Draft

STATE OF WASHINGTON

Pharmacy Quality Assurance Commission

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

December 4, 2020
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# 574-477-971
Phone +1 (562) 247 8321
Access Code: 153-277-861
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 – December 4, 2020
   - **1.2** Meeting Minutes Approval – October 1, 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 October 2020

2.2 Pharmaceutical Firms Application Report Approval – Open/Closed

- **a.** September 29 thru November 20, 2020

2.3 Ancillary Utilization Plans Approval

- **a.** Cascara Health Virginia Mason
- **b.** Cherry Hill Pharmacy
- **c.** Doctors Pharmacy
- **d.** Garfield County Hospital
- **e.** Gibbons multiple pharmacies
- **f.** OP Pharmacy LLC
- **g.** Pacific Northwest Specialty Pharmacy
- **h.** RLS USA
- **i.** Salish Cancer Center
- **j.** The Medicine Shoppe
- **k.** Yakima Neighborhood Health Services

2.4 Pharmacy Technician Training Program Approval

- **a.** Chesterfield Pharmacy TTP
- **b.** Malleys Compounding Pharmacy
- **c.** Ostroms Drug TTP

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 Commission on Medical Commission's rule making regarding prescribers engagement in collaborative drug therapy agreements. (CR101)

3.2 Suspicious Orders Exemption Application

3.3 Suspicious Order Letter of Cooperation (LOC)

3.4 Commission Delegation Forms

3.5 Guidance Document – Intern Registration

10:00 am

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 Discuss NABP's memo regarding change in processing requests for ADA testing accommodations and if the Commission requests an exemption.

4.2 Review, for approval, a draft of self-inspection worksheet for Health Care Entities.

4.3 Discuss the Food and Drug Administration's MOU addressing inordinate amounts of distributions of compounded human drug products interstate.

4.4 Identify Commissioner(s) who will participation in the Office of Health Profession's legislation review calls.
4.5 Pharmacy Changes of Ownership

11:30 am

5. 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)

11:50 am

6. Panel Review (Panel B)
6.1 Pharmacist applicant requests Commission approval of her study plan for reauthorization to take the MPJE.
6.2 Pharmacist applicant requests Commission approval of her study plan for reauthorization to take the NAPLEX **.**

12:00 pm

7. Commission Member Reports - *Information/Action.*
7.1 Update from HPAC Subcommittee
7.2 Commissioner Reports
7.3 Commissioners' open discussion related to items or issues relevant to Commission business/pharmacy practice.

12:30 pm

8. Staff Reports *Information/Action.*
8.1 Executive Director – Lauren Lyles-Stolz
8.2 Deputy Executive Director – Christie Strouse
8.3 Assistant Attorney General – Christopher Gerard
8.4 Pharmacist Inspector Supervisor – Lisa Hunt

12:45 pm

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

1:00 pm (approximately)
Business Meeting Adjourned.

Pharmacy Quality Assurance Commission
Mission Statement

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

Vision Statement

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

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

Next scheduled business meeting:

January 21 -22, 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.

STATE OF WASHINGTON

DEPARTMENT OF HEALTH

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

Attestation of Exemption from Suspicious Order Reporting Requirements under WAC 246-945-585

Wholesalers may apply to the commission for an exemption from the suspicious order reporting requirements in WAC 246-945-585 if they do not distribute controlled substances or drugs of concerns.

This Attestation of Exemption from Suspicious Order Reporting Requirements under WAC 246-945-585 ("Attestation") is submitted by:

Legal Name:
State Wholesaler License Number:
Wholesaler Address:

By submitting this Attestation, ____ [Company Name and State Wholesaler License Number] _____ attest that we do not distribute controlled substances or drugs of concerns into the State of Washington.

The individual who signs this Attestation below on behalf of the named wholesaler represents that he or she has authority to attest on behalf of the named wholesaler.

_____
Print Name

_____
Signature
(Electronic Signature please place /s/ before Name)

_____
Date

PLEASE NOTE: If your Company begins to distribute controlled substances at any time after submission of this Exemption Letter of Attestation, this document will no longer be in effect. In addition, you must comply with WAC 246-945-585.

STATE OF WASHINGTON

DEPARTMENT OF HEALTH

Date:

Licensee and address:

Case No.

Dear:

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

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

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

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

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

The report states that your pharmacy exceeded its normal threshold for ordering *****_drug_***. On approximately ***_date_***, ***_wholesaler_** flagged an order regarding ***_specific details, order, and quantity_***.

Please provide your signed written response to the following information request:

Please elaborate on the cause for exceeding your threshold. Please include any information you would like PQAC to consider, including but not limited to, any documentation you may have sent to the wholesaler to validate this order(s).

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

Sincerely,

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

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

Dated Date _____ at

_____ , Washington

_____

Washington State Department of Health

Form 1-1-19C: Delegation of Decision- Making

I,_____, Chair of the Washington State

_____
(the board or commission), acting upon authorization of the board or commission and under the authority of RCW 18.130.050(10), delegates each of the functions indicated below:

Legal Services: (Pharmacy Commission only)

☐ Brief Adjudicative Proceedings (Initial Orders) – Office of Investigative and Legal Services Office Director and Supervising Staff Attorney

Legal Services: (All other professions)

☐ Brief Adjudicative Proceedings (Initial Orders) – Office of Investigative and Legal Services Office Director and Deputy Director

Review Officer:

☐ Brief Adjudicative Proceedings (review of initial orders) – Review Officer in the Office of the Secretary

☐ **Adjudicative Services** (Delegated to presiding officer serving in the Adjudicative Service Unit) – RCW 18.130.050(10)

☐ To serve as the decision-maker in response to an ex parte motion for summary suspension of a license in which the respondent is alleged to have violated RCW 18.130.400.

☐ To serve as the decision-maker in response to an ex parte motion for summary suspension of a license in which the respondent is alleged to have violated RCW 18.130.370.

☐ To serve as the decision-maker in response to a motion for an investigative mental health or physical health examination under RCW 18.130.170(2)(b).

☐ To serve as the final decision-maker in adjudicative proceedings in which a respondent is in default for failure to submit a request for adjudicative proceeding. This delegation does not include cases pertaining to standards of practice or where clinical expertise is necessary.

☐ To serve as the final decision-maker in adjudicative proceedings in which the respondent is alleged to have violated RCW 18.130.180(5).

☐ To serve as the final decision-maker in adjudicative proceedings where the board or commission has brought a motion for noncompliance.

☐ To serve as the final decision-maker in adjudicative proceedings in which the respondent is charged with violation of RCW 18.130.180(9).

☐ To serve as the final decision-maker in adjudicative proceedings in which the respondent is alleged to have violated RCW 18.130.180(17).

☐ Notwithstanding RCW 18.130.062 to serve as the final decision-maker in adjudicative proceedings in which the respondent is alleged to have violated RCW 18.130.180(24).

☐ To serve as the final decision-maker in adjudicative proceedings in which the respondent is alleged to have violated RCW 18.130.180(23).

☐ To serve as the final decision-maker in adjudicative proceedings in which the respondent is alleged to have violated RCW 18.130.180(6).

☐ To serve as the final decision-maker in adjudicative proceedings in which the respondent is alleged to have violated RCW 18.130.170.

☐ To approve or deny proposed settlements in all cases other than those that pertain to standards of practice or where clinical expertise is necessary, that are filed nine (9) calendar days before the scheduled hearing.

☐ To serve as the final decision-maker in proceedings related to reinstatement of a license previously suspended, revoked, or restricted by the board or commission.

