Draft

STATE OF WASHINGTON

Pharmacy Quality Assurance Commission

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December 3, 2020

COVID-19, Rulemaking and Chapter 246-945 Review

Agenda

Time:	9:00 AM (Open Session)
Location:	Webinar
Contact:	Doreen Beebe, Program Manager (360) 236-4834 doreen.beebe@doh.wa.gov or Commission Office: wspqac@doh.wa.gov

Participate in person or register as an attendee by webinar ID# 509-709-859
Phone +1 (415) 655-0060
Access Code: 336-919-479
Audio PIN: Shown after joining the webinar

All attendees will join the call with their audio connection muted. If you wish to speak, please be sure to enter an audio pin given to you when you sign in.

The times on the agenda for this meeting are approximate and subject to change. The commission may need to adjust times or order of agenda items. The commission may take final action on any matter listed on the agenda, and/or on any matter added to the agenda in a regular meeting. The commission may meet in an executive session closed to the public for any reason listed in RCW 42.30.110, and may take final action in the public portion of the meeting following an executive session. The reason for the executive session and duration will be announced prior to the start of the executive session. The commission may meet in a closed session during this meeting for any reason listed in RCW 42.30.140, including but not limited to deliberations on enforcement (quasi-judicial) matters.

This business meeting is being held by webinar due to the current state of emergency and Governor Inslee's Proclamation 20-05 waiving and suspending the portions of Open Public Meetings Act that requires in-person meetings. This meeting is being recorded for the Department of Health, Pharmacy Quality Assurance Commission's Official Rule-Making file and for future reference.

9:00 am

1. **Call to Order** Tim Lynch, Chair ***Action***
   - **1.1** Meeting Agenda Approval – December 3, 2020

9:05 am

2.COVID-19 Update

2.1 Department of Health Vaccine Update**.**

9:30 am

3. Rulemaking. ***Action/Information.***

3.1 Review for adoption expedited rule making filed under WSR 20-16- 045 proposing to repeal former commission rule chapters replaced by chapter 246-945 WAC.

3.2 Review draft rule language for approval to de-schedule Epidiolex, and to authorize staff to prepare and file notice of proposed rule/public hearing (CR 102 permanent rules).

BREAK (10 minutes)

10:10 am

3.3 Commission needs to be updated on the joint authority for the SSB 5380 e-prescribing waivers. Commission will need to re-approve filing the CR-101 under joint authority with the Department

3.4 Commission needs to review and approve draft rule language for ESHB 1551 AIDS education repeal. Once approved staff will file CR-105.

3.5 Review for approval draft rule language to make technical corrections to chapter 246-945 WAC*),* and to authorize staff to prepare and file notice with the code reviser's office. (CR-105 Expedited Rules)

LUNCH (30 minutes)

12:00 pm

4. Discuss issues related to chapter 246-945 WAC/Implementation. ***Action/Information***

4.1 Provide guidance for discontinue credential statute for Retired Pharmacists (formerly under WAC 246-863-080).

4.2 Provide guidance on discontinued credential qualifications for foreign pharmacist graduates with applicants in pending status or active pharmacy intern credentials before July 1, 2020 as it relates to internship hours [WAC 246-945-162(2)(c)].

4.3 Commission will be updated on the implementation of the 2-year renewal cycle and the fees rules package.

4.4 Access to drugs stored outside of the pharmacy by unlicensed staff [WAC 246-945-455].

2:00 pm

5. Open Forum (10 minutes)

The purpose of the open forum is to provide the public an opportunity to address the Commission on issues of significance to or affecting the practice of pharmacy. Discussion items may not relate to topics for which a hearing has or will be scheduled. ***Information Only.***

2:10 pm

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

2:30 pm (approximately)
Business Meeting Adjourned.

Pharmacy Quality Assurance Commission
Mission Statement

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

Vision Statement

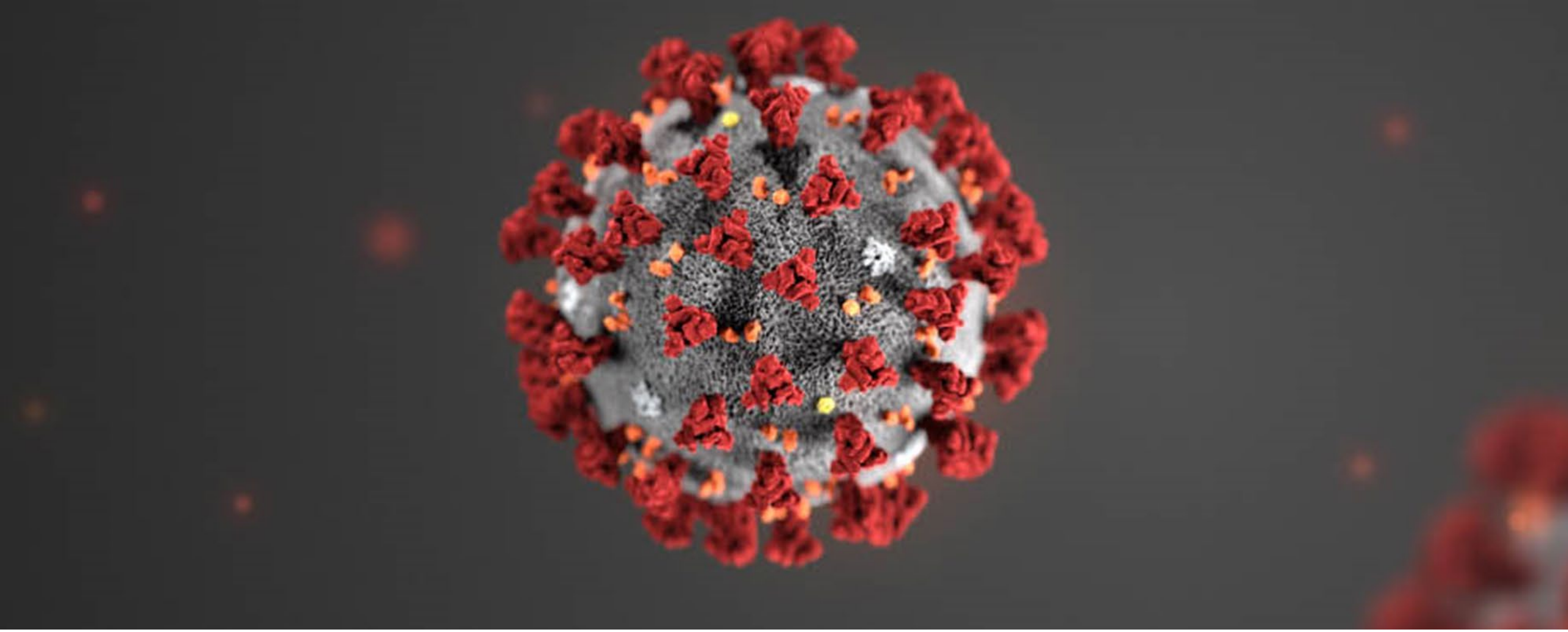
The Washington State Pharmacy Quality Assurance Commission leads in creating a climate for the patient-focused practice of pharmacy as an integral part of an accessible, quality–based health care system.

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

Next scheduled business meeting:

December 4, 2020
Business Meetings
9:00 a.m.
Virtual – by Webinar

Accessibility: This meeting is accessible to persons with disabilities. Special aids and services can be made available upon advance request. Requests must be made no later than ten (10) days prior to the meeting. If you would like general information about this meeting, please call (360) 236-4947. If you need assistance with special services, you may leave a message with that request at 1-800-525-0127 or if calling outside Washington State call (360) 236-4052. TDD may be accessed by calling the TDD relay service at 711. If you need assistance due to a speech disability, Speech-to-Speech provides human voices for people with difficulty being understood. The Washington State Speech to Speech toll free access number is 1-877-833-6341.



