacy over the years for PQAC and congratulated Christie on her new role.

7. Requests for Review by Commission Panel C (Uyen Thorstensen, Ken Kenyon, Jerrie Allard, and William Hayes)

Panel C convened reviews at 11:55 a.m.

7.1 Pharmacist applicant requests commission approval of a study plan submitted by applicant to retake MPJE fourth time.

MOTION: Ken Kenyon moves to approve applicant's study plan and retake the MPJE a fourth time. Jerri Allard, second. Motion carries, 4:0.

7.2 Pharmacist applicant requests commission approval of a study plan submitted by applicant to retake MPJE third time

MOTION: Ken Kenyon moves to approve applicant's study plan and retake the MPJE a third time. William Hayes, second. Motion carries, 4:0.

7.3 Pharmacist applicant requests commission approval of a study plan submitted by applicant to retake NAPLEX and MPJE fourth time.

MOTION: Ken Kenyon moves to authorize intern credential for this applicant and require 750 hours internship hours to be conducted and completed prior to coming back to the commission to request re-sit for the NAPLEX; also, panel authorized the study plan and re-sitting for the MPJE a fourth time. Jerrie Allard, second. Motion carries, 4:0.

7.4 Pharmacist applicant requests commission approval of study plan submitted by applicant and to retake NAPLEX fourth time.

MOTION: William Hayes moves to table consideration of reauthorizing the NAPLEX until the July 2021 business meeting and notification that the applicant has successfully passed the MPJE. At that point the commission will also consider potentially requiring internship hours before granting the authorization to sit for the NAPLEX. Motion carries 4:0.

7.5 Pharmacist applicant requests commission approval of a study plan submitted by applicant to retake MPJE.

MOTION: Ken Kenyon moves to approve applicant's study plan and retake the MPJE a fourth time. Uyen Thorstensen, second. Motion carries, 4:0.

Panel C completed reviews at 1:08 p.m.

Roll Call 1:09 p.m.

Commission Members:

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

8. Open Forum – no comments.

9. Commission Member Reports

9.1 Commissioner Reports – none.

9.2 Commissioners' open discussion related to items or issues relevant to Commission business/pharmacy practice.

- Commission members and staff acknowledged and thanked Tim Lynch for his dedicated work as PQAC chair.

- Craig Ritchie recommended two books that may assist understanding what/how the commission works:
  - Killshot, Jason Dearen (ISBN 9780593085783)
  - Death in Mud Lick: A Coal Country Fight against the Drug Companies That Delivered the Opioid Epidemic, Erick Eyre (ISBN 9781982105310)

10. Staff Reports *Information/Action.*

10.1 Executive Director – Lauren Lyles-Stolz

Lauren Lyles-Stolz thanked Tim Lynch for his service and leadership for the commission and the program this last year.

Informed the commissionvirtual meetings will be held through the end of 2021.

Remind licensees telemedicine training requirements are effective June 30, 2021. This legislation was passed in the 2020 session requiring all health care professionals who offer telemedicine to seek training. We will send out a GovDelivery out next week linking resources available to the free training.

ESHB 1196 passed this year. It gives more detail on what will be reimbursed for audio only telemedicine services. Customarily perform duties of audio-only technology (not faxing or emails).

10.2 Deputy Director – Christie Strouse – no report

10.3 Assistant Attorney General – Christopher Gerard – no report

Both Christie Strouse and Christopher Gerard expressed gratitude for Tim Lynch's dedication and leadership of PQAC.

11. Summary of Meeting Action Items

- 2 – Authorize staff to file CR-103 under the joint authority of DOH to include the responses.
- 4.2 – Final revision of self-inspection worksheets for posting to GovDelivery with guidance from the commission.
- 5.1 – Staff follow up with NABP and include information when we have additional information from NABP
- 5.2 – Delegation…
  - … of Signature Authority – uncheck the second statement (fourth box down)
  - … of Decision Making – inform DOH this was approved and has no changes.
  - … of Appointment of a Brief Adjudicative Proceeding (BAP) Officer BAP officer – inform DOH this was approved and has not changes.
- 6.1 – Refile the emergency rules and refile reauthorization of COVID Scheduling II
- 7.3 – Follow up with candidate needing the intern license.

Business Meeting Adjourned. 1:25 p.m.

Pharmacy Quality Assurance Commission
Mission Statement

The mission of the Pharmacy Quality Assurance Commission is to promote public health and safety by establishing the highest standards in the practice of pharmacy and to advocate for patient safety through effective communication with the public, profession, Department of Health, Governor, and the Legislature.

Vision Statement

The Washington State Pharmacy Quality Assurance Commission leads in creating a climate for the patient-focused practice of pharmacy as an integral part of an accessible, quality–based health care system.

- As a result, the citizens of Washington State:
- Are well informed about medications;
- Take responsibility for their health;
- Utilize pharmacists and other health care providers appropriately; and
- Experience the highest level of health and wellness.

Next scheduled business meeting:

July 16, 2021
Business Meetings
9:00 a.m.
Virtual – by Webinar

Accessibility: This meeting is accessible to persons with disabilities. Special aids and services can be made available upon advance request. Requests must be made no later than ten (10) days prior to the meeting. If you would like general information about this meeting, please call (360) 236-4947. If you need assistance with special services, you may leave a message with that request at 1-800-525-0127 or if calling outside Washington State call (360) 236-4052. TDD may be accessed by calling the TDD relay service at 711. If you need assistance due to a speech disability, Speech-to-Speech provides human voices for people with difficulty being understood. The Washington State Speech to Speech toll free access number is 1-877-833-6341.

Attachment #1 – Public Comments: Public Hearing on SSB 5380

Submitter	Organization	Subsection	Comment	Department's Recommendations
Greg Lind	Nurse Practitioner		Cannot afford to do electronic medical records. Serves hundreds of firefighters. Support of rule but will need a waiver for this specialized practice.	The department does not recommend changing the rule language because this type of practice may qualify for the exemption in (3)(c)(ii) under "other exceptional circumstances," which does not have a waiver limit. The department recommends signing up for the 5380 e-prescribing rule list on GovDelivery to receive updates, including when the waivers are available.
Jeb Shepard; Billie Dickinson	WSMA	2a	WSMA is concerned by language in (2)(a) that limits the waivers for economic and technical hardship to three years. This three-year limit is an arbitrary figure and is not required by SB 5380. For practices experiencing economic or technical hardships, including those due to the pandemic, it can take years to financially recover and this waiver process was designed to accommodate those circumstances.	The legislature requires the Department to develop an electronic prescribing (e-prescribing) waiver process for practitioners' experiencing an economic hardship, technological limitations not reasonably in the control of the practitioner, or other exceptional circumstance under SSB 5380. Several stakeholders expressed similar concerns during stakeholder workshops. Many of those concerns, including ones around the waiver's lifecycle, have been incorporated into this draft rule presented today. This is notable in (2)(b), which does not prohibit the number of waivers a practitioner may apply for due to exceptional circumstances (e.g., widespread health care emergencies.) The department sees a great benefit to patients due to the mitigation of potential medication errors with e-prescribing and optimized care. Limiting the waivers is also in line with the intent of the legislation to require e-prescribing. Therefore, the department does not recommend changing the proposed rule language.
Lynn Kovacevich Renne; Gail Toraason McGaffick	WSPMA	2a-b	While SB 5380 allows DOH to set the waiver time frame, it does not give DOH the authority to limit the number of times an entity may apply for a waiver. Because of that, WSPMA asks that the following changes be made to subsections (2)(a) and (b):	The legislature requires the Department to develop an electronic prescribing (e-prescribing) waiver process for practitioners' experiencing an economic hardship, technological limitations not reasonably in the control of the practitioner, or other exceptional circumstance under SSB 5380.

			(2) A practitioner who has submitted an attestation for a waiver from the mandate in RCW 69.50.312 is exempt from the electronic prescribing mandate for the calendar year in which the attestation is signed, beginning with the effective date of this section. (a) For any category of waiver, a practitioner may submit an unlimited number of annual attestations. ~~economic hardship and technical limitations, a practitioner may attest to the need for a waiver up to three times, giving the practitioner three years to come into compliance with the mandate.~~ ~~(b) There is no limit on the number of other exceptional circumstance waivers under subsection (3)(c) of this section that a practitioner can submit.~~	Several stakeholders expressed similar concerns during stakeholder workshops. Many of those concerns, including ones around the waiver's lifecycle, have been incorporated into this draft rule presented today. This is notable in (2)(b), which does not prohibit the number of waivers a practitioner may apply for due to exceptional circumstances (e.g., widespread health care emergencies.) The department sees a great benefit to patients due to the mitigation of potential medication errors with e-prescribing and optimized care. Limiting the waivers is also in line with the intent of the legislation to require e-prescribing. Therefore, the department does not recommend changing the proposed rule language.
Jeb Shepard; Billie Dickinson	WSMA	3a	The definition of economic hardship in (3)(a) is exceedingly narrow. Limiting the parameters to bankruptcy, new or closing practices, and operating a low-income clinic does not reflect the full spectrum of economic hardship that a practice may be facing, including those caused by the pandemic. We recommend striking the language in (3)(a)(i) through (3)(a)(iv).	This issue has received diverse input from stakeholders. The definition aligns with CMS's Provider Application for Hardship Exception as well as other states that have implemented similar rules such as Iowa and New York. Additionally, issues imposed by the pandemic may fall under 'other exceptional circumstance' which does include a broad spectrum of situations that may impact practice. The department's e-prescription waiver process is aimed at promoting increased interoperability and reducing barrier for providers and patients. The department does not recommend changing the proposed rule language.
Lynn Kovacevich Renne; Gail Toraason McGaffick	WSPMA	3a	The parameters for economic hardship in subsection (3)(a) are too narrow, and don't consider the financial impact of the pandemic on provider practices. There is a wide gulf between bankruptcy/closing a practice, and significant reductions in revenue due to the pandemic. WSPMA believes that there shouldn't be any limits for economic hardship.	This issue has received diverse input from stakeholders. The definition aligns with CMS's Provider Application for Hardship Exception as well as other states that have implemented similar rules such as Iowa and New York. Additionally, issues imposed by the pandemic may fall under 'other exceptional circumstance' which does include a broad spectrum of situations that may impact practice. The