☐ To serve as the final decision-maker in proceedings related to modification of any disciplinary order previously issued by the board or commission.

This delegation remains in effect until revoked, terminated or modified. To the extent that this delegation conflicts with prior delegations to presiding officers at the Adjudicative Service Unit, this delegation prevails.

DATED this_____day of_____,_____.

(Signature) _____

(Name)_____
Chairperson

(Board/Commission) _____

Department of Health
Pharmacy Quality Assurance Commission

Guidance Document

Title: Enforcement of Intern Registration Renewal Limit		*Number:* 690-337
References:	WAC 246-945-155(3), WAC 246-907-030, RCW 18.64.080	
Contact:	Dr. Lauren Lyles-Stolz, Executive Director, Pharmacy Quality Assurance Commission	
Phone:	360-236-4946	
Email:	WSPQAC@doh.wa.gov	
Effective Date:	October 1, 2020	
Supersedes:	N/A	
Approved By:	Tim Lynch, PharmD, MS, FABC, FASHP, Pharmacy Quality Assurance Commission Chair	

At its October 1, 2020 business meeting the Pharmacy Quality Assurance Commission (commission) determined that it 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.

Background: The commission recently completed a 2.5-year process to consolidate thirty-three (33) chapters of WAC into one new chapter (chapter 246-945 WAC). Chapter 246-945 WAC went into effect on July 1, 2020. This effective date applied to all sections within the chapter, except the continuing education rules (clarified in another guidance document) and the fee rules (chapter 246-907 WAC). Rulemaking is currently in progress on the fee rules which, when complete, will implement a new fee schedule and the two-year license renewal cycle. Until this rules package is complete, the 1-year license renewal cycle remains in effect as determined by WAC 246-907-030(1).

RCW 18.64.080(3) states "Any person enrolled as a student of pharmacy in an accredited college may file with the department an application for registration as a pharmacy intern…" Further, "All certificates issued to pharmacy interns shall be valid for a period to be determined by the commission…" Under WAC 246-945-155(3), "A pharmacy intern registration can only be renewed twice." Any registration renewed prior to the completion of the fee rules is for a 1-year duration since WAC 246-907-030 remains in effect.

Conclusion: To ensure that pharmacy interns have adequate time to hold their registration, the commission will not enforce WAC 246-945-155(3) until the fee rules package is complete and the 2-year license renewal cycle is implemented.

NABP
National Association of Boards of Pharmacy

847/391-4406
Fax: 847/375-1114

1600 Feehanville Dr
Mount Prospect, IL 60056
help@nabp.pharmacy

TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY

FROM: Natasha Niedbalec, Competency Assessment Pharmacist Manager

DATE: April 30, 2020

RE: Testing Accommodation Changes for NAPLEX and MPJE

To assist the boards of pharmacy, the National Association of Boards of Pharmacy (NABP) will evaluate all candidate testing accommodation requests, and finalize the accommodations to be provided, beginning May 13, 2020.

By May 7, 2020, NABP kindly requests that boards deciding to opt out of NABP-evaluated accommodations do so by emailing NABP Executive Office Staff at ExecOffice@nabp.pharmacy. Boards that opt out will receive requests for evaluation from NABP by United States Postal Service mail, secure fax, or secure file transfer protocol. Because of the sensitive nature of personally identifiable information PII, NABP will only use secure methods to send and receive accommodations finalizations and communications. NABP is unable to accept accommodations requests, or related communications, via email due to the security risk. NABP will work with those boards to determine the best communication method.

NABP is also streamlining the accommodations process for candidates. Candidates will no longer be required to submit their requests to each board for which they are seeking licensure. Candidates will be prompted to securely upload their requests to the NABP database when applying for exam eligibility and the accommodations finalizations will be applied to all NABP exams during the validity period. This change will help ensure the uniform evaluation of each candidate's accommodation request, protect PII, and decrease the burden on the candidates and boards.

Questions regarding the testing accommodation changes may be directed to adarequest@nabp.pharmacy.

NABP looks forward to further supporting the boards and candidates.

Attachment

cc: NABP Executive Committee

Request for Testing Accommodations
NABP Examinations

The Request for Testing Accommodations form (Form) is provided to assist the board of pharmacy, the school of pharmacy, and/or the National Association of Boards of Pharmacy® (NABP®) in evaluating a request for testing accommodations under the Americans with Disabilities Act (ADA).

Instructions

Download, complete, and submit all three parts of the fillable Form as applicable, including supporting documentation in its entirety as required. Retain a copy for your records.

- Part I: Candidate Statement, **including detailed written summary of disability**
- Part II: Practitioner Statement, **including practitioner's supporting written summary(ies)**
- Part III: Academic, Institution, School, or College Statement
  If you did not receive accommodations in pharmacy school, graduated from pharmacy school more than three years ago, or achieved Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) Certification, Part III: Academic, Institution, School, or College Statement does not need to be completed.

Additional details are available in the *NAPLEX/MPJE Candidate Application Bulletin,* the *FPGEC Candidate Application Bulletin,* and the Programs section of the NABP website at *www.nabp.pharmacy.*

Submission, Review, and Approval Processes

The process for the Pharmacy Curriculum Outcomes Assessment® (PCOA®) differs from that of the North American Pharmacist Licensure Examination® (NAPLEX®), Multistate Pharmacy Jurisprudence Examination® (MPJE®), and Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®), as explained below.

Please note that during the evaluation process for all NABP examinations, NABP may contact the candidate, practitioner(s), or school if more information is required to support the request. NABP may share information that a candidate provides, including, but not limited to, the Form, the candidate's medical history, the nature of the diagnosis(es), the accommodations provided in the academic environment, or a health care practitioner's statement.

NAPLEX/MPJE/FPGEE Candidates

Upload the completed Form and supporting documentation in your NABP e-Profile account during the online application process for examinations. These requests will be reviewed by NABP and the board of pharmacy, if applicable. NABP will contact you after the review of your request is completed. Candidates whose requests have been approved must schedule their testing appointment with Pearson VUE.

PCOA Candidates

Complete Parts I and II and submit the Form and supporting documentation to your school of pharmacy. The school of pharmacy will complete Part III and forward the request to NABP by uploading the Form and supporting documentation to your NABP e-Profile. Once the request is approved, the school of pharmacy may notify the candidate.

Validity Periods

Accommodations approval is valid for one year from the date of notification of approval to the candidate. The Form may be considered for any NABP examination occurring within the validity period. Candidates must resubmit a new Form and supporting documents if their disability status or requested accommodation(s) changes. NABP may require additional documentation or modify formerly approved accommodations.

Request for ADA Testing Accommodations
NABP Examinations

PART I: INDIVIDUAL/CANDIDATE STATEMENT

Please type or print the requested information, unless a signature is required. *Enter your name exactly as it appears on your ID and e-Profile, including first, middle or initial(s), and last names including any suffixes.

Name:_____

Address: _____

_____

e-Profile ID Number:_____Telephone Number: _____

Birth Date:_____Examination Applying for: ☐ NAPLEX ☐ MPJE ☐ PCOA ☐ FPGEE

Date the PCOA was taken (if applicable)_____Accommodations used for the PCOA _____
Month, Year

Briefly describe the disability: _____

_____

Please attach a detailed written summary that describes your disability, support for the requested accommodation(s), and current treatment/therapy prescribed or recommended for the disability (eg, medication regiment, physical aids, etc).

List each practitioner (eg, physician, therapist). Attach additional sheets if necessary.
Each treating practitioner must complete Part II: Practitioner's Statement.

