

April 23, 2021

Washington State Pharmacy Quality Assurance Commission



Commission Business Meeting Agenda

SAFETY.

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STATE OF WASHINGTON
Pharmacy Quality Assurance Commission

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

**April 23, 2021
Commission Business Meeting**

Agenda

Time: 9:00 AM (Open Session)
Location: Webinar
Contact: Joanne Miller, Program Manager (360) 236-4834
Joanne.Miller@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 – April 23, 2021
 - 1.2** Meeting Minutes Approval – March 4, 2021
 - 1.3** Meeting Minutes Approval -March 5, 2021

April 23, 2021

Pharmacy Quality Assurance Commission Page 2 of 6

9:10 am

- 2. EXECUTIVE SESSION.** The Commission will meet in executive session to discuss with legal counsel representing the Commission matters relating to Commission enforcement actions, or to discuss with legal counsel representing the Commission litigation or potential litigation to which the Commission is, or is likely to become, a party, when public knowledge regarding the discussion is likely to result in an adverse legal or financial consequence to the Commission pursuant to RCW 42.30.110(1)(i). This event is not open to the public.

10:15 am

- 3a. 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.***

3.1 National Precursor Log Exchange Monthly Dashboard-March

3.2 Pharmaceutical Firms Application Report

- February 12th thru March 30, 2021– new and closed firms

3.3 Ancillary Utilization Plans Approval –

- 3.3.1 Alto Pharmacy
- 3.3.2 Bonney Lake Pharmacy
- 3.3.3 Cascade Park
- 3.3.4 Evergreen Hospital Medical Center Pharmacy
- 3.3.5 Mary Bridge Children’s Hospital
- 3.3.6 Pharm-A-Save Granite Falls
- 3.3.7 Providence Sacred Heart-Providence
- 3.3.8 St. Joseph Medical Center Pharmacy
- 3.3.9 Virginia Mason Hospital Pharmacy
- 3.3.10 Washington Center for Bleeding Disorders

3.4 Pharmacy Technician Training Program Approval

- 3.2.1 Bartell Drugs
- 3.2.2 Chastains-Own Pharmacy
- 3.2.3 Fred Meyer
- 3.2.4 Purdy Cost Less
- 3.2.5 Saars Supermarket
- 3.2.6 The Owl Tri State

- 3b. 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.

10:45 am

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

4.1 Re-approval and re-authorization of SSB 6086 Rule Language

4.2 Virtual Inspections Presentation

- 4.3 Re-authorization of Retired Pharmacist Status Emergency Rules
- 4.4 WAC 246-945-585 Zero reports/ Suspicious Order Process Update

Break (10 minutes if needed)

11:30 am

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

Information/Action.

- 5.1 Wholesaler Third Party Inspection Program Request: National Coalition for Drug Quality & Security
- 5.2 Clarification of Tetrahydrocannabinol (THC) Compounds other than Delta-9 under Chapter 69.50 RCW
- 5.3 Rules Petition

12:15 pm

- 6. **Rules and Legislative Session Updates - *Information/Action.***

- 6.1 2021 Legislation Update – Bill Report
- 6.2 Medication Assistance Emergency and Permanent Rulemaking Update

12:45

- 7. **Requests for Review by Commission Panel**

- 7.1 Approval from applicant:
 - Consider for approval a study plan submitted by applicant to retake NAPLEX and MPJE

1:15 pm

- 8. **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.***

1:30 pm

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

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

1:40 pm

- 10. **Staff Reports *Information/Action.***

- 10.1 Executive Director – Lauren Lyles-Stolz
- 10.2 Deputy Director – Christie Strouse
- 10.3 Assistant Attorney General – Christopher Gerard

1:50 pm

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

2:00 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:

June 3-4, 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 23, 2021	9:00 a.m.	By Webinar
June 3 – 4, 2021	9:00 a.m.	By Webinar
July 15 – 16, 2021	9:00 a.m.	By Webinar
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



STATE OF WASHINGTON
Pharmacy Quality Assurance Commission
PO Box 47852 • Olympia, Washington 98504-7852
Tel: 360-236-4030 • 711 Washington Relay Service

Pharmacy Quality Assurance Commission Meeting
March 4, 2021 - Minutes

Convene: Chair, Tim Lynch called the meeting to order March 4, 2021, 9:04 a.m.

Commission Members:

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

Commission Member(s) Absent:

William Hayes, PharmD, CCHP

Staff Members:

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

1. Call to Order

1.1 Meeting Agenda Approval – March

MOTION: Craig Ritchie moves to accept meeting agenda; Patrick Gallaher, second. Motion carries 9:0.

2. Presentation: NABP FDA MOU, Information Sharing Network Presentation. Presented by Melissa Madigan, PharmD, JD and William Cover, BSPharm, RPh

3. Review public/stakeholder comments for self-inspection worksheets – HCE, Wholesaler, and Manufacturer.

Wholesaler and Manufacturer self-inspection form to move forward and posted on the website. HCE self-inspection form to be edited and brought back to the commission at the June 3-4 business meeting.

MOTION: Ken Kenyon moves to accept the changes to the updates to the self-inspection forms as presented today; Teri Ferreira, second. Motion carries 9:0.

MOTION: Craig Ritchie moves that the deadline for the wholesalers and manufacturer self-inspection sheets to be completed no later than June 30, 2021; Hawkins DeFrance, second. Motion carries 9:0.

MOTION: Craig Ritchie moves until the HCE self-inspection sheet is finalized and approved by the commission, it will not be a requirement for licensees; Ken Kenyon, second. Motion carries 9:0.