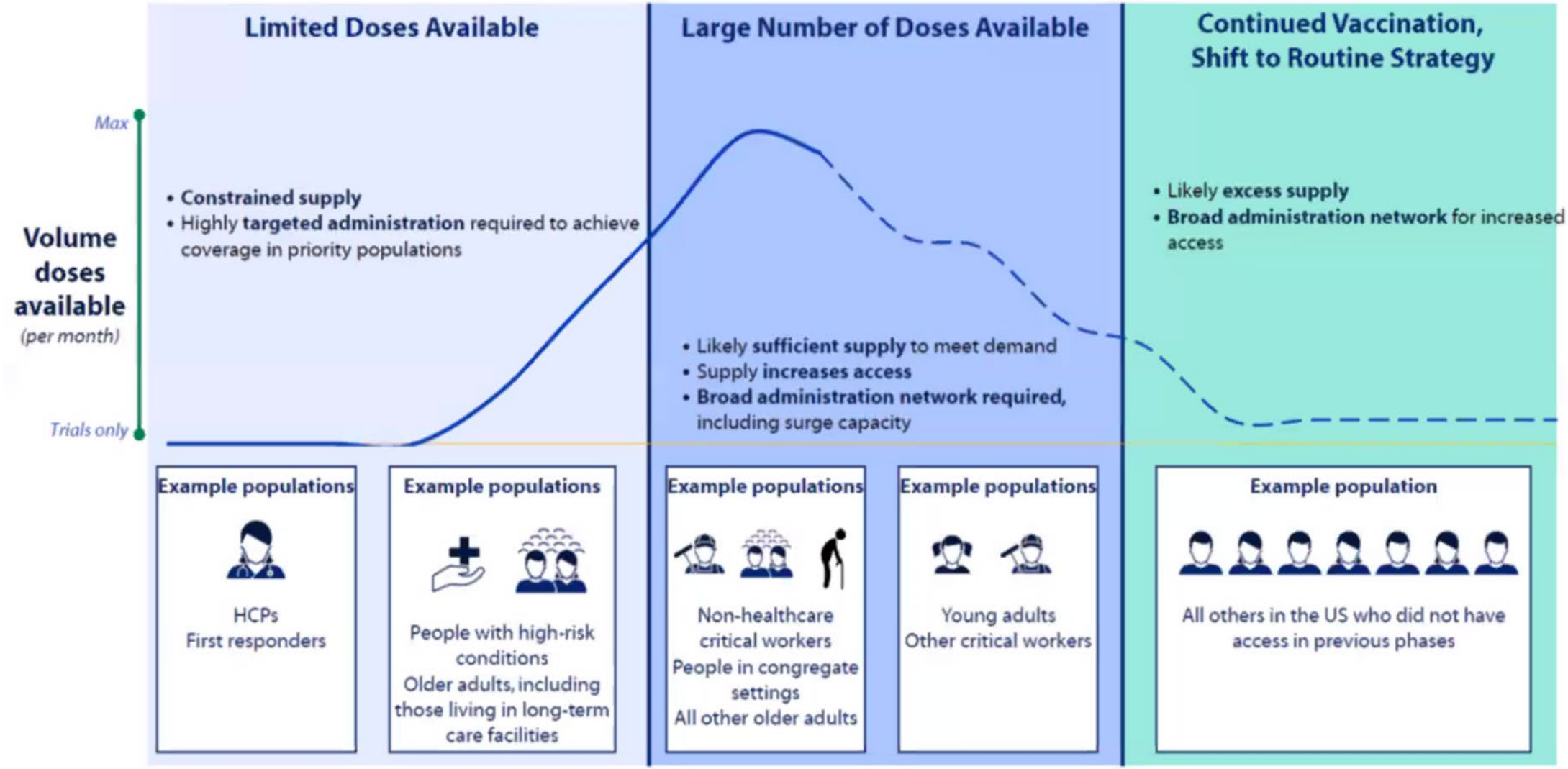
Washington State Department of Health

COVID-19 Vaccine Update

December 3, 2020

Kathy Bay DNP, RN, CENP
Office of Immunizations and Child Profile

Distribution will adjust as volume of vaccine doses increases



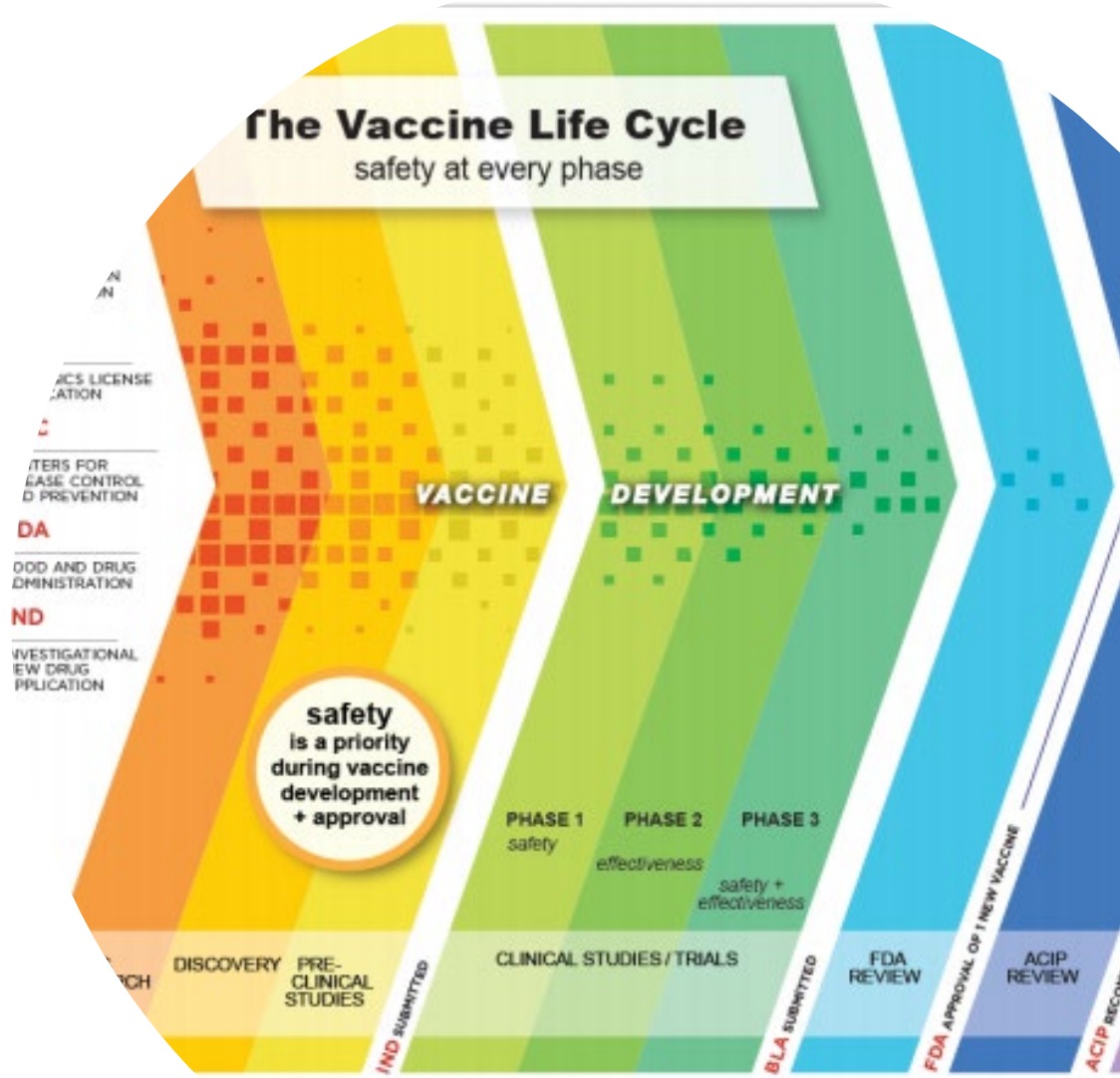
Complex and evolving landscape for COVID-19 vaccine

- One vs. two doses series, products not interchangeable
- Varying presentations
- Vaccine efficacy and adverse event profile in different populations
- Need for socially distanced vaccination practices
- Communication and education
- Some high-risk groups for COVID-19 may distrust public health

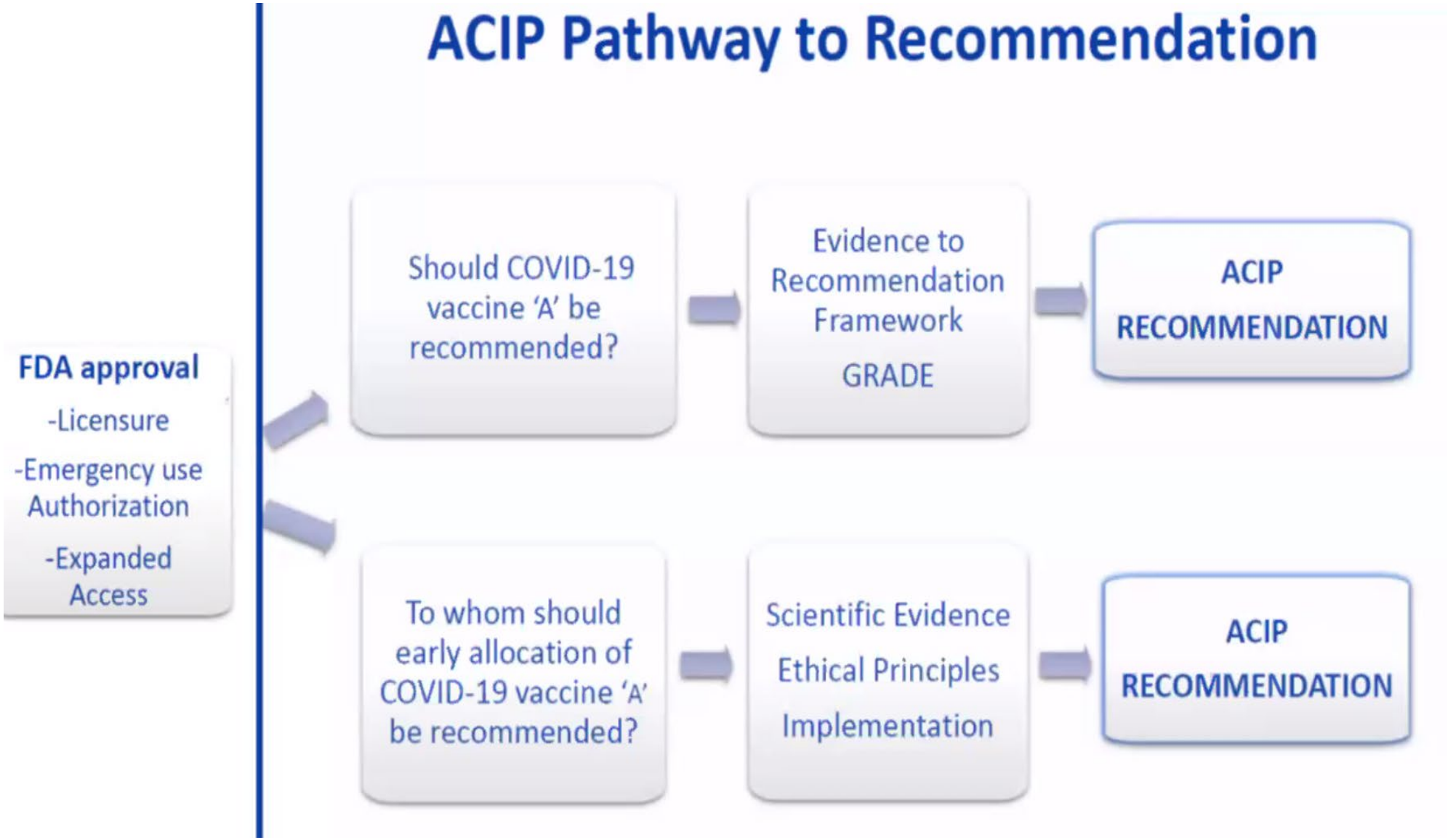
Vaccine Safety & WA

DOH statement: https://www.doh.wa.gov/Newsroom/Articles/ID/2366/Update-on-COVID-19-vaccine-distribution-planning-progress-in-Washington-State.

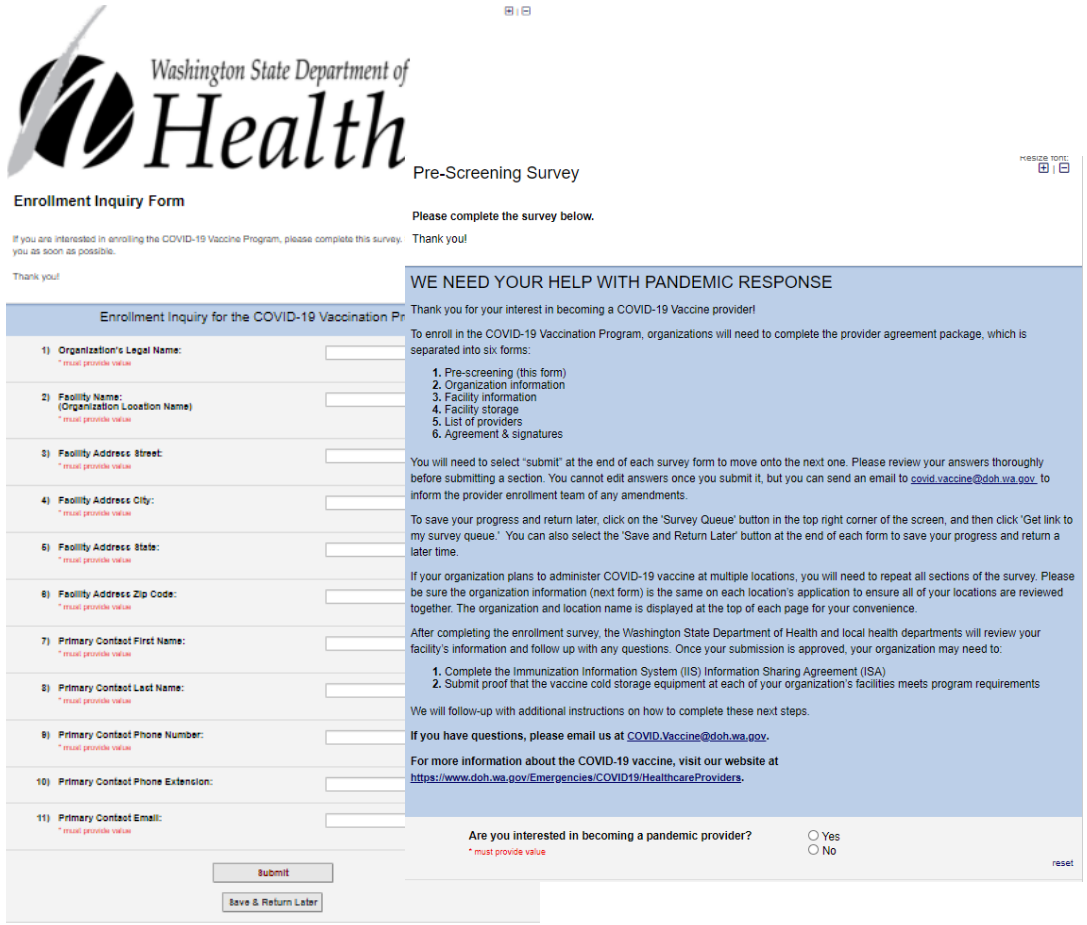
"DOH is committed to science and the need to critically evaluate these new vaccines for their safety and efficacy in an unbiased way before their use," said Dr. Kathy Lofy, State Health Officer. "We will be watching the FDA approval process closely to make sure it is thorough and transparent."



ACIP Pathway to Recommendation



Provider Enrollment via Department of Health



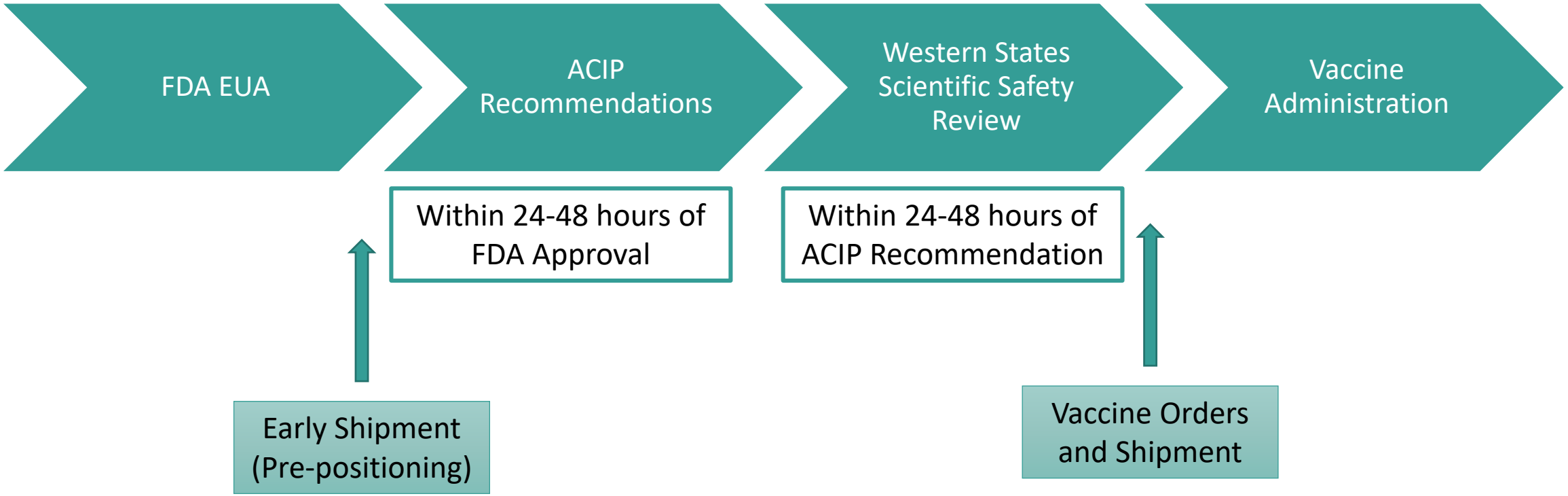
- Complete the provider inquiry form. We will follow-up with your organization as soon as possible. You can use the COVID-19 Provider Enrollment Guide (PDF) to help you through the enrollment process.
- Each facility enrolling will need to complete a survey
  - One survey per facility (i.e., location where vaccine will be shipped)
- Continue to expand recruitment of sites to enroll over the subsequent weeks.

https://www.doh.wa.gov/Emergencies/COVID19/HealthcareProviders/VaccineInformationforHealthcareProviders

Early Shipment (aka pre-position)

- Identifying hospital system locations with ultra-cold (-80C) freezers.
- Option to ship vaccine after EUA, but before ACIP recommendations to position vaccine to select sites with ultra-cold freezers
- Originally limited to 5 sites. Expanded to include more.
- Need to finalize list of sites to prepare
- Provider enrollment completion required for all sites receiving vaccine
- Time window between early shipment and regular ordering/shipping after ACIP recommendation will be short. ACIP anticipated to meet within 24-48 hours of FDA EUA approval.
- Vaccine not to be administered until ACIP recommendations in place and western states' vaccine scientific safety workgroup complete review of FDA approved vaccine.

