July 14, 2022 Washington State Pharmacy Quality Assurance Commission

Commission Business Meeting Materials

SAFETY. QUALITY. INNOVATION.

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
May 12, 2022 - Minutes

Convene: Chair, Teri Ferreira called the meeting to order May 12, 2022, 9:00 a.m.

Commission Members:
Teri Ferreira, RPh, Chair
Jerrie Allard, Public Member, Vice Chair
Uyen Thorstensen, CPhT
Hawkins DeFrance, Nuclear Pharmacist
Judy Guenther, Public Member
William Hayes, PharmD, CCHP
Helen H. Jung, PharmD, MBA
Ken Kenyon, PharmD, BCPS
Tim Lynch, PharmD, MS, FABC, FASHP
Craig Ritchie, RPh, JD
Matthew Ray, PharmD
Ann Wolken, PharmD, RPh

Commission Members Absent:
Bonnie Bush, Public Member
Patrick Gallaher, BS, BPharm, MBA, MPH

Staff:
Marlee O'Neill, Interim Executive Director, Pharmacy Commission
Lindsay Trant, Interim Deputy Director, Pharmacy Commission
Noelle Chung, AAG
Christopher Gerard, AAG
Hope Kilbourne, Policy Analyst
Joshua Munroe, Legislative and Rules Consultant
Irina Tiginyanu, Pharmacy Tech Consultant
Taifa "Nomi" Peaks, Pharmacist Consultant
Joanne Miller, Program Manager, Pharmacy
Amy L Robertson, Administrative Assistant, Pharmacy

Guest:
Ashley Bell, Behavioral Health Programs Coordinator, HSQA

1. Call to Order Teri Ferreira, Chair

1.1 Meeting Agenda Approval – May 12, 2022.

MOTION: Craig Ritchie moved to approve the meeting agenda for May 12, 2022. Hawkins DeFrance, second. Motion carries, 12:0.

1.2 Meeting Minutes Approval – March 24-25, 2022

MOTION: Craig Ritchie moved to approve the meeting minutes for March 24-25, 2022 correcting Ken Kenyon as absent and William Hayes as pulling items from consent agenda for discussion. Hawkins DeFrance, second. Motion carries, 12:0.

2. Consent Agenda

2.1 National Precursor Log Exchange Monthly Dashboard-March 2022
2.2 Pharmaceutical Firms Application Report
March 2, 2022, thru May 1, 2022
2.3 Ancillary Utilization Plans Approval

2.3.1 Brewster Pharmacy
2.3.2 Community Health Center of Snohomish Country
2.3.3 ENT Meds
2.3.4 Kelley Ross Pharmacy
2.3.5 Mercury Pharmacy
2.3.6 Penninsula Community Health Services
2.3.7 Rosauers Supermarket
2.3.8 Snoqualmie Valley Hospital
2.3.9 South Kitsap Pharmacy
2.3.10 Sultan Pharmacy and Natural Care
2.3.11 Tri-Area Pharmacy
2.3.12 Village Pharmacy Services

2.4 Pharmacy Technician Training Program Approval

2.4.1 Charter Collage
2.4.2 Cle Elum Pharmacy multiple locations
2.4.3 Custom Prescription Shoppe
2.4.4 Hi-School Pharmacy multiple locations
2.4.5 New Health Programs Association multiple locations
2.4.6 Olympic Pharmacy and Healthcare Services
2.4.7 Albertsons
2.4.8 Pharmaca

MOTION: Craig Ritchie moved to approve the consent agenda minus the agenda items pulled for discussion in 2.5. Jerrie Allard, second. Motion carries, 12:0.

2.5 Regular Agenda/Items Pulled from Commissioners pulled the following items from 2.3 and 2.4 for further discussion.

2.3 Ancillary Utilization Plans Approval

2.3.3 ENT Meds (Hayes)

MOTION: William Hayes moved to approve 2.3.3 contingent upon the entity change its references to WAC 246-901 to the new WAC 246-945 and adding that ancillary staff may perform other duties as assigned by the supervising pharmacist as long as consistent with their scope of practice. Craig Ritchie, second. Motion carries, 12:0.

2.3.4 Kelley Ross Pharmacy (Hayes)

MOTION: Tim Lynch moved to approve 2.3.4 contingent on the language for technicians/assistants stating "will perform duties within scope of practice, including, but not limited to…" as well as updating the immunization language per the guidance G003 Pharmacy Technician Administration Guidance (wa.gov). Craig Ritchie, second. Motion carries, 12:0.

2.3.9 South Kitsap Pharmacy (Hayes)

MOTION: Tim Lynch moved to approve 2.3.9 as written with the understanding the subcommittee will draft new language for future sample AUPs. William Hayes, second. Motion carries, 12:0.

2.3.10 Sultan Pharmacy and Natural Care (Hayes)

MOTION: William Hayes moved to approve 2.3.10 contingent upon updating AUP with the newest WAC citation. Craig Ritchie, second. Motion carries, 12:0.

2.3.12 Village Pharmacy Services (Hayes)

MOTION: William Hayes moved to approve 2.3.12 contingent upon updating the immunization and testing language per policy guidance G003 Pharmacy Technician Administration Guidance (wa.gov). Craig Ritchie, second. Motion carries, 12:0.

2.4 Pharmacy Technician Training Program Approval

2.4.4 Hi-School Pharmacy multiple locations (Hayes)

MOTION: Teri Ferreira moved to approve 2.4.4 contingent on the pharmacy adding to their policy that "all student specific records must be retained on site and kept for a minimum of two years as well as be made available within 72 hours of request." Craig Ritchie, second. Motion carries, 12:0.

2.4.5 New Health Programs Association multiple locations (Hayes)

MOTION: Teri Ferreira moved to approve 2.4.5 contingent on adding language in line with the SBAR: "The pharmacy commission must be notified in writing or email prior to any significant changes to the program, including change in director, course content, and timeframe" and "all student specific records must be retained on site and kept for a minimum of two years as well as be made available within 72 hours upon request." And remove "program staff must be available to students on a 24-hour basis daily with a policy and procedure in place for this." Craig Ritchie, second. Motion carries, 12:0.

2.4.6 Olympic Pharmacy and Healthcare Services (Ferreira)

MOTION: Teri Ferreira moved to approve 2.4.6 contingent upon adding immunization language and program staff must be available to students. Craig Ritchie, second. Motion carries, 12:0.

2.4.8 Pharmaca (Hayes)

MOTION: William Hayes moved to approve 2.4.8 contingent upon the pharmacy providing the following language in their policies: "The pharmacy commission must be notified in writing or email prior to any significant changes to the program. And all student-specific records must either be retained on site and kept for a minimum of two years as well as be available within 72 hours of request. Additionally, the pharmacy must provide an AUP specific to the program." Craig Ritchie, second. Motion carries, 12:0.

3 Old Business

3.1 SSB 5229: Update on Health Equity CE Rulemaking – Ashley Bell provided an update on the implementation of SSB 5229 and the Department's rulemaking on continuing education requirements for health equity and presented a draft of new language for WAC 246-12-710.

3.2 Update on Commission Workgroup Participation – Taifa "Nomi" Peaks, Pharmacist consultant provided an update on her participation in the STI and HBV Legislative Advisory Group and the Washington State After Action Review Task Force. .

