January 22, 2021

Washington State Pharmacy Quality Assurance Commission

Commission Business Meeting Agenda

SAFETY. QUALITY. INNOVATION.

STATE OF WASHINGTON

Pharmacy Quality Assurance Commission

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

January 22, 2021
Commission Business Meeting
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# 209-025-275
Phone +1 (631) 992-3221
Access Code: 902-027-067
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 due to the current state of emergency and 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 the Department of Health, Pharmacy Quality Assurance Commission's Official Rule-Making file and for future reference.

9:00 am

1. **Call to Order** Tim Lynch, Chair ***Action***
   - **1.1** Meeting Agenda Approval – January 22, 2020
   - **1.2** Meeting Minutes Approval – December 3, 2020
   - **1.3** Meeting Minutes Approval – December 4, 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** National Precursor Log Exchange December 2020 and End-of-Year Roll-up
- **2.2** Pharmaceutical Firms Application Report Approval
  - November 6, 2020 thru January 13, 2021 – new and closed firms
- **2.3** Ancillary Utilization Plans Approval
  - **a.** HealthPoint
  - **b.** Providence St. Luke's Rehabilitation Institute
- **2.4** Acceptance of WRAPP Reports – deliverables per contract

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.

9:25 am

3. **Old Business –** The Commission will discuss, for clarification or decision, ongoing topics and issues from previous meetings. ***Information/Action.***
   - **3.1** Update/Discuss the Food and Drug Administration's MOU addressing inordinate amounts of distributions of compounded human drug products interstate and complaints.
   - **3.2** Update on NABP ADA testing accommodation approval process.
   - **3.3** Update Commission on Medical Commission's rule making regarding prescribers' engagement in collaborative drug therapy agreements.

10:00

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

- **4.1** Zero Order Report/Process Status Update

10:15

5. **Rules and Legislative Session Updates -** ***Information/Action.***
   - **5.1** Review for approval draft rule language developed for the implementation of SSB 6086 *Increasing access to medications for opioid use disorder*. Authorize filing CR-102.
   - **5.2** Review for approval draft rule language developed for the implementation of SSB 5380establishing the criteria for the waivers on the e-prescribing requirement. Authorize filing CR-102.

5.3 Consider re-filing emergency rules for dispensing Schedule II controlled substances during the COVID-19 pandemic
5.4 Consider re-filing emergency rules removing Epidiolex from Schedule V
5.5 Stakeholder Workshop on the draft rule language for the implementation of SSB 6526 (Safe Donation and Reuse of Unexpired Prescription Drugs)
5.6 2021 Legislation Update – Bill Report

12:00 pm

6. 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.***

BREAK (10 minutes)

12:20 pm

7. Commission Member Reports - ***Information/Action.***
7.1 Update from Subcommittee
7.2 Commissioner Reports
- Labor & Industries and PQAC Joint COVID-19 Safety Guidance and Reminder

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

1:00 pm

8. Staff Reports ***Information/Action.***
8.1 Executive Director – Lauren Lyles-Stolz
- Correspondence

8.2 Deputy Executive Director – Christie Strouse
8.3 Assistant Attorney General – Christopher Gerard
8.4 Pharmacist Inspector Supervisor – Lisa Hunt

1:20 pm

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

1:25 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:

March 4-5, 2021
Business Meetings
9:00 a.m.
Virtual – by Webinar

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

Commission Meeting Schedule

Agendas for the meetings listed below are made available in advance via e-mail list and the Department of Health website (see below). Every attempt is made to ensure that the agenda is up-to-date. However, the commission reserves the right to change or amend agendas at the meeting.

Date	Time	Location
January 22, 2021	9:00 a.m.	By Webinar
March 4-5, 2021	9:00 a.m.	By Webinar
April 22 – 23, 2021	9:00 a.m.	By Webinar
June 3 – 4, 2021	9:00 a.m.	By Webinar/TBD
July 15 – 16, 2021	9:00 a.m.	By Webinar/TBD
September 2 – 3, 2021	9:00 a.m.	By Webinar/TBD
October 21 – 22, 2021	9:00 a.m.	By Webinar/TBD
December 16 – 17, 2021	9:00 a.m.	By Webinar/TBD

Draft

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 – Minutes
COVID-19, Rulemaking and Chapter 246-945 Review
December 3, 2020
9:00 AM (Open Session)

Convene: Chair, Tim Lynch called the meeting to order December 3, 2020, 9:00 a.m.

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

Staff Members:
Lauren Lyles-Stolz, Executive Director, Pharmacy Commission
Christie Strouse, Deputy Director, Pharmacy Commission
Chris Gerard, AAG
Marlee O'Neill, Deputy Director, OILS
Adam Wood, Supervising Investigator
Cori N. Tarzwell, staff member
Lindsay Trant, Rules Program Manager, Pharmacy
Lisa V. Hunt, Pharmacist Supervisor
Doreen Beebe, Program Manager, Pharmacy
Amy L Robertson, Administrative Assistant, Pharmacy

1.1 **MOTION: December 3, 2020 Meeting Agenda Approval** – Craig Ritchie moved to approve draft meeting agenda; Patrick Gallaher, second. Motion carried (12-0).

2.1 **Department of Health Vaccine Update** – Kathy Bay, RN, CENP, Doctorate Nursing Practice; Clinical, Quality, Epidemiology, and School Section Manager; Office of Immunizations and Child Profile updated the commission on upcoming vaccines – Pfizer and Moderna. Guidelines on distribution, handling, storage, administration of vaccine (timeline, PPE, syringes, etc.), reimbursement will be provided.

Question: **Eric Lintner, stakeholder – may a facility choose to use their preferred pharmacy rather than CVC or Walgreen's as matched by the CDC.**

Answer: While the CDC has matched all LTC facilities with either CVC or Walgreens through a national program. The facility does have the right to decline the partnership and

may use the pharmacy they prefer. Questions may be directed to the COVID.Vaccine@doh.wa.gov.

Question: **Andrew Burton, stakeholder – solutions in place for smaller rural facilities that cannot use a full 975 doses of the Pfizer vaccine?**

Answer: Ensure when you are enrolling your facility that you state the facility/need, at that point we will help support that process either through redistribution/networking or the smaller Moderna as a different option.

3.1 Review for adoption expedited rule making filed under WSR 20-16- 045 proposing to repeal former commission rule chapters replaced by chapter 246-945 WAC.

MOTION: Teri Ferreira moved to approve the rules as proposed and authorizing staff to file the CR-103 adoption of the repeal of old WAC chapters replaced by chapter 246-945 WAC; Judy Guenther, second. Motion carried (13-0).

3.2 Review draft rule language for approval to de-schedule Epidiolex, and to authorize staff to prepare and file notice of proposed rule/public hearing (CR 102 permanent rules).

MOTION: Craig Ritchie moves to approve the proposed rule language and authorize staff to file a CR-102 permanent rules and set date for public rules hearing; Ken Kenyon, second. Motion carried (13-0).

3.3 Commission needs to be updated on the joint authority for the SSB 5380 e-prescribing waivers. Commission will need to re-approve filing the CR-101 under joint authority with the Department

MOTION: Ken Kenyon moves to withdraw the CR-101 filed under WSR 20-03-020 and to re-file a CR-101 under joint authority with DOH; Craig Ritchie, second. Motion carried (13-0).

3.4 Commission needs to review and approve draft rule language for ESHB 1551 AIDS education repeal. Once approved staff will file CR-105.

MOTION: Craig Ritchie, moves to adopt the proposed rules as written or with non-substantive changes repealing the AIDS education requirement and authorize staff to file CR-105 permanent rules; second Patrick Gallaher, second. Motion carried (13-0).

Clarification: International graduates fall under this rule as well.

3.5 Review for approval draft rule language to make technical corrections to chapter 246-945 WAC*)*, and to authorize staff to prepare and file notice with the code reviser's office. (CR-105 Expedited Rules)

MOTION: Craig Ritchie moves to approve the appropriate changes utilizing "and" instead of "and/or" to WAC 246-945-590 (Document 2) and authorize the technical

correction be included in a CR-105 rules package with previous proposed rule amendments (Document 1); Teri Ferreira, second. Motion carried (13-0).