			As a result, WSPMA asks for the following changes to subsection (3)(a): (3) A practitioner required to electronically prescribe under RCW 69.50.312 may submit an attestation for a waiver from this mandate due to: (a) Economic hardship ~~in the following circumstances: (i) A bankruptcy in the previous year or submitted an attestation for a waiver under this chapter due to a bankruptcy in the previous year;~~ ~~(ii) Opening a new practice after January 1, 2020;~~ ~~(iii) Intent to discontinue operating in Washington prior to December 31, 2021; or~~ ~~(iv) Operating a low-income clinic, that is defined as a clinic serving a minimum of thirty percent medicaid patients~~.	department's e-prescription waiver process is aimed at promoting increased interoperability and reducing barrier for providers and patients. The department does not recommend changing the proposed rule language.
Jeb Shepard; Billie Dickinson	WSMA	4	We also request that language in (4) be amended to clarify that practitioners must have intended to file a false attestation rather than simply making a mistake while completing the paperwork. Additionally, we request that before DOH files a complaint with the relevant board or commission, that the practitioner is given an opportunity to comply. This is a new rule and a new process for practitioners and DOH alike – we can reasonably expect some confusion as to who is exempt and who is not, as well as how DOH will interpret the language related to the waivers.	The department recommends that the commission accept this recommendation and approve the edits made to the proposed rule, specifically adding the word "knowingly" before "submitting a false attestation" in subsection (4).The department believes this aligns with the intent of the statute. Additionally, providing time to come into compliance is not needed with the further clarification that the false attestation must be "knowingly" submitted to be a violation of the rule.
Lynn Kovacevich Renne; Gail Toraason McGaffick	WSPMA	4	Please amend subsection (4) to require that practitioners must have intended to file a false attestation, rather than simply made a mistake. In addition, prior to filing a complaint with the relevant disciplinary	The department recommends that the commission accept this recommendation and approve the edits made to the proposed rule, specifically adding the word "knowingly" before "submitting a false attestation" in subsection (4).

			commission or board, please give the practitioner an opportunity to comply. This is a new rule, and we can reasonably expect some confusion as to who's exempt and who's not, as well as how DOH will interpret the language related to the waivers. (4) The department may audit waiver attestations submitted by a practitioner to determine compliance with this chapter. Submitting an intentionally false attestation is grounds for disciplinary action against a practitioner's license by the appropriate disciplinary authority as well as fines pursuant to RCW 69.50.312(5). Prior to filing a complaint, the department shall give the practitioner a reasonable opportunity to comply with RCW 69.50.312.	The department believes this aligns with the intent of the statute. Additionally, adding the last suggested sentence in the rule language is not needed with the further clarification that the false attestation must be "knowingly" submitted to be a violation of the rule.

3.1 NPLEx Dashboard Report May 2021

MONTHLY PROGRAM ADMINISTRATOR'S DASHBOARD

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

NEW USERS THIS MONTH	TOP USAGE AGENCIES	TOP AGENCIES BY ACTIVE WATCHES
New Users = 0		1. NW HIDTA (74)
Total Accounts = 139	TOP USERS BY USAGE	2. ICE - King County (6)
Active Users = 2		

TRANSACTION SUMMARY STATISTICS (2021)

	JAN	FEB	MAR	APR	MAY	TOTAL
PURCHASES	58,504	51,943	70,640	82,986	78,777	**342,850**
BLOCKS	2,433	2,301	2,931	3,933	3,515	**15,113**
GRAMS SOLD	130,934	117,632	165,200	197,654	185,979	**797,399**
BOXES SOLD	66,771	59,470	79,346	92,123	87,787	**385,497**
GRAMS BLOCKED	6,569	7,011	8,009	11,356	9,993	**42,938**
BOXES BLOCKED	2,700	2,897	3,183	4,360	3,929	**17,069**
AVG GRAMS PER BOX BLOCKED	2.43	2.42	2.52	2.60	2.54	**2.50**

PHARMACY PARTICIPATION STATISTICS (May 2021)

Enabled Pharmacies	998
Pharmacies Submitting a Transaction	942
Pharmacies Logging in Without a Transaction	0
Inactive Pharmacies	56
Pharmacy Participation for May	94.39%

PHHC.FX.61173286	ACTIVE	5/18/2021
PHHC.FX.61146401	ACTIVE	5/19/2021
PHHC.FX.61157847	ACTIVE	5/19/2021
PHHC.FX.61173274	ACTIVE	5/19/2021
PHHC.FX.61173268	ACTIVE	5/19/2021
PHHC.FX.61173245	ACTIVE	5/19/2021
PHHC.FX.61173263	ACTIVE	5/19/2021
PHNR.FO.61180756	ACTIVE	5/19/2021
PHNR.FO.61180746	ACTIVE	5/19/2021
PHNR.FO.61080343	ACTIVE	5/19/2021
PHWH.FX.61180725	ACTIVE	5/19/2021
PHWH.FX.61180761	ACTIVE	5/19/2021
PHHC.FX.61157670	ACTIVE	5/20/2021
PHHC.FX.61173238	ACTIVE	5/21/2021
PHHC.FX.61173277	ACTIVE	5/21/2021
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PHNR.FO.61193780	ACTIVE	6/28/2021
PHNR.FO.61193813	ACTIVE	6/28/2021

Credential #	Status	First Issuance Date	Effective Date
PHNR.FO.60952510	CLOSED	04/12/2019	06/01/2021
PHNR.FO.60790165	CLOSED	09/12/2017	06/01/2021
PHNR.FO.60438557	CLOSED	03/21/2014	06/01/2021
PHNR.FO.61038545	CLOSED	02/05/2020	06/01/2021

Commission SBAR Communication

Agenda Item/Title: **Pharmacy Changes of Ownership**

Date SBAR Communication Prepared: June 16, 2020

Reviewer: Lauren Lyles-Stolz, ED

Link to Action Plan:

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

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

The DOH team supporting the commission is looking for guidance on whether a stock purchase involving more than 50% of the shares in a pharmacy corporation triggers the commission's "Change of Ownership" process.

Background: (Briefly state the pertinent history):

The owner of a pharmacy is required to immediately notify the commission and pay the original license fee whenever there is a change of ownership. (RCW 18.64.043(3), WAC 246-945-230(3)(c) and WAC 246-907-040(2)). A failure to comply with applicable laws and rules can subject a pharmacy to a finding of a deficiency in an inspection or enforcement action (WAC 246-945-005 and RCW 18.64.165).

Pharmacy statutes and rules do not define the phrase "change of ownership". However, the pharmacy commission's new rules chapter and fee rule explain that a "change of ownership" includes changes in business or organizational structure such as a change from sole proprietorship to a corporation, or a change of more than fifty percent ownership in a corporation (WAC 246-945-230(3)(c) and WAC 246-907-040(2)). This is not an exhaustive list but does provide some examples of when the commission will consider a "change of ownership" to have occurred.

A stock purchase involves a person purchasing a business's stock. A purchase of the majority of stock in a business generally results in the transfer of the ownership of the business entity itself, and the entity will continue to own the same assets and have the same liabilities. This is because the shares in a corporation represent proprietary interests in the corporation (RCW 23B.01.400(37)) and an individual or entity who purchases more than 50% of the shares in a corporation would now have a controlling interest in the corporation (RCW 23B.01.400(4)).

The credentialing team with DOH has historically only considered a change in UBI number as triggering the "change of ownership" process. The "Unified Business Identifier" (UBI) number is a nine-digit unique identifier issued to each business that operates within Washington State by the Department of Revenue (DOR). DOH has confirmed with DOR that a sale of the majority of shares in a corporation would not necessarily result in a change to the business's UBI number.

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

It appears very likely that a stock purchase involving more than 50% of the shares in a pharmacy corporation triggers the pharmacy commission's "Change of Ownership" process based on the applicable laws and rules. This is because a purchase of more than 50% of the shares in a pharmacy involves a change of more than fifty percent ownership in a corporation (WAC 246-945-230(3)(c) and WAC 246-907-040(2)).

DRAFT

Commission SBAR Communication

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

The DOH team recommends the commission find that a stock purchase involving more than 50% of the shares in a pharmacy corporation triggers the commission's "Change of Ownership" process based on the applicable laws and rules.

To implement this decision the pharmacy commission could direct the DOH team to do one, or more, of the following:

1. Publish this FAQ to the listserv and website:

   Updated July 2021:

   Does an individual's (or businesses') acquisition of more than 50% of the shares in a pharmacy corporation trigger the commission's "change of ownership" process?

   Yes, according to statute and rule, pharmacies should immediately notify the commission and comply with the commission's "change of ownership" process if an individual or business acquires more than 50% of the shares in a pharmacy corporation, such as through a stock sale [see RCW 18.64.043(3), WAC 246-945-230(3)(c) and WAC 246-907-040(2)].