4 New Business

4.1 Voting Delegate at NABP Annual Meeting, Sharing of Proposed Amendments, and Consideration of Proposed Resolutions

MOTION: Ken Kenyon moved to delegate voting rights to Teri Ferreira at the 118th NABP Annual Meeting with back-up rights for Jerrie Allard. Craig Ritchie, second. Motion carries, 12:0.

Marlee O'Neill presented two amendments NABP is proposing for discussion in 2023 at the 119th annual meeting:

Technical Amendment Set 1: Allows a member of a board of pharmacy serving on a NABP standing committee to continue serving on that committee even if they are no longer a board of pharmacy member as long as they were a member at the time they were appointed to the NABP committee.

Technical Amendment Set 2: Allows for voting on proposed resolutions and amendments to occur electronically and not just by voice vote or standing vote.

Marlee O'Neill presented eight resolutions that will be discussed and voted on at the 118th NABP Annual Meeting.

- **Proposed Resolution:** NABP works with the FDA, its member Boards and other stakeholders, to develop a pathway to enable a 503A Pharmacy under common ownership with a 503B Outsourcing Facility to dispense preparations compounded by such 503B Outsourcing Facility.

  MOTION: Tim Lynch moved to support this resolution. Hawkins DeFrance, second. Motion carries, 10:1:1 (Yay: 10; Nay:1, Ritchie; Abstain: 1, Ray)

  Stakeholder comments:

  Dawn Ipsen, Compounding Pharmacist, has concerns with the statement simply from lack of understanding of intention, purpose, or need. Without further information, it would be in the best interest of our residents of Washington State to abstain from participating or take a "no stance" until further information or need is demonstrated.

  One concern is 503A compounding pharmacies are prohibited from dispensing prescription medications that are not patient specific. It is vital that we ensure that we never go out of that path onto anything that would make us appear to be a wholesaler. If we do become a wholesaler in any instance of that, then we are no longer a 503A and become a 503B. I agree with Commissioner Allard, until provided clear detail information, the State of Washington needs to abstain from this.

  Heejoo Park (chat): What is the current status on selling 503B compounded products to others? What if the 503A is in a different state, but owned by the same owner. I agree that this is too unclear to make any good decision.

Erika Anderson believes this involves 503B companies wanting to distribute products to their own 503A; not within their own companies. This may be a quality issue as well.

- **Proposed Resolution:** NABP formally request that the FDA provide timely guidance to states around how they intend to assess whether a state's licensing statutes, regulations and processes are consistent with the national licensing standards. NABP formally request that the FDA focus its assessment of consistency in areas that truly impact patient safety. NABP encourage the boards of pharmacy to provide public comment on the proposed regulations.

  MOTION: Craig Ritchie moved to authorize commission delegates to support this proposed resolution. Ken Kenyon, second. Motion carries, 12:0.

- **Proposed Resolution:** NABP continue its efforts to educate the DEA and Congress on the importance of state regulation of telepharmacy and the potential negative impact that DEA regulation could have on patient access to medications. NABP offer to assist the DEA to better understand models of care, including those concerning models, that DEA broadly is defining as telepharmacy to ensure the focus of impending regulations align with areas of concerning practices. NABP continue to encourage boards of pharmacy to engage with DEA and their congressional delegation, if allowed, on any proposed regulations.

  MOTION: Ken Kenyon moved to support the resolution as stated. Craig Ritchie, second. Motion carries, 12:0.

  William Hayes spoke on the record how important this resolution is.

- **Proposed Resolution:** NABP convene a task force that includes appropriate stakeholders to examine this issue and recommend amending, if necessary, the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy to include a foundational definition of pharmacists as health care providers.

  MOTION: Craig Ritchie moved to support the resolution to include a foundational definition of pharmacists as health care providers. Hawkins DeFrance, second. Motion carries, 12:0.

- **Proposed Resolution:** NABP conduct a survey of states and U.S. jurisdictions to collect data regarding pharmacy e-prescribing concerns and if appropriate, appoint a task force to further study the issue and make recommendations for improving e-prescribing functionality.

  MOTION: Ken Kenyon moved to support the electronic prescribing functionals in pharmacy practice resolution. Craig Ritchie, second. Motion carries, 12:0.

- **Proposed Resolution:** National Association of Boards of Pharmacy along with other stakeholders including, but not limited to, the Alliance for Pharmacy Compounding, will form a joint committee to convene, deliberate, and make recommendations on this important issue no later than Autumn 2022.

  MOTION: Craig Ritchie moved to approve authorizing our representatives to vote for the National Association of Boards of Pharmacy along with other stakeholders including, but not limited to, the Alliance for Pharmacy Compounding, will form a joint committee to convene, deliberate, and make recommendations on this important issue no later than Autumn 2022. Hawkins DeFrance, second. Motion carries, 12:0.

- **Proposed Resolution:** NABP create a system to allow efficient interstate portability of a state licensure compact.

  MOTION: Ken Kenyon moved to support the resolution on efficient interstate portability of state licensure. Craig Ritchie, second. Motion carries, 12:0.

- **Proposed Resolution:** NABP examine the development of a national standardized pharmacy jurisprudence examination for the state boards of pharmacy to assess competence for licensure.

  MOTION: Ken Kenyon moved to approve the resolution for NABP examine the development of a national standardized pharmacy jurisprudence examination for the state boards of pharmacy to assess competence for licensure. Judy Guenther, second. Motion carries, 12:0.

  After significant discussion, commissioners and stakeholders expressed similar thoughts in that this resolution is worth investigating.

4.2 NABP Committees and Task Forces - NABP is seeking volunteers to serve on its 2022-2023 committees and task forces. Commission staff will investigate for additional information.

William Hayes expressed interest in the Committee on Law Enforcement/Legislation, but he is not able to participate this year. Helen Jung expressed interest in the Advisory Committee on Examinations.

4.3 Power of Providers Advisory Group Nominations – Joanne Miller informed the commission of this opportunity to work on this advisory group that recognizes the power all licensed health care providers have in encouraging COVID-19 vaccination in the community. Their purpose is to work on strategies to support healthcare providers in their COVID-19 vaccination efforts with the unique challenges and pressures providers are facing in this pandemic. Meetings are first Thursday each month 1:30-2:30 p.m.

MOTION: Jerrie Allard moved to nominate Tim Lynch and Patrick Gallaher (if available) to serve on the advisory group. Ken Kenyon, second. Motion carries, 12:0.

4.4 Euthanasia Training Program approval – Joanne Miller informed the commission of the request by Shelter Medicine University of Florida for approval of their euthanasia training program. This program maintains the list of individuals who completed the program and veterinarians providing the training indefinitely.

MOTION: Craig Ritchie moved to approve the program. Hawkins DeFrance, second. Motion carries, 12:0.

4.5 Inspection Reports for 2022 Renewals for Nonresident Pharmacies – Marlee O'Neill informed the commission that a number of non-resident pharmacies are unable to timely get an inspection for renewal due to workload because of (mostly) COVID related issues. To address this issue, the Commission may consider the following options: 1) do nothing; 2) grant extensions; or 3) grant a waiver. The office of customer service (OCS) can accommodate the decision of the commission, however, of these choices, a one-time one-year waiver option would be less workload on our OCS and pharmacy staff.

