

**Pharmacy Quality Assurance Commission  
April 2, 2026 - Minutes**

Convene: Hawkins DeFrance, Chair, called the meeting to order April 2, 2026, 9:02 a.m.

**Commission Members:**

Hawkins DeFrance, Chair  
Ann Wolken, Vice Chair  
Jerrie Allard  
Stephanie Bardin  
Teri Ferreira  
Patrick Gallaher  
Judy Guenther  
Kenneth Kenyon  
Craig Ritchie

**Staff:**

Marlee O’Neill, Executive Director  
Lindsay Trant-Sinclair, Deputy Director  
Si Bui, Inspector Supervisor  
Christopher Gerard, AAG  
Rachel Sahi  
Taifa “Nomi” Peaks  
Joshua Munroe  
Haleigh Mauldin  
Julia Katz  
Irina Harris  
Madison Washington  
Amy L Robertson

**Commission Members Absent:**

William Hayes  
Matthew Ray  
Uyen Thorstensen  
Huey Yu

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

**1.1. Meeting Agenda Approval – April 2, 2026**

**MOTION:** Craig Ritchie moved to approve April 2, 2026, business meeting agenda without edits. Ken Kenyon, seconded. Motion carried, 9:0.

**1.2. Meeting Minutes Approval – February 5, 2026**

**MOTION:** Craig Ritchie moved to approve February 5, 2026, meeting minutes without edits. Ken Kenyon, seconded. Motion carried, 9:0.

**2. Consent Agenda**

**2.1. Correspondence**

- 2.1.1.** National Precursor Log Exchange Monthly Dashboard – January and February
- 2.1.2.** Commission Rules Tracker

## **2.2. Ancillary Utilization Plans Approval**

- 2.2.1. Bob Johnson's Pharmacy
- 2.2.2. Davenport Pharmacy
- 2.2.3. Duvall Family Drugs
- 2.2.4. Lopez Island Pharmacy
- 2.2.5. Morton Pharmacy
- 2.2.6. Paramount Pharmacy
- 2.2.7. Samaritan Hospital
- 2.2.8. Village Pharmacy Services

## **2.3. Pharmacy Technician Training Program Approval**

- 2.3.1. Family Health Centers
- 2.3.2. Kirk's Pharmacy at Hartland
- 2.3.3. Markers Compounding Pharmacy
- 2.3.4. Mattawa Community Medical Clinic Pharmacy
- 2.3.5. Samy's Drug Store
- 2.3.6. Whole Health Pharmacy
- 2.3.7. Yokes Pharmacy

**MOTION:** Jerrie Allard moved to approve the consent agenda 2.1, 2.2, and 2.3, without edits. Patrick Gallaher, seconded. Motion carried, 9:0.

## **3. New Business**

### **3.1. HSQA Legislative Session Wrap-Up**

Cori Tarzwell, HSQA Legislative Affairs Manager, presented a review of the 2026 legislative session.

### **3.2. Lists and Labels**

**MOTION:** Ken Kenyon moved to not recognize Provenbase or CVS Health as a "professional association" or "educational organization" and to convey this decision to the requestors and to DOH's public records unit. Jerrie Allard, seconded. Motion carried, 9:0.

### **3.3. National Associations of Boards of Pharmacy (NABP) Presentation on NAPLEX, MPJE, and UMPJE**

Neal Watson, Member Relations/Government Affairs Director; Jasmina Bjegovic, Director Competency Assessment; and Liz Ferro, Director Exam Development from the National Associations of Boards of Pharmacy, provided a presentation on the NAPLEX, MPJE, and UMPJE.

### 3.3.1. Commission Discussion of UMPJE

**MOTION:** Ken Kenyon moved to adopt the UMPJE as the approved jurisprudence examination but to allow for both the MPJE and UMPJE to be taken for up to 180-days after adoption of the UMPJE. Craig Ritchie, seconded. Motion carried, 9:0.

**MOTION:** Ken Kenyon moved to direct staff to work with NABP to develop plus module options and bring this back to the commission at the May business meeting. Ann Wolken, seconded. Motion carried, 9:0.

**MOTION:** Ken Kenyon moved to allow students to sit for the UMPJE at the start of the students' Advanced Pharmacy Practice Experience (APPE) rotations. Stephanie Bardin, seconded. Motion carried, 9:0.

### 3.4. Resolutions for NABP Annual Meeting

**MOTION:** Ken Kenyon moved to support District 2's resolution (co-supported by District 1) on lyophilization and compounding. Jerrie Allard, seconded. Motion carried, 9:0.

**MOTION:** Ann Wolken moved to support District 2's resolution on public access to vaccination services by pharmacy personnel. Patrick Gallaher, seconded. Motion carried, 9:0.

**MOTION:** Ken Kenyon moved to support District 2's resolution on reviewing the blueprint inspection report to ensure compliance with USP. Stephanie Bardin, seconded. Motion carried, 9:0.

**MOTION:** Ken Kenyon moved to support District 2's resolution on model regulations for virtual facilities. Stephanie Bardin, seconded. Motion carried, 9:0.

**MOTION:** Ken Kenyon moved to support District 6's resolution on community health workers. Patrick Gallaher, seconded. Motion carried, 9:0.

**MOTION:** Ken Kenyon moved to support the Missouri Board of Pharmacy's resolution on medication safety for high-alert medications. Stephanie Bardin, seconded. Motion carried, 9:0.

**MOTION:** Ken Kenyon moved to delegate any decisions on future resolutions to the Leadership Committee (Hawkins DeFrance, Ann Wolken, and Ken Kenyon). Jerrie Allard, seconded. Motion carried, 9:0.

## 4. Panel Review – Study Plan (Panel C)

**MOTION:** Stephanie Bardin moved to delegate the study plan review to Ken Kenyon, Ann Wolken, and Jerrie Allard. Hawkins DeFrance, seconded. Approved 9:0.

### 4.1. PHRM.PH.70023270

**MOTION:** Ken Kenyon moved to approve the study plan. Jerrie Allard, seconded. Approved 3:0.

## 5. Old Business

### 5.1. Policies and Procedures Updates

**MOTION:** Ken Kenyon moved to approve the updated guidance documents for the Opioid Treatment Program – Drugs that May Be Ordered, Possessed, and Used by an Opioid Treatment Program and Chart Orders and Signature Use of a Practitioner’s Authorized Agent in Long-Term Care Facilities and Hospice Programs, without edits. Craig Ritchie, seconded. Motion carried, 9:0.

## 6. Rule and Legislative Updates

### 6.1. 2027 Legislative Request Concept Paper Update

**MOTION:** Ken Kenyon moved to remove the proposed repeal of RCW 70.115.050 Retail sale of Hypodermic Syringes, Needles – Duty of Retailer from the 2027 legislative proposal. Craig Ritchie, seconded. Motion carried, 9:0.

### 6.2. Rules Petition: Change of Ownership

**MOTION:** Ann Wolken moved to grant the petition on change of ownership requirements and task staff with issuing an official response to the petitioners and filing a CR-101 Rule Inquiry Package to initiate rulemaking. Ken Kenyon, seconded. Motion carried, 9:0.

### 6.3. Rulemaking Request: Updating WAC 246-945-043

**MOTION:** Ken Kenyon moved to authorize rulemaking to update WAC 246-945-043 Designation of Nonnarcotic Stimulant Drugs for the Purposes of RCW 69.50.402 (1)(C) and task staff with preparing and filing a CR-101 Rule Inquiry package. Stephanie Bardin, seconded. Motion carried, 9:0.

### 6.4. Alternative Distribution Models Rulemaking Update

**MOTION:** Ken Kenyon moved to withdraw the CR-101 Rule Proposal package on Alternate Distribution Models. Stephanie Bardin, seconded. Motion carried, 9:0.

### 6.5. Rules Petition: Fluoride and RCW 69.38.010(4)

**MOTION:** Ken Kenyon moved to deny the petition on designating fluoride as a poison for the purposes of RCW 69.38, and task staff with drafting the denial letter based on the commission’s determination and discussion. Jerrie Allard, seconded. Motion carried, 9:0.

## 7. Strategic Plan

### 7.1. Implementation Plan Update

**MOTION:** Ken Kenyon moved to adopt changes to the strategic plan implementation and place the implementation plan on the consent agenda moving forward. Jerrie Allard, seconded. Motion carried, 9:0.

## 8. Open Forum

No public comments were received.

## 9. Commission Member Reports

### 9.1.

No commission member reports were received.

## 10. Staff Reports

### 10.1. Executive Director – Marlee O’Neill

- Marlee and Inspector Michael Kelly presented at the Southwest Washington Pharmacy Association (SWPA) in February 2026.
- Marlee reached out to the Governor’s office again on March 20, 2026, about commission member appointments.
- The next commission meeting is Thursday, May 28, 2026. The Monday of that week is Memorial Day.
- The commission will hold leadership elections for 2026-2027 at the May business meeting. Staff will send commissioners an email reminder.

### 10.2. Deputy Director – Lindsay Trant-Sinclair

- Lindsay advised that due to staffing changes, the Operations Manager position is vacant.
- The agency has informed staff that there are continued budget challenges at the Department of Health.
- As a part of the forthcoming accessible labeling rules, dispensing facilities are required to display a sign in the 10 most common non-English languages to notify patients of accessible labeling services available. Staff are working on a template for that signage and will make it available on the commission’s website when completed.

### 10.3. Pharmacist Supervisor – Si Bui

- Si noted that the transition from ILRS to HELMS has been going well. Inspectors have adjusted their work flows accordingly. Si thanked the inspectors for their hard work.

- Marlee specifically thanked Si Bui and Tina Lacey for their direct work in testing HELMS with inspectors and allowing for a smoother transition.

#### 10.4. Assistant Attorney General – Christopher Gerard

- Christopher provided information on the legal challenge to the 340B legislation.
- Christopher provided an update that the Agricultural & Health Division has two impactful retirements and major changes to client assignments. There is no change to the Pharmacy Commission, but more work will now be spread around fewer people for a temporary period.

### 11. Summary of Meeting Action Items

- **1.2 Meeting Minutes Approval** – Staff will finalize and post the minutes on the commission’s website.
- **2. Consent Agenda** – Staff will convey the decision to the applicants and the Office of Customer Service.
- **3.2 Lists and Labels** – Staff will send the decisions to the public disclosure unit.
- **3.2.1 Commission Discussion of UMPJE** – Staff will communicate the decision of the commission to adopt the UMPJE with a 180-day transition period and allow students to take the exam during their APPE year. Staff will also work with NABP to explore options for the plus module and bring them back to May business meeting.
- **3.3 Resolutions for NABP Annual Meeting** – Hawkins DeFrance will vote, as determined by the commission, at the NABP annual meeting in May. If any future resolutions are brought forward, the commission’s leadership committee will determine how Hawkins DeFrance will vote.
- **4. Panel Review – Study Plan (Panel C)** – Staff will convey the decisions to the credentialing team.
- **5.1 Policies and Procedures Updates** – Staff will replace the two guidance documents with the updated versions on the commission’s website.
- **6.1 2027 Legislative Request Concept Paper Update** – Staff will continue working on the concept paper but remove the request to repeal the statute on retail sales of hypodermic needles.
- **6.2 Rules Petition: Change of Ownership** – Staff will file a CR-101 for the commission to consider its requirements on changes of ownership.
- **6.3 Rulemaking Request: Updating WAC 246-945-043** – Staff will file a CR-101 to amend WAC 246-945-043, the designation of non-narcotic stimulants.
- **6.4 Alternate Distribution Models Rulemaking Update** – Staff will withdraw the CR-101 on Alternate Distribution Models.
- **6.5 Rules Petition: Fluoride and RCW 69.38.010(4)** – Staff will draft and send the petition denial response letter to the petitioner.
- **7.1 Implementation Plan Update** – Staff will finalize the changes approved by the commission and upload the updates to Box.com and place the implementation plan on the consent agenda moving forward.

1:53 p.m. Business Meeting Adjourned

## 2.1.1. National Precursor Log Exchange Monthly Dashboard – March and April

### MONTHLY PROGRAM ADMINISTRATOR'S DASHBOARD - March 2026

0 Logins - 0 Searches - 0 Report Queries - 0 Active Watches - 0 Active Watch Hits		
<b>NEW USERS THIS MONTH</b> New Users = 0 Total Accounts = 147 Active Users = 0	<b>TOP USAGE AGENCIES</b>  <b>TOP USERS BY USAGE</b>	<b>TOP AGENCIES BY ACTIVE WATCHES</b>

TRANSACTION SUMMARY STATISTICS (2026)				
	JAN	FEB	MAR	TOTAL
<b>PURCHASES</b>	83,923	81,370	89,779	<b>255,072</b>
<b>BLOCKS</b>	3,675	3,387	4,200	<b>11,262</b>
<b>GRAMS SOLD</b>	157,521	152,625	174,578	<b>484,724</b>
<b>BOXES SOLD</b>	85,217	82,544	91,011	<b>258,772</b>
<b>GRAMS BLOCKED</b>	8,708	8,434	10,379	<b>27,521</b>
<b>BOXES BLOCKED</b>	3,893	3,631	4,444	<b>11,968</b>
<b>AVG GRAMS PER BOX BLOCKED</b>	2.24	2.32	2.34	<b>2.30</b>

PHARMACY PARTICIPATION STATISTICS (Mar 2026)	
Enabled Pharmacies	890
Pharmacies Submitting a Transaction	773
Pharmacies Logging in Without a Transaction	0
Inactive Pharmacies	117
Pharmacy Participation for Mar	86.85%

**DISCLAIMER:** This is an automated report meant to give you a quick snapshot of the NPLeX system in your state. The statistics listed in this report are only meant to be a general overview and not necessarily the exact final numbers. Prior to releasing any statistics mentioned in this report, we highly recommend that you verify the numbers with your NPLeX customer relationship manager. For questions or issues, please contact [krista.mccormick@equifax.com](mailto:krista.mccormick@equifax.com).

MONTHLY PROGRAM ADMINISTRATOR'S DASHBOARD - April 2026

0 Logins - 0 Searches - 0 Report Queries - 0 Active Watches - 0 Active Watch Hits		
<p>NEW USERS THIS MONTH</p> <p>New Users = 0</p> <p>Total Accounts = 147</p> <p>Active Users = 0</p>	<p>TOP USAGE AGENCIES</p> <p>TOP USERS BY USAGE</p>	<p>TOP AGENCIES BY ACTIVE WATCHES</p>

TRANSACTION SUMMARY STATISTICS (2026)					
	JAN	FEB	MAR	APR	TOTAL
PURCHASES	83,923	81,370	89,779	86,364	341,436
BLOCKS	3,675	3,387	4,200	4,296	15,558
GRAMS SOLD	157,521	152,625	174,578	176,870	661,594
BOXES SOLD	85,217	82,544	91,011	87,440	346,212
GRAMS BLOCKED	8,708	8,434	10,379	11,260	38,781
BOXES BLOCKED	3,893	3,631	4,444	4,563	16,531
AVG GRAMS PER BOX BLOCKED	2.24	2.32	2.34	2.47	2.34

PHARMACY PARTICIPATION STATISTICS (Apr 2026)	
Enabled Pharmacies	892
Pharmacies Submitting a Transaction	774
Pharmacies Logging in Without a Transaction	1
Inactive Pharmacies	117
Pharmacy Participation for Apr	86.88%

**DISCLAIMER:** This is an automated report meant to give you a quick snapshot of the NPLeX system in your state. The statistics listed in this report are only meant to be a general overview and not necessarily the exact final numbers. Prior to releasing any statistics mentioned in this report, we highly recommend that you verify the numbers with your NPLeX customer relationship manager. For questions or issues, please contact [krista.mccormick@equifax.com](mailto:krista.mccormick@equifax.com).

**PQAC RULES TRACKER FOR COMMISSION BUSINESS MEETING (MAY 2026)**

**Ongoing Rulemaking**

Title	Short Description	Priority	Current Filing Type	Staff Lead	Recent Actions / Next Steps
Accessible Labeling Program Refinement	Amending WACs 246-945-015, 246-945-026, 246-945-027, 246-945-028, and 246-945-029 to adjust compliance standards for the prescription drug accessible labeling program.	High	CR-101 (Standard) WSR 25-23-064, filed November 18, 2025	Josh	Recent actions: SA and SBEIS reviewed Next steps: CR-102 package review
Clarifying Ancillary Utilization Plans	Amend WAC 246-945-410 to clarify the pharmacy-only submission policy for Ancillary Utilization Plans approved by the commission	Medium	CR-102 (Standard) WSR 26-09-060, filed April 13, 2026	Josh	Recent actions: CR-102 filed Next steps: Conduct public hearing
Change of Ownership	Consider amending WACs 246-945-230 and 246-945-992 to update the commission's change of ownership rules and relevant licensure policies.	Medium	Not yet filed	Josh	Recent actions: Petition approved and CR-101 initiated Next steps: File CR-101
Mobile OTP Unit licenses (standard)	Open WAC 246-945-060 to exempt mobile units from acquiring separate licenses if associated physical location is already licensed	Medium	CR-102 (Standard) WSR 26-09-118, filed April 21, 2026	Haleigh	Recent actions: CR-102 filed Next steps: Conduct public hearing

Utilization of Pharmacy Ancillary Personnel	Rulemaking to amend WACs 246-945-001, 246-945-315, 246-945-317, 246-945-320, and new sections to chapter 246-945 WAC related to pharmacy technician final product, pharmacy assistants scope-of-practice, and the use of technology	Medium	CR-101 (Standard) WSR 24-18-032, filed August 26, 2024	Haleigh	Recent actions: Rule language approved at February business meeting Next steps: Draft CR-102
Incorporations by Reference Update	Rulemaking to update the incorporations by reference in WACs 246-945-030, 246-945-032, 246-945-040, 246-945-550, 246-945-565, and 246-945-600.	Medium	CR-105 (Expedited) WSR 26-05-078, filed February 17, 2026	Haleigh	Recent actions: CR-105 filed Next steps: Public comment period ends April 20, 2026
Manufacturers and Wholesalers	Amending WACs 246-945-246 and 246-945-247, and add new sections, if necessary, to clarify the application process for physical and virtual wholesalers, manufacturers, and OTC-only wholesalers.	Medium	Not yet filed	Haleigh	Recent actions: CR-101 in review Next steps: File CR-101
Training Requirements for Pharmacy Assistants Under Age 18	Amending WAC 246-945-200 to add a competency requirement for pharmacy assistants under the age of 18 related to the transmission of bloodborne pathogens.	Medium	Not yet filed	Haleigh	Recent actions: Commission approved initiating rulemaking Next steps: File CR-101

Accreditation of Colleges of Pharmacy	Amending WACs 246-945-155, -162, -163, and potentially add a new section of WAC to codify the policy statement.	Medium	Not yet filed	Haleigh	Recent actions: Commission approved initiating rulemaking Next steps: File CR-101
Alternate Distribution Models (Transfer Practices for Dispensed Prescription Drugs)	Related to regulation of white bagging, brown bagging, or any other transfer of a prescription or drug for the purpose of re-dispensing or subsequent administration to a patient	High	CR-101 Withdrawal WSR 26-10-040, filed May 1, 2026	Julia	Recent actions: CR-101 withdrawal memo filed 5/1/26 Next steps:
Tamper-Resistant Prescription Pads and Papers	Adding a section in Chapter 246-945 WAC to regulate security features and processes pertaining to tamper-resistant prescription pads and papers.	Medium	CR-101 (Standard) WSR 25-21-079, filed October 15, 2025	Julia	Recent actions: CR-102 authorized at February 2026 business meeting Next steps: File CR-102 (on hold for Incorporations by Reference)
Pharmacy Personnel Examinations and Approval Process	Amending WACs 246-945-165 and 246-945-205 related to updating approved examinations for pharmacist and pharmacist technician applicants and the study plan approval process for pharmacists attempting approved examinations 4 or more times.	Medium	CR-101 (Standard) WSR 26-10-090, filed April 26, 2026	Julia	Recent actions: CR-101 filed Next steps: Rule workshop at July 2026 business meeting

Euthanasia Training Program Guidelines	Amending WACs 246-945-254 and 246-945-503 and potentially adding a section in Chapter 246-945 WAC to establish guidelines for euthanasia training programs.	Medium	CR-101 (Standard) WSR 256-09-021, Filed April 6, 2026	Julia	Recent actions: CR-101 filed Next steps: Rule workshop at May 2026 business meeting
Updates to Designated Nonnarcotic Stimulant Drugs	Amending WAC 246-945-043 to update outdated references for most of the designated nonnarcotic stimulant drugs	Medium	Not yet filed	Julia	Recent actions: Rulemaking authorized at April 2026 business meeting Next steps: File CR-101
Implementing FDA MOU	Rulemaking needed to implement the FDA MOU should the commission choose to sign the MOU. This rulemaking would add a new section related to the regulation of the distribution of human compounded products.	On Hold	Not yet filed	Josh	On hold