2. Ask the DOH team to communicate this decision internally to the credentialing team, inspectors, and investigators that directly support the commission.

DRAFT

Prescription Monitoring Program (PMP) rules for Apple Health (Medicaid) for October 2021

Ryan Pistoresi, PharmD, MS

Assistant Chief Pharmacy Officer

Washington State Health Care Authority

July 2021

Washington State Health Care Authority

Overview

- What is the SUPPORT Act?
- What does Section 5042 do?
- What is Health Care Authority (HCA) doing?
- What is the new clinical policy?
- What is the new monitoring program?
- How is HCA communicating these changes?
- How do I contact HCA?

What is the SUPPORT Act?

- The **S**ubstance **U**se-Disorder **P**revention that **P**romotes **O**pioid **R**ecovery and **T**reatment for Patients and Communities Act (SUPPORT Act) was signed into law in 2018 to direct federal agencies to act on the opioid crisis.

- Different than HB 1427 (2017) which was Washington State Legislation which convened boards and commissions to update opioid prescribing rules (WACs) by January 1, 2019.

- Both SUPPORT Act and HB 1427 WACs apply to Apple Health clients.
  - HB 1427 WACs apply to all **opioid** prescriptions in Washington State
  - SUPPORT ACT laws apply to all **controlled substances** prescriptions for Medicaid

What does Section 5042 do?

- Section 5042 of the SUPPORT Act (codified in 42 USC §1396w–3a) directs all state Medicaid programs to require providers check the PMP prior to prescribing controlled medications.

- "Beginning October 1, 2021, a State shall require each covered provider to check, in accordance with such timing, manner, and form as specified by the State, the prescription drug history of a covered individual being treated by the covered provider through a qualified prescription drug monitoring program … before prescribing to such individual a controlled substance."

What does Section 5042 do?

- 42 USC §1396w–3a(e) requires all States to submit annual reports to the Centers for Medicare and Medicaid Services (CMS) on the outcomes of this legislation.

- Washington State must report “whether or not the State requires (and a detailed explanation as to why the State does or does not require) pharmacists to check the prescription drug history of a covered individual through a qualified prescription drug monitoring program described in subsection (b) before dispensing a controlled substance to such individual.”

What is HCA doing?

- HCA is updating its rules and procedures to comply with this new federal law by October 1, 2021.

- To comply, HCA is:
  - publishing a clinical policy on how providers should check the PMP;
  - creating a compliance monitoring process, which may include prescriber education regarding the policy requirements;
  - Preparing to submit annual reports to CMS as described in 42 USC 1396w-3a(e)(1); and
  - providing communications to external stakeholders impacted by this law

What is the new clinical policy?

- Prescribers writing a prescription for any controlled medication for an Apple Health patient must check the Washington State Prescription Monitoring Program (PMP) no more than 10 days prior to writing the prescription.
- Pharmacists will be required to check the PMP no more than 48 hours prior to or after filling any controlled medication for an Apple Health patient.
- HCA is adding requirements to WAC and the provider guide(s).
- Checks will not stop or limit opioid prescriptions.

What is a PMP check?

- Prescribers and pharmacists must review all current prescriptions documented in the PMP.
  - Prescribers and pharmacists may delegate this PMP review to authorized staff if they review all current prescriptions.

- Prescribers and pharmacists must review the patient's history in the PMP and document date and time in the patient's record.
  - If unable to access the PMP after a good faith effort, they must document this in the patient's record with intended follow up action.

What is the new monitoring program?

- HCA will measure PMP qualified checks performed by prescribers, pharmacists, or their delegates. A qualified check will be measured by matching date written on prescriptions in claims data with PMP data.

- HCA will use claims data to identify the date filled for a prescription. PMP data will reflect whether any pharmacist or their delegate checked the PMP within 48-hours of the date filled.

What is the new monitoring program?

- HCA will determine a prescriber check was made by consulting the PMP log.
  - The PMP log shows whether the prescriber, their delegate, or their facility accessed the patient's prescription drug history no more than 10 days prior to the date written on the prescription.
  - A check by a prescriber outside the 10-day window, either before or after, will count as an unqualified check.
- HCA will document prescriptions without any PMP checks as unchecked prescriptions.

What is the new monitoring program?

- HCA will determine a pharmacist check was made by consulting the PMP log.
  - The PMP log shows whether the pharmacist or their delegate accessed the patient's prescription drug history no more than 48 hours prior to or after the date filled on the prescription.
  - A check by a pharmacist outside the 48-hour window, either before or after, will count as an unqualified check.
- HCA will document prescriptions without any PMP checks as unchecked prescriptions.

What is the new monitoring program?

- HCA may send educational letters to prescribers and pharmacists who fall below a threshold for qualifying checks.

- Once the previous federal fiscal year's claims are finalized (e.g., October 1, 2021 to September 30, 2022), HCA will need to identify qualifying claims and match to PMP data for all identified clients to be reported by the next Drug Utilization Review (DUR) report (e.g., June 30, 2023).

How is HCA communicating these changes?

- HCA has developed a plan to communicate new requirements to prescribers and pharmacists which leverages:
  - Provider alerts
  - Speaking opportunities

- One of the best ways you can stay up-to-date is by signing up for provider alerts from HCA.

How do I contact HCA?

- To stay current with the SUPPORT Act implementation: https://www.hca.wa.gov/about-hca/apple-health-medicaid/support-act

- For opioid policy questions, email: Apple Health Pharmacy Policy

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

White-Bagging Of Medications and Consequences on Individual and Organizational Patient Safety

David Chen , R.Ph., M.B.A.

Assistant Vice President for Pharmacy Leadership and Planning

Pharmacy Practice Sections

ASHP

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State Policy & Advocacy Associate

Office of Government Relations

ASHP

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What is White-Bagging of Prescription Drugs?

- Payer mandated use of a designated retail/specialty pharmacy to dispense and bill a patient's prescription medication. The dispensed prescription is mailed to a hospital or physician's office. (i.e. prescription is mailed in a "white-bag" bypassing the patient taking ownership of their prescription).
- The receiving location must store drug, compound drug, re-dispense drug, coordinate the patient visit, prepare drug for administration, administer the drug, monitor the patient, and manage hazardous medical waste without compensation.

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Patient Consequences of White-Bagging

Patient Experience and Time to Treat

1. Difficulty in care coordination
2. Delayed treatment due to drug delivery misdirection from PBM designated pharmacy
3. Interferes with conditions that require just-in-time treatment decisions due to labs and disease progression
4. Patients impacted include our nations most vulnerable and sickest patients (ex. Cancer care, rare diseases, and complex multiple diseases)
5. Patient may pay co-pay charged by the PBM designated pharmacy for drug they do not receive due to fragmented process.

Prescribers and pharmacists have become patient protectors from harm due to payer's white-bagging mandated business models

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Potential for Harm

Safety for the Individual and Organization's Patients

1. Fragmentation and corruption of established health care record for prescriptions
2. Process introduces multiple risk points
3. EHR integrity
4. Negative impact on overall medication use system
5. Complicates FDA drug recall processes

White-bagging is counter to ISMP/TJC standards for patient safety

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Negative Impact on Transitions of Care

1. Patients delays in arranging for post-discharge dose increasing risk of hospital-acquired infection
2. Patient readmissions due to delay in mail order delivery resulting in exacerbation/ life threatening symptoms
3. Re-directed labor consumption in complicated care coordination in efforts to mitigate risks.

White-bagging can negatively impact ADTs and patient outcomes

ADT = Admissions/Discharges/Transfers

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Case Studies

- Patient who's insurance required white bagging for emapalumab-lzsg (Gamifant®) for rare hemophagocytic lymphohistiocytosis (HLH). Hospital pharmacy could not get the insurance company to permit organization to purchase and obtain the drug even though they had ability to do so. Patient was unable to access the drug in the last few months of her life due to this restriction. Insurance company could not provide solutions for other infusion centers to administer this medication with white bagging requirements.
- "Three different patients who had their treatment delayed by more than two months due to complications with the payer designated specialty pharmacy. These meds were Entyvio ®, Simponi Aria ®, and Ocrevus ®."
- Multiple case reports of medication being delivered to the wrong place, as certain payer designated specialty pharmacies have a policy that does not allow them to ship to other pharmacies, so they are unable to put "Attn Inpatient Pharmacy" on the shipping label.
- "Neulasta® arrived to our clinic two days after it was due. Med found days after it arrived in clinic (instead of infusion) without refrigeration, making this also an example of increased medication waste. We closed the risk gap by providing our own drug to the patient on time."
- 72-bed rural healthcare system: "…once the delayed product finally gets here, sometimes we get three months of doses because they over shipped to 'rectify' the situation from earlier. So now we have storage issues, as well as workflow problems."

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ASHP Process of Evaluation and Final Direction

Issue Evaluated by:

- ASHP Member White Bagged Medications Workgroup
- Section of Pharmacy Practice Leaders and Section of Specialty Pharmacy Executive Committees
- Pharmacy Executive Leadership Alliance Advisory Panel
- ASHP Board

Final Direction: The frequency and volume of payer mandated white bagging of medications has become untenable and is creating a significant patient and organizational safety risk, negatively impacting continuity of care, and creating regulatory and legal compliance issues for pharmacies receiving a white-bagged medication and the practice needs to be prevented and discontinued.