4. Open Forum

Gail Elliot: Are pharmacists allowed to electronically sign the Collaborative Drug Therapy Agreement (CDTA), as opposed to a wet signature?

The commission will allow electronic and wet signatures until there is more information.

MOTION: Hawkins DeFrance motions to allow electronic signatures for pharmacists for CDTA and authorize the staff to look into the necessary changes to make this permanent; Craig Ritchie, second. Motion carries 9:0.

5. Action Items

1. NABP:
 - a. Follow up with NABP while we wait for the FDA/MOU letter
 - b. Connect on some of the outstanding questions
2. Self-Inspection worksheets:
 - a. Post wholesaler and manufacturer self-inspection worksheets.
 - b. HCE self-inspection worksheet will have another public comment period and return to commission in June.
 - c. Staff to develop USP 800/825 self-inspection sheet.
3. CDTA agreement – update to allow pharmacists to electronically sign a CDTA.

Meeting adjourned: 12:25 p.m.

Next scheduled business meeting:

March 5, 2021

Business Meetings

9:00 a.m.

Virtual – by Webinar



STATE OF WASHINGTON
Pharmacy Quality Assurance Commission
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**Pharmacy Quality Assurance Commission Meeting
March 5, 2021 – Minutes**

Convene: Chair, Tim Lynch called the meeting to order March 4, 2021, 9:05 a.m.

Commission Members:

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

Commission Member(s) Absent:

William Hayes, PharmD, CCHP

Staff Members:

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

1. **Call to Order**

1.1. Meeting Agenda Approval – March 5, 2021

MOTION: Craig Ritchie moves to approve the March 5, 2021 meeting agenda; Hawkins DeFrance, second. Motion carries.

1.2. Meeting Minutes Approval – January 22, 2021

MOTION: Craig Ritchie moves to approve the January 22, 2021 meeting minutes with the addition of Uyen Thorstensen as attending. Ken Kenyon, second. Motion carries.

2. **Executive Session**

The Commission convened in executive session between 9:05 am and 10:15 am to discuss with legal counsel representing the Commission matters relating to Commission enforcement actions, or to discuss with legal counsel representing the Commission litigation or potential litigation to which the Commission is, or is likely to become, a party, when public knowledge regarding the discussion is likely to result in an adverse legal or financial consequence to the Commission pursuant to RCW 42.30.110(1)(i).

3. **Consent Agenda**

MOTION: Craig Ritchie moved to approve consent agenda with the exception of 3.3.7 Nooksack Valley Drug Store; Teri Ferreira second. Motion carries.

3b. **Items pulled from Consent Agenda: 3.3.7 Nooksack Valley Drug Store**

MOTION: Patrick Gallaher moves to approve Nooksack Valley Drug Store; Craig Ritchie, second. Motion carries.

4a. **Enforcement Discretion on USP 800 and 825 currently set to expire March 31**

MOTION: Teri Ferreira moves to extend enforcement discretion on USP 800 and 825 for six months; Hawkins DeFrance, second. Motion carries.

4c. **The Commission was provided with an update on the Washington Medical Commission's rulemaking regarding prescribers' engagement in collaborative drug therapy agreements.**

4b. **Labor & Industries and PQAC Joint COVID-19 Safety Reminder and Guidance**

MOTION: Craig Ritchie moves to approve this guidance document as amended with the changes discussed, so public/pharmacists will have accurate guidance in the future; Patrick Gallaher, second. Motion carries.

5.1. **New Rule Clarification on Facility and Pharmacy Modifications and Remodels.**

MOTION: Tim Lynch motions to craft an interpretive statement or guidance for PQAC inspectors that states any licensed facilities (HCE, HPACs, wholesalers, manufacturers) that undergo a remodel or modification of their facility as it relates to compounding and/or anything that negatively impacts security (e.g., increase diversion risk) requires a remodel inspection and must complete the commission remodel application process and pay an inspection fee.. For pharmacies, anything negatively affecting the security square footage access to drugs, compounding, or relocation would require the same as in rule (WAC 246-945-230(3)). Craig Ritchie, second. Motion carries.

8. **Open Forum**

Cindy Wilson, stakeholder requested consideration to extend self-inspection sheet completion deadline.

MOTION: Judy Guenther moves to pass a one-time extension that all pending self-inspection sheets (including general self-inspection) must be completed by June 30, 2021. Second, Craig Ritchie. Motion carries.

Teresa O'Sullivan, stakeholder requested correction/clarification on the New Pharmacist License application. Staff will review.

9a. **Budget Subcommittee Update.** Ken Kenyon reports PQAC has a surplus of 2.9 million (not taking into account the HELMS assessment and other future expenses). The new licensing fee structure is instrumental in this surplus. However, due to the biennium budget and the new fee structure, HCE consolidations, etc, it is too early to review fees and assess impact. Budget Subcommittee will meet quarterly to review/report to the commission.

10a. **Executive Director, Lauren Lyles-Stolz.**

Martin Pittioni, Office Director, Office of Health Professions, notified the commission that it had been granted a hiring freeze exception to recruit for the open positions of pharmacy supervisor and pharmacist consultant.

Congratulations to commissioners being awarded the Fred T. Mahaffey award by NABP.

10c. **Assistant Attorney General – Christopher Gerard.**

1. The commission was provided information contained in the Joint Operating Agreement (JOA) related to lobbying.
2. The commission was provided with information related to the jurisdiction of Labor & Industries (L&I) for meal and rest breaks for pharmacists based on communications the commission received from an L&I representative a few years ago.

