Draft

STATE OF WASHINGTON

Pharmacy Quality Assurance Commission

PO Box 47852 • Olympia, Washington 98504-7852
Tel: 360-236-4946 • TTY Relay: 800-833-6384

October 1, 2020
Commission Business Meeting
Strategic Planning
New Rules Implementation Review
***Amended* Agenda**

Time:	9:00 AM (Open Session)
Location:	Webinar
Contact:	Doreen Beebe, Program Manager (360) 236-4834 doreen.beebe@doh.wa.gov or Commission Office: wspqac@doh.wa.gov

Participate in person or register as an attendee by webinar ID# 509-709-859
Phone +1 (415) 655-0060
Access Code: 336-919-479
Audio PIN: Shown after joining the webinar

All attendees will join the call with their audio connection muted. If you wish to speak, please be sure to enter an audio pin given to you when you sign in.

The times on the agenda for this meeting are approximate and subject to change. The commission may need to adjust times or order of agenda items. The commission may take final action on any matter listed on the agenda, and/or on any matter added to the agenda in a regular meeting. The commission may meet in an executive session closed to the public for any reason listed in RCW 42.30.110, and may take final action in the public portion of the meeting following an executive session. The reason for the executive session and duration will be announced prior to the start of the executive session. The commission may meet in a closed session during this meeting for any reason listed in RCW 42.30.140, including but not limited to deliberations on enforcement (quasi-judicial) matters.

This business meeting is being held by webinar per Governor Inslee's Proclamation 20-05 waiving and suspending the portions of Open Public Meetings Act that requires in-person meetings. This meeting is being recorded for future reference.

9:00 am

1. **Call to Order** Tim Lynch, Chair ***Action***
   - **1.1** Meeting Agenda Approval – October 1, 2020
   - **1.2** Meeting Minutes Approval – August 27, 2020
   - **1.3** Meeting Minutes Approval – August 28, 2020

9:10 am

2a. Consent Agenda Items listed under the consent agenda are considered routine and necessary commission matters and will be approved by a single motion of the Commission without separate discussion. If separate discussion is desired, that item will be removed from the consent agenda and placed on the regular business agenda. ***Action item.***

2.1 August 2020 National Precursor Exchange Log report (NPLEx)

2.2 Pharmaceutical Firms Application Report Approval

- August 14 – September 29, 2020

2.3 Ancillary Utilization Plans Approval

a. Cherry Hill Pharmacy
b. Doctors Pharmacy
c. Furness Drug
d. Garfield Country Pharmacy
e. St. Michael Medical Center Pharmacy
f. West Pasco Pharmacy
g. Whidbey Health Community Pharmacy
h. RLS USA Inc.

2.4 Washington Recovery Assistance Program for Pharmacy (WRAPP) reports

- April thru June 2020

2b. Regular Agenda/Items Pulled from 2a. The Commission will discuss items removed from the consent agenda and placed on the regular agenda for separate discussion.

9:15 am

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

3.1 Suspicious Orders Update WAC 246-945-585

3.2 Euthanasia Training Program Guidelines for Animal Control Agencies and Humane Societies Review WAC 246-945-503

9:25 am

4.New Business/Subcommittee Report –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.***

4.1 Strategic Planning Discussion

4.2 Review Compounding Subcommittee's USP 800 and USP 825 Policy Statement Proposal and Policy #60 for re-approval (include USP options from subcommittee meeting in meeting materials)

4.3 USP Applicability Clarification: Non-compounding pharmacies versus Compounding pharmacies

4.4 Monitoring of Drug Therapy: Pharmacists Conducting Health Screenings WAC 246-945-355; RCW 18.64.011(28)

11:15am

5.New Rule Implementation-Review. *Action.*

5.1 Prescription Adaptation Clarification: Dosage Formulation (WAC 246-945-335; WAC 246-945-001(25)

5.2 Wholesaler licenses for Out-of-state Manufacturers WAC 246-945-246
5.3 Internship Registration Renewal WAC 246-945-155(3)
5.4 WAC 246-945-430 vs -455 frequently asked questions

Break 10 minutes (11:45 AM)

11:55 am

6. Rules, Legislation, Program and Department Update – ***Information/Action.***

6.1 SSB 6086 Stakeholder Workshop
6.2 Authorization to re-file Emergency Rules
a. Epidiolex – (WAC 246-945-056)
b. Schedule II – Emergency provision for dispensing Schedule II Controlled Substances (WAC 246-945-010)
6.3 Medical Commission files CR-101 Re: CDTA ***Information.***

12:15 pm

7. Open Forum (10 minutes)

The purpose of the open forum is to provide the public an opportunity to address the Commission on issues of significance to or affecting the practice of pharmacy. Discussion items may not relate to topics for which a hearing has or will be scheduled. ***Information Only***

12:25 pm

8.Commission Member Reports - *Information/Action.*

8.1 Commissioner Reports
8.2 Commissioners open discussion related to items or issues relevant to Commission business/pharmacy practice.

9.Staff Reports *Information/Action.*

9.1 Executive Director – Lauren Lyles-Stolz
9.2 Assistant Attorney General – Christopher Gerard
9.3 Pharmacist Supervisor –Lisa Hunt
9.3.1 Virtual Inspection Process

12:35 pm

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

1:00 pm (approximately)
Business Meeting Adjourned.

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: **Thursday, December 3, 2020**
Friday, December 4, 2020

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.

August 27, Meeting Minutes

STATE OF WASHINGTON
Pharmacy Quality Assurance Commission
PO Box 47852 • Olympia, Washington 98504-7852
Tel: 360-236-4946 • TTY Relay: 800-833-6384
Business Meeting – Meeting Minutes
August 27, 2020
9:00 AM (Open Session)

Convene: Vice Chair, Teri Ferreira called the meeting to order August 27, 2020 at 9:01 a.m.

Commission Members:
Tim Lynch, Commission Chair
Teri Ferreira, Commission Vice Chair
Jerrie Allard, Public Member
Bonnie Bush, Public Member
Olgy Diaz, Public Member
Judy Guenther, Public Member
Ken Kenyon, PharmD, BCPS
Craig Ritchie, RPh, JD
Sepi Soleimanpour, RPh, MBA-HA
Uyen Thorstensen, CPhT
Kat Wolf Khatchatourin, PharmD, MBA

ABSENT
Patrick Gallaher, BS, BPharm, MBA, MPH

Staff Members:
Chris Gerard, AAG
Lauren Lyles-Stolz, Executive Director, Pharmacy Commission
Christie Strouse, Deputy Director, Pharmacy Commission
Doreen Beebe, Program Manager, Pharmacy Commission
Lindsay Trant, Rules and Legislative Coordinator, Pharmacy Commission
Marlee O'Neill, Deputy Director, Office of Investigation and Legal Services
Cori N. Tarzwell, staff member
Amy L Robertson, Administrative Assistant, Pharmacy Commission

1.1 **Meeting Agenda Approval -- MOTION**: Craig Ritchie moved to approve the agenda as written; Jerrie Allard, second; motion carried.

2.1 Lauren Lyles-Stolz briefed the Commission on the implementation of WAC 246-945-585 and the obstacles/differences that may necessitate delayed enforcement of all requirements detailed in the WAC.

Suspicious Orders – In addition to PQAC's development of forms/reports for WAC 246-945-585, the NABP and DEA are working on a national reporting system (DEA, SORS and ARCOS. Leah Lindahl (Healthcare Distribution Alliance, "HDA") suggests/requests a 30-60 day adjustment period for the wholesalers to integrate their systems once a system is approved..

MOTION: Craig Ritchie motioned that PQAC delay enforcement of the suspicious order reporting until the October business meeting. Also, PQAC would not find licensees deficient or take enforcement action against its licensees for failure to comply with WAC 246-945-585 (Suspicious Orders and Due Diligence Rule). . Ken Kenyon, second. Motion carried.

2.2 Lauren Lyles-Stolz briefed the Commission on the issues of applying **Statement of Deficiency (SOD) and Plan of Correction (POC)** methodology according to WAC 246-945-005. Currently, this only applies to "pharmaceutical firms," not all license types under the Commission's authority. Non-traditional firms e.g., controlled substance registrants, do not fit this category.

The Commission also concurred **annual self-inspection forms do not need to be developed for non-traditional firms.**

MOTION: Craig Ritchie moved we apply the SOD and POC methodology to all registrants and develop a written statement outlining the Commission's position. Bonnie Bush, second. Motion carries.

2.3 **Prescription Transfer Rules-**

Lauren Lyles-Stoltz led the following discussions:[Tim enters commission meeting] The Commission determined:

1. The Commission clarified transferring by electronic means is defined as using an electronic device (e.g., facsimile) to transmit a prescription. Entering a written prescription into a database or other electronic device does not make it an electronic prescription.

2. The Commission clarified "emergency" will be determined by the pharmacist to rely on his/her professional judgement to ensure the best interests of the patient..

3. The commission considers the function of transferring a non-controlled prescription legend drugs by electronic means to be a nondiscretionary function delegable to a pharmacy technician.

4. **MOTION**: Tim Lynch motioned that it is permissible for a pharmacy technician to transfer a non-controlled legend drug prescriptions under the immediate supervision of a pharmacist by electronic means (including facsimile), this excludes verbal (or oral) transfers as they cannot be delegated. Sepi Thorstensen or Bonnie Bush, seconded. Motion carried.