Regulatory and Accreditation

Legal Analysis Is Required

1. Interpretation of “re-dispensing” laws. (e.g. Hospital has to open drug dispensed and billed to a patient and ‘re-dispense’ so it can be administered to patient)
2. Should hospitals be taking “ownership” of patient’s white-bagged drug?
3. What are the legal requirements on drug returns and/or disposal?
4. Regulations on “re-mailing” if needed (e.g. patient can not travel to original site of care)
5. Interpretation of DSCSA violations (Note - rare and exceptional cases and “common ownership” scenarios are permitted under DSCSA)
6. Lack of indemnification to protect the hospital & patient for drug integrity dispensed from payer designated pharmacy.

White-bagging is essentially a micro-wholesaler model that skirts established safety regulations & standards

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Is White Bagging Dispensing or Distributing?

- *"**Dispense** to patients* means the act of delivering a prescription drug product to a patient or an agent of the patient …"
- *"**Distribute*** means the act of delivering, other than by dispensing, a drug product to any person."

- **Is a Health Care Entity the patient's agent?**

Source : [REDACTED]08.3(b)

Are White Bagged Drugs Redispensed?

- “Dispensed” white bagged drugs often require sterile compounding or reconstitution prior to administration
- Is it lawful to manipulate and re-label a previously dispensed prescription drug prior to administration?
  - “Redispensing” is not a defined term in most Pharmacy Practice Acts
  - Additional guidance needed to establish safe practices related to redispensing

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Who Owns White Bagged Drugs?

- “Dispensed” patient-specific medications are property of the patient
- Administering provider never takes formal ownership of the medication
  - How do providers lawfully dispose of unusable product?
  - Drugs cannot be returned to dispensing specialty pharmacy
  - Restrictions on transferring product to a different physical address

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Maintaining Product Integrity

- How is burden of responsibility established for drugs that become adulterated as a result of mishandling?
  - Dispensing pharmacy vs. receiving pharmacy vs. carrier
- Who is responsible for replacing mishandled and adulterated product?
  - Difficult to establish burden of proof in many scenarios

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Are All White Bagged Drugs Suspect Products?

- Hospitals can't determine if drugs are counterfeit, diverted, stolen, adulterated, or subject of a fraudulent transaction

(d) Heightened vigilance includes the examination of required records (invoices, shipping documents, Transaction History, and Transaction Statement) for suspicious business practices and the physical examination of Products for factors that increase the risk of a Product being suspect, such as:

(1) a Trading Partner that has been involved in business Transactions where they sold or delivered Illegitimate Product;

(2) a Trading Partner that has a history of problematic or potentially false Transaction Histories or pedigrees, such as those that contain misspelled words or incomplete information;

(3) a Trading Partner that is reluctant to provide a Transaction History associated with the Product being purchased or does not do so in a timely manner;

Need for Safe Practice Procedures

- Many Boards require pharmacies under common ownership to demonstrate policies and procedures outlining safe practices for dispensing, distributing and transporting drugs from one pharmacy to another
- These requirements do not extend to dispensing of drugs between pharmacies that are not under common ownership

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Is White Bagging a form of Central Fill?

- Many states require pharmacies to have signed shared service agreements before engaging in Central Fill operations
- Hospitals argue that white bagging is a form of coerced shared service arrangement with the plan-affiliated specialty pharmacy acting as the central fill facility

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State BOP Actions

- Virginia BOP finalized white and brown bagging regulations in June 2021
  - Rules for proper storage, handling and transfer of clinician-administered drugs
  - Requires shared service arrangements between specialty pharmacies and providers
- Florida BOP established an ad hoc committee to explore white bagging patient safety concerns

Critical Issues Requiring Assessment

- Who is accountable for verifying authenticity and integrity of the drug before administration?
- Who is responsible when a delay in therapy, due to a lack of coordination between the payer mandated pharmacy, patient, prescriber, and hospital pharmacy, leads to adverse outcomes for patients?
- Is white bagging dispensing or distribution?
- Under what conditions is redispensing permissible?
- How should unadministered white bagged drug stock be handled?
- Who is responsible for replacing adulterated drug?
- Is white bagging technically a ‘suspect drug’ under the DSCSA?
- Who is accountable for proper hazardous waste management of unused white bagged medications?
- Which products can be reasonably self-administered by a patient or a patient’s caregiver? Which products cannot?

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Questions

June 10, 2021

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ASHP NewsLink: Special White Bagging Edition

ASHP to Meet with FDA Regarding White Bagging

Next week, ASHP will meet with Food and Drug Administration (FDA) officials to discuss the payer-mandated drug distribution model known as “white bagging.” ASHP, along with 61 health systems and group purchasing organizations, and our partners at the American Hospital Association, sent letters to the FDA commissioner requesting the meeting to discuss patient safety and supply chain security concerns regarding payer-mandated white bagging.

White Bagging Impact on Patient Care

ASHP's new white bagging infographic details how payer-mandated white bagging disrupts patient care and highlights risks to patient safety. The infographic is part of ASHP's advocacy encouraging policymakers to prohibit health plans and pharmacy benefit managers (PBMs) from requiring white bagging of clinician-administered drugs.

To learn more and stay up to date on white bagging advocacy efforts, visit ASHP's website.

States Make Progress on White Bagging Reform

Five states have introduced bills intended to directly address white bagging in 2021, with Louisiana, Virginia, and Indiana passing bills to combat white bagging practices. PBM reforms in several states also seek to rein in payers' ability to steer patients toward plan-affiliated specialty pharmacies.

- Louisiana Senate Bill 191: Louisiana's state legislators passed SB 191, which prevents healthcare plans and PBMs from refusing to pay a participating provider or pharmacy for providing covered physician-administered drugs. This law also mandates that all white bagged drugs must meet supply chain security controls set forth by the Drug Supply Chain Security Act.
- Virginia House Bill 2219: Virginia's state legislators passed HB 2219, which requires insurers and PBMs to allow non-contracted pharmacies to dispense covered drugs and be reimbursed at in-network rates. This bill also prevents

healthcare plans from imposing unequal cost-sharing on patients who select out-of-network pharmacy providers.

- Indiana House Bill 1405: Indiana's state legislators passed HB 1405, which requires the Indiana Department of Insurance, Department of Health, and Board of Pharmacy to conduct a study on the impact of white bagging and issue recommendations for best practices by Dec. 31, 2022.
- Arkansas House Bill 1907: Arkansas' state legislators passed HB 1907, which states that if a healthcare provider and enrollee determine it is in the patient's best interest for the provider to administer any covered prescription medication, then the payer must reimburse the provider. This bill also prevents the payer from imposing unequal cost sharing or financial penalties on patients or providers.

ASHP Testifies Before Florida Board of Pharmacy Regarding White Bagging

ASHP's State Policy & Advocacy Associate Kyle Robb testified before members of the Florida Board of Pharmacy in April regarding payer-mandated white bagging and brown bagging practices. ASHP strongly encouraged Florida's Board of Pharmacy to consider the patient safety and supply chain security risks of white bagging and take appropriate action to protect patients. The Florida Board of Pharmacy Rules Committee voted unanimously to recommend creation of an ad hoc committee to explore potential actions to address patient safety concerns related to white and brown bagging.

In addition to ASHP and the Florida Society of Health-System Pharmacists testifying at a Florida Board of Pharmacy Meeting regarding white bagging, three other state affiliates have also testified

to their boards of pharmacy this year. These other states include Texas, California, and Missouri.

Additional White Bagging Resources

- **Webinar: Financial and Regulatory Considerations with White and Brown Bagging**: There is CE credit available for this course. Registration for this session on June 29 at 3 p.m. ET is now open.
- **ASHPOfficial Podcast**: Advocating for Impact: White Bagging - Implications for Patient Safety and Access to Care
- **340B Insight Podcast**: ASHP Discusses Payer-Mandated White Bagging of Drugs with 340B Health

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WHITE BAGGING
Jeopardizes Patient Care

White bagging occurs when payers require a narrow network of plan-selected pharmacies to dispense clinician-administered drugs and bill a patient's prescription medication plan. White bagging is a risk prone process that should only be considered when determined by the provider to be necessary and appropriate to support patient care.

How Does White Bagging Work?

Provider makes diagnosis, develops medication treatment plan

PAYER-MANDATED WHITE BAGGING MODEL

Diagnosis and medication treatment plan entered into electronic health record (EHR)

Payer mandates provider must use an external specialty pharmacy

Provider must write an additional prescription order and send to the **payer-mandated pharmacy**

Bypasses EHR comprehensive safety checks

Health-system pharmacy has to coordinate medication delivery

Payer-mandated pharmacy receives prescription, dispenses drug and bills to patient, mails drug to health system

***POTENTIAL ISSUES:** misdirected mail, drug integrity, treatment plan changes, delayed delivery, patient scheduling*

Health-system pharmacy prepares **white-bagged** medication. Considers changes in patient's clinical status that may require updates to treatment plan

Treatment plan updated

Issues result in delayed treatment

No changes

HOSPITAL AND HEALTH-SYSTEM MODEL

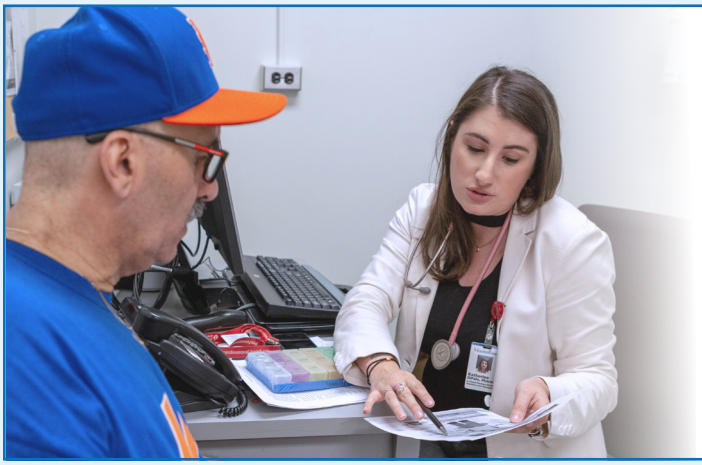
Diagnosis and medication treatment plan entered into EHR. **EHR provides comprehensive medication safety checks and information**

Health-system pharmacy receives medication order

Health-system pharmacy prepares medication the **day of clinic infusion** from its inventory. Considers changes in patient's clinical status that may require updates to treatment plan

Patient receives medication infusion after interprofessional consultation

What are the Consequences?



