



STATE OF WASHINGTON

## Pharmacy Quality Assurance Commission

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### Compounding Subcommittee Meeting Agenda

July 12, 2022

11:00 AM (Open Session)

#### Participate by Zoom Webinar

Please click the link to join: <https://us02web.zoom.us/j/84078252680>

Or One tap mobile: US: +12532158782,,84078252680#

Or Telephone: US: +1 253 215 8782 OR +1 669 444 9171

Webinar ID: 840 7825 2680

Contact: Joanne Miller, Program Manager [Joanne.Miller@doh.wa.gov](mailto:Joanne.Miller@doh.wa.gov) or  
Commission Office: [WSPQAC@doh.wa.gov](mailto:WSPQAC@doh.wa.gov)

All attendees will join the call 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 times or order of agenda items.

#### 11:00 AM

1. **Call to Order** Hawkins DeFrance, Chair *Action*

#### 11:05 AM

2. **Compounding Subcommittee** – The commission will discuss for clarification or decision ongoing topics. *Information/Action*.
  - 2.1 Review of White Bagging Legislation in Other States
  - 2.2 Review of the Nonresident Pharmacy List of Approved Inspection Programs Directive

**1:00 p.m. approximately** - Compounding Subcommittee Meeting Adjourned.

## 2022 PQAC BUSINESS MEETINGS

<https://us02web.zoom.us/j/86114958466>

- July 14-15
- September 22-23
- November 17-18

Begins: 9 a.m. PST

**Please be advised: PQAC is now using  
Zoom as the platform of choice.**

*(All meetings subject to change.)*

## 2022 ADDITIONAL MEETINGS – via Zoom

- **Legislative Subcommittee** – first Friday each month  
<https://us02web.zoom.us/j/82317153848>
- **Pharmacy practice subcommittee** – August 16  
<https://us02web.zoom.us/j/81727923994>
- **Compounding subcommittee** – September 27  
<https://us02web.zoom.us/j/84078252680>
- **Facility subcommittee** – September 9  
<https://us02web.zoom.us/j/89209473951>

## 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

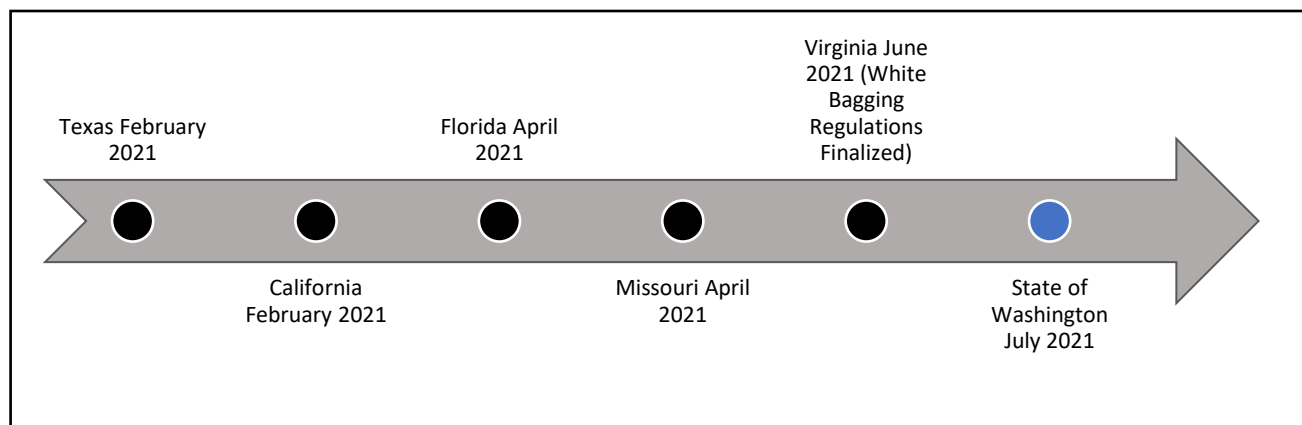
The Washington State Pharmacy Quality Assurance Commission leads in creating a climate for the patient-focused practice of pharmacy as an integral part of an accessible, quality-based health care system. As a result, the citizens of Washington State:

- 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.