11. **Summary of Meeting Action Items**

1. **3.37 Nooksack Valley Drug Store** – notify that the pharmacy technician must complete a commission approved training.
2. **USP 800 / 825** – Update policy statement to reflect the commission approved an extension of six months.
3. **L&I and PQAC COVID-19 Safety Guidance** – update the letter with the amended changes approved today.
4. **Remodel/Modifications** – craft guidance/interpretive statement and review language for proposed rulemaking regarding facilities/remodels/modifications.
5. Pharmacist Application correction / post to website.
6. GovDelivery regarding self-inspection sheet completion deadline extended to until June 30, 2021.
7. Interview Panel / Recruitment – Commission members who have availability/interest serving on interview panel, contact Lauren.

Meeting adjourned 12:56 p.m.

Next scheduled business meeting:

April 22-23, 2021
Business Meetings
9:00 a.m.
Virtual – by Webinar

From:



External Email

MONTHLY PROGRAM ADMINISTRATOR'S DASHBOARD

2 Logins - 1 Searches - 0 Report Queries - 37 Active Watches - 0 Active Watch Hits

NEW USERS THIS MONTH

New Users = 0

Total Accounts =
139

Active Users = 2

TOP USAGE AGENCIES

1. West Sound Narcotics Enforcement Team

TOP USERS BY USAGE

1. Kathleen Chittenden, West Sound
Narcotics Enforcement Team

TOP AGENCIES BY ACTIVE WATCHES

1. NW HIDTA (74)
2. ICE - King County (13)

TRANSACTION SUMMARY STATISTICS (2021)

	JAN	FEB	MAR	TOTAL
PURCHASES	58,504	51,943	70,640	181,087
BLOCKS	2,433	2,301	2,931	7,665
GRAMS SOLD	130,934	117,632	165,200	413,766
BOXES SOLD	66,771	59,470	79,346	205,587
GRAMS BLOCKED	6,569	7,011	8,009	21,589
BOXES BLOCKED	2,700	2,897	3,183	8,780
AVG GRAMS PER BOX BLOCKED	2.43	2.42	2.52	2.46

PHARMACY PARTICIPATION STATISTICS (Mar 2021)

Enabled Pharmacies	997
Pharmacies Submitting a Transaction	944
Pharmacies Logging in Without a Transaction	1
Inactive Pharmacies	52

Pharmacy Participation for Mar	94.78%
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DISCLAIMER: This is an automated report meant to give you a quick snapshot of the NPLEx system in your state. The statistics listed in this report are only meant to be a general overview and not necessarily the exact final numbers. Prior to releasing any statistics mentioned in this report, we highly recommend that you verify the numbers with your NPLEx customer relationship manager. For questions or issues, please contact kmccormick@appriss.com.

Credential #	Status	First Issuance Date	Effective Date	Expiration Date
PHNR.FO.61159827	ACTIVE	03/23/2021	03/23/2021	05/31/2022
PHNR.FO.61159835	ACTIVE	03/23/2021	03/23/2021	05/31/2022
PHWH.FX.61153700	ACTIVE	03/22/2021	03/22/2021	09/30/2021
PHNR.FO.61156443	ACTIVE	03/18/2021	03/18/2021	05/31/2022
PHNR.FO.61158082	ACTIVE	03/18/2021	03/18/2021	05/31/2022
PHAR.CF.61130138-HOSP	ACTIVE	03/17/2021	03/17/2021	05/31/2022
PHWH.FX.61157899	ACTIVE	03/17/2021	03/17/2021	09/30/2021
PHHC.FX.61011704	ACTIVE	03/16/2021	03/16/2021	09/30/2021
PHNR.FO.61157814	ACTIVE	03/16/2021	03/16/2021	05/31/2022
PHNR.FO.61156434	ACTIVE	03/16/2021	03/16/2021	05/31/2022
PHNR.FO.61139777	ACTIVE	03/16/2021	03/16/2021	05/31/2022
PHNR.FO.61157154	ACTIVE	03/16/2021	03/16/2021	05/31/2022
PHWH.FX.61157206	ACTIVE	03/15/2021	03/15/2021	09/30/2021
PHWH.FX.61157186	ACTIVE	03/15/2021	03/15/2021	09/30/2021
PHWH.FX.61157128	ACTIVE	03/15/2021	03/15/2021	09/30/2021
PHAR.CF.61112590	ACTIVE	03/12/2021	03/12/2021	05/31/2022
PHHC.FX.61137654	ACTIVE	03/12/2021	03/12/2021	09/30/2021
PHWH.FX.61157246	ACTIVE	03/12/2021	03/12/2021	09/30/2021
PHHC.FX.61146557	ACTIVE	03/08/2021	03/08/2021	09/30/2021
PHHC.FX.61126872	ACTIVE	03/08/2021	03/08/2021	09/30/2021
PHWH.FX.61147782	ACTIVE	03/08/2021	03/08/2021	09/30/2021
PHWH.FX.61154779	ACTIVE	03/08/2021	03/08/2021	09/30/2021
PHHC.FX.61146731	ACTIVE	03/03/2021	03/03/2021	09/30/2021
PHMF.FX.61148757	ACTIVE	03/03/2021	03/03/2021	09/30/2021
PHNR.FO.61116975	ACTIVE	03/03/2021	03/03/2021	05/31/2022
PHWH.FX.61136049	ACTIVE	03/03/2021	03/03/2021	09/30/2021
PHAR.CF.61004424	ACTIVE	03/02/2021	03/02/2021	05/31/2022
PHAR.CF.61130357	ACTIVE	03/02/2021	03/02/2021	05/31/2022