4.1 **Provide guidance for discontinue credential statute for Retired Pharmacists (formerly under WAC 246-863-080).** The Commission is asked to consider emergency rules to issue a retired active pharmacist license status with limited practice as defined in the draft rule.

MOTION: Craig Ritchie, move we approve the draft rule without amendment and authorize staff to file emergency rules AND move we authorize a CR-101 to begin rulemaking to examine the need for permanent rules; Bonnie Bush, second. Motion carried (13-0).

4.2 **Provide guidance on discontinued credential qualifications for foreign pharmacist graduates with applicants in pending status or active pharmacy intern credentials before July 1, 2020 as it relates to internship hours [WAC 246-945-162(2)(c)].**

MOTION: Teri Ferreira, move we adopt the amended motion as written below:

Option 2: Foreign Pharmacist graduate are granted a waiver and shall meet the internship hours as required under WAC 246-863-040 and policy #45 if:
a. The applicant applied for a Washington Pharmacist license before July 1, 2020 shall meet the internship hours as required under WAC 246-863-040 and policy #45; or
b. The applicant was issued a Washington Pharmacy Intern registration before July 1, 2020, and who has completed their intern hours and applied for a Washington pharmacist license on or before June 30, 2021.

Judy Guenther, second. Motion carried (13-0).

4.3 **Commission will be updated on the implementation of the 2-year renewal cycle and the fees rules package.**

MOTION: Patrick Gallaher motions to authorize staff to re-file the CR-103 as it relates to the CE rules WAC 246-945-178 Pharmacist continuing education, and 246-945-220 Pharmacy technician—Continuing education delaying implementation until December 1, 2021; Teri Ferreira, second. Motion carried (13-0).

4.4 **Access to drugs stored outside of the pharmacy by unlicensed staff [WAC 246-945-455].**

The Pharmacy Commission will be engaging in a review of WAC 246-945-455. Specifically, the requirement in WAC 246-945-455(1)(c) that drugs stored outside the pharmacy can only be accessed by health care professionals licensed under the chapters specified in RCW 18.130.040 acting with their scope and nursing students.

The Pharmacy Commission has been informed of potential unintended disruption to the drug chain supply within institutional facilities by requiring only licensed health care

professionals to access drugs stored outside the pharmacy. Historical practices have permitted unlicensed employees of institutional facilities to access certain drug products for supply chain management needs. To avoid continued disruption, the Commission is providing this guidance to ensure continuous patient care.

While engaging in this review, the Pharmacy Commission will not find licensees deficient or take enforcement action for violations of WAC 246-945-455(1)(c) when unlicensed employees of an institution access drugs stored outside the pharmacy if the following conditions are met:

- The unlicensed employee of the institution is operating within the scope of their employment;
- The unlicensed employee is only accessing drugs for the purposes of supply chain management within the institution;
- The unlicensed employee is only accessing drugs listed in a policy and procedure that is in a readily retrievable form;
- The unlicensed employee cannot access controlled substances under any circumstances or access drug products as part of dispensing a prescription or order; and
- The pharmacy meets all other requirements of WAC 246-945-455 and applicable laws.

MOTION: Craig Ritchie, move we adopt the interim guidance as Chris Gerard set forth above; Patrick Gallaher, second. Motion carried (13-0).

MOTION: Craig Ritchie, move to approve authorizing staff to file a CR-101 to amend WAC 246-945-455 or add an additional section if necessary to deal with the issue of the interim guidance; Patrick Gallaher, second. Motion carried (13-0).

6. **Summary of Meeting Action Items**

- Draft guidance related to 246-945-455(1)(c)
- Rulemaking packages
- Provide guidance and communication for foreign pharmacists re: the new rule requiring 1500 internship hours allowing them to June 30 to complete internship hours and apply for license.
- Update guidance related to pharmacy CE and the two-year renewal cycle from March 1 to December 1.
- Retired pharmacists re: emergency rulemaking and pursue permanent rulemaking.

Business Meeting Adjourned at 1:31.
The Commission will reconvene on December 4 at 9 a.m.

Draft

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 – Minutes
COVID-19, Rulemaking and Chapter 246-945 Review
December 4, 2020
9:00 AM (Open Session)

Convene: Chair, Tim Lynch called the meeting to order December 4, 2020, 9:08 a.m.

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

Staff Members:
Lauren Lyles-Stolz, Executive Director, Pharmacy Commission
Christie Strouse, Deputy Director, Pharmacy Commission
Christopher Gerard, AAG
Marlee O'Neill, Deputy Director, OILS
Adam Wood, Supervising Investigator
Lindsay Trant, Rules Program Manager, Pharmacy
Lisa V. Hunt, Pharmacist Supervisor
Doreen Beebe, Program Manager, Pharmacy
Amy L Robertson, Administrative Assistant, Pharmacy

1.1 **MOTION: December 4, 2020 Meeting Agenda Approval** – Craig Ritchie moved to approve draft meeting agenda; Judy Guenther, second. Motion carried (13-0).

1.2 **MOTION: October 1, 2020 Meeting Minutes** – Craig Ritchie moved to approve meeting minutes as amended; Jerrie Allard, second. Motion carried (12-0).

2.3 **MOTION:** Ken Kenyon move to approve consent agenda except for 2.3b, 2.3c, 2.3j; Patrick Gallaher, second. Motion carried (12-0).

2b Items removed for discussion from 2.3 consent agenda.

2.3b **Cherry Hill Pharmacy** – missing/conflicting information has been corrected or is acceptable.

MOTION: William Hayes move to approve the technician and assistant AUP for Cherry Hill Pharmacy; Craig Ritchie, second. Motion carried (12-0).

2.3c **Doctors Pharmacy** – missing information (key individual license number, signature) was updated in ILRS.

MOTION: Patrick Gallaher moves to approve 2.3c AUP for Doctors Pharmacy; Craig Ritchie, second. Motion carried (12-0).

2.3j **The Medicine Shoppe** – Pharmacy AUP form missing. Shelly Feldner-Schuerman updated the Commission on the specific aspects of this case.

MOTION: Patrick Gallaher moves to approve 2.3j The Medicine Shoppe AUP; Kat Khachatourian, second. Motion carried (12-0).

3.1 **Update Commission on Medical Commission's rule making regarding prescribers' engagement in collaborative drug therapy agreements. (CR101).** Lauren Lyles-Stolz confirmed no action at this time. The CR102 seems to be out until January 20, 2022. The Medical Commission website has an option for public commenting on the CDTA/rulemaking.

3.2 **Suspicious Orders Exemption Application**. **MOTION:** Bonnie Bush moves to approve this form with the stated modifications of PQAC staff; Jeri Allard, second. Motion carried (12-0).

3.3 **Suspicious Order Letter of Cooperation (LOC)**. **MOTION:** Craig Ritchie moves to approve the Suspicious LOC as modified; Bonnie Bush, second. Motion carried (12-0).

3.4 **Commission Delegation Forms**. **MOTION:** Craig Ritchie moves to approve the delegation form as edited; Patrick Gallaher, second. Motion carried (12-0).

3.5 **Guidance Document – Intern Registration**. PQAC will not enforce WAC 246-945-155(3), which states that an intern registration can only be renewed twice, until the 2-year license renewal cycle is implemented.

MOTION: Ken Kenyon moves to approve the Guidance Document as written; Craig Ritchie, second. Motion carried (12-0).

4.1 **Discuss NABP's memo regarding change in processing requests for ADA testing accommodations and if the Commission requests an exemption**. PQAC staff will supply the Commission with further information at the next meeting (opt out/in criteria; percentages of accommodation requests).

4.2 **Review, for approval, a draft of self-inspection worksheet for Health Care Entities**. PQAC staff will supply the Commission with further information after collecting public comments from licensees/stakeholders.

4.3 **Discuss the Food and Drug Administration's MOU addressing inordinate amounts of distributions of compounded human drug products interstate.** PQAC staff will supply the Commission with further information at the next meeting after determining impact on staff workload.