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# WHITE BAGGING

## State Boards of Pharmacy Discussions Related to Payer-Mandated White Bagging (2021)<sup>1</sup>



### ➤ **WA DOH PQAC Meeting July 16, 2021**

- Presentation on white bagging by Mr. David Chen and Dr. Kyle Robb of American Society of Health-System Pharmacists (ASHP)
- Motion carries for staff to conduct research on other states' rules/statutes regarding the topic of white bagging.

### ➤ **Payer-Mandated White Bagging Defined<sup>2</sup>**

- Also known as white bagging.
- Third-party specialty pharmacy is required by patient's insurance plan to buy and dispense medications that are administered by a clinician and are specific to the patient.
- The medications ship directly from the specialty pharmacy to the clinician for administration.
- Reimbursement for medication cost goes to the specialty pharmacy and reimbursement for medication administration goes to the clinician.
- Distinguished from brown bagging and clear bagging.<sup>3</sup>

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<sup>1</sup> Data provided by Dr. Kyle Robb. ASHP. *Summary of Recent State Legislation to Address Payer Mandated White Bagging*. Power Point presentation. Accessed October 22, 2021.

<sup>2</sup> Data provided by Dr. Kyle Robb. ASHP. *How Boards of Pharmacy Are Addressing White and Brown Bagging*. Power Point presentation. Accessed October 22, 2021.

<sup>3</sup> Brown bagging involves a specialty pharmacy sending a medication to a patient directly, and the patient stores and transports the medication to the clinician for administration. Clear bagging reimburses a specialty pharmacy that is under shared common ownership with a clinician, for distributing patient-specific medications to that clinician, who is then reimbursed for administering the medications.

## State Legislation Addressing Payer-Mandated White Bagging <sup>4</sup>

State	Legislation
<ul style="list-style-type: none"> <li>Arkansas</li> </ul>	<ul style="list-style-type: none"> <li>Arkansas House Bill 1907</li> </ul>
<ul style="list-style-type: none"> <li>Louisiana</li> </ul>	<ul style="list-style-type: none"> <li>Louisiana Senate Bill 191</li> </ul>
<ul style="list-style-type: none"> <li>Massachusetts</li> </ul>	<ul style="list-style-type: none"> <li>Massachusetts Senate Docket 1808/ House Docket 3407</li> <li>Massachusetts Bill S.695/Bill H.1199<sup>5,6</sup></li> </ul>
<ul style="list-style-type: none"> <li>New York</li> </ul>	<ul style="list-style-type: none"> <li>New York Senate Bill S7252<sup>7</sup></li> </ul>
<ul style="list-style-type: none"> <li>Tennessee</li> </ul>	<ul style="list-style-type: none"> <li>Tennessee Senate Bill 1617</li> </ul>
<ul style="list-style-type: none"> <li>Texas</li> </ul>	<ul style="list-style-type: none"> <li>Texas House Bill 1586<sup>8</sup></li> </ul>
<ul style="list-style-type: none"> <li>Virginia</li> </ul>	<ul style="list-style-type: none"> <li>Virginia House Bill 2219<sup>9</sup></li> </ul>