FOR PATIENTS

- Delayed care for urgent treatment changes
- Delayed treatments due to payer benefit requirements
- Difficulty in care coordination
- May be charged co-pays for drugs not received due to shipping errors, treatment changes, etc.
- Anxiety when payer unnecessarily requires use of an additional unfamiliar pharmacy provider

FOR THE HOSPITAL

- Negative impact on overall medication-use system
- Introduces multiple risk points
- Fragments established healthcare record for prescriptions
- Undermines EHR integrity

How to Protect Patients

White bagging threatens practices that healthcare organizations have established to keep patients safe and hinders the ability of pharmacists to ensure medication and supply chain integrity.

ASHP IS WORKING TO:

Advocate that the Food and Drug Administration enforce safety requirements in the **Drug Supply Chain Security Act** undermined by white bagging

Encourage state policymakers to **prohibit insurers and pharmacy benefit managers from mandating white bagging** or from steering patients away from health systems that refuse to accept potentially dangerous white-bagged drugs

For more information and resources, visit
ashp.org/whitebagging

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STATE OF WASHINGTON

DEPARTMENT OF HEALTH

To: Department of Health

Cc: Martin Pittioni, Director, HSQA – Office of Health Professions, Terri Ferreira, Pharmacy Quality Assurance Commission Chair

From: Lauren Lyles-Stolz, Executive Director, Pharmacy Quality Assurance Commission

Date: July 16, 2021

Subject: PQAC Sunrise Review Comments: Midwifery Scope of Practice

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The Pharmacy Quality Assurance Commission (PQAC) thanks the Department of Health for the opportunity to provide remarks on the Sunrise Review: Midwifery Scope of Practice Expansion Draft. PQAC appreciates the Midwives' Association of Washington State for their initiative to further advance their profession's scope of practice, education, and training through the sunrise review process. We understand that enhancing the reproductive health of individuals is instrumental to improving population's health for Washingtonians and nationwide.

After review of the bill request #1639.1/21 draft, PQAC has identified the following areas of concerns:

- Section 2(2)(e) – For those candidates seeking a limited prescriptive license extension, additional study and training is required, as prescribed by the department by rule.
    - Comment: It is unclear how comprehensive the proposed study and trainings are. PQAC recommends any proposed bill specifically identify minimal standards for the additional study and training (e.g., pharmacology, pharmacokinetics, pharmacodynamics) such as the minimum educational requirements for midwives in RCW 18.50.040(2)(b).

- Section 4 – A midwife licensed under this chapter who has been granted a limited prescriptive license extension by the secretary may prescribe, obtain, and administer medications and therapies for the prevention and treatment of common prenatal and postpartum conditions, and hormonal nonhormonal family planning methods, as prescribed by rule.
    - Comment: PQAC requests clarification: will those midwives granted with a limited prescriptive license extension be the only midwives allowed to prescribe? If so, is that prescriptive authority restricted to those drugs and devices outlined in WAC 246-834-250 and RCW 18.50.115, or will they have broader authority to prescribe?

- Comment: PQAC recommends that if this bill creates two tiers of licenses, that there be a specific identifier on those midwives' credentials who have been granted a limited prescriptive license extension. This will ensure pharmacy licensees are able to determine if the person writing the prescription has the authority to do so.

- Comment: PQAC has identified that the appropriate and necessary statutes have not been amended in order for midwives to have prescriptive authority as outlined in H1639.1/21. For midwives to obtain prescriptive authority, amendments should be made to the Legend Drug Act, chapter 69.41 RCW. Specifically, RCW 69.41.030(1) and 69.41.010(17)(a) would need to be amended to further align midwives with others health care professions under the Legend Drug Act. In addition, if the intent is for midwives to obtain the ability to prescribe controlled substances then amendments should be made to the Uniform Controlled Substances Act, chapter 69.50 RCW. Specifically, RCW 69.50.101(mm)(1) would need to be amended.

Section 4 – The secretary, after consultation with representatives of the midwife advisory committee, the pharmacy quality assurance commission, and the Washington medical commission, may adopt rules that authorize licensed midwives to ((~~purchase and use~~)) prescribe, obtain, and administer legend drugs and devices in addition to the drugs authorized in this chapter.

- Comment: Under the language of 1639.1/21, PQAC is unsure when it will be consulted by the secretary of health. Specifically, will PQAC be consulted when rules are adopted to identify medications and therapies for the prevention and treatment of common prenatal and postpartum conditions, and hormonal nonhormonal family planning methods for those who possess the limited prescriptive license extension?

We also encourage the Midwifery Advisory Committee to ensure appropriate checks and balances are in place to supervise prescribing midwives. In addition, we would encourage the Secretary of Health to ensure that every licensee is registered with the Prescription Monitoring Program (PMP) if controlled substances are prescribed.

PQAC appreciates the opportunity to comment on the Sunrise Review: Midwifery Scope of Practice and supports further collaboration on amendments to the applicant's report to ensure patient safety, health, and welfare.

DRAFT

STATE OF WASHINGTON

DEPARTMENT OF HEALTH

To: Department of Health

Cc: Martin Pittioni, Director, HSQA – Office of Health Professions, Terri Ferreira, Pharmacy Quality Assurance Commission Chair

From: Lauren Lyles-Stolz, Executive Director, Pharmacy Quality Assurance Commission

Date: July 16, 2021

Subject: PQAC Sunrise Review Comments: Optometrist Scope of Practice Expansion

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The Pharmacy Quality Assurance Commission (PQAC) thanks the Department of Health for the opportunity to provide remarks on the Sunrise Review: Optometrist Scope of Practice Expansion Draft. PQAC appreciates the Optometric Physicians of Washington for their initiative to further advance their profession's scope of practice, education, and training through the legislature's sunrise review process. We understand that optometry care and access is instrumental to improving the ocular health of Washingtonians.

The Legislature has provided in current statute the expectations for optometrists who prescribe and administer drugs and devices in Washington. This includes: no oral corticosteroids; no administration of injections or infusions except epinephrine by injection for the treatment of anaphylactic shock' and the ability to prescribe oral non-legend drugs, oral Schedule III-V controlled substances, and Schedule II hydrocodone combinations products, if authorized by the Board of Optometry (board). In addition, an optometrist may not 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.

Additionally, the board, with the approval of and in consultation with the PQAC, may establish in rule, the specific guidelines for the prescription and administration of drugs by optometrists so that licensed optometrists and persons filling their prescriptions have a clear understanding of which drugs and which dosages or forms are included in the authority granted by this section.

Draft

After review of the bill request #3085.2/21 2nd draft, PQAC has identified the following three areas of concerns:

Section 2. (1)(iv) includes dispensing of samples as new service for optometrists which was previously banned under the former rules. This would require further amendments to RCW 69.45.010 to recognize optometrist(s) as a practitioner notwithstanding their current scope of practice. This amendment would legally authorize drug manufacturers to distribute drug samples to optometrists.

This proposal would also lift a prohibition on optometrists performing and prescribing steroid injections and infusions. PQAC requests further clarification on the intent and additional training behind the significant prescribing and practice shift and the perceived impact on patient care before providing additional recommendations.

Section 2. (10)(a) states: Any optometrist authorized by the board shall be permitted to purchase diagnostic pharmaceutical agents for use in the practice of optometry. Any optometrist authorized by the board shall be permitted to prescribe therapeutic pharmaceutical agents in the practice of optometry. *Optometrists authorized by the board to purchase pharmaceutical agents shall obtain them from licensed drug suppliers or pharmacists on written orders placed in the same or similar manner as any physician or other practitioner so authorized*. Purchases shall be limited to those pharmaceutical agents specified in this section, based upon the authority conferred upon the optometrist by the board consistent with the educational qualifications of the optometrist as established in this section.

The proposed *italicized* language should align with the current term of art in the pharmacy practice for both "drug suppliers" and "written orders." Instead it should read "wholesalers" in lieu of "drug suppliers," unless drug supplier is intended to have different meaning. If so, could the applicant provide further explanation on what is meant by "drug suppliers" for overall clarity? In addition, "written order" should be replaced with "prescription and/or chart order." Further clarification on the latter would be appreciated to fully understand the intent behind the use of written orders versus prescriptions. It's also worth noting that controlled substances will be required to be transmitted electronically beginning January 1, 2022 unless a practitioner has qualified for a waiver through the Department of Health. This should be taken into consideration when providing additional clarity regarding the use of the term written order above.

Finally, we would be remissed not to express support for inclusion of the ICD-10 code or diagnosis on an optometrist's prescription to help pharmacists determine if a prescription is within the scope of practice.