## 2.1.3. Proposed 2027 Commission Meeting Dates



Pharmacy Quality Assurance Commission  
PO Box 47852 Olympia, WA 98504  
www.doh.wa.gov · TDD Relay: 711

### 2027 PQAC Business Meetings

<b>Date</b>	<b>Time</b>	<b>Location</b>
February 11, 2027	9:00 am – 4:00 pm	Zoom and TBD
April 1, 2027	9:00 am – 4:00 pm	Zoom and TBD
May 20, 2027	9:00 am – 4:00 pm	Zoom and TBD
July 15, 2027	9:00 am – 4:00 pm	Zoom and TBD
September 9, 2027	9:00 am – 4:00 pm	Zoom and TBD
November 4, 2027	9:00 am – 4:00 pm	Zoom and TBD
December 16, 2027	9:00 am – 4:00 pm	Zoom and TBD

2.1.4 Quarterly Credential Counts

## Licensee Counts - Pharmacy

License Type ↑	Status ↑	Sub Status ↑	Record Count
Drug Animal Control/Humane Society Registration Sodium Pentobarbital	Active	Active	32
		In Renewal	147
Drug Controlled Substance Researcher Registration	Active	Active	198
		In Renewal	10
Drug Dog Handlers K9 Registration	Active	Active	6
		In Renewal	1
Drug Itinerant Vendor Registration	Active	Active	74
Drug Other Controlled Substance Registration	Active	Active	22
		In Renewal	7
Drug Precursor Chemicals Registration	Active	Active	164
Drug Sample Distributor Registration	Active	Active	474
Hospital Pharmacy Associated Clinic	Approved	Approved	30
Pharmaceutical Manufacturer License	Active	Active	1537
Pharmaceutical Wholesaler License	Active	Active	908
		In Renewal	103
		Not Renewable	2
	Renewable	Not Renewable	2
		Non Renewable	16
	Active On Probation	Enforcement Action	2
	Pharmacist License	Active	Active
In Renewal			1723
Military License Portability Public Law No. 117-333			1
Law No. 117-33			3
Active On Probation			1
Active On Probation		Enforcement Action	9
		In Renewal	3
		Conditions	4
Conditions		Enforcement Action	4
		In Renewal	4
		Inactive	4
Inactive		Inactive	4
		In Renewal	10
		Not Practicing	34
Inactive Military Related		Spouse Or Domestic Partner	6
		Military	26
Military		Active Duty	3
	In Renewal	1	
Retired	Not Practicing	1	
Retired Active	Emergent Intermittent	171	
	In Renewal	46	
	Limited Practice	12	

Pharmacy Assistant License	Active	Active	9512
		Credential Not Renewed	1
		Eligible for Late Renewal	2
		In Renewal	1557
		Military License Portability Public Law No. 117-333	1
	Active On Probation		1
	Conditions	Enforcement Action	1
		Enforcement Action	1
Pharmacy Collaborative Drug Therapy Agreement	Approved		1
		Active	46
		Approved	6452
	Initial Approval	1	
Inactive	Inactive	8	
Pharmacy Health Care Entity License	Active	Active	697
Pharmacy License	Active	Active	1092
		In Renewal	91
	Restrictions	In Renewal	1
Pharmacy License Hospital	Active	Active	40
		In Renewal	72
Pharmacy Non Resident License	Active	Active	622
		In Renewal	393
Pharmacy Technician Certification	Active	Active	8616
		Eligible for Late Renewal	1
		In Renewal	1486
		Military License Portability Public Law No. 117-333	5
	Active On Probation	Enforcement Action	3
	Conditions	Enforcement Action	1
Enforcement Action		1	
Poison Distributor License	Active	Active	4
PTEC Formal Training Program	Approved	Approved	17
Training Program Pharmacy	Approved	Approved	862
		In Renewal	14
Wildlife Chemical Capture Drug Registration	Active	Active	14
<b>Total</b>			<b>47102</b>

# Pharmacy Commission

FY2026 Starting Fund Balance  
**\$6.26M**

Current Fund Balance  
**\$5.50M**

Revenue  
**\$5.52M**

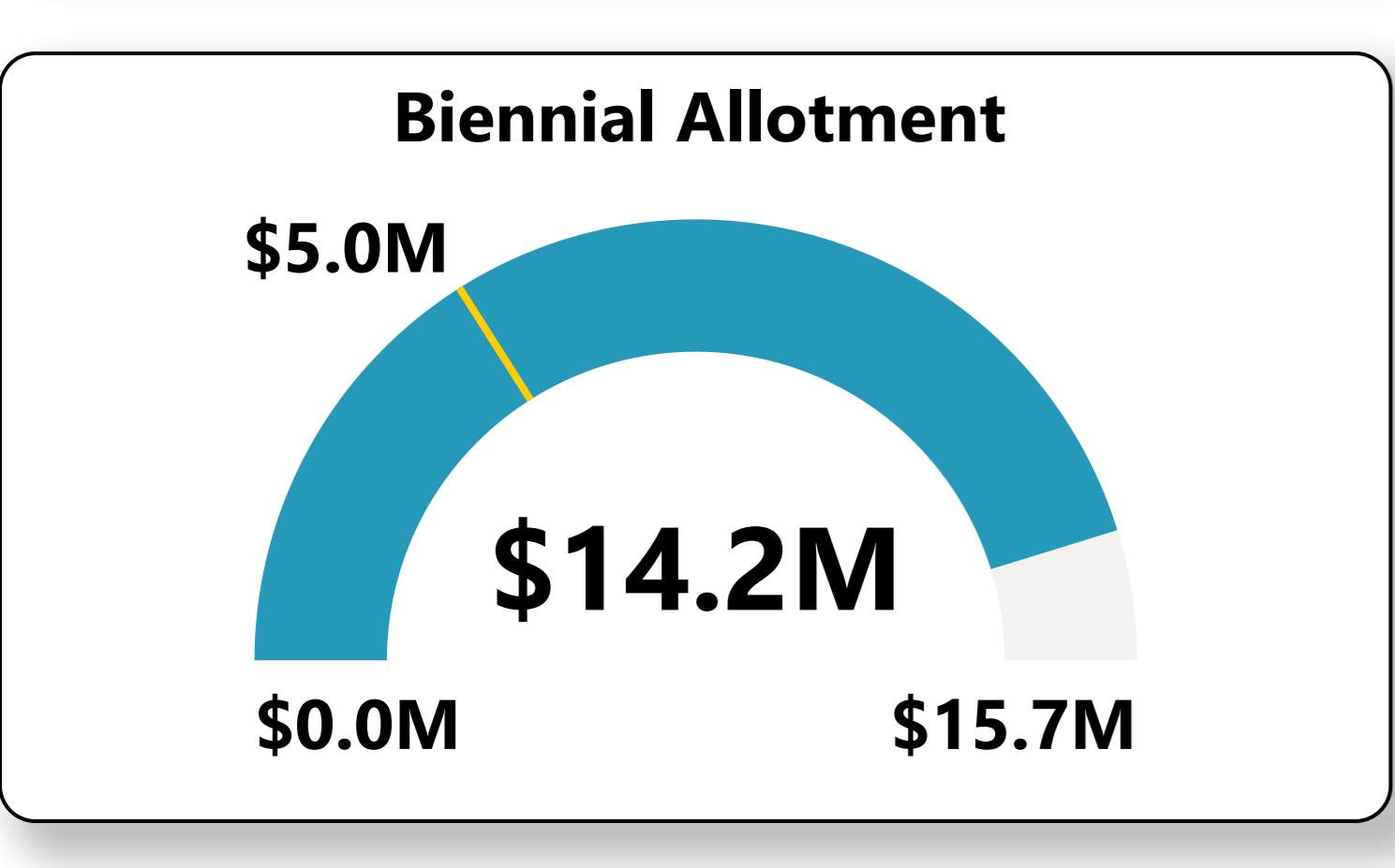
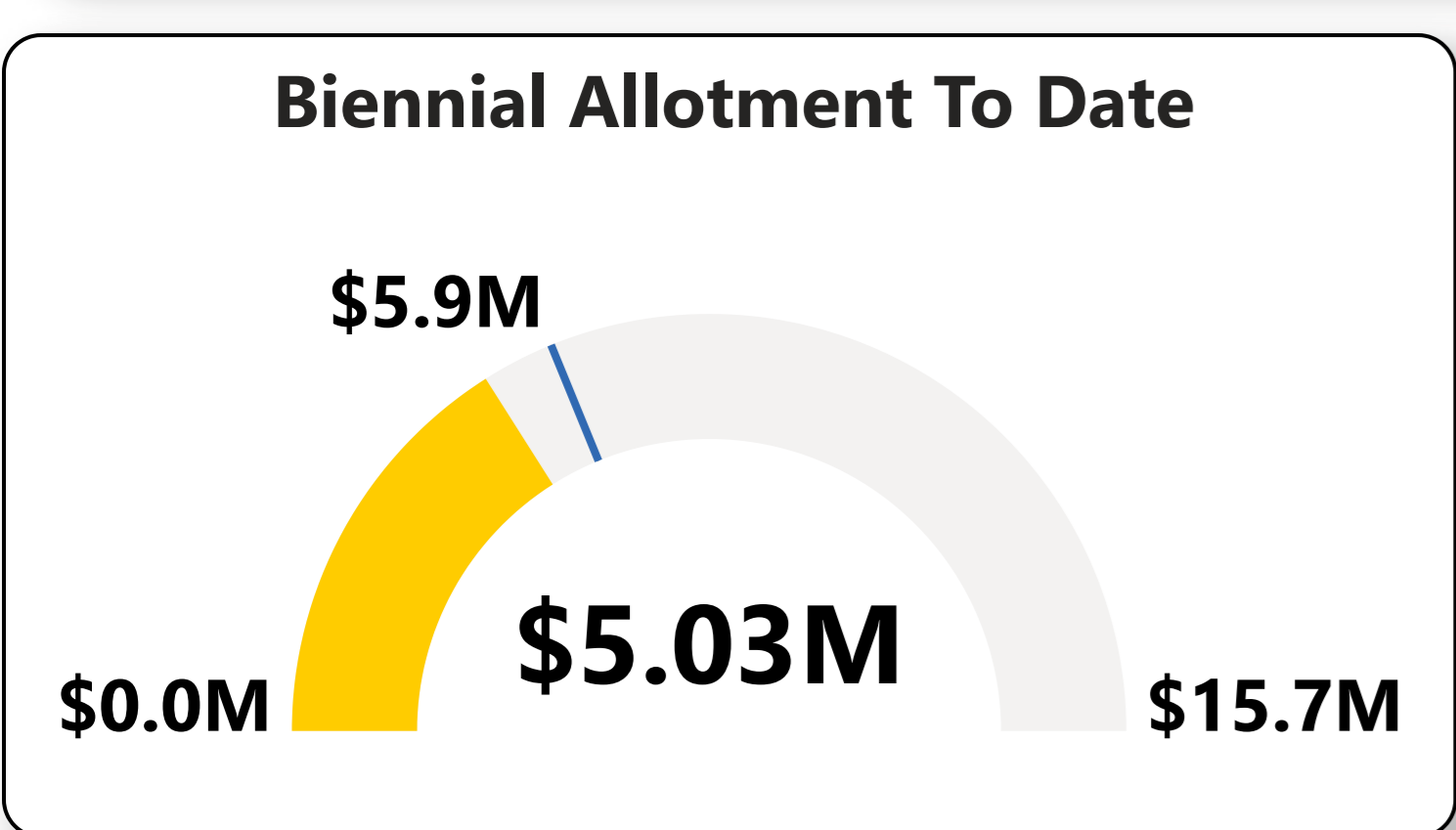
Expenses+Total Indirect  
**\$6.29M**

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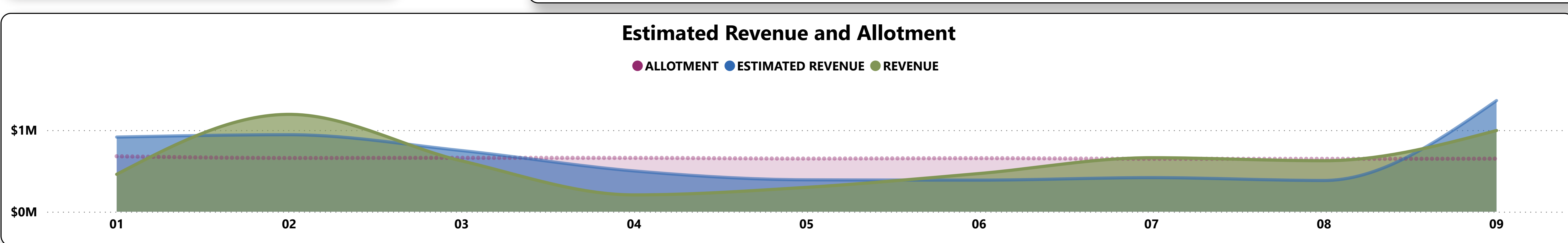


2026
2027

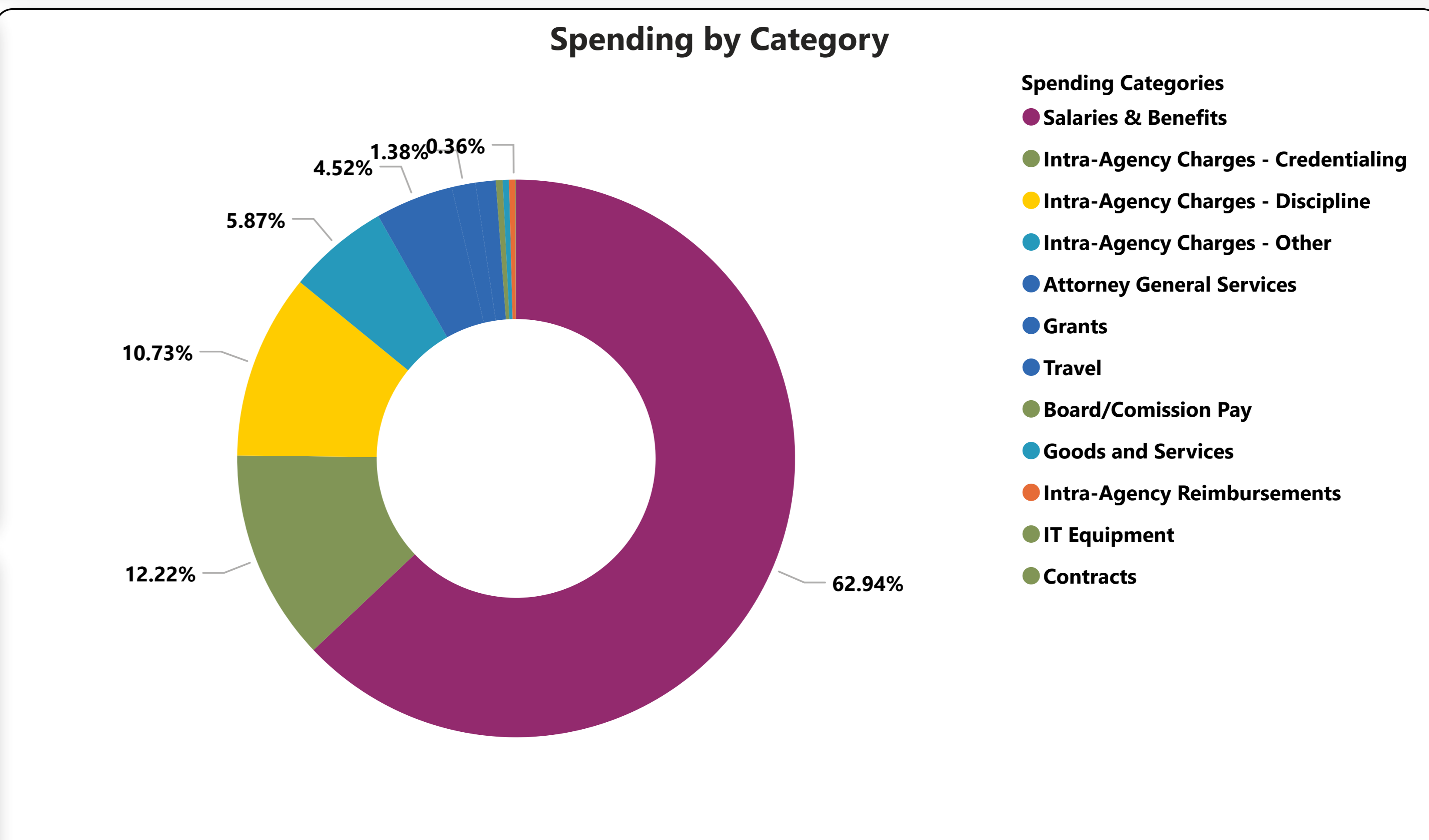
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02	04	06	08	10	12	14	16	18	20	22	24



Health Professions	TOTAL EXPENSES AND INDIRECT COSTS	ALLOTMENT TO DATE	VARIANCE TO DATE
Pharmacy Commission	\$6,292,439.99	\$5,910,126	\$882,705
Attorney General Services	\$227,126.67	\$240,300	\$13,173
Board/Comission Pay	\$19,753.50	\$36,000	\$16,247
Contracts	\$1,116.50	\$5,000	\$3,884
Goods and Services	\$18,383.86	\$33,775	\$15,391
Grants	\$69,249.92	\$81,450	\$12,200
Indirect	\$1,265,018.88		
Intra-Agency Charges - Credentialing	\$614,473.46	\$1,089,164	\$474,691
Intra-Agency Charges - Discipline	\$539,528.23	\$619,341	\$79,813
Intra-Agency Charges - Other	\$295,170.63	\$360,520	\$65,349
Intra-Agency Reimbursements	\$18,006.81		(\$18,007)
IT Equipment	\$1,333.17	\$17,700	\$16,367
Salaries & Benefits	\$3,164,417.40	\$3,367,686	\$203,269
Travel	\$58,860.96	\$59,190	\$329
<b>Total</b>	<b>\$6,292,439.99</b>	<b>\$5,910,126</b>	<b>\$882,705</b>