Sample Timeline for Pfizer Vaccine



This guidance is guaranteed to change

- Federal guidance pending
- Clinical results pending
  - Efficacy in transmission blocking vs. reduction in severe disease
  - Duration of protection (e.g., immunity)
  - Safety and efficacy with different groups (e.g., age, comorbidities, pregnancy)
- Vaccine information pending
  - Differences among vaccines (e.g., timing, supply, # of doses, cold chain)
- Local epidemic conditions and information
  - Examples: transmission differences among populations, underlying conditions and factors driving risk, outbreak, other social/economic/legal environment
- Ongoing engagement with community

This guidance aims to help us plan in a harmonized manner and we commit to updating the guidance and communicating the changes as new information emerges

Phase 1

1A
- High-risk workers in healthcare settings
- High-risk first responders

1B
- People with comorbid and underlying conditions that put them at *significantly* higher risk (2 or more comorbidities)
- People living in congregate or overcrowded settings where the majority are people ≥ 65 years of age and/or people with comorbid and underlying conditions (example settings: long-term care facilities; farmworker housing; prisons; group homes; homeless shelters)

1C
- Critical workers at highest risk of exposure working in congregate settings (example worker groups: agricultural; food processing)

Red = Differences from NAM Framework

Phase 2
- K-12 teachers and school staff and child care workers
- Critical workers in high-risk settings (incl. healthcare) – workers who are in industries essential to the functioning of society and at substantially higher risk of exposure
- People with comorbid and underlying conditions that put them at *moderately* higher risk (1 comorbidity or condition)
- People in homeless shelters or group homes for individuals with disabilities, including serious mental illness, development and intellectual disabilities, and physical disabilities or in recovery not already covered in Phase 1
- People with disabilities that prevent them from adopting protective measures
- People in prisons, jails, detention centers, and similar congregate facilities, and staff who work in such settings
- All people ≥ 65 years of age not covered in Phase 1

Phase 3
- Young adults
- Children
- Workers in industries and occupations essential to the functioning of society and at increased risk of exposure not included in Phase 1 or 2

Phase 4
- Everyone residing in Washington State who did not have access to the vaccine in previous phases

EQUITY IS A CROSS-CUTTING FOCUS OF THIS FRAMEWORK

Certain population groups have been prioritized with an aim to mitigate health inequities recognizing that specific populations are disproportionately impacted by COVID-19 due to external social factors and systemic inequities. Examples of populations disproportionately affected due to such factors include:

- People of color
- People with limited English proficiency
- People in shared housing, crowded housing, and multi-generational homes
- People in poverty and low-wage earners
- People with disabilities
- People with access barriers to healthcare

Washington State has also developed a social vulnerability index which includes social determinants factors (e.g., socio-economic, ethnicity/language, housing/transport, etc.) to identify highest vulnerability areas that will be one of several inputs informing vaccine allocation decisions to ensure equitable allocation.

Note: the following factors DO NOT impact an individual's eligibility: immigration status or health insurance status

Ancillary Supplies

Ancillary supplies will be packaged in kits and will be automatically ordered in amounts to match vaccine orders in VTrckS.

A. For centrally distributed vaccines, each kit will contain supplies to administer 100 doses of vaccine, including:
   - Needles, 105 per kit (various sizes for the population served by the ordering vaccination provider)
     - 25-gauge, 1" (if vaccination indicated for pediatric population)
     - 22–25-gauge, 1-1.5" (adult)
   - Syringes, 105 per kit (ranging from 1–3 mL)
   - Alcohol prep pads, 210 per kit
   - 4 surgical masks and 2 face shields for vaccinators per kit
   - COVID-19 vaccination record cards for vaccine recipients, 100 per kit
   - Vaccine needle guide detailing the appropriate length/gauge for injections based on route, age (for children), gender, and weight (for adults)

   If a COVID-19 vaccine that requires mixing with diluent is ordered and shipped from CDC's centralized distributor, a mixing kit that includes the necessary needles, syringes, and alcohol prep pads will also be automatically added to the order. For centrally distributed vaccines, providers will have the option to submit the order in a way that opts out of receiving the administration and mixing kits.

B. For vaccines that are shipped directly from the manufacturer, a combined kit will be included. This combined kit will include administration supplies (as noted above), mixing supplies, and vials of diluent to prepare the vaccine for use. Because it contains diluent, providers will not have the option to opt out of requesting this combined ancillary kit.

Ancillary supply kits will not include sharps containers, gloves, and bandages. Additional personal protective equipment (PPE) may be needed depending on vaccination provider site needs.

Resource: https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf#page=29

- COVID-19 **vaccine and ancillary supplies** will be procured and distributed by the federal government at **no cost** to enrolled COVID-19 vaccination providers.
- Some vaccine candidates may require reconstitution with diluent or adjuvants. Federally supplied **mixing kit** to reconstitute a vaccine product.
- Does NOT include sharps containers, gloves, bandages

(See next two slides for updated ancillary kit supply list as of 11/19/20)

Pfizer Product – Ancillary Supply Kit (as of 11/19/20)

Kit Description	Product	Product Description	QTY/EA
Pfizer Ancillary Adult	Needles	22-25G /1"	829
24 in x 20 in x 24 in	Needles	22-25G /1.5"	200
	Syringes	1ml	1,024
40 lbs	Needles, Mixing	21-25G x 1.5”	205
	Syringes, Mixing	3ml or 5ml	205
	Alcohol Pads	Sterile, Individual	2,458
	Vaccination Card		1000
	Needle Card		10
	Face Shield		20
	Face Mask		40
	Diluent		200

- The Pfizer ancillary kit will support administration of 975 doses, the minimum order size for the Pfizer vaccine, and includes an overage of needles, syringes, and alcohol prep pads.
- The composition of a Pfizer kit listed in table.

Moderna/Other Product - Ancillary Supply Kit (as of 11/19/20)

Kit Description	Product	Product Description	QTY/EA
Ancillary Adult	Needles	22-25G /1"	85
14 in x 13 in x 9 in	Needles	22-25G /1.5"	20
3.5lbs	Syringes	1ml or 3 ml	105
	Alcohol Pads	Sterile, Individual	210
	Vaccination Card		100
	Needle Card		1
	Face Shield		2
	Face Mask		4

- For all of the vaccines, except for the Pfizer vaccine, the ancillary kits will be built to support 100 doses. We refer to these as the standard kits.
- The composition of a standard kit, designed for use in adults, is as follows:
- Note - We have included a 5% safety level of needles, syringes & alcohol prep pads.

mRNA Vaccines

Pfizer Vaccine

- Prefusion spike transcript
- 2 doses 21 days apart
- VE = 95% efficacy
- 162 cases of symptomatic disease in placebo, 8 in vaccine group
- 10 cases of severe disease; 9 in placebo, 1 in vaccine
- VE 94% in those > 65

Moderna Vaccine

- Prefusion spike transcript
- 2 doses 28 days apart
- VE = 94.5% efficacy
- 90 cases of symptomatic disease in placebo; 5 in vaccine group
- 11 cases of severe disease – all 11 in placebo group
- No difference in VE by age and ethnicity

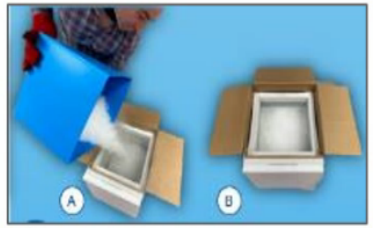
Pfizer Vaccine Storage Options at the Point of Vaccination

1 Ultra-Low Temperature Freezer

- Store as frozen liquid at -75°C±15°C for long term storage.
  - Emergency Use vials are labeled as -70°C±10°C, however they can be safely stored in a freezer set to -75°C±15°C
- Different size of ULT freezers are available in the market.

A small size (under or over the countertop ULT Freezers can store as much as 30K doses)

2 Thermal Shipper Designed for Temporary Storage



- Within 24 hours of receipt and after opening the thermal shipper, replenish/inspect with dry ice (using proper personal protective equipment and dry ice handling).
- With every re-icing, thermal shipper can maintain ultra-low temperature storage for 5 days with 2 openings per day.
- Multiple dry ice replenishments possible; up to 3 re-icings.
- Local dry ice suppliers can be used for re-icing the thermal shipper.
- The thermal shipper to be returned within 10 business days and no later than 20 business days including temperature data logger (picked up by Pfizer/BioNTech contracted supplier)
- Apply appropriate dry ice monitor

3 2 to 8°C Refrigerator

- Can be stored at 2 to 8°C up to 5 days
- Room temperature hold time is no more than 2 hours.
- Thawing: 3 hours at 2 to 8°C or 30 min at room temperature.
- Post-dilution in use period is 6 hours.

*Product temperature must always be monitored to ensure adherence to temperature requirements for different storage conditions are being met in alignment with site Standard Operating Procedures.

Please note that it is possible that the final preparation and logistical requirements may change in light of forthcoming data on dosing, stability, manufacturing and shipping requirements, but this deck reflects the Company's current understanding based on the totality of available data currently. Current as of September 8, 2020.

Vaccine A

Vaccine Storage

Shipped CONUS < 24 hours

Thermal shipping container maintains -60° C to -80° C up to 10 days without opening at room temperature

- Thermal shipping container must be opened and inspected upon receipt
- Initial inspection must be completed in less than 5 minutes
- The thermal shipping container can only be opened twice per day for two minutes during each opening

24 hours

If the thermal shipping container will be used for storage it must be re-iced within 24 hours of initial inspection and then every 5 days thereafter. Up to 3 re-icings are authorized.

Option 1
Placed in ultra-cold temperature freezer

Product stable for ~6 months → **6 Months**

Option 2
Maximize use of thermal shipping container

Re-ice → 5 Days → Re-ice → 5 Days → Re-ice → 5 Days → Refrigeration 2°-8° C → 5 Days → **20 Days**

Option 3
One-time re-ice of thermal shipping container

Re-ice → 5 Days → Refrigeration 2°-8° C → 5 Days → **10 Days**

Option 4
Immediately placed in refrigerator

Refrigeration 2°-8° C → 5 Days → **5 Days (120 hours)**

Vaccine Thawing

Ultra-cold freezer | Thermal shipping container | Refrigeration

Thermal shipping container

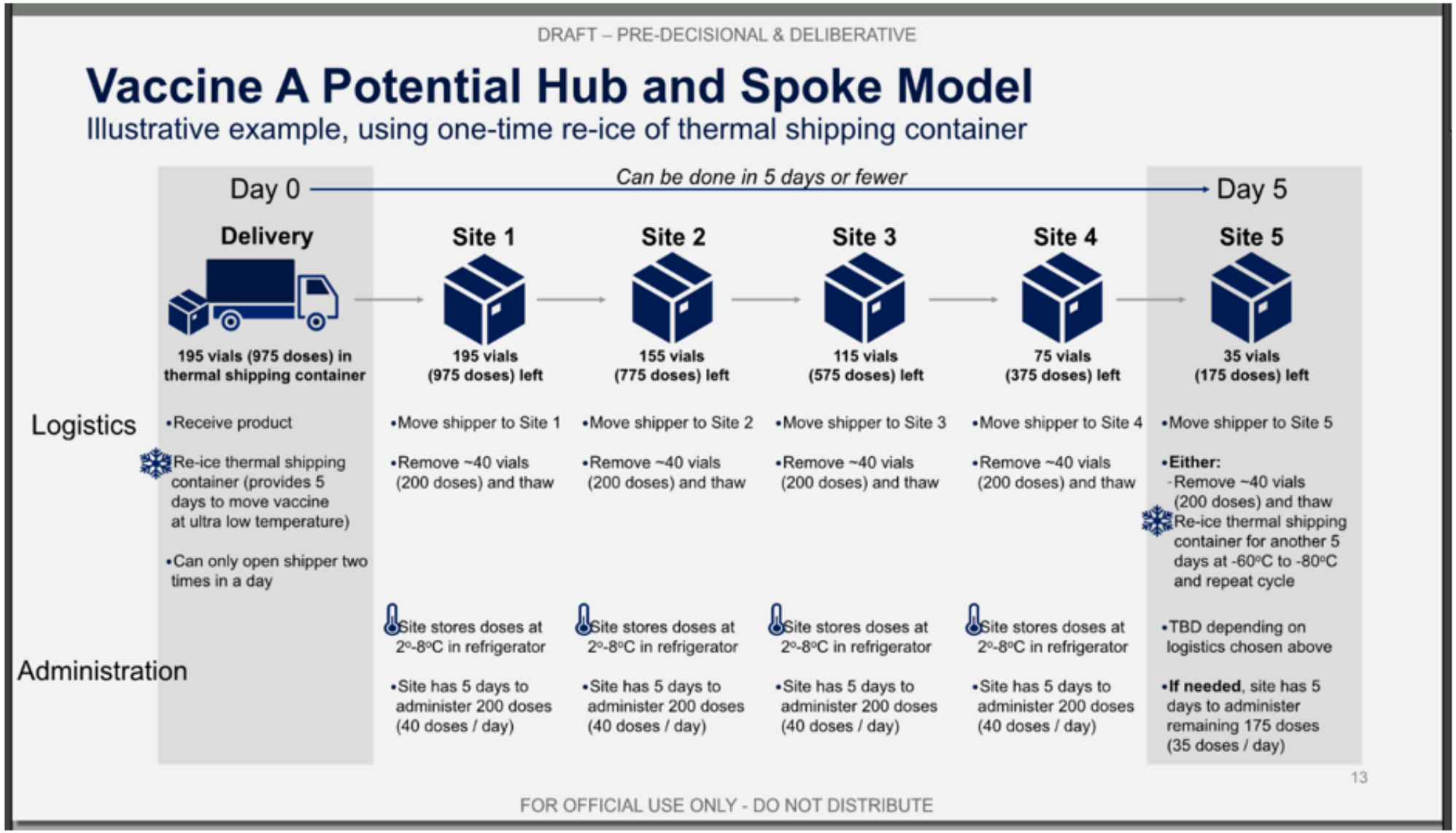
Minimum shipper quantity: 1 tray (**195 vials, 975 doses**)
Maximum shipper quantity: 5 trays (**975 vials, 4875 doses**)