PHNR.FO.61139331	ACTIVE	03/02/2021	03/02/2021	05/31/2022
PHNR.FO.61121726	ACTIVE	03/02/2021	03/02/2021	05/31/2022
PHNR.FO.61142972	ACTIVE	03/02/2021	03/02/2021	05/31/2022
PHWH.FX.61139774	ACTIVE	03/01/2021	03/01/2021	09/30/2021
PHWH.FX.61148306	ACTIVE	03/01/2021	03/01/2021	09/30/2021
PHWH.FX.61142987	ACTIVE	03/01/2021	03/01/2021	09/30/2021
PHHC.FX.61143710	ACTIVE	02/24/2021	02/24/2021	09/30/2021
PHNR.FO.61143050	ACTIVE	02/23/2021	06/01/2021	05/31/2022
PHWH.FX.61138311	ACTIVE	02/23/2021	02/23/2021	09/30/2021
PHHC.FX.61138054	ACTIVE	02/19/2021	02/19/2021	09/30/2021
PHWH.FX.61130524	ACTIVE	02/19/2021	02/19/2021	09/30/2021
PHNR.FO.61139825	ACTIVE	02/18/2021	06/01/2021	05/31/2022
PHWH.FX.61139562	ACTIVE	02/18/2021	02/18/2021	09/30/2021
PHWH.FX.61139441	ACTIVE	02/18/2021	02/18/2021	09/30/2021
PHWH.FX.61105396	ACTIVE	02/18/2021	02/18/2021	09/30/2021
PHWH.FX.61147037	ACTIVE	02/18/2021	02/18/2021	09/30/2021
PHWH.FX.61148822	ACTIVE	02/18/2021	02/18/2021	09/30/2021
PHWH.FX.61148829	ACTIVE	02/18/2021	02/18/2021	09/30/2021
PHHC.FX.61065354	ACTIVE	02/11/2021	02/11/2021	09/30/2021

Facility Name	Site Attention	Site Address 1	Site Address 2
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No Closed to report

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 and pay applicable fees established by the Secretary.
- 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 from 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.

Commission SBAR Communication

Agenda Item/Title: Virtual Inspection Follow-up

Date SBAR Communication Prepared: 04/14/2021

Reviewer: Christie Strouse and Lauren Lyles

Link to Action Plan:

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

Situation:

At the October 1, 2020 business meeting, PQAC staff presented on the use of virtual inspections for licensees. During this meeting, the Commission requested pharmacist inspector feedback regarding this topic in six months.

Background:

Due to the suspension of routine inspections prompted by the COVID-19 pandemic, the agency and the commission have greater leveraged technology to offer virtual inspections as an option for licensees in certain cases and for the promotion of public health and safety for all. Prior to October 1, 2020, virtual inspections were being conducted to support the continuation of operations during the pandemic. At the October 1, 2020 business meeting, the Commission approved to continue virtual inspections on a trial basis. During this trial, virtual inspections are conducted in collaboration with the licensee as well as with the professional judgement of the inspectors and consultation from a supervisor as needed.

In preparation for the follow-up presentation at the April 2021 business meeting, data was collected from the pharmacist inspectors in drafting this report. Information was obtained regarding the number and nature of the inspections, along with comments on strengths, and/or the challenges encountered.

Assessment:

During the timeframe of October 1, 2020 through March 19, 2021, the pharmacist inspection team conducted and completed 122 non-routine inspections. Fifty-one of those inspections were conducted virtually. Virtual inspections were conducted on the following examination types/situations:

- Initial (HCE, manufacturer, pharmacy, researcher, and wholesaler)
- Change of location (HCE, manufacturer, pharmacy, and wholesaler)
- Change of ownership (HCE)
- Closures (HCE, manufacturer, pharmacy, and wholesaler)
- Remodel (manufacturer and pharmacy)
- Controlled substances endorsement

The type of inspection conducted was based on licensee preference, inspector preference, scope of the inspection, technology available, and weather conditions.

I. The following information was obtained from the pharmacy inspection team regarding virtual and onsite in person inspections:

Commission SBAR Communication

Virtual Inspections – Strengths:

- Better fit for limited-in-scope inspections where document review was possible off-site and prior to inspection
- Best choice during inclement weather conditions as it allows the ability to continue operations in a safe manner
- Mitigation of potential risk of exposure to COVID-19 in practice settings
- New and innovative approach leveraging technology to help reduce inspection backlog by expediting inspections that may be narrow in scope

Virtual Inspections – Weaknesses:

- Technology challenges, internet connectivity, and availability of mobile devices
- Lack of visualization of the site and documents
- Additional facility staff are needed to assist and guide the inspector virtually through the facility
- The limited ability to utilize the sensory functions of sight; hearing; touch; and smell which better equips the inspector to gather additional contextual information, and evaluate the entire site and scope of practice
- Several examples were given where a virtual inspection would not have identified significant areas of concern, such as particle board and tape in the sterile compounding suite, expired drugs in the usable drug stock, temperature of medication storage areas, and unsecured drug stock

Onsite Inspections – Strengths:

- A more collaborative relationship and stronger rapport with licensees which creates the ability to provide additional technical assistance
- Improved flow of the inspection as it is not necessary for the inspector to direct camera angling and provide instruction for video user instructions
- Observations that are not attainable through a camera lens
- Broader or highly detailed inspections, such as routine or clean room inspections, would be better suited for in-person
- Due to data security concerns and size limitations with electronic transmissions, onsite inspections provide a better opportunity to review protected health information and proprietary documents