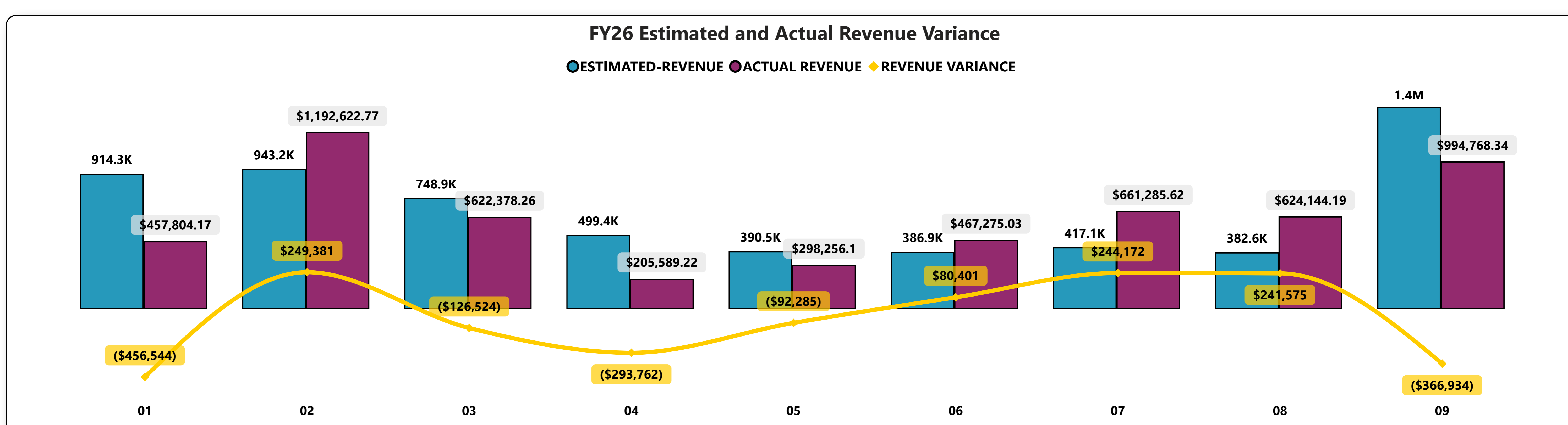
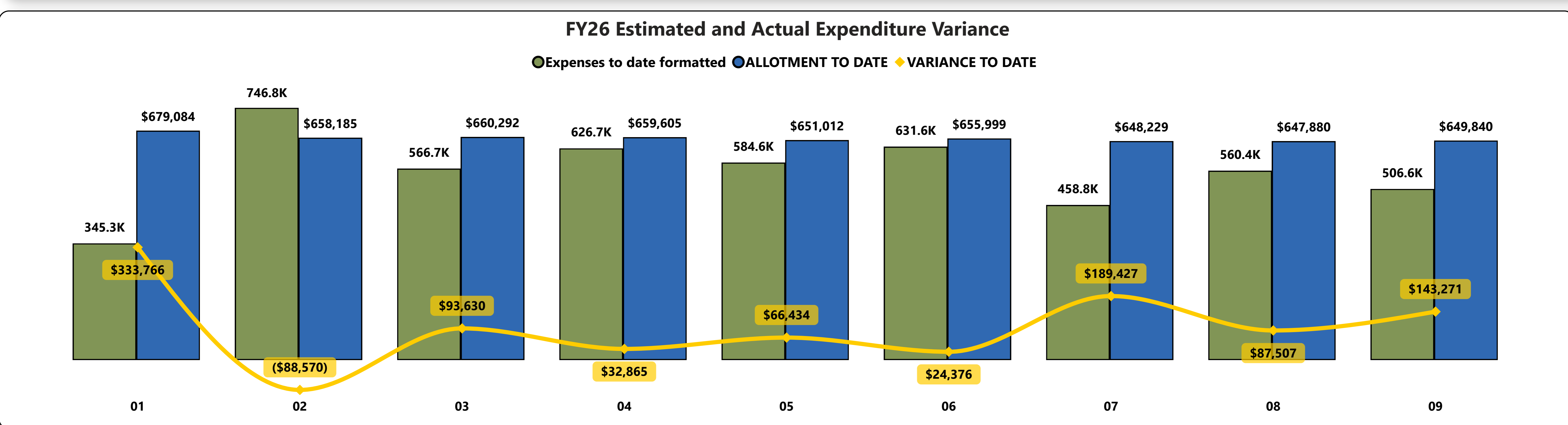
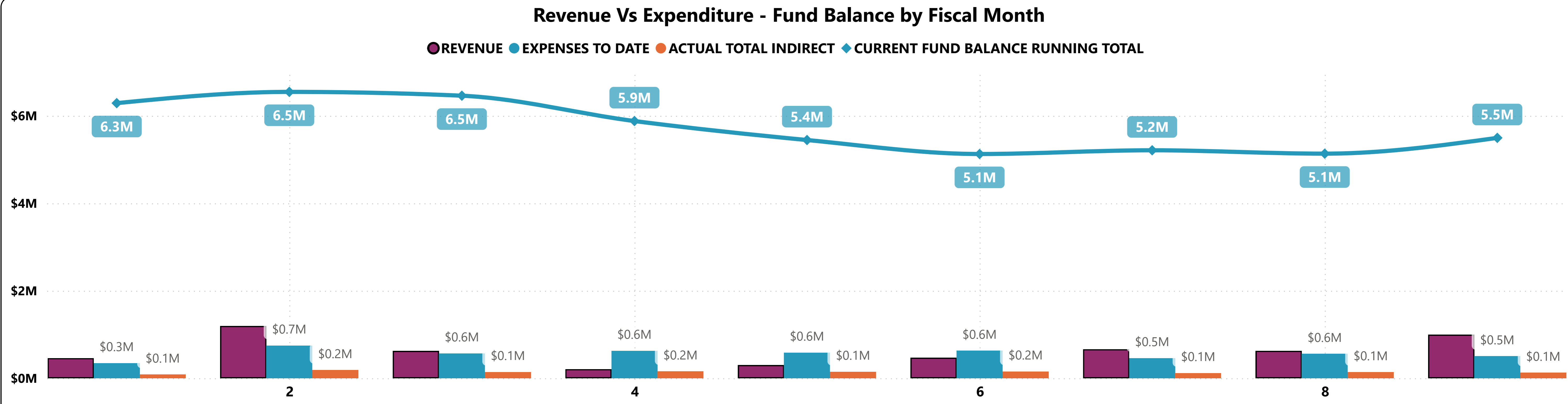


Job (POS)	Vacant	Permanent	Positions
ADMINISTRATIVE ASSISTANT 3	0		0
EXEC DIRECTOR, PHARMACY COMMISSION - DOH			0
HEALTH SERVICES CONSULTANT 1			0
HEALTH SERVICES CONSULTANT 2			0
HEALTH SERVICES CONSULTANT 4			0
MANAGEMENT ANALYST 4			1
PHARMACIST - INVESTIGATOR			1
PHARMACIST SUPERVISOR			0
WMS BAND 2			0
<b>Total</b>			<b>2</b>



Master Indexes+Title	EXPENSES BY STAFF MONTHS -PAYROLL	ALLOTMENT TO DATE BY STAFF MONTHS
62401600 - PHARMACY COMMISSION	182.10	189.00
62401603 - PHARMACY COMMISSION CREDENTIALING	64.59	67.00
62401601 - PHARMACY INVESTIGATIONS	38.41	37.08
<b>Total</b>	<b>285.10</b>	<b>293.08</b>

Health Professions	REVENUE	ESTIMATED REVENUE	REVENUE VARIANCE
Pharmacy Commission	\$5,524,124	\$6,044,643.00	(\$520,519)
<b>Total</b>	<b>\$5,524,124</b>	<b>\$6,044,643.00</b>	<b>(\$520,519)</b>



## 4.2 Acupuncture and Eastern Medicine Practitioner Medication Procurement Issues

### Title: Acupuncture and Eastern Medicine Practitioner Medication Procurement Issues

Date: May 28, 2026

Staff Contact: Lindsay Trant-Sinclair and Marlee O'Neill

Purpose (select one):       Decision                       Help/Feedback                       Awareness

#### Situation

Pharmacy Quality Assurance Commission (commission) staff have had several communications with members of the Washington Acupuncture and Eastern Medicine Association (WAEMA) dating back to late 2024. Staff have been assisting WAEMA in identifying issues related to acupuncturists and Eastern medicine providers (AEMPs) acquiring procaine and lidocaine. Staff request that the commission review and approve the response below to assist staff with these communications.

#### Background

During the 2021 Washington state legislative session, the legislature amended [RCW 18.64.010](#) to add oxygen, epinephrine and local anesthetics to substances which may be used while AEMPs provide point injection therapy. The Department of Health then updated [WAC 246-803-030](#) to align with this statutory change.

In July 2022, commission staff provided a joint letter with the Executive Director of the Acupuncture and Eastern Medicine Advisory Committee, which include the information summarized below, for AEMPs to provide to wholesalers.

Members of WAEMA reached out again to commission staff in December of 2024 to seek assistance in acquiring procaine and lidocaine for point injection therapy, citing issues with multiple wholesalers and pharmacies not recognizing the authority of AEMPs to possess legend drugs. Staff met with WAEMA and provided the following information.

The definition of acupuncture and Eastern medicine includes point injection therapy. [RCW 18.06.010\(1\)\(m\)](#). Point injection therapy “includes injection of local anesthetics, such as lidocaine and procaine, for reduction of pain during point injection therapy, consistent with the practice of acupuncture and Eastern medicine and training requirements as defined in rule.” [RCW 18.06.010\(1\)\(m\)](#). We understand that acupuncture and Eastern medicine practitioners are having a difficult time obtaining stock supplies of lidocaine and procaine.

Lidocaine and procaine are both legend drugs. The definition of “practitioner” in the legend drug act does include “an acupuncturist or acupuncture and Eastern medicine practitioner to the extent authorized under chapter [18.06](#) RCW and the rules adopted under [RCW 18.06.010\(1\)\(m\)](#).” [RCW 69.41.010\(17\)](#). [RCW 69.41.030](#) states that it is unlawful “for any person to sell or deliver any legend drug, or knowingly possess any legend drug, or knowingly use any legend drug in a public place, except upon the order or prescription of” and then lists the healthcare providers that can order or prescribe legend drugs. Acupuncture and Eastern medicine practitioners are *not* in this list which would make it illegal for them to sell, deliver, or possess any legend drug. But, the next clause states “PROVIDED, HOWEVER, That the *above provisions shall not apply to sale, delivery, or possession by drug wholesalers or drug*

*manufacturers, or their agents or employees, or to any practitioner acting within the scope of his or her license, or to a common or contract carrier or warehouse operator, or any employee thereof, whose possession of any legend drug is in the usual course of business or employment ....” (emphasis added). A drug wholesaler or drug manufacturer can sell and deliver legend drugs to any practitioner acting within the scope of their license.*

In looking at chapter 18.06 RCW and RCW 69.41.010 and RCW 69.41.030, we believe that it is within an acupuncture and Eastern medicine practitioner’s scope to acquire, possess, and administer lidocaine and procaine. Therefore, they can acquire lidocaine and procaine from a licensed drug wholesaler.

Commission staff had several follow-up communications and recently received a request from the WAEMA in April 2026 requesting the commission grant AEMPs limited prescriptive authority to issue prescriptions for local anesthetics such as procaine and lidocaine to circumvent issues acquiring the drugs from a wholesaler. Currently, AEMPs do not have prescriptive authority under Washington law.

### **Assessment**

The commission does not have the authority to expand the scope of practice of AEMPs to include prescriptive authority. Only the Washington State Legislature has this authority. The expansion of AEMPs’ scope of practice to include prescriptive authority requires the legislature to amend relevant provisions of RCW 18.06, RCW 69.41 (including RCW 69.41.030), and RCW 69.50 (for controlled substances).

### **Recommendation**

Staff recommend the commission make a motion affirming the information staff previously provided to WAEMA that is listed above as well as the following.

*The Pharmacy Quality Assurance Commission (commission) interprets Washington law to permit acupuncturists and Eastern medicine providers (AEMPs) to acquire, possess and administer lidocaine and procaine consistent with RCW 69.41 and RCW 18.06. This would include acquiring lidocaine and procaine from appropriately licensed wholesalers for appropriate use and administration in the provider’s practice.*

*The commission does not have authority to expand the scope of practice of AEMPs to include prescriptive authority. This authority rests with the Washington State Legislature. The expansion of the scope of practice of AEMPs to include prescriptive authority would require amendments to relevant provisions of RCW 18.06, RCW 69.41 (for noncontrolled legend drugs) and RCW 69.50 (for controlled substances).*

### **Appendix**

Joint Letter for Wholesalers with Executive Director of the Acupuncture and Eastern Medicine Advisory Committee



STATE OF WASHINGTON  
DEPARTMENT OF HEALTH  
PO Box 47852 · Olympia Washington 98504-7852

July 21, 2022

To Whom It May Concern:

This letter is to clarify that a licensed acupuncturist or acupuncture and Eastern medicine practitioner in Washington state is permitted to purchase and administer injectable preparations and other substances for the administration of point injection therapy.

RCW 18.06.010 was revised in the 2021 legislative session to add oxygen, epinephrine and local anesthetics to substances which may be used while providing point injection therapy. In 2016, the RCW allowed for this profession to purchase and administer substances limited to saline, sterile water, herbs, minerals, vitamins in liquid form, and homeopathic and nutritional substances, consistent with the practice of acupuncture Eastern medicine. Point injection therapy also includes injection of local anesthetics, such as lidocaine and procaine and use oxygen and epinephrine for potential emergency purposes. Point injection therapy does not include injection of controlled substances contained in Schedules I through V of the uniform controlled substances act, chapter [69.50](#) RCW or steroids as defined in RCW [69.41.300](#).

WAC 246-803-030 Acupuncture or Eastern medicine was amended to read:

...

(13) Point injection therapy:

...

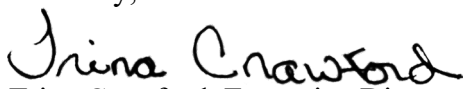
(b) Also includes injection of local anesthetics, such as lidocaine and procaine, for reduction of pain during point injection therapy, consistent with the practice of acupuncture and Eastern medicine and training requirements as defined in WAC 246-803-040.


(c) Used by an acupuncturist or acupuncture and Eastern medicine practitioner who has met the training and education requirements in RCW 18.06.230, may administer oxygen and epinephrine for potential emergency purposes, such as an allergic or adverse reaction, for patient care and safety.

....

If you have any questions, feel free to contact either Trina Crawford, Executive Director of the acupuncture and Eastern medicine practitioner program by phone at 360-236-4890 or email at [trina.crawford@doh.wa.gov](mailto:trina.crawford@doh.wa.gov) or Marlee O'Neill, Executive Director of the Pharmacy Quality Assurance Commission by phone at 360-236-4845 or email at [marlee.oneill@doh.wa.gov](mailto:marlee.oneill@doh.wa.gov).

Sincerely,

  
Trina Crawford, Executive Director  
Acupuncture and Eastern medicine  
practitioner program

  
Marlee B. O'Neill, Executive Director  
Pharmacy Quality Assurance Commission

## Washington State Department of Health Pharmacy Quality Assurance Commission

To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email [doh.information@doh.wa.gov](mailto:doh.information@doh.wa.gov).

### Procedure

<b>Title:</b>	Exception Application Procedure
<b>Document Number:</b>	
<b>References:</b>	RCW 18.64.163, RCW 18.64A.055, and RCW 18.130.055
<b>Contact:</b>	Marlee B. O’Neill, Executive Director Pharmacy Quality Assurance Commission
<b>Phone:</b>	(360) 236-4946
<b>Email:</b>	wspqac@doh.wa.gov
<b>Effective Date:</b>	
<b>Supersedes:</b>	8/28/2020 version
<b>Approved By:</b>	Hawkins DeFrance, PharmD Chair, Pharmacy Quality Assurance Commission

The Washington State Pharmacy Quality Assurance Commission (commission) receives and processes applications for pharmacist licenses, pharmacy intern registrations, pharmacy technician certifications and pharmacy assistant registrations.

As part of the application process, applicants for these credentials are required to answer personal data questions and undergo a criminal background check. If there is a positive response to one of the personal data questions or the criminal background check, then the application is considered an “exception” application. This procedure establishes the process and guidelines the commission, and its staff, will follow when considering an “exception” application.

#### Process

1. Staff at the Department of Health (DOH) will identify if an application meets criteria as an “exception” application based on either a positive response to one of the personal data questions or a criminal background check.
2. If the application is identified as an “exception” application and the “exception” application criteria, then DOH staff will summarize the application, including the reason why the application meets

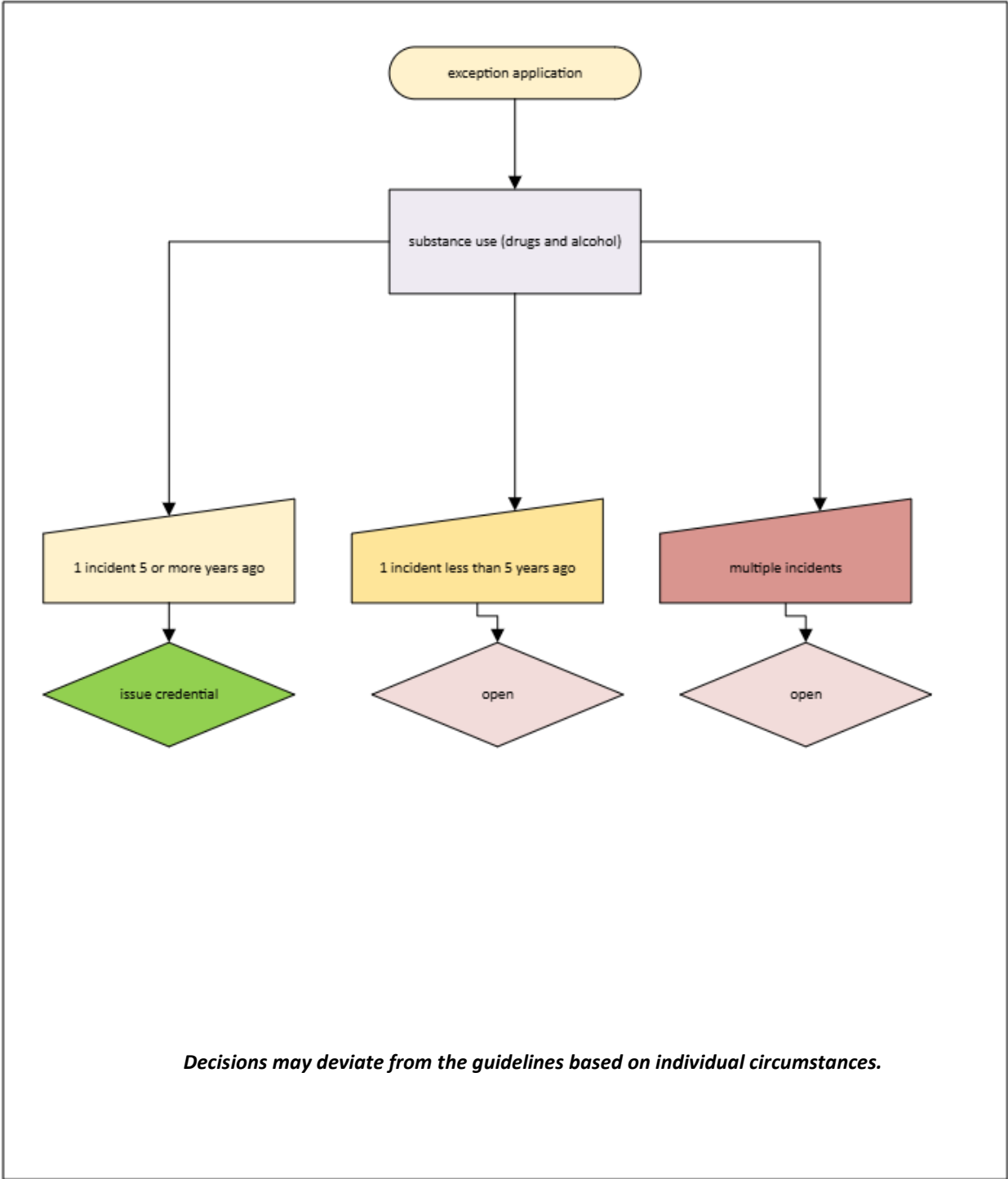
criteria as an “exception” application, and then send the summary to one of the commission’s disciplinary panels.

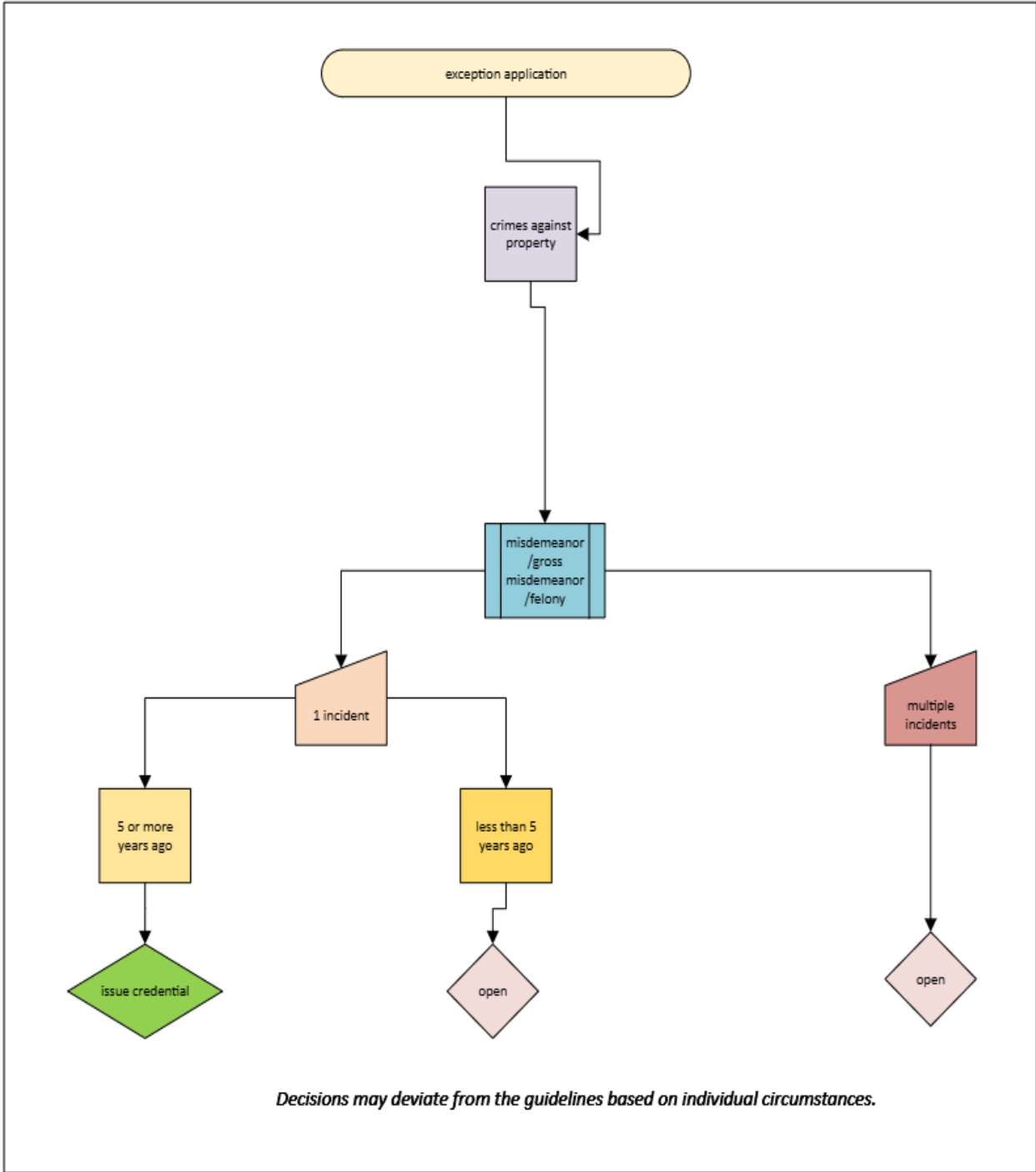
3. Once the summary is received, the commission’s disciplinary panel will determine whether to issue the credential or “open” the application for further review, using the guidelines provided below and the flowchart attached to this procedure as “Attachment A”. If the commission’s disciplinary panel decides to issue the credential, then this procedure is completed. If not, then the application will move to step four.
4. If the commission’s disciplinary panel decides to “open” the application for further review, DOH staff will send the complete application file to a Reviewing Commission Member (RCM). The RCM will review the application file and then schedule a time to present their review and recommendation to the disciplinary panel the RCM is assigned to.
5. After presentation by the RCM, the disciplinary panel will determine whether to issue the credential, issue the credential with conditions, deny the credential, proceed with a Notice of Required Evaluation (NRE), or authorize investigation of the application. In making this decision, the disciplinary panel will consider the guidelines provided below and the flowchart attached to this procedure as “Attachment A”. Department Staff will proceed consistently with the disciplinary panel’s decision.