Name:_____

Office Address: _____

Telephone Number:_____Length of Time as Patient: _____

If you have previously been provided with testing accommodation(s), please list the provider, the time frame, and a description of the accommodations. If no accommodations were provided to you in the past, please provide a written explanation of why accommodations are requested now and why they were not requested in the past.

_____

_____

Authorization, Release, and Attestation:

I hereby authorize each treating practitioner listed herein to release to and discuss with the school or college of pharmacy at which I am enrolled (School), Board of Pharmacy (Board), and the National Association of Boards of Pharmacy® (NABP®) and its ADA Committee any and all Information about me or my disability described herein. "Information" means all information about me in the possession of, or derived from, treating practitioners or providers of health care in connection with the disability for which I am requesting accommodations. I further authorize NABP, School, and Board (individually "Organization" and two or more are, collectively, "Organizations") to discuss Information with an Organization, Organizations, or an Organization or Organizations may discuss Information with a treating practitioner. I agree that this authorization, release, and attestation (AR&A) shall be valid for one year, unless earlier revoked in writing by me. I understand that an Organization may use the Information obtained pursuant to this AR&A to review my accommodation request in connection with any NABP examination for which I request accommodations during the validity period of this AR&A. The Board of Pharmacy and NABP reserve the right to require additional Information or documentation to support this request for accommodation or to obtain an independent assessment by another health care professional or treatment provider. I hereby attest that the foregoing statements and those that I make in any documents that may accompany my accommodations request are true, correct, and complete. I understand and agree that false, incomplete, or inaccurate information may be cause for NABP to delay issuance or invalidate the NABP examination score or results; delay or deny authorization to sit for an NABP examination; delay or deny authorization to other NABP examinations, tests, or assessments, such as the NAPLEX or MPJE; or pursue any other remedies available under law. I hereby attest that I personally completed this request Form and agree to verify Information at any time that I may be requested.

Signature:_____Date: _____

Request for ADA Testing Accommodations
NABP Examinations

PART II: PRACTITIONER'S STATEMENT

Each treating practitioner must complete Part II: Practitioner's Statement and return it along with all supporting documentation to the patient, who is a candidate for an NABP examination. Please type or print the requested information, unless a signature is required.

Practitioner Name: _____

Professional Title: _____

Professional Training, Credentials, Licensing, and Specialization to Support Relevant Diagnoses and Appropriate Recommendation (please attach appropriate written documentation citing credentials):

_____

_____

_____

Office Address: _____

Telephone Number: _____ State License Number: _____

Patient's Name: _____ Patient's Address: _____

Date Patient First Consulted: _____ Date Patient Last Consulted: _____

Number of Years as a Patient: _____

Diagnosis of Disability: _____

_____

Recommended Accommodation(s): _____

I. Please attach a written statement explaining the diagnosis and its impact on the candidate's abilities relative to the request for special accommodations. *(In order to ensure that a current diagnosis is presented, it is preferred that the evaluations have been conducted within the past three to five years. Please provide an explanation of any gaps in medical evaluations taking place prior to the request for accommodations.)*

II. Please attach a written explanation for each recommended accommodation(s), including the current treatment for the disability (eg, any medication management or physical aids). Any current and applicable test used to support the diagnosis or recommendation for accommodations should be submitted.

III. If no accommodations were provided to the candidate in the past, please provide a written explanation of why accommodations are requested now and why they were not requested in the past.

Certification

I hereby certify that the information that I provide pursuant to this Practitioner Statement is true and correct and is provided pursuant to the authorization to release information signed by my patient. I further certify that I have the necessary specialized training to make the diagnosis herein, that I personally examined the candidate named herein, and that I used my professional judgment to render the diagnosis herein and assess the accommodation request. I acknowledge that the school or college of pharmacy at which my patient is enrolled, Board of Pharmacy, or National Association of Boards of Pharmacy® (NABP®) may contact me, pursuant to the candidate's permission to obtain further information if necessary, and that the Board of Pharmacy or NABP may obtain an independent assessment by another professional.

Practitioner's Signature: _____ Date: _____

Request for ADA Testing Accommodations
NABP Examinations

PART III: ACADEMIC, INSTITUTION, SCHOOL, OR COLLEGE STATEMENT

The individual named below is requesting testing accommodations for the North American Pharmacist Licensure Examination®, the Multistate Pharmacy Jurisprudence Examination®, and/or the Pharmacy Curriculum Outcomes Assessment®. Please type or print the requested information to complete the Form and provide the signature of an authorized representative of the academic institution, school, or college (School) to provide the data requested in this statement. Please complete this Form and return it and all supporting documentation to the candidate.

I hereby authorize the designated academic institution to provide the requested information regarding the accommodations that the School provided to me:

Candidate Name (please print) _____ Candidate Signature _____

School Statement

School Name: _____

Name of Person Completing Form: _____ Title: _____

Address: _____ Phone Number: _____

Time period student was affiliated with the School: _____

Please describe the accommodation(s) and the basis for the approval of the accommodation(s).

_____

_____

_____

_____

Month/Year Accommodations Started and Ended: _____

The accommodation was_____a one-time event or_____an ongoing accommodation. (Select one.)

Please attach any testing results and recommendations from a qualified practitioner who assessed the student and the student's accommodations request. Please list the information and documentation that supported the accommodation approval:

_____

_____

_____

_____

Certification

I hereby certify that I am an authorized representative of the School and that the information provided pursuant to this statement is true, accurate, and complete, and is provided pursuant to the authorization and release signed by the candidate named herein. I understand that the Board of Pharmacy or NABP may contact me or other School representatives to obtain further information if necessary.

Signature of School Representative: _____ Date: _____

Read this Page Carefully

Pharmacy Quality Assurance Commission

2021 Health Care Entity (HCE) Self-Inspection Worksheet

Attention: Responsible Pharmacy Manager (or Equivalent Manager)

Washington law holds the responsible pharmacy manager (or equivalent manager) and all pharmacy personnel are responsible for ensuring compliance with all state and federal laws governing the practice of pharmacy. Failure to complete this annual worksheet and applicable self-inspection worksheet addendums within the month of March or within 30 days of becoming responsible pharmacy manager (as required by WAC 246-945-005) may result in disciplinary action.

Following your self-inspection and completion of the worksheet(s), please review it with your staff, correct any deficiencies noted, sign and date the worksheet(s), and file it so it will be readily available to Commission inspectors. DO NOT SEND to the Commission office. You are responsible for ensuring your completed worksheet(s) is available at the time of inspection.

The primary objective of this worksheet, and your self-inspection, is to provide an opportunity to identify and correct areas of non-compliance with state and federal law. (NOTE: Neither the self-inspection nor a Commission inspection evaluates your complete compliance with all laws and rules of the practice of pharmacy.) The inspection worksheet also serves as a necessary document used by Commission inspectors during an inspection to evaluate a HCE's level of compliance.

When a Commission inspector discovers an area of non-compliance, they will issue an Inspection Report with Noted Deficiencies. The responsible pharmacy manager (or equivalent manager) must provide a written response (plan of correction) addressing all areas of non-compliance. Identifying and correcting an area of non-compliance prior to a Commission inspection, or during an inspection, may eliminate that item from being included as a deficiency on an Inspection Report. Do not *assume* compliance with any statement; take the time to personally verify that compliance exists. If you have any questions, please contact your inspector.