4.4 **Identify Commissioner(s) who will participation in the Office of Health Profession's legislation review calls.** Tim Lynch, Patrick Gallaher, Craig Ritchie, Hawkins DeFrance, and William Hayes volunteered to participate (Wednesdays, 8:30-9a).

4.5 **Pharmacy Changes of Ownership**. Commission recommended PQAC staff gather additional information/historical content for further evaluation. In addition, stakeholder Richard Molitor asked about if the Commission has a 'rapid response' plan for immediate change of ownership (i.e., by court order).

6 **Panel Review (Panel B)**. **MOTION:** Ken Kenyon moves to delegate himself, Craig Ritchie, Hawkins DeFrance, Kat Khachatourian, Tim Lynch, and Bonnie Bush for Panel Review (Panel B); Jeri Allard, second. Motion carried (12-0).

6.1 **Pharmacist applicant requests Commission approval of her study plan for reauthorization to take the MPJE**. **MOTION:** Ken Kenyon moves to delegate himself, Craig Ritchie, Hawkins DeFrance, Kat Khachatourian, Tim Lynch, and Bonnie Bush for Panel Review (Panel B); Jeri Allard, second. Motion carried (12-0).

MOTION: Kat Khachatourian moves to allow applicant to take a fifth (and final) attempt to pass the MPJE; Craig Ritchie, second. Motion carried (6-0).

6.2 **Pharmacist applicant requests Commission approval of her study plan for reauthorization to take the NAPLEX**.

MOTION: Craig Ritchie moves to authorize applicant to attempt the NAPLEX a final time; Hawkins DeFrance, second. Motion carried (6-0).

7.1 **Update from HPAC Subcommittee**. Further research is needed for defining what does a hospital license actually entail as far as those outpatient clinics as well as when does one need an HPAC registration. An SBAR should be considered brought to the Commission in January to begin to refine the rules.

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

January agenda: discussion related to entity licensees and complaints in terms of the conditions that exist when an investigation is authorized (information collected; what led to error/reporting; ensure inspectors adequately informed; when to use Notice of Correction rather than discipline; capturing error data voluntarily).

8.1 **Staff Report: Executive Director, Lauren Lyles-Stolz**

- Emailed the following correspondence to commissioners:

  a) Slides from the FDA intergovernmental meeting on compounding.

  b) FDA MOU from the American Pharmacy Association Alliance for Pharmacy Compounding, the National Alliance of State Pharmacy Association, and National Community Pharmacists Association have strong concerns related to the MOU.

- SSB 6061 – Telehealth services – beginning January 1, 2021 if a pharmacist/pharmacy intern are providing telehealth services, they are required to complete a telehealth training. UW telehealth collaborative is working on this training. WSPA as well. This bill passed in 2020 session. The department does recognize this may impact licensees and boards of commission. The department is evaluating strategies to respond to this new telehealth requirement.

- Vaccination legislation, Dentists – possible legislation in the 2021 session where dentists will be pursuing adding vaccinations in their scope of practice.

- Guidance document – Accessing drugs outside a pharmacy: changed "institutional" with "healthcare" facilities.

8.3 **Staff Report: Christopher Gerard, Assistant Attorney General**

- Governor proclamations that impact pharmacy were extended through December 7 (healthcare worker and facility licensing).

- Commission review: CREPP act declaration fourth amendment by HHS: authorizes healthcare personnel using telehealth to order/administer COVID countermeasures (diagnostic tests, etc.).

- Monitoring of Drug Therapy – in the scope of practice of pharmacists to screen in/out specific drug therapy for a patient upon a patient request that the patient is already being prescribed. (January agenda item.)

8.4 **Staff Report: Lisa Hunt, Pharmacist Inspector Supervisor**

- Draft self-inspection forms for hospital, HCEs, wholesalers, and manufacturers in the final stages. Nuclear, general and long-term care pharmaceutical facilities also updated. These all include updated citations to the new rules.

- Reviewed application forms provided update notes on those. Mapped the process workflows from start-to-finish and developed SOD letters and POC process for our licensing software.

- All inspectors have been stepping up to help review documents, email influx, on-boarding new staff, providing training, while doing the 'normal' job.

- Commission requested an overview of problematic trends in general areas.

9 **Summary of Meeting Action Items**.

1) 3.2 Suspicious Order Exemption Application to add an email address to application; then post.
2) Suspicious Letter of Cooperation – no action
3) Commission delegation form – adopted Bonnie's recommendation to left side that.
4) NABP ADA testing accommodating – review any liability concerns; more information from NABP regarding basis of denial of ADA request.
5) Self-Inspection worksheets – HCEs, wholesalers, and manufacturers – release for public comment.
6) 4.3 FDA MOU – more research and finalize questions/concerns to the FDA (further modifications based on concerns identified today; estimate of resource impact to comply with MOU; implications of FDA MOU corporate vs small compounding pharmacy)
7) Legislative Update calls – send OHP the five commissioners volunteering to serve on these calls.
8) Change of Ownership rule – research implications of impact to corporations that may pursue mergers as well as transfer of stock.
9) Monitoring of Drug Therapy – additional research of where screening in/out drug therapy falls into the practice of pharmacy.
10) Research/discuss NOC feasibility for entities
11) Develop – list of questions for investigation team on assessing entities patterns/trends in mis-fills/errors.

Business meeting adjourned, 1:00 p.m.

The Commission will meet next on January 21-22, 2021.

MONTHLY PROGRAM ADMINISTRATOR'S DASHBOARD

TRANSACTION SUMMARY STATISTICS (2020)

	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC	TOTAL
PURCHASES	95,473	94,353	132,234	81,256	77,472	78,783	74,589	67,364	64,554	66,191	62,539	63,663	**958,471**
BLOCKS	2,848	3,066	6,826	3,956	4,906	3,757	3,995	2,903	2,478	2,617	2,556	2,593	**42,501**
GRAMS SOLD	188,604	190,659	281,184	191,005	184,990	189,881	178,222	157,479	147,638	148,369	137,776	141,729	**2,137,536**
BOXES SOLD	105,743	105,360	148,176	90,182	86,036	87,363	83,705	75,792	72,863	75,291	71,393	72,878	**1,074,782**
GRAMS BLOCKED	7,373	7,949	18,567	11,446	13,874	10,718	11,580	8,247	7,164	7,139	6,726	7,098	**117,881**
BOXES BLOCKED	3,181	3,516	7,821	4,429	5,367	4,224	4,413	3,257	2,818	2,898	2,874	2,960	**47,758**
AVG GRAMS PER BOX BLOCKED	2.32	2.26	2.37	2.58	2.59	2.54	2.62	2.53	2.54	2.46	2.34	2.40	**2.46**

PHARMACY PARTICIPATION STATISTICS (Dec 2020)

Enabled Pharmacies	995
Pharmacies Submitting a Transaction	940
Pharmacies Logging in Without a Transaction	2
Inactive Pharmacies	53
Pharmacy Participation for Dec	94.67%

DISCLAIMER: This is an automated report meant to give you a quick snapshot of the NPLEx system in your state. The statistics listed in this report are only meant to be a general overview and not necessarily the exact final numbers.