If removed directly from ultra-cold temperatures, thaw vial at room temperature 30 minutes to 2 hours before dilution

Once vaccine is thawed, it must be diluted within 2 hours; if unable to dilute within 2 hours, store at 2°– 8°C

Must use diluted vaccine within 6 hours (discard any unused, diluted vaccine after 6 hours)

Vaccine A: example movement in Thermal Shipper



Site types for Vaccine A product –

Vaccination site	Ordering assumptions			Operating assumptions				
	Order size	Storage conditions	Patient flow	Number of immunizers	Patients per immunizer	Hours per day	Vaccines per day	Shipment model
 **A – large outpatient center (mass vx)**	1 tray (975 doses)	Thermal box with dry-ice, 2-8CR fridge, for product estimated at site (5 days)	~500/day	10 immunizers	6 patient/hour (~10 min/Vx)	8 hours	480 vaccinations	1 tray; 2-3 times per week
 **B – hospital or outpatient center**	1 tray (975 doses)	ULT freezer, Thermal box with dry-ice, 2-8C fridge, for product estimated at site (5 days)	Variable	4 immunizers	6 patient/hour (~10 min/Vx)	8 hours	192 vaccinations	1 tray; every week
 **C – large hospital with affiliated outpatient center**	5 trays (4,875 doses)	ULT freezer, Thermal box,2-8C fridge, for product estimated at site (5 days)	Variable	7 immunizers (hospital outpatient clinic)	6 patients/hour (~10 min/Vx)	8 hours	340 vaccinations	1 tray; 1-2 times a week
 **D – outdoor parking lot** vaccination hub at large retail pharmacy	1 tray (975 doses)	2-8C fridge, for product estimated at site (5 days)	~200/day	5 immunizers	6 patients/hour (~10 min/Vx)	N/A	240 vaccinations	1 tray; every week
 **E – mobile vaccination** in targeted geographies	5 trays (4,875 doses)	2-8C fridge, for product estimated in mobile unit (5 days)	Variable	3 immunizers	6 patients/hour (~10 min/Vx)	Not specified	150 vaccinations	1 tray; every week

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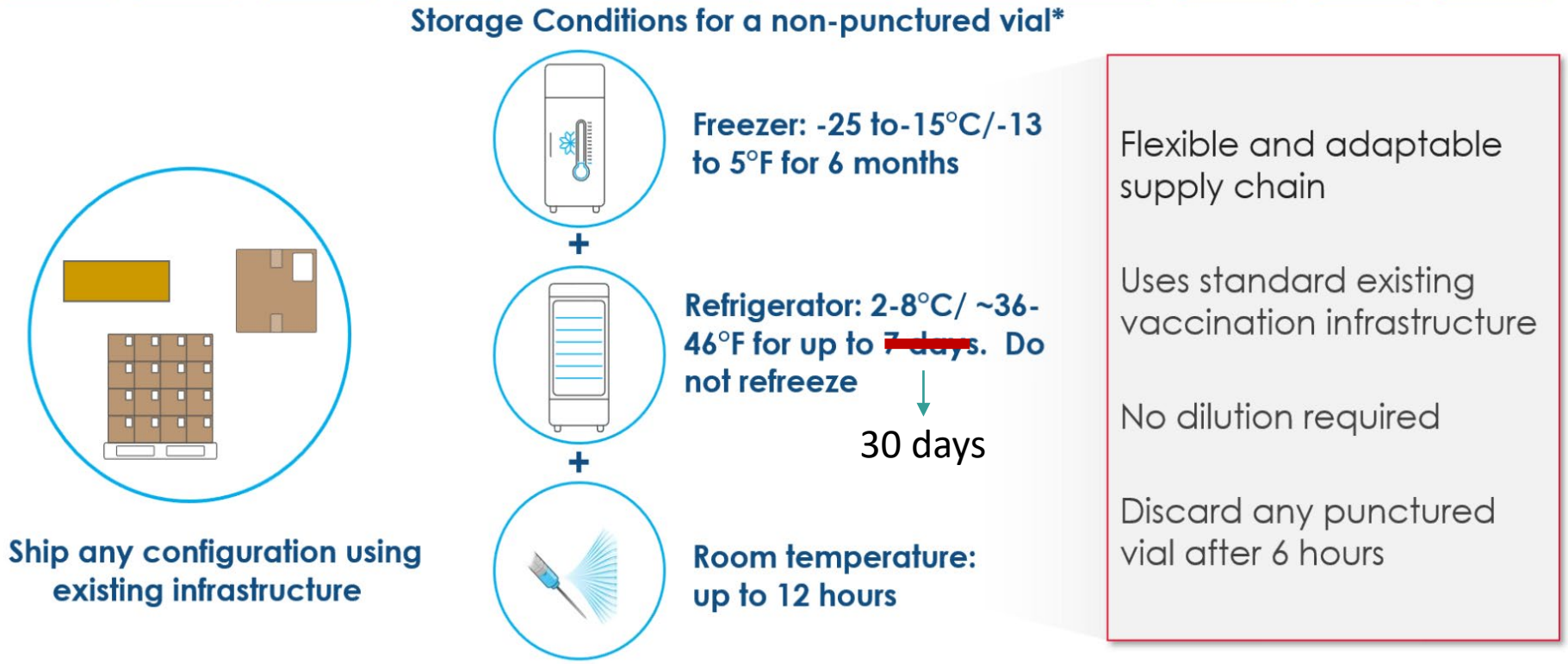
Moderna Vaccine – Distribution & Storage

mRNA-1273 distribution to and storage at immunization locations using existing infrastructure



*Shelf life is expected based on current data available; Product characteristics subject to regulatory review and authorization

Moderna Vaccine - Other key takeaways

- 60-day post vaccination safety data will be released in the next couple weeks.
- Duration of protection from post COVID-19 vaccination is currently unknown.
- EUA will be submitted in a matter of weeks.
- 20 million doses will be ready to ship by the end of the year; 500million – 1 billion doses within the next year.
- Dimensions of box will be coming out shortly.
- Once the vaccine is thawed it should stay out (and should not go back into the fridge)

Additional takeways for mRNA vaccine products

- To have 2 large scale efficacy trials enrolled and completed independently, with such similar results, is remarkable.
- The spike part of the RNA transcript is essentially identical; allowing one to feel quite comfortable about the veracity of the efficacy data.
- The safety data needs to be made public, so one can evaluate it. Available data suggest the vaccines are well tolerated, more side effects with the second dose and somewhat lower severity of systemic side effects in older persons.
- The similarity of the data means either vaccine can do the job and should simplify that part of the distribution process.

But we are not done!

- Vaccines don't save lives; vaccinating people saves lives!
- USG contracts for mRNA is 100 million doses from each company.
- Timeline uncertain, but supposedly we will get these cumulative 200 million by April/May 2021
  - 25 million doses Pfizer and 15 million Moderna in December
  - 30 million doses Pfizer and 20 million Moderna in January
  - 35 million doses Pfizer and 25 million Moderna in February and March
  - This is enough for first responders, medical personnel, elderly and staff in nursing homes; getting close to the complete NAM 1B group.
- Keeping the ongoing trials, as well as creating way to test the Recombinant Protein Platforms post EUA is critical for overall vaccine strategy and getting everyone back to school and work.

Additional Updates for Planning

- Pfizer product storage and handling information available soon
  - 20M and 7M dose planning scenarios (nationally)
- Moderna expected to remain stable at 2-8 degree C for 30 days, up from previous estimate of 7 days
  - 15M dose scenario (nationally)
- First Dry ice recharge
  - USG will provide first dry ice recharge for Pfizer Product
  - Will include dry ice and starter kit (gloves, scoop, instructions)
  - This will be auto ordered with vaccine. Sites may opt out of receiving dry ice.
  - Additional details on dry ice operations coming
- Thermal Shipper temp monitoring device
  - For Pfizer thermal shippers, temperature device will deactivate at time of product receipt
  - For sites using the thermal shipper as a storage unit, temp monitoring smart device may be reactivated for continued use for duration of product storage and handling (in thermal shipper)
  - Additional details on reactivation process and monitoring device plan coming.

COVID-19 Vaccine CPT Codes

CPT CODE	CPT Description	CVX Code	Vaccine Name	Comments	Last Updated Date
91301	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 100 mcg/0.5mL dosage, for intramuscular use	207	COVID-19, mRNA, LNP-S, PF, 100 mcg/0.5 mL dose	COVID-19 Vaccine - Potential EUA authorization	11/11/2020
91300	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3mL dosage, diluent reconstituted, for intramuscular use	208	COVID-19, mRNA, LNP-S, PF, 30 mcg/0.3 mL dose	COVID-19 Vaccine - Potential EUA authorization	11/11/2020

CPT Code Updates https://www2.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=cpt

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WACs Repealing with CR-105 Rulemaking		
Repealing?	**WAC #**	**WAC Title**
Yes	246-856	Board of pharmacy—General.
Yes	246-858	Pharmacists—Internship requirements.
Yes	246-860	Standards of professional conduct.
NO	246-861	Pharmacists—Professional pharmaceutical education.
Yes	246-863	Pharmacists—Licensing.
Yes	246-865	Pharmaceutical services—Extended care facility.
Yes	246-867	Impaired pharmacist rehabilitation.
Yes	246-869	Pharmacy licensing.
Yes	246-870	Electronic transmission of prescription information.
Yes	246-871	Pharmaceutical—Parenteral products for nonhospitalized patients.
Yes	246-873	Pharmacy—Hospital standards.
NO	246-873A	HPAC emergency rules
Yes	246-874	Pharmacy and technology.
Yes	246-875	Pharmacy—Patient medication record systems.
Yes	246-877	Pharmaceutical—Sales prohibited.
Yes	246-878	Good compounding practices.
Yes	246-879	Pharmaceutical wholesalers.
Yes	246-881	Pharmacy—Prescription drug price advertising.
Yes	246-883	Pharmaceutical—Sales requiring prescriptions.
Yes	246-885	Pharmacy—Identification, imprints, markings, and labeling of legend drugs.
Yes	246-886	Animal control—Legend drugs and controlled substances.
Yes	246-887	Pharmacy—Regulations implementing the Uniform Controlled Substances Act.
Yes	246-888	Medication assistance.
Yes	246-889	Pharmaceutical—Precursor substance control.
Yes	246-891	Pharmacy—Prophylactics.
Yes	246-895	Pharmacy—Good manufacturing practice for finished pharmaceuticals.
Yes	246-897	Pharmacy—Drug availability.

Yes	246-899	Pharmaceutical—Drug product substitution.
Repealing all **except** WAC 246-901-061	246-901	Pharmacy ancillary personnel.
Yes	246-903	Nuclear pharmacies and pharmacists.
Yes	246-904	Health care entities.
Yes	246-905	Pharmacy—Home dialysis program.
NO (Rulemaking done by Secretary)	246-907	Pharmaceutical Licensing Periods and Fees

WAC 246-945-056 Schedule V. The commission finds that the following substances have low potential for abuse relative to substances in Schedule IV under RCW 69.50.210 and WAC 246-945-055 and have currently accepted medical use in treatment in the United States and that the substances have limited physical dependence or psychological dependence liability relative to the substance in Schedule IV. In addition to the substances listed in RCW 69.50.212, the commission places each of the following drugs and substances by whatever official name, common or usual name, chemical name, or brand name in Schedule V.

Depressants. Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts:

(1) Brivaracetam ((2S)-2-[(4R)-2-oxo-4-propylpyrrolidin-1-yl] butanamide); also referred to as BRV; UCB-34714; Briviact;

(2) Ezogabine [N-[2-amino-4-(4-fluorobenzylamino)-phenyl]-carbamic acid ethyl ester].

~~(3) Approved cannabidiol drugs. A drug product in finished dosage formulation that has been approved by the U.S. Food and Drug Administration that contains cannabidiol (2-[1R-3-methyl-6R-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-benzenediol) derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols, also known as Epidiolex.~~

[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, § 246-945-056, filed 6/1/20, effective 7/1/20.]

Reviser's note: The brackets and enclosed material in the text of the above section occurred in the copy filed by the agency.