We acknowledge the perceived challenge of access to ocular health services identified in the proposal; however, PQAC does not support the applicant's proposal as written. PQAC appreciates the opportunity to comment on the Sunrise Review: Optometrist Scope of Practice Expansion Draft and supports further collaboration on amendments to the applicant's report.

Draft

PROPOSED RULE MAKING

CR-102 (December 2017)
(Implements RCW 34.05.320)
Do **NOT** use for expedited rule making

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: May 28, 2021
TIME: 11:03 AM

WSR 21-12-074

Agency: Department of Health

☒ **Original Notice**

☐ **Supplemental Notice to WSR**

☐ **Continuance of WSR**

☒ **Preproposal Statement of Inquiry was filed as WSR** 20-14-129 **; or**

☐ **Expedited Rule Making--Proposed notice was filed as WSR ; or**

☐ **Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1).**

☐ **Proposal is exempt under RCW .**

Title of rule and other identifying information: (describe subject) Chapter 246-945 WAC. The Department of Health (department), in consultation with the Pharmacy Quality Assurance Commission (commission), is proposing three new sections of rule to move fees for all license types collected by the commission into the newly created chapter 246-945 WAC. These proposed sections are WAC 246-945-990 - Pharmaceutical licensing fees and renewal cycle, WAC 246-945-991 - Hospital pharmacy associated clinics fees and renewal cycle, and WAC 246-945-992 - Fee payment. The department, in consultation with the commission, is also proposing changing licenses to a two-year renewal cycle for pharmacy professionals as requested by interested parties and adding a new fee for the registration of a remote dispensing site created by the passage of Substitute Senate Bill (SSB) 6086.

Hearing location(s):			
Date:	**Time:**	**Location:** (be specific)	**Comment:**
7/6/2021	11:00 am	In response to the coronavirus disease 2019 (COVID-19) public health emergency, the Department of Health will not provide a physical location for this hearing to promote social distancing and the safety of the citizens of Washington State. A virtual public hearing, without a physical meeting space, will be held instead. Register in advance for this webinar: https://us02web.zoom.us/webinar/register/WN_w1wRPWnXREeTRh0qrEphiA After registering, you will receive a confirmation email containing information about joining the webinar.	

Date of intended adoption: 07/14/2021 (Note: This is **NOT** the **effective** date)

Submit written comments to:

Name: Cori Tarzwell

Address: 111 Israel Rd SE
Tumwater, WA 98501
Email: https://fortress.wa.gov/doh/policyreview
Fax: N/A
Other: HSQAfeerules@doh.wa.gov
By (date) 07/06/2021

Assistance for persons with disabilities:
Contact Cori Tarzwell
Phone: 3602364981
Fax: N/A
TTY: 711
Email: hsqafeerules@doh.wa.gov
Other: N/A
By (date) 06/30/2021

Purpose of the proposal and its anticipated effects, including any changes in existing rules: The purpose of this proposal is threefold. First, this proposal will move all existing fees for license types collected by the commission into the newly created chapter 246-945 WAC. The commission recently completed a nearly three-year project to update all the rules under the commission's authority and combine them into one streamlined chapter, chapter 246-945 WAC. As fees fall under the authority of the Secretary of Health (secretary), the commission could not move the fee rules as part of that original package. The proposed rule moves: pharmaceutical licensing fees and renewal cycles in WAC 246-907-030 to WAC 246-945-990; fees for hospital pharmacy associated clinics and renewal cycles in WAC 246-907-0302 to WAC 246-945-991; and rules regarding fee payments in WAC 246-907-040 to WAC 246-945-992.

Second, this proposal transitions licenses to a two-year renewal cycle for pharmacists, pharmacy technicians, pharmacy interns, and pharmacy assistants. This was requested by interested parties during the chapter update which established chapter 246-945 WAC. Effectively, licensees would still pay the same total amount over a two-year period, however licensees would pay that cost one time at the beginning of the two-year license cycle, rather than spreading it across two years.

Finally, this proposal establishes a new fee for the Opioid Use Disorder (OUD) remote dispensing site registration in WAC 246-945-030. SSB 6086 established a registration allowing a pharmacy to apply for a registration that would extend the pharmacy's license to cover a remote dispensing site specifically for FDA-approved medications indicated for the treatment of OUD. SSB 6086 also granted the department authority to establish a fee for this registration. Department staff reviewed this registration and have proposed a fee of $55. This aligns with fees for similar registration or licenses collected by the commission. Once this fee is in place and the department begins collecting data on the actual cost to maintain this registration, department fiscal staff will review and analyze this fee to determine if any changes are needed. Establishing a registration fee for the OUD remote dispensing sites is necessary as part of implementing SSB 6086. Furthermore, the operational costs of a profession must be fully borne by that profession by law.

Originally the CR101 for this proposal, WSR 20-14-129, stated the department and commission would consider restructuring the drug researcher fee to allow for a non-controlled substance researcher fee. However, the commission has determined further evaluation is necessary before a restructuring is feasible, so this item has been removed from this package at this time.

Reasons supporting proposal: Moving fees collected by the commission into the chapter recently created and updated by the commission will streamline the rules and make it easier for licensees to find necessary information related to their license. It also aligns the structure of the commission's rules chapter with other professions, making it easier for the public to find information. While the commission could not address the fees and transition to a two-year cycle directly in the chapter re-write, the commission did create continuing education (CE) rules that align with a two-year renewal cycle. Those sections of the new chapter have a delayed effective date to align with this fee proposal. If this proposal is not adopted, the commission will need to perform additional rulemaking to adjust the CE sections accordingly.

Establishing a registration fee for the OUD remote dispensing sites is necessary as part of implementing SSB 6086. Furthermore, the operational costs of a profession must be fully borne by that profession by law.

Statutory authority for adoption: RCW 43.70.110; RCW 43.70.250; and SSB 6086 (chapter 244, Laws of 2020)

Statute being implemented: SSB 6086 (chapter 244, Laws of 2020)

Is rule necessary because of a:

Federal Law?	☐ Yes	☒ No
Federal Court Decision?	☐ Yes	☒ No
State Court Decision?	☐ Yes	☒ No

If yes, CITATION:

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters: N/A

Name of proponent: (person or organization) Washington State Department of Health

☐ Private
☐ Public
☒ Governmental

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting:	Cori Tarzwell	111 Israel Rd SE, Olympia, WA 98504	360-236-4981
Implementation:	Lindsay Trant	111 Israel Rd SE, Olympia, WA 98504	360-236-2932
Enforcement:	Lauren Lyles	111 Israel Rd SE, Olympia, WA 98504	360-236-4853

Is a school district fiscal impact statement required under RCW 28A.305.135? ☐ Yes ☒ No

If yes, insert statement here:

The public may obtain a copy of the school district fiscal impact statement by contacting:
Name:
Address:
Phone:
Fax:
TTY:
Email:
Other:

Is a cost-benefit analysis required under RCW 34.05.328?

☐ Yes: A preliminary cost-benefit analysis may be obtained by contacting:
Name:
Address:
Phone:
Fax:
TTY:
Email:
Other:

☒ No: Please explain: Under RCW 34.05.328 a cost-benefit analysis is not required for fee rulemaking.

Regulatory Fairness Act Cost Considerations for a Small Business Economic Impact Statement:

This rule proposal, or portions of the proposal, **may be exempt** from requirements of the Regulatory Fairness Act (see chapter 19.85 RCW). Please check the box for any applicable exemption(s):

☐ This rule proposal, or portions of the proposal, is exempt under RCW 19.85.061 because this rule making is being adopted solely to conform and/or comply with federal statute or regulations. Please cite the specific federal statute or regulation this rule is being adopted to conform or comply with, and describe the consequences to the state if the rule is not adopted.

Citation and description:

☐ This rule proposal, or portions of the proposal, is exempt because the agency has completed the pilot rule process defined by RCW 34.05.313 before filing the notice of this proposed rule.

☐ This rule proposal, or portions of the proposal, is exempt under the provisions of RCW 15.65.570(2) because it was adopted by a referendum.

☒ This rule proposal, or portions of the proposal, is exempt under RCW 19.85.025(3). Check all that apply:

- ☐ RCW 34.05.310 (4)(b) (Internal government operations)
- ☐ RCW 34.05.310 (4)(c) (Incorporation by reference)
- ☐ RCW 34.05.310 (4)(d) (Correct or clarify language)
- ☐ RCW 34.05.310 (4)(e) (Dictated by statute)
- ☒ RCW 34.05.310 (4)(f) (Set or adjust fees)
- ☐ RCW 34.05.310 (4)(g) ((i) Relating to agency hearings; or (ii) process requirements for applying to an agency for a license or permit)

☐ This rule proposal, or portions of the proposal, is exempt under RCW .

Explanation of exemptions, if necessary:

COMPLETE THIS SECTION ONLY IF NO EXEMPTION APPLIES

If the proposed rule is **not exempt**, does it impose more-than-minor costs (as defined by RCW 19.85.020(2)) on businesses?

☐ No Briefly summarize the agency's analysis showing how costs were calculated.

☐ Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses, and a small business economic impact statement is required. Insert statement here:

The public may obtain a copy of the small business economic impact statement or the detailed cost calculations by contacting:

Name:
Address:
Phone:
Fax:
TTY:
Email:
Other:

Date: 05/27/2021	**Signature:** 
Name: Jessica Todorovich for Umair A. Shah, MD, MPH	
Title: Chief of Staff for Secretary of Health	

AMENDATORY SECTION (Amending WSR 18-21-123, filed 10/18/18, effective 1/1/19)

WAC 246-907-030 Pharmaceutical licensing fees and renewal cycle. (1) Pharmacist, pharmacy technician, pharmacy intern, and pharmacy assistant credentials must be renewed every two years on the practitioner's birthday as provided in chapter 246-12 WAC((~~, Part 2~~)).