NPLEx – National Precursor Log Exchange – End of the Year Report

EOY 20	YTD Boxes Sold			YTD Grams Sold			YTD Boxes Blocked			YTD Grams Blocked			Unique Purchasers YTD		
State	2019	2020	% Change	2019	2020	% Change	2019	2020	% Change	2019	2020	% Change	2019	2020	% Change
AL	760,965	679,727	-10.68%	1,563,858.97	1,467,971	-6.13%	23,691	24,226	2.21%	58,026.12	63,529	8.66%	343,517	284,172	-20.88%
AR	170,067	163,775	-3.70%	311,753.48	307,948	-1.22%	7,497	8,113	7.59%	19,299.38	21,300	9.39%	77,471	66,824	-15.93%
AZ	1,187,800	1,066,498	-10.21%	2,555,810.73	2,445,347	-4.32%	41,524	47,415	12.42%	106,494.15	130,660	18.50%	519,928	413,541	-25.73%
CA	4,582,187	3,754,437	-18.06%	9,933,605	8,700,363	-12.41%	167,735	169,607	1.10%	449,243	463,133	3.00%	2,151,614	1,621,870	-32.66%
DE	189,572	162,267	-14.40%	409,809.65	372,291	-9.16%	8,427	8,104	-3.99%	22,607.91	22,522	-0.38%	81,595	62,331	-30.91%
FL	3,261,858	2,797,076	-14.25%	6,893,764.80	6,316,721	-8.37%	107,884	108,641	0.70%	273,324.23	298,600	8.46%	1,526,885	1,167,687	-30.76%
GA	1,592,351	1,393,660	-12.48%	3,400,478.23	3,161,279	-7.03%	45,812	51,107	10.36%	118,066.70	142,206	16.97%	714,760	572,095	-24.94%
HI	172,670	128,983	-25.30%	353,862.10	289,272	-18.25%	5,777	5,372	-7.54%	12,430.44	14,694	15.40%	90,566	56,985	-58.93%
IA	634,212	555,101	-12.47%	1,274,886.38	1,200,500	-5.83%	18,461	19,812	6.82%	46,037.25	53,607	14.12%	264,053	208,300	-26.77%
ID	289,015	264,254	-8.57%	566,872.55	564,157	-0.48%	10,189	10,763	5.33%	24,490.94	28,295	13.45%	125,463	103,521	-21.20%
IL	2,338,660	1,945,395	-16.82%	4,369,512.65	3,803,378	-12.96%	89,696	93,316	3.88%	199,423.54	215,211	7.34%	968,961	711,741	-36.14%
IN	1,247,677	1,083,373	-13.17%	2,376,722.06	2,159,404	-9.14%	42,844	46,815	8.48%	95,556.49	112,408	14.99%	513,292	399,363	-28.53%
KS	577,633	504,241	-12.71%	1,232,930.20	1,146,227	-7.03%	18,644	20,191	7.66%	47,897.67	55,295	13.38%	229,329	178,641	-28.37%
KY	596,715	491,708	-17.60%	1,175,355.54	1,021,433	-13.10%	31,251	35,179	11.17%	78,812.00	92,552	14.85%	305,594	236,431	-29.25%
LA	737,283	641,033	-13.05%	1,552,251.61	1,411,465	-9.07%	22,985	23,728	3.13%	57,390.10	63,175	9.16%	336,862	267,979	-25.70%
ME	193,557	152,802	-21.06%	348,027.42	309,077	-11.19%	5,686	6,374	10.79%	13,864.98	17,245	19.60%	85,932	61,194	-40.43%
MI	1,929,794	1,636,385	-15.20%	4,089,004.63	3,699,219	-9.53%	63,070	67,284	6.26%	155,893.95	186,647	16.48%	824,490	625,737	-31.76%
MO	978,224	854,423	-12.66%	1,992,337.54	1,851,659	-7.06%	32,755	38,758	15.49%	81,280.62	101,979	20.30%	394,331	312,650	-26.13%
MT	180,053	164,459	-8.66%	337,462.36	335,649	-0.54%	5,287	5,892	10.27%	11,478.39	15,168	24.33%	78,336	63,701	-22.97%
NC	1,745,495	1,469,430	-15.82%	3,586,660.10	3,233,798	-9.84%	55,058	59,494	7.46%	137,990.15	163,367	15.53%	849,610	637,011	-33.37%
ND	138,331	124,795	-9.79%	154,015.93	163,422	6.11%	4,119	4,458	7.60%	5,711.65	8,927	36.02%	50,161	39,329	-27.54%
NE	462,067	404,291	-12.50%	950,412.33	895,852	-5.74%	15,945	16,428	2.94%	40,614.84	44,835	9.41%	178,532	139,299	-28.16%
NH	279,595	234,087	-16.28%	586,069	531,237	-9.36%	9,255	9,777	5.34%	23,688	27,380	13.49%	133,544	98,511	-35.56%
NV	458,817	410,385	-10.56%	1,012,753	973,778	-3.85%	16,743	18,686	10.40%	42,831	52,270	18.06%	212,006	163,938	-29.32%
NY	2,572,951	2,015,842	-21.65%	5,487,742	4,570,998	-16.71%	103,110	105,250	2.03%	285,113	295,338	3.46%	1,177,340	835,094	-40.98%
OH	2,247,475	1,918,361	-14.64%	4,698,302	4,272,890	-9.05%	65,766	72,964	9.87%	166,989	203,307	17.86%	913,399	700,059	-30.47%
OK	797,357	717,950	-9.96%	1,711,039	1,623,729	-5.10%	26,762	27,631	3.15%	68,484	73,831	7.24%	324,392	261,498	-24.05%
PA	2,228,136	1,871,872	-15.99%	4,767,508	4,267,847	-10.48%	72,260	74,311	2.76%	175,845	202,055	12.97%	885,997	667,478	-32.74%
SC	888,257	769,272	-13.40%	1,858,133	1,708,516	-8.05%	26,936	27,239	1.11%	66,165	74,983	11.76%	418,564	323,486	-29.39%
SD	197,704	181,509	-8.19%	424,590	419,053	-1.30%	6,148	6,822	9.88%	15,328	18,667	17.89%	82,127	68,268	-20.30%
TN	917,297	754,875	-17.71%	1,799,396	1,550,546	-13.83%	52,526	52,200	-0.62%	142,481	145,613	2.15%	503,095	389,406	-29.20%
TX	4,984,330	4,090,508	-17.93%	11,073,797	9,614,768	-13.18%	174,263	189,781	8.18%	426,853	524,952	18.69%	2,065,230	1,635,537	-26.27%
VA	1,600,554	1,329,669	-16.92%	3,423,374	3,042,560	-11.12%	52,546	55,287	4.96%	128,921	151,673	15.00%	680,486	502,262	-35.48%
VT	77,257	60,878	-21.20%	141,316	125,175	-11.42%	2,703	2,892	6.54%	6,575	7,840	16.14%	36,976	25,813	-43.25%
WA	1,292,147	1,074,782	-16.82%	2,401,237	2,177,665	-9.31%	44,451	47,758	6.92%	99,576	118,465	15.94%	564,369	403,590	-39.84%
WI	1,031,435	876,875	-14.98%	2,094,063	1,930,563	-7.81%	44,564	44,437	-0.29%	108,509	115,492	6.05%	430,138	326,585	-31.71%
WV	192,308	162928	-15.28%	367,824	332,343	-9.65%	10,997	12,552	12.39%	29,096	34,808	16.41%	103,086	82,230	-25.36%

Credential Type = DRAN - Drug Animal Control/Humane Society Registration Sodium Pentobarbital,DRCH - Drug Precursor Chemicals Registrat Controlled Substances Registration,DRDG - Drug Dog Handlers K9 Registration,DRIV - Drug Itinerant Vendor Registration,DRRS - Drug Controlle Registration,DRSD - Drug Sample Distributor Registration,DRWL - Wildlife Chemical Capture Drug Registration,HPAC - Hospital Pharmacy Asso Pharmacy License Hospital,PHAR
- Pharmacy License,PHNR - Pharmacy Non Resident License,PHWH - Pharmaceutical Wholesaler License,P License,POIM - Poison Manufacturer LicenseCredential Type = DRAN - Drug Animal Control/Humane Society Registration Sodium Pentobarbital, Chemicals Registration,DRCS - Drug Other Controlled Substances Registration,DRDG - Drug Dog Handlers K9 Registration,DRIV - Drug Itinerant Drug Controlled Substance Researcher Registration,DRSD - Drug Sample Distributor Registration,DRWL - Wildlife Chemical Capture Drug Regis Associated Clinic,PHAR - HOSP - Pharmacy License Hospital,PHAR - Pharmacy License,PHNR - Pharmacy Non Resident License,PHWH - Phar License,POID - Poison Distributor License,POIM - Poison Manufacturer License