A common reason for issuing an Inspection Report with Noted Deficiencies is either not having or not being able to readily retrieve required documents and records. Because Commission inspections are unscheduled, it is common for the responsible manager to be absent or unavailable. For this reason, you are asked to provide a list of the specific locations of required documents. Having all required documents and records maintained in a well-organized and readily retrievable manner (a binder is recommended) reduces the chance that you will receive an Inspection Report with Noted Deficiencies.

By answering the questions and referencing the appropriate laws/rules/CFR provided, you can determine whether you are compliant with many of the rules and regulations. If you have corrected any deficiencies, please write corrected and the date of correction by the appropriate question. Questions highlighted in blue are questions that will be focused on during routine HCE inspections.

Washington State Department of Health

2021 Health Care Entity Self-Inspection Worksheet

All responsible pharmacy managers (or equivalent managers) of HCEs MUST complete and sign this self-inspection worksheet within the month of March or within 30 days of becoming responsible pharmacy manager. The form must be available for inspection as required by WAC 246-945-005. Do NOT send to the Commission office.

Date Responsible Pharmacy Manager inspection was performed: _____

Change in Responsible Pharmacy Manager and effective date of change: _____

Print Name of Responsible Pharmacy Manager & License #: _____

Signature of Responsible Pharmacy Manager: _____

Responsible Pharmacy Manager E-mail: _____

Health Care Entity: _____ Telephone: _____ Fax: _____

Address: _____ DEA #: _____

Health Care Entity License #: _____

Endorsements:

☐ Dispense Controlled Substances

In Washington State, compounding is defined in RCW 18.64.011(6) and means "the act of combining two or more ingredients in the preparation of a prescription." This includes what is traditionally considered reconstitution. If pharmacy personnel reconstitute medications or ads flavoring, it is considered compounding and the sterile and/or non-sterile compounding self-inspection worksheets must also be completed.

Yes	No	
☐	☐	Do pharmacy personnel engage in non-sterile compounding or reconstitution of medications? If yes, please complete the 2021 Non-Sterile Compounding Self-Inspection Addendum in addition to the Health Care Entity Self-Inspection Worksheet.
☐	☐	Do pharmacy personnel engage in sterile compounding? If yes, you must also complete the 2021 Sterile Compounding Self-Inspection Addendum.

Document and Record Review Where are the following items located inside the HCE (be as specific as possible, there can be many filing cabinets and binders)? The documentation listed below are required by rule references to be available during inspection, by listing the location of these documents you are also confirming your compliance with the referenced rule.	
	Rule Reference
Responsible Pharmacy Manager Self-Inspection Worksheet for last 2 years Location:	WAC 246-945-005(4)(a) "The responsible pharmacy manager, or equivalent manager, shall sign and date the completed self-inspection worksheet(s), and maintain completed worksheets for two years from the date of completion." WAC 246-945-005(4)(b) "When a change in responsible pharmacy manager, or equivalent manager occurs, the new responsible pharmacy manager, or equivalent manager, shall conduct a self-inspection as required under this section. The new responsible pharmacy manager, or equivalent manager, shall sign and date the self-inspection worksheet(s) within thirty days of becoming responsible pharmacy manager, or equivalent manager, and maintain completed worksheets for two years from the date of completion."
Health Care Entity License Location:	RCW 18.64.450(1) "In order for a health care entity to purchase, administer, dispense, and deliver legend drugs, the health care entity must be licensed by the department."
DEA Registration Location:	WAC 246-945-040(2) "A separate registration is required for each place of business, as defined in 21 C.F.R. Sec. 1301.12, where controlled substances are manufactured, distributed, or dispensed."

Document and Record Review Where are the following items located inside the HCE (be as specific as possible, there can be many filing cabinets and binders)? The documentation listed below are required by rule references to be available during inspection, by listing the location of these documents you are also confirming your compliance with the referenced rule.	
Current Biennial Controlled Substance Inventory Location:	WAC 246-945-420(2) "A facility shall conduct an inventory of controlled substances every two years." WAC 246-945-420(3)(a) "Within thirty days of designating a responsible pharmacy manager. The incoming responsible pharmacy manager, or designee, shall conduct a complete controlled substance inventory. 21 C.F.R. 1304.04(h)(1) "Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all of the records of the registrant; and. (2) Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant."
Completed CII order forms (DEA Form 222) and/or finalized CSOS documentation for the last 2 years Location:	WAC 246-945-040(6) "A federal order form is required for each distribution of a Schedule I or II controlled substance. Credential holders and pharmaceutical firms must keep and make readily available these forms and other records to the commission or its designee." 21 C.F.R. 1305.13(e) "The purchaser must record on its copy of the DEA Form 222 the number of commercial or bulk containers furnished on each item and the dates on which the containers are received by the purchaser." 21 C.F.R. 1305.22(g) "When a purchaser receives a shipment, the purchaser must create a record of the quantity of each item received and the date received. The record must be electronically linked to the original order and archived."

Document and Record Review Where are the following items located inside the HCE (be as specific as possible, there can be many filing cabinets and binders)? The documentation listed below are required by rule references to be available during inspection, by listing the location of these documents you are also confirming your compliance with the referenced rule.	
Schedule II Invoices for the last 2 years Location:	WAC 246-945-040(3)(a) "Every registrant shall keep and maintain inventory records required by 21 C.F.R. Sec. 1304.04. Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug;" WAC 246-945-040(4) "Credential holders and pharmaceutical firms shall maintain records for Schedule II drugs separately from all other records."
Schedule III-V Invoices for the last 2 years Location:	WAC 246-945-040(3)(a) "Every registrant shall keep and maintain inventory records required by 21 C.F.R. Sec. 1304.04. Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug;" WAC 246-945-040(5) "Credential holders and pharmaceutical firms may maintain records for Schedule III, IV, and V drugs either separately or in a form that is readily retrievable from the business records of the registrant."

Document and Record Review Where are the following items located inside the HCE (be as specific as possible, there can be many filing cabinets and binders)? The documentation listed below are required by rule references to be available during inspection, by listing the location of these documents you are also confirming your compliance with the referenced rule.	
Completed loss by theft or destruction forms (DEA Form 106) for the last 2 years Location:	WAC 246-945-040(3)(c) "In the event of a significant loss or theft, two copies of DEA 106 (report of theft or loss of controlled substances) must be transmitted to the federal authorities and a copy must be sent to the commission." 21 C.F.R. 1301.76(b) "The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft..."
Power of Attorney for staff authorized to order controlled substances Location:	WAC 246-945-040(1) "The commission adopts 21 C.F.R. as its own." 21 C.F.R. 1305.05(a) "A registrant may authorize one or more individuals, whether or not located at his or her registered location, to issue orders for Schedule I and II controlled substances on the registrant's behalf by executing a power of attorney for each such individual, if the power of attorney is retained in the files, with executed Forms 222 where applicable, for the same period as any order bearing the signature of the attorney. The power of attorney must be available for inspection together with other order records."

Document and Record Review Where are the following items located inside the HCE (be as specific as possible, there can be many filing cabinets and binders)? The documentation listed below are required by rule references to be available during inspection, by listing the location of these documents you are also confirming your compliance with the referenced rule.	
Change of Responsible Pharmacy Manager forms for the last 2 years Location:	WAC 246-945-480(1) "The outgoing and incoming responsible pharmacy manager must report in writing to the commission a change in a responsible pharmacy manager designation within ten business days of the change." WAC 246-945-020 (1) "Unless an alternative standard for a specified record type, form, or format is expressly stated a pharmaceutical firm must maintain and retain records required as evidence of compliance with statutes and rules enforced by the commission in a readily retrievable form and location for at least two years from the date the record was created or received, whichever date is later. (2) A pharmaceutical firm must allow the commission, or its designee, access to the pharmaceutical firm's records upon request for the purposes of monitoring compliance with statutes and rules enforced by the commission."
Prescription Records for the last 2 years Location:	WAC 246-945-410(12) "A facility's paper prescriptions must be maintained in accordance with WAC 246-945-020 and as follows: (a) Paper prescriptions for Schedule II drugs must be maintained as a separate file from other prescriptions. (b) Paper prescriptions for Schedule III, IV, and V drugs must be maintained as a separate file or maintained in a separate file with prescriptions for non-controlled legend drugs as allowed under federal law."