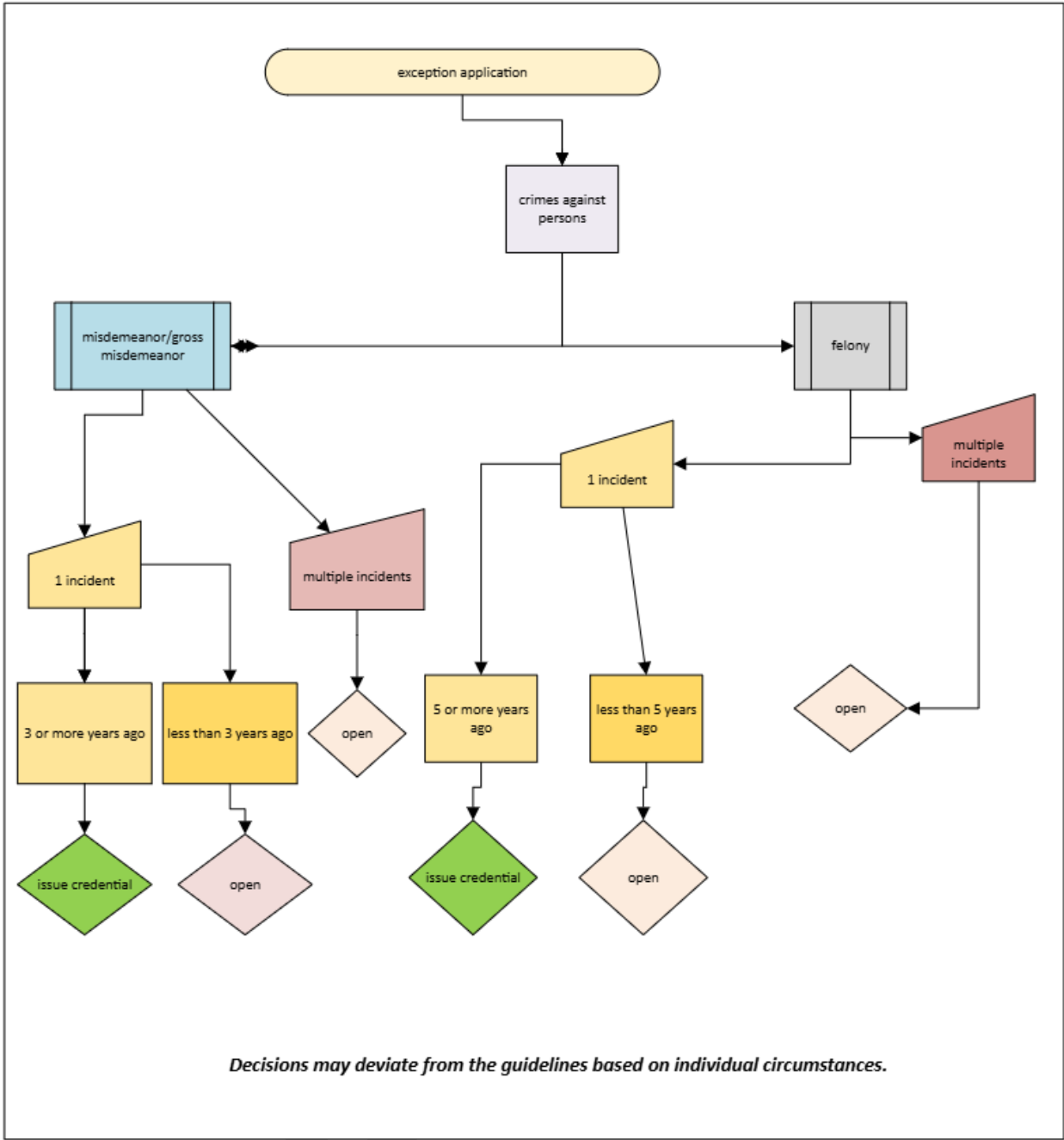
#### Guidelines

When reviewing “exception” applications, commissioners should consider the following non-exclusive list of factors:

- The number of convictions.
- The nature and classification of any conviction, as well as the surrounding facts of a conviction or other event triggering a positive response.
- The relationship of any conviction, or other event triggering a positive response, to the duties of a pharmacist, pharmacy intern, pharmacy technician or pharmacy assistant.
- The length of time since the conviction or other event triggering a positive response.
- The age and maturity of the applicant when the offense(s), or other event triggering a positive response, occurred.
- Whether the applicant has made any required restitution, as well as any evidence of rehabilitation.
- The activities of the applicant since the conviction or other event triggering a positive response.
- Whether any stated medical condition prevents an applicant from practicing with reasonable skill and safety.
- Whether any stated medical condition is controlled or alleviated with prescribed medication(s) or device(s), or other treatment ordered or provided by a health care professional.







**Washington State Department of Health**  
**Pharmacy Quality Assurance Commission**

To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email [doh.information@doh.wa.gov](mailto:doh.information@doh.wa.gov).

## Guidance Document

<b>Title:</b>	Guidance for Implementing the UMPJE in Washington State
<b>Document Number:</b>	G010
<b>References:</b>	WAC 246-945-165
<b>Contact:</b>	Marlee B. O'Neill, Executive Director Pharmacy Quality Assurance Commission
<b>Phone:</b>	360.236.4946
<b>Email:</b>	WSPQAC@doh.wa.gov
<b>Effective Date:</b>	May 28, 2026
<b>Supersedes:</b>	
<b>Approved By:</b>	Hawkins DeFrance, PharmD Chair, Pharmacy Quality Assurance Commission

WAC 246-945-165 requires an individual applying for a pharmacist license to take and pass a pharmacy licensure examination and jurisprudence examination approved by the Pharmacy Quality Assurance Commission (commission). Historically, the jurisprudence examination approved by the commission has been the Multistate Pharmacy Jurisprudence Examination (MPJE).

At its April 2, 2026, business meeting, the commission voted to approve the Uniform MPJE (UMPJE) as the jurisprudence examination for pharmacist license applicants in Washington state. In addition, the commission also voted to allow those students who are beginning their Advanced Pharmacy Practice Experience (APPE) training to take the UMPJE prior to graduation from pharmacy school. This guidance document clarifies the commission's approach to implementing the UMPJE in Washington state.

Upon authorization by the commission, individuals applying for a pharmacist license in Washington state can sit for the **UMPJE** beginning **July 2, 2026**. As a result, the commission will begin accepting passing scores for the **UMPJE**, if the examination was taken on or after **July 2**,

**2026.** Passing scores for UMPJE attempts taken prior to **July 2, 2026**, will not be accepted by the commission.

In addition, individuals applying for a pharmacist license in Washington state can sit for the **MPJE** until **December 29, 2026**. As a result, the commission will accept any passing score for the MPJE so long as the examination was taken on or before **December 29, 2026**. Put another way, the commission will not accept a passing score for the **MPJE** if the examination was taken after **December 29, 2026**.

<b>Summary of Dates the Commission will Accept Passing Scores for the MPJE and UMPJE</b>	
<i>Date Applicant Sat for the Examination</i>	<i>Examination Passing Scores Accepted</i>
Prior to July 2, 2026	MPJE only
July 2, 2026 – December 29, 2026	Both the UMPJE and MPJE
December 30, 2026, and later	UMPJE only*

Below are a series of hypothetical scenarios that illustrate how this guidance document would apply:

Hypothetical #1

An applicant takes the MPJE on July 30, 2026, and obtains a passing score. The applicant also applies for a pharmacist license in July 2026. The commission **will accept** the MPJE passing score because the examination was taken on or before December 29, 2026.

Hypothetical #2

An applicant takes the UMPJE on July 30, 2026, and obtains a passing score. The applicant also applies for a pharmacist license in July 2026. The commission **will accept** the UMPJE passing score because the examination was taken on or after July 2, 2026.

Hypothetical #3

An applicant takes the UMPJE on May 30, 2026, and obtains a passing score. The applicant applied for a pharmacist license in January 2026. The commission **will not accept** the UMPJE passing score because the examination was taken before July 2, 2026.

Hypothetical #4

An applicant takes the MPJE on July 30, 2026, and obtains a passing score. The applicant applies for a pharmacist license in January 2027. The commission **will accept** the MPJE passing score because the examination was taken on or before December 29, 2026.

Hypothetical #5

An applicant takes the MPJE on July 30, 2026, and does not obtain a passing score. The applicant then re-takes the MPJE on January 30, 2027, and obtains a passing score. The applicant applied for their pharmacist license back in March 2026. The commission **will not accept** the MPJE passing score because the examination was taken on or after December 30, 2026. This applicant

will need to take and obtain a passing score for the UMPJE.

*Authorization to Test:* For the UMPJE, students will need to receive authorization to test from the National Association for Boards of Pharmacy (NABP) by purchasing an eligibility application. Students taking the UPMJE early (i.e., prior to graduation from pharmacy school) do not need to apply for a pharmacist license with the commission before purchasing an eligibility application from NABP. There is no change to the authorization to test process for the North American Pharmacist Licensure Examination (NAPLEX). Students will need to apply for a pharmacist license with the commission before they are authorized to test for the NAPLEX.

Any changes to this guidance document will be made at an open public meeting.

DRAFT

## 5.3 UMPJE Plus Module

**Title:** UMPJE Plus Module

**Meeting Date:** May 28, 2026

**Staff Contact:** Marlee O'Neill

**Purpose (select one):**       **Decision**                       **Help/Feedback**                       **Awareness**

### **Situation**

At the April 2026 business meeting, the commission tasked staff with meeting with the National Association for Boards of Pharmacy (NABP) to determine what options are available for developing a Plus module to the Uniform Multistate Jurisprudence Exam (UMPJE) to educate pharmacist applicants about Washington state specific laws and rules.

### **Background**

At its April 2, 2026, business meeting the commission voted to recognize the UMPJE as its approved jurisprudence exam and tasked staff with working through some of the implementation steps such as the development of a Plus module. The intent of the Plus module is to cover Washington state specific laws that would not be captured in the UMPJE.

### Options

Staff met with NABP and there are various options for the commission's consideration.

- Pre-recorded webinar
- Recorded presentation using graphics
- Document(s) for the applicant to review

At the completion of the Plus module, the commission can choose to have applicants do one of the following.

- Sign an attestation that they completed the Plus module
- Complete a short quiz to ensure applicants viewed or read the Plus module

It will take approximately 45-days to develop the Plus module. This is dependent on the option the commission chooses. The webinar and presentation would be 1 hour in length *at most*. Again, this depends on the amount of content to be covered.

Applicants will complete the Plus module after taking and passing the UMPJE.

### Assistance from NABP

NABP is available to help in a myriad of different ways.

- Developing content
- Developing graphics, webinar, or document
- ACPE accreditation

- Hosting the commission's Plus module and sharing the link to the content when an applicant is ready to view the Plus module
- Hosting the attestation or short quiz

There is a cost for NABP to assist with this work. The cost depends on the amount and type of assistance NABP provides. The cost ranges from \$800.00 to \$3,600.00. ACPE accreditation through NABP is \$1,200.00.

### **Assessment**

The UMPJE is designed to assess knowledge of concepts and general principles of state and federal law that are uniform to all jurisdictions. The intent of the Plus module is to ensure new pharmacist licensees are aware of and understand laws and rules that are specific to Washington state. The commission should consider how best to accomplish this, keeping in mind the various costs and recognizing the impact on applicants of the various options.

### **Recommendation**

Staff recommend the commission consider the varying options. Staff believe there are pros and cons to the various options and will carry out whatever the commission decides.



# PROPOSED RULE MAKING

**CR-102 (June 2024)**  
**(Implements RCW 34.05.320)**  
 Do **NOT** use for expedited rule making

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER  
 STATE OF WASHINGTON  
 FILED

DATE: April 21, 2026

TIME: 8:51 AM

WSR 26-09-118

**Agency:** Department of Health – Pharmacy Quality Assurance Commission

**Original Notice**

**Supplemental Notice to WSR**

**Continuance of WSR**

**Preproposal Statement of Inquiry was filed as WSR 23-18-046; or**

**Expedited Rule Making--Proposed notice was filed as WSR \_\_\_\_; or**

**Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1); or**

**Proposal is exempt under RCW \_\_\_\_.**

**Title of rule and other identifying information:** Pharmacy registration for mobile opioid treatment program units. The Pharmacy Quality Assurance Commission (commission) is proposing amendments to researcher and other controlled substance registration rules, WAC 246-945-060 and 246-945-250, to add registration exemptions for mobile opioid treatment program (OTP) units and amend facility requirements for other controlled substance registrants.

**Hearing location(s):**

<b>Date:</b>	<b>Time:</b>	<b>Location:</b> (be specific)	<b>Comment:</b>
May 28, 2026	1:00 p.m.	<p><b>Physical Location:</b>                      Department of Labor &amp; Industries                      7273 Linderson Way SW                      Tumwater, WA 98501</p> <p><b>Virtual Location: Zoom</b>                      To access the meeting on May 28, 2026, at 1:30 pm, go to <a href="https://us02web.zoom.us/j/86309299195">https://us02web.zoom.us/j/86309299195</a>                      or  <a href="https://zoom.us/join">https://zoom.us/join</a> and use the Webinar ID 863 0929 9195</p> <p>The access options include one tap mobile:                      +12532158782,,86309299195#                      US (Tacoma)                      +12532050468,,86309299195#                      US</p> <p>Or Telephone: Dial (for higher quality, dial a number based on your current location):                      +1 253 215 8782 US (Tacoma)                      +1 253 205 0468 US</p>	The commission will hold a hybrid hearing. Attendees are welcome to attend either in-person at the physical location or virtual via Zoom.

**Date of intended adoption:** May 28, 2026 (Note: This is **NOT** the **effective** date)

**Submit written comments to:**

Name      Haleigh Mauldin

**Assistance for persons with disabilities:**

Contact      Haleigh Mauldin

Address	PO Box 47852, Olympia, WA 98504-7852	Phone	360-236-4946
Email	PharmacyRules@doh.wa.gov	Fax	N/A
Fax	N/A	TTY	711
Other	<a href="https://fortress.wa.gov/doh/policyreview/">https://fortress.wa.gov/doh/policyreview/</a>	Email	PharmacyRules@doh.wa.gov
Beginning (date and time)	At the time and date of filing	Other	N/A.
By (date and time):	May 14, 2026 at 11:59 p.m.	By (date):	April 30, 2026

**Purpose of the proposal and its anticipated effects, including any changes in existing rules:** The commission is proposing amending WAC 246-945-060 and 246-945-250 to exempt mobile opioid treatment program (OTP) units from having to obtain separate registrations, as long as they are covered under the OTP site's controlled substance registration, and to incorporate comprehensive facility requirements for analytical laboratories and dog handlers among other facilities that are licensed under the other controlled substance registration.

To operate in Washington state and possess controlled substances, OTPs must be licensed by the Washington Department of Health (department) as a behavioral health agency and register with the commission to obtain an "other controlled substances registration." Previously, if an OTP were to operate a mobile component, they were required to obtain a separate registration and licensure for each mobile component in order to possess controlled substances. In July 2021, the federal Drug Enforcement Agency (DEA) lifted its moratorium on mobile units, eliminating a separate registration requirement for OTP mobile units by adding a "mobile component" to an OTP's existing registration. The department adopted permanent rules for licensed behavioral health agencies to approve these units as an extension of an existing OTP license and certification, though they must also register with the commission to possess controlled substances by obtaining the "other controlled substance registration."

While state law currently requires each mobile unit to register separately with the commission, RCW 69.50.302(4) allows the commission to waive by rule the requirement for registration of certain entities upon finding it consistent with public health and safety. The proposed rule amends WAC 246-945-060, Other controlled substance registrants—Requirements and WAC 246-945-250 Researcher and other controlled substance registration, to exempt mobile units from having to register separately with the commission, allowing an OTP to extend its registration to cover its mobile units. The commission determined that there is no public health and safety issue from allowing existing OTPs to cover mobile units because the mobile unit would still be operating under the authority, oversight, and other controlled substance registration of the existing OTP license and all drugs return to the existing OTP each night. This change is intended to reduce administrative burden for OTPs that wish to expand services by adding mobile components to their registrations. These mobile units increase access to treatment for Washingtonians with opioid use disorder to assist in combating the ongoing opioid epidemic, which the commission considers a significant public health issue.

The amended rules also incorporate comprehensive facility requirements for all other controlled substance registrants, including analytical laboratories and dog handlers, focusing on enhancing drug security and product integrity. This amendment is to align with state and federal regulations and provide clarity to licensees and inspectors regarding the commission's expectations for the controlled substance registration.

**Reasons supporting proposal:**

To better align with the statute's intent, to protect public health, safety, and welfare, the commission is proposing amendments to waive the requirement that each mobile unit must register separately with the commission and incorporate comprehensive facility requirements for other controlled substance registrants. The proposed rules mirror DEA regulations and processes by incorporating sections of Title 21 CFR and allowing an OTP to extend its other controlled substance registration to cover its mobile units aligning the process with federal regulations to reduce administrative burden for registrants. The commission determined that there is no public health and safety issue from allowing existing OTPs to cover mobile units because the mobile unit would still be operating under the authority, oversight, and other controlled substance registration of the existing OTP license and all drugs return to the existing OTP each night.

**Statutory authority for adoption:** RCW 18.64.005 and 69.50.302

**Statute being implemented:** RCW 18.64.005 and 69.50.302

**Is rule necessary because of a:**

- Federal Law?  Yes  No
- Federal Court Decision?  Yes  No
- State Court Decision?  Yes  No

If yes, CITATION:

**Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters:** None

**Name of proponent:** Pharmacy Quality Assurance Commission

**Type of proponent:**  Private.  Public.  Governmental.

**Name of agency personnel responsible for:**

	Name	Office Location	Phone
Drafting	Haleigh Mauldin	111 Israel Rd SE, Tumwater, WA 98501	360-890-0720
Implementation	Haleigh Mauldin	111 Israel Rd SE, Tumwater, WA 98501	360-890-0720
Enforcement	Marlee O'Neill	111 Israel Rd SE, Tumwater, WA 98501	360-236-4946

**Is a school district fiscal impact statement required under [RCW 28A.305.135](#)?**

Yes  No

If yes, insert statement here:

The public may obtain a copy of the school district fiscal impact statement by contacting:

Name  
Address  
Phone  
Fax  
TTY  
Email  
Other

**Is a cost-benefit analysis required under [RCW 34.05.328](#)?**

Yes: A preliminary cost-benefit analysis may be obtained by contacting:

Name Haleigh Mauldin  
Address PO Box 47852, Olympia, WA 98504-7852  
Phone 360-236-4947  
Fax N/A  
TTY 711  
Email PharmacyRules@doh.wa.gov  
Other None

No: Please explain:

**Regulatory Fairness Act and Small Business Economic Impact Statement**

Note: The [Governor's Office for Regulatory Innovation and Assistance \(ORIA\)](#) provides support in completing this part.

**(1) Identification of exemptions:**

This rule proposal, or portions of the proposal, **may be exempt** from requirements of the Regulatory Fairness Act (see [chapter 19.85 RCW](#)). For additional information on exemptions, consult the [exemption guide published by ORIA](#). Please check the box for any applicable exemption(s):

This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.061](#) because this rule making is being adopted solely to conform and/or comply with federal statute or regulations. Please cite the specific federal statute or regulation this rule is being adopted to conform or comply with, and describe the consequences to the state if the rule is not adopted.

Citation and description:

This rule proposal, or portions of the proposal, is exempt because the agency has completed the pilot rule process defined by [RCW 34.05.313](#) before filing the notice of this proposed rule.