Credential #	Status	First Issuance Date	Expiration Date	Facility Name	Site Address 1	Site City	Site State	Site Zip Code
PHWH.FX.61102125	ACTIVE	01/13/2021	09/30/2021	Arise Pharmaceuticals LLC	12 Roszel Rd Ste B202	Princeton	NJ	08540-6295
PHWH.FX.61126817	ACTIVE	01/13/2021	09/30/2021	Independent Pharmacy Distributor LLC	1107 W Market Center Dr	High Point	NC	27260-1642
PHWH.FX.61139359	ACTIVE	01/13/2021	09/30/2021	Intuity Medical, Inc.	3500 W Warren Ave	Fremont	CA	94538-6499
PHWH.FX.61122870	ACTIVE	01/13/2021	09/30/2021	Meridian Bioscience Corporation	3471 River Hills Dr	Cincinnati	OH	45244-3023
PHWH.FX.61046117	ACTIVE	01/13/2021	09/30/2021	TannerGAP, Inc.	1808 Associates Ln Ste A	Charlotte	NC	28217-2837
PHWH.FX.61098201	ACTIVE	01/13/2021	09/30/2021	Valley Drug	208 E Main St	Everson	WA	98247-9126
PHNR.FO.61118595	ACTIVE	01/11/2021	05/31/2021	Alto Pharmacy	6201 West Plano Pkwy Ste 400	Plano	TX	75093
PHNR.FO.61095612	ACTIVE	01/11/2021	05/31/2021	Theracom LLC dba Theracom	345 International Blvd Ste 200	Brooks	KY	40109-6202
PHNR.FO.61137774	ACTIVE	01/08/2021	12/31/2021	Advanced Diabetes Supply	2544 Campbell Pl Ste 150	Carlsbad	CA	92009-1768
PHNR.FO.61134348	ACTIVE	01/08/2021	05/31/2021	AlixaRx	10132 W 76th St	Eden Prairie	MN	55344-3728
PHNR.FO.61135698	ACTIVE	01/08/2021	05/31/2021	Covetrus Pharmacy Services, LLC	2401 W Grandview Rd Ste 100	Phoenix	AZ	85023-3116
PHNR.FO.61136057	ACTIVE	01/08/2021	05/31/2021	MedQuickRx	5757 Wilshire Blvd Ste 320	Los Angeles	CA	90036-3686
PHWH.FX.61137624	ACTIVE	01/07/2021	09/30/2021	Pharming Healthcare, Inc.	10 Independence Blvd Ste 401	Warren	NJ	07059-2730
PHWH.FX.61137815	ACTIVE	01/07/2021	09/30/2021	TG Therapeutics, Inc.	343 Thornall St Ste 740	Edison	NJ	08837-2224
PHNR.FO.61118895	ACTIVE	01/06/2021	05/31/2021	Good Shepherd Health	1256 Union Ave	Memphis	TN	38104-3411
PHWH.FX.61135508	ACTIVE	01/05/2021	09/30/2021	A2A Integrated Logistics Inc	1830 Owen Dr Ste 10-2	Fayetteville	NC	28304-3412
PHWH.FX.61122217	ACTIVE	01/05/2021	09/30/2021	Hilco Vision	3908 N 5th St	North Las Vegas	NV	89032-1205
PHWH.FX.61136240	ACTIVE	01/05/2021	09/30/2021	Medexus Pharma, Inc	29 N Wacker Dr Ste 704	Chicago	IL	60606-9590
PHWH.FX.61127883	ACTIVE	01/05/2021	09/30/2021	NextGen Pharmaceuticals LLC	1613 Broadway	Brooklyn	NY	11207-1002
PHWH.FX.61116406	ACTIVE	01/05/2021	09/30/2021	O&M Halyard, Inc.	500 Independence Ave	Mechanicsburg	PA	17055-5451
PHWH.FX.61135183	ACTIVE	01/05/2021	09/30/2021	Sheffield Pharmaceuticals, LLC	170 Broad St	New London	CT	06320-5313
PHWH.FX.61135854	ACTIVE	01/05/2021	09/30/2021	Spectrum Pharmaceutical Distributors	1220 Rankin Dr	Troy	MI	48083-6004
PHWH.FX.61130289	ACTIVE	01/05/2021	09/30/2021	US Vet, INC.	7635 Edgecomb Dr	Liverpool	NY	13088-3543
DRSD.FX.61019987	ACTIVE	12/30/2020	09/30/2021	Amarin Pharma Inc.	440 US Highway 22 Ste 300	Bridgewater	NJ	08807-2477
PHAR.CF.61061502	ACTIVE	12/30/2020	05/31/2021	Okanogan Pharmacy	240 Queen St	Okanogan	WA	98841
PHAR.CF.61047659	ACTIVE	12/30/2020	05/31/2021	Omnicare of Spokane	2820 N Astor St	Spokane	WA	99207-2112
PHHC.FX.61122909	ACTIVE	12/30/2020	09/30/2021	Acute Respiratory Clinic	1225 E Kincaid St	Mount Vernon	WA	98273
PHHC.FX.61114771	ACTIVE	12/30/2020	09/30/2021	Multicare Respiratory Clinic - University Place	4310 Bridgeport Way W	University Place	WA	98466-4337
PHAR.CF.61017037	ACTIVE	12/29/2020	05/31/2021	Kaiser Permanente Riverfront Infusion Pharmacy	322 W North River Dr	Spokane	WA	99201-3208
PHHC.FX.60996929	ACTIVE	12/18/2020	09/30/2021	Sageview Family Care	908 10th Ave SW	Quincy	WA	98848-1376
DRCS.FX.61102869	ACTIVE	12/17/2020	05/31/2021	METER Group Inc. USA	1300 NE Henley Ct Ste 6	Pullman	WA	99163-5662