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
General Licensing						
			1	Does the Health Care Entity (HCE) have a current license?	RCW 18.64.450(1) “In order for a health care entity to purchase, administer, dispense, and deliver legend drugs, the health care entity must be licensed by the department.”	
			2	Does the HCE have a current DEA registration?	WAC 246-945-040(2) "A separate registration is required for each place of business, as defined in 21 C.F.R. Sec. 1301.12, where controlled substances are manufactured, distributed, or dispensed.”	
			3	Is the responsible pharmacy manager licensed to practice pharmacy in the State of Washington?	WAC 246-945-310 “Responsible pharmacy manager. The responsible pharmacy manager must be licensed to practice pharmacy in the state of Washington. The responsible pharmacy manager designated by a facility as required under WAC 246-945-410 shall have the authority and responsibility to assure that the area(s) within the facility where drugs are stored, compounded, delivered, or dispensed are operated in compliance with all applicable state and federal statutes and regulations.”	
Facility Standards						
			4	Is the facility appropriately constructed and equipped to protect equipment, records, drugs/devices and other restricted items from unauthorized access? ***Including samples under the control of the HCE***	RCW 69.45.040(2) “Drug samples shall be maintained in a locked area to which access is limited to persons authorized by the manufacturer.” WAC 246-945-410(1) “The facility shall be constructed and equipped with adequate security to protect equipment, records, and supply of drugs, devices, and other restricted sale items from unauthorized access, acquisition, or use.”	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
			5	Is the facility properly equipped to ensure proper operation, prescription preparation, and product integrity?	WAC 246-945-410(2) "The facility shall be properly equipped to ensure the safe, clean, and sanitary condition necessary for the proper operation, the safe preparation of prescriptions, and to safeguard product integrity."	
			6	Is the facility appropriately staffed?	WAC 246-945-410(3) "The facility shall be staffed sufficiently to allow appropriate supervision, operate safely and, if applicable, remain open during posted hours of operation."	
			7	Is the facility adequately stocked?	WAC 246-945-410(4) "The facility shall be adequately stocked to maintain at all times a representative assortment of drugs in order to meet the pharmaceutical needs of its patients in compliance with WAC 246-945-415."	
			8	Does the facility have a designated responsible pharmacy manager?	WAC 246-945-410(5) "The facility shall designate a responsible pharmacy manager: (a) By the date of opening; and (b) Within thirty calendar days of a vacancy."	
			9	Are the drug storage areas appropriately secure from unauthorized access and are staff working within their scope of practice?	WAC 246-945-410(10) "Access to the drug storage area located within the facility should be limited to pharmacists unless one of the following applies: (a) A pharmacy intern, or pharmacy ancillary personnel enter under the immediate supervision of a pharmacist; or (b) A pharmacist authorizes temporary access to an individual performing a legitimate nonpharmacy function under the immediate supervision of the pharmacist; or (c) The facility has a policy and procedure restricting access to a health care professional licensed under the chapters specified in RCW 18.130.040, and the actions of the health care professional are within their scope of practice."	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
			10	Are refrigerators temperatures maintained between2- 8°C (36-46°F)? *** Electronic monitoring is acceptable. *****	WAC 246-945-410(2) "The facility shall be properly equipped to ensure the safe, clean, and sanitary condition necessary for the proper operation, the safe preparation of prescriptions, and to safeguard product integrity."	
			11	Are freezers between -25°& -10°C (-13° & 14°F)?	WAC 246-945-410(2) "The facility shall be properly equipped to ensure the safe, clean, and sanitary condition necessary for the proper operation, the safe preparation of prescriptions, and to safeguard product integrity."	
			12	Is drug stock stored under proper conditions (temperature, humidity, light) as recommend by the drug label? ***Including samples under the control of the HCE****	RCW 69.45.040(3) "Drug samples shall be stored and transported in such a manner as to be free of contamination, deterioration, and adulteration. (4) Drug samples shall be stored under conditions of temperature, light, moisture, and ventilation so as to meet the label instructions for each drug." WAC 246-945-410(2) "The facility shall be properly equipped to ensure the safe, clean, and sanitary condition necessary for the proper operation, the safe preparation of prescriptions, and to safeguard product integrity."	
			13	Is all drug stock in date? ***Including OTC medications and samples under the control of the HCE****	RCW 69.04.100 "Whenever the director shall find in intrastate commerce an article subject to this chapter which is so adulterated or misbranded that it is unfit or unsafe for human use and its immediate condemnation is required to protect the public	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
				It's advised to perform an inventory check for expired medications while filling out this self-inspection worksheet.	health, such article is hereby declared to be a nuisance and the director is hereby authorized forthwith to destroy such article or to render it unsalable for human use." RCW 69.45.040(5) "Drug samples which have exceeded the expiration date shall be physically separated from other drug samples until disposed of or returned to the manufacturer." WAC 246-945-410(2) "The facility shall be properly equipped to ensure the safe, clean, and sanitary condition necessary for the proper operation, the safe preparation of prescriptions, and to safeguard product integrity."	
Policies and Procedures						
			14	Does the HCE have policies and procedures in place for the following: a) Purchasing b) Ordering c) Storing d) Compounding e) Delivering f) Dispensing g) Administration	WAC 246-945-410(6) "The facility shall create and implement policies and procedures related to: (a) Purchasing, ordering, storing, compounding, delivering, dispensing, and administering legend drugs, including controlled substances."	
			15	Does the HCE have a policy and procedure in place that restricts drug access to licensed health care professionals?	WAC 246-945-410(10) "Access to the drug storage area located within the facility should be limited to pharmacists unless one of the following applies:	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
				Including nursing student access	…(c) The facility has a policy and procedure restricting access to a health care professional licensed under the chapters specified in RCW 18.130.040, and the actions of the health care professional are within their scope of practice." WAC 246-945-450(1) "Nursing students may be given access privileges to technology used to dispense medications for patient administration as provided for in this section."	
			16	Does the HCE have policies and procedures addressing administration of patient owned medications?	WAC 246-945-440 "Facilities shall develop written policies and procedures for the administration of patient owned medications."	
			17	Does the HCE have policies and procedures addressing return and reuse of drugs or devices?	WAC 246-945-485(1) "A dispensed drug or prescription device must only be accepted for return and reuse as follows: (a) Noncontrolled legend drugs that have been maintained in the custody and control of the institutional facility, dispensing pharmacy, or their related facilities under common control may be returned and reused if product integrity can be assured. (b) Those that qualify for return under the provisions of chapter 69.70 RCW."	
			18	Does the HCE have policies and procedures addressing return and destruction of drugs or devices?	WAC 246-945-485(2) "A dispensed drug or prescription device may be accepted for return and destruction if: (a) The dispensed drug or prescription device was dispensed in a manner inconsistent with the prescriber's instructions; (b) The return is in compliance with the Washington state safe medication return program laws and rules, chapters 69.48 RCW and 246-480 WAC; or	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					(c) The return and destruction is in compliance with the facility's policies and procedures."	
			19	Does the HCE have policies and procedures addressing computer system downtime?	WAC 246-945-417(7) "HCEs or HPACs that maintain an electronic record system must be done in accordance with subsections (2) through (7) of this section." WAC 246-945-417(4) "The pharmacy shall have policies and procedures in place for system downtime. (a) The procedure shall provide for the maintenance of all patient recordkeeping information as required by this chapter. (b) Upon restoration of operation of the electronic recordkeeping system the information placed in the auxiliary recordkeeping procedure shall be entered in each patient's records within two working days, after which the auxiliary records may be destroyed. (c) This section does not require that a permanent dual recordkeeping system be maintained."	
Recordkeeping						
			20	Are complete patient medical records maintained in either paper or electronic format?	WAC 246-945-418 "If an HPAC or HCE does not maintain an electronic recordkeeping system their manual records must contain all information required in WAC 246-945-417."	
			21	If applicable, does the HCE maintain electronic record system including patient allergies, idiosyncrasies or chronic conditions, and prescription, refill, transfer information, and other information necessary to	WAC 246-945-417(1) "A pharmacy shall use an electronic recordkeeping system to establish and store patient medication records, including patient allergies, idiosyncrasies or chronic conditions, and prescription, refill, transfer information, and other information necessary to provide safe and appropriate patient care." (see Appendix A)	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
				provide safe and appropriate patient care?	WAC 246-945-417(7) HCEs or HPACs that maintain an electronic record system must be done in accordance with subsections (2) through (7) of this section.	
			22	Does the electronic recordkeeping system include security features to protect confidentiality and integrity of patient records?	WAC 246-945-417(3) "The electronic recordkeeping system must include security features to protect the confidentiality and integrity of patient records including: (a) Safeguards designed to prevent and detect unauthorized access, modification, or manipulation of prescription information and patient medication records; and (b) Functionality that documents any alteration of prescription information after a prescription is dispensed, including the identification of the individual responsible for the alteration."	
			23	If applicable, does the manual patient medical record system have the capability to store patient medication records e.g. allergies, idiosyncrasies or chronic conditions, and prescription, refill, transfer, and other information as required in WAC 246-945-417?	WAC 246-945-418 "If an HPAC or HCE does not maintain an electronic recordkeeping system their manual records must contain all information required in WAC 246-945-417. The record system consists of the hard copy of the original prescription and a card or filing procedure that contains all data on new and refill prescriptions for a patient. This data must be organized in such a fashion that information relating to all prescription drugs used by a patient will be reviewed each time a prescription is filled."	
			24	Are suitable record of drugs readily retrievable or maintained separately from all other records? ***Including drug samples under the control of the HCE***	RCW 18.64.470 "Every proprietor or manager of a health care entity shall keep readily available a suitable record of drugs, which shall preserve for a period of not less than two years the record of every drug used at such health care entity. The record shall be maintained either separately from all other records of the health care entity or in such form that	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					the information required is readily retrievable from ordinary business records of the health care entity. All recordkeeping requirements for controlled substances must be complied with."	
			25	Are all records readily retrievable for at least two years from the date the record was created or received, whichever is later?	WAC 246-945-020(1) "Unless an alternative standard for a specified record type, form, or format is expressly stated a pharmaceutical firm must maintain and retain records required as evidence of compliance with statutes and rules enforced by the commission in a readily retrievable form and location for at least two years from the date the record was created or received, whichever date is later." WAC 246-945-001(7) ""Readily retrievable" means a record that is kept by automatic data processing systems or other electronic, mechanized, or written recordkeeping systems in such a manner that it can be separated out from all other records in a reasonable time."	
Controlled Substances						
			26	Are all controlled substances in the HCE locked and secured to prevent unauthorized access?	WAC 246-945-040(1) "The commission adopts 21 C.F.R. as its own." 21 C.F.R. 1301.75(a) "Controlled substances listed in Schedule I shall be stored in a securely locked, substantially constructed cabinet. (b) Controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet." WAC 246-945-410(1) "The facility shall be constructed and equipped with adequate security to protect equipment, records, and supply of drugs,	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					devices, and other restricted sale items from unauthorized access, acquisition, or use."	