Arkansas	Louisiana	Massachusetts
<ul style="list-style-type: none"> <li>Arkansas House Bill 1907</li> <li>Effective Jan. 1, 2022</li> </ul> <p><b>Summary:</b></p> <ul style="list-style-type: none"> <li>Currently specific to patients with hematology or oncology diagnosis, or patients the insurance commissioner deems eligible.</li> <li>A healthcare payer or pharmacy benefits carrier shall allow a healthcare provider to make “appropriate decisions that are in the best interest of patients.” Payers cannot require a healthcare provider and patient to participate in white bagging if it is not in the best interest of the patient.<sup>10</sup></li> </ul>	<ul style="list-style-type: none"> <li>Louisiana Senate Bill 191</li> <li>Effective June 1, 2021</li> </ul> <p><b>Summary:</b></p> <ul style="list-style-type: none"> <li>White bagging must adhere to supply chain security controls established by the Drug Supply Chain and Security Act.</li> <li>Insurance plans can deem a facility within their networks a “center of excellence” and create cost-sharing tiers to differentiate between those facilities that are centers of excellence and those that are not.</li> <li>A healthcare payer or pharmacy benefits carrier shall not refuse payment to a participating provider for a physician-administered drug if the provider obtains the drug from a pharmacy</li> </ul>	<ul style="list-style-type: none"> <li>Mass. Senate Docket 1808/House Docket 3407</li> </ul> <p><b>Summary:</b></p> <ul style="list-style-type: none"> <li>White bagging allowed only for medications in “ready-to-administer” dosage form and whose pedigree had been certified prior to administration.</li> <li>Any specialty pharmacy can distribute clinician-administered drugs that are covered by payer.<sup>12</sup></li> </ul> <hr/> <ul style="list-style-type: none"> <li>Mass. S.695/H.1199 (pending)</li> </ul> <p><b>Summary:</b></p> <ul style="list-style-type: none"> <li>Relative to specialty medications and patient safety. Recent hearing in September 2021 addressed concerns that white bagging</li> </ul>

<sup>4</sup> Data provided by Dr. Kyle Robb. ASHP. *Summary of Recent State Legislation to Address Payer Mandated White Bagging*. Power Point presentation. Accessed October 22, 2021.

<sup>5</sup> Still pending as of October 22, 2021. Hearing held on September 21, 2021.

<sup>6</sup> Recording of hearing available at <https://malegislature.gov/Events/Hearings/Detail/3966>

<sup>7</sup> Still pending as of October 22, 2021.

<sup>8</sup> Died in Texas Senate in May 2021.

<sup>9</sup> Effective as of July 2021.

<sup>10</sup> [HB1907 as engrossed on 04-22-2021 13:28:48 \(state.ar.us\)](https://legis.state.ar.us/bills/2021/engrossed/04-22-2021/13:28:48)

<sup>12</sup> [MA - SD 1808 | GovHawk](https://www.govhawk.com/legislation/MA-SD-1808)

	that is not in the payer's network. <sup>11</sup>	may encourage poor medication adherence. <sup>13</sup>
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New York	Tennessee	Texas	Virginia
<ul style="list-style-type: none"> <li>New York S7252 (pending)</li> <li>Introduced June 2021.</li> </ul> <p><b>Summary:</b></p> <ul style="list-style-type: none"> <li>Addresses patient safety and quality assurance related to patient-specific medications from insurer-designated pharmacies.</li> <li>Calls for the provision of medication pedigree certification and use of ready-to-administer dosage form for white bagged, patient-specific medications.<sup>14</sup></li> </ul>	<ul style="list-style-type: none"> <li>Tennessee Senate Bill 1617 (amended)</li> <li>Passed June 2021</li> </ul> <p><b>Summary:</b></p> <ul style="list-style-type: none"> <li>“Prohibits pharmacy benefits managers (PBMs) from charging unequal co-pays to patients for obtaining clinician-administered drugs between pharmacies that are contracted with the plan.”<sup>15,16</sup></li> </ul>	<ul style="list-style-type: none"> <li>Texas House Bill 1586</li> <li>Final adjournment in May of 2021 (<b>died</b> in Texas Senate).</li> <li>Amendment restricted the bill to apply specifically to patients with cancer-related diagnosis.<sup>17</sup></li> </ul>	<ul style="list-style-type: none"> <li>Virginia House Bill 2219</li> <li>Effective July 1, 2021</li> </ul> <p><b>Summary:</b></p> <ul style="list-style-type: none"> <li>Insurance plans cannot withhold coverage for medications that enrollees fill at non-affiliated pharmacies. These plans can also not place unequal cost burdens on patients who use out-of-network-pharmacies.</li> <li>Requires “direct service agreements” between non-contracted pharmacies and insurance plans.<sup>18</sup></li> </ul> <p>Related Virginia Board of Pharmacy Regulations are found in <b>18VAC110-20-275</b>: “One pharmacy may fill prescriptions and deliver the prescriptions to a second pharmacy for patient pickup or direct delivery to the patient provided the two pharmacies have the same owner, or have a written contract or agreement</p>

<sup>11</sup> [Bill Text: LA SB191 | 2021 | Regular Session | Chaptered | LegiScan](#)

<sup>13</sup> [Bill S.695 \(malegislature.gov\)](#)

<sup>14</sup> [S7252 \(nysenate.gov\)](#)

<sup>15</sup> Data provided by Dr. Kyle Robb. ASHP. *Summary of Recent State Legislation to Address Payer Mandated White Bagging*. Power Point presentation. Accessed October 22, 2021.