II. The following information was obtained from licensees regarding virtual inspections:

Virtual Inspections – Strengths:

- Appreciation of the option to have a virtual inspection when an in-person inspection was not possible due to weather
- Those who were more tech-savvy, reported higher satisfaction with virtual inspections

Commission SBAR Communication

Virtual Inspections – Weaknesses:

- Challenges with technology, and limited internet connectivity
- Unfamiliarity with software
- Inability to fully visualize the site and introduction of potential bias

While virtual inspections have proven useful during the COVID-19 pandemic, there are significant limitations. Virtual inspections should not be considered as a replacement for in-person onsite inspections but may be considered as an alternative during times of public health outbreaks, poor road conditions, natural disasters, and at the discretion of the inspector and professional judgement of the PQAC leadership team.

Recommendation: The commission can consider one or more of the following options:

Option 1: Continue conducting virtual inspections as an option during times of public health emergencies, poor road conditions, natural disasters, inclement weather, limited in-scope inspections (e.g., remodels/modifications, change of ownership) and at the discretion of the inspector and professional judgement of the PQAC leadership team.

Option 2: Discontinue conducting virtual inspections at the conclusion of the COVID-19 proclaimed emergency.

Option 3: The commission may also choose to take no action or an alternative course of action.

Follow-up Action:

The PQAC team will proceed as directed and communicate the commission's decision to licensees through GovDelivery and updated facility applications as deemed appropriate.



RULE-MAKING ORDER EMERGENCY RULE ONLY

CR-103E (December 2017) (Implements RCW 34.05.350 and 34.05.360)

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: February 01, 2021

TIME: 1:39 PM

WSR 21-04-116

Agency: Department of Health- Pharmacy Quality Assurance Commission

Effective date of rule:

Emergency Rules

- ☒ Immediately upon filing.
☐ Later (specify)

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

- ☐ Yes ☒ No If Yes, explain:

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

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

Citation of rules affected by this order:

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

Statutory authority for adoption: RCW 18.64.005; RCW 18.64.205

Other authority: N/A

EMERGENCY RULE

Under RCW 34.05.350 the agency for good cause finds:

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

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

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

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

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

The number of sections adopted in order to comply with:

Federal statute:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Federal rules or standards:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Recently enacted state statutes:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>

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

New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
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The number of sections adopted on the agency's own initiative:

New	<u>1</u>	Amended	<u>0</u>	Repealed	<u>0</u>
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The number of sections adopted in order to clarify, streamline, or reform agency procedures:

New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
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The number of sections adopted using:

Negotiated rule making:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Pilot rule making:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Other alternative rule making:	New	<u>1</u>	Amended	<u>0</u>	Repealed	<u>0</u>

Date Adopted: 02/01/2021

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

Title: Pharmacy Quality Assurance Commission Chair

Signature:



NEW SECTION

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

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

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

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

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

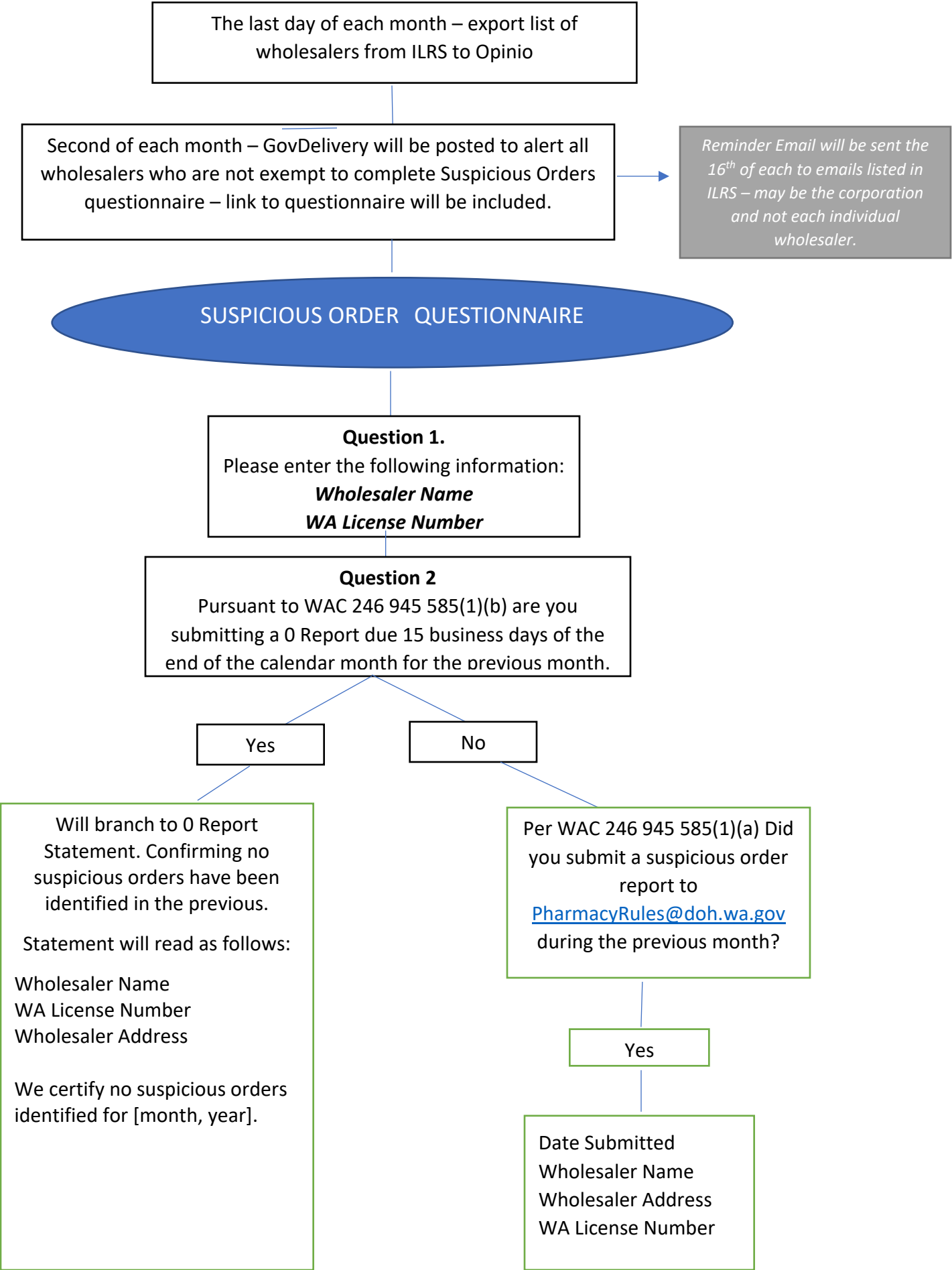
(a) "Emergent" includes, but is not limited to, earthquakes, floods, times of declared war or other states of emergency.