CERTIFICATION OF ENROLLMENT

SUBSTITUTE SENATE BILL 5380

Chapter 314, Laws of 2019

66th Legislature
2019 Regular Session

OPIOID USE DISORDER

EFFECTIVE DATE: July 28, 2019—Except for section 16, which becomes effective January 1, 2021.

Passed by the Senate April 26, 2019
Yeas 45 Nays 1

CYRUS HABIB

President of the Senate

Passed by the House April 26, 2019
Yeas 97 Nays 0

FRANK CHOPP

Speaker of the House of Representatives

Approved May 8, 2019 4:15 PM

JAY INSLEE

Governor of the State of Washington

CERTIFICATE

I, Brad Hendrickson, Secretary of the Senate of the State of Washington, do hereby certify that the attached is **SUBSTITUTE SENATE BILL 5380** as passed by the Senate and the House of Representatives on the dates hereon set forth.

BRAD HENDRICKSON

Secretary

FILED

May 13, 2019

Secretary of State
State of Washington

SUBSTITUTE SENATE BILL 5380

AS AMENDED BY THE CONFERENCE COMMITTEE

Passed Legislature - 2019 Regular Session

State of Washington 66th Legislature 2019 Regular Session

By Senate Health & Long Term Care (originally sponsored by Senators Cleveland, Rivers, Frockt, Walsh, Keiser, King, Randall, O'Ban, Conway, Darneille, Saldaña, Das, Dhingra, Hunt, Wilson, C., and Zeiger; by request of Office of the Governor)

READ FIRST TIME 02/28/19.

AN ACT Relating to opioid use disorder treatment, prevention, and related services; amending RCW 69.41.055, 69.41.095, 70.41.480, 70.168.090, 70.225.010, 70.225.040, 71.24.011, 71.24.560, 71.24.585, 71.24.590, 71.24.595, 28A.210.260, and 28A.210.270; amending 2005 c 70 s 1 (uncodified); reenacting and amending RCW 69.50.312, 69.50.312, 70.225.020, and 71.24.580; adding a new section to chapter 18.22 RCW; adding a new section to chapter 18.32 RCW; adding a new section to chapter 18.57 RCW; adding a new section to chapter 18.57A RCW; adding a new section to chapter 18.64 RCW; adding a new section to chapter 18.71 RCW; adding a new section to chapter 18.71A RCW; adding a new section to chapter 18.79 RCW; adding new sections to chapter 43.70 RCW; adding a new section to chapter 69.50 RCW; adding a new section to chapter 70.225 RCW; adding new sections to chapter 71.24 RCW; adding new sections to chapter 74.09 RCW; adding a new section to chapter 41.05 RCW; adding a new section to chapter 48.43 RCW; adding new sections to chapter 28A.210 RCW; adding a new section to chapter 28B.10 RCW; creating new sections; providing an effective date; and providing an expiration date.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

NEW SECTION. **Sec. 1.** The legislature declares that opioid use disorder is a public health crisis. State agencies must increase

access to evidence-based opioid use disorder treatment services, promote coordination of services within the substance use disorder treatment and recovery support system, strengthen partnerships between opioid use disorder treatment providers and their allied community partners, expand the use of the Washington state prescription drug monitoring program, and support comprehensive school and community-based substance use prevention services.

This act leverages the direction provided by the Washington state interagency opioid working plan in order to address the opioid epidemic challenging communities throughout the state.

Agencies administering state purchased health care programs, as defined in RCW 41.05.011, shall coordinate activities to implement the provisions of this act and the Washington state interagency opioid working plan, explore opportunities to address the opioid epidemic, and provide status updates as directed by the joint legislative executive committee on health care oversight to promote legislative and executive coordination.

Sec. 2. 2005 c 70 s 1 (uncodified) is amended to read as follows:

The legislature finds that drug use among pregnant ((~~women~~)) individuals is a significant and growing concern statewide. ((~~The legislature further finds that methadone, although an effective alternative to other substance use treatments, can result in babies who are exposed to methadone while in uteri being born addicted and facing the painful effects of withdrawal.~~)) Evidence-informed group prenatal care reduces preterm birth for infants, and increases maternal social cohesion and support during pregnancy and postpartum, which is good for maternal mental health.

It is the intent of the legislature to notify all pregnant ((~~mothers~~)) individuals who are receiving ((~~methadone treatment~~)) medication for the treatment of opioid use disorder of the risks and benefits ((~~methadone~~)) such medication could have on their baby during pregnancy through birth and to inform them of the potential need for the newborn baby to be ((~~taken care of~~)) treated in a hospital setting or in a specialized supportive environment designed specifically to address ((~~newborn addiction problems~~)) and manage neonatal opioid or other drug withdrawal syndromes.

NEW SECTION. **Sec. 3.** A new section is added to chapter 18.22 RCW to read as follows:

By January 1, 2020, the board must adopt or amend its rules to require podiatric physicians who prescribe opioids to inform patients of their right to refuse an opioid prescription or order for any reason. If a patient indicates a desire to not receive an opioid, the podiatric physician must document the patient's request and avoid prescribing or ordering opioids, unless the request is revoked by the patient.

NEW SECTION. **Sec. 4.** A new section is added to chapter 18.32 RCW to read as follows:

By January 1, 2020, the commission must adopt or amend its rules to require dentists who prescribe opioids to inform patients of their right to refuse an opioid prescription or order for any reason. If a patient indicates a desire to not receive an opioid, the dentist must document the patient's request and avoid prescribing or ordering opioids, unless the request is revoked by the patient.

NEW SECTION. **Sec. 5.** A new section is added to chapter 18.57 RCW to read as follows:

By January 1, 2020, the board must adopt or amend its rules to require osteopathic physicians who prescribe opioids to inform patients of their right to refuse an opioid prescription or order for any reason. If a patient indicates a desire to not receive an opioid, the osteopathic physician must document the patient's request and avoid prescribing or ordering opioids, unless the request is revoked by the patient.

NEW SECTION. **Sec. 6.** A new section is added to chapter 18.57A RCW to read as follows:

By January 1, 2020, the board must adopt or amend its rules to require osteopathic physicians' assistants who prescribe opioids to inform patients of their right to refuse an opioid prescription or order for any reason. If a patient indicates a desire to not receive an opioid, the osteopathic physician's assistant must document the patient's request and avoid prescribing or ordering opioids, unless the request is revoked by the patient.

NEW SECTION. **Sec. 7.** A new section is added to chapter 18.64 RCW to read as follows:

A pharmacist may partially fill a prescription for a schedule II controlled substance, if the partial fill is requested by the patient or the prescribing practitioner and the total quantity dispensed in all partial fillings does not exceed the quantity prescribed.

NEW SECTION. **Sec. 8.** A new section is added to chapter 18.71 RCW to read as follows:

By January 1, 2020, the commission must adopt or amend its rules to require physicians who prescribe opioids to inform patients of their right to refuse an opioid prescription or order for any reason. If a patient indicates a desire to not receive an opioid, the physician must document the patient's request and avoid prescribing or ordering opioids, unless the request is revoked by the patient.

NEW SECTION. **Sec. 9.** A new section is added to chapter 18.71A RCW to read as follows:

By January 1, 2020, the commission must adopt or amend its rules to require physician assistants who prescribe opioids to inform patients of their right to refuse an opioid prescription or order for any reason. If a patient indicates a desire to not receive an opioid, the physician assistant must document the patient's request and avoid prescribing or ordering opioids, unless the request is revoked by the patient.

NEW SECTION. **Sec. 10.** A new section is added to chapter 18.79 RCW to read as follows:

By January 1, 2020, the commission must adopt or amend its rules to require advanced registered nurse practitioners who prescribe opioids to inform patients of their right to refuse an opioid prescription or order for any reason. If a patient indicates a desire to not receive an opioid, the advanced registered nurse practitioner must document the patient's request and avoid prescribing or ordering opioids, unless the request is revoked by the patient.

NEW SECTION. **Sec. 11.** A new section is added to chapter 43.70 RCW to read as follows:

(1) The department must create a statement warning individuals about the risks of opioid use and abuse and provide information about

safe disposal of opioids. The department must provide the warning on its web site.

(2) The department must review the science, data, and best practices around the use of opioids and their associated risks. As evidence and best practices evolve, the department must update its warning to reflect these changes.

(3) The department must update its patient education materials to reflect the patient's right to refuse an opioid prescription or order.

NEW SECTION. **Sec. 12.** A new section is added to chapter 43.70 RCW to read as follows:

The secretary shall be responsible for coordinating the statewide response to the opioid epidemic and executing the state opioid response plan, in partnership with the health care authority. The department and the health care authority must collaborate with each of the agencies and organizations identified in the state opioid response plan.

Sec. 13. RCW 69.41.055 and 2016 c 148 s 15 are each amended to read as follows:

(1) Information concerning an original prescription or information concerning a prescription refill for a legend drug may be electronically communicated between an authorized practitioner and a pharmacy of the patient's choice with no intervening person having access to the prescription drug order pursuant to the provisions of this chapter if the electronically communicated prescription information complies with the following:

(a) Electronically communicated prescription information must comply with all applicable statutes and rules regarding the form, content, recordkeeping, and processing of a prescription or order for a legend drug;

(b) ((~~The system used for transmitting electronically communicated prescription information and the system used for receiving electronically communicated prescription information must be approved by the commission. This subsection does not apply to currently used facsimile equipment transmitting an exact visual image of the prescription. The commission shall maintain and provide, upon request, a list of systems used for electronically communicating prescription information currently approved by the commission;~~

~~(c)~~)) An explicit opportunity for practitioners must be made to indicate their preference on whether or not a therapeutically equivalent generic drug or interchangeable biological product may be substituted. This section does not limit the ability of practitioners and pharmacists to permit substitution by default under a prior-consent authorization;

((~~(d)~~)) (c) Prescription drug orders are confidential health information, and may be released only to the patient or the patient's authorized representative, the prescriber or other authorized practitioner then caring for the patient, or other persons specifically authorized by law to receive such information;

((~~(e)~~)) (d) To maintain confidentiality of prescription records, the electronic system shall have adequate security and systems safeguards designed to prevent and detect unauthorized access, modification, or manipulation of these records((~~. The pharmacist in charge shall establish or verify the existence of policies and procedures which ensure the integrity and confidentiality of prescription information transmitted to the pharmacy by electronic means. All managers, employees, and agents of the pharmacy are required to read, sign, and comply with the established policies and procedures~~)); and

((~~(f)~~)) (e) The pharmacist shall exercise professional judgment regarding the accuracy, validity, and authenticity of the prescription drug order received by way of electronic transmission, consistent with federal and state laws and rules and guidelines of the commission.

(2) The electronic or digital signature of the prescribing practitioner's agent on behalf of the prescribing practitioner for a resident in a long-term care facility or hospice program, pursuant to a valid order and authorization under RCW 18.64.550, constitutes a valid electronic communication of prescription information. Such an authorized signature and transmission by an agent in a long-term care facility or hospice program does not constitute an intervening person having access to the prescription drug order.

(3) The commission may adopt rules implementing this section.

Sec. 14. RCW 69.41.095 and 2015 c 205 s 2 are each amended to read as follows:

(1)(a) A practitioner may prescribe, dispense, distribute, and deliver an opioid overdose reversal medication: (i) Directly to a

person at risk of experiencing an opioid-related overdose; or (ii) by prescription, collaborative drug therapy agreement, standing order, or protocol to a first responder, family member, or other person or entity in a position to assist a person at risk of experiencing an opioid-related overdose. Any such prescription, standing order, or protocol ((~~order~~)) is issued for a legitimate medical purpose in the usual course of professional practice.

(b) At the time of prescribing, dispensing, distributing, or delivering the opioid overdose reversal medication, the practitioner shall inform the recipient that as soon as possible after administration of the opioid overdose reversal medication, the person at risk of experiencing an opioid-related overdose should be transported to a hospital or a first responder should be summoned.

(2) A pharmacist may dispense an opioid overdose reversal medication pursuant to a prescription, collaborative drug therapy agreement, standing order, or protocol issued in accordance with subsection (1)(a) of this section and may administer an opioid overdose reversal medication to a person at risk of experiencing an opioid-related overdose. At the time of dispensing an opioid overdose reversal medication, a pharmacist shall provide written instructions on the proper response to an opioid-related overdose, including instructions for seeking immediate medical attention. The instructions to seek immediate ((~~medication~~)) medical attention must be conspicuously displayed.

(3) Any person or entity may lawfully possess, store, deliver, distribute, or administer an opioid overdose reversal medication pursuant to a prescription ((~~or~~)), collaborative drug therapy agreement, standing order, or protocol issued by a practitioner in accordance with subsection (1) of this section.

(4) The following individuals, if acting in good faith and with reasonable care, are not subject to criminal or civil liability or disciplinary action under chapter 18.130 RCW for any actions authorized by this section or the outcomes of any actions authorized by this section:

(a) A practitioner who prescribes, dispenses, distributes, or delivers an opioid overdose reversal medication pursuant to subsection (1) of this section;

(b) A pharmacist who dispenses an opioid overdose reversal medication pursuant to subsection (2) or (5)(a) of this section;

(c) A person who possesses, stores, distributes, or administers an opioid overdose reversal medication pursuant to subsection (3) of this section.

(5) The secretary or the secretary's designee may issue a standing order prescribing opioid overdose reversal medications to any person at risk of experiencing an opioid-related overdose or any person or entity in a position to assist a person at risk of experiencing an opioid-related overdose. The standing order may be limited to specific areas in the state or issued statewide.