PHNR.FO.61132165	ACTIVE	12/17/2020	05/31/2021	Humana Pharmacy Inc	5701 E Hillsborough Ave Ste 2140	Tampa	FL	33610-5432
PHHC.FX.61097687	ACTIVE	12/11/2020	09/30/2021	Multicare Tacoma Plastics and Reconstructive	316 Martin Luther King Jr Way Ste 203	Tacoma	WA	98405-4254
PHNR.FO.61130603	ACTIVE	12/11/2020	05/31/2021	Cheveux Rx	4425 E Agave Rd Ste 110	Phoenix	AZ	85044-0620
PHWH.FX.61130273	ACTIVE	12/11/2020	09/30/2021	Orphazyme US, Inc.	180 N La Salle St Ste 3475	Chicago	IL	60601-2501
PHWH.FX.61130248	ACTIVE	12/11/2020	09/30/2021	Quipment Inc.	1640 Arport Rd Ste 105	Kennesaw	GA	30144
PHWH.FX.61130278	ACTIVE	12/11/2020	09/30/2021	Southern Anesthesia and Surgical, Inc	2308 N Sweet Gum Ave	Broken Arrow	OK	74012-2398
PHNR.FO.61127869	ACTIVE	12/09/2020	05/31/2021	Amazon Pharmacy #001	4500 S Pleasant Valley Rd Ste 201	Austin	TX	78744-2911
PHNR.FO.61075802	ACTIVE	12/09/2020	05/31/2021	Nephron Pharmacy LLC	4500 12th Street Ext	West Columbia	SC	29172-3025
PHWH.FX.61046494	ACTIVE	12/09/2020	09/30/2021	Chommerce, LLC	9631 NE 183rd St Unit A	Bothell	WA	98011-3519
PHWH.FX.61126876	ACTIVE	12/04/2020	09/30/2021	Celgene Corporation	556 Morris Ave Bldg S12	Summit	NJ	07901-1330
PHWH.FX.61110255	ACTIVE	12/04/2020	09/30/2021	Royal Pharmaceuticals, LLC	1967 Hwy 34 Ste 103	Wall	NJ	07719
PHWH.FX.61110195	ACTIVE	12/03/2020	09/30/2021	Seton Pharmaceuticals, LLC	1967 Hwy 34 Ste 103	Wall	NJ	07719
PHAR.CF.61094999-HOSP	ACTIVE	11/30/2020	05/31/2021	St. Michael Medical Center Pharmacy	1800 NW Myhre Rd	Silverdale	WA	98383-7663
PHMF.FX.61109253	ACTIVE	11/30/2020	09/30/2021	Impel NeuroPharma, Inc.	201 Elliott Ave W Ste 260	Seattle	WA	98119-4265
PHNR.FO.61116243	ACTIVE	11/30/2020	05/31/2021	Sterling Pharmacy	2035 FM 359 Rd Ste K	Richmond	TX	77406-1142
PHAR.CF.61102133	ACTIVE	11/25/2020	05/31/2021	Furness Drug	114 Pacific Ave S	Kelso	WA	98626-1616
PHHC.FX.61121572	ACTIVE	11/25/2020	09/30/2021	Astria Ambulatory Surgical Center	111 S 11th Ave Ste 220	Yakima	WA	98902-3270
PHNR.FO.61118543	ACTIVE	11/23/2020	05/31/2021	PFSP	398 W Grand Ave	Rahway	NJ	07065-3416
PHWH.FX.61118849	ACTIVE	11/23/2020	09/30/2021	Aurinia Pharma U.S., Inc.	77 Upper Rock Cir Ste 700	Rockville	MD	20850-4021
PHWH.FX.61118404	ACTIVE	11/23/2020	09/30/2021	Chewy Wholesale, LLC	11403 Bluegrass Pkwy Ste 675	Louisville	KY	40299-2398
PHNR.FO.61118472	ACTIVE	11/19/2020	05/31/2021	AFA Pharmacy, LLC	14021 Southwest Fwy Ste B	Sugar Land	TX	77478-4575
PHNR.FO.61116234	ACTIVE	11/19/2020	05/31/2021	Cedarmak Pharmacy	8737 Beverly Blvd Ste 102	West Hollywood	CA	90048-1835
PHNR.FO.61114754	ACTIVE	11/19/2020	05/31/2021	Coram CVS/Specialty Infusion Services	8248 Lackland Rd Ste 101	Saint Louis	MO	63114-4509
PHNR.FO.61115477	ACTIVE	11/19/2020	05/31/2021	CVS/Specialty	7930 Woodland Center Blvd Ste 500	Tampa	FL	33614-2435
PHNR.FO.61115469	ACTIVE	11/19/2020	05/31/2021	CVS/Specialty	1307 Allen Dr Ste H	Troy	MI	48083-4010
PHNR.FO.61115444	ACTIVE	11/19/2020	05/31/2021	CVS/Specialty	25 Birch St Bldg 100	Milford	MA	01757-3585
PHNR.FO.61116114	ACTIVE	11/19/2020	05/31/2021	PURformance Wellness Pharmacy LLC	600 SE Indian St Ste 3	Stuart	FL	34997-5540
PHHC.FX.61107223	ACTIVE	11/18/2020	09/30/2021	Pulse Cardiac Rehabilitation - Gig Harbor	4545 Point Fosdick Dr Ste 110	Gig Harbor	WA	98335-1700
PHWH.FX.61111110	ACTIVE	11/06/2020	09/30/2021	Fennec Pharmaceuticals INC dba Fennec Pharma	221 River St 9th Fl	Hoboken	NJ	07030-5990

Pharmaceutical Firms CLOSED,EXPIRED,EXPIRED IN RENEWAL,INOPERABLE,SUMMARY SUSPENSION between Nov 6 thru Jan 13, 2021

Credential Type = DRAN - Drug Animal Control/Humane Society Registration Sodium Pentobarbital,DRCH - Drug Precursor Chemicals Registrat Controlled Substances Registration,DRDG - Drug Dog Handlers K9 Registration,DRIV - Drug Itinerant Vendor Registration,DRRS - Drug Controlle Registration,DRSD - Drug Sample Distributor Registration,DRWL - Wildlife Chemical Capture Drug Registration,HPAC - Hospital Pharmacy Asso Pharmacy License Hospital,PHAR - Pharmacy License,PHNR - Pharmacy Non Resident License,PHWH - Pharmaceutical Wholesaler License,P License,POIM - Poison Manufacturer LicenseCredential Type = DRAN - Drug Animal Control/Humane Society Registration Sodium Pentobarbital, Chemicals Registration,DRCS - Drug Other Controlled Substances Registration,DRDG - Drug Dog Handlers K9 Registration,DRIV - Drug Itinerant Drug Controlled Substance Researcher Registration,DRSD - Drug Sample Distributor Registration,DRWL - Wildlife Chemical Capture Drug Regis Associated Clinic,PHAR - HOSP - Pharmacy License Hospital,PHAR - Pharmacy License,PHNR - Pharmacy Non Resident License,PHWH - Phar License,POID - Poison Distributor License,POIM - Poison Manufacturer License

Credential #	Status	First Issuance Date	Effective Date	Expiration Date	Facility Name	Site Address 1	Site City	Site State
	No Report							

STATE OF WASHINGTON

DEPARTMENT OF HEALTH

PO Box 47890 • Olympia, Washington 98504-7890
. Tel: 360-236-4030 • 711 Washington Relay Service

January 8, 2021

TO: U.S. Food and Drug Administration
Center for Drug Evaluation and Research
Office of Compliance
Office of Unapproved Drugs and Labeling Compliance
10903 New Hampshire Avenue
Bldg. 51, Suite 5100
Silver Spring, MD 20993-0002
Telephone: (301) 796-3110
Email: StateMOU@fda.hhs.gov

FROM: Washington State Pharmacy Quality Assurance Commission

SUBJECT: Concerns regarding the Memorandum of Understanding Addressing Certain Distributions of Compounding Human Drug Products Between Washington State And The U.S. Food and Drug Administration

Thank you for your collaboration with the state boards and commissions on the further development and implementation of the Memorandum of Understanding Addressing Certain Distributions of Compounding Human Drug Products ("FDA MOU"). The Washington State Pharmacy Quality Assurance Commission (PQAC) has identified the following concerns that require further clarification before signing the FDA MOU. We ask FDA to consider these concerns and, if in agreement, further modify the FDA MOU.

Consideration #1: Section III.a.1 states that the Commission "will investigate" complaints of adverse drug experiences and product quality issues related to compounded drug products.

While PQAC most likely would investigate complaints of adverse drug experiences and product quality issues related to compounded drugs, there is concern that the current language in Section III.a.1 removes PQAC's discretion on whether a complaint warrants investigation. We would ask that FDA consider amending this language to reflect the state's regulatory authority and discretion.

Consideration #2: Section III.a.5 refers to "pharmacies," but does not make a distinction between resident and nonresident pharmacies.

We would ask that the FDA clarify that the reference to "pharmacy" in Section III.a.5 is for pharmacies physically located in Washington or in the state identified in the FDA MOU. The current FDA MOU language just states "pharmacy" which includes nonresident pharmacies.

In addition, Section III.a.5 requires PQAC to report serious adverse drug experiences or serious product quality issues at a pharmacy distributing interstate as soon as possible, but no later than 5 business days after receiving a serious complaint. All reports to PQAC must be submitted through the Washington Department of Health's (DOH) complaint intake unit prior to being assessed by PQAC. We would ask that the FDA clarify that the submission timeline begins — i.e., the point of "receiving a serious complaint" — begins once the disciplinary authority, PQAC, has assessed the report. This clarification and interpretation allow the disciplinary authority, in this case PQAC, to meet this requirement.

Consideration #3: Section III.b.2 requires PQAC to identify pharmacies that distributed "inordinate amounts" of compounded drug products and provide the information to the FDA annually.

Section III.b.2 requires PQAC to identify pharmacies that distributed inordinate amounts of compounded human drug products and provide this information annually but is very ambiguous about how PQAC will accomplish this. The MOU explains PQAC will identify these pharmacies "using surveys, reviews of records during inspections, data submitted to an Information Sharing Network, or other mechanisms available to PQAC." The disjunctive "or" suggests PQAC could choose one of these mechanisms but it is unclear how this should be executed, or to what degree the FDA expects PQAC to engage in this exercise. We ask that the FDA further clarify the "how" and provide further information regarding the Information Sharing Network.