			27	Does the pharmacy maintain records of receipt and distribution of all controlled substances?	WAC 246-945-040(3) "Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: (a) Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug; (b) Distribution records, including invoices, or any other document regardless of how titled from wholesalers, manufacturers, or any other entity to which the substances were distributed and prescriptions records for dispensers; (d) For transfers of controlled substances from one dispenser to another, a record of the transfer must be made at the time of transfer indicating the drug, quantity, date of transfer, who it was transferred to, and from whom. Records must be retained by both the transferee and the transferor. These transfers can only be made in emergencies pursuant to 21 C.F.R. Sec. 1307.11."	
			28	Are records of Schedule II drugs maintained separately from all other controlled substance records?	WAC 246-945-040(4) "Credential holders and pharmaceutical firms shall maintain records for Schedule II drugs separately from all other records."	
			29	Does the HCE have completed DEA 222 forms or their electronic equivalent for each acquisition or distribution of Schedule II drugs?	WAC 246-945-040(6) "A federal order form is required for each distribution of a Schedule I or II controlled substance. Credential holders and pharmaceutical firms must keep and make readily available these forms and other records to the commission or its designee."	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
			30	Are records of Schedule III-V drugs maintained either separately or in a form that is readily retrievable from other records?	WAC 246-945-040(5) "Credential holders and pharmaceutical firms may maintain records for Schedule III, IV, and V drugs either separately or in a form that is readily retrievable from the business records of the registrant." 21 C.F.R 1304.04(h)(3) "…Inventories and records of Schedules III, IV, and V controlled substances shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy."	
			31	Is an inventory of controlled substances being performed every 2 years? ***Including controlled substance samples under the control of the HCE*** An inventory of controlled substances must be completed within 30 days of a new responsible pharmacy manager or on the effective date of the addition of a substance to a schedule of controlled substances.	WAC 246-945-420(2) "A facility shall conduct an inventory of controlled substances every two years." WAC 246-945-420(3)(a) "Within thirty days of designating a responsible pharmacy manager. The incoming responsible pharmacy manager, or designee, shall conduct a complete controlled substance inventory. (b) On the effective date of an addition of a substance to a schedule of controlled substances. Each facility that possesses the substance shall take an inventory of the substance on hand, and thereafter, include the substance in each inventory." 21 C.F.R. 1304.11(a) "Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location."	
			32	Does the HCE have power of attorney forms for ordering	21 C.F.R. 1305.05(a) "A registrant may authorize one or more individuals, whether or not located at his or her registered location, to issue orders for Schedule I and II	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
				schedule II-controlled substances?	controlled substances on the registrant's behalf by executing a power of attorney for each such individual, if the power of attorney is retained in the files, with executed Forms 222 where applicable, for the same period as any order bearing the signature of the attorney. The power of attorney must be available for inspection together with other order records."	
			33	Has the HCE reported significant losses or disappearances of controlled substances to PQAC and the DEA in the previous 24 months?	21 CFR 1301.76(b) "The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft." WAC 246-945-040(3)(c) "In the event of a significant loss or theft, two copies of DEA 106 (report of theft or loss of controlled substances) must be transmitted to the federal authorities and a copy must be sent to the commission; …"	
Dispensing						
			34	Does the HCE dispense prescriptions to patients?	RCW 18.64.450(4) "A health care entity may only administer, dispense, or deliver legend drugs and controlled substances to patients who receive care within the health care entity and in compliance with rules of the commission…"	
			35	If HCEs dispense medications without a pharmacist's involvement, are they restricting medications dispensed to a seventy-two (72) hour supply?	RCW 18.64.450(4) "…Nothing in this subsection shall prohibit a practitioner, in carrying out his or her licensed responsibilities within a health care entity, from dispensing or delivering to a patient of the health care entity drugs for that patient's personal use in an amount not to exceed seventy-two hours of usage."	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
			36	Does the HCE have valid prescription records for all drugs dispensed to patients?	WAC 246-945-410(7) "Prescription drugs must only be dispensed pursuant to a valid prescription as required by WAC 246-945-011." WAC 246-945-011(1) "Prior to dispensing and delivering a prescription, a pharmacist shall verify its validity." (2) A prescription shall be considered invalid if: (a) At the time of presentation, the prescription shows evidence of alteration, erasure, or addition by any person other than the person who wrote it; (b) The prescription does not contain the required information as provided in WAC 246-945-010; (c) The prescription is expired; or (d) The prescription is for a controlled substance and does not comply with the requirements in RCW 69.50.308. (3) A prescription is considered expired when: (a) The prescription is for a controlled substance listed in Schedule II through V and the date of dispensing is more than six months after the prescription's date of issue. (b) The prescription is for a noncontrolled legend drug or OTC's and the date of dispensing is more than twelve months after the prescription's date of issue."	
			37	Are all uncontrolled legend drugs prescribed orally promptly transcribed to a written or electronic prescription?	WAC 246-945-010(8) "A noncontrolled legend drug can only be dispensed pursuant to a valid prescription in accordance with WAC 246-945-011, or an oral prescription. An oral prescription for a noncontrolled legend drug must be promptly reduced to a written or electronic prescription that complies with WAC 246-945-011."	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
			38	Do all prescriptions for non-controlled legend drugs include all required elements? a) Prescriber's Name b) Name of Patient/Authorized Entity/Animal Name and Species c) Date of Issuance d) Drug Name, Strength, and Quantity e) Directions for Use f) Number of Refills g) Substitution Directions h) Prescribers Signature i) If written, on Tamper-Resistant Paper	WAC 246-945-010(3) "A prescription for a noncontrolled legend drug must include, but is not limited to, the following: (a) Prescriber's name; (b) Name of patient, authorized entity, or animal name and species; (c) Date of issuance; (d) Drug name, strength, and quantity; (e) Directions for use; (f) Number of refills (if any); (g) Instruction on whether or not a therapeutically equivalent generic drug or interchangeable biological product may be substituted, unless substitution is permitted under a prior-consent authorization; (h) Prescriber's manual or electronic signature, or prescriber's authorized agent signature if allowed by law; and (i) If the prescription is written, it must be written on tamper-resistant prescription pad or paper approved by the commission pursuant to RCW 18.64.500"	
			39	Do all prescriptions for controlled substances include additional required elements? a) Elements from Question 38 b) Patient's Address c) Dosage Form d) Prescriber's Address e) Prescriber's DEA Number	WAC 246-945-010(4) "A prescription for a controlled substance must include all the information listed in subsection (1) of this section and the following: (a) Patient's address; (b) Dosage form; (c) Prescriber's address; (d) Prescriber's DEA registration number; and (e) Any other requirements listed in 21 C.F.R., Chapter II."	
			40	Are all prescriptions properly labeled and stored, in accordance with federal and state statutes, rules, and regulations? ***Includes drug samples under the control of the HCE***	RCW 18.64.246(1) "To every box, bottle, jar, tube or other container of a prescription which is dispensed there shall be fixed a label bearing the name and address of the dispensing pharmacy, the prescription number, the name of the prescriber, the prescriber's directions, the name and strength of the medication, the name of the patient, the date, and the expiration date."	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					RCW 69.41.050(1) “To every box, bottle, jar, tube or other container of a legend drug, which is dispensed by a practitioner authorized to prescribe legend drugs, there shall be affixed a label bearing the name of the prescriber, complete directions for use, the name of the drug either by the brand or generic name and strength per unit dose, name of patient and date: PROVIDED, That the practitioner may omit the name and dosage of the drug if he or she determines that his or her patient should not have this information and that, if the drug dispensed is a trial sample in its original package and which is labeled in accordance with federal law or regulation, there need be set forth additionally only the name of the issuing practitioner and the name of the patient.” WAC 246-945-016(1) and (3) “(1) All licensees of the commission who dispense legend drugs to outpatients shall affix a label to the prescription container that meets the requirements of RCW 69.41.050 and 18.64.246, and shall also include: (a) Drug quantity; (b) The number of refills remaining, if any; (c) The following statement, "Warning: State or federal law prohibits transfer of this drug to any person other than the person for whom it was prescribed.", except when dispensing to an animal, when a warning sufficient to convey "for veterinary use only" may be used; (d) The name and species of the patient, if a veterinary prescription; and (e) The name of the facility or entity authorized by law to possess a legend drug, if patient is the facility or entity. . . (3) For the purposes of determining an expiration date as required in RCW 18.64.246, the dispenser shall take the following factors into	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					account: (a) The nature of the drug; (b) The container in which it was packaged by the manufacturer and the expiration date; (c) The characteristics of the patient's container, if the drug is repackaged for dispensing; (d) The expected conditions to which the drug may be exposed; (e) The expected length of time of the course of therapy; and (f) Any other relevant factors."	
			41	Are all legend drugs dispensed in child-resistant containers, as required by federal law or regulation? *(This includes special packaging used such as customized patient medication packages; blister packs, med-minders, etc.)* *** Best practice: It is recommended that these authorizations are updated annually. *****	WAC 246-945-032 (1) "All legend drugs shall be dispensed in a child-resistant container as required by federal law or regulation, including 16 C.F.R., Part 1700, unless: (a) Authorization is received from the prescriber to dispense in a container that is not child-resistant. (b) Authorization is obtained from the patient or a representative of the patient to dispense in a container that is not child-resistant."	
			42	Is supplemental information provided to the patient with each dispensed prescription?	WAC 246-945-410(9) "Each drug dispensed and delivered to a patient must bear a complete and accurate label as required by WAC 246-945-015 through 246-945-018. The information contained on the label shall be supplemented by oral or written information as required by WAC 246-945-325." **WAC 246-945-325** (1) The pharmacist shall offer to counsel: (a) Upon the initial fill of a prescription for a new or change of therapy.	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					(b) When the pharmacist using their professional judgment determines counseling is necessary to promote safe and effective use and to facilitate an appropriate therapeutic outcome for that patient. ***(2) This does not apply to medications that are administered by a licensed health professional acting within their scope of practice.***	
			43	Do the electronic recordkeeping system (i.e., prescription records) contain a complete auditable trail?	WAC 246-945-417(2) "The electronic recordkeeping system must be capable of real-time retrieval of information pertaining to the ordering, verification, and processing of the prescription where possible."	
			44	Are paper prescriptions maintained in appropriate files?	WAC 246-945-410(12) "A facility's paper prescriptions must be maintained in accordance with WAC 246-945-020 and as follows: (a) Paper prescriptions for Schedule II drugs must be maintained as a separate file from other prescriptions. (b) Paper prescriptions for Schedule III, IV, and V drugs must be maintained as a separate file or maintained in a separate file with prescriptions for noncontrolled legend drugs as allowed under federal law."	
			45	Are electronic prescriptions maintained appropriately?	WAC 246-945-417(6) "Electronic prescriptions for prescription drugs must be maintained by the pharmacy in a system that meets the requirements of 21 C.F.R. Sec. 1311." (7) HCEs or HPACs that maintain an electronic record system must be done in accordance with subsections (2) through (7) of this section.	
Pharmacist Professional Requirements						