2.4 **Euthanasia Training Program**- **MOTION**: Bonnie Bush motioned that the Pharmacy Commission adopt the provisions of our former rules WAC 246-886-040 as guidance for

programs that wish to develop euthanasia programs and using that document to evaluate programs when they submit for approval. Second, Craig Ritchie. Motion carried.

3. Summary of Meeting Action Items

2.1 Work with Leah Lindahl (Healthcare Distribution Alliance, "HDA") and monitor the implementation of the DEA's SORS system and research the status ofNABP's potential reporting system for implementation of WAC 246-945-585 Suspicious Orders to discuss at the October meeting..

2.2 Create FAQ an SOD/POC methodology application to all registrants under the Commission's jurisdiction. Ensure all pharmacy inspectors are informed of this update.

2.3 Create FAQ – the pharmacist will use professional judgement in determining an emergency situation under the new rules for transferring a prescription. Also, the pharmacy technicians will be able to transfer non-controlled prescription drugs via electronic means. The Commission will also maintain the DEA's policy for unfilled original prescriptions of CII transfers.

2.4 Create a guidance document outlining the former WAC for euthanasia training programs.

11:08 am (approximately)
Business Meeting Adjourned.

Next scheduled business meeting: **August 28, 2020**
Business Meetings
9:00 a.m.

STATE OF WASHINGTON

Pharmacy Quality Assurance Commission

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Business Meeting – Minutes
August 28, 2020
9:00 AM (Open Session)

Convene: Chair, Tim Lynch called the meeting to order August 28, 2020 at 9:05 a.m.

Commission Members
Teri Ferreira, RPh, Vice Chair
Bonnie Bush, Public Member
Craig Ritchie, RPh, JD
Jerrie Allard, Public Member
Judy Guenther, Public Member
Kat Wolf-Khatchatourian, PharmD, MBA
Ken Kenyon, PharmD, BCPS
Olgy Diaz, Public Member
Sepi Soleimanpour, RPh, MBA-HA (joined late)
Uyen Thorstensen, CPhT

Absent Commission Members
Patrick Gallaher, BS, BPharm, MBA, MPH

Staff Members
Lauren Lyles-Stolz, Executive Director, Pharmacy Commission
Christie Strouse, Deputy Director, Pharmacy Commission
Chris Gerard, AAG
Lindsey Trant, Rules Program Manager
Cori Tarzwell, staff member
Marlee O'Neill
Martin Pittioni, Office of Health Professions
Doreen Beebe Program Manager, Pharmacy Commission
Amy Robertson, Administrative Assistant, Pharmacy Commission

1.1 **August 28, 2020 Meeting Agenda Approval** – **MOTION** – Craig Ritchie moved to approve the August 28, 2020 meeting agenda as written. Jerrie Allard, second. Motion carries, 10-0.

1.2 **July 17, 2020 Minutes Approval** – **MOTION** – Craig Ritchie moved to approve the July 17, 2020 minutes per the edit suggestions made by Chris Gerard, AAG. Ken Kenyon, second. Motion carries, 10-0.

1.3 **April 8, 2020 Minutes Approval** – **MOTION** – Craig Ritchie moved to approve the April 8, 2020 minutes per the edit suggestions made by Chris Gerard, AAG. Ken Kenyon, second. Motion carries, 10-0.

1.4 **April 1, 2020 Minutes Approval** – **MOTION** – Craig Ritchie moved to approve the April 1, 2020 minutes per the edit suggestions made by Chris Gerard, AAG. Ken Kenyon, second. Motion carries, 10-0.

2a. **Consent Agenda Approval** – **MOTION** – Craig Ritchie moved to approve the consent agenda as written, excluding 2.5 WRAPP reports to be updated at October 1 Commission meeting. Bonnie Bush, second. Motion carries, 10-0.

3.1 **Psych Review Workgroup / Sunrise Review update** – Lauren Lyles-Stoltz notified the Commission the sunrise review report is not ready, but will bring a completed report to the October 1 business meeting. The workgroup (Gallaher, Gerard, Lyles-Stoltz, Ritchie, Strouse) wanted to remind the Commission of the following overall points:

- The Commission does not maintain any list of other prescribers, so why would we do it for psychologists?
- The bill does not actually amend all the necessary RCWs to allow psychologists to have prescriptive authority.
- A sunrise review (RCW 18.120) can be requested by legislature to the DOH to see if a profession meets the requirements needed to expand scope of practice or establish a new profession.

3.2.a **Self-inspection worksheets, update** – **MOTION** – Ken Kenyon moves that the Commission approve the compounding sub-committee's recommendations from that public hearing/review. Craig Ritchie, second. Motion carries. 10-0.

3.2.b **Self-inspection worksheets, review input by stakeholders** – Lauren Lyles-Stolz reviewed new items/public comments the subcommittee recommends adding to the self-inspection sheets.

#10 WAC 246-945-100 Compounding minimum standards / USP 825 – Lauren confirmed for Erika Anderson (stakeholder) that the Commission is currently "applying enforcement discretion" on USP 825. The compounding subcommittee will meet to decide what will happen after the December 1, 2020 when the USP goes into effect.

#26 WAC 246-945-415 Dispensing and delivery of prescription drugs (7) – Craig Pederson (stakeholder) questioned why this question was included. The Commission agreed #26 should be moved to a future HCE self-inspection sheet.

MOTION – Bonnie Bush moves to accept the recommendations by the compounding sub-committee as discussed. Kat Wolf-Khatchatourian, second. Motion carries, 10-0.

3.2.c **Self-inspection worksheets, finalize** – **MOTION** – Ken Kenyon moves that we approve the new WACs and questions for the self-inspection worksheets that were just reviewed. Sepi Soleimanpour, second. Motion carries, 11-0.

4.1 **Review Commission authorized policies, guidance, and interpretive statements for updates, re-approval, and rescind** led by Lauren Lyles-Stoltz.

4.1.1 **MOTION** – Craig Ritchie moved to approve the non-substantive changes. Bonnie Bush, second. Motion carries, 11-0.

(1) PQAC 3_Accreditation of Colleges of Pharmacy
(3) PQAC 35_CE Credit for Attending Commission Mtg
(4) PQAC 38 Continuing Ed Req for New Graduates
(5) PQAC 53 Procedure Diversion Inv 2.2017
(6) PQAC 54 Pharmacy Intern Registration
(7) PQAC 57 Nonresident Pharmacy Discipline Guideline
(8) PQAC 43a_Verification of Age by Applicant
(9) Interpretive Statement - Emergency Medical Reasons
(10) 690-331 ESRD or Kidney Dialysis Center Guidance
(11) PQAC 56_Labeling of Outpatient Meds for Adminss V2
(12) MD2015-13TreatingPartnersOfPatientsWithSTDsGuideline
(13) PQAC 61 - USP 795 Nonsterile Compounding Information
(14) D001 Use of photos-videos by OII pharmacists
(15) 690330 Directive Nonresident recognized states
Category 1 Non-Substantive Changes Keep

4.1.2 **MOTION** – Teri Ferreira moved to rescind the policy statements, as they are included in the current WACs as identified. Jerri Allard, second. Motion carries, 11-0.

(1) PQAC 39_Closing a Pharmacy - Patient Notification
(2) PQAC 47_ HIV-AIDS Education for Initial Credentialing
(3) PQAC 43_Official Transcripts - Reciprocity Applicants
(4) PQAC 36_Postgraduate Intern Registration.doc
(5) PQAC 63 Licensing of Virtual Manufacturer and Virtual Wholesaler
(6) PQAC 49 Absence of a Pharmacist
(7) PQAC 50 - Closed Door Long-Term Pharm-Personnel v 3
(8) PQAC 34_Job shadowing
(9) Directive - Parenteral Product Non-Enforcement
(10) PQAC 28_Internship Experience in Federal Facilities
(11) PQAC 45_ Internship Hours
Category 2 Rescind

4.1.3 Lauren Lyle-Stoltz and Christopher Gerard reviewed documents/policies for further direction from Commission. Commissioners agreed to all staff suggestions.

(1) PQAC 44_ Exception Application Guidelines
(2) PQAC 40_Qualification for Re-exam NAPLEX
(3) 690327InterimCDTAGuidanceBookletRev0
(4) Hazardous Drugs USP 797 vs 800
(5) PQAC 51 E Signature- Delegation Authority LTC
(6) PQAC 59 Opioid Overdose Medication - ED PS

(7) 690-329 Guideline OTP medications
(8) PQAC 52 Patient Counseling Procedure 3.2017 PS
(9) PQAC 62 PQAC Technology and Services Guidelines
(10) Transfer of Unfilled or On-hold Prescriptions
Category 3 - Keep Commission Review

MOTION – Bonnie Bush moved to accept the recommendations as discussed in Category 3. Second, Jerrie Allard. Motion carries, 11-0.

4.2 **Review COVID-19 Technical Assistance Letter –** Lauren Lyles-Stoltz, Marlee O'Neill, and Christopher Gerard explained these COVID-19 Technical Assistance letters will provide healthcare providers assistance if reported for allegedly not following or violating Governor issued proclamations related to the COVID-19 state of emergency. The NPDB would not be notified in the case of these allegations, but the allegations would be public record.