MOTION: Craig Ritchie moved to waive the inspection for the 2022 renewal cycle (one-year) if the non-resident pharmacy provides a letter from their home-state stating that the home-state cannot timely complete an inspection. Teri Ferreira, second. Motion carries, 12:0.

Stakeholder comments:

Erika Anderson – Suggested the commission consider accepting an inspection report from a state board of pharmacy for those pharmacies that do not have USP <797> as a minimum requirement (particularly pertaining to compounding). This might help in this interim process.

4.6 Commission Leadership Elections

Vice Chair – Jerrie Allard was unanimously elected (12:0) to continue her work as vice chair as there were no further nominations (no motion needed).

MOTION: Jerrie Allard moved to nominate Teri Ferreira as chair beginning July 1, 2022. Judy Guenther, second. Motion carries, 12:0.

5. Summary of Meeting Action Items

1.2 Consent Agenda – staff revise consent agenda to reflect items removed from the consent agenda

2.5 Regular Agenda Items pulled from Consent Agenda – Staff will follow-up on contingent AUPs and technician approvals as directed. Work will continue with the pharmacy practice subcommittee to revise the sample AUP.

3.1 SSB 5229: Update on Health Equity CE Rulemaking – Staff will follow-up with Ashley Bell with information requested.

4.1 NABP Annual meeting – Teri Ferreira and Jerrie Allard will serve as voting delegates at the annual meeting with guidance from the commission.

4.2 NABP Committees and Task Forces – staff will gather more information on the NABP's law enforcement legislation task force and the advisory committee on examinations as well as time commitment for participation.

4.3 Power of Providers Advisory Group Nominations – Staff will contact Patrick Gallaher regarding ability/willingness to serve on this committee. Staff will confirm Tim Lynch and Patrick Gallaher (if available) to serve on POP Advisory Group.

4.4 Euthanasia Training Program – Staff will inform Shelter Medicine University (FL) that their program was approved.

4.5 Inspection Reports for 2022 Renewals for Nonresident Pharmacies – Staff will notify and work with OCS on the commission's that they will waive the inspection requirement for non-resident pharmacies for the 2022 renewal cycle (one-year) if the non-resident pharmacy provides a letter from their home-state stating that the home-state cannot timely complete an inspection.

Meeting adjourned: 12:47 p.m.

STATE OF WASHINGTON
Pharmacy Quality Assurance Commission
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Pharmacy Quality Assurance Commission Meeting
May 13, 2022 - Minutes

Convene: Chair, Teri Ferreira called the meeting to order May 13, 2022, 9:01 a.m.

Commission Members:
Teri Ferreira, RPh, Chair
Jerrie Allard, Public Member, Vice Chair
Uyen Thorstensen, CPhT
Hawkins DeFrance, Nuclear Pharmacist
Judy Guenther, Public Member
William Hayes, PharmD, CCHP
Helen H. Jung, PharmD, MBA
Ken Kenyon, PharmD, BCPS
Tim Lynch, PharmD, MS, FABC, FASHP
Craig Ritchie, RPh, JD
Matthew Ray, PharmD

Commission Members Absent:
Bonnie Bush, Public Member
Patrick Gallaher, BS, BPharm, MBA, MPH
Ann Wolken, PharmD, RPh

Staff:
Marlee O'Neill, Interim Executive Director, Pharmacy Commission
Lindsay Trant, Interim Deputy Director, Pharmacy Commission
Christopher Gerard, AAG
Hope Kilbourne, Policy Analyst
Joshua Munroe, Legislative and Rules Consultant
Taifa "Nomi" Peaks, Pharmacist Consultant
Joanne Miller, Program Manager, Pharmacy
Amy L Robertson, Administrative Assistant, Pharmacy

1. Call to Order Teri Ferreira, Chair

1.1 Meeting Agenda Approval – May 13, 2022.

MOTION: Craig Ritchie moved to approve the meeting agenda for May 12, 2022. Ken Kenyon, second. Motion carries, 11:0.

2. New Business

2.1 Compounding Animal Drugs from Bulk Drug Substances – Taifa "Nomi" Peaks informed the commission that staff members recommend the commission affirm that while it is aware of the FDA's GFI# 256, Washington law only permits a pharmacist in a state-licensed pharmacy to compound animal drugs from BDS for office stock for nonfood-producing animals if one of the exceptions in RCW 18.64.011(21) applies, or the pharmacy has also obtained a manufacturer license. Exceptions:

- The activities of a practitioner who, as an incident to his or her administration or dispensing such substance or device in the course of his or her professional practice, personally prepares, compounds, packages, or labels such substance or device.
- The activities of a licensed pharmacy that compounds a product on or in anticipation of an order of a licensed practitioner for use in the course of their professional practice to administer to patients, either personally or under their direct supervision;

- The practice of a licensed pharmacy when repackaging commercially available medication in small, reasonable quantities for a practitioner legally authorized to prescribe the medication for office use only;
- The distribution of a drug product that has been compounded by a licensed pharmacy to other appropriately licensed entities under common ownership or control of the facility in which the compounding takes place; or
- The delivery of finished and appropriately labeled compounded products dispensed pursuant to a valid prescription to alternate delivery locations, other than the patient's residence, when requested by the patient, or the prescriber to administer to the patient, or to another licensed pharmacy to dispense to the patient.

MOTION: Craig Ritchie moved to direct staff to create an FAQ to address the exceptions discussed and clearly identify what is and is not allowed. Jerrie Allard, second. Motion carries, 11:0.

Stakeholder input:

- **Dawn Ipsen, chair, WSPA** Compounding Special Interest Group (SIG) and **Michelle Moser** (owner, Makers Compounding Pharmacy in Mount Vernon, compounding pharmacist) asked/discussed the following:
  1. If a compounded medication is needed on Saturday, and the pharmacies do not open until Monday, do these exceptions apply?
  2. Does FDA's GFI #256 allow veterinarians to have office stock to resell? Nomi Peaks – the FDA's GFI# 256 at page 16; section 4, may help address question about resale.
  3. When will the compounding subcommittee meet?

- **Aja Senestraro, Veterinarian, Veterinary Board member** – an FAQ would be very helpful. Dawn described a very common scenario. The whole office use and dispensing from that office use is not well understood.

2.2 Plan for Return to In-person Meetings

MOTION: Ken Kenyon moved to hold the July 2022 meeting virtually as it is not reasonably safe to hold the meeting in person and to have staff explore venues to reserve for future in-person meetings once it is reasonably safe to do so. Craig Ritchie, second. Motion carries, 11:0.

3. Rules and Legislative Updates.

3.1 Overview of Rules Process Presentation – Joshua Munroe delivered a presentation on rules and the rulemaking process.

3.2 Update on Uniform Facilities Enforcement Framework – Lindsay Trant updated the commission on the UFEF: The draft is almost finished – it includes adding fining authority, placing conditions on a license, and a statement of deficiencies/plan of correction process for facility enforcement in addition to the process we have for inspections. The division will send the full request to the agency to consider presenting it the legislature in 2023.