(2) Pharmacy location credentials, controlled substance researcher registration, drug dog handler K9 registration, and other Controlled Substances Act registrations will expire on June 1st of each year.

(3) All other credentials, including health care entity, will expire on October 1st of each year, except the shopkeeper endorsement which expires annually associated with a business license issued by the department of revenue.

(4) The following nonrefundable fees will be charged for pharmacy professionals:

(a) All pharmacy professionals:

Title of fee	Fee
Verification of credential	$25.00
Duplicate credential	10.00

(b) Pharmacist:

((~~Original~~)) Initial credential	((~~$200.00~~)) $400.00
Renewal	((~~265.00~~)) 530.00
Late renewal penalty	((~~135.00~~)) 265.00
Expired credential reissuance	265.00
Inactive credential renewal	265.00
Retired active credential status application	((~~25.00~~)) 50.00
Retired active credential status renewal	((~~25.00~~)) 50.00
Temporary practice permit	100.00
Reciprocity (license by license transfer)	465.00

(c) Pharmacy technician:

((~~Original~~)) Initial credential	((~~$70.00~~)) $140.00
Renewal	((~~70.00~~)) 140.00
Late renewal penalty	((~~50.00~~)) 70.00
Expired credential reissuance	70.00

(d) Pharmacy intern:

((~~Original~~)) Initial credential	((~~$45.00~~)) $90.00
Renewal	((~~45.00~~)) 90.00
Late renewal penalty	((~~45.00~~)) 50.00
Verification of internship hours	25.00

Expired credential reissuance	45.00

(e) Pharmacy assistant:

((~~Original~~)) Initial credential	((~~$35.00~~)) $70.00
Renewal	((~~35.00~~)) 70.00
Late renewal penalty	((~~35.00~~)) 50.00
Expired credential reissuance	35.00

(5) The following nonrefundable fees will be charged for pharmaceutical firms:

(a) All pharmaceutical firms:

Verification of credential	$25.00
Duplicate credential	10.00
Facility inspection	400.00

(b) Pharmacy (includes hospital pharmacies):

Pharmacy credential (for hospital pharmacy associated clinics, see WAC ((~~246-907-0302~~)) 246-945-991)	
((~~Original~~)) Initial credential	$540.00
Renewal	540.00
Late renewal penalty	270.00
Pharmacy technician utilization	
((~~Original~~)) Initial utilization	100.00
Renewal	100.00
Controlled substances authority	
((~~Original~~)) Initial credential	150.00
Renewal	150.00
With differential hours	
((~~Original~~)) Initial credential	55.00
Renewal	55.00

(c) Nonresident pharmacy:

Pharmacy credential	
((~~Original~~)) Initial credential	$540.00
Renewal	540.00
Late renewal penalty	270.00
Controlled substances authority	
((~~Original~~)) Initial credential	150.00
Renewal	150.00

(d) Controlled substance researcher:

((~~Original~~)) Initial credential	$400.00
Renewal	400.00

(e) Other controlled substances act registrations (i.e., analytical laboratories, school laboratories):

((~~Original~~)) Initial credential	$360.00
Renewal	360.00

(f) Drug dog handler K9 registration:

((~~Original~~)) Initial credential	$55.00
Renewal	55.00

(g) Health care entity:

Health care entity credential	
((~~Original~~)) Initial credential	$540.00
Renewal	540.00
Late renewal penalty	270.00
Controlled substances authority	
((~~Original~~)) Initial credential	150.00
Renewal	150.00

(h) Drug manufacturer:

Manufacturer credential	
((~~Original~~)) Initial credential	$825.00
Renewal	825.00
Late renewal penalty	300.00
Controlled substances authority	
((~~Original~~)) Initial credential	150.00
Renewal	150.00

(i) Drug wholesaler - Full line:

Wholesaler credential	
((~~Original~~)) Initial credential	$825.00
Renewal	825.00
Late renewal penalty	300.00
Controlled substances authority	
((~~Original~~)) Initial credential	150.00
Renewal	150.00

(j) Drug wholesaler - Export:

Wholesaler credential	
((~~Original~~)) Initial credential	$825.00
Renewal	825.00
Late renewal penalty	300.00

(k) Drug wholesaler - OTC only:

((~~Original~~)) Initial credential	$465.00
Renewal	465.00
Late renewal penalty	235.00

(l) Drug wholesaler - Export nonprofit humanitarian organization:

Wholesaler credential	
((~~Original~~)) Initial credential	$25.00
Renewal	25.00
Late renewal penalty	25.00

(m) Legend drug sample distributor:

Distributor credential	
((~~Original~~)) Initial credential	$540.00
Renewal	540.00

Late renewal penalty	270.00
Controlled substances authority	
((~~Original~~)) Initial credential	150.00
Renewal	150.00

(n) Poison manufacturer/seller:

((~~Original~~)) Initial credential	$55.00
Renewal	55.00
Late renewal penalty	50.00

(o) Precursor chemicals:

((~~Original~~)) Initial credential	$55.00
Renewal	55.00
Late renewal penalty	50.00

(p) Itinerant vendor:

((~~Original~~)) Initial credential	$55.00
Renewal	55.00
Late renewal penalty	50.00

(q) Sodium pentobarbital for animal euthanization:

((~~Original~~)) Initial credential	$55.00
Renewal	55.00
Late renewal penalty	50.00

(r) Shopkeeper:

((~~Original~~)) Initial credential	$55.00
Renewal	55.00

(s) Remote dispensing site for opioid use disorder medications registration:

Initial credential	$55.00
Renewal	55.00
Late renewal penalty	50.00

AMENDATORY SECTION (Amending WSR 18-21-123, filed 10/18/18, effective 1/1/19)

WAC 246-907-0302 Hospital pharmacy associated clinics fees and renewal cycle. (1) Parent hospital pharmacy licenses with one or more hospital pharmacy associated clinics (HPAC) expire on June 1st of each year.

(2) A parent hospital pharmacy must submit fees for HPACs in addition to fees set in WAC ((~~246-907-030(4)~~)) 246-945-990(5). HPAC fees are due annually, except as provided under subsection (3)(d) of this section.

(3) A parent hospital pharmacy must submit the following nonrefundable fees based on category and number of HPACs as defined in WAC ((~~246-873A-020~~)) 246-945-233(3) added to the parent hospital pharmacy license.

(a) **Category 1 HPAC.** A parent hospital pharmacy must submit the Category 1 HPAC fee according to the number of Category 1 HPACs under the parent hospital pharmacy license.

HPAC tier	Number of Category 1 HPACs under parent hospital pharmacy license	Total annual fee
A	1-10	$895.00
B	11-50	$2,240.00
C	51-100	$3,125.00
D	Over 100	$4,025.00

(b) **Category 2 HPAC.** A parent hospital pharmacy must submit the Category 2 HPAC fee for each Category 2 HPAC under the parent hospital pharmacy license.

Category 2 HPAC fee	$755.00

(c) The department charges a processing fee of fifty-five dollars for an amended license to change the number of HPACs.

(d) If at any time a parent hospital pharmacy submits an addendum increasing the number of HPACs on the parent hospital pharmacy license, which changes the applicable HPAC tier to a higher fee amount, the parent hospital pharmacy shall submit the difference in fees with the addendum.

(e) The department will not refund fees when a tier reduction occurs between renewal periods.

AMENDATORY SECTION (Amending WSR 91-19-028, filed 9/10/91, effective 10/11/91)

WAC 246-907-040 Fee payment. (1) A licensed pharmacist, wholesaler, or manufacturer shall pay a facility inspection fee in lieu of the original license fee when there is only a change of facility location within the premises identified by the license address. Any change of location to a different address shall require a new application and payment of the original license fee.

(2) An original license fee shall be paid whenever there is any change in ownership, including change in business structure or organizational structure such as a change from sole proprietorship to a corporation, or a change of more than fifty percent ownership in a corporation.

(3) All fees for pharmacy professionals are charged on ((~~an annual~~)) a biennial basis and will not be prorated.

(4) All fees for pharmaceutical firms are charged on an annual basis and will not be prorated.

NEW SECTION

The following sections of the Washington Administrative Code are decodified and recodified as follows:

Old WAC Number	New WAC Number
246-907-030	246-945-990
246-907-0302	246-945-991
246-907-040	246-945-992

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: June 02, 2021
TIME: 8:24 AM

WSR 21-12-096

Agency: Department of Health- Pharmacy Quality Assurance Commission

Effective date of rule:

Emergency Rules

☒ Immediately upon filing.
☐ Later (specify)

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

☐ Yes ☒ No If Yes, explain:

Purpose: WAC 246-945-171 Retired active pharmacist license status, establishing a new section of rule. This adopted emergency rule will extend WSR 21-04-116 filed on February 1, 2021. On March 26, 2020, Governor Inslee signed proclamation 20-32 to help increase the number of healthcare workers available to meet the needs of patients during the coronavirus disease 2019 (COVID-19) pandemic. This proclamation included a provision that allows a pharmacist with a retired active pharmacist license status to practice pharmacy. Specifically, the proclamation amended WAC 246-863-080(2) to allow holders of a retired active pharmacist license status to practice pharmacy while the proclamation remains in effect.