This rule proposal, or portions of the proposal, is exempt under the provisions of [RCW 15.65.570\(2\)](#) because it was adopted by a referendum.

This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.025\(3\)](#). Check all that apply:

- |  |   |
|--|---|
| <input type="checkbox"/> <a href="#">RCW 34.05.310</a> (4)(b)<br>(Internal government operations)        | <input type="checkbox"/> <a href="#">RCW 34.05.310</a> (4)(e)<br>(Dictated by statute)  |
| <input checked="" type="checkbox"/> <a href="#">RCW 34.05.310</a> (4)(c)<br>(Incorporation by reference) | <input type="checkbox"/> <a href="#">RCW 34.05.310</a> (4)(f)<br>(Set or adjust fees)   |
| <input type="checkbox"/> <a href="#">RCW 34.05.310</a> (4)(d)<br>(Correct or clarify language)           | <input type="checkbox"/> <a href="#">RCW 34.05.310</a> (4)(g)<br>(i) Relating to agency hearings; or (ii) process requirements for applying to an agency for a license or permit) |

This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.025\(4\)](#). (Does not affect small businesses).

This rule proposal, or portions of the proposal, is exempt under RCW \_\_\_\_\_.

Explanation of how the above exemption(s) applies to the proposed rule: The amendments to WAC 246-945-060 were already required in chapter 69.41 RCW and Title 21 of the Code of Federal Regulations (CFR). Because the proposed amendments are incorporating what is already required in other state and federal regulations, they meet the requirements provided in RCW 34.05.310(4)(c) and are eligible for exemption for the small business economic impact statement.

**(2) Scope of exemptions:** *Check one.*

The rule proposal: Is fully exempt. (*Skip section 3.*) Exemptions identified above apply to all portions of the rule proposal.

The rule proposal: Is partially exempt. (*Complete section 3.*) The exemptions identified above apply to portions of the rule proposal, but less than the entire rule proposal. Provide details here (consider using [this template from ORIA](#)):

The rule proposal: Is not exempt. (*Complete section 3.*) No exemptions were identified above.

**(3) Small business economic impact statement:** *Complete this section if any portion is not exempt.*

If any portion of the proposed rule is **not exempt**, does it impose more-than-minor costs (as defined by RCW 19.85.020(2)) on businesses?

- No Briefly summarize the agency's minor cost analysis and how the agency determined the proposed rule did not impose more-than-minor costs.

**A brief description of the proposed rule including the current situation/rule, followed by the history of the issue and why the proposed rule is needed. A description of the probable compliance requirements and the kinds of professional services that a small business is likely to need in order to comply with the proposed rule.**

The commission is proposing amending WAC 246-945-060 and 246-945-250 to exempt mobile OTP units from having to obtain separate registrations, as long as they are covered under the OTP site's controlled substance registration, and to incorporate comprehensive facility requirements for analytical laboratories and dog handlers among other facilities that are licensed under the other controlled substance registration.

To operate in Washington state and possess controlled substances, OTPs must be licensed by the Washington Department of Health (department) as a behavioral health agency and register with the commission to obtain an "other controlled substances registration." Previously, if an OTP were to operate a mobile component, they were required to obtain a separate registration and licensure for each mobile component in order to possess controlled substances. In July 2021, the federal Drug Enforcement Agency (DEA) lifted its moratorium on mobile units, eliminating a separate registration requirement for OTP mobile units by adding a "mobile component" to an OTP's existing registration. The department adopted permanent rules for licensed behavioral health agencies to approve these units as an extension of an existing OTP license and certification, though they must also register with the commission to possess controlled substances by obtaining the "other controlled substance registration."

While state law currently requires each mobile unit to register separately with the commission, RCW 69.50.302(4) allows the commission to waive by rule the requirement for registration of certain entities upon finding it consistent with public health and safety. The proposed rule amends WAC 246-945-060, Other controlled substance registrants—Requirements and WAC 246-945-250 Researcher and other controlled substance registration, to exempt mobile units from having to register separately with the commission, allowing an OTP to extend its registration to cover its mobile units. The commission determined that there is no public health and safety issue from allowing existing OTPs to cover mobile units because the mobile unit would still be operating under the authority, oversight, and other controlled substance registration of the existing OTP license and all drugs return to the existing OTP each night. This change is intended to reduce administrative burden for OTPs that wish to expand services by adding mobile components to their registrations. These mobile units increase access to treatment for Washingtonians with opioid use disorder to assist in combating the ongoing opioid epidemic, which the commission considers a significant public health issue.

The amended rules also incorporate comprehensive facility requirements for all other controlled substance registrants, including analytical laboratories and dog handlers, focusing on enhancing drug security and product integrity. This amendment is to align with federal and state regulations and provide clarity to licensees and inspectors regarding the commission's expectations for the controlled substance registration.

In order to comply with the proposed rule, the OTPs that would like to add a mobile unit must notify the commission within 30 days and pay an inspection fee of \$400. After the initial inspection fee, the mobile unit would be included with the OTP's existing registration and would not incur additional licensing costs.

**Identification and summary of which businesses are required to comply with the proposed rule using the North American Industry Classification System (NAICS).**

**SBEIS Table 1. Summary of Businesses Required to comply to the Proposed Rule**

NAICS Code (4, 5 or 6 digit)	NAICS Business Description	Number of businesses in Washington State	Minor Cost Threshold
621420	Outpatient Mental Health and Substance Abuse Centers	239	\$8,531.28
541380	Testing Laboratories and Services	203	\$7,988
541715	Research and development	322	\$38,114
611310	Schools (laboratories)	149	\$11,015

**Analysis of probable costs of businesses in the industry to comply to the proposed rule and includes the cost of equipment, supplies, labor, professional services, and administrative costs. The analysis considers if compliance with the proposed rule will cause businesses in the industry to lose sales or revenue.**

**Exempted from Analysis: WAC 246-945-060 Other controlled substance registrants—Requirements.**

**Description:** The current rule establishes the requirements for licensees holding other controlled substance registrations including inventory and drug storage rules, among others. The proposed amendments to WAC 246-945-060 develop more comprehensive facility requirements for other controlled substance registrants and provide definitions for “mobile unit” and “opioid treatment program.” The facility requirements listed in the proposed amendments are incorporations of requirements found in other state and federal regulations. The additions to WAC 246-945-060 were already required in chapter 69.41 RCW and Title 21 of the Code of Federal Regulations (CFR). Because the proposed amendments are incorporating what is already required in other state and federal regulations, they meet the requirements provided in RCW 34.05.310(4)(d) and are eligible for exemption from analysis.

**WAC 246-945-250 Researcher and other controlled substance registration.**

**Description:** The current rule establishes the application process for initial registration and renewal for researchers or those designated as other controlled substance registrants. Currently each mobile unit must apply for an initial other controlled substance registration which incurs a fee of \$360. On top of the initial fee, each mobile unit must renew their registration annually for another \$360.

The proposed amendments to WAC 246-945-250 outline the application process, notification requirements, when inspections are required, and related fees for the addition, for researcher and other controlled substance registrations. The amendments note that adding a mobile unit would not require a separate registration with an annual renewal fee, however, it would incur an inspection fee of \$400 since adding a mobile unit would be considered a modification.

**Cost(s):** The proposed amendments to WAC 246-945-250 have the greatest effect on OTPs wanting to add a mobile unit. There are approximately 14 mobile units currently operating in Washington state that are run by 5 OTP facilities. For simplicity, the department and commission produced a costing example for one OTP facility operating one mobile over multiple years without changes. The department and commission acknowledge that many OTP facilities run multiple mobile units and anticipate that all OTP facilities will incur cost savings over time under the proposed rule.

Each mobile unit currently holds a separate other controlled substances registration, but with the proposed amendments, the OTPs would be required to notify the commission and pay an inspection fee (\$400) when adding a mobile unit. They must also notify the commission when removing a unit and receive an inspection but there is no associated fee. This would mean that an OTP would only have to pay the one-time \$400 inspection fee when they add a mobile unit instead of an initial (one-time) other controlled substance registration fee (\$360) and yearly renewals (\$360). Although the initial cost of the proposed rule is \$40 more, OTPs will incur cost savings within 2 years because they will no longer be required to pay annual renewal fees for each mobile unit. As the rule is currently written, an OTP would pay \$720 in initial application fees and annual renewal fees in two years for a separate registration, but with the proposed rule the OTP would only have to pay the one-time \$400 for the initial inspection for each mobile unit to extend its registration results in a cost savings of \$360 in the following year, or year two, plus savings of \$360 each additional year. Costs and potential savings between current and proposed rule for a single OTP facility operating a single mobile unit is depicted in Table 1.

Table 1. Understanding costs between current and proposed rules for OTP facilities operating a single mobile unit\*

Rule	Initial cost	Annual Fee	First year costs	Second Year costs	Savings in Year 2	Savings each additional year
Current	\$360 licensing fee	\$360	\$360	\$360	NA	NA
Proposed	\$400 inspection fee	\$0	\$400	\$0	(\$360)	(\$360)

\*This table depicts potential costs for one OTP facility operating a single mobile unit and assumes the OTP facility does not make any changes or add any new mobile units, which could result in additional costs or savings.

For other facility types covered by researcher and other controlled substances registrations, the amendments to WAC 246-945-250 will incur a cost. Currently when a registrant makes modifications to their facility that negatively impacts security, an inspection--and subsequent inspection fee--is not required. The proposed amendments would require an inspection and inspection fee for these modifications. However, based on feedback from the commission's inspector supervisor, registrants rarely undergo these types of changes to structure, square footage, or security. The commission anticipates this type of inspection to occur about once every two years across all registrants (approximately 100 active researcher registrants and 100 active other controlled substance registrants) because they are infrequent. This would be a cost of \$400 for the inspection fee approximately every two years for one registrant.

**Analysis on if the proposed rule may impose more than minor costs for businesses in the industry. Includes a summary of how the costs were calculated.**

No, the costs of the proposed rule, an increase in costs of \$40 in the first year (and potential costs in subsequent years, are less than the minor cost threshold of \$8,531.28 for Outpatient Mental Health and Substance Abuse Centers, \$7,988 for Testing Laboratories and Services, \$38,114 for Research and Development Laboratories, and \$11,015 for School Laboratories.

**Summary of how the costs were calculated**

The cost of compliance with this rule for OTPs was calculated by producing a costing example for one OTP facility operating one mobile over multiple years without changes. An OTP would have to pay a one-time inspection fee, \$400, when they add a mobile unit. This \$400 inspection fee is \$40 more than the current cost of an other controlled substance registration, however, the inspection fee is a one-time cost and does not require an annual fee. By year 2, the OTP will incur cost savings because they are no longer required to pay annual renewal fees. Costs and potential savings between current and proposed rule for a single OTP facility operating a single mobile unit is depicted in Table 1.

For other facility types covered by researcher and other controlled substance registrations the cost of compliance for this rule was calculated by determining the frequency of modifications that negatively impact security. The amount of modifications are infrequent, one inspection approximately every two years for one registrant, so the cost was determined to be \$400 for the inspection fee approximately every two years for one registrant.

Yes      Calculations show the rule proposal likely imposes more-than-minor cost to businesses and a small business economic impact statement is required. Insert the required small business economic impact statement here:

The public may obtain a copy of the small business economic impact statement or the detailed cost calculations by contacting:

Name      Haleigh Mauldin  
Address    PO Box 47852, Olympia, WA 98504-7852  
Phone      360-236-4947  
Fax         N/A  
TTY         711  
Email      PharmacyRules@doh.wa.gov  
Other      N/A

**Date:** April 21, 2026

**Name:** Hawkins DeFrance, PharmD

**Title:** Pharmacy Quality Assurance Commission Chair

**Signature:**



**WAC 246-945-060 Other controlled substance registrants—Requirements.** (1) All persons and firms, except persons exempt from registration, must register with the commission in order to legally possess or use controlled substances.

(2) Persons or firms which are not classified as pharmacies, wholesalers, manufacturers, or researchers will be classified as other controlled substance registrants. Examples of persons or firms in this classification include analytical laboratories, dog handlers/trainers who use dogs for drug detection purposes, school laboratories, opioid treatment programs (OTP), and other agencies which have a legitimate need to use precursor chemicals as defined in WAC 246-945-053.

(3) For the purposes of this section:

(a) "Mobile unit" means a component of an opioid treatment program that the DEA has approved to operate as a mobile narcotic treatment program pursuant to 21 C.F.R. § 1301.13.

(b) "Opioid treatment program(s)" or "OTP(s)" means a behavioral health agency that has been licensed by the department and certified as an opioid treatment program.

(4) The applicant for a controlled substance registration must complete and return an application form supplied by the commission. A list of the controlled substances to be used, the purpose for such use, and the names of the persons authorized to access the controlled substances must be listed on the application or on an addendum. An applicant for a controlled substance registration who is an OTP must also identify any mobile units operated by the agency, if any, in the application or in an addendum.

~~((4) All controlled substances must be stored in a substantially constructed locked cabinet. The registrant shall maintain records in sufficient detail in order to account for the receipt, use, and disposition of all controlled substances. The registrant shall inventory all controlled substances in the possession of the registrant every two years on the anniversary of the issuances of the registration and shall maintain the inventory list for two years. The registrant shall return unwanted, outdated, or unusable controlled substances to the source from which it was obtained or surrendered to the DEA.))~~ (5) An other controlled substance registrant shall:

(a) Ensure all controlled substances are stored in a substantially constructed locked cabinet to prevent unauthorized access;

(b) Maintain records in sufficient detail in order to account for the receipt, use, and disposition of all controlled substances;

(c) Inventory all controlled substances in the possession of the registrant every two years on the anniversary of the issuance of the registration and shall maintain the inventory for two years;

(d) Return unwanted, outdated, or unusable controlled substances to the source from which it was obtained, surrendered to the DEA, or as otherwise permitted by state and federal law; and

(e) Affix a label to every box, bottle, jar, tube, or other container that is dispensed and delivered to an ultimate user that meets the labeling requirements in RCW 69.41.050.

(6) Other controlled substance registrants that are OTPs, who have notified the department that they will be operating a mobile unit must:

(a) Notify the local DEA office and receive explicit written approval from the local DEA office prior to operating the mobile opioid treatment program unit;

(b) Possess valid county/city and Washington state vehicle licensing and registration prior to transporting controlled substances;

(c) Not reverse distribute, share, or transfer controlled substances from one mobile component to another mobile component while deployed away from the registered location;

(d) Establish policies and procedures to ensure, if the mobile unit becomes inoperable, that all controlled substances on the inoperable mobile unit are accounted for, removed, and secured at the registered location of the OTP;

(e) Return to the registered location at the completion of each operation and remove all controlled substances to secure within the registered location; and

(f) Notify the commission of any changes to the information provided on the application, including the addition or removal of a mobile unit.

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

**WAC 246-945-250 Researcher and other controlled substance registration.** (1) Applicants for initial registration and renewal for researcher or other controlled substance registrations shall submit to the commission a complete application, as described in WAC 246-945-060(4), with fees relevant to the registration type.

(a) Researcher:

(i) Noncontrolled legend drugs; or

(ii) Researchers requiring to purchase, possess, administer or dispense controlled substances shall apply for a controlled substance authority on its license with the commission and register with the DEA.

(b) Other controlled substance registrations:

(i) Opioid treatment programs;

(ii) Analytical laboratories;

(iii) Dog handler; and

(iv) Other agencies who have demonstrated a legitimate need to use precursor chemicals.

(2) ~~((The application shall:~~

~~(a) List all legend drugs and controlled substances to be used and the purpose for its use;~~

~~(b) Name the primary registrant; and~~

~~(c) List the names of the individuals authorized to access the controlled substances.~~

~~(3) Applicants))~~ An OTP who has notified the department they will be operating a mobile unit pursuant to chapter 246-341 WAC is not required to obtain a separate controlled substance registration for each mobile unit if the OTP's main fixed location has obtained an other controlled substance registration from the commission.

(3) Researcher and other controlled substance registrants shall notify the commission within 30 days of any changes to the information provided on their application.

(4) An applicant for initial registration and closure for researcher and other controlled substance registrations, including when an OTP removes a mobile unit from its registration, shall undergo an ((initial)) inspection ((and)). A registrant will be subject to periodic inspections as deemed appropriate by the commission.

(5) Researcher and other controlled substance registrants shall notify the commission and pay an inspection fee, as established in WAC 246-945-990 (5)(a), if any of the following occur:

(a) Changes to structural element(s) such as walls, floors, and load bearing elements that negatively impact security as determined by the registrant;

(b) Changes impacting square footage that negatively impact security as determined by the registrant;

(c) Changes to access to controlled substances that negatively impact security as determined by the registrant;

(d) Changes of location; or

(e) Adding a mobile unit to an OTP registration.

(6) For the purposes of this section:

(a) "Mobile unit" means a component of an opioid treatment program that the DEA has approved to operate as a mobile narcotic treatment program pursuant to 21 C.F.R. § 1301.13.

(b) "Opioid treatment program(s)" or "OTP(s)" means a behavioral health agency that has been licensed by the department and certified as an opioid treatment program.

Animal Euthanasia Training Program Guidelines Draft Rule

**WAC 246-945-503 Humane societies, animal control agencies, and department of fish and wildlife chemical capture programs—Authorized personnel.**

(1) Each ~~registered~~ humane society, animal control agency, and department of fish and wildlife chemical capture program location registered with the commission shall ensure only authorized personnel possess or administer approved legend drugs and approved controlled substances at the registered location.

(2) For registered humane societies and animal control agencies, authorized personnel are those individuals who have:

(a) Successfully completed a commission-approved training program approved by the commission pursuant to WAC 246-945-504 or training that is substantially equivalent; and

(b) Been approved by the designated person.

(3) For registered department of fish and wildlife chemical capture programs, authorized personnel are those individuals who have:

(a) Completed Successfully completed a commission-approved training program approved by the commission pursuant to WAC 246-945-504 or training that is substantially equivalent;

(b) Been approved by the department of fish and wildlife; and

(c) Are a department of fish and wildlife officer, biologist, or veterinarian.

~~(4) A commission-approved training program shall include didactic and practical training under the direction of a licensed veterinarian. The commission-approved training program should ensure that authorized personnel shall be able to demonstrate adequate knowledge of the potential hazards and proper techniques used in administering approved legend and controlled substances.~~

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-503, filed 6/1/20, effective 7/1/20.]

NEW SECTION:

**WAC 246-945-504 Humane societies, animal control agencies, and department of fish and wildlife chemical capture programs—Euthanasia Training Programs.**

~~(1) The commission must approve a training program for authorized personnel of a humane society, animal control agency or department of fish and wildlife chemical capture program prior to the initiation of the training program.~~

~~(2) An application for approval of a training program for authorized personnel of a humane society or animal control agency must be submitted to the commission. The application shall demonstrate the training program meets the following requirements:~~

~~(a) Be at a minimum four hours in length;~~

~~(b) Be instructed by a licensed veterinarian;~~

(c) Require a passing score of no less than seventy-five percent on a final examination;  
and

(d) Require both didactic and practical training, as applicable, in the following topics:

(i) Anatomy and physiology;

(ii) Methods of euthanasia;

(iii) Routes of drug administration;

(iv) Use of sedatives;

(v) Drug dosing;

(vi) Use of restraints;

(vii) Process and verification of death;

(viii) Pharmacology of the drugs;

(ix) Use of approved legend drugs and sodium pentobarbital under the direction of a licensed veterinarian;

(x) Potential hazards and proper techniques used in administering approved legend and sodium pentobarbital;

(xi) Indications, contraindications, and adverse effects;

(xii) Human hazards;

(xiii) Disposal of medical waste (needles, syringes, etc.);

(xiv) Recordkeeping and security requirements; and

(xv) Applicable federal and state laws and rules.

(3) An application for approval of a training program for authorized personnel of a department of fish and wildlife chemical capture program must be submitted to the

commission. The application shall demonstrate the training program meets the following requirements:

(a) Be at a minimum four hours in length;

(b) Be instructed by a licensed veterinarian;

(c) Require a passing score of no less than seventy-five percent on a final examination;

and

(d) Require both didactic and practical training, as applicable, in the following topics:

(i) Anatomy and physiology;

(ii) Methods of euthanasia;

(iii) Routes of drug administration;

(iv) Use of sedatives;

(v) Drug dosing;

(vi) Use of restraints;

(vii) Process and verification of death;

(viii) Pharmacology of the drugs;

(ix) Use of approved legend drugs and controlled substances under the direction of a licensed veterinarian;

(x) Potential hazards and proper techniques used in administering approved legend and controlled substances;

(xi) Indications, contraindications, and adverse effects;

(xii) Human hazards;

(xiii) Disposal of medical waste (needles, syringes, etc.);

(xiv) Recordkeeping and security requirements; and

(xv) Applicable federal and state laws and rules.