Consideration #4: Section III.c.1 requires PQAC to disclose identifying information of the complainant when submitting reports under Section III.a.5 and Section III.a.6 to the FDA.

Section III.c.1 requires PQAC to disclose the name of a complainant when submitting certain reports to the FDA (specifically reports under Section III.a.5 and III.a.6). PQAC is unable to identify an individual as a complainant unless the complainant does not meet the statutory definition of a whistleblower or has signed a waiver of the state law whistleblower protection (*see* RCW 43.70.075).

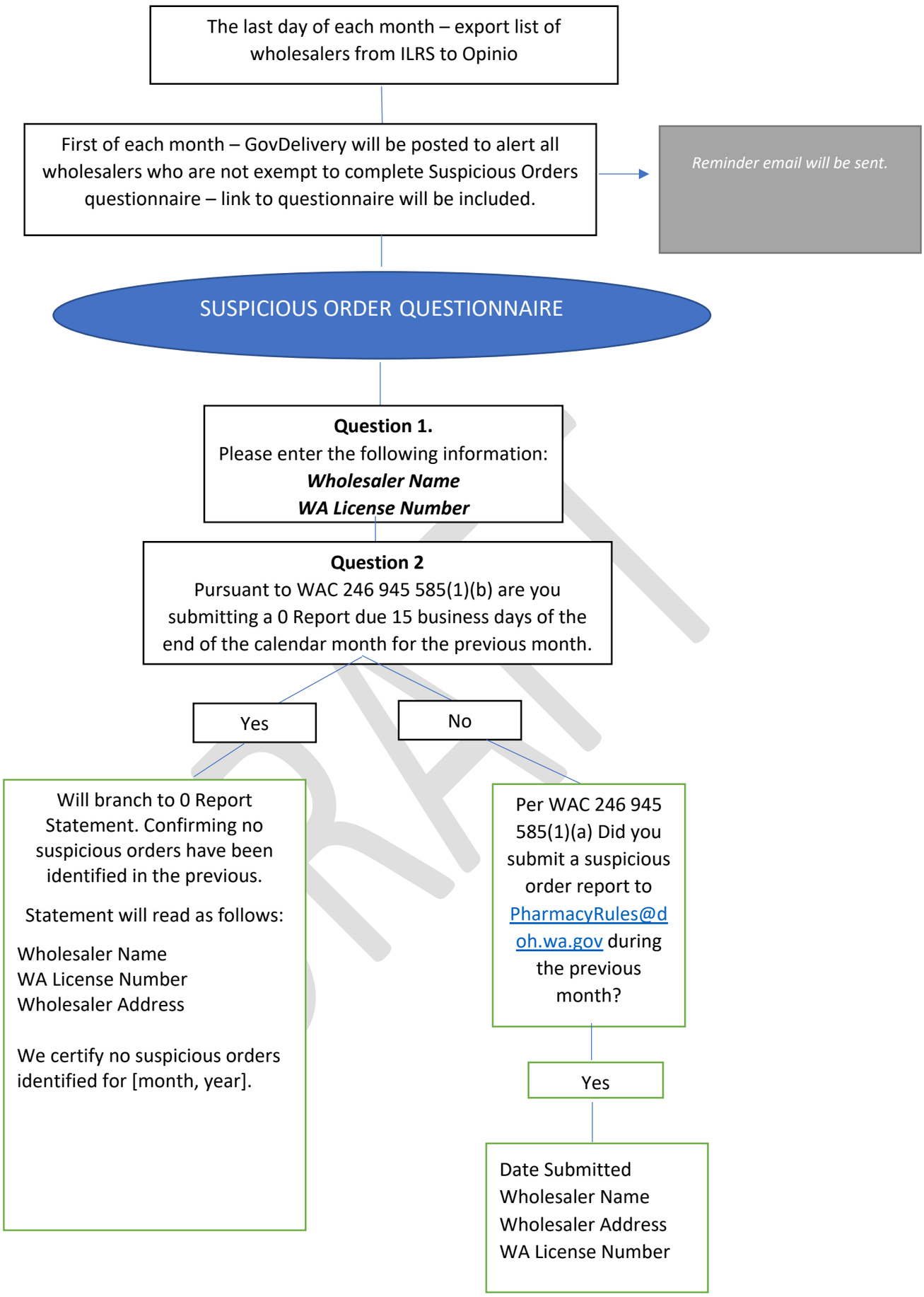
In addition, Section III.c.1 requires PQAC to submit an assessment of whether the complaint was substantiated which may contain attorney/client privileged information or attorney work product. While Section III.3 of the MOU does discuss sharing information in compliance with applicable laws, it then only cites to federal laws and not applicable state laws. We ask the FDA to further clarify that state laws such as the whistleblower law and others will be applicable under this MOU.

We hope that further clarifications on the above concerns will provide necessary clarity and guidance needed for PQAC to make an informed decision. In addition, we ask that the necessary alterations be made to the FDA MOU to reflect the outlined considerations. PQAC looks forward to hearing from you if you have further questions or comments.

Sincerely,

Lauren Lyles-Stolz, PharmD
Executive Director
Washington State Pharmacy Quality Assurance Commission

WAC 246 945 585 – ZERO REPORT SUSPCIOUS ORDERS QUESTIONNAIRE PROCESS



Draft Rule Language for SSB 6086

NEW SECTION

WAC 246-945-457 Remote dispensing sites for opioid use disorder medications. A pharmacy may extend its license to a remote dispensing site where technology is used to dispense medications indicated by the FDA for treatment of opioid use disorder. A pharmacy using this registration is the supplying pharmacy and must comply with subsections (1) through (5) of this section and all applicable regulations in Title 21 C.F.R.

1) The supplying pharmacy must separately register each remote dispensing site with the commission by completing and returning an application form supplied by the commission.
2) Medications stored in registered remote dispensing sites shall remain under the control of, and be routinely monitored by, the supplying pharmacy.
3) 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.
4) 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.
5) Ensure the registered remote dispensing site is appropriately equipped to secure and protect medications from diversion or tampering.

NEW SECTION

246-945-014 Electronic Prescribing Mandate Waiver

(1) A practitioner may submit an attestation to the department for a waiver from the electronic prescribing mandate in RCW 69.50.312, if the practitioner is experiencing an economic hardship, technological limitations not reasonably in the control of the practitioner, or other exceptional circumstance. A practitioner does not need to submit a waiver if exempted from the mandate under RCW 69.50.312(2)(a) through (j). A practitioner must submit an attestation for the waiver using forms provided by the department. The department shall deem the waiver granted upon submission of an attestation and the practitioner will be deemed exempt under RCW 69.50.312(2)(k).

(2) A practitioner who has submitted an attestation for a waiver from the mandate in RCW 69.50.312 is exempt from the electronic prescribing mandate for the calendar year in which the attestation is signed, beginning with the effective date of this section.
   a. For economic hardship and technical limitations, a practitioner may attest to the need for a waiver up to three times, giving the practitioner three years to come into compliance with the mandate.
   b. There is no limit on the number of other exceptional circumstance waivers under subsection (3)(c) of this section that a practitioner can submit.

(3) A practitioner required to electronically prescribe under RCW 69.50.312 may submit an attestation for a waiver from this mandate due to:
   a. Economic hardship in the following circumstances:
      i. A bankruptcy in the previous year or submitted an attestation for a waiver under this chapter due to a bankruptcy in the previous year;
      ii. Opening a new practice after January 1, 2020;
      iii. Intent to discontinue operating in Washington prior to December 31, 2021; or
      iv. Operating a low-income clinic, that is defined as a clinic serving a minimum of 30% Medicaid patients.
   b. Technological limitations outside the control of the practitioner if the practitioner is in the process of transitioning to an electronic prescription system.
   c. Other exceptional circumstances:
      i. The practitioner is providing services at a free clinic;
      ii. The practitioner generates fewer than 100 prescriptions of Schedules II through V drugs in a one-year period, including both new and refill prescriptions;
      iii. The practitioner is located in an area without sufficient internet access to comply with the e-prescribing mandate; or
      iv. Unforeseen circumstances that stress the practitioner or health care system in such a way that compliance is not possible. Examples may include, but are not limited to, natural disasters, widespread health care emergencies, unforeseeable barriers to electronic prescribing, or unforeseen events that result in a statewide emergency.