MOTION – Craig Ritchie moved we adopt the use of the technical assistance letters process as deemed appropriate when no violation of law has occurred and no potential for patient harm; has occurred. Ken Kenyon, second. Motion carries, 11-0.

4.3 **Commission Delegations** – Delegation of Decision-Making document tabled until Doreen Beebe can meet with and edit documents for clarity. Review at the October meeting.

MOTION – Craig Ritchie moves to update the Signature Delegation. Teri Ferreira, second. Motion carries, 11-0.

5. **Open Forum** –

- Cindy Wilson, stakeholder: **Is there any information whether or not the Governor's proclamation 2036.4 would be extended? Specifically, part that relates to license of location, it expires at the end of this month.**

  Lauren Lyles-Stoltz informed Cindy we usually only find out about 24 hours prior to the extension. We will be communicating and updating the Plan 19 as soon as possible, but do not have an update at this time.

  HCE follow-up question: Is an HCE by definition a pharmaceutical firm and how does that work? Request a clarification document defining these types of 'locations' and how do we ensure we apply the rules and applying them correctly.

  Lauren Lyles-Stolz and staff will convene a subcommittee meeting to develop an HCE self-inspection will identify the rules that apply to HCEs. Also, incorporate this into the POC communication which also addresses periodic inspections and which facilities.

- Justin Yee, stakeholder: **In regards to the change of dosage form, if a provider writes for one form and it is the salt forms that are different, kinetically the two agents may be different but pharmacodynamically and clinically, they are used for the exact same indications. Does the pharmacist have the ability to interchange those salt forms in order to best serve the patient?**

  After some discussion, this question will be tabled until the next meeting on October 1, 2020.

- Mike Li, stakeholder: **Some transactions are not appearing in the Prescription Monitoring Program database. Is the Commission aware? Also, request a communication be sent to stakeholders due to safety and quality risk**.

  Lauren Lyles-Stoltz will connect with the PMP program for more information to be discussed at the next Commission meeting October 1, 2020.

6.1 **Pharmacist applicant study plan approval and reauthorization to take MPJE a fifth time** – **MOTION** – Ken Kenyon motioned we delegate 6.1 panel review to Ken Kenyon, Jerrie Allard, and Sepi Soleimanpour, and Uyen Thorstensen. Second, Uyen Thorstensen. Motion carries, 11-0.

The subcommittee has reviewed applicant's study plan and have the following recommendations:

- Find a mentor to help guide applicant through study plan.
- Do not take as soon as possible as this is the last attempt. Take the time to ensure applicant knows material.
- Create a study routine every day.

Doreen Beebe will supply resource information to applicant.

MOTION – Ken Kenyon move we approve candidate to sit for his next examination at a time he feels most appropriate for him. Uyen Thorstensen, second. Motion carries, 4-0.

7.2 **Commissioner's Open Discussion**.

- On behalf of Patrick Gallaher, Teri Ferreira presents:

  Patrick Gallaher is requesting and offering to author infection control guidelines for vaccine administration in the COVID environment. The guidance would be used for licensees under our authority and not direct how a shot is administered, but provide direction for workplace steps to reduce the risk of transmission of COVID while administering vaccine.

Lauren Lyles-Stoltz will find more information regarding vaccine-coordinating group to bring back to the October 1, 2020 meeting.

There was some discussion on the possibility of liability on the Commission. Suggestions to create sources for our licensees rather than create a document/guideline that must be continually updated was made.

- Ken Kenyon would like to request that we have a subcommittee meeting in September to discuss HPACs so we may collate the remaining questions and concerns (i.e., DEA) to bring back information at the October meeting.

  Commission agrees.

8.1 **Executive Director Update**.

1. **Strategic planning meeting** – requests use day 1 of our 2 day meeting In October to do deeper strategic planning. Sending survey to Commission members to define priorities better.

   Commissioners concur this should happen and ensure differentiation between strategy, visionary, priority for Commission. Delineation between strategic plan and tactical plan.

   Lauren Lyles-Stolz, Bonnie Bush, Jerrie Allard, and Christie Strouse will work on the Commission strategic plan.

2. **Lisa V. Hunt**, new pharmacist supervisor starting next week. Welcome!

8.3 **Christopher Gerard, AAG, update** – continually monitoring the governor issued declarations addressing issues related to the practice of pharmacy and in regular communication with Lauren on these pieces. Waiting on news related to extension.

9 **Summary of Action items**:

1. Lauren Lyles-Stolz
   a. Reach out to the PMP regarding why information is not crossing over in the database.
   b. Adaptation language
   c. Work with the Department of Health and vaccination coordinators for guidance documents; as well as CDC and other recommendations for the October meeting.
   d. Strategic planning
      i. Develop survey with Tim Lynch and Teri Ferreira
      ii. Work with Jerrie Allard and Bonnie Bush for planning session for October meeting.
2. HPAC sub-committee initiated by Ken Kenyon.

3. HCE Inspection tool to be created to clarify facility vs. pharmaceutical firm questions.
4. SOD/POC – staff continue work on these documents to update licensees on the inspections.

Business Meeting Adjourned 12:38 p.m.

Commission SBAR Communication

Agenda Item/Title: 3.2 Suspicious Order Update

Date SBAR Communication Prepared: 9/29/2020

Reviewer: Lauren Lyles-Stolz

Link to Action Plan:

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

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

Pharmacy Quality Assurance Commission (commission) staff have received a number of questions related to WAC 246-945-585 Wholesaler – Suspicious orders and due diligence that may require clarification or action from the commission. The requirement for wholesalers to electronically report suspicious orders went into effect on July 1st.

The commission can consider whether or not to continue its enforcement discretion and/or provide wholesalers with a certain period of time to comply with WAC 246-945-585.

Background: (Briefly state the pertinent history):

The requirement for wholesalers to reports suspicious orders of controlled substances or drugs of concern is new in chapter 246-945 WAC. Previous WAC only required reporting on precursor substances. The requirements in WAC 246-945-585 came out of the work done with the Office of the Attorney General requested by the Washington State Opioid Response Workgroup.

WAC 246-945-585 both requires that wholesalers report suspicious orders to the commission as well as engage in due diligence to identify customers who might be diverting controlled substances of drugs of concern. The language in WAC 246-945-585 largely mirrors what is in the NABP's Model State Pharmacy Act and Model Rules. The reports that must be reported to the commission are suspicious orders within 5 business days of the identification (WAC 246-945-585(1)(a)) or "zero" reports when no suspicious orders have been identified (WAC 246-945-585(1)(b)). Zero reports must be submitted within 15 business days after the end of the calendar month. Wholesalers may apply for an exemption from reporting if they do not distribute controlled substances or drugs of concern (WAC 246-945-585(1)(c)). Additionally, wholesalers are required to electronically report any customer that is believed to be engaged in diversion, including those that they refuse to sell to, within 30 days of the refusal, cessation, or identification (WAC 246-945-585(5)).

WAC 246-945-585 states that these reports must be submitted to the commission electronically, but it does not specify how or in what format. WAC 246-945-585(6) states that the reports should be submitted in DEA ARCOS format where applicable. The required fields for suspicious orders are: customer name, customer address, customer DEA registration number, state license number, transaction date, drug name, NDC number, quantity ordered, and indication of whether the drug was shipped, and if not, the basis for the refusal to ship. For reports of customers believed to be engaged in diversion, the report must include customer name, customer address, DEA number, state license number, and an explanation of why the wholesaler identified the customer as a possible diversion risk.

While the ARCOS format (shown in the "transaction record" template) and other states' suspicious order forms/memos contains some of the same fields as required by WAC 246-945-585, there are some distinct differences. *(see table below)* For example, state license number and reason for refusal are not required fields in the ARCOS format, but are required for suspicious order reports in WAC 246-945-585.

Under the SUPPORT Act, the DEA was directed to create a new centralized suspicious order database, Suspicious Order Reporting System (SORS), launched on October 23, 2019. The SUPPORT Act requires that **all** DEA registrants that **distribute** controlled substances report suspicious orders to DEA.

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

The suspicious reporting requirement in WAC 246-945-585 went into effect on July 1st, but wholesalers may need additional time to come into compliance with this new rule. Some wholesalers have automated systems set up to submit reports to the DEA and other states using either a ARCOS format report, online SORS submission, or by developing their modified State DEA report to reflect each state's requirements. These automated systems may require reconfiguration to add the fields required in WAC 246-945-585.

The PQAC team has been focusing their efforts on the feasibility of implementing a suspicious order process and system to comply with the new rules. The suspicious order reporting aspect seems more attainable with the current resources, however, the monitoring and compliance of licensees submitting "zero" reports, meaning without a suspicious order activity, may be more challenging due to limited resources. There are currently over 1,300 licensed wholesalers in Washington, meaning there could be a high volume of monthly "zero" reports for commission staff to process. Additionally, these submissions would have to be cross-referenced to ensure each wholesaler has submitted one of the required monthly reports (suspicious or zero).

As this is a new requirement in chapter 246-945 WAC, the commission could exercise its enforcement discretion to grant a period of time for wholesalers to comply with WAC 246-945-585. The commission could also approve a guidance document or FAQ to communicate this enforcement discretion to licensees. The commission should further clarify that the ARCOS format is not required.