DRAFT



# PROPOSED RULE MAKING

**CR-102 (June 2024)**  
**(Implements RCW 34.05.320)**  
 Do **NOT** use for expedited rule making

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER  
 STATE OF WASHINGTON  
 FILED

DATE: April 13, 2026

TIME: 9:48 AM

WSR 26-09-060

**Agency:** Department of Health – Pharmacy Quality Assurance Commission

**Original Notice**

**Supplemental Notice to WSR**

**Continuance of WSR**

**Preproposal Statement of Inquiry was filed as WSR 25-22-008; or**

**Expedited Rule Making--Proposed notice was filed as WSR \_\_\_\_\_; or**

**Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1); or**

**Proposal is exempt under RCW \_\_\_\_\_.**

**Title of rule and other identifying information:** Clarifying conditions for Ancillary Utilization Plans (AUPs) submitted to the Pharmacy Quality Assurance Commission (commission) for approval. The commission is proposing to amend WAC 246-945-410 to clarify that only pharmacies may submit an AUP, per RCW 18.64A.040 and 18.64A.060, for approval by the commission to utilize pharmacy ancillary personnel as defined in RCW 18.64A.010(5).

**Hearing location(s):**

<b>Date:</b>	<b>Time:</b>	<b>Location: (be specific)</b>	<b>Comment:</b>
5/28/2026	1:30 p.m.	<p><b>Physical location:</b>                      Labor &amp; Industries Building                      7273 Linderson Way SW                      Tumwater, WA 98501</p> <p><b>Virtual:</b>                      To access the meeting on May 28, 2026 at 1:30 pm, go to <a href="https://zoom.us/join">https://zoom.us/join</a> or <a href="https://us02web.zoom.us/j/86309299195">https://us02web.zoom.us/j/86309299195</a> and use the Webinar ID 863 0929 9195</p> <p>The access options include one tap mobile: US:                      +12532158782,,86309299195#                      or                      +16699009128,,86309299195#</p> <p>Or Telephone: Dial(for higher quality, dial a number based on your current location):                      US: +1 253 215 8782 or                      +1 669 900 9128 or                      +1 346 248 7799 or                      +1 669 444 9171 or                      +1 386 347 5053 or                      +1 564 217 2000 or</p>	The commission will hold a hybrid hearing. Attendees are welcome to attend either in-person at the physical location or virtual via Zoom.

		+1 646 558 8656 or +1 646 931 3860 or +1 301 715 8592 or +1 312 626 6799 Webinar ID: 861 1495 8466  International numbers available: <a href="https://us02web.zoom.us/j/6606unOZ">https://us02web.zoom.us/j/6606unOZ</a>	
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**Date of intended adoption:** 5/28/2026 (Note: This is **NOT** the **effective** date)

<b>Submit written comments to:</b> Name Joshua Munroe Address PO Box 47852, Olympia, WA 98504-7852 Email PharmacyRules@doh.wa.gov Fax 360-236-2901 Other <a href="https://fortress.wa.gov/doh/policyreview">https://fortress.wa.gov/doh/policyreview</a> Beginning (date and time) The date and time of filing By (date and time) 5/14/2026 at 11:59 p.m.	<b>Assistance for persons with disabilities:</b> Contact Joshua Munroe Phone 360-502-5058 Fax 360-236-2901 TTY 711 Email PharmacyRules@doh.wa.gov Other None By (date) 5/14/2026
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**Purpose of the proposal and its anticipated effects, including any changes in existing rules:**  
At the June 26, 2025 business meeting, the commission discussed two AUPs submitted by health care entities (HCEs) for approval. The facilities submitting the AUPs cited a passage in WAC 246-945-410(11) that could be interpreted to allow a non-pharmacy entity to submit an AUP based on the use of the term “facility” in that section of rule and how that term is defined in WAC 246-945-405(2). The commission discussed the two AUPs and denied them on the basis of statutory limitations on who can submit AUPs to the commission. Following the discussion, commission staff were tasked with researching the statutes that authorize use of ancillary personnel and AUP submission and approval.  
  
Staff confirmed that RCW 18.64A.040 and 18.64A.060 only allow pharmacies to submit AUPs for commission approval. The commission then decided to initiate rulemaking to ensure WAC 246-945-410 matches the commission's determination that only pharmacies can utilize ancillary personnel as defined in RCW 18.64A.010(5) and submit AUPs.

**Reasons supporting proposal:**  
The use of the term “facility” as used in WAC 246-945-410 is not consistent with the AUP submission and approval process as outlined in RCWs 18.64A.040 and 18.64A.060. Rulemaking to amend WAC 246-945-410 by replacing the term “facility” with “pharmacy” is the best method to clarify that only pharmacies may submit a plan for the use of ancillary personnel to the commission for approval.

**Statutory authority for adoption:** RCW 18.64.005, 18.64A.040, and 18.64A.060

**Statute being implemented:** RCW 18.64A.040 and 18.64A.060, 18.64A.010(5)

**Is rule necessary because of a:**

Federal Law?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Federal Court Decision?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
State Court Decision?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No

If yes, CITATION:

**Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters:** None.

**Name of proponent:** (person or organization) Pharmacy Quality Assurance Commission  
**Type of proponent:**  Private.  Public.  Governmental.

**Name of agency personnel responsible for:**

	Name	Office Location	Phone
Drafting	Joshua Munroe	111 Israel Rd SE, Tumwater, WA 98501	360-502-5058
Implementation	Joshua Munroe	111 Israel Rd SE, Tumwater, WA 98501	360-502-5058
Enforcement	Marlee O’Neill	111 Israel Rd SE, Tumwater, WA 98501	360-480-9108

**Is a school district fiscal impact statement required under [RCW 28A.305.135](#)?**  Yes  No

If yes, insert statement here:

The public may obtain a copy of the school district fiscal impact statement by contacting:

Name  
Address  
Phone  
Fax  
TTY  
Email  
Other

**Is a cost-benefit analysis required under [RCW 34.05.328](#)?**

Yes: A preliminary cost-benefit analysis may be obtained by contacting:

Name  
Address  
Phone  
Fax  
TTY  
Email  
Other

No: Please explain: The proposed rule is exempt under RCW 34.05.328(5)(b)(iv) because it amends WAC 246-945-410 and clarifies without changing the implementation of the rule who may submit an AUP for approval by the commission to use pharmacy ancillary personnel.

**Regulatory Fairness Act and Small Business Economic Impact Statement**

Note: The [Governor's Office for Regulatory Innovation and Assistance \(ORIA\)](#) provides support in completing this part.

**(1) Identification of exemptions:**

This rule proposal, or portions of the proposal, **may be exempt** from requirements of the Regulatory Fairness Act (see [chapter 19.85 RCW](#)). For additional information on exemptions, consult the [exemption guide published by ORIA](#). Please check the box for any applicable exemption(s):

This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.061](#) because this rule making is being adopted solely to conform and/or comply with federal statute or regulations. Please cite the specific federal statute or regulation this rule is being adopted to conform or comply with, and describe the consequences to the state if the rule is not adopted.

Citation and description:

This rule proposal, or portions of the proposal, is exempt because the agency has completed the pilot rule process defined by [RCW 34.05.313](#) before filing the notice of this proposed rule.

This rule proposal, or portions of the proposal, is exempt under the provisions of [RCW 15.65.570](#)(2) because it was adopted by a referendum.

This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.025](#)(3). Check all that apply:

- |   |  |
|---|--|
| <input type="checkbox"/> <a href="#">RCW 34.05.310</a> (4)(b)<br>(Internal government operations)         | <input type="checkbox"/> <a href="#">RCW 34.05.310</a> (4)(e)<br>(Dictated by statute)   |
| <input type="checkbox"/> <a href="#">RCW 34.05.310</a> (4)(c)<br>(Incorporation by reference)             | <input type="checkbox"/> <a href="#">RCW 34.05.310</a> (4)(f)<br>(Set or adjust fees)  |
| <input checked="" type="checkbox"/> <a href="#">RCW 34.05.310</a> (4)(d)<br>(Correct or clarify language) | <input type="checkbox"/> <a href="#">RCW 34.05.310</a> (4)(g)<br>((i) Relating to agency hearings; or (ii) process requirements for applying to an agency for a license or permit) |

This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.025](#)(4). (Does not affect small businesses).

This rule proposal, or portions of the proposal, is exempt under RCW \_\_\_\_\_.

Explanation of how the above exemption(s) applies to the proposed rule: The proposed rule amends WAC 246-945-410 and clarifies without changing the implementation of the rule who may submit an AUP for approval by the commission to use pharmacy ancillary personnel.

**(2) Scope of exemptions: Check one.**

The rule proposal: Is fully exempt. (Skip section 3.) Exemptions identified above apply to all portions of the rule proposal.

- The rule proposal: Is partially exempt. (*Complete section 3.*) The exemptions identified above apply to portions of the rule proposal, but less than the entire rule proposal. Provide details here (consider using [this template from ORIA](#)):
- The rule proposal: Is not exempt. (*Complete section 3.*) No exemptions were identified above.

**(3) Small business economic impact statement:** *Complete this section if any portion is not exempt.*

If any portion of the proposed rule is **not exempt**, does it impose more-than-minor costs (as defined by RCW 19.85.020(2)) on businesses?

- No Briefly summarize the agency's minor cost analysis and how the agency determined the proposed rule did not impose more-than-minor costs.
- Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses and a small business economic impact statement is required. Insert the required small business economic impact statement here:

The public may obtain a copy of the small business economic impact statement or the detailed cost calculations by contacting:

Name  
Address  
Phone  
Fax  
TTY  
Email  
Other

**Date:** April 13, 2026

**Name:** Hawkins DeFrance, PharmD

**Title:** Pharmacy Quality Assurance Commission Chair

**Signature:**



**WAC 246-945-410 Facility standards.** A facility must meet the following minimum requirements:

(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.

(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.

(3) The facility shall be staffed sufficiently to allow appropriate supervision, operate safely and, if applicable, remain open during posted hours of operation.

(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.

(5) The facility shall designate a responsible pharmacy manager:

(a) By the date of opening; and

(b) Within (~~thirty~~) 30 calendar days of a vacancy.

(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.

(b) Accuracy of inventory records, patient medical records as related to the administration of controlled substances and legend drugs, and any other records required to be kept by state and federal laws.

(c) Adequate security of legend drugs, including controlled substances.

(d) Controlling access to legend drugs, including controlled substances.

(7) Prescription drugs must only be dispensed pursuant to a valid prescription as required by WAC 246-945-011.

(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.

(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.

(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.

(11) In accordance with RCW 18.64A.060 prior to utilizing pharmacy ancillary personnel a (~~facility~~) pharmacy shall submit to the commission a utilization plan for pharmacy technicians and pharmacy assistants:

(a) Utilization plan for pharmacy technicians. The application for approval must describe the manner in which the pharmacy technicians will be utilized and supervised, including job descriptions, task analysis or similar type documents that define the duties performed and the conditions under which they are performed, number of positions in each category, as well as other information as may be required by the commission. The commission will be notified of all changes to the utilization plan. A copy of the utilization plan must be maintained in the pharmacy. The utilization plan must comply with WAC 246-945-315 and 246-945-320.

(b) Utilization plan for pharmacy assistants. The application for approval shall list the job title or function of the pharmacy assistant and comply with WAC 246-945-315(3).

(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.

## 9.1 Rulemaking Authorization: Pharmacy Technician Licensing

### **Title: Rulemaking Authorization: Pharmacy Technician Licensing**

**Meeting Date:** May 28, 2026

**Staff Contact:** Marlee O'Neill

**Purpose (select one):**       **Decision**                       **Help/Feedback**                       **Awareness**

#### **Situation**

Staff have encountered several areas of the commission's rules regarding pharmacy technicians that warrant consideration for rulemaking.

First, [WAC 246-945-203](#), pharmacy technician-in-training authority for experiential training, has been more complicated to implement than originally believed and has created confusion for applicants and licensees.

Second, there have been several instances of pharmacists seeking licensure as technicians. There is no separate pathway for this in the commission's rules. [WAC 246-945-205](#).

Finally, [WAC 246-945-215](#) requires commission-approved technician training programs to include on-the-job training of at least 520 hours. Certain technician training programs are considered approved by the commission if they are accredited, approved, or administered by the American Society of Health-System Pharmacists, the Accreditation Council for Pharmacy Education, the Pharmacy Technician Certification Board, or the United States Armed Forces. However, not all of these bodies require on-the-job training.

#### **Background**

##### *Technician-in-Training Endorsement*

During the commission's rules rewrite project, the commission developed a technician-in-training endorsement for experiential training for pharmacy assistants enrolled in a technician training program. [WAC 246-945-203](#).

The pharmacist to technician ratio was removed on September 14, 2019. [WSR 19-17-034](#). The commission's rules rewrite project was effective on July 1, 2020. Since July 1, 2020, staff have continued to field questions and navigate challenges with this rule. Many assistants believe they must apply for a technician-in-training endorsement even if they are not enrolling in a technician training program. Many assistants that are enrolling in a technician training program do not realize they have to also get the technician-in-training endorsement and many of the technician training programs are not ensuring their students have the endorsement. This has resulted in many deficiencies, licensure delays, and nonroutine applications for both the pharmacy assistant and pharmacy technician credential. Academic training programs have expressed confusion as to whether the endorsement is needed before beginning the program or before beginning the experiential component of the training.

##### *Pharmacists Applying for a Technician License*

WAC 246-945-205 provides a pathway for someone to get licensed as a pharmacy technician if they completed a commission-approved training program, have a pharmacy technician license in another Rulemaking Authorization: Pharmacy Technician Licensing  
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state, or are a graduate of a foreign school, university or college of pharmacy or medicine whose professional degree program is approved by the commission. However, this rule does not provide a pathway for a pharmacist to get a technician license. Recently, the commission has received several applications from pharmacists who are applying for technician credentials. As an example, a retired pharmacist who wants to help their small community pharmacy out by taking a part-time job as a pharmacy technician. The commission can consider rulemaking to provide a more streamlined path for a licensed pharmacist to obtain a technician credential.

#### *Experiential Component for Training Programs*

WAC 246-945-215(1) states as follows.

(1) A pharmacy technician-training program shall be considered approved by the commission if it is accredited, approved, or administered by:

- (a) The American Society of Health-System Pharmacists (ASHP);
- (b) The Accreditation Council for Pharmacy Education;
- (c) Pharmacy Technician Certification Board; or
- (d) The United States Armed Forces.

Staff have learned that not all entities listed in (a) – (d) above require an experiential component. The commission does require at least 520 hours of on-the-job training for all other technician training programs that it approves. The commission can consider whether to update this list, or other options, based on a lack of an experiential component.

#### **Assessment**

Staff would like the commission to consider opening rulemaking to consider alternatives to the technician-in-training endorsement. During the rulemaking, staff and commissioners can explore more streamlined options that would also create a more manageable workload for staff.

Staff would also like the commission to consider opening rulemaking to consider providing a pathway for licensed pharmacists to get a technician license and to revisit the list of entities whose accreditation, approval, or administration of a technician training program automatically makes them commission-approved for those organizations that do not require an experiential component.

#### **Recommendation**

Staff recommend that the commission authorize a CR101 rule inquiry package to update WACs 246-945-203, 246-945-205, and 246-945-215, and potentially add a new section(s) to address the pharmacy technician-in-training endorsement, pharmacy technician licensing, and pharmacy technician training program requirements. In addition, the commission previously authorized a rulemaking package on examinations for both pharmacist and pharmacy technician applicants. That rulemaking package creates an overlap with one section of rule (WAC 246-945-205) with this rulemaking. As such, staff also suggest adding the commission's previously authorized rulemaking topic on codifying the approved examinations for pharmacy technician licensure into this rulemaking package.

## 9.2. Rulemaking Authorization: Requirement for Submission of Collaborative Drug Therapy Agreements (CDTAs)

### Title: Rulemaking Authorization: Requirement for Submission of Collaborative Drug Therapy Agreements (CDTAs)

Meeting Date: May 28, 2026

Staff Contact: Joshua Munroe

Purpose (select one):       Decision                       Help/Feedback                       Awareness

#### Situation

Commission staff received feedback regarding the requirement to have a valid collaborative drug therapy agreement (CDTA) on file with both the commission and at the practice location, per [WAC 246-945-350\(1\)](#). Staff requests that the commission review existing CDTA submission practices and approve rulemaking to amend the requirement that a CDTA be kept on file with the commission.

#### Background

[WAC 246-945-350 Collaborative Drug Therapy Agreements](#) requires pharmacists licensed by the commission to have a valid CDTA on file with the commission and at their practice location. The commission and staff do not reference the CDTAs kept on file for each licensed pharmacist. Instead, only the pharmacist's CDTA kept at their practice location is accessed during a routine inspection. Additionally, due to the requirement to submit the CDTA to the commission, there has been a lot of confusion from licensees over the years as to whether the commission needs to approve the CDTA. The commission has never formally "approved" CDTAs but this confusion has resulted in delays in care under a CDTA.

#### Assessment

Staff determined that requiring licensees to submit a copy of their CDTA to the commission to keep on file represents a redundancy, area of confusion, and an unnecessary time commitment for licensees. Staff and the commission will still be able to access CDTAs, whether for an inspection or investigation, because of the requirement to keep a copy of the CDTA at the practice site. Staff are also mindful of not wanting to collect information when we can access it in other ways. The commission is granted rulemaking authority relating to pharmacists and the practice of pharmacy under [RCW 18.64.005](#) and can amend WAC 246-945-350 and adjust the existing requirement that licensees submit an additional copy of their CDTA to the commission to be kept on file.

#### Recommendation

Staff recommend that the commission make a motion to initiate standard rulemaking to remove the requirement that licensees submit a copy of their CDTA to the commission and to task staff with drafting and filing a CR-101 Rules Inquiry on that topic.

## 9.3 Rulemaking Authorization Scheduling Multiple Synthetic Benzodiazepines

### Title: Rulemaking Authorization: Scheduling Multiple Synthetic Benzodiazepines

**Meeting Date:** May 28, 2026

**Staff Contact:** Joshua Munroe

**Purpose (select one):**       **Decision**                       **Help/Feedback**                       **Awareness**

#### Situation

Pharmacy Quality Assurance Commission (commission) staff discovered two rulemaking notices issued by the United States Drug Enforcement Administration (DEA) placing certain synthetic benzodiazepines—clonazepam, diclazepam, etizolam, flualprazolam, flubromazolam, and bromazolam—and their respective salts, isomers, and salts of isomers in schedule I of the Controlled Substances Act. Staff requests that the commission review the DEA’s proposed rulemaking and approve its own rulemaking to place these synthetic benzodiazepines in [WAC 246-945-051 Schedule I](#).

#### Background

The DEA published an [order](#) in the Federal Register on July 26, 2023, temporarily placing clonazepam, diclazepam, etizolam, flualprazolam, and flubromazolam—all of which fall under the broader drug category of benzodiazepines—in schedule I of the Controlled Substances Act (CSA) based upon a finding that these substances pose an imminent hazard to the public safety under [21 U.S.C. 811\(h\)\(1\)](#). The temporary scheduling was later extended to [July 26, 2026](#) to allow the DEA time to complete its [rulemaking to permanently schedule these substances in schedule I](#). An [additional rule](#) was issued on March 16, 2026, placing another synthetic benzodiazepine, bromazolam, in schedule I. The DEA cited numerous reasons to schedule these synthetic benzodiazepines, including the drugs’ actual or relative potential for abuse, the scientific knowledge surrounding these substances, and observed public use and misuse of benzodiazepines.

When commission staff were made aware of the temporary scheduling status and DEA rulemaking, they determined that it would be in the commission’s interest to consider placing the named synthetic benzodiazepines in WAC 246-945-051 Schedule I. This would align state WAC relating to the designation of those synthetic benzodiazepines with federal law.

#### Assessment

In RCW 69.50.201, the commission is granted authority to add, delete, or reschedule any substance listed in RCW 69.50.204, 69.50.206, 69.50.208, 69.50.210, or 69.50.212 via the rulemaking process.

When making a determination on a substance the commission must consider the following factors:

- (i) the actual or relative potential for abuse;
- (ii) the scientific evidence of its pharmacological effect, if known;
- (iii) the state of current scientific knowledge regarding the substance;
- (iv) the history and current pattern of abuse;
- (v) the scope, duration, and significance of abuse;
- (vi) the risk to the public health;
- (vii) the potential of the substance to produce psychic or physiological dependence liability; and
- (viii) whether the substance is an immediate precursor of a controlled substance.

Rulemaking Authorization: Scheduling Multiple Synthetic Benzodiazepines  
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However, RCW 69.50.201(2) allows the commission to “consider findings of the federal Food and Drug Administration or the Drug Enforcement Administration as prima facie evidence relating to one or more of the determinative factors.” Further, RCW 69.50.201(5) allows the commission to “schedule a substance in Schedule I regardless of whether the substance is substantially similar to a controlled substance in Schedule I or II if the commission finds that scheduling of the substance on an emergency basis is necessary to avoid an imminent hazard to the public safety and the substance is not included in any other schedule or no exemption or approval is in effect for the substance under Section 505 of the federal Food, Drug, and Cosmetic Act, 21 U.S.C. Sec. 355. ... A rule may not be adopted under this subsection until the commission initiates a rule-making proceeding under subsection (a) [(1)] of this section with respect to the substance.”