(a) A pharmacist shall dispense an opioid overdose reversal medication pursuant to a standing order issued in accordance with this subsection, consistent with the pharmacist's responsibilities to dispense prescribed legend drugs, and may administer an opioid overdose reversal medication to a person at risk of experiencing an opioid-related overdose. At the time of dispensing an opioid overdose reversal medication, a pharmacist shall provide written instructions on the proper response to an opioid-related overdose, including instructions for seeking immediate medical attention. The instructions to seek immediate medical attention must be conspicuously displayed.

(b) Any person or entity may lawfully possess, store, deliver, distribute, or administer an opioid overdose reversal medication pursuant to a standing order issued in accordance with this subsection (5). The department, in coordination with the appropriate entity or entities, shall ensure availability of a training module that provides training regarding the identification of a person suffering from an opioid-related overdose and the use of opioid overdose reversal medications. The training must be available electronically and in a variety of media from the department.

(c) This subsection (5) does not create a private cause of action. Notwithstanding any other provision of law, neither the state nor the secretary nor the secretary's designee has any civil liability for issuing standing orders or for any other actions taken pursuant to this chapter or for the outcomes of issuing standing orders or any other actions taken pursuant to this chapter. Neither the secretary nor the secretary's designee is subject to any criminal liability or professional disciplinary action for issuing standing orders or for any other actions taken pursuant to this chapter.

(d) For purposes of this subsection (5), "standing order" means an order prescribing medication by the secretary or the secretary's

designee. Such standing order can only be issued by a practitioner as defined in this chapter.

(6) The labeling requirements of RCW 69.41.050 and 18.64.246 do not apply to opioid overdose reversal medications dispensed, distributed, or delivered pursuant to a prescription, collaborative drug therapy agreement, standing order, or protocol issued in accordance with this section. The individual or entity that dispenses, distributes, or delivers an opioid overdose reversal medication as authorized by this section shall ensure that directions for use are provided.

(7) For purposes of this section, the following terms have the following meanings unless the context clearly requires otherwise:

(a) "First responder" means: (i) A career or volunteer firefighter, law enforcement officer, paramedic as defined in RCW 18.71.200, or first responder or emergency medical technician as defined in RCW 18.73.030; and (ii) an entity that employs or supervises an individual listed in (a)(i) of this subsection, including a volunteer fire department.

(b) "Opioid overdose reversal medication" means any drug used to reverse an opioid overdose that binds to opioid receptors and blocks or inhibits the effects of opioids acting on those receptors. It does not include intentional administration via the intravenous route.

(c) "Opioid-related overdose" means a condition including, but not limited to, ((~~extreme physical illness,~~)) decreased level of consciousness, nonresponsiveness, respiratory depression, coma, or death that: (i) Results from the consumption or use of an opioid or another substance with which an opioid was combined; or (ii) a lay person would reasonably believe to be an opioid-related overdose requiring medical assistance.

(d) "Practitioner" means a health care practitioner who is authorized under RCW 69.41.030 to prescribe legend drugs.

(e) "Standing order" or "protocol" means written or electronically recorded instructions, prepared by a prescriber, for distribution and administration of a drug by designated and trained staff or volunteers of an organization or entity, as well as other actions and interventions to be used upon the occurrence of clearly defined clinical events in order to improve patients' timely access to treatment.

Sec. 15. RCW 69.50.312 and 2013 c 276 s 4 and 2013 c 19 s 105 are each reenacted and amended to read as follows:

(1) Information concerning a prescription for a controlled substance included in Schedules II through V, or information concerning a refill authorization for a controlled substance included in Schedules III through V((~~,~~))_,_ may be electronically communicated to a pharmacy of the patient's choice pursuant to the provisions of this chapter if the electronically communicated prescription information complies with the following:

(a) Electronically communicated prescription information must comply with all applicable statutes and rules regarding the form, content, recordkeeping, and processing of a prescription for a legend drug;

(b) The system used for transmitting electronically communicated prescription information must ((~~be approved by the commission and in accordance~~)) comply with federal rules for electronically communicated prescriptions for controlled substance((~~,~~))s included in Schedules II through V, as set forth in Title 21 C.F.R. Parts 1300, 1304, 1306, and 1311((~~. This subsection does not apply to currently used facsimile equipment transmitting an exact visual image of the prescription. The commission shall maintain and provide, upon request, a list of systems used for electronically communicating prescription information currently approved by the commission~~));

(c) An explicit opportunity for practitioners must be made to indicate their preference on whether a therapeutically equivalent generic drug may be substituted;

(d) Prescription drug orders are confidential health information, and may be released only to the patient or the patient's authorized representative, the prescriber or other authorized practitioner then caring for the patient, or other persons specifically authorized by law to receive such information;

(e) To maintain confidentiality of prescription records, the electronic system shall have adequate security and systems safeguards designed to prevent and detect unauthorized access, modification, or manipulation of these records((~~. The pharmacist in charge shall establish or verify the existence of policies and procedures which ensure the integrity and confidentiality of prescription information transmitted to the pharmacy by electronic means. All managers, employees, and agents of the pharmacy are required to read, sign, and comply with the established policies and procedures~~)); and

(f) The pharmacist shall exercise professional judgment regarding the accuracy, validity, and authenticity of the prescription drug order received by way of electronic transmission, consistent with federal and state laws and rules and guidelines of the commission.

(2) The commission may adopt rules implementing this section.

Sec. 16. RCW 69.50.312 and 2013 c 276 s 4 and 2013 c 19 s 105 are each reenacted and amended to read as follows:

(1) Information concerning a prescription for a controlled substance included in Schedules II through V, or information concerning a refill authorization for a controlled substance included in Schedules III through V((~~[,] may~~)), must be electronically communicated to a pharmacy of the patient's choice pursuant to the provisions of this chapter if the electronically communicated prescription information complies with the following:

(a) Electronically communicated prescription information must comply with all applicable statutes and rules regarding the form, content, recordkeeping, and processing of a prescription for a legend drug;

(b) ((~~The system used for transmitting electronically communicated prescription information must be approved by the commission and in accordance with federal rules for electronically communicated prescriptions for controlled substance[s] included in Schedules II through V, as set forth in Title 21 C.F.R. Parts 1300, 1304, 1306, and 1311. This subsection does not apply to currently used facsimile equipment transmitting an exact visual image of the prescription. The commission shall maintain and provide, upon request, a list of systems used for electronically communicating prescription information currently approved by the commission;~~

~~(c) An explicit opportunity for practitioners must be made to indicate their preference on whether a therapeutically equivalent generic drug may be substituted;~~

~~(d)~~)) Prescription drug orders ((~~are confidential health information, and~~)) may be released only to the patient or the patient's authorized representative, the prescriber or other authorized practitioner then caring for the patient, or other persons specifically authorized by law to receive such information;

((~~(e) To maintain confidentiality of prescription records, the electronic system shall have adequate security and systems safeguards designed to prevent and detect unauthorized access, modification, or~~

~~manipulation of these records. The pharmacist in charge shall establish or verify the existence of policies and procedures which ensure the integrity and confidentiality of prescription information transmitted to the pharmacy by electronic means. All managers, employees, and agents of the pharmacy are required to read, sign, and comply with the established policies and procedures; and~~

~~(f)~~)) (c) The pharmacist shall exercise professional judgment regarding the accuracy, validity, and authenticity of the prescription drug order received by way of electronic transmission, consistent with federal and state laws and rules and guidelines of the commission.

(2) ((~~The commission may adopt rules implementing this section.~~)) The following are exempt from subsection (1) of this section:

(a) Prescriptions issued by veterinarians, as that practice is defined in RCW 18.92.010;

(b) Prescriptions issued for a patient of a long-term care facility as defined in RCW 18.64.011, or a hospice program as defined in RCW 18.64.011;

(c) When the electronic system used for the communication of prescription information is unavailable due to a temporary technological or electronic failure;

(d) Prescriptions issued that are intended for prescription fulfillment and dispensing outside Washington state;

(e) When the prescriber and pharmacist are employed by the same entity, or employed by entities under common ownership or control;

(f) Prescriptions issued for a drug that the United States food and drug administration or the United States drug enforcement administration requires to contain certain elements that are not able to be accomplished electronically;

(g) Any controlled substance prescription that requires compounding as defined in RCW 18.64.011;

(h) Prescriptions issued for the dispensing of a nonpatient specific prescription under a standing order, approved protocol for drug therapy, collaborative drug therapy agreement, in response to a public health emergency, or other circumstances allowed by statute or rule where a practitioner may issue a nonpatient specific prescription;

(i) Prescriptions issued under a drug research protocol;

(j) Prescriptions issued by a practitioner with the capability of electronic communication of prescription information under this

section, when the practitioner reasonably determines it is impractical for the patient to obtain the electronically communicated prescription in a timely manner, and such delay would adversely impact the patient's medical condition; or

(k) Prescriptions issued by a prescriber who has received a waiver from the department.

(3) The department must develop a waiver process for the requirements of subsection (1) of this section for practitioners due to economic hardship, technological limitations that are not reasonably in the control of the practitioner, or other exceptional circumstance demonstrated by the practitioner. The waiver must be limited to one year or less, or for any other specified time frame set by the department.

(4) A pharmacist who receives a written, oral, or faxed prescription is not required to verify that the prescription properly meets any exemptions under this section. Pharmacists may continue to dispense and deliver medications from otherwise valid written, oral, or faxed prescriptions.

(5) An individual who violates this section commits a civil violation. Disciplinary authorities may impose a fine of two hundred fifty dollars per violation, not to exceed five thousand dollars per calendar year. Fines imposed under this section must be allocated to the health professions account.

(6) Systems used for the electronic communication of prescription information must:

(a) Comply with federal laws and rules for electronically communicated prescriptions for controlled substances included in Schedules II through V, as required by Title 21 C.F.R. parts 1300, 1304, 1306, and 1311;

(b) Meet the national council for prescription drug prescriber/pharmacist interface SCRIPT standard as determined by the department in rule;

(c) Have adequate security and systems safeguards designed to prevent and detect unauthorized access, modification, or manipulation of these records;

(d) Provide an explicit opportunity for practitioners to indicate their preference on whether a therapeutically equivalent generic drug may be substituted; and

(e) Include the capability to input and track partial fills of a controlled substance prescription in accordance with section 7 of this act.

NEW SECTION. **Sec. 17.** A new section is added to chapter 69.50 RCW to read as follows:

(1) Any practitioner who writes the first prescription for an opioid during the course of treatment to any patient must, under professional rules, discuss the following with the patient:

(a) The risks of opioids, including risk of dependence and overdose;

(b) Pain management alternatives to opioids, including nonopioid pharmacological treatments, and nonpharmacological treatments available to the patient, at the discretion of the practitioner and based on the medical condition of the patient; and

(c) A written copy of the warning language provided by the department under section 11 of this act.

(2) If the patient is under eighteen years old or is not competent, the discussion required by subsection (1) of this section must include the patient's parent, guardian, or the person identified in RCW 7.70.065, unless otherwise provided by law.

(3) The practitioner shall document completion of the requirements in subsection (1) of this section in the patient's health care record.

(4) To fulfill the requirements of subsection (1) of this section, a practitioner may designate any individual who holds a credential issued by a disciplining authority under RCW 18.130.040 to conduct the discussion.

(5) Violation of this section constitutes unprofessional conduct under chapter 18.130 RCW.

(6) This section does not apply to:

(a) Opioid prescriptions issued for the treatment of pain associated with terminal cancer or other terminal diseases, or for palliative, hospice, or other end-of-life care of where the practitioner determines the health, well-being, or care of the patient would be compromised by the requirements of this section and documents such basis for the determination in the patient's health care record; or

(b) Administration of an opioid in an inpatient or outpatient treatment setting.

(7) This section does not apply to practitioners licensed under chapter 18.92 RCW.

(8) The department shall review this section by March 31, 2026, and report to the appropriate committees of the legislature on whether this section should be retained, repealed, or amended.

Sec. 18. RCW 70.41.480 and 2015 c 234 s 1 are each amended to read as follows:

(1) The legislature finds that high quality, safe, and compassionate health care services for patients of Washington state must be available at all times. The legislature further finds that there is a need for patients being released from hospital emergency departments to maintain access to emergency medications when community or hospital pharmacy services are not available, including medication for opioid overdose reversal and for the treatment for opioid use disorder as appropriate. It is the intent of the legislature to accomplish this objective by allowing practitioners with prescriptive authority to prescribe limited amounts of prepackaged emergency medications to patients being discharged from hospital emergency departments when access to community or outpatient hospital pharmacy services is not otherwise available.

(2) A hospital may allow a practitioner to prescribe prepackaged emergency medications and allow a practitioner or a registered nurse licensed under chapter 18.79 RCW to distribute prepackaged emergency medications to patients being discharged from a hospital emergency department in the following circumstances:

(a) During times when community or outpatient hospital pharmacy services are not available within fifteen miles by road ((~~or~~));

(b) When, in the judgment of the practitioner and consistent with hospital policies and procedures, a patient has no reasonable ability to reach the local community or outpatient pharmacy; or

(c) When, in the judgment of the practitioner and consistent with hospital policies and procedures, a patient is at risk of opioid overdose and the prepackaged emergency medication being distributed is an opioid overdose reversal medication. The labeling requirements of RCW 69.41.050 and 18.64.246 do not apply to opioid overdose reversal medications dispensed, distributed, or delivered pursuant to a prescription, collaborative drug therapy agreement, standing order, or protocol issued in accordance with this section. The individual or entity that dispenses, distributes, or delivers an opioid overdose

reversal medication as authorized by this section must ensure that directions for use are provided.