3.3 Implementation for SHB 1675: Dialysate/dialysis device manufacturer and wholesalers – Joshua Munroe updated the commission on the implementation of SHB 1675, specifically for the commission to consider amending WACs 246-945-090 through –093 to include manufacturers and wholesalers.

MOTION: Jerrie Allard moved to direct staff to draft a policy document to review at the next meeting as well as staff continue to monitor the priority list of our rulemaking projects. Craig Ritchie, second. Motion carries, 11:0.

Stakeholder input:

- **Gail McGaffick,** lobbyist, Fresenius Medical Care North America urged the commission to prioritize this issue. Also, if a guidance document is issued, can stakeholders legally rely on the guidance document in lieu of rules?

  Chris Gerard – informed the commission the question cannot be answered until the guidance document is complete.

- **Jessica Fortescue,** lobbyist, Baxter Healthcare – agree with Gail to speed up and prioritize the rulemaking if possible.

- **Jenny Arnold,** WSPA – this law change was reflecting what is currently existing in practice and ensure the law is up to date and accurate. I do not think it is urgent, but important.

3.4 Initial Discussion for Rulemaking on Accessible Labeling – Joshua Munroe reviewed the status of CR-101 related to accessible labeling. A survey distributed to licensees was proposed for the purpose of collecting data on whether and how accessibility services are currently provided by licensees. Lindsay Trant informed the commission the status of PQAC staff resources and how we are moving forward to complete this rulemaking.

Craig Ritchie would also like to have information from software vendors. Matthew Ray expressed concern to specifically connect to the more rural stakeholders.

MOTION: Craig Ritchie moved to authorize staff to develop a survey to licensee(s) to determine what is available and what impact is anticipated. Hawkins DeFrance, second. Motion carries, 11:0.

Stakeholder input:

- **Sharla Glass, Envision America** – suggests obtaining guidance into the standards from USP the committees that drafted Chapter 17 and 1265. As well as Wisconsin Health Literacy group has a lot of information.

- **Jenny Arnold, WSPA** – Nevada also has rules that could be used as a model. Encourage the commission to consider a rule making workshop.

- **David Streeter, Washington State Hospital Association** – An important rule making and would like to offer to help develop and distribute the survey. Technological capabilities required of pharmacies to implement both vision/language translation services. Also, the cost element has varied greatly. I have other recommendations that we would be happy to provide to the commission offline.

- **Don Downing, University of Washington School of Pharmacy** – the definition of label should be considered broader than the traditional prescription container label and that cloud-

based information should be considered part of a label, even if it's a QR code or something to ensure patients and non-resident pharmacies and providers can access the information needed for safety. I have not heard any discussion about the effectiveness and safety of these various solutions. Finally, small business economic impact study would need to be addressed.

- **Marci Carpenter, President National Federation of the Blind in Washington and member of the Federation's national Board** – we also would like to partner with the commission with the goal that everyone have safe, timely, and independent access to prescription label information.

  Domeg Moore, Health Equity Circle Language Access Team – a team of health science students, ready to collaborate on this issue. What is the typical time frame for data collection process? Also, could a policy statement be applied during the rulemaking process for this issue?

  Lindsay Trant responded once the survey goes out, it would be out for a few weeks and then determine the results. The commission would need to determine if a policy statement is needed. A policy statement is not as feasible as it would require a similar amount of stakeholder work as rulemaking to determine what is included in the policy statement.

3.5 Emergency rule refiling – COVID CII Prescribing WSR 22-07-063

MOTION: Craig Ritchie moved that the commission find that the emergency still exist and that emergency rule WSR 22-07-063 should be refiled. Hawkins DeFrance, second. Motion carries, 11:0.

MOTION: Craig Ritchie moved that the commission allow staff to insert correct rule number pertaining to dispensing emergency oral CII prescription drugs. Hawkins DeFrance, second. Motion carries, 11:0.

3.6 Emergency rule refiling – Medication Assistance WSR 22-07-063

MOTION: Craig Ritchie move that the commission find that the emergency still exist and that emergency rule WSR 22-07-063 should be refiled. Hawkins DeFrance, second. Motion carries, 11:0.

4. Open Forum.

- **Jenny Arnold, WSPA**
  - **Medication errors being criminally liable** – Tennessee Nurses case where nurse was found criminally liable for having a medication error in her practice setting. I ask the commission be mindful and potentially bring up on a future meeting the discussion of criminalizing medication errors vs. keeping with a just culture and looking at systems of errors and ensure we are committed to transparency, open discussion of medication errors, and not criminalizing any one individual that might be caught in that process. Many of us reviewing the TN Nurses case saw opportunities where better processes should have been put in place to minimize. I think that individual was left holding the bag. ISMP write up also addresses criminalizing medication errors.

- **White bagging** – there is an absolute urgency for the commission to address this issue. The compounding committee is working on this, but urgently need to have a meeting of the compounding committee to regulate the process of white bagging. Our pharmacies are being put in very compromising positions having to manage and dispense medication that have not been their possession. There is concern it is only a matter of time before patient harm occurs because of white bagging.

- **Pharmacist screening/evaluating** – the ability of a pharmacist to offer a screening or some evaluation such as blood pressure was tied directly to medications and having a medication or diagnosis code on file. I think that compromises the ability of pharmacists to offer blood pressure screening or other services that have been consistent with the practice of pharmacy for the last (at least) 20 years. I think we need to look at the potential of opening up rules. There are other emergency proclamations needing to be evaluated and potentially discontinuing.

- **Marci Carpenter, National Federation of the Blind** – thanks the commission for being willing to move to using Zoom. Apple's screen reader does not work well with GoToWebinar.

- **Erika Anderson** re: non-resident pharmacies. Is there an update regarding the system for stakeholders to validate the non-resident pharmacies who do not follow the minimum requirements and require a third-party inspection – outside of sending a public records request? Secondly, regarding approved third-party inspections, it is not clear if California Board of Pharmacy report and there was no other third-party … is that acceptable as a third-party even though it is not listed in the policy statement and inspection from another state who is following minimum requirements.

  Lindsay Trant mentioned the option now is the public records request, but this has been submitted as a request for the new licensing platform (HELMS) which is quite a way off, but they are aware.

  Commissioner Tim Lynch responded that the out-of-state licensees go through an exception process with a quorum of the commission. If they are not able to provide the documentation for licensure, a quorum of the commission reviews each application and determines if the submitted materials are acceptable or may ask for additional information. If they are an approved licensed pharmacy in Washington, they either met all the requirements or have gone through the exception process.

  Chris Gerard: The way that the directive is written, the non-resident pharmacy can submit an inspection report from any approved inspection program, not restricted to their home state or the one third-party inspection program that is approved.

5. Commission Member Reports. *Information/Action.*

5.1 Commissioner Reports

- **Chair**
  - **NABP Annual Meeting** – Jerrie Allard and Teri Ferreira will be attending the annual NABP meeting next week. Teri will be the voting delegate and Jerrie is the alternate for PQAC.
  - **Northwest Pharmacy Convention** – Nomi Peaks and Teri Ferreira will be presenting at the end of May.
- **Pharmacy Practice Subcommittee** – met in November and tasked staff with a few action items. Since that time staff have revised the sample AUP with the subcommittee's feedback as well as revisited the misfill investigation guidelines. Both of these documents will return to the subcommittee prior to presenting to the full commission. The subcommittee will also take up the

pharmacy assistant scope of practice questions raised in the last business meeting. Next meeting June 14, 2022.