The following table includes the options currently available for Suspicious Order Reporting:

Type of Report	Required information in WAC 246-945-585 , but not Included in following Reports
ARCOS Report	• Customer Address • State license number • Indication of whether the drug was shipped, and if not, the basis for the refusal to supply
SORS Report	• Customer Name • Customer Address • Drug Name
Other State's DEA Report to the BOP	• State License Number • Transaction Date • NDC Number

	• Indication of whether the drug was shipped, and if not, the factual basis for the refusal to supply

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

Suspicious Order Reports/Customer Reports: (Motion Required)

1. **Recommended:** Commission could consider applying enforcement discretion for a defined period of time (recommend ~180 days due to COVID-19 response) until licensees can reconfigure their system to comply with Washington state pharmacy rules. Commission will accept Suspicious Order reports. The format for the report may be selected by the wholesaler; however, it must include all information as required in WAC 246-945-585.

   Note: Reports should be submitted to pharmacyrules@doh.wa.gov with the following subject line nomenclature Date_CompanyName_SuspiciousOrderReporting_WAstate or Date_CompanyName_CustomerOrderReporting_WAstate

2. Commission to consider applying enforcement discretion of the new rules WAC 246-945-585 until the DEA regulations are final (approx. 1-2 years)

3. Commission could consider accepting an ARCOS or SORs report with enforcement discretion on fields not included in the respective report until full compliance or future rulemaking is done by the commission.

Exemption Reports:

1. Commission could consider applying enforcement discretion of the new rules until the PQAC team can develop an Exemption Application for those Wholesalers that do not distribute controlled substances or drugs of concerns. Motion may be required.

Zero Reports:

2. Commission could consider applying enforcement discretion of this requirement until a future commission meeting discussion.

Follow-up Action:

The PQAC team will update FAQ or develop guidance document with the commission's clarifications and bring it back to the commission for a vote on adoption, if applicable.

The PQAC team will create an Exemption Application for those Wholesalers that do not distribute controlled substances or drugs of concerns.

The PQAC team will send communication through GovDelivery on the process for submitting reports as required by WAC 246-945-585 as well as provide the links to any additional guidance document, if applicable.

STATE OF WASHINGTON

DEPARTMENT OF HEALTH

Date: 08/18/2020

Licensee and address:

Case No.

Dear:

The Pharmacy Quality Assurance Commission (PQAC), is investigating a report of a suspicious order for controlled drugs involving your pharmacy. The specific allegation is discussed below.

PQAC is authorized to investigate allegations and complaints of violations of laws or regulations under its jurisdiction. RCW 18.64.005 & 18.64.310(3).

State law requires you to cooperate with an investigation. WAC 246-945-005(6). Please provide a full and complete explanation of the matter in writing to the questions listed below. We may use your response if we take disciplinary action or in a hearing. You may have an attorney assist you prior to making your response, but this will be at your expense.

If an attorney represents you, please have the attorney send me a Letter of Representation. The letter will ensure any correspondence with you will be provided to your attorney.

The Health Care Information Act requires you to disclose health care information about a patient without patient authorization. RCW 70.02.050(2)(a).

Please provide your signed, written response/statement/answers to the following information/questions: In the first paragraph of your statement please provide your name, DOB, title, and a brief education and work history.

The allegation states that your pharmacy exceeded its normal threshold for ordering *****drug***. On approximately ***date***, ***wholesaler*** flagged an order regarding ****specific details, order, and quantity***. Please answer the following questions regarding this incident.

1) Is your pharmacy aware of an order for this quantity on approximately this date?
2) Please elaborate on the cause for exceeding your threshold. Please include if the matter warranted any internal investigations and the results of those investigations.
3 If you were not aware of this activity or order, what steps, if any, do you plan to take now that you are aware of this matter?
4 Please generally describe the process and oversight for ordering controlled substances at your facility. Please include a copy of any policy and procedure related to the ordering of controlled substances.
5 Please include any additional information you would like PQAC to consider.

The information is due **21 days** from receipt of this letter. You may email me PDF documents at or mail your response to the address below. Please contact me if you have any questions or cannot provide the information by the due date. Thank you for your cooperation.

Sincerely,

Pharmacist Investigator
Washington State Department of Health
16201 E. Indiana Ave Suite 1500
Spokane Valley, WA 99216
(P) 509-329-2207
(F) 509-329-2167
Enclosure

I declare under penalty of perjury under the laws of the State of Washington that I placed this letter addressed to the person named above at the address listed on the date identified in the United States mail in a properly addressed and stamped envelope.

Dated Date _____ at

_____ , Washington

_____

DEPARTMENT OF HEALTH
PHARMACY QUALITY ASSURANCE COMMISSION
PROCEDURE

Title:	Euthanasia Training Program Guidelines for Animal Control Agencies and Humane Societies	**Number:**
Reference:	RCW 69.50.310 Sodium pentobarbital—Registration of humane societies and animal control agencies for use in animal control. RCW 69.41.080 Animal control—Rules for possession and use of legend drugs. WAC 246-945-354 Animal control and humane society registration. WAC 246-945-503(2)(b), and (4) Authorized personnel.	
Contact:	Lauren Lyles-Stolz, PharmD., Executive Director	
Effective Date:	October 2, 2020	
Approved:	Tim Lynch, PharmD, MS, FABC, FASHP, Pharmacy Quality Assurance Commission Chair	

POLICY STATEMENT:
This procedure establishes guidelines for euthanasia training programs seeking to meet substantially equivalent training requirements as a commission-approved program.

The instructor of the training program must be a licensed veterinarian. The program must use a manual approved by the commission or approved by a nationally recognized authority on euthanasia. The training cannot be less than four hours in length. The training will hold a final examination of the course where the passing score is not less than seventy-five percent correct.

The training program is required to include both didactic and practical training to include but not limited to the following topics:

(a) Anatomy and physiology:
  (1) Methods of euthanasia;
  (2) Routes of drug administration;
  (3) Use of sedatives;
  (4) Drug dosing;
  (5) Use of restraints; and
  (6) Process and verification of death;
(b) Pharmacology of the drugs;
(c) Indications, contraindications, and adverse effects;
(d) Human hazards;
(e) Disposal of medical waste (needles, syringes, etc.);
(f) Recordkeeping and security requirements; and

(g) Applicable federal and state laws and rules.

Training programs will retain a list of persons who have successfully completed the program for a minimum of two years. Upon successful completion of the training, a certificate of completion will be issued. The certificate will include the following:

- Recipient name;
- Date; and
- Signature of the veterinarian(s) who lead the training.

A person who has successful completed a training program that meets these guidelines is deemed to have completed an approved program. A humane society or animal control agency may designate a person who can document completion of approved training as *authorized personnel*.

Under the *Sodium Pentobarbital* registration, authorized personnel are defined as a person trained and approved by the humane society or animal control agency to possess and administer approved legend drugs and controlled substances to euthanize injured, sick, homeless, or unwanted domestic pets and animals.

The commission will maintain a registry of approved training programs and manuals. Interested persons may request a copy of the registry by contacting the commission office.

Department of Health

Pharmacy Quality Assurance Commission

Policy Statement

Revised – 10/18/11

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

Disclaimer: The policy statement may be revised from the 6 month enforcement discretion timeline to the 12-month enforcement discretion timeline based on the commission's decision.

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

The commission will not find deficiencies or take enforcement action against its licensees for failure to comply with USP 800 through at least March 1, 2021. This position will take effect immediately.

The commission will not find deficiencies or take enforcement action against its licensees for failure to comply with USP 825 through at least May 1, 2021. This position will take effect immediately.

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

The commission will consider extending its use of enforcement discretion for USP 800 and USP 825 if USP has not made the revised USP chapters <795> (USP 795) and <797> (USP 797) official. In addition, if USP makes the revised USP 795 and USP 797 official prior to March 1, 2021 or May 1, 2021, the commission will consider whether to

extend its use for enforcement discretion for an additional six-month period to allow licensees to comply with all applicable USP chapters.

USP Chapters	Enforcement Discretion
USP 800	October 1, 2020 –March 1, 2021
USP 825	December 1, 2020-May 1, 2021
Revised USP 795 and 797	N/A; Revised Chapters have not been released
Current USP 795 and 797 **These chapters will continue to be enforced.**	

Table of PQAC's Enforcement Discretion Timeline with Different Timeline

Note: Please see Policy #60 regarding direct conflicts between USP 797 and USP 800.

USP Chapters	Enforcement Discretion
USP 800	December 1, 2020-May 1, 2021
USP 825	December 1, 2020-May 1, 2021
Revised USP 795 and 797	N/A; Revised Chapters have not been released
Current USP 795 and 797 **These chapters will continue to be enforced.**	

Table of PQAC's Enforcement Discretion Timeline with Same Timeline

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

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

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

The commission recognizes that there are discrepancies between USP 797 and USP 800 in its current form; however, its approach to these discrepancies is established in a separate policy statement (#60), "Regulation of the Handling of Hazardous Drugs" available on the commission's website.

Further, the commission will not take enforcement action or find licensees deficient for failure to comply with USP 800 through at least March 1, 2021. In addition, the commission will not take enforcement action or find licensees deficient for failure to comply with USP 825 through at least May 1, 2021.

The commission may consider extending this use of enforcement discretion at a future open public meeting. This will occur either at the business meeting before March 1, 2021 and May 1, 2021, or at the earliest possible meeting after USP makes the revised USP 795 and USP 797 official.