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

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

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

WAC 246 945 585 – ZERO REPORT SUSPCIOUS ORDER
QUESTIONNAIRE PROCESS





Standards

V1.1 10/10/2019

Business Information

1. The business is appropriately registered or incorporated and carries general and product liability insurance.
2. The business has a defined organizational structure and clear lines of authority (management and supervision).
3. The facility has and maintains appropriate current, valid federal licensure, permits and/or registrations
4. The facility has and maintains appropriate current, valid state licensure, permits and/or registrations in its home state and in any state into which products are distributed. This includes any state-issued controlled substance license/registration/permit.
5. There is a process for ensuring compliance and keeping up-to-date with state and federal laws, rules and regulations, including all states into which products are distributed.
6. There is a process for keeping informed and up-do-date with industry best practices and compliance with accreditation requirements and standards.
7. There is a process to complete appropriate reporting to federal and state agencies and accreditation organizations; and to complete and keep on file self-inspections or reports where required.
8. The business has a finance department or uses a CPA, develops an annual budget or plan and reviews periodic financial reports of performance to the budget.
9. Co-located businesses, if any, have appropriate physical and electronic segregation of products and operations.



10. The business has a designated representative for the facility who has appropriate education, training and experience and is actively involved in the day-to-day operations of a single facility.

Administration

1. There is a document control policy and procedure that describes how policies and procedures are developed, reviewed, revised, approved, and archived.
2. There is a document retention policy that includes where documents are stored, how documents are kept secure, how documents are accessed and by whom, and how documents are destroyed at the end of the required storage time.

Safety and Crisis Operations

1. A safety and crisis plan is developed and a hard copy of the safety and crisis plan is kept on the premises and with key personnel.
2. Contact lists are maintained for emergency services and for repair vendors (such as electric company, HVAC repair, etc.). A list of employee contact information is maintained.
3. Maps are posted indicating exits, location of fire extinguishers and first aid kits, and safe areas to congregate for weather emergencies (tornado, etc.) as appropriate.
4. Plans address people safety, business continuity, product security and disposition, and paper and electronic data security and disposition.

Environment

1. Neat, clean, free from pests and of adequate size for the volume of business.
2. Products are stored off the floor.



3. Appropriate storage areas for controlled substances, listed chemicals, and EPA hazardous products.
4. All areas where products are stored (including quarantine areas, refrigerators and freezers) are continuously monitored for temperature. Probes are placed based on temperature mapping when appropriate and replaced or calibrated annually.
5. Products are stored within conditions indicated on the packaging or labeling for the products. If there is no indication of storage conditions, product will be stored at USP defined controlled room temperature.
6. General product storage and quarantine areas are also monitored for humidity.
7. Temperature and humidity excursions are communicated to appropriate staff in real time and there is an action plan that includes the quarantine of product that has experienced an excursion.

Security

1. An alarm system is present and operational, and includes appropriate alarm contacts at entry points and additional monitoring such as glass break, motion detectors, etc. as appropriate. There is a procedure for responding to alarms.
2. Doors are kept locked from the outside.
3. Authorized staff have unique alarm codes, alarm system arming and disarming reports are reviewed to monitor after-hours access.
4. Access to drug storage areas is restricted.
5. Visitors (all non-employees) are required to provide current, valid ID and sign in and out of the facility on a log sheet or book, and are accompanied when in drug storage and handling areas.



6. Cameras are in use with appropriate placement, there is a process to secure the recorded data from alteration or deletion, and recordings are kept for the length of time to be useful in investigating inventory discrepancies or other issues. There is a procedure for the appropriate use and review of recordings.
7. Controlled substance cages and vaults are locked, part of the alarm system and included in the camera monitoring system.
8. Access to the controlled substance cage/vault limited to authorized personnel with a list of authorized personnel posted, a log kept of non-authorized person's access, and a procedure to ensure non-authorized persons are accompanied when in the cage/vault.
9. Computer systems
 - a. Unique ID and passwords. Passwords are required to be updated at least every 90 days unless using biometrics.
 - b. Access level is restricted and dependent on position.
 - c. Remote access is through a VPN or other secure, encrypted process.