(4) The department may audit waiver attestations submitted by a practitioner to determine compliance with this chapter. Submitting a false attestation is grounds for disciplinary action against a practitioner's license by the appropriate disciplinary authority as well as fines pursuant to RCW 69.50.312(5).

Draft rule language for SSB 6526
For questions, contact PharmacyRules@doh.wa.gov

NEW SECTION
WAC 246-945-486 Return and reuse of unexpired medications—Department of corrections
Facilities served by the Washington state department of correction's pharmacy may accept for return and reuse noncontrolled legend drugs in unit does packages, or full or partial multiple dose medications cards, if product integrity can be assured and the pharmacy complies with RCW 69.70.050(1), (2), and (5).

NEW SECTION
WAC 246-945-488 Safe donation of unexpired prescription drugs

(1) For the purposes of this section, the definitions in RCW 69.70.010 apply.
(2) A pharmacy that accepts, distributes, or dispenses prescription drugs and supplies that are donated shall:
    (a) Comply with the requirements in RCW 69.70.020, RCW 69.70.030, RCW 69.70.040, and RCW 69.70.050, when applicable.
    (b) Must complete and return an attestation form developed and supplied by the commission.
    (c) A pharmacy must notify the commission in writing if it is no longer accepting donated prescription drugs and supplies. This notification must occur within thirty calendar days of the pharmacy no longer accepting donated prescription drugs and supplies.
    (d) Not accept donations of prescription drugs and supplies via a drop box.
    (e) Ensure that prescription drugs and supplies donated by the person to whom the prescription drug was prescribed or the person's representative are accompanied by the department's drug donation form in accordance with RCW 69.70.020(2).
    (f) Ensure clear separation of the pharmacy's donated prescription drug stock from the rest of the pharmacy's drug stock.
    (g) Maintain a separate inventory of all prescription drugs and supplies donated to the pharmacy.
    (h) Develop and implement policies and procedures addressing:
        (i) When prescription drugs or supplies may be accepted and dispensed. The policy and procedure shall require a pharmacist to inspect the donated prescription drugs and supplies, and that a pharmacist notify a prescriber when delivering donated prescription drugs and supplies to a patient.
        (ii) How the pharmacy will respond when it is informed of a recall for donated prescription drugs and supplies.
(3) Practitioners, pharmacists, medical facilities, drug manufacturers, drug wholesalers, persons to whom a prescription drug was prescribed, or the persons representative, are not required to obtain a wholesaler license when donating prescription drugs to a pharmacy.

Department of Health
Pharmacy Quality Assurance Commission

Guidance Document

Title: Continuing Education Requirements		*Number:* G001
References:	WAC 246-945-178, WAC 246-945-220, WAC 246-861-090, and WAC 246-901-061.	
Contact:	Dr. Lauren Lyles-Stolz, Executive Director, Pharmacy Quality Assurance Commission	
Phone:	360-236-4946	
Email:	WSPQAC@doh.wa.gov	
Effective Date:	July 1, 2020 (Updated December 3, 2020)	
Supersedes:	N/A	
Approved By:	Tim Lynch, PharmD, MS, FABC, FASHP Chair, Pharmacy Quality Assurance Commission	

Pharmacists whose licenses expire on or after December 1, 2022, shall complete the equivalent of 3.0 continuing pharmacy education (CPE)[1] administered by an ACPE accredited provider prior to renewing their license pursuant to WAC 246-945-178. Pharmacists whose licenses expire before December 1, 2022 shall complete the equivalent of 1.5 continuing education units (CEU)[2] prior to renewing their license pursuant to WAC 246-861-090(1).

Pharmacy technicians whose certifications expire on or after December 1, 2022, shall complete the equivalent of 2.0 CPE[3] administered by an ACPE accredited program prior to renewing their certification pursuant to WAC 246-945-220. Pharmacy technicians whose certifications expire before December 1, 2022 shall complete the equivalent of 1.0 CEU[4] prior to renewing their certification. The 1.0 CEU shall include at least one (1) hour of course work in pharmacy law and nine (9) hours in any course work that relates to the practice of pharmacy pursuant to WAC 246-901-061(1).

The Pharmacy Quality Assurance Commission (commission) recently completed a 2.5-year process to consolidate their thirty-three (33) chapters of WAC into one new chapter (chapter 246-945 WAC). While the vast majority of rules contained in chapter 246-945 WAC were effective on July 1, 2020, the new continuing pharmacy education (CPE) requirements for pharmacists and pharmacy technicians will not become effective until **December 1, 2021**. The following table provides a comparison between the older continuing education requirements and the new continuing education requirements:

[1] The 3.0 CPE requirement is equivalent to thirty (30) hours of continuing education.
[2] The 1.5 CEU requirement is equivalent to fifteen (15) hours of continuing education.
[3] The 2.0 CPE requirement is equivalent to twenty (20) hours of continuing education.
[4] The 1.0 CEU requirement is equivalent to ten (10) hours of continuing education.

Profession	Older CE Requirement	New CE Requirement
Pharmacists	1.5 CEU[5]	3.0 CPE[6]
Pharmacy Technicians	1.0 CEU[7]	2.0 CPE[8]

The new CPE requirements for pharmacists and pharmacy technicians will not become effective until December 1, 2021 because the commission is transitioning all individual licenses (pharmacists, pharmacy technicians, and pharmacy assistants) to a two-year renewal cycle. The transition to a two-year renewal cycle for licenses has necessitated changing CPE requirements to a two-year cycle as well. Consequently, the commission intends for the new CPE rules to be effective on December 1, 2021, when the transition to a two-year renewal cycle is complete.

To avoid confusion and provide pharmacists and pharmacy technicians with clear expectations as it relates to CPE requirements, the commission has developed the following table that identifies how much CPE will be required prior to renewal based on when the pharmacist license or pharmacy technician certification expires:

If my license **EXPIRES** between		CE required for pharmacists	CE required for pharmacy technicians
N/A	June 30, 2020	1.5 CEU	1.0 CEU
July 1, 2020*	November 30, 2021	1.5 CEU	1.0 CEU
December 1, 2021**	November 30, 2022	1.5 CEU	1.0 CEU
December 1, 2022	N/A	3.0 CPE	2.0 CPE

* Chapter 246-945 WAC is effective, except for the new CPE rules (WAC 246-945-178 and WAC246-945-220).
** The transition to a two-year renewal cycle will be complete and the new CPE rules (WAC 246-945-178 and WAC 246-945-220) will become effective.

Conclusion: Under new CPE rules effective December 1, 2021, pharmacists whose licenses expires on or after December 1, 2022, shall complete the equivalent of 3.0 CPE administered by an ACPE accredited provider prior to renewing their license pursuant to WAC 246-945-178. Pharmacists whose licenses expire before December 1, 2022 shall complete the equivalent of 1.5 CEU prior to renewing their license pursuant to WAC 246-861-090(1).

Under new CPE rules effective December 1, 2021, pharmacy technicians whose certifications expire on or after December 1, 2022, shall complete the equivalent of 2.0 CPE administered by an ACPE accredited program prior to renewing their certification pursuant to WAC 246-945-220. Pharmacy technicians whose certifications expire before December 1, 2022 shall complete the equivalent of 1.0 CEU prior to renewing their certification. The 1.0 CEU shall include at least one (1) hour of course work in pharmacy law and nine (9) hours in any course work that relates to the practice of pharmacy pursuant to WAC 246-901-061(1).

[5] WAC 246-861-090(1).
[6] WAC 246-945-178.
[7] WAC 246-945-220; pharmacy technician continuing education hall include at least one (1) hour of course work in pharmacy law and nine (9) hours in any course work that relates to the practice of pharmacy.
[8] WAC 246-945-220