If USP makes the revised USP 795 and USP 797 official prior to March 1, 2021 or May 1, 2021, the commission will consider whether to extend its use for enforcement discretion for an additional six-month period to allow licensees to comply with all applicable USP chapters.

Department of Health
Pharmacy Quality Assurance Commission

Policy Statement

Revised – 10/18/11

Title:	Regulation of the Handling of Hazardous Drugs *Number: 60*
References:	RCW 18.64.270(2), WAC 246-945-016, WAC 246-945-017, WAC 246-945-100 United States Pharmacopeia Chapters <795>, <797>, <800>, and <825>
Contact:	Lauren Lyles-Stolz, PharmD, Executive Director
Phone:	(360) 236-4946
Email:	wspqac@doh.wa.gov
Effective Date:	February 2, 2018 (reaffirmed August 28, 2020)
Supercedes:	N/A
Approved By:	Tim Lynch, PharmD, MS, FABC, FASHP, Pharmacy Quality Assurance Commission Chair

This policy establishes the approach of the Pharmacy Quality Assurance Commission (commission) as it relates to direct conflicts between United States Pharmacopeia (USP) chapters <797> (USP 797) and <800> (USP 800). This policy also attempts to clarify uncertainty related to USP 797, USP 800 and the Washington State Department of Labor and Industries' (LNI) General Occupational Health Standards rules on Hazardous Drugs (WAC 296-62-500 *et al).*

The commission will not find deficiencies or take enforcement action against its licensees for adhering to the standards of USP 800 that are in direct conflict with USP 797. Additionally, licensees who elect to adopt USP 800 standards prior to the commission's enforcement of the chapter will not be found deficient or have enforcement action taken against them while this policy is in effect.

After consultation with LNI, it has been determined that licensees who are compliant with USP 797 and USP 800 will be considered compliant with LNI's General Occupational Health Standards rules on Hazardous Drugs (WAC 296-62-500 *et al).*

BACKGROUND: Following a 2012 meningitis outbreak stemming from unsterile compounding at the New England Compounding Center in Massachusetts, several states worked to adopt standards around sterile and non-sterile compounding of medications. In 2013, the Washington State legislature adopted standards set by the USP, a national leader in compounding standards, as the standards pharmacies must meet in order to compound medication. RCW 18.64.270(2) states "Any medicinal products that are compounded for patient administration or distribution to a licensed practitioner for patient use or administration shall, at a minimum, meet the

standards of the official United States pharmacopeia as it applies to nonsterile products and sterile administered products." The USP is a non-governmental organization that establishes national consensus standards and guidelines for the pharmaceutical industry.

The commission has enforced standards published by USP for sterile and non-sterile compounding since 2014. Sterile compounding standards are currently published in USP 797 and non-sterile compounding standards are published in USP chapter <795> (USP 795). In September 2015, when a revision to USP 797 was published for public comment, it was anticipated that a finalized update would be published sometime in 2016, and subsequently made official sometime in 2017. Due to the large number of comments received by the USP, the final publication of the update has been delayed several times.

During the revision process for USP 797, the USP developed and adopted USP 800, which addresses the handling of hazardous drugs in healthcare settings. USP 800 was initially projected to go into effect on July 1, 2018. This delayed effective date was intended to allow facilities that would need to go through renovations or new construction some additional time to become compliant with USP 800. Standards for hazardous drug compounding were supposed to be eliminated in the initial proposed revision to USP 797 and only exist in USP 800. The delay in formal adoption or release of an updated revision draft for USP 797 has created some direct conflicts between the two chapters.

At this time, the commission has identified the following provisions of USP 797 and USP 800 that are in direct conflict:

USP 797	**USP 800**
All hazardous drugs shall be prepared in a BSC [biological safety cabinet] or a CACI [compounding aseptic containment isolator] that meets or exceeds the standards for CACI in this chapter. The ISO [international organization for standardization] Class 5 [] BSC or CACI shall be placed in an ISO Class 7[] area that is physically separated . . . (*Hazardous Drugs as Compounded Sterile Preparations).* If the PEC [primary engineering control] is a CAI [compounding aseptic isolator] or a CACI that does not meet the requirements above or is a LAFW [laminar airflow workbench] or BSC that cannot be located within an ISO Class 7 [] buffer area, then only low-risk level nonhazardous and radiopharmaceutical CSPs [compounded sterile preparations] pursuant to a physician order for a specific patient may be prepared, and administration of the CSP	The C-PEC [containment primary engineering control] must be located in a C-SEC [containment secondary engineering control], which may either be an ISO Class 7 buffer room with an ISO Class 7 ante-room (preferred) or an unclassified [containment] segregated compounding area (C-SCA). *(5.3.2 Sterile Compounding).*

shall commence within 12 hours of preparation or as recommend in the manufacturer's package insert, whichever is less. *(Placement of Primary Engineering Controls).*	
In facilities that prepare a low volume of hazardous drugs, the use of two tiers of containment (e.g., a CSTD [closed-system drug-transfer system] within a BSC or CACI that is located in a non-negative pressure room) is acceptable. *(Hazardous Drugs as CSPs)*.	Elimination of the current allowance in <797> for facilities that prepare a low volume of hazardous drugs that permits placement of a BSC or CACI in a non-negative pressure room. *(USP 800 Briefing)*.

These direct conflicts have created uncertainty amongst licensees as to which standard the commission will enforce at inspections or in disciplinary action.

On September 29, 2017, the USP announced a delay in the official effective date of USP 800, postponing it from July 1, 2018 to December 1, 2019. However, USP postponed enforcement while appeals on related provisions in USP <795> and <797> are resolved. During this appeals process, USP <800> will be "informational and not compendial applicable, USP encourages utilization of <800> in the interest of advancing public health."

Several licensed facilities in Washington State have already sought capital expenditures from their organizations to begin renovation or new construction to comply with USP 800. The commission wishes to encourage its licensees to comply with USP 800, rather than risk being found deficient or subject to enforcement action because USP 800 standards reflect safer handling of hazardous drugs, ensuring patients receive the highest quality hazardous drug products.

While examining its position on direct conflicts between USP 797 and USP 800, the commission also analyzed potential areas of conflict between USP 797, USP 800 and LNI's General Occupational Health Standards rules on Hazardous Drugs (WAC 296-62-500 *et al)*. During this analysis, LNI expressed to the commission that if the commission's licensees are compliant with USP 797 and USP 800, they will also be compliant with LNI's rules.

CONCLUSION: The commission will not take enforcement action on a licensee if the licensee adheres to USP 800 standards that are in conflict with current USP 797 standards. The commission believes USP 800 furthers the commission's mission of ensuring patient safety, particularly in the compounding of hazardous drugs.

In addition, licensees may elect to adopt USP 800 standards prior to the commission's enforcement of the chapter; and in doing so, will not be found non-compliant with RCW 18.64.270(2), which requires adherence to currently adopted USP standards, specifically USP

797 in its current release. This provision will allow for adequate time to plan for capital and process changes to meet proposed USP standard changes.

If licensees are complaint with USP 797 and USP 800, they will also be compliant with LNI's General Occupational Health Standards rules on Hazardous Drugs (WAC 296-62-500 *et al)*.

4.3 USP Applicability Clarification: Non-compounding pharmacies versus Compounding pharmacies

Does the WAC 246-945-100 (Compounding minimum standards) require compliance with USP 800 for licensees that are only handling and not compounding hazardous drugs?

No, USP 800 only applies to licensees compounding hazardous drugs.

Commission SBAR Communication

Agenda Item/Title: 4.4 Monitoring of Drug Therapy: Pharmacists Conducting Health Screenings and Point-of-Care Testing

Date SBAR Communication Prepared: 9/24/2020

Reviewer: Lauren Lyles-Stolz

Situation: (Brief Description)

During Pharmacy Commission (commission) discussions addressing the ability of pharmacists to conduct COVID-19 testing earlier this year, a number of stakeholders and commissioners highlighted that pharmacists already provide point-of-care testing and health screenings for patients.

After a thorough discussion, it was made clear that pharmacists have been able to engage in point-of-care testing and health screenings to some extent because it was conducted either:

(i) Pursuant to the terms of a CDTA,
(ii) Pursuant to another standing order or protocol developed with an interdisciplinary team within a health care facility or system, or
(iii) Under the pharmacist's independent ability to monitor drug therapy 'monitoring of drug therapy' rule (*old* WAC 246-863-110; *new* WAC 246-945-355).

Commission members then raised concerns about the ability of pharmacists to conduct COVID-19 testing under the 'monitoring of drug therapy' option, when there is no approved drug therapy specifically for COVID-19. This led to additional follow-up questions from licensees for further clarification of a pharmacist's scope of practice regarding point-of-care testing and health screenings.

The existing impression described by many pharmacists was that they could procure or order tests as part of their scope of practice for items like point-of-care testing for walk-in flu or strep testing, A1c, gut inflammation mail-in tests, vitamin d levels, and genetic profile testing, among others. There has also been the understanding amongst some licensees that these tests do not require a written protocol (CDTA) **or** a current drug therapy that the pharmacist is monitoring for those testing orders. Therefore meaning the pharmacists could provide cognitive services with a visit and perform screening and/or lab ordering with no existing diagnosis of a condition, with no CDTA, or with no current drug therapy--then contact an individual's prescriber to recommend a prescription if necessary.