<sup>16</sup> [Bill Text: TN SB1617 | 2021-2022 | 112th General Assembly | Chaptered | LegiScan](#)

<sup>17</sup> [Bill Text: TX HB1586 | 2021-2022 | 87th Legislature | Engrossed | LegiScan](#)

<sup>18</sup> [Bill Tracking - 2021 session > Legislation \(virginia.gov\)](#)

			specifying the services to be provided by each pharmacy, the responsibilities of each pharmacy, and the manner in which each pharmacy will comply with all applicable federal and state law.” <sup>19</sup>
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**Key Questions Regarding White Bagging<sup>20</sup>:**

- How does white bagging impact patient safety?
- How would a pharmacy appropriately dispose of any unused portion of a white-bagged drug?
- Will payers’ motivations come at a cost to patients’ financial benefits?
- Can a healthcare provider serve as a patient’s agent when receiving medications?
- What about the distinction between dispensing and distributing [21 CFR 208.3(b)]?
- Can pharmacies re-label a white-bagged drug after its delivery but prior to its administration?
- What policies and procedures would be in place to ensure the integrity of white-bagged drugs?
- Is dispensing white-bagged pharmaceuticals considered repackaging?
- Should white bagging be addressed specifically in a facility’s policies and procedures?
  - [WAC 246-945-440](#): discusses the administration of patient owned medications.

<sup>19</sup> [Virginia Regulatory Town Hall Show XML](#)

<sup>20</sup> Data provided by Dr. Kyle Robb. ASHP. *Summary of Recent State Legislation to Address Payer Mandated White Bagging*. Power Point presentation. Accessed October 22, 2021.

- How might white bagging be impacted by the Drug Supply Chain Security Act product tracing requirements of 2023?
- Who will handle reimbursement rate challenges for pharmacies and medication administrators?

July 2022 Preliminary Analysis of States' **Approved** Inspection Programs

State	Substantially Equivalent Standards to Washington State
Alabama	Yes
Arizona	Yes
Arkansas	Yes
California	Yes
Colorado	Yes
Connecticut	Yes
Georgia	Yes
Idaho	Requires Further Review
Illinois	Yes*
Indiana	Requires Further Review
Iowa	Yes
Kansas	Yes
Kentucky	Yes
Louisiana	Yes
Maryland	Yes
Massachusetts	Yes
Michigan	Yes
Minnesota	Yes
Mississippi	Yes
Missouri	Yes
Montana	Yes
Nevada	Yes
New Hampshire	Yes
New Jersey	Yes
New Mexico	Yes
North Carolina	Yes
North Dakota	Yes
Ohio	Yes
Oklahoma	Yes
Oregon	Yes
Pennsylvania (inspections conducted after June 22, 2019)	Yes
Rhode Island	Yes
South Carolina	Yes
South Dakota	Yes
Tennessee	Requires Further Review
Texas	Yes
Utah	Yes
Vermont	Yes
Virginia	Yes
West Virginia	Yes
Wyoming	Requires Further Review
NABP VPP	Yes



July 2022 Preliminary Analysis of States' **Approved** Inspection Programs

\*Approved while USP 800 is not enforced in WA.

Reference: 2022 Survey of Pharmacy Law\_Final.pdf



**Department of Health  
Pharmacy Quality Assurance Commission  
Directive**

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

[RCW 18.64.360\(1\)\(b\)](#) 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

### **Approved Inspection Programs for Nonresident Pharmacies Who Attest They Do Not Engage in Compounding**

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 ***but only for*** 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:

Alaska	
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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 [RCW 18.64.360\(1\)\(b\)](#) 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](#).*