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
			46	***Unless an exception applies***, does the HCE conduct a drug utilization review (DUR) of each prescription before dispensing and delivery? OR If a pharmacist is involved in the dispensing process, is drug utilization review completed?	WAC 246-945-001(29) "'Drug utilization review" includes, but is not limited to, the following activities: (a) Evaluation of prescriptions and patient records for known allergies, rational therapy-contraindications, appropriate dose, and route of administration and appropriate directions for use; (b) Evaluation of prescriptions and patient records for duplication of therapy; (c) Evaluation of prescriptions and patient records for interactions between drug-drug, drug-disease, and adverse drug reactions; and (d) Evaluation of prescriptions and patient records for proper utilization, including over- or under-utilization, and optimum therapeutic outcomes." WAC 246-945-410(8) "A drug utilization review of each prescription before dispensing and delivery shall occur ***except in emergent medical situations, or if***: (a) The drug is a subsequent dose from a previously reviewed prescription; (b) The prescriber is in the immediate vicinity and controls the drug dispensing process; (c) The medication delivery system is being used to provide access to medications on override and only a quantity sufficient to meet the immediate need of the patient is removed; or (d) Twenty-four hour pharmacy services are not available, and a pharmacist will review all prescriptions added to a patient's profile within six hours of the facility opening."	
			47	If a pharmacist is involved in the dispensing process, do pharmacists perform patient counseling?	WAC 246-945-325(1) "The pharmacist shall offer to counsel: (a) Upon the initial fill of a prescription for a new or change of therapy. (b) When the pharmacist using their professional judgment determines counseling is necessary to promote safe and effective	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					use and to facilitate an appropriate therapeutic outcome for that patient."	