Human Resources

1. Hiring process includes verification of education and work history, criminal background checks and drug screening. Financial background checks for select personnel.
2. Training process developed that includes initial training, training on new or revised policies and procedures, and ongoing annual training that includes how training is tracked and documented.
3. Content of training includes orientation, review of job description, policies and procedures, crisis plans, safety training, and training specific to the position and any equipment to be used.



4. There is an employee performance and competency review process that includes how reviews are documented.
5. Routine, random and for-cause criminal and financial background checks and drug screening process for all employees is in place and documented including the process for handling results.
6. Stepped disciplinary process including a procedure for reporting, if appropriate
7. Process to deal with termination or resignation of employees that includes immediate deactivation of alarm codes and computer access.

Vendors

1. Vendors for prescription products procure products directly from manufacturers or repackagers, or from wholesale distributors that purchase directly from manufacturers or repackagers. If the product has additional transactions, transactions are only between manufacturers, repackagers and wholesale distributors. There are no transactions showing the product was purchased from a pharmacy, dispenser, or other healthcare provider or facility.
2. Vendors for OTC products procure products directly from manufacturers or repackagers, or from wholesale distributors that purchase directly from manufacturers or repackagers. If the product has additional transactions, transactions are only between manufacturers, repackagers and wholesale distributors. There are no transactions showing the product was purchased from a pharmacy, dispenser, or other healthcare provider or facility. Transactions can be traced directly back to the manufacturer.
3. Initial verification and authentication of vendors, including licensure verification directly with licensing agencies (state and federal), any disciplinary actions, verification of wholesaler and 3PL reporting to FDA, and verification of vendors sources of products (including OTC vendors).



4. Process for when unable to authenticate and verify a vendor, including reporting.
5. Process for authentication of vendor licensing when license expires.
6. Process for authentication of vendors at least annually (in addition to the time of license expiration).

Product receipt

1. Process for receiving products from vendors including verification against the purchase order, review of transaction data, and physical inspection of outer containers or boxes and inner packs and units.
2. Process for quarantine of products that are damaged or exposed to temperature excursions during transit that may affect product integrity.
3. Process for quarantine of products when a discrepancy is detected (does not match purchase order, transaction data, etc.).
4. Process for quarantine of product that may be suspicious or illegitimate.
5. Process for handling controlled substances and refrigerated/frozen products.
6. Process for quarantine of product returns received from customers.

Product storage

1. Process to detect and prevent diversion, theft and loss of product within the facility.
2. Process for defacing, shredding or destruction of labels, containers, product boxes and cases to prevent their use in counterfeiting.
3. Inventories
 - a. Full physical inventory of all products process.



- b. Cycle count processes including frequency of controlled substance and listed chemical inventories.
- c. Inventory discrepancy procedure for documentation, investigation and reporting.
- d. Process for short-dated and expired products, and for products that have been damaged or whose integrity is questionable (temperature excursions, etc.).
- e. Process for investigation, documentation and reporting of suspected theft or significant loss.
- f. Process for handling products that are recalled or withdrawn from the market.
- g. Procedure for handling requests for information or notifications regarding suspicious or illegitimate product from trading partners, state agencies, DEA and FDA.
- h. Process to segregate product (physically or electronically) that is 340B, limited distribution or specific contract product to prevent distribution to unauthorized customers.

Quarantine

- 1. Separate, distinct and secure areas for quarantined product (general, refrigerated, frozen, controlled substance).
- 2. Separation and labeling of products or areas for different types of products in quarantine.
- 3. Quarantined product is part of the physical inventory processes.
- 4. Process to handle recalls and withdrawals disposition and documentation.
- 5. Process to evaluate customer-returned product and documentation.



6. Process to evaluate products that have experienced a temperature excursion or other condition that may affect product integrity and documentation.
7. Process to investigate product quarantined due to other discrepancies including appropriate notifications and reporting to FDA, DEA, state regulatory agencies and trading partners as appropriate, such as:
 - a. Orders received damaged.
 - b. Issues matching product received to purchase orders.
 - c. Transaction data missing, incomplete, or other discrepancies.
 - d. Suspicious product procedure.
 - e. Illegitimate product procedure.
8. Process to handle and document disposition of quarantined product including:
 - a. Product returns to manufacturer or distributor.
 - b. Sending products to a reverse distributor for credit or destruction including receiving confirmation of destruction.
 - c. In-house destruction of products.

Customers

1. Prior to distribution of products, initial verification and authentication of customers that includes the process to review ARCOS data (for controlled substances), licensure information verified directly with the state or federal licensing agency (including any disciplinary actions noted), confirming “ship to” address is legitimate.
2. Process to follow if unable to authenticate and verify a customer including reporting.
3. Process for authentication of customer licensing when license expires.
4. Process for authentication of customers at least annually (in addition to the time of license expiration).



Customer orders

1. Process for suspicious order detection, investigation and reporting.
2. Process to prevent distribution to customers whose license has expired, or when there is an issue, discrepancy, or active investigation of a suspicious order.
3. Process to prevent distribution to a different address than the licensed or authorized address on file.
4. Process to ensure accuracy in picking products.
5. Packing orders process that includes:
 - a. Visual inspection of products for damage and accuracy of picked order verified prior to packing.
 - b. Confirming appropriate materials are used in packing orders to ensure the integrity of temperature sensitive products, protection from heat and protection from products being frozen.
 - c. If using temperature indicators, provision of instructions to customers.
 - d. Proper handling and packing of hazardous product including an indication to the customer that a product is hazardous.
6. Shipping orders
 - a. Process to provide transaction data to customers at or before the time the customer receives products.
 - b. Process to ensure security and storage conditions of packed shipments as appropriate prior to carrier pick up.
 - c. Verification and authentication of common carriers used, that includes verification of their driver security training, background checks and drug testing of drivers.
 - d. Process to track orders.