- **Compounding Subcommittee** – date of next meeting has not been set.
- **Legislative Subcommittee** – meeting Friday, June 3. Will meet regularly on the first Friday of each month thereafter.

5.2 Open discussion related to items or issues relevant to commission business/pharmacy practice – None.

6. Staff Reports *Information/Action.*

6.1 Interim Executive Director – Marlee O'Neill

- **Scheduling meetings** – Please respond if staff reaches out to schedule meetings.
- **Staff Kudos** – Attorney General Ferguson announced a resolution in a case against opioid distributors. Last week an AAG contacted Marlee and wanted to thank DOH staff for their assistance. I wanted to publicly acknowledge OILS, PQAC, OCS, etc. staff spent hundreds of hours explaining our processes and procedures, going over laws and rules, ILRS reports, gathering files, documenting, being deposed and signing declarations… all under significant time restraints during their/our regular duties.
- **Staffing update** – hired a permanent Deputy Director for the commission: Lindsay Trant!

6.2 Deputy Director – Lindsay Trant

- Thank you all.
- **Staffing update** –
  - **Rules and Legislative Coordinator** – Joshua Munroe has been permanently hired for this position.
  - **Open Positions**
    - **Permanent Pharmacy Inspector** – interviews have completed and moving through the recruitment process.
    - **Project Pharmacy Inspector** – of the three positions, one has been filled, a second one soon, and one remaining.
    - **Nonpermanent HSC4** – reposted.
    - **Pharmacy Inspector Supervisor** – reposted.
    - **Executive Director** – reposted to reflect the pharmacist qualification is a preferred requirement.

6.3 Assistant Attorney General – Christopher Gerard

- **Accessible Labeling Item** – to provide further feedback, I would highly recommend the commission not consider a policy/guidance document related to this issue. The amount of work it will take to put this together would be the same amount of work put into rulemaking.
- **Staff Kudos** – Thank you, Marlee, for recognizing the work and effort on the opioid distributor case. The pharmacy commission was heavily emphasized in the litigation which involved significant amount of time for DOH/PQAC staff.

7. **Summary of Meeting Action Items –** Commissioner and staff will revisit action items identified during today's business meeting.

- **2.1 Compounding Animal Drugs from Bulk Drug Substances.** Staff will craft an FAQ to address the exceptions and definitions of manufacturers in the questions raised today.
- **2.2 Plan for Return to In-person Meetings.** July meeting will be remote. Staff will explore sites for future meetings.
- **3.3 Implementation for SHB 1675: Dialysate/dialysis device manufacturer and wholesalers.** Policy statement and guidance document will be developed.
- **3.5 Implementation for SHB 1675: Dialysate/dialysis device manufacturer and wholesalers.** Staff will craft a survey for stakeholders to assist in moving forward with the rulemaking process.
- **3.5 Emergency rule refiling – COVID CII Prescribing WSR 22-07-063.**
- **3.6 Emergency rule refiling – Medication Assistance WSR 22-07-063.**

Business Meeting Adjourned – 11:47 am

4.1

New Firms as of May 5, 2022

PHNR.FO.61305885	ACTIVE	05/05/2022
PHWH.FX.61239148	ACTIVE	05/05/2022
PHWH.FX.61207852	ACTIVE	05/05/2022
PHHC.FX.61258020	ACTIVE	05/10/2022
PHHC.FX.61252012	ACTIVE	05/10/2022
PHNR.FO.61275109	ACTIVE	05/10/2022
PHNR.FO.61309394	ACTIVE	05/10/2022
PHWH.FX.61310067	ACTIVE	05/10/2022
PHWH.FX.61307126	ACTIVE	05/10/2022
PHWH.FX.61302352	ACTIVE	05/12/2022
PHNR.FO.61277841	ACTIVE	05/13/2022
PHNR.FO.61303518	ACTIVE	05/13/2022
PHNR.FO.61307592	ACTIVE	05/13/2022
PHNR.FO.61273762	ACTIVE	05/13/2022
PHHC.FX.61271561	ACTIVE	05/18/2022
PHMF.FX.61277634	ACTIVE	05/18/2022
PHNR.FO.61311821	ACTIVE	05/18/2022
PHWH.FX.61302466	ACTIVE	05/18/2022
PHWH.FX.61310332	ACTIVE	05/18/2022
PHHC.FX.61283595	ACTIVE	05/25/2022
PHWH.FX.61269247	ACTIVE	05/25/2022
PHWH.FX.61148680	ACTIVE	05/25/2022
PHWH.FX.61315041	ACTIVE	05/25/2022
PHWH.FX.61210637	ACTIVE	05/25/2022

PHWH.FX.61293515	ACTIVE	05/25/2022
PHWH.FX.61225462	ACTIVE	05/27/2022
PHWH.FX.61315061	ACTIVE	05/27/2022
PHWH.FX.61216956	ACTIVE	05/27/2022

Closed:

PHAR.CF.00004015	CLOSED	06/12/1991	06/01/2022
PHAR.CF.60515420	CLOSED	02/02/2015	06/01/2022
PHNR.FO.60289258	CLOSED	07/27/2012	06/01/2022
PHNR.FO.61146414	CLOSED	03/24/2021	06/01/2022
PHWH.FX.60146721	CLOSED	04/12/2010	06/03/2022

FAQ on Veterinary Drug Products Compounded from Bulk Drug Substances for Use by Veterinarians as Office Stock
Date: July 7, 2022

Question: May pharmacies licensed by the Pharmacy Quality Assurance Commission (commission) compound veterinary drugs from bulk drug substances (BDS) for use as office stock in nonfood-producing animals?

Answer: While the U.S. Food and Drug Administration's Guidance for Industry # 256 would permit "a pharmacist in a state-licensed pharmacy or federal facility" to compound animal drugs from BDS for office stock for nonfood-producing animals under certain conditions, Washington law restricts the ability of a pharmacist in a state-licensed pharmacy from compounding animal drugs from BDS for office stock for nonfood-producing animals. This is because compounding *any* drug for office stock is generally considered to be manufacturing and requires a manufacturer license (RCW 18.64.011(21) and (22)). There are exceptions to this general rule in RCW 18.64.011(21), which provide that a pharmacy may engage in the following conduct without being licensed as a manufacturer:

A. The activities of a licensed pharmacy that compounds a product on or in anticipation of an order of a licensed practitioner for use in the course of their professional practice to administer to patients, either personally or under their direct supervision;
B. The practice of a licensed pharmacy when repackaging commercially available medication in small, reasonable quantities for a practitioner legally authorized to prescribe the medication for office use only;
C. The distribution of a drug product that has been compounded by a licensed pharmacy to other appropriately licensed entities under common ownership or control of the facility in which the compounding takes place; or
D. The delivery of finished and appropriately labeled compounded products dispensed pursuant to a valid prescription to alternate delivery locations, other than the patient's residence, when requested by the patient, or the prescriber to administer to the patient, or to another licensed pharmacy to dispense to the patient.

