

STATE OF WASHINGTON

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

# **Compounding Subcommittee Meeting - Agenda September 27, 2022** 11:00 AM (Open Session)

**Participate by Zoom Webinar -** ID: 840 7825 2680 Or One tap mobile: US: +12532158782,,84078252680# Or Telephone: US: +1 253 215 8782 OR +1 669 444 9171

Olympia Timberland Library 313 8<sup>th</sup> Ave SE, Olympia

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All attendees will join the webinar with their audio connection muted.

The times on the agenda for this meeting are approximate and subject to change. The commission may need to adjust the times or order of agenda items.

# 11:00 AM

1. Call to Order Hawkins DeFrance, Chair Action

### 11:05 AM

2. Review of the Nonresident Pharmacy List of Approved Inspection Programs Directive

1:00 PM Compounding Subcommittee Meeting Adjourned.

Date	Time	Location
October 7 – Legislative Subcommittee November 4 and December 2 – Venue TBD	12:00 p.m.	Zoom Webinar ID: 823 1715 3848 <u>Tumwater Timberland Library</u> 7023 New Market St SW, Tumwater
November 17, 2022 – Business Meeting	9:00 a.m.	Zoom Webinar ID: 861 1495 8466 Capital Region ESD 113 6005 Tyee DR SW, Tumwater

# **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.



# Department of Health Pharmacy Quality Assurance Commission Directive

Title:	Nonresident Pharmacy: List of Approved Inspection Programs
Reference:	RCW 18.64.360
Contact:	Lindsay Trant, MPP, Interim Deputy Director
Effective Date:	December 17, 2021
Supersedes:	Nonresident Pharmacy: Approved List of Recognized States
Approved:	Teri Ferreira, RPh, Pharmacy Quality Assurance Commission Chair

<u>RCW 18.64.360(1)(b)</u> requires a nonresident pharmacy, upon initial licensure and at renewal, to submit a copy of an inspection report that is conducted by an inspection program approved by the Pharmacy Quality Assurance Commission (Commission) as having substantially equivalent standards to those of the Commission, and that was issued within the last two years. This directive identifies those inspection programs the Commission has approved as having substantially equivalent standards to those of the Commission.

The Commission considered multiple factors when choosing whether to approve an inspection program. This includes using the National Association of Boards of Pharmacy (NABP) Multistate Pharmacy Inspection Blueprint Program criteria. The Commission also considered whether the inspection program required nonresident pharmacies who engage in compounding to comply with the minimum standards of the official United States Pharmacopeia (USP).

## **Approved Inspection Programs**

The Commission has approved the inspection programs of the following state boards of pharmacy (or equivalent state regulatory agency) and one third-party inspection program as having substantially equivalent standards to those of the Commission:

Alabama	Montana
Arkansas	NABP's Verified Pharmacy Program
Arizona	Nevada
California	New Hampshire
Colorado	New Jersey
Connecticut	New Mexico
Georgia	North Carolina
Idaho	North Dakota
Illinois*	Ohio
Indiana	Oklahoma
Iowa	Oregon
Kansas	Pennsylvania (inspections conducted after June 22, 2019)
Kentucky	Rhode Island
Louisiana	South Dakota
Maryland	Tennessee
Massachusetts	Texas
Michigan	Utah
Minnesota	Virginia
Mississippi	Vermont
Missouri	West Virginia
Wyoming	

\*Approved while USP 800 is not enforced in Washington (see Policy #65.2).

### Approved Inspection Programs That Do Not Meet Commission Frequency Standards

The Commission has approved the inspection programs of the following state boards of pharmacy (or equivalent state regulatory agency) as having substantially equivalent standards to those of the Commission. The Commission also understands these inspection programs do not conduct inspections every two years. Nonresident pharmacies are reminded that inspection reports submitted as part of an application or as part of the renewal process must have occurred within the last two years. So while inspection reports conducted by the following state boards of pharmacy (or equivalent state regulatory agency) are acceptable, they must have occurred within the last two years or another inspection report from an approved inspection program will need to be submitted:

Delaware	Nebraska
Maine	New York

### <u>Approved Inspection Programs for Nonresident Pharmacies Who Attest They Do Not</u> <u>Engage in Compounding</u>

The Commission has approved the inspection programs of the following state boards of pharmacy (or equivalent state regulatory agency) as having substantially equivalent standards to those of the Commission <u>but only for</u> nonresident pharmacies who attest that they do not engage in compounding as defined in RCW 18.64.011(6). This is because the following inspection programs do not require nonresident pharmacies to comply with the minimum standards of USP when engaging in compounding.

Florida	Pennsylvania
South Carolina	Wisconsin

#### Inspection Programs That Have Not Been Approved by the Commission

The Commission has determined that inspections from the following state board of pharmacy (or equivalent state regulatory agency) are not substantially equivalent to those of the Commission and will not be accepted:

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The Commission is aware the Hawaii Board of Pharmacy does not conduct inspections. Nonresident pharmacies located in Hawaii are still required to comply with <u>RCW</u> <u>18.64.360(1)(b)</u> and must provide an inspection report from an approved inspection program as outlined in this Directive.

The Commission will review this Directive on an annual basis.

Need more information? See *frequently asked questions*.