With the above framework, the commission has the authority to schedule clonazepam, diclazepam, etizolam, flualprazolam, flubromazolam, and bromazolam on both a permanent and emergency basis.

### **Recommendation**

Staff recommend that the commission make a motion to initiate standard rulemaking to consider placing clonazepam, diclazepam, etizolam, flualprazolam, flubromazolam, and bromazolam in WAC 246-945-051 Schedule I and to task staff with drafting and filing a CR-101P Rules Inquiry on that topic. The commission can also make the determination that scheduling these synthetic benzodiazepines in Washington state represents an immediate need to protect public health and safety and task staff with initiating emergency rulemaking by filing a CR-103E.

# PETITION FOR RULEMAKING

Submitted to:

## Pharmacy Quality Assurance Commission

State of Washington

**PRIMARY STATUTORY AUTHORITY: RCW 69.38.010(4) — "Poison" Defined**

### **Re: A Petition for Formal Designation of Elemental Mercury (Hg<sup>0</sup>) and Methylmercury (CH<sub>3</sub>Hg<sup>+</sup>) as Poisons Pursuant to RCW 69.38.010(4)**

*Submitted pursuant to RCW 34.05.330 (Petition for Adoption, Amendment, or Repeal of Rules)*

**April 26, 2026**

#### **PETITIONER:**

Bill Osmunson DDS MPH

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[Billosmunson3@gmail.com](mailto:Billosmunson3@gmail.com)

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## **I. INTRODUCTION AND NATURE OF THE PETITION**

Petitioner(s) respectfully submit this Petition for Rulemaking to the Pharmacy Quality Assurance Commission (the "Commission") pursuant to RCW 34.05.330. This petition asks the Commission to exercise the express authority granted to it under **RCW 69.38.010(4)** — the single most direct statutory mechanism available in Washington law for this purpose — to formally designate:

- Elemental mercury (Hg<sup>0</sup>; CAS No. 7439-97-6), including as delivered to the human body through continuous vapor emission from dental amalgam restorations; and
- Methylmercury (CH<sub>3</sub>Hg<sup>+</sup>; CAS No. 22967-92-6), the organic mercury compound that accumulates in the food chain and is the primary mercury hazard from fish consumption;

as "poisons" within the meaning of Chapter 69.38 RCW, triggering the full suite of poison register, sale, labeling, manufacturer licensing, and disciplinary enforcement requirements of that chapter.

This designation would be made under subsection (4) of RCW 69.38.010, which reserves to the Commission precisely this authority: to add to the statutory list of named poisons "**[a]ny other substance designated by the pharmacy quality assurance commission which, when introduced into the human body in quantities of sixty grains or less, causes violent sickness or death.**" Both elemental mercury and methylmercury satisfy this statutory standard without qualification, as established by decades of toxicological research, federal regulatory findings, and international treaty consensus.

In conjunction with that designation, petitioner(s) also request that the Commission:

1. **Require mandatory POISON labeling** on all products incorporating elemental mercury or methylmercury — including dental amalgam alloys — at the point of manufacture, wholesale distribution, and clinical dispensing in Washington State, pursuant to RCW 69.40.030;
2. **Impose poison register and licensing requirements** on manufacturers and distributors of dental amalgam under RCW 69.38.030 and RCW 69.38.060;
3. **Adopt protective WAC rules** under the Commission's authority in Chapter 18.64 RCW and WAC 246-945 requiring informed consent documentation and clinical certification for amalgam use in FDA-identified high-risk populations; and
4. **Transmit a legislative recommendation** to the Washington State Legislature that Chapter 69.38 RCW be amended to add elemental mercury and methylmercury to the chapter's statutory enumeration by name, and that the Commission be granted express authority to prohibit clinical placement of mercury-containing dental amalgam in the State of Washington.

## II. THE PRIMARY STATUTORY AUTHORITY: RCW 69.38.010(4)

### A. Text of the Statute

Chapter 69.38 RCW, titled "Poisons — Sales and Manufacturing," defines "poison" at RCW 69.38.010 as follows:

*"As used in this chapter 'poison' means: (1) Arsenic and its preparations; (2) Cyanide and its preparations, including hydrocyanic acid; (3) Strychnine; and (4) Any other substance designated by the pharmacy quality assurance commission which, when introduced into the human body in quantities of sixty grains or less, causes violent sickness or death."*

Subsection (4) is a **delegation of direct rulemaking authority to the Commission**. The Legislature has made the policy judgment that the three named poisons — arsenic, cyanide, and strychnine — warrant statutory enumeration, and has entrusted to the Commission the ongoing expert authority to add further substances by designation when they satisfy the same functional standard: causing violent sickness or death when introduced into the human body in quantities of sixty grains (approximately 3.9 grams) or less. This is exactly the kind of expert regulatory judgment Washington law assigns to the Commission.

### B. The Standard: "Violent Sickness or Death" in Quantities of Sixty Grains or Less

Sixty grains equals approximately 3.888 grams, or 3,888 milligrams. The relevant question under RCW 69.38.010(4) is whether elemental mercury and/or methylmercury cause violent sickness or death when introduced into the human body at or below that quantity.

### ***Elemental Mercury***

The answer is unambiguously yes. The U.S. Agency for Toxic Substances and Disease Registry (ATSDR) and the U.S. EPA have established that acute inhalation of elemental mercury vapor at concentrations achievable from a few grams of liquid mercury causes severe neurological damage, respiratory failure, and death. The **minimum lethal dose of elemental mercury in humans is well below 60 grains**. Acute exposure to as little as 1–2 grams of elemental mercury vapor — a fraction of the 60-grain threshold — is documented to cause fulminant neurological injury and has resulted in fatalities. At lower chronic doses, elemental mercury causes progressive neurological destruction, renal failure, and systemic organ damage — each constituting "violent sickness" within the plain meaning of the statute.

Of particular relevance to the dental context: **an average amalgam filling contains approximately 500–1,000 milligrams (7.7–15.4 grains) of elemental mercury**. A full dental amalgam load of multiple restorations may contain several grams. Mercury vapor is continuously released throughout the life of each restoration. While the rate of chronic daily release is low (estimated at 1–27 micrograms/day per person by the WHO), the cumulative body burden over decades of exposure, and the acute spikes from placement, removal, grinding, and chewing, constitute exactly the kind of exposure pathway that the toxicology of this substance warrants regulating under the poison framework.

### ***Methylmercury***

Methylmercury is one of the most potent neurotoxins known to science. The **lethal oral dose of methylmercury compounds in humans is well below 60 grains**. Documented mass poisoning events — including the Minamata disease disaster in Japan and the Iraqi grain poisoning of the 1970s — established that ingestion of methylmercury in quantities causing blood levels above 200 micrograms/liter results in severe neurological disability and death. Sub-lethal exposures cause permanent brain damage, developmental disability, blindness, and paralysis. These are paradigmatic examples of "violent sickness" as the Legislature intended that phrase in RCW 69.38.010(4).

### **C. The Dental Amalgam Exemption Gap: RCW 69.38.020**

RCW 69.38.020 provides that substances regulated under chapters 15.58, 17.21, 69.04, 69.41, 69.45, and 69.50 RCW are exempt from Chapter 69.38. Dental amalgam is **not regulated under any of those chapters**. It is not a controlled substance (ch. 69.50), a legend drug (ch. 69.41), a pesticide (ch. 17.21 or 15.58), a drug or cosmetic for purposes of the Washington Food, Drug, and Cosmetic Act (ch. 69.04) in the sense that would trigger exemption, or a precursor chemical (ch. 69.45). Dental amalgam alloy distributed from dental supply manufacturers to dental practices therefore **falls entirely within Chapter 69.38's scope**, with no applicable exemption. The Commission's designation of elemental mercury under RCW 69.38.010(4) would directly and immediately subject mercury-containing dental products to the chapter's full requirements.

### **D. Practical Consequences of Designation Under RCW 69.38**

A designation under RCW 69.38.010(4) would trigger the following requirements of Chapter 69.38 with respect to elemental mercury and methylmercury, including as present in dental amalgam products:

- **Poison Register (RCW 69.38.030):** Every seller of a designated poison must, before completing a sale, record the purchaser's name and address, the date of sale, the article sold, the quantity sold, and the purpose for which it was purchased. Both buyer and seller must sign the register. This would apply to dental supply manufacturers and distributors selling amalgam alloy to dental practices.

- **Purchaser Identification (RCW 69.38.030):** The purchaser must present photo identification. No sale may be made unless the seller is satisfied the poison will be used for a lawful purpose.
  - **Poison Register Inspection and Preservation (RCW 69.38.040):** Registers must be open to inspection by law enforcement and health officials at all times and preserved for at least two years. Failure to maintain the register is a misdemeanor.
  - **Manufacturer and Seller Licensing (RCW 69.38.060):** Manufacturers and sellers of designated poisons are required to obtain a license. The Commission controls this licensing, and the uniform disciplinary act (ch. 18.130 RCW) governs discipline of licensees.
  - **False Representation Prohibition (RCW 69.38.050):** Any person making a false representation to a seller when purchasing a designated poison commits a separate statutory violation.
  - **Enforcement Through Chapter 18.64 (RCW 69.38.070):** Chapter 18.64 RCW governs the denial of licenses and discipline of persons licensed under Chapter 69.38, keeping the Commission's enforcement authority fully engaged.
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### III. SUPPORTING STATUTORY AUTHORITIES

#### A. RCW 69.40.030 — Mandatory "POISON" Labeling

*"It shall be unlawful for any person to sell at retail or furnish any repackaged poison drug or product without affixing . . . the word 'poison' distinctly shown . . . The pharmacy quality assurance commission shall have the authority to promulgate rules for the enforcement and implementation of this section."*

Once elemental mercury is designated a poison under RCW 69.38.010(4), any dental amalgam product sold or furnished at retail in Washington must bear a POISON label under RCW 69.40.030. The Commission has express rule-promulgation authority for this requirement.

#### B. RCW 18.64.005 and WAC 246-945 — General Commission Rulemaking Authority

The Commission's general rulemaking authority under RCW 18.64 and Chapter 246-945 WAC supports imposition of additional dispensing controls, informed consent requirements, and clinical certification requirements for amalgam use in high-risk populations — complementing and reinforcing the RCW 69.38 designation.

#### C. RCW 34.05.330 — Petition for Rulemaking

Any person may petition a Washington state agency to adopt, amend, or repeal a rule. The Commission must respond within 60 days, either by initiating rulemaking or by denying the petition in writing with stated reasons. This petition is submitted pursuant to that authority.

## IV. SCIENTIFIC AND MEDICAL BASIS

### A. Mercury Is an Established, Recognized Neurotoxin with No Safe Threshold

Mercury is classified by the World Health Organization (WHO) as one of the ten chemicals of greatest public health concern globally (Mercury, Lead, Arsenic, Cadmium, Asbestos, Benzene, Dioxins, PCBs, Air pollution, and Highly hazardous pesticides.) The WHO, the U.S. EPA, and the U.S. Agency for Toxic Substances and Disease Registry (ATSDR) have each independently concluded that:

- Mercury targets the central nervous system, kidneys, liver, immune system, and respiratory system;
- Elemental mercury vapor, once inhaled, crosses the blood-brain barrier with ease due to its lipid solubility, is converted to inorganic mercury in brain cells by catalase oxidation, and persists in the brain with a half-life estimated at up to several decades;
- Recent studies suggest mercury may have no threshold below which some adverse effects do not occur — placing it in the same no-threshold category as ionizing radiation and certain carcinogens; and
- Children, fetuses, and individuals with genetic variants affecting mercury detoxification (including CPOX4 and APOE4 polymorphisms, present in an estimated 25–50% of the population) experience significantly amplified neurotoxic effects at exposures previously considered safe for the general population.

### B. Dental Amalgam Is the Primary Source of Elemental Mercury Exposure for Most Americans

Dental amalgam restorations, composed of approximately 45–55% elemental mercury by weight, continuously emit elemental mercury vapor throughout their lifespan. Key facts established by the scientific literature:

- Approximately 80% of inhaled mercury vapor from amalgam is absorbed through the lungs and distributed systemically, accumulating in the brain, kidney, liver, and gastrointestinal tract;
- The WHO estimates daily mercury intake from amalgam of 1–27 micrograms per day; research has estimated that 67–122 million Americans exceed the mercury vapor intake levels considered safe by the U.S. or California EPA due to dental amalgam alone;
- Actions including chewing, grinding, and hot beverage consumption cause acute mercury vapor spikes 7 to 20 times baseline levels;
- The half-life of mercury in the kidney is approximately 58 days; mercury deposited in the brain can remain for decades; and
- Amalgam placement and removal create the highest transient exposure spikes, with vapor concentrations reaching levels associated with acute neurological symptoms.

The dose-response relationship between occupational mercury exposure in dental workplaces and adverse reproductive outcomes in female dental workers provides independent, human-population evidence that elemental mercury vapor causes violent sickness — including miscarriage, premature birth, and perinatal death — well within the exposure quantities contemplated by RCW 69.38.010(4). Six independent studies across five countries document this relationship:

- *Nixon et al. (1979, UK): Female dentists experienced higher than expected rates of spontaneous abortion and perinatal mortality compared to population norms (Br Dent J 146: 39–42).*

- *Heidam (1984, Denmark): Dental assistants showed elevated spontaneous abortion rates compared to occupationally unexposed controls (J Epidemiol Community Health 38: 149–155).*
- *Sikorski et al. (1987, Poland): Female dental workers demonstrated significantly elevated rates of miscarriage and premature delivery compared to controls, with findings linked to measurable mercury exposure levels (Int Arch Occup Environ Health 59: 551–557).*
- *Rowland et al. (1992/1995, USA — 7,000 California dental assistants): Women with the highest unscavenged mercury and nitrous oxide exposures experienced a 50% spontaneous abortion rate compared to 8% in unexposed women (RR 2.6; 95% CI 1.3–5.0). Published in the New England Journal of Medicine (327: 993–997) and American Journal of Epidemiology (141: 531–538).*
- *Lindbohm et al. (2007, Finland — 222 miscarriage cases, 498 controls): Women dental workers with moderate occupational exposure to mercury amalgam had twice the miscarriage risk of unexposed controls (OR 2.0; 95% CI 1.0–4.1), with blinded occupational hygienist assessment of exposure (Occup Environ Med 64: 127–133).*
- *Naimi-Akbar et al. (2012, Sweden): Sons of female dental nurses showed excess neonatal mortality during the high-mercury-exposure era of the 1960s, with risk declining across subsequent decades as mercury hygiene in Swedish dental offices improved — a natural dose-response experiment across time confirming mercury as the operative exposure (Scand J Work Environ Health 38: 546–552).*

This body of occupational epidemiology establishes that elemental mercury vapor, at concentrations achievable in dental workplaces handling amalgam, such as dental offices, dental and dental hygiene schools, causes violent sickness and death within the meaning of RCW 69.38.010(4). The declining harm observed as hygiene standards improved — and the rising harm documented in earlier, higher-exposure eras — is the signature of a genuine dose-response relationship with mercury, not a confounded or artifactual association.

### **C. Dental Schools and Training Environments Present Elevated and Inadequately Controlled Mercury Vapor Exposure**

Dental schools represent a distinct and particularly concerning mercury vapor exposure environment. Student operators are inexperienced in amalgam handling technique, training conditions frequently replicate the highest-risk clinical scenarios, and the populations present — including students, faculty, patients, and administrative staff — include individuals of reproductive age who may be pregnant. Multiple independent studies have measured mercury vapor concentrations in dental school environments and found conditions that routinely exceed occupational safety thresholds. Dental School Laboratories often do not provide exhaust protection when many students are working on mercury at the same time.

Warwick, O'Connor & Lamey (2013) — University of Alberta (*J Occup Med Toxicol* 8:27; *PMC3850894*)

Three dental students at their own school measured ambient mercury vapor during amalgam removal under three conditions routinely used in dental student training. When water spray and suction were both used, vapor levels ranged from 4.0 to 19.0  $\mu\text{g}/\text{m}^3$  (mean 8.0  $\mu\text{g}/\text{m}^3$ ) — below the 25  $\mu\text{g}/\text{m}^3$  occupational threshold limit value. When suction alone was used without water spray — a common training condition — levels ranged from 14.0 to 999.0  $\mu\text{g}/\text{m}^3$  (mean 141.0  $\mu\text{g}/\text{m}^3$ ), exceeding the threshold 8% of the time. When neither water spray nor suction was used, levels ranged from 34.0 to 796.0  $\mu\text{g}/\text{m}^3$  (mean 214.0

µg/m<sup>3</sup>), with 36% of readings exceeding the absolute ceiling value of 125 µg/m<sup>3</sup> — a limit that is not to be exceeded at any time under Alberta law, and is comparable to U.S. OSHA and NIOSH limits. The researchers further observed that dental students routinely roll up their sleeves during laboratory work, creating significant skin-contact exposure to amalgam particulate in addition to inhalation — a route of mercury absorption not captured by air monitoring alone.

Torres-Reyes et al. (2008) — University of Puerto Rico School of Dentistry (*J Exposure Sci Environ Epidemiol*; PMID 18203562)

Mercury vapor was measured in both the Dental Simulation Laboratory (DSL) and the Dental Clinic (DC) at the University of Puerto Rico's School of Dentistry. Vapor concentrations in the simulation laboratory reached 3.3 mg/m<sup>3</sup> (3,300 µg/m<sup>3</sup>) — more than 130 times the OSHA permissible exposure limit for an 8-hour workday. In the active dental clinic, vapor levels reached 102.7 µg/m<sup>3</sup>, exceeding the absolute ceiling value. These concentrations would require immediate evacuation and hazmat response in any regulated industrial workplace.

Tezel et al. (2001) — Dental School, Turkey (*Br Dent J* 191: 449–452; PMID 11720018)

This study measured plasma mercury in dental students and dental school faculty at the start and end of an academic year and found a result that goes well beyond training technique. Plasma mercury concentrations increased significantly in all groups by year's end — including in first-year students who had not yet begun clinical work, and in controls working only in teaching classrooms. The authors concluded that the increases were attributable to background mercury exposure from the accumulation of spilled mercury and amalgam residues in floors and at floor level throughout the building. Mercury vaporizing from historic floor contamination was elevating blood mercury in people who had never handled amalgam. This finding establishes that the risk in a dental school is not limited to students performing procedures: it extends to anyone who spends time in the building.

Ritchie et al. (2004) — 180 Dental Practices, West of Scotland (*Br Dent J* 197(10): 625–632; PMID 15611750)

Although this landmark study surveyed established dental practices rather than schools, its environmental findings are directly applicable to any dental workplace, including training facilities. Of 180 dental surgeries visited, 67.8% had mercury measurements above the Occupational Exposure Standard in at least one area, with the highest levels found at floor level — at the skirting boards and around the base of the dental chair. In 25% of practices, the personal dosimetry measurement in the breathing zone of dental staff exceeded the OES. Dentists had urinary mercury levels averaging more than four times those of control subjects. A 35-year Scottish dental monitoring program confirmed these findings over time, documenting that administrative staff with no direct amalgam contact had systemic mercury exposure detectable in hair, nail, and urine samples — and that staff wearing open-toed shoes had significantly higher toenail mercury than those wearing closed shoes, confirming floor-level contamination as a primary exposure route.

What these findings collectively establish for this petition:

Dental school environments present mercury vapor exposures that: (1) routinely exceed occupational safety thresholds during standard training procedures; (2) expose people who never handle amalgam — including first-year students, faculty, and administrative staff — through floor contamination; and (3) occur in environments where pregnant students,

pregnant faculty, pregnant patients, and pregnant support staff may be present without any warning that the substance responsible for these vapor levels is handled, stored, and trained with in the same building where they work and learn.

Washington State licenses dental schools and regulates the practice of dentistry through the Commission's enabling statutes. The Commission's designation of elemental mercury as a poison under RCW 69.38.010(4) would, at minimum, require that the poison register and seller licensing requirements of Chapter 69.38 apply to amalgam distributed to those schools, and would create a framework within which the Commission could establish mercury hygiene standards for training environments as a condition of licensure. The evidence reviewed here establishes that the current state of training — where standard student technique produces vapor concentrations exceeding safety limits in a substantial percentage of measurements — is itself a public health problem that Washington State's regulatory framework exists to address.