Appendix A: Patient Medical Record Compliance Audit

The purpose of this audit is to ensure noted allergies and chronic conditions are entered into the patient medical record. Find 5 prescriptions with noted allergies and 5 prescriptions with noted conditions/ICD codes. Confirm the identified allergy/condition(s) are entered into the patient's medical record.

1. Document the prescription number below in the Rx # field.

2. Document the allergy/condition(s) noted on the identified prescription in the Allergy/Chronic Condition field.

3. Check "Yes" or "No" if the allergy/condition(s) noted on the prescription was in the patient medical record.

Additional information on Allergy and Chronic Condition Tracking

HCEs should review their policy and procedures on collecting allergy and chronic condition information. Having a proper procedure in place and following it, helps perform adequate drug utilization reviews and provide better care to patients. Consider the following:

Double check prescriptions to ensure all the information on the prescription is entered into your system.

Ask new patients for allergy or chronic conditions at their first visit to your HCE.

Regularly ask returning patients for updates to their patient profile including allergies, new chronic conditions, and indications for chronic medications.

	Patient Name or Identifier	Allergy/Chronic Conditions	Documented in Patient Record?	
			Yes	No
	Example: John Doe or MRN12345	*PCN/Hypertension*	√	√

1			☐	☐
2			☐	☐
3			☐	☐
4			☐	☐
5			☐	☐
6			☐	☐
7			☐	☐
8			☐	☐
9			☐	☐
10			☐	☐

Commission SBAR Communication

Agenda Item/Title: FDA Memorandum of Understanding

Date SBAR Communication Prepared: November 18th, 2020

Reviewer: Lauren Lyles-Stolz, PharmD, Executive Director

Link to Action Plan:

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

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

The commission should decide whether to approve or reject the FDA's Memorandum of Understanding (MOU). The commission has until October 27th, 2021 before the FDA limits interstate distribution of compounded drug products to 5 percent of the total prescription orders dispensed or distributed by a pharmacy. If the FDA MOU is signed then this limit is not applicable.

Background: (Briefly state the pertinent history):

While the commission has several rules in place to ensure the safety of compounded drug products (see WAC 246-945-100, WAC 246-945-410, WAC 246-945-490, and RCW 18.64.270), compounded drug products are not approved by the FDA for quality and safety. As such, the FDA issues an MOU as an agreement which states may enter regarding the distribution of inordinate amounts of compounded human drug products and the investigation of complaints related to human compounded drug products. As described in the Federal Food, Drug, and Cosmetic Act, the FDA works with the National Association of Boards of Pharmacy (NABP) in developing the MOU. The MOU does not apply to "veterinary drug products, biological products subject to licensure under section 351 of the Public Health Service Act (42 U.S.C. 262), and drugs that are compounded by outsourcing facilities under section 503B of the FD&C Act" (MOU, Sec. I).

The FDA defines "inordinate amounts" if "the number of prescription orders for compounded human drug products that the pharmacy distributed interstate during any calendar year is greater than 50 percent of the sum of: (i) the number of prescription orders for compounded human drug products that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year; plus (ii) the number of prescription orders for compounded human drug products that were dispensed (e.g., picked up by a patient) at the facility in which they were compounded during that same calendar year" (MOU, Appendix A).

Further, the FDA clarifies that "interstate distribution" means that "a pharmacy or physician has sent (or caused to be sent) a compounded drug product out of the State in which the drug was compounded" (MOU, Appendix A).

Commission SBAR Communication

There are several considerations for the commission to consider regarding the MOU. Rejecting to adopt the MOU would limit interstate distribution of compounded drug products to 5 percent of the total prescription orders dispensed or distributed by a pharmacy (MOU, Sec. II.b.2).

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

Without approving the MOU, distribution of compounded drug products out-of-state would be limited to 5 percent of the total prescription orders dispensed or distributed by a pharmacy. Limiting distribution may come with operational costs and barriers for the commission to consider.

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

After discussing the MOU, the commission may choose to adopt the following options in part or in whole. It is recommended that the commission come to a decision within 365 days of the MOU's publication.

OPTION 1: Approve the MOU.

OPTION 2: Reject the MOU. This determination would limit interstate distribution of compounded drug products to 5 percent of the total prescription orders dispensed or distributed by a pharmacy.

OPTION 3: The commission may also direct the PQAC team to communicate with the FDA on any points of concern or clarification. Discuss at future commission meetings as a standing agenda item and continue communications with WMC and Department of Health.

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

Depending on the options identified above, the PQAC team will proceed as directed and communicate to licensees through GovDelivery.

Commission SBAR Communication

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

Date SBAR Communication Prepared: June 16, 2020

Reviewer: Lauren Lyles-Stolz, ED

Link to Action Plan:

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

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

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

Background: (Briefly state the pertinent history):

The owner of a pharmacy is required to immediately notify the commission and pay the original license fee whenever there is a change of ownership. (RCW 18.64.043(3), WAC 246-945-230(3)(c) and WAC 246-907-402(2)). A failure to comply with applicable laws and rules can subject a pharmacy to a finding of a deficiency in an inspection or enforcement action (WAC 246-945-005 and RCW 18.64.165).

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

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

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

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

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

Commission SBAR Communication

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

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

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

1. Publish this FAQ to the listserv and website:

   > Does a pharmacy corporation prompt the commission's "Change of Ownership" process when a stock purchase involves more than 50% of the shares in the pharmacy corporation?
   >
   > Yes, pharmacies should immediately notify the commission and comply with the commission's "Change of Ownership" process if a stock purchase involves more than 50% of the shares in the pharmacy corporation.

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