Washington law would only permit a pharmacy to compound animal drugs from BDS for a veterinarian as office stock for nonfood-producing animals if one of the exceptions in RCW 18.64.011(21) listed above applied, or if the pharmacy obtained a manufacturer license.

5.5

June 3, 2021

Important Update For Wholesalers WAC 246-945-585(1)(b) – Suspicious Orders and Due Diligence – Zero Reports:

Updated Guidance from the Commission

At the June 3, 2021 business meeting, the commission provided additional guidance on WAC 246-945-585(1)(b) (Wholesaler – Suspicious Orders and Due Diligence – Zero Reports).

Zero Reports: At the June 3, 2021 business meeting, the commission voted to authorize rulemaking to amend WAC 246-945-585(1)(b) in order to modify the zero report submission requirement. In this rulemaking, the commission will consider alternatives to the zero report requirement such as storing them onsite in lieu of submitting them to the commission. This approach varies from the current submission to the commission option for zero reports.

The commission voted to extend enforcement discretion of the submission of zero reports for 12 months until (June 1, 2022) or until the rulemaking is complete whichever comes first.

Suspicious Order Reports: As of June 1, 2021, suspicious order reports **must be submitted** to hsqacomplaintintake@doh.wa.gov. Reports may be submitted in any readable electronic format (e.g. email, Excel attachment), but must include **all** information required in WAC 246-945-585(1)(a)(i)-(ix)

Suspicious Order Reports: As of June 1, 2021, suspicious order reports **must be submitted** to hsqacomplaintintake@doh.wa.gov. Reports may be submitted in any readable electronic format (e.g. email, Excel attachment), but must include **all** information required in WAC 246-945-585(1)(a)(i)-(ix):

(i) Customer name;
(ii) Customer address;
(iii) Customer DEA registration number;
(iv) State license number(s);
(v) Transaction date;
(vi) Drug name;
(vii) NDC number;
(viii) Quantity ordered;
(ix) Indication of whether the drug was shipped, and if not, the factual basis for the refusal to supply.

If possible, please send reports with the following subject line nomenclature: Date_CompanyName_SuspiciousOrderReporting_WAstate_DEA# (date format: mmddyy)

Exemption from Reporting: Wholesalers may apply to the commission for an exemption from the reporting requirements if they do not distribute controlled substances or drugs of concern using this form.

Please contact us with any questions at PharmacyRules@doh.wa.gov.

5.6

Sample Ancillary Personnel Utilization Plans

Pharmacy Assistant and Pharmacy Technician

2022

Pharmacies licensed by the Pharmacy Quality Assurance Commission (commission) must submit an Ancillary Personnel Utilization Plan (AUP) to the commission for approval, prior to the utilization of pharmacy assistants or pharmacy technicians (RCW 18.64A.060).

An AUP must contain information regarding how ancillary personnel will be utilized and supervised while working in the pharmacy, projected staffing ratios, explanations of delegated tasks, and the conditions under which personnel are expected to perform their tasks (WAC 246-945-410).

It is important to note that an AUP must be approved by the commission, but the responsible pharmacy manager maintains discretion regarding its implementation. The duties and responsibilities listed in the tables below are also subject to the discretion of the supervising pharmacist on duty (WAC 246-945-315).

The commission recognizes that many pharmacies face challenges related to adequate staffing. For reference, WAC 246-945-410 addresses sufficient staffing in the pharmacy. WAC 246-945-460 specifically addresses the staffing and supervision of pharmacy personnel, which the responsible pharmacy manager determines. Chapter 18.64A RCW addresses the duties of pharmacy technicians and assistants, limitations on practice, and the handling of staffing ratios in an AUP.

Note: Ancillary personnel utilization must be approved by the responsible pharmacy manager. The tasks performed by ancillary personnel are subject to the discretion of the supervising pharmacist and shall not include those listed in WAC 246-945-320.

Pharmacy Assistant		
Duties and Responsibilities	Yes	No
Greets customers/patients arriving at the pharmacy.		
Operates cash register and/or digital signature pad used to document prescription pick-up.		
Assists customers/patients who are waiting to check out at the pharmacy.		
Greets customers/patients calling the pharmacy and answers inquiries regarding:		
a) The price of a prescription that has been filled and is ready for pick-up.		
b) The pharmacy's hours of operation.		
c) The number of refills remaining on a prescription.		
d) The request to refill a medication when provided the prescription number.		
e) The date a prescription medication will be returned to stock.		
f) The date and time of a customer's/patient's vaccination appointment.		
g) The availability of goods and services (may require directing the phone call to a pharmacy technician or pharmacist).		
h) Calls customers/patients to let them know their medications are ready for pick-up.		
Calls a prescriber's office to request refill authorization. The refill requests shall be made stating the patient's name, medication name and strength, number of doses, and date of prior refills. Any additional inquiries by the office concerning the prescription must be referred to the pharmacist.		
Hands out refills when specifically requested to do so by a pharmacist and when a pharmacist has determined that counseling is not necessary.		
Provides vaccine screening forms for customers/patients to complete and for the pharmacist to review.		
Following direction from a pharmacist, contacts a wholesaler or distributor to place or verify the status of an order.		
Receives and unpacks delivery totes containing drugs and/or supplies. The supervising pharmacist may require that only pharmacists unpack delivery totes containing controlled substances.		
Files and retrieves various pharmacy records as required by the pharmacist, including order invoices and receipts.		
Maintains assigned work area and equipment in clean and orderly condition, including the pharmacy counters and shelves. Protects secure patient information from plain view and disposal in common wastebaskets.		
May count out a medication that has been poured from a stock bottle retrieved for the assistant by a pharmacy technician or a pharmacist. The count must be performed for individual prescriptions, under the direct supervision of a licensed pharmacist. The accuracy of the prescription's contents must be verified by a licensed pharmacist and noted by that pharmacist's initials on the prescription label.		
May generate a label for a refill prescription only when there has been no change to the required elements of the prescription.		
Systematically files completed prescriptions that have been verified and prepared by the pharmacist for customer/patient pick-up.		

Pharmacy Assistant Additional Duties and Responsibilities (not listed above) ***Please write legibly or type in the fields below. If required, please also use the space provided on the final page of the plan.***	Yes	[redacted]
A1.		
A2.		
A3.		
A4.		
A5.		
A6.		
A7.		
A8.		
A9.		
A10.		
A11.		
A12.		

Number of pharmacy assistant positions anticipated _____.

Note: Ancillary personnel utilization must be approved by the responsible pharmacy manager. The tasks performed by ancillary personnel are subject to the discretion of the supervising pharmacist.

Pharmacy Technician			
Duties and Responsibilities	Yes	No	Not Applicable
Greets customers/patients arriving at the pharmacy.			
Operates cash register and/or digital signature pad used to document prescription pick-up.			
Assists customers/patients waiting to check out at the pharmacy.			
Greets customers/patients calling the pharmacy and answers inquiries regarding:			
a) The price of a prescription that has been filled and is ready for pick-up.			
b) The pharmacy's hours of operation.			
c) The number of refills remaining on a prescription.			
d) The request to refill a medication when provided the prescription number.			
e) The date a prescription medication will be returned to stock.			
f) The date and time of a customer's/patient's vaccination appointment.			
g) The availability of goods and services (may require directing the phone call to a pharmacist).			
Calls customers/patients to let them know their medications are ready for pick-up.			
Handles calls from a prescriber's office authorizing refills provided that no changes in the prescription are involved.			