#### **D. Fetal and Infant Exposure — The Case for Urgent Action**

The evidence that prenatal and neonatal exposure to elemental mercury from maternal dental amalgam causes harm to the developing human is substantial and multi-sourced:

- The human placenta does not constitute an effective barrier to elemental mercury vapor. Mercury concentrations in fetal brain, liver, and kidneys correlate significantly and dose-dependently with the number of maternal amalgam fillings;
- A prospective case-controlled study found both maternal serum mercury and umbilical cord mercury significantly higher in women with amalgam fillings than controls ( $p = 0.006$  and  $p = 0.010$ , respectively);
- The Norwegian Mother and Child Cohort Study (MoBa) — 72,038 pregnant women — found a statistically significant dose-response relationship between maternal amalgam-filled teeth and risk of perinatal death, surviving full covariate adjustment (adjusted OR 1.041; 95% CI 1.008–1.076;  $p = 0.015$ );
- Fetal hair mercury concentrations are significantly elevated in infants of mothers with amalgam fillings, whether placed before or during pregnancy; and
- Mercury is excreted in breast milk in a dose-dependent relationship with the number of maternal amalgam fillings, particularly in the first days and weeks postpartum.

#### **D. The FDA Has Formally Identified Dental Amalgam as Unsafe for High-Risk Populations**

In September 2020, the U.S. FDA issued a Safety Communication advising that dental amalgam should be avoided "whenever possible and appropriate" in:

- Pregnant women and their developing fetuses;
- Women planning to become pregnant;
- Nursing mothers and their newborns and infants;
- Children, especially those younger than six years of age;
- People with preexisting neurological disease such as multiple sclerosis, Alzheimer's disease, or Parkinson's disease;
- People with impaired kidney function; and
- People with known heightened sensitivity to mercury or other amalgam components.

The Commission has independent authority — and this petition asserts an independent obligation — to translate this federal risk determination into enforceable Washington State regulatory action through the mechanism the Legislature provided specifically for this purpose: **RCW 69.38.010(4)**.

### E. International Legal Obligations: The Minamata Convention

The United States ratified the Minamata Convention on Mercury in 2013. The Convention, in force since 2017, obligates signatory nations to implement measures to phase down dental amalgam use and to protect vulnerable populations. At the fourth Conference of the Parties (2022), more than 130 nations agreed to an amendment specifically protecting vulnerable populations from dental amalgam. Washington State regulatory action is consistent with and supports U.S. compliance with these binding international obligations.

### F. The Persistence of Disparate Harm in Vulnerable Populations

A 2024 study published in the *Journal of the American Dental Association* (Lamsal et al., JADA 155(10): 816–824) found that while amalgam use declined by 81% overall between 2017 and 2023, the decline was **smallest among the most socially vulnerable patients** — those with Medicaid coverage and the highest Social Vulnerability Index scores. This finding demonstrates that market forces and voluntary guidance systematically fail the populations most in need of regulatory protection, making the Commission's exercise of its RCW 69.38.010(4) designation authority not merely appropriate but necessary.

### G. The Manufacturer's Own Safety Data Sheet<sup>1</sup> Confirms the Poison Designation Is Warranted — and Reveals the Precise Regulatory Gap This Petition Seeks to Close

The Commission need not rely solely on independent scientific literature or federal regulatory findings to establish that elemental mercury causes violent sickness or death in quantities of sixty grains or less. **Dentsply Sirona's own official Safety Data Sheet for Dispersalloy®** — the leading pre-dosed dental amalgam product in the United States, manufactured by the world's largest dental products company — independently establishes every element of the RCW 69.38.010(4) standard and, simultaneously, demonstrates the precise labeling gap that the Commission's designation would close.

*Dispersalloy® Dispersed Phase Alloy (Capsules)*, SDS Code 556899, Dentsply Milford, revised April 18, 2016 (the most recent publicly accessible version), is the controlling manufacturer document for the product most widely distributed to Washington State dental practices. The full text of the operative hazard statements, as they appear on the manufacturer's own label, are reproduced below.

#### **1. What the Dispersalloy® Label Actually Says**

The manufacturer's GHS-compliant label bears the signal word **"DANGER"** — the highest GHS signal word category, reserved for substances presenting severe acute hazards — and includes the following verbatim hazard statements:

<sup>1</sup> Source: *Dentsply Milford Safety Data Sheet, Dispersalloy® Dispersed Phase Alloy (Capsules)*, SDS Code 556899, revised April 18, 2016. Available at: [https://www.dentsplysirona.com/content/dam/dentsply/pim/en\\_US/Restorative/Direct\\_Restoration/Amalgams/Dispersed\\_Phase\\_Amalgams/Dispersalloy\\_Dispersed\\_Phase\\_Alloy/GR556899DispersalloyCapsulesSDS%20rev%204-18-2016.pdf](https://www.dentsplysirona.com/content/dam/dentsply/pim/en_US/Restorative/Direct_Restoration/Amalgams/Dispersed_Phase_Amalgams/Dispersalloy_Dispersed_Phase_Alloy/GR556899DispersalloyCapsulesSDS%20rev%204-18-2016.pdf) The 1997 Dispersalloy MSDS including explicit contraindications for children under 6 and expectant mothers was formerly posted at [www.caulk.com/MSDSDFU/DispersDFU.html](http://www.caulk.com/MSDSDFU/DispersDFU.html) and has since been removed from public access.

▶ **"Danger — Toxic if inhaled. Avoid breathing vapours. Use in a well ventilated area. IF INHALED: remove to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or Doctor if you feel unwell."**

▶ **"Danger — May cause damage to kidneys and central nervous system through prolonged or repeated exposure. Do not breathe vapours. May be harmful if swallowed. Get medical advice if you feel unwell."**

▶ **"Danger — Very Toxic to aquatic life with long lasting effects. Avoid release to the environment."**

The label also states, under California Proposition 65: *"This product contains mercury, a chemical known to the State of California to cause birth defects or other reproductive harm."*

The manufacturer directs users, in the event of any exposure, to **call a Poison Center** — the dedicated emergency resource maintained by the federal government precisely for exposures to **poisons**. That the manufacturer instructs practitioners to treat any exposure as a poison emergency, while the product itself bears no "POISON" label, is the regulatory contradiction this petition is designed to resolve.

## **2. What the Safety Data Sheet Establishes Beyond the Label**

The full SDS contains additional admissions from the manufacturer that independently satisfy each element of the RCW 69.38.010(4) standard:

- **Mercury content confirmed at 50% by weight.** The SDS lists mercury (CAS No. 7439-97-6) as comprising 50% of the final product by weight. A single pre-dosed Dispersalloy® capsule contains approximately 400–1,000 milligrams of elemental mercury — a quantity of 6.2 to 15.4 grains. The statutory threshold under RCW 69.38.010(4) is 60 grains (3.888 grams). Each individual capsule therefore contains elemental mercury in a quantity below the 60-grain threshold, and mercury at those quantities causes violent sickness and death, as the manufacturer's own toxicological data confirm.
- **Neurotoxicity confirmed by the manufacturer.** Under Section 11 (Toxicological Information), the SDS states verbatim: *"The brain is the critical organ in humans for chronic vapor exposure; in severe cases, spontaneous degeneration of the brain cortex can occur as a late sequela to past exposure."* The manufacturer further confirms: teratogenicity in animal inhalation studies at 1 mg/m<sup>3</sup> during gestation days 1–20; reproductive effects on male spermatogenesis and post-implantation mortality at sub-microgram vapor concentrations; and mutagenicity data at 150 µg/m<sup>3</sup> in humans.
- **Corrosive hazardous materials classification for shipping.** The SDS classifies Dispersalloy® as *DOT Hazard Class 8 (Corrosive), UN Number 3506*, requiring a Corrosive hazmat label for transport. A product shipped under corrosive hazmat rules reaches the dental office without the word "POISON" anywhere on its clinical-use packaging.
- **SARA Title III / EPCRA Section 313 reporting required.** The SDS confirms that mercury in this product is subject to Annual Release Reporting Requirements under SARA Title III, Section 313 (40 CFR 372), with a Reportable Quantity of 1 pound. Facilities handling this substance in sufficient quantities are required to report releases to federal environmental authorities. The same substance, delivered into the mouth of a pregnant patient in a Washington dental office, is subject to no equivalent state-law disclosure or control.
- **CERCLA Reportable Quantity of 1 pound.** Under CERCLA Section 103, any spill of mercury exceeding 1 pound (approximately 454 grams, or 7,006 grains) must be reported to the National Response Center. The RCW 69.38.010(4) threshold of 60 grains is roughly 117

times lower than the CERCLA reporting quantity — confirming that Washington's poison statute is calibrated to protect against **far smaller quantities** than even federal environmental emergency law requires reporting.

- **The original contraindications were removed from public access.** The predecessor MSDS for Dispersalloy®, dated September 24, 1997 and posted by Dentsply/Caulk at www.caulk.com, explicitly listed contraindications including: children 6 and under; expectant mothers; and patients with severe renal deficiency. That document was removed from the manufacturer's website within approximately six months of posting. The 2016 SDS that replaced it does not include these contraindications in equivalent explicit form, though the hazard data underlying them remain present. The Commission should be aware that the most protective version of the manufacturer's own warnings was the one that was withdrawn from public access.

### 3. The Critical Label Omission: "POISON" Does Not Appear

A complete review of the Dispersalloy® SDS (SDS Code 556899, April 18, 2016) confirms the following: **the word "POISON" does not appear anywhere on the product label or packaging**, other than in the phrase "Call a POISON CENTER or Doctor if you feel unwell" — a direction to seek emergency poison-response services, not a declaration that the product itself is a poison.

**Table IV-G: Dispersalloy® Label Language Compared to Washington State Poison Requirements**

Requirement / Standard	What Dispersalloy® Label Currently Shows	What WA Law Requires After Designation
<b>Signal Word</b>	"DANGER" (GHS)	<b>"POISON"</b> (RCW 69.40.030) prominently displayed
<b>Poison Center Reference</b>	<i>"Call a POISON CENTER or Doctor if you feel unwell"</i>	Product itself must be labeled a poison; Poison Center direction retained
<b>Poison Register at Point of Sale</b>	<b>None</b> — no purchase record required	Required under RCW 69.38.030: buyer ID, signature, stated purpose
<b>Seller Licensing</b>	<b>None</b> — no poison-seller license required in WA	Required under RCW 69.38.060; Commission controls licensure
<b>Pregnancy Warning</b>	<i>CA Prop 65 only</i> — no WA-specific warning	Informed consent + clinical certification rules required under WAC 246-945
<b>Shipping Classification</b>	DOT Class 8 Corrosive, UN 3506 — hazmat label required in transit	Corrosive + POISON label required at clinical-use destination in WA

Requirement / Standard	What Dispersalloy® Label Currently Shows	What WA Law Requires After Designation
<b>Contraindications for Children / Pregnant Women</b>	<i>Removed from public-facing labeling after 1997 MSDS withdrawal</i>	Restored and enforced through Commission clinical certification rules

**4. The Manufacturer's Label Is Itself Evidence That the Designation Is Required**

The Dispersalloy® SDS demonstrates, in the manufacturer's own words, that elemental mercury is a substance that: causes acute neurological toxicity by inhalation; causes degeneration of the brain cortex with chronic exposure; causes kidney and central nervous system damage; is teratogenic in animal studies; is classified as a hazardous air pollutant under the Clean Air Act; is a Priority Pollutant and Toxic Pollutant under the Clean Water Act; requires SARA Section 313 release reporting; triggers CERCLA Reportable Quantity obligations at 1 pound; requires DOT corrosive hazmat placarding in transport; and mandates that any person exposed immediately contact a Poison Center.

Every one of these characteristics is consistent with — and most are direct evidence of — a substance that **"when introduced into the human body in quantities of sixty grains or less, causes violent sickness or death"** within the meaning of RCW 69.38.010(4). The manufacturer has, in effect, already made the Commission's case. The only remaining step is for the Commission to exercise the authority the Legislature delegated to it and make the formal designation that the product's own safety documentation demands.

Washington State currently requires a **hazmat shipping label** when this product is transported across the country, and directs any person exposed to it to call a **Poison Center** — but does not require the word "POISON" to appear on the product when it is placed into the mouth of a pregnant woman or a child. That is the gap this petition asks the Commission to close.

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**V. SPECIFIC RELIEF REQUESTED**

**Petitioner(s) respectfully request that the Commission take the following actions:**

- 5. Primary Designation Under RCW 69.38.010(4).** Adopt a rule designating elemental mercury (Hg<sup>0</sup>; CAS No. 7439-97-6) and methylmercury (CH<sub>3</sub>Hg<sup>+</sup>; CAS No. 22967-92-6), in all forms and delivery mechanisms including dental amalgam restorations, as "poisons" under RCW 69.38.010(4), with the finding that each substance, when introduced into the human body in quantities of sixty grains or less, causes violent sickness or death as required by the statute.
- 6. Poison Register Requirements.** Require that all manufacturers, wholesalers, and distributors of products containing elemental mercury or methylmercury — including dental amalgam alloy — comply with the poison register, purchaser identification, and transaction recording requirements of RCW 69.38.030.

7. **Manufacturer and Seller Licensing.** Require that manufacturers and sellers of products containing designated mercury compounds obtain licensure under RCW 69.38.060, subject to the Commission's licensing authority and the disciplinary provisions of the Uniform Disciplinary Act (ch. 18.130 RCW).
8. **Mandatory POISON Labeling.** Require, pursuant to RCW 69.40.030 and the Commission's rule-promulgation authority thereunder, that all dental amalgam products sold, furnished, or distributed at retail in Washington State bear a label displaying the word "POISON" conspicuously, along with all FDA-required labeling and a statement identifying the mercury content by weight.
9. **Informed Consent and Clinical Certification Rules.** Adopt rules under WAC 246-945 requiring that: (a) any licensed dentist placing dental amalgam in Washington must obtain documented written informed consent disclosing that amalgam contains approximately 50% elemental mercury, a designated poison; citing the FDA's 2020 high-risk guidance; and identifying mercury-free alternatives; and (b) placement of amalgam in any FDA-identified high-risk patient (including pregnant women, children under six, and those with neurological or renal conditions) requires a written clinical determination that no clinically appropriate alternative is available.
10. **Legislative Recommendation.** Transmit a formal written recommendation to the Washington State Legislature that: (a) Chapter 69.38 RCW be amended to add elemental mercury and methylmercury to the statutory enumeration in subsections (1)–(3); (b) the Commission be granted express statutory authority to prohibit the clinical placement and non-prescription sale of mercury-containing dental amalgam in Washington; and (c) a mandatory phaseout date be established consistent with the Minamata Convention.
11. **Initiation of CR-101 Proceedings.** Publish a pre-proposal statement of inquiry (CR-101) within 60 days of receipt of this petition, initiating formal rulemaking proceedings under RCW 34.05.320, and schedule a public hearing on the proposed designation.

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## VI. ADDRESSING ANTICIPATED OBJECTIONS

### A. "Dental amalgam is regulated by the FDA — Washington cannot act."

Federal FDA device regulation of dental amalgam does not preempt state poison law. The FDA's own 2020 Safety Communication expressly acknowledges that states may and should implement additional protective measures. Washington's authority to designate mercury as a poison under its own law — a core exercise of the state's traditional police power over public health — is not occupied or preempted by FDA device classification. The FDA has itself stated that high-risk populations should avoid amalgam "whenever possible"; Washington State regulation translates that guidance into enforceable obligation within the state's boundaries.

### B. "The amounts released from amalgam are too low to constitute 'violent sickness or death.'"

RCW 69.38.010(4) asks whether the **substance**, not the chronic daily release rate from a specific product, causes violent sickness or death in quantities of sixty grains or less. Elemental mercury unambiguously does so — acute inhalation of even one to two grams causes neurological injury and death in documented cases. The statute does not require that the specific product deliver the full sixty-grain dose in a single exposure; it designates the **substance** as a poison based on its inherent toxicity. Arsenic, cyanide, and strychnine — the named comparators in the statute — are

similarly present in various products at concentrations that do not cause acute death with every use; they are designated because the substance itself is inherently toxic at sixty grains or less.

### **C. "Amalgam has been used safely for 150 years."**

Longevity of use is not evidence of safety at the regulatory margin. Lead-based paint, asbestos, and thalidomide all had lengthy histories of widespread use before their toxicological harms were fully characterized. The relevant question is what the current state of science shows about the substance's effects on the most vulnerable populations — pregnant women, fetuses, infants, and children — not whether the average healthy adult tolerated routine exposure. The current evidence base is the product of biomarker-based cohort science that simply did not exist when amalgam's widespread use was established.

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## **VII. SUPPORTING AUTHORITIES**

### **Washington State Statutes**

- RCW 69.38.010 — "Poison" defined (primary authority for designation)
- RCW 69.38.020 — Exemptions from Chapter 69.38 (dental amalgam not exempt)
- RCW 69.38.030 — Poison register and purchaser identification requirements
- RCW 69.38.040 — Poison register inspection and preservation requirements
- RCW 69.38.050 — False representation when purchasing a poison — penalty
- RCW 69.38.060 — Manufacturer and seller licensing requirements
- RCW 69.38.070 — Enforcement through Chapter 18.64 and Uniform Disciplinary Act
- RCW 69.40.030 — Mandatory "POISON" labeling; Commission rule-promulgation authority
- RCW 18.64.005 — Pharmacy Quality Assurance Commission general authority
- RCW 34.05.320–.330 — Washington Administrative Procedure Act, rulemaking and petitions
- WAC 246-945 — Commission rules (dispensing, legend drugs, controlled substances)

### **Federal Regulatory Actions**

- U.S. FDA Safety Communication (September 2020): Dental Amalgam Fillings — Recommendations for Certain High-Risk Groups
- U.S. EPA ATSDR Toxicological Profile for Mercury (2022 update)
- U.S. EPA Reference Concentration (RfC) for elemental mercury vapor: 0.0003 mg/m<sup>3</sup>
- U.S. National Toxicology Program (NTP): Classification of mercury compounds as toxic substances

### **International Authorities**

- Minamata Convention on Mercury (2013), Annex A — Dental Amalgam Phasedown Measures; entered into force August 16, 2017
- Fourth Conference of the Parties to the Minamata Convention (2022) — Amendment protecting vulnerable populations

- European Union Regulation 2017/852 on Mercury, as amended (banning amalgam use in children under 15, pregnant women, and breastfeeding mothers from 2018)
- World Health Organization (2005). Mercury in Health Care: Policy Paper; and WHO (2011). Guidance for Identifying Populations at Risk from Mercury Exposure

### **Scientific Literature (Selected)**

- Björkman L. et al. (2018). Perinatal death and exposure to dental amalgam fillings during pregnancy in the population-based MoBa cohort. PLoS ONE 13(12): e0208803.
- Drasch G. et al. (1994). Mercury burden of human fetal and infant tissues. European Journal of Pediatrics 153(8): 607–610.
- Findik R.B. et al. (2016). Mercury concentration in maternal serum, cord blood, and placenta in patients with amalgam dental fillings. Journal of Maternal-Fetal & Neonatal Medicine 29(22): 3665–3669.
- Just A. and Kall J. (2017). Why We All Don't Get Sick in the Same Way: The Science Behind Dental Mercury. International Academy of Oral Medicine and Toxicology.
- Lamsal R. et al. (2024). Declining US Dental Amalgam Restorations in US Food and Drug Administration-Identified Populations: 2017–2023. JADA 155(10): 816–824.
- Lindow S.W. et al. (2003). Maternal and neonatal hair mercury concentrations: the effect of dental amalgam. BJOG 110(3): 287–291.

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## **VIII. CONCLUSION**

RCW 69.38.010(4) exists for exactly this purpose. The Legislature, in enacting Chapter 69.38, named three poisons — arsenic, cyanide, and strychnine — and then delegated to the Commission the continuing scientific and regulatory judgment to add any other substance that causes violent sickness or death when introduced into the human body in quantities of sixty grains or less. Elemental mercury and methylmercury satisfy that standard without any question or ambiguity. They are recognized globally as among the most dangerous substances known to toxicology. The only reason they do not already appear on Washington's poison list is that the Commission has not yet been asked to exercise the authority it was given.

That changes with this petition. Petitioner(s) ask the Commission to act on the authority the Legislature gave it, on the evidence science has produced, and on the regulatory determination the FDA itself has already reached with respect to the most vulnerable members of our community: pregnant women, their fetuses, newborns, infants, and young children. The poison register, labeling, and licensing requirements of Chapter 69.38 exist to protect Washington residents from exactly the substances being identified here. The Commission is the body the Legislature entrusted to make this determination. The scientific record compels it. The public health requires it.

Petitioner(s) respectfully request that the Commission grant this petition, issue a written response within 60 days as required by RCW 34.05.330, and initiate formal rulemaking proceedings under RCW 34.05.320 at the earliest practicable opportunity.

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## IX. CERTIFICATION AND SIGNATURE

I, the undersigned petitioner, certify under penalty of perjury under the laws of the State of Washington (RCW 9A.72.085) that the factual statements contained in this petition are true and correct to the best of my/our knowledge, information, and belief, and that this petition is submitted in good faith for the purpose of protecting public health.

**Signature:** *Bill Osmunson DDS MPH* **Date:** *April 26, 2026*