Background: (Briefly state the pertinent history):

Below are the relevant statutes and rules that shape the scope of practice of pharmacy in WA state and the highlighted portions that grant pharmacist the ability to engage in point-of-care testing and health screenings for patients related to an existing diagnosis and drug therapies for optimization of drug therapy.

Commission SBAR Communication

RCW 18.64.011(28)- "Practice of pharmacy" includes the practice of and responsibility for: Interpreting prescription orders; the compounding, dispensing, labeling, administering, and distributing of drugs and devices; the monitoring of drug therapy and use; the initiating or modifying of drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs; the participating in drug utilization reviews and drug product selection; the proper and safe storing and distributing of drugs and devices and maintenance of proper records thereof; the providing of information on legend drugs which may include, but is not limited to, the advising of therapeutic values, hazards, and the uses of drugs and devices.

The commission's new chapter (chapter 246-945 WAC) went into effect on July 1, 2020. WAC 246-945-355 **Monitoring of drug therapy by pharmacist** states that in the absence of a CDTA, the term "monitoring drug therapy" used in RCW 18.64.011 shall mean a review of the drug therapy regimen of patients by a pharmacist for the purpose of evaluating or rendering advice to the prescribing practitioner or patient regarding the patients drug therapy. Monitoring of drug therapy includes, but is not limited to, the evaluation of the patient through history taking, physical examination, ordering, administering or reviewing laboratory tests, imaging, and social evaluation **related to an existing diagnosis and drug therapies for optimization of drug therapy**.

Former rule for reference,
WAC 246-863-110
Monitoring of drug therapy by pharmacists.
The term "monitoring drug therapy" used in RCW 18.64.011(11) shall mean a review of the drug therapy regimen of patients by a pharmacist for the purpose of evaluating and rendering advice to the prescribing practitioner regarding adjustment of the regimen. Monitoring of drug therapy shall include, but not be limited to:
(1) Collecting and reviewing patient drug use histories;
(2) Measuring and reviewing routine patient vital signs including, but not limited to, pulse, temperature, blood pressure and respiration; and
(3) Ordering and evaluating the results of laboratory tests relating to drug therapy including, but not limited to, blood chemistries and cell counts, drug levels in blood, urine, tissue or other body fluids, and culture and sensitivity tests when performed in accordance with policies and procedures or protocols applicable to the practice setting, which have been developed by the pharmacist and prescribing practitioners and which include appropriate mechanisms for reporting to the prescriber monitoring activities and results

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

After further review of the practice of pharmacy and revised rule language, pharmacists are authorized to engage in POC testing and health screenings as part of their scope without a CDTA or protocol; however, it must be related to an existing diagnosis and drug therapy as stated in WAC 246-945-355.

In addition, if the patient initiates (e.g., walk-in) the request for a health screening or CLIA-waived POC tests, the pharmacist may carry out the ordering and administering of those tests as the patient has determined that they may have an existing diagnosis and

drug therapy that prompts further optimization. This example would fall within the scope of monitoring drug therapy.

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

Provide licensees with the following clarification:

Pharmacists may engage in the ordering and administering of CLIA-waived POC tests to the extent it falls within the scope of practice of a pharmacist as defined in RCW 18.64.011(28). Pharmacists should consider whether the ordering of a CLIA-waived POC test is part of the monitoring of drug therapy as defined in WAC 246-9454-355.

For completeness, pharmacists do not need a CDTA or protocol for ordering and administering of CLIA-waived POC tests or conducting health screenings. In addition, there is nothing prohibiting a pharmacist from including health screenings and CLIA-waived POC tests in their CDTA, standing order, or protocol along with other disease state management services agreed upon with the authorized prescriber if deemed necessary.

Follow-up Action: (Next Steps After the meeting – Document the commission's decision and/or any additional steps or follow-up requested; such as, report back in 6-months, etc.)

Commission staff will finalize an FAQ of this clarification for licensees and include the FAQ in the next NABP's newsletter.

Consider a future legislative ask to optimize the monitoring of drug therapy language in RCW 18.64.011(28) or consider future rulemaking to allow pharmacist to initiate the offer of health screenings and CLIA-waived POC tests to patients.

Commission SBAR Communication

Agenda Item/Title: Prescription Adaption: Clarification of Dosage Form (WAC 246-945-335)

Date SBAR Communication Prepared: 9/24/2020

Reviewer: Lauren Lyles-Stolz

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

Licensees have asked the commission to further clarify the interpretation or meaning of dosage forms as stated in WAC 246-945-335 Prescription adaptation.

Background: (Briefly state the pertinent history):

The commission's new chapter (chapter 246-945 WAC) went into effect on July 1, 2020, including their new section regarding Prescription Adaptation (WAC 246-945-335). This section was generated by feedback from licensees during the rule re-write out of the need for greater flexibility and guidance in adapting prescriptions to provide comprehensive care to patients in unforeseen circumstances e.g., commercial availability, formulation changes for pediatrics or elderly adults, etc.

While "dosage form" is not defined in rule, it is included in the definition of "drug product" in WAC 246-945-001(25):

> "Drug product" means a finished dosage form (e.g., tablet, capsule, solution) that contains an active drug ingredient generally, but not necessarily, in association with inactive ingredients. The term also includes a finished dosage form that does not contain an active ingredient but is intended to be used as a placebo.

Licensees have requested clarification on the intent of WAC 246-945-335, especially as it relates to subsection (2), change in dosage form.

> **WAC 246-945-335 Prescription adaptation.** Upon patient consent, a pharmacist may adapt drugs as specified in this rule, provided that the prescriber has not indicated that adaptation is not permitted.
> (1) Change quantity. A pharmacist may change the quantity of medication prescribed if:
> (a) The prescribed quantity or package size is not commercially available;
> (b) The change in quantity is related to a change in dosage form;
> (c) The change is intended to dispense up to the total amount authorized by the prescriber including refills in accordance with RCW 18.64.520; or
> (d) The change extends a maintenance drug for the limited quantity necessary to coordinate a patient's refills in a medication synchronization program in accordance with RCW 48.43.096.
> (2) Change dosage form. A pharmacist may change the dosage form of the prescription if it is in the best interest of patient care, so long as the prescriber's directions are also modified to equate to an equivalent amount of drug dispensed as prescribed.

Commission SBAR Communication

(3) Complete missing information. A pharmacist may complete missing information on a prescription if there is evidence to support the change.
(4) Documentation. A pharmacist who adapts a prescription in accordance with these rules must document the adaptation in the patient's record.

The commission can consider confirming their intent and interpretation of WAC 246-945-335(2).

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

After further review, dosage forms as stated in WAC 246-945-335(1)(b) and (2) and in the definition of drug product in WAC 246-945-001(25) means to describe the conventional finished dosage form e.g. tablet, capsule, solution, suppository, sublingual, etc. Therefore, the new WAC authorizes pharmacist(s) the option to adapt the prescription to another finished dosage forms in the best interest of the patient. Changing the drug products outside of the conventional dosage forms (e.g., salts) would fall outside the interpretation and intention of this provision.

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

The commission can consider confirming if the above assessment highlights the commission's intent and interpretation of the Prescription Adaptation rule (WAC 246-945-335) regarding changing dosage forms. ***No further action required.***

Follow-up Action: (Next Steps After the meeting – Document the commission's decision and/or any additional steps or follow-up requested; such as, report back in 6-months, etc.)

FAQ development on this topic if deemed necessary.

Commission SBAR Communication

Agenda Item/Title: 5.2 Wholesaler licenses for out-of-state manufacturers

Date SBAR Communication Prepared: 09/28/2020

Reviewer: Lauren Lyles-Stolz

Link to Action Plan:

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

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

Out-of-state manufactures are required to seek a wholesaler license in Washington if they choose to distribute drugs into the state.

An inspection report is required for a wholesaler license in the new chapter, as stated in WAC 246-945-246(3)(a). A copy of a site inspection conducted by the state's regulatory authority or a third-party inspection program recognized by the commission within the last two years and every two years with the distributor's renewal are acceptable by the commission. Further, the commission has approved the NABP Drug Distributor Accreditation program as a third-party program for licensees seeking a wholesaler license.

The commission is also considering other approved third-party inspection reports such as the Food and Drug Administration (FDA) Inspection Observations or FDA Form 483 used during routine or surveillance inspections. The commission has asked the PQAC team to explore the option of accepting the FDA as a third-party program for wholesale licensee holders.

Background: (Briefly state the pertinent history):

Federal Perspective: A goal of the Food and Drug Administration, Center for Drug Evaluation and Research (CDER), is ensuring safe and effective drugs are available to improve the health of people in the United States. CDER performs Establishment Inspection Reports (EIR) and regulates over the counter and prescription drugs, including biological therapeutics and generic drugs. CDER also covers non-medicines, like fluoride toothpaste, antiperspirants, dandruff shampoos, and sunscreens.

FDA's Office of Regulatory Affairs (ORA) is responsible for inspections and enforcement. ORA investigators or Consumer Safety Officers (CSO) may observe conditions they deem to be objectionable or deficient when inspecting an entity and will capture these observations in the FDA Form 483. These observations are usually listed in order of significance and discussed with the entity.

FDA Form 483 is issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts, in their judgment.

For further information as well as an example of a standard citation, visit the FDA's Inspectional Observations: Citations and Frequently Asked Questions pages.