(3) A hospital may only allow this practice if: The director of the hospital pharmacy, in collaboration with appropriate hospital medical staff, develops policies and procedures regarding the following:

(a) Development of a list, preapproved by the pharmacy director, of the types of emergency medications to be prepackaged and distributed;

(b) Assurances that emergency medications to be prepackaged pursuant to this section are prepared by a pharmacist or under the supervision of a pharmacist licensed under chapter 18.64 RCW;

(c) Development of specific criteria under which emergency prepackaged medications may be prescribed and distributed consistent with the limitations of this section;

(d) Assurances that any practitioner authorized to prescribe prepackaged emergency medication or any nurse authorized to distribute prepackaged emergency medication is trained on the types of medications available and the circumstances under which they may be distributed;

(e) Procedures to require practitioners intending to prescribe prepackaged emergency medications pursuant to this section to maintain a valid prescription either in writing or electronically in the patient's records prior to a medication being distributed to a patient;

(f) Establishment of a limit of no more than a forty-eight hour supply of emergency medication as the maximum to be dispensed to a patient, except when community or hospital pharmacy services will not be available within forty-eight hours. In no case may the policy allow a supply exceeding ninety-six hours be dispensed;

(g) Assurances that prepackaged emergency medications will be kept in a secure location in or near the emergency department in such a manner as to preclude the necessity for entry into the pharmacy; and

(h) Assurances that nurses or practitioners will distribute prepackaged emergency medications to patients only after a practitioner has counseled the patient on the medication.

((~~(3)~~)) (4) The delivery of a single dose of medication for immediate administration to the patient is not subject to the requirements of this section.

((~~(4)~~)) (5) Nothing in this section restricts the authority of a practitioner in a hospital emergency department to distribute opioid overdose reversal medication under RCW 69.41.095.

(6) For purposes of this section:

(a) "Emergency medication" means any medication commonly prescribed to emergency ((~~room~~)) department patients, including those drugs, substances or immediate precursors listed in schedules II through V of the uniform controlled substances act, chapter 69.50 RCW, as now or hereafter amended.

(b) "Distribute" means the delivery of a drug or device other than by administering or dispensing.

(c) "Practitioner" means any person duly authorized by law or rule in the state of Washington to prescribe drugs as defined in RCW 18.64.011((~~(24)~~)) (29).

(d) "Nurse" means a registered nurse as defined in RCW 18.79.020.

Sec. 19. RCW 70.168.090 and 2010 c 52 s 5 are each amended to read as follows:

(1)(a) By July 1991, the department shall establish a statewide data registry to collect and analyze data on the incidence, severity, and causes of trauma, including traumatic brain injury. The department shall collect additional data on traumatic brain injury should additional data requirements be enacted by the legislature. The registry shall be used to improve the availability and delivery of prehospital and hospital trauma care services. Specific data elements of the registry shall be defined by rule by the department. To the extent possible, the department shall coordinate data collection from hospitals for the trauma registry with the health care data system authorized in chapter 70.170 RCW. Every hospital, facility, or health care provider authorized to provide level I, II, III, IV, or V trauma care services, level I, II, or III pediatric trauma care services, level I, level I-pediatric, II, or III trauma-related rehabilitative services, and prehospital trauma-related services in the state shall furnish data to the registry. All other hospitals and prehospital providers shall furnish trauma data as required by the department by rule.

(b) The department may respond to requests for data and other information from the registry for special studies and analysis consistent with requirements for confidentiality of patient and quality assurance records. The department may require requestors to

pay any or all of the reasonable costs associated with such requests that might be approved.

(2) The department must establish a statewide electronic emergency medical services data system and adopt rules requiring licensed ambulance and aid services to report and furnish patient encounter data to the electronic emergency medical services data system. The data system must be used to improve the availability and delivery of prehospital emergency medical services. The department must establish in rule the specific data elements of the data system and secure transport methods for data. The data collected must include data on suspected drug overdoses for the purposes of including, but not limited to, identifying individuals to engage substance use disorder peer professionals, patient navigators, outreach workers, and other professionals as appropriate to prevent further overdoses and to induct into treatment and provide other needed supports as may be available.

(3) In each emergency medical services and trauma care planning and service region, a regional emergency medical services and trauma care systems quality assurance program shall be established by those facilities authorized to provide levels I, II, and III trauma care services. The systems quality assurance program shall evaluate trauma care delivery, patient care outcomes, and compliance with the requirements of this chapter. The systems quality assurance program may also evaluate emergency cardiac and stroke care delivery. The emergency medical services medical program director and all other health care providers and facilities who provide trauma and emergency cardiac and stroke care services within the region shall be invited to participate in the regional emergency medical services and trauma care quality assurance program.

((~~(3)~~)) (4) Data elements related to the identification of individual patient's, provider's and facility's care outcomes shall be confidential, shall be exempt from RCW 42.56.030 through 42.56.570 and 42.17.350 through 42.17.450, and shall not be subject to discovery by subpoena or admissible as evidence.

((~~(4)~~)) (5) Patient care quality assurance proceedings, records, and reports developed pursuant to this section are confidential, exempt from chapter 42.56 RCW, and are not subject to discovery by subpoena or admissible as evidence((~~.~~)) in any civil action, except, after in camera review, pursuant to a court order which provides for the protection of sensitive information of interested parties

including the department: (a) In actions arising out of the department's designation of a hospital or health care facility pursuant to RCW 70.168.070; (b) in actions arising out of the department's revocation or suspension of designation status of a hospital or health care facility under RCW 70.168.070; (c) in actions arising out of the department's licensing or verification of an ambulance or aid service pursuant to RCW 18.73.030 or 70.168.080; (d) in actions arising out of the certification of a medical program director pursuant to RCW 18.71.212; or ((~~(c)~~)) (e) in actions arising out of the restriction or revocation of the clinical or staff privileges of a health care provider as defined in RCW 7.70.020 (1) and (2), subject to any further restrictions on disclosure in RCW 4.24.250 that may apply. Information that identifies individual patients shall not be publicly disclosed without the patient's consent.

Sec. 20. RCW 70.225.010 and 2007 c 259 s 42 are each amended to read as follows:

The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

(1) "Controlled substance" has the meaning provided in RCW 69.50.101.

(2) "Department" means the department of health.

(3) "Patient" means the person or animal who is the ultimate user of a drug for whom a prescription is issued or for whom a drug is dispensed.

(4) "Dispenser" means a practitioner or pharmacy that delivers a Schedule II, III, IV, or V controlled substance to the ultimate user, but does not include:

(a) A practitioner or other authorized person who administers, as defined in RCW 69.41.010, a controlled substance; or

(b) A licensed wholesale distributor or manufacturer, as defined in chapter 18.64 RCW, of a controlled substance.

(5) "Prescriber" means any person authorized to order or prescribe legend drugs or schedule II, III, IV, or V controlled substances to the ultimate user.

(6) "Requestor" means any person or entity requesting, accessing, or receiving information from the prescription monitoring program under RCW 70.225.040 (3), (4), or (5).

Sec. 21. RCW 70.225.020 and 2013 c 36 s 2 and 2013 C 19 S 126 are each reenacted and amended to read as follows:

(1) The department shall establish and maintain a prescription monitoring program to monitor the prescribing and dispensing of all Schedules II, III, IV, and V controlled substances and any additional drugs identified by the pharmacy quality assurance commission as demonstrating a potential for abuse by all professionals licensed to prescribe or dispense such substances in this state. The program shall be designed to improve health care quality and effectiveness by reducing abuse of controlled substances, reducing duplicative prescribing and overprescribing of controlled substances, and improving controlled substance prescribing practices with the intent of eventually establishing an electronic database available in real time to dispensers and prescribers of controlled substances. As much as possible, the department should establish a common database with other states. This program's management and operations shall be funded entirely from the funds in the account established under RCW 74.09.215. Nothing in this chapter prohibits voluntary contributions from private individuals and business entities as defined under Title 23, 23B, 24, or 25 RCW to assist in funding the prescription monitoring program.

(2) Except as provided in subsection (4) of this section, each dispenser shall submit to the department by electronic means information regarding each prescription dispensed for a drug included under subsection (1) of this section. Drug prescriptions for more than one day use should be reported. The information submitted for each prescription shall include, but not be limited to:

(a) Patient identifier;

(b) Drug dispensed;

(c) Date of dispensing;

(d) Quantity dispensed;

(e) Prescriber; and

(f) Dispenser.

(3)(a) Until January 1, 2021, each dispenser shall submit the information in accordance with transmission methods established by the department, not later than one business day from the date of dispensing or at the interval required by the department in rule, whichever is sooner.

(b) Beginning January 1, 2021, each dispenser must submit the information as soon as readily available, but no later than one

business day from the date of distributing, and in accordance with transmission methods established by the department.

(4) The data submission requirements of subsections (1) through (3) of this section do not apply to:

(a) Medications provided to patients receiving inpatient services provided at hospitals licensed under chapter 70.41 RCW; or patients of such hospitals receiving services at the clinics, day surgery areas, or other settings within the hospital's license where the medications are administered in single doses;

(b) Pharmacies operated by the department of corrections for the purpose of providing medications to offenders in department of corrections institutions who are receiving pharmaceutical services from a department of corrections pharmacy, except that the department of corrections must submit data related to each offender's current prescriptions for controlled substances upon the offender's release from a department of corrections institution; or

(c) Veterinarians licensed under chapter 18.92 RCW. The department, in collaboration with the veterinary board of governors, shall establish alternative data reporting requirements for veterinarians that allow veterinarians to report:

(i) By either electronic or nonelectronic methods;

(ii) Only those data elements that are relevant to veterinary practices and necessary to accomplish the public protection goals of this chapter; and

(iii) No more frequently than once every three months and no less frequently than once every six months.

(5) The department shall continue to seek federal grants to support the activities described in chapter 259, Laws of 2007. The department may not require a practitioner or a pharmacist to pay a fee or tax specifically dedicated to the operation and management of the system.

NEW SECTION. **Sec. 22.** A new section is added to chapter 70.225 RCW to read as follows:

(1) In order to expand integration of prescription monitoring program data into certified electronic health record technologies, the department must collaborate with health professional and facility associations, vendors, and others to:

(a) Conduct an assessment of the current status of integration;

(b) Provide recommendations for improving integration among small and rural health care facilities, offices, and clinics;

(c) Comply with federal prescription drug monitoring program qualification requirements under 42 U.S.C. Sec. 1396w-3a to facilitate eligibility for federal grants and establish a program to provide financial assistance to small and rural health care facilities and clinics with integration as funding is available, especially under federal programs;

(d) Conduct security assessments of other commonly used platforms for integrating prescription monitoring program data with certified electronic health records for possible use in Washington; and

(e) Assess improvements to the prescription monitoring program to establish a modality to identify patients that do not wish to receive opioid medications in a manner that allows an ordering or prescribing physician to be able to use the prescription monitoring program to identify patients who do not wish to receive opioids or patients that have had an opioid-related overdose.

(2)(a) By January 1, 2021, a facility, entity, office, or provider group identified in RCW 70.225.040 with ten or more prescribers that is not a critical access hospital as defined in RCW 74.60.010 that uses a federally certified electronic health records system must demonstrate that the facility's or entity's federally certified electronic health record is able to fully integrate data to and from the prescription monitoring program using a mechanism approved by the department under subsection (3) of this section.

(b) The department must develop a waiver process for the requirements of (a) of this subsection for facilities, entities, offices, or provider groups due to economic hardship, technological limitations that are not reasonably in the control of the facility, entity, office, or provider group, or other exceptional circumstance demonstrated by the facility, entity, office, or provider group. The waiver must be limited to one year or less, or for any other specified time frame set by the department.

(3) Electronic health record system vendors who are fully integrated with the prescription monitoring program in Washington state may not charge an ongoing fee or a fee based on the number of transactions or providers. Total costs of connection must not impose unreasonable costs on any facility, entity, office, or provider group using the electronic health record and must be consistent with current industry pricing structures. For the purposes of this

subsection, "fully integrated" means that the electronic health records system must:

(a) Send information to the prescription monitoring program without provider intervention using a mechanism approved by the department;

(b) Make current information from the prescription monitoring program available to a provider within the workflow of the electronic health records system; and

(c) Make information available in a way that is unlikely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information, in accordance with the information blocking provisions of the federal twenty-first century cures act, P.L. 114-255.

Sec. 23. RCW 70.225.040 and 2017 c 297 s 9 are each amended to read as follows:

(1) ((~~Prescription~~)) All information submitted to the ((~~department must be~~)) prescription monitoring program is confidential, ((~~in compliance with chapter 70.02 RCW and~~)) exempt from public inspection, copying, and disclosure under chapter 42.56 RCW, not subject to subpoena or discovery in any civil action, and protected under federal health care information privacy requirements ((~~and not subject to disclosure~~)), except as provided in subsections (3)((~~, (4), and (5)~~)) through (6) of this section. Such confidentiality and exemption from disclosure continues whenever information from the prescription monitoring program is provided to a requestor under subsection (3), (4), (5), or (6) of this section except when used in proceedings specifically authorized in subsection (3), (4), or (5) of this section.