Pharmacy Technician			
Duties and Responsibilities	Yes	No	Not Applicable
Hands out refills when specifically requested to do so by a pharmacist and when a pharmacist has determined that counseling is not necessary.			
Provides vaccine screening forms for customers/patients to complete and for the pharmacist to review.			
Following direction from a pharmacist, contacts a wholesaler or distributor to place or verify the status of an order.			
Receives and unpacks delivery totes containing supplies and/or non-controlled *and* controlled drugs.			
Receives and unpacks delivery totes containing supplies and/or non-controlled drugs (supervising pharmacist requires that only pharmacists handle delivery totes containing controlled drugs).			
Files and retrieves various pharmacy records as required by the pharmacist, including order invoices and receipts.			
Maintains assigned work area and equipment in clean and orderly condition, including the pharmacy counters and shelves. Protects secure patient information from plain view and disposal in common wastebaskets.			
Pours and counts out a medication from a stock bottle. The count must be performed for individual prescriptions, under the direct supervision of a licensed pharmacist. The accuracy of the prescription's contents must be verified by a licensed pharmacist and noted by that pharmacist's initials on the prescription label.			
May generate a label for a refill prescription only when there has been no change to the required elements of the prescription (WAC 246-945-010).			
Systematically files completed prescriptions that have been verified and prepared by the pharmacist for customer/patient pick-up.			
Medication reconstitution (i.e., restoration of the original form of medication previously altered for preservation and storage by addition of a specific quantity of distilled water or provided diluent requiring no calculation). In 100% of the cases, the accuracy of the technician's work is verified by a licensed pharmacist. The verification is documented by the licensed pharmacist's initials on the label(s) affixed to the verified reconstituted medication(s).			
Utilizes the pharmacy software system to enter prescription data electronically, print corresponding labels, scan stock bottles, and prepare prescriptions for verification by a licensed pharmacist. "Prepare" means a pharmacy technician sequesters a filled prescription in a basket, small tote, or on the pharmacy bench for the pharmacist to review.			
Accurately types prescription orders which are then checked and initialed by a licensed pharmacist.			
Reviews a customer's/patient's medication profile to retrieve specific information related to third-party billing, adjudication, medication refill frequency, and vaccination history, as directed by a licensed pharmacist.			
Handles calls to and/or from a prescriber's office regarding a customer's/patient's profile information that does not require interpretation (e.g., medication quantity, date last filled, and price).			
Obtains individually prepackaged, labeled medications for prescriptions~~, under the supervision of a licensed pharmacist~~.			
Filling unit dose cassettes ~~under the supervision of a licensed pharmacist~~.*			
Preparing IV admixtures ~~under the supervision of a licensed pharmacist.~~*			
Pharmacy Technician Additional Duties and Responsibilities (not listed above) ***Please write legibly or type in the fields below. If required, please also use the space provided on the final page of the plan.***	Yes		
T1.			
T2.			

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Deleted: Counts out a medication that has been poured

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Deleted: Transcribes orders with transcription accuracy

Deleted: Performs tasks under a licensed pharmacist's supervision, such as obtaining

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Deleted: ~~and preparing IV admixtures~~

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T3.		
T4.		
T5.		
Pharmacy Technician Additional Duties and Responsibilities (not listed above) ***Please write legibly or type in the fields below. If required, please also use the space provided on the final page of the plan.***	Yes	
T6.		
T7.		
T8.		
T9.		
T10.		
T11.		
T12.		

Number of pharmacy technician positions anticipated _____.

*Formerly addressed in the old rule, WAC 246-901-100. Currently addressed in WAC 246-945-410.

Supplemental **Pharmacy Assistant** **Additional Duties and Responsibilities (not listed above).** ***Please write legibly or type in the fields below.***	Yes	
A13.		
A14.		
A15.		
A16.		
A17.		
A18.		
A19.		
A20.		
A21.		
A22.		
A23.		
Supplemental **Pharmacy Technician** **Additional Duties and Responsibilities (not listed above).** ***Please write legibly or type in the fields below.***	Yes	
T13.		
T14.		
T15.		
T16.		
T17.		
T18.		
T19.		
T20.		
T21.		

T22.		[redacted]
T23.		

DEPARTMENT OF HEALTH
PHARMACY QUALITY ASSURANCE COMMISSION
PROCEDURE

Title:	Guidelines for Investigating Misfill Cases	**Number:**	G003
Reference(s):	Chapter 18.64 RCW Pharmacist Chapter 18.130 RCW Regulation of Health Professions – Uniform Disciplinary Act		
Contact:	Marlee O'Neill, JD, Interim Executive Director		
Effective Date:	June 14, 2022		
Approved:	**Chairperson, Pharmacy Quality Assurance Commission**		

POLICY STATEMENT:
This procedure establishes appropriate guidelines for information the commission requests the investigators collect when investigating misfill cases.

BACKGROUND:
Each case presents unique facts and must be assessed based on the facts presented. However, in the course of investigating and assessing misfill cases, there are several common pieces of information and evidence that the Commission would like to attempt to obtain in order to evaluate each case better. This procedure sets out those common pieces of information and evidence. These guidelines are not intended to be an exclusive list of information and evidence.

GUIDELINES:
Questions to Ask

1. Date licensee became aware of misfill
2. How did the licensee become aware of misfill?
3. Date licensee reported misfill and to whom
4. Were there any adverse effects or adverse impacts to the patient related to the misfill?
5. How were the patient's healthcare needs addressed?
    For example:
        i. Was the patient's provider contacted?
        ii. Was the patient provided the correct medication?
        iii. What policies, processes, and technologies were available to reduce the risk of misfill errors?
            1. Were those policies, processes, and technologies utilized during the misfill incident?
6. What processes were used in investigating the event?
    a. Root cause analysis
        i. Trend analysis included
    b. Internal investigation by
        i. Risk or quality staff
        ii. Responsible manager
        iii. Other
    c. Interviews with the involved licensee or other clinicians
    d. Internal experts(s)
    e. External expert(s)

    f. Review of medical records
    g. Investigation by manager
7. What was determined to be the primary cause of the event?
8. List action plan(s) developed to reduce misfill/error instances and training provided.
    a. Was a measurement of severity tool utilized?
    b. Does the pharmacy have a continuous quality improvement (CQI) process in place?
        i. Is the pharmacy able to point to this CQI process in its policies and procedures?
    c. Were the actions taken adequate and effective to prevent or reduce a recurrence of misfills?
9. What are follow-up measures for the success of action plan(s)?
10. What role does the responsible pharmacy manager have in determining how the facility operates in compliance with state or federal law?
    a. Does the responsible pharmacy manager have the authority to create and amend the policies and procedures that impact their facility?
    b. How was the pharmacy staffed at the time of the misfill incident?

The investigator should, if possible, gather any evidence to support these questions, such as a copy of the internal investigation or a copy of the action plan, etc.