However, the Pharmacy Quality Assurance Commission (commission) recently updated and consolidated all rules under its authority into one new chapter (chapter 246-945 WAC). In this rewrite process the requirements from WAC 246-863-080 and the retired active pharmacist license status no longer exist. Beginning July 1, 2020 chapter 246-945 WAC took effect and the commission no longer enforces WAC 246-863-080. This emergency rule matches the intent of the Governor's proclamation by reinstating a retired active pharmacist license status allowing retired pharmacists to practice pharmacy during emergent or intermittent circumstances and assist with the COVID-19 response. This emergency rule also reinstates the process for applying for a retired active pharmacist license and establishes the criteria for returning to active status.

Citation of rules affected by this order:

New: WAC 246-945-171
Repealed: N/A
Amended: N/A
Suspended: N/A

Statutory authority for adoption: RCW 18.64.005; RCW 18.64.205

Other authority:

EMERGENCY RULE

Under RCW 34.05.350 the agency for good cause finds:

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

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

Reasons for this finding: The immediate adoption of WAC 246-945-171 is necessary for the preservation of public health, safety, and general welfare. This rule allows retired pharmacists to assist in the response during public health emergencies such as the COVID-19 pandemic and is in line with the intent of Governor Inslee's proclamation 20-32. This emergency rule allows retired pharmacists to help meet the needs of patients during the COVID-19 pandemic through performing pharmacy services such as vaccine administration. Observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the public interest and the Governor's orders.

The commission has also authorized permanent rules on this topic and will proceed with standard rulemaking for permanent rules as soon as the COVID-19 response allows.

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

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

The number of sections adopted in order to comply with:

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

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

	New	0	Amended	0	Repealed	0

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

	New	1	Amended	0	Repealed	0

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

	New	0	Amended	0	Repealed	0

The number of sections adopted using:

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

Date Adopted: 05/28/2021	**Signature:** 
Name: Tim Lynch, PharmD, MS, FABC, FASHP	
Title: Pharmacy Quality Assurance Commission Chair	

NEW SECTION

WAC 246-945-171 Retired active pharmacist license status. (1) A pharmacist may apply for a retired active pharmacist license status if they:

(a) Hold an active pharmacist license issued by the commission under chapter 18.64 RCW that is in good standing;

(b) Submit an application on a form provided by the commission; and

(c) Pay the retired credential application fee as specified in WAC 246-907-030.

(2) A pharmacist with a retired active pharmacist license status shall practice only in emergent or intermittent circumstances.

(a) "Emergent" includes, but is not limited to, earthquakes, floods, times of declared war or other states of emergency.

(b) "Intermittent" means no more than a total of ninety days each year in Washington state.

(3) A pharmacist with a retired active pharmacist license status must renew every year, comply with WAC 246-12-130 and pay the retired credential renewal fee in WAC 246-907-030.

(4) To return to active status, a retired active pharmacist must comply with WAC 246-12-140 and pay the pharmacist license renewal fee in WAC 246-907-030.

PHARMACY QUALITY ASSURANCE COMMISSION (PQAC)
STRATEGIC PLANNING BRIEFING
2020-2022

Washington State Department of Health

Office of Health Professions (OHP)
Health System Quality Assurance (HSQA)

Vision

The Pharmacy Commission leads in creating a climate for the patient-focused practice of pharmacy as an integral part of an accessible, quality-based health system.

As a result, the citizens of Washington State:

Are well informed about their medication therapy;
Take responsibility and actively participate in their health outcomes;
Utilize pharmacists and other healthcare providers appropriately; and
Experience the highest level of health and wellness.

Mission

The mission of the Washington State Pharmacy Quality Assurance Commission is to promote public health and safety by establishing the highest standards in the practice of pharmacy and to advocate for patient safety through effective communication with the public, profession, Department of Health, governor and the legislature.

Strategic Planning Session Outcomes and Objectives

PQAC will review and vote on the following:

- New innovative goals
- Updated policy priorities
- Discuss next steps in strategic planning

PQAC New Innovative Goals

PQAC New Innovative Goals

1. Promote Public Health, Safety, and Quality Standards of Care in the Practice of Pharmacy
2. Promote Health Innovation to Increase Patient Access and Patient Outcomes
3. Ensure Health Equity and Mitigate Health Disparities

PQAC Sub-committees and Priorities

Leadership Committee: • Legislation • Commission Recruitment • Staffing/Training and SOP*	**Teri Ferreira & Jerrie Allard**
Budget Committee: • HELMS	**Ken Kenyon, Patrick Gallaher, Judy Guenther, & William Hayes**
Compounding Committee: • FDA MOU • Self-Inspection Worksheets	**Tim Lynch, Ken Kenyon, Uyen Thorstensen, & Hawkins DeFrance**
HPACs Committee: • Suspicious Orders	**Teri Ferreira, William Hayes, & Ken Kenyon**
CDTA WMC Committee: • Facility Enforcement Authority	**Tim Lynch & Teri Ferreira**
Strategic Planning Committee	**Jerrie Allard & Bonnie Bush**
Misfill and Pharmacy Work Condition Workgroup and Sunrise Committee	**Hawkins DeFrance, Patrick Gallaher, & Craig Ritchie**

Next Steps

Summary of Action Items

Strategic Planning Session: Action Items
1. Add Quarterly Standing Strategic Planning Sessions
2. Re-visit the Commission's mission and vision statement at Strategic Planning Session
3. [Insert Others….]

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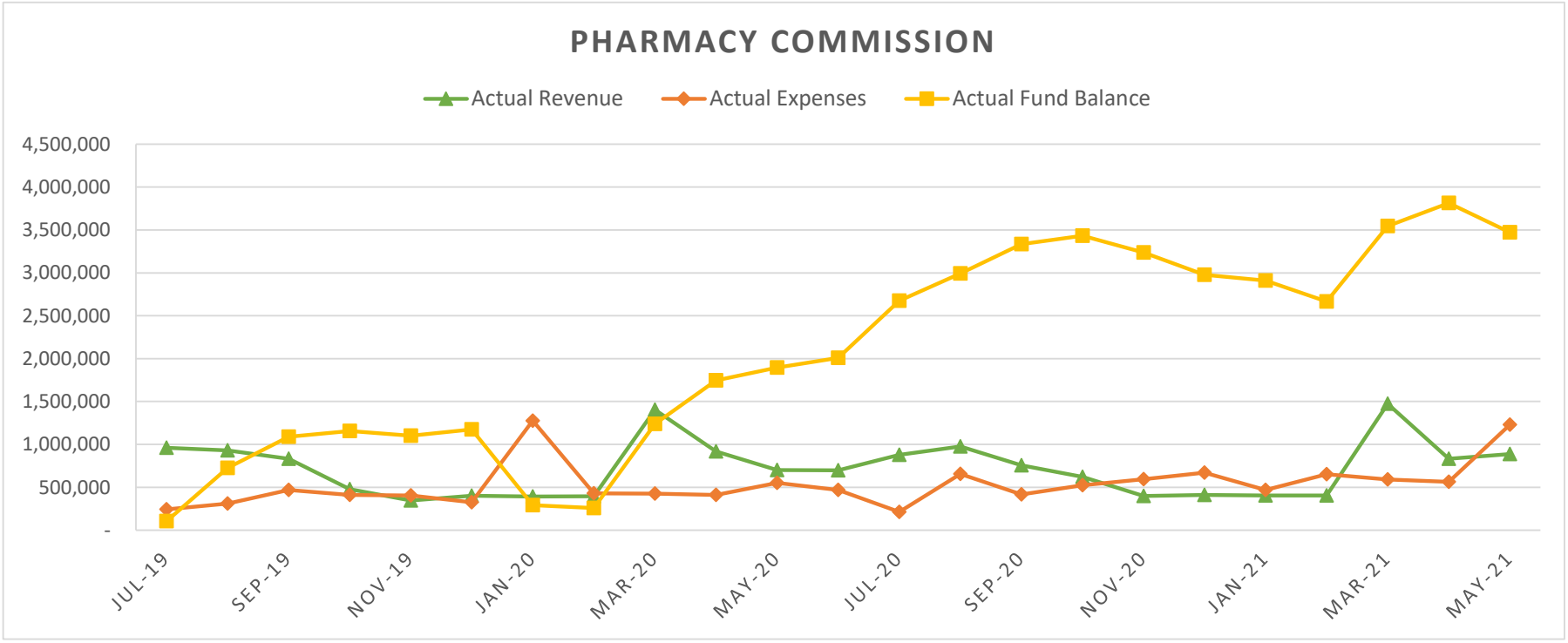
Washington State Department of Health

Pharmacy Quality Assurance Commission
2019-21 Biennial Budget Status Overview
For the period of July 1, 2019 to May 31, 2021

Health Professions Account Beginning Fund Balance on July 1, 2019	(615,920)
Revenue-to-Date	16,497,935
FY20 HELMS Assessment	(115,203)
Expenses-to-Date	(12,295,422)
Health Professions Account Fund Balance as of period end	3,471,389



Under the legislature's new compounding law (SHB 1445), should I continue to follow USP <797> requirements when diluting a reconstituted sterile medication, such as Remicade, according to federal food and drug administration-approved labeling?

Yes, the new compounding law exempts non-sterile and sterile products that only require reconstitution and mixing according to food and drug administration-approved labeling. Further manipulation of a reconstituted product**, such as dilution,** should be an indicator that compounding is occurring and USP <797> should be followed, per RCW 18.64.270(2). Additionally, under the new pharmacy standard of care rules, the commission expects pharmacists to utilize their professional judgment in the best interest of the patient.

Please note: This law will become effective July 25, 2021.