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Other State's Perspective:

Only a few states are currently accepting Inspection Observations or Form FDA 483's inspection reports directly from the applicant. Whereas other states are in the initial phases of considering this as a future option. Other states agree that FDA inspections are highly comprehensive and rigorous as they cover Current Good Manufacturing Practices (cGMPs); however, they have also identified some operational challenges in implementation of this newer reporting model (e.g., unpredictable timelines in overall inspection process, lengthy exception application review process, resource intensiveness, necessary subject matter expertise, staffing constraints,).

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

The FDA has jurisdiction over wholesalers, but they typically do not perform routine inspections of wholesaler facilities. They have deferred regulation of wholesalers to state agencies per 21 CFR 205.

Due to statutory limitations, we license out-of-state manufacturers as wholesalers. The wholesaler standards in WAC 246-945 are less stringent than the *Current Good Manufacturing Practices* (cGMP) (Title 21 CFR 210 through 21 CFR 212) used by CDER to inspect manufacturers. Further, the CDER inspection standards align with the commission requirements for all state manufactures (WAC 246-945-550).

Examples of areas focused on during a Washington wholesaler inspection:

1. Well lighted & ventilated
2. General cleanliness & sanitation
3. Adequate space for operation; restrooms
4. Items stored at proper temperatures & humidity

Examples of where cGMP is more restrictive than Washington inspection standards may be found in USP 797 and included in the 12-page comparison of USP <797> to cGMP (retrieved for an FDA presentation by Branch Chief Ian Deveau, Ph.D.)

<797>	Proposed <797>	CGMP
Required sterile gowning items		
Gloves, only	Gloves and sleeve covers, only	Gloves and all other gowning items
Exposed skin?		
Neck, checks, eyes, and forehead allowed. Wrist skin not allowed.	Neck, checks, eyes, and forehead allowed. Wrist skin not allowed.	None allowed
Reuse of gowning items?		
Gloves and mask, no. All others, yes, if gloves/mask stored in ISO-8 anteroom.	Gloves, sleeve and mask, no. If other items sterile when first donned, then no. If other items were non-sterile when donned, then yes if stored in ISO-8	No

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

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The options listed below may be adopted by the Commission in part or whole.

Option 1: No action. Applicants may follow the current practice of submitting a copy of a State Board inspection reports from their resident state or NABP Drug Distributor Accreditation if completed within the previous 2 years.

Option 2: The Commission may accept FDA Inspection Reports (e.g., Establishment Inspection Reports (EIR) and FDA Form 483) in lieu of the resident State Board inspection report or NABP report and utilize the current exception application process to review applications. (This review process would align with other states processes.)

In addition, due to the emergency situation of COVID-19 and this being a new workflow within PQAC, the commission may also consider issuing a wholesaler licensee subject to review upon receiving the FDA inspection report to prevent any delay for those licensees engaged in the COVID-19 response.

The Commission's review may determine whether any deficiencies or observations listed by FDA constitute a significant risk to Washingtonians residents; or ask for a synopsis by the applicant of any violations and corresponding corrective action plan. The Commission may also ask for a recommendation by a pharmacist inspector, which would create a new workload and require expertise to support this new review process.

Follow-up Action:

The PQAC team will proceed as directed and communicate the commission's determination to licensees.

Department of Health
Washington State Pharmacy Quality Assurance Commission
P.O. Box 7874, Olympia, Washington 98504-7874
Telephone: 360/236-4817 Facsimile: 360/586-0123

Pharmaceutical Wholesaler Inspection Report

(Chapter 246-879 WAC)

Last Inspection: _____

Name and Address:

_____
_____
_____
_____

_____

Telephone:
Facsimile: _____

Date of Inspection: _____

Exam Number: _____ ___
Type of License:
OTC _____
Full Line _____
Full Line/Controlled Substances _____
Export _____
Export/Non-Profit _____
E-Mail Address: _____

DOH Credential Number: _____ DEA Registration Number: _____

_____ _____
Name and title of person responsible for facility Name and title of person permitting inspection

ADEQUACY OF FACILITY

1. _____ Well lighted & ventilated
2. _____ Employees & apparel clean
3. _____ General cleanliness & sanitation
4. _____ Adequate space for operation; restrooms
   (If residence, is separate space provided?) _____

Purpose of Inspection:

New _____
Routine _____
Closure _____
Technical Assistance _____

STORAGE CONDITIONS

5. _____ Items stored at proper temperatures & humidity (records for full-line)
   Products or product types _____
   _____
6. _____ Appropriate storage for flammable items
7. _____ Minimum equipment - properly maintained
8. _____ Environmental conditions prevent drug contamination (free of noxious odors)
9. _____ Security (describe):
   A. Alarm systems/exterior premises lighting _____
   B. Quarantine area (for full-line) _____
   C. Additional protection for controlled substances (compliance with 21 CFR) _____

RECORDS

10. _____ Invoices (describe):
    A. Source/suppliers _____
    B. Recipient/customers _____
    C. Proper controlled substance records _____
11. _____ Letters of verification from consulate of destination country (Export Wholesaler only)
12. _____ Policies & procedures for full-line (receipt, security, storage, inventory, distribution, stock rotation, recalls, emergencies, & outdates)
13.

Comments (see other pages of this report): ☐ Yes ☐ No

_____ _____
Signature of Person Permitting Inspection Signature of Pharmacist Investigator

Pharmaceutical Wholesaler Inspection Report
Inspection Comments

Washington State Pharmacy Quality Assurance Commission
Telephone Contact Numbers

Management and Other Resources		Pharmacist Investigator Supervisor
Lauren Lyles, Executive Director	360-236-4946	
Doreen Beebe, Program Manager	360-236-4834	

Websites

Washington State Pharmacy Quality Assurance Commission	www.doh.wa.gov/pharmacy
Washington Pharmacy Quality Assurance Commission (email)	WSPQAC@doh.wa.gov
Drug Enforcement Administration (DEA)	www.deadiversion.usdoj.gov
Food & Drug Administration (FDA)	www.fda.gov/cder
U.S. Pharmacopeia (USP)	www.usp.org

Commission SBAR Communication

Agenda Item/Title: Intern registration renewals in WAC 246-945-155(3)

Date SBAR Communication Prepared: 9/16/2020

Reviewer: Lauren Lyles-Stolz

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

The commission's new chapter (chapter 246-945 WAC) went into effect on July 1, 2020. While the chapter rewrite process included all rules under the commission's authority, the fee rules remain under the authority of the Secretary of Health (Secretary). These rules (chapter 246-907 WAC) are still in progress. When the fee rules are complete, the Department of Health (department) and commission staff will implement the two-year license renewal cycle for licensees.

Presently, while the new chapter is in effect but the two-year renewal cycle is not, there are implications for the intern registration requirements the commission can consider. Specifically, WAC 246-945-155(3) states that a pharmacy intern registration can only be renewed twice. Since chapter 246-907 WAC remains effective until the fee rules are complete, this means that a pharmacy intern may renew their registration twice for a 1-year duration. In other words, a pharmacy intern may be prevented from renewing their license after holding it for 3 years, at a minimum.

The commission can consider providing guidance on intern registration renewals in anticipation of the 2-year renewal cycle.

Background: (Briefly state the pertinent history):

Chapter 246-945 WAC went into effect on July 1, 2020. This effective date applied to all sections within the chapter, except the continuing education (CE) sections (WAC 246-945-178 and WAC 246-945-220), which have a delayed effective date to align with the fee rules package and the implementation of the two-year license renewal cycle. The CE requirements from the old rules remain in effect until the two-year renewal cycle is implemented.

The fee rules, currently in chapter 246-907 WAC are under the authority of the Secretary. Rulemaking is currently in process to implement a new fee schedule as well as the two-year license renewal cycle. Until this rules package is complete, the 1-year license renewal cycle determined by WAC 246-907-030(1) remains in effect.

Under current rule, "A pharmacy intern registration can only be renewed twice" (WAC 246-945-155(3)). With the 1-year renewal cycle currently in place (WAC 246-907-030), a pharmacy intern registration renewal is for a 1-year duration, potentially limiting a pharmacy intern registration to a total duration of 3 years. The initial registration would be for one year, followed by two renewals for a year each.

RCW 18.64.080(3) states "Any person enrolled as a student of pharmacy in an accredited college may file with the department an application for registration as a pharmacy intern…" Further, "All certificates issued to pharmacy interns shall be valid for a period to be determined by the

commission…" There was no defined number of renewals on intern registrations in the old rules (chapter 246-858 WAC), although WAC 246-858-020(4) required "To retain a certificate as a pharmacy intern, the intern must make continuing satisfactory progress in completing the pharmacy course."

With the planned implementation of the two-year renewal cycle to accompany chapter 246-945 WAC, the PQAC team believes that the intention of WAC 246-945-155(3) was to allow the pharmacy intern registration to be held for a total duration of approximately 6 years. The commission can consider clarifying this requirement and exercising its enforcement discretion on WAC 246-945-155(3) until the two-year license renewal cycle is implemented.

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

The commission can consider exercising its enforcement discretion on WAC 246-945-155(3) until the two-year renewal cycle is implemented, or for a defined period of time. Without any action, the limit on intern registration renewals means that some licensees may have shorter total durations with an intern registration than others depending on when they renew and the implementation of the two-year renewal cycle.