Appendix A

GUIDELINES:

Occurrence						
Severity		1	2	3	4	5
	1	2	3	4	5	6
	2	3	4	5	6	7
	3	4	5	6	7	8
	4	5	6	7	8	9
	5	6	7	8	9	10

Severity of Misfill	Occurrence
1. Patient did not consume	1. First Misfill
2. Patient consumed medication - no adverse outcome	2. Second misfill occurring more than 1 yr. after first
3. Patient consumed medication - negative outcome experienced	3. Third misfill occurring more than 2 yrs. after first
4. Negative outcome requiring non-emergent medical intervention	4. Second misfill occurring within 1 yr. of the first
5. Negative outcome requiring emergent medical intervention	5. Third or more misfill within 1 yr.

Risk Priority

2-5 points –

- Close
- Notice of Correction (NOC)

6-7 points –

- NOC
- Statement of Allegations/Stipulation to Informal Disposition (SOA/STID)

8-10 points –

- SOA/STID
- Statement of Charges/Agreed Order (SOC/AO)

Washington State Department of Health

Commission SBAR Communication

Agenda Item/Title: Lockers for Prescription Delivery

Date SBAR Communication Prepared: June 15, 2022

Reviewer: Taifa "Nomi" Peaks

Link to Action Plan:

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

Situation

The Pharmacy Quality Assurance Commission (commission) staff have received multiple questions as to whether a pharmacy licensed by the commission could deliver filled prescriptions for **non-controlled** legend drugs to lockers owned and operated by that pharmacy.

Background

In March of 2020, commission staff created an SBAR addressing a request by Walgreens to provide medications to employees of Microsoft by having pharmacy technicians deliver medications to the Microsoft campus via a secure locker system. It is important to note that the Walgreens/Microsoft scenario is not the focus of this analysis. In that example, the pharmacy, Walgreens, was proposing the placement of filled non-controlled prescriptions in lockers owned by Microsoft. This analysis concentrates on situations where the lockers are owned by the pharmacy.

To sell, deliver, or possess drugs in the state of Washington, a person (an individual or a business) must have the legal authority to do so. This legal authority is provided in the Legend Drug Act, chapter 69.41 RCW (LDA). It allows a patient to possess drugs based on the receipt of a valid prescription (RCW 69.41.030(1)). It also grants "practitioners" legal authority to sell, deliver, and possess drugs when acting within the scope of their license (RCW 69.41.030(1)). Because the definition of "practitioner" in the LDA includes a pharmacy (RCW 69.41.010(17)(b)), a pharmacy may sell, deliver, and possess drugs within the scope of its pharmacy license.

A pharmacy cannot possess drugs outside of its licensed location unless the law otherwise permits the possession because a pharmacy license is a "license of location." This allows the operation of a pharmacy "at the location specified" in its application (RCW 18.64.043(1)), but it does not expressly permit pharmacies to store filled prescriptions for non-controlled legend drugs in lockers owned and operated by the pharmacy for patient pick-up outside of its licensed location.

The storage of drugs outside of the pharmacy *is* discussed in WAC 246-945-455. This rule includes the requirement that access to drugs stored outside the pharmacy be limited to "health care professionals licensed under the chapters specified in RCW 18.130.040 acting within their scope, and nursing students as provided in WAC 246-945-450" (WAC 246-945-455(1)(c)). It does not, however, give patients the authority to access drugs stored in lockers outside the pharmacy, even if the lockers contain drugs that have been prescribed to them. The rule also specifies that the facility where drugs are stored is "able to possess and store drugs" (WAC 246-945-455(1)(e)).

Additionally, while WAC 246-945-415 does not explicitly mention the use of pharmacy lockers, it does provide that: A pharmacy may deliver filled prescriptions as long as appropriate measures are taken to ensure product integrity and receipt by the patient or patient's agent (WAC 246-945-415(1)) and; Filled prescriptions ***may be picked up*** or returned for delivery ***by authorized personnel*** when the pharmacy is closed for business ***if the prescriptions are placed in a secured delivery area outside of the drug storage area***. The secured delivery area ***must be a part of a licensed pharmacy***, and equipped with adequate security, including an alarm or comparable monitoring system, to prevent unauthorized entry, theft, or diversion. Access to the secured delivery area must be addressed by the policies and procedures developed by the responsible pharmacy manager (WAC 246-945-415(6)).

The commission staff utilized the above laws and rules to formulate an assessment that summarizes two options for the commission to consider.

Assessment

A pharmacy may deliver filled prescriptions for non-controlled legend drugs to lockers owned and operated by the pharmacy. The commission has two options to consider when implementing this position.

Option 1: Permit pharmacies to use pharmacy-owned lockers if the lockers are included as part of the pharmacy's license (i.e., included as part of the space licensed as a pharmacy), or;

Option 2: Permit pharmacies to use pharmacy-owned lockers to deliver filled prescriptions without the lockers being included as part of the pharmacy license (i.e., outside of the space licensed as a pharmacy).

Option 1	
Advantage(s)	Disadvantage(s)
This option allows the commission to inspect the use of lockers with rules that are already in place for pharmacies. This would include the specific rules in WAC 246-945-415(6) that address security and access requirements.	• The current rule language would mean pharmacies could only use lockers for delivery of filled prescriptions when the pharmacy is closed. The commission would need to engage in rulemaking to modify this requirement and permit pharmacies to use lockers when the pharmacy is open. • This option could result in the commission including physical spaces that are not traditionally licensed as pharmacies. This could potentially lead to pharmacies attempting to extend their pharmacy licenses to locations beyond the traditional pharmacy when this has typically required legislation to accomplish. The commission would need to communicate this to its inspectors and credentialing staff at the Department of Health. It would also need to make it clear that lockers must be annexed to the main pharmacy space. • The pharmacy license application may require an amendment to include pharmacy locker locations.

Option 2	
Advantage(s)	Disadvantage(s)
This option allows pharmacies to use lockers under a broader reading of WAC 246-945-415(1). It will likely allow pharmacies more flexibility on where lockers can be located.	• It requires the commission to provide an explanation of how delivery of patients' filled prescriptions to pharmacy-owned lockers does not fall under the commission's rules on drugs stored outside of a pharmacy in WAC 246-945-455. • The standards a pharmacy would be subject to for placing filled prescriptions in lockers under this option are fairly limited: (1) ensure product integrity of the filled prescription and (2) ensure receipt by the patient or patient's agent. • There would be almost no restriction on where the lockers could be located.

Recommendation

The commission may review the two options listed above in its determination of how to best implement the position that a pharmacy may deliver filled prescriptions for non-controlled legend drugs to lockers owned and operated by the pharmacy. As it pertains to Option 2, the commission may also wish to produce a policy document or guidance document that outlines the commission's understanding of WAC 246-945-415 and WAC 246-945-455 in the context of this topic, and consider additional rulemaking in the future. The commission staff will document the commission's decision and any additional steps or follow-up requests.

2023 proposed commission meeting dates

January 12-13, 2023

March 9-10, 2023

May 4-5, 2023

June 29-30, 2023

Aug 24-25, 2023

Oct 19-20, 2023

Dec 14-15, 2023