Quality Program

1. There is a quality committee, meetings are held quarterly (or more often), and are documented.
2. There is a process to gather data, investigate, review and analyze data, trend data over time, create improvements and evaluate effectiveness (CAPA).
3. The process includes (but is not limited to) a review of:
 - a. Vendors: failed authentication or verification, supply issues.
 - b. Customers: comments and complaints, failed authentication or verification, suspicious orders.
 - c. Carriers: delivery/damage issues, theft/loss.
 - d. Inventory: failed product receipt, inventory adjustment records, theft/loss, temperature and humidity records, suspicious or illegitimate product investigations and requests/notifications from trading partners or regulatory agencies.
 - e. HR: performance, disciplinary actions, background checks and drug testing results.
 - f. Internal audits, external audits, inspections or survey results.

Update History:

V1.1 10/1/19 approved 10/10/19

Vendors. Added additional clarification to items (1.) and (2.) to indicate products may have multiple transactions in the history, and that no transactions are allowed where the product was obtained from a dispenser, pharmacy, or other healthcare provider.



National Coalition for Drug Quality & Security

Denise Frank, Director of Accreditation and Inspections



History and Programs

- Unmet need for accreditation of small, independent, secondary and specialty wholesale distributors
- Unmet need for inspection services for wholesalers in a state that does not perform inspections regularly
- Launched the Quality and Security (QAS) wholesale drug distributor accreditation program and inspection program in September 2019.
- Provides Board of Pharmacy compliance officer training on the inspection of distributors including common items of noncompliance.
- Provides Consultant training in accreditation standards.



QAS Accreditation and Inspection

- Iowa recognized NCDQS QAS accreditation for licensure by waiver in 2019 until the rule was revised in late 2020 to require either NCDQS or NABP accreditation for licensure.
- Accreditation recognized and inspections accepted by Nebraska, Maryland, Vermont, Mississippi and New Hampshire.
- Inspections also accepted by Kansas and by Minnesota (limited).
- Working with other states for recognition of the NCDQS QAS accreditation and acceptance of NCDQS QAS inspections for licensure.



QAS Programs

- What's the difference between an **accreditation** and an **inspection**?
- **We are educational rather than punitive in approach.** Our goal is to promote the quality and security of the pharmaceutical supply chain.
- **We support the smaller, independent and specialty wholesale distributors** that do not have the resources to maintain a regulatory compliance team. We are clear and transparent with the information needed to become compliant with the standards.



Conflict of Interest

- The advisory board is not involved in the accreditation decisions and does not have access to applicant materials.
- Staff involved in accreditation, and contract reviewers, surveyors and inspectors do not have interest in, or management of, any drug manufacturing or distribution facilities.
- We do not provide any paid (for profit) consulting services.



Accreditation Standards

1. Business Information
2. Administration
3. Safety and Crisis Operations
4. Environment
5. Security
6. Human Resources
7. Vendors
8. Product Receipt
9. Product Storage
10. Quarantine
11. Customers
12. Customer Orders
13. Quality Program



Accreditation Process

- Application and Submission
- Document Review
- Site Survey
- Remediation
- Accreditation
 - Standard three-year accreditation
 - One-year conditional for new businesses
- Year 2 and Year 3 reviews



Inspections

- Inspections are performed only by licensed pharmacists to be accepted by boards of pharmacy that require all inspections to be performed by licensed pharmacists.
- Pictures may be taken and incorporated into the report, as appropriate.
- Inspections range from 2.5 to 6 hours in total, depending on the type and size of the facility, and the number and range of products carried.



Inspection Includes

- Cover page
- Summary page that includes items of noncompliance and a response or plan from the facility to remediate any issues
- The detailed inspection report



Inspection Sections

- Facility Information
- Administration
- Crisis Operations
- Facility Environment and Security
- Human Resources
- Product Flow
- Quality Program



Inspection Report Example

IV. FACILITY ENVIRONMENT AND SECURITY

1. Outside perimeter of the building is well lit.	Compliant
2. All doors locked from outside	Compliant
3. Visitors (non-employees) ID checked, sign in, accompanied ID checked if the person is unknown or unexpected.	Compliant
4. Doors cannot be opened from the inside undetected to prevent diversion Fire doors can be opened from the inside without a sound.	Non-compliant
5. Drug storage and handling areas are restricted access to only authorized personnel.	Compliant
6. Does the facility carry controlled substances schedule III-V ?	Yes
a. Cage is kept locked Cage door was standing open when staff was inside working.	Unknown or Partially Compliant
b. Access to cage restricted to authorized personnel, list posted on cage No list of authorized persons posted.	Non-compliant
c. Cage entry is part of the alarm system	Compliant
d. Cage is covered by security camera	Compliant
e. Sign-in log to document non-authorized persons accessing cage No sign-in log or other documentation of persons accessing cage who are not on the authorized person list.	Non-compliant

Observations are color-coded for easy identification of items requiring attention.

Notes from the inspector are also included.

If pictures were taken to address a particular item, they would also appear with the item in the report.



Questions?

Please send questions and comments to:

NCDQS info@ncdqs.org

Denise Frank denise@ncdqs.org



Thank you!