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

The commission can consider any of the following, or consider taking no action. The PQAC team recommends approving a policy statement or guidance document.

OPTION 1: Approve either a policy statement, guidance document, or other form of communication outlining the commission's enforcement discretion on WAC 246-945-155(3) until the two-year renewal cycle is implemented; and/or

OPTION 2: Approve rulemaking to change the language in WAC 246-945-155(3), removing the two renewal limit. (Note: This would likely require standard rulemaking, which may take 12 months to complete).

Follow-up Action: (Next Steps After the meeting – Document the commission's decision and/or any additional steps or follow-up requested; such as, report back in 6- months, etc.)

Commission staff will prepare the policy statement or guidance document and initiate the DOH review process, if necessary.

Commission staff will also communicate the decision to credentialing to make sure that this discrepancy does not prevent an eligible pharmacy intern from renewing their license.

If necessary, staff will prepare rulemaking package.

What rules apply to pharmacies storing, dispensing, and delivering drugs to patients without a pharmacist on-site?

In addition to the generally applicable pharmacy laws and rules that apply to pharmacies, WAC 246-945-430 contains specific requirements for pharmacists storing, dispensing, and delivering drugs to patients without a pharmacist on-site. Further, WAC 246-945-420(4) requires pharmacies that exclusively store, dispense, and deliver drugs to patients without a pharmacist on-site shall maintain a perpetual inventory.

While the Pharmacy Commission does not evaluate an individual pharmacy's model. Examples of such situations that would require compliance with WAC 246-945-430 and WAC 246-945-420(4) would include, but are not limited to, pharmacies that dispense and deliver medications via a pharmacy technician without a pharmacist physically on-site, or pharmacies that dispense and deliver medications via technological means without pharmacy personnel physically on-site.

Can a pharmacist supervise ancillary personnel or interns remotely?

Yes, but pharmacists should ensure ancillary personnel or interns are supervised in a manner that meets the Pharmacy Commission's definition of "immediate supervision". Immediate supervision is defined in WAC 246-945-011(44), this includes the ability of pharmacists to employ technological means to supervision ancillary personnel or interns remotely. Pharmacists are encouraged to review WAC 246-945-011(44) in its entirety when remotely supervising ancillary personnel or interns.

How does a pharmacy register a remote dispensing site for storage and dispensing of medications approved by the FDA for treatment of opioid use disorder?

Pharmacies interested in registering a remote dispensing sites should review the pharmacy commission's policy statement ("Regulatory Standards Applicable to Remote Dispensing Sites – Opioid Use Disorder") and application form.

Do licensed health care entities (HCE) who have medications stored on-site that are supplied and remain under the control of a pharmacy have to comply with WAC 246-945-455?

Yes.

PREPROPOSAL STATEMENT OF INQUIRY

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

Do **NOT** use for expedited rule making

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: August 18, 2020
TIME: 11:00 AM

WSR 20-17-123

Agency: Department of Health- Pharmacy Quality Assurance Commission

Subject of possible rule making: The Pharmacy Quality Assurance Commission (commission) is considering a new section in chapter 246-945 WAC for the implementation of Substitute Senate Bill (SSB) 6086, an act relating to increasing access to medications for people with opioid use disorder.

Statutes authorizing the agency to adopt rules on this subject: RCW 18.64.005 and SSB 6086 (chapter 244, Laws of 2020)

Reasons why rules on this subject may be needed and what they might accomplish: SSB 6086 mandates that the commission adopt rules to establish the minimum standards for opioid use disorder (OUD) medication remote dispensing sites. Consequently, there is no alternative to adopting rules. Current rules related to storing drugs outside of a pharmacy do not adequately cover the minimum standards and exclude certain facilities from having remote dispensing sites, which does not align with the intent of the law. Furthermore, these regulations must be in rule to enforceable.

Identify other federal and state agencies that regulate this subject and the process coordinating the rule with these agencies: Every pharmacy that dispenses controlled substances must have a separate registration with the drug enforcement agency (DEA). The FDA-approved OUD medications (e.g. buprenorphine, methadone, and naltrexone) at these remote dispensing sites are controlled substances and will therefore require separate DEA registrations. Any regulations created by this rulemaking would be in addition to any DEA requirements, and the commission is working closely with the Attorney General's Office to ensure any state regulations would not conflict.

Process for developing new rule (check all that apply):

- ☐ Negotiated rule making
- ☐ Pilot rule making
- ☐ Agency study
- ☒ Other (describe) Collaborative

Interested parties can participate in the decision to adopt the new rule and formulation of the proposed rule before publication by contacting:

	(If necessary)
Name: Lindsay Trant	Name:
Address: PO Box 47852, Olympia, WA, 98504-7852	Address:
Phone: 360-236-2932	Phone:
Fax: 360-236-2321	Fax:
TTY: 711	TTY:
Email: PharmacyRules@doh.wa.gov	Email:
Web site:	Web site:
Other:	Other:

Additional comments: Interested parties can sign up for notifications regarding the rulemaking process by signing up for GovDelivery at the following address: https://public.govdelivery.com/accounts/WADOH/subscriber/new

Date: 08/18/2020

Signature:

Name: Tim Lynch, PharmD, MS, FABC, FASHP

Title: Pharmacy Quality Assurance Commission Chair

WAC 246-945-457 Remote dispensing sites for opioid use disorder medications. In accordance with RCW 18.64.600, a pharmacy licensed by the commission may extend their license to a remote dispensing site for FDA-approved medications to treat opioid use disorder. Pharmacies using this registration must comply with subsections (1) through (4) of this section.

1) Medications stored in registered remote dispensing sites shall remain under the control of, and be routinely monitored by, the supplying pharmacy.
2) The supplying pharmacy shall develop and implement policies and procedures to:
    a) Prevent and detect unauthorized access to the registered remote dispensing site;
    b) Document medications used, returned, and wasted at the registered remote dispensing site;
    c) Require the supplying pharmacy to perform a perpetual inventory of medications stored at the registered remote dispensing site; and
    d) Ensure that only the supplying pharmacy is stocking medications stored at a registered remote dispensing site.
3) Access and retrieval of medications from the registered remote dispensing site (other than by the supplying pharmacy) must be:
    a) Pursuant to a valid prescription or chart order; and
    b) Limited to health care professionals licensed under the chapters specified in RCW 18.130.040 who are acting within their scope of practice, and nursing students as provided in WAC 246-945-450.
4) Ensure the registered remote dispensing site is appropriately equipped to secure and protect medications at the registered remote dispensing site from diversion or tampering.

Commission SBAR Communication

Agenda Item/Title: 8.3.1Virtual Inspection Process

Date SBAR Communication Prepared: 9/24/2020

Reviewer: **Lauren Lyles-Stolz**

Link to Action Plan:

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

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

Due to COVID-19 restrictions and nationwide shortages of Personal Protective Equipment (PPE), staff have identified a creative way to conduct inspections that allow for continuity of care through virtual inspections. Virtual inspections allow pharmacy inspectors to continue inspections in a timely manner and take necessary safety precations by adopting a virtual process. In addition, there are also unavoidable impediments such as storms, poor road conditions, wildfires, and major traffic accidents that may warrant a virtual inspections.

Background: (Briefly state the pertinent history):

While virtual inspections are not considered a replacement for an in-person inspection, the aforementioned situations may warrant a virtual inspection when there is mutual agreementwith the applicants or licensee. Trial virtual inspections have occurred secondarily to a lack of PPE and high risks facilities associated with COVID-19. The process includes using the Microsoft Team conferencing software to perform virtual tours in real-time with the applicant/licensees at their respected facility. This allows the inspector to direct the video focus on areas under examination, ask questions and engae in a collaborative dialogue, as if there in person. Items such as labels can be read and evaluated, locked storage boxes for controlled substances can be seen, and techniques and documentation can be observed. The use of this technology has been successful.

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https://www.google.com/search?q=controlled+substance+lockbox&rlz=1C1GCEA_enUS917US917&source=lnms&tbm=isch&sa=X&ved=2ahUKEwjjhN_6nIPsAhWOu54KHZrZA90Q_AUoAnoECAwQBA&biw=1920&bih=937#imgrc=bOTk56ssh4qlpM

Commission SBAR Communication

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

Oservations of virtual inspections being conducted by Commission inspectors have been successful . This technique has served to mitigate issues that might otherwise impede on-site inspection in unavoidable impediments.

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

The options listed below may be adopted by the Commission in part or whole.

Option 1: Commission adopts a process to allow virtual inspections upon request from the inspector with the applicant/licensee agreement when in-person inspections cannot take place.

Proposed Virtual Process w/o approval:

1. Inspector and Applicant/Licensee agrees to a virtual inspection
2. Conduct Virtual Inspection

Option 2: Commission adopts option 1 and inspector recieves approval of Pharmacist Supervisor and/or Executive Director.

Proposed Virtual Process w/ approval:

3. Inspector and Applicant/Licensee agrees to a virtual inspection
4. Inspector request a virtual inspection due to unavoidable situations, COVID-19, and or PPE shortages
5. Pharmacist Supervisor approves virtual inspection and consult with PQAC leadership team if needed
6. Conduct Virtual Inspection

Option 3: Commission does not adopt a new virtual process.

Commission SBAR Communication

Follow-up Action:

The PQAC team will proceed as directed.