(2) The department must maintain procedures to ensure that the privacy and confidentiality of ((~~patients and patient~~)) all information collected, recorded, transmitted, and maintained including, but not limited to, the prescriber, requestor, dispenser, patient, and persons who received prescriptions from dispensers, is not disclosed to persons except as in subsections (3)((~~, (4), and (5)~~)) through (6) of this section.

(3) The department may provide data in the prescription monitoring program to the following persons:

(a) Persons authorized to prescribe or dispense controlled substances or legend drugs, for the purpose of providing medical or pharmaceutical care for their patients;

(b) An individual who requests the individual's own prescription monitoring information;

(c) A health professional licensing, certification, or regulatory agency or entity in this or another jurisdiction. Consistent with current practice, the data provided may be used in legal proceedings concerning the license;

(d) Appropriate law enforcement or prosecutorial officials, including local, state, and federal officials and officials of federally recognized tribes, who are engaged in a bona fide specific investigation involving a designated person;

(e) ((~~Authorized practitioners of the department of social and health services and the health care authority regarding medicaid program recipients;~~

~~(f)~~)) The director or the director's designee within the health care authority regarding medicaid ((~~clients for the purposes of quality improvement, patient safety, and care coordination. The information may not be used for contracting or value-based purchasing decisions~~)) recipients and members of the health care authority self-funded or self-insured health plans;

((~~(g)~~)) (f) The director or director's designee within the department of labor and industries regarding workers' compensation claimants;

((~~(h)~~)) (g) The director or the director's designee within the department of corrections regarding offenders committed to the department of corrections;

((~~(i)~~)) (h) Other entities under grand jury subpoena or court order;

((~~(j)~~)) (i) Personnel of the department for purposes of:

(i) Assessing prescribing and treatment practices((~~, including controlled substances related to mortality and morbidity~~)) and morbidity and mortality related to use of controlled substances and developing and implementing initiatives to protect the public health including, but not limited to, initiatives to address opioid use disorder;

(ii) Providing quality improvement feedback to ((~~providers~~)) prescribers, including comparison of their respective data to

aggregate data for ((~~providers~~)) prescribers with the same type of license and same specialty; and

(iii) Administration and enforcement of this chapter or chapter 69.50 RCW;

((~~(k)~~)) (j) Personnel of a test site that meet the standards under RCW 70.225.070 pursuant to an agreement between the test site and a person identified in (a) of this subsection to provide assistance in determining which medications are being used by an identified patient who is under the care of that person;

((~~(l)~~)) (k) A health care facility or entity for the purpose of providing medical or pharmaceutical care to the patients of the facility or entity, or for quality improvement purposes if((~~:~~

~~(i)~~)) the facility or entity is licensed by the department or is licensed or certified under chapter 71.24, 71.34, or 71.05 RCW or is an entity deemed for purposes of chapter 71.24 RCW to meet state minimum standards as a result of accreditation by a recognized behavioral health accrediting body, or is operated by the federal government or a federally recognized Indian tribe; ((~~and~~

~~(ii) The facility or entity is a trading partner with the state's health information exchange;~~

~~(m)~~)) (l) A health care provider group of five or more ((~~providers~~)) prescribers or dispensers for purposes of providing medical or pharmaceutical care to the patients of the provider group, or for quality improvement purposes if((~~:~~

~~(i)~~)) all the ((~~providers~~)) prescribers or dispensers in the provider group are licensed by the department or the provider group is operated by the federal government or a federally recognized Indian tribe; ((~~and~~

~~(ii) The provider group is a trading partner with the state's health information exchange;~~

~~(n)~~)) (m) The local health officer of a local health jurisdiction for the purposes of patient follow-up and care coordination following a controlled substance overdose event. For the purposes of this subsection "local health officer" has the same meaning as in RCW 70.05.010; and

((~~(o)~~)) (n) The coordinated care electronic tracking program developed in response to section 213, chapter 7, Laws of 2012 2nd sp. sess., commonly referred to as the seven best practices in emergency medicine, for the purposes of providing:

(i) Prescription monitoring program data to emergency department personnel when the patient registers in the emergency department; and

(ii) Notice to local health officers who have made opioid-related overdose a notifiable condition under RCW 70.05.070 as authorized by rules adopted under RCW 43.20.050, providers, appropriate care coordination staff, and prescribers listed in the patient's prescription monitoring program record that the patient has experienced a controlled substance overdose event. The department shall determine the content and format of the notice in consultation with the Washington state hospital association, Washington state medical association, and Washington state health care authority, and the notice may be modified as necessary to reflect current needs and best practices.

(4) The department shall, on at least a quarterly basis, and pursuant to a schedule determined by the department, provide a facility or entity identified under subsection (3)((~~(l)~~)) (k) of this section or a provider group identified under subsection (3)((~~(m)~~)) (l) of this section with facility or entity and individual prescriber information if the facility, entity, or provider group:

(a) Uses the information only for internal quality improvement and individual prescriber quality improvement feedback purposes and does not use the information as the sole basis for any medical staff sanction or adverse employment action; and

(b) Provides to the department a standardized list of current prescribers of the facility, entity, or provider group. The specific facility, entity, or provider group information provided pursuant to this subsection and the requirements under this subsection must be determined by the department in consultation with the Washington state hospital association, Washington state medical association, and Washington state health care authority, and may be modified as necessary to reflect current needs and best practices.

(5)(a) The department may publish or provide data to public or private entities for statistical, research, or educational purposes after removing information that could be used directly or indirectly to identify individual patients, requestors, dispensers, prescribers, and persons who received prescriptions from dispensers. Direct and indirect patient identifiers may be provided for research that has been approved by the Washington state institutional review board and by the department through a data-sharing agreement.

(b)(i) The department may provide dispenser and prescriber data and data that includes indirect patient identifiers to the Washington state hospital association for use solely in connection with its coordinated quality improvement program maintained under RCW 43.70.510 after entering into a data use agreement as specified in RCW 43.70.052(8) with the association. The department may provide dispenser and prescriber data and data that includes indirect patient identifiers to the Washington state medical association for use solely in connection with its coordinated quality improvement program maintained under RCW 43.70.510 after entering into a data use agreement with the association.

(ii) The department may provide data including direct and indirect patient identifiers to the department of social and health services office of research and data analysis, the department of labor and industries, and the health care authority for research that has been approved by the Washington state institutional review board and, with a data-sharing agreement approved by the department, for public health purposes to improve the prevention or treatment of substance use disorders.

(iii) The department may provide a prescriber feedback report to the largest health professional association representing each of the prescribing professions. The health professional associations must distribute the feedback report to prescribers engaged in the professions represented by the associations for quality improvement purposes, so long as the reports contain no direct patient identifiers that could be used to identify individual patients, dispensers, and persons who received prescriptions from dispensers, and the association enters into a written data-sharing agreement with the department. However, reports may include indirect patient identifiers as agreed to by the department and the association in a written data-sharing agreement.

(c) For the purposes of this subsection((~~,~~)):

(i) "Indirect patient identifiers" means data that may include: Hospital or provider identifiers, a five-digit zip code, county, state, and country of resident; dates that include month and year; age in years; and race and ethnicity; but does not include the patient's first name; middle name; last name; social security number; control or medical record number; zip code plus four digits; dates that include day, month, and year; or admission and discharge date in combination; and

(ii) "Prescribing professions" include:

(A) Allopathic physicians and physician assistants;

(B) Osteopathic physicians and physician assistants;

(C) Podiatric physicians;

(D) Dentists; and

(E) Advanced registered nurse practitioners.

(6) The department may enter into agreements to exchange prescription monitoring program data with established prescription monitoring programs in other jurisdictions. Under these agreements, the department may share prescription monitoring system data containing direct and indirect patient identifiers with other jurisdictions through a clearinghouse or prescription monitoring program data exchange that meets federal health care information privacy requirements. Data the department receives from other jurisdictions must be retained, used, protected, and destroyed as provided by the agreements to the extent consistent with the laws in this state.

(7) Persons authorized in subsections (3)((~~, (4), and (5)~~)) through (6) of this section to receive data in the prescription monitoring program from the department, acting in good faith, are immune from any civil, criminal, disciplinary, or administrative liability that might otherwise be incurred or imposed for acting under this chapter.

Sec. 24. RCW 71.24.011 and 1982 c 204 s 1 are each amended to read as follows:

This chapter may be known and cited as the community ((~~mental~~)) behavioral health services act.

NEW SECTION. **Sec. 25.** A new section is added to chapter 71.24 RCW to read as follows:

(1) Recognizing that treatment strategies and modalities for the treatment of individuals with opioid use disorder and their newborns continue to evolve, and that improved health outcomes are seen when birth parents and their infants are allowed to room together, the authority must provide recommendations to the office of financial management by October 1, 2019, to better support the care of individuals who have recently delivered and their newborns.

(2) These recommendations must support:

(a) Successful transition from the early postpartum and newborn period for the birth parent and infant to the next level of care;

(b) Reducing the risk of parental infant separation; and

(c) Increasing the chance of uninterrupted recovery of the parent and foster the development of positive parenting practices.

(3) The authority's recommendations must include:

(a) How these interventions could be supported in hospitals, birthing centers, or other appropriate sites of care and descriptions as to current barriers in providing these interventions;

(b) Estimates of the costs needed to support this enhanced set of services; and

(c) Mechanisms for funding the services.

Sec. 26. RCW 71.24.560 and 2017 c 297 s 11 are each amended to read as follows:

(1) All approved opioid treatment programs that provide services to ((~~women~~)) individuals who are pregnant are required to disseminate up-to-date and accurate health education information to all their pregnant ((~~clients~~)) individuals concerning the ((~~possible addiction and health risks that their treatment may have on their baby~~)) effects opioid use and opioid use disorder medication may have on their baby, including the development of dependence and subsequent withdrawal. All pregnant ((~~clients~~)) individuals must also be advised of the risks to both themselves and their ((~~baby~~)) babies associated with ((~~not remaining on the~~)) discontinuing an opioid treatment program. The information must be provided to these ((~~clients~~)) individuals both verbally and in writing. The health education information provided to the pregnant ((~~clients~~)) individuals must include referral options for ((~~the substance-exposed baby~~)) a baby who has been exposed to opioids in utero.

(2) The department shall adopt rules that require all opioid treatment programs to educate all pregnant ((~~women~~)) individuals in their program on the benefits and risks of medication-assisted treatment to ((~~their~~)) a developing fetus before they are ((~~provided~~)) prescribed these medications, as part of their treatment. The department shall also adopt rules requiring all opioid treatment programs to educate individuals who become pregnant about the risks to both the expecting parent and the fetus of not treating opioid use disorder. The department shall meet the requirements under this subsection within the appropriations provided for opioid

treatment programs. The department, working with treatment providers and medical experts, shall develop and disseminate the educational materials to all certified opioid treatment programs.

(3) For pregnant individuals who participate in medicaid, the authority, through its managed care organizations, must ensure that pregnant individuals receive outreach related to opioid use disorder when identified as a person at risk.

Sec. 27. RCW 71.24.580 and 2018 c 205 s 2 and 2018 c 201 s 4044 are each reenacted and amended to read as follows:

(1) The criminal justice treatment account is created in the state treasury. Moneys in the account may be expended solely for: (a) Substance use disorder treatment and treatment support services for offenders with a substance use disorder that, if not treated, would result in addiction, against whom charges are filed by a prosecuting attorney in Washington state; (b) the provision of substance use disorder treatment services and treatment support services for nonviolent offenders within a drug court program; and (c) the administrative and overhead costs associated with the operation of a drug court. Amounts provided in this subsection must be used for treatment and recovery support services for criminally involved offenders and authorization of these services shall not be subject to determinations of medical necessity. During the 2017-2019 fiscal biennium, the legislature may direct the state treasurer to make transfers of moneys in the criminal justice treatment account to the state general fund. It is the intent of the legislature to continue in the 2019-2021 biennium the policy of transferring to the state general fund such amounts as reflect the excess fund balance of the account. Moneys in the account may be spent only after appropriation.

(2) For purposes of this section:

(a) "Treatment" means services that are critical to a participant's successful completion of his or her substance use disorder treatment program, including but not limited to the recovery support and other programmatic elements outlined in RCW 2.30.030 authorizing therapeutic courts; and

(b) "Treatment support" includes transportation to or from inpatient or outpatient treatment services when no viable alternative exists, and child care services that are necessary to ensure a participant's ability to attend outpatient treatment sessions.

(3) Revenues to the criminal justice treatment account consist of: (a) Funds transferred to the account pursuant to this section; and (b) any other revenues appropriated to or deposited in the account.

(4)(a) For the fiscal year beginning July 1, 2005, and each subsequent fiscal year, the state treasurer shall transfer eight million two hundred fifty thousand dollars from the general fund to the criminal justice treatment account, divided into four equal quarterly payments. For the fiscal year beginning July 1, 2006, and each subsequent fiscal year, the amount transferred shall be increased on an annual basis by the implicit price deflator as published by the federal bureau of labor statistics.

(b) In each odd-numbered year, the legislature shall appropriate the amount transferred to the criminal justice treatment account in (a) of this subsection to the department for the purposes of subsection (5) of this section.

(5) Moneys appropriated to the authority from the criminal justice treatment account shall be distributed as specified in this subsection. The authority may retain up to three percent of the amount appropriated under subsection (4)(b) of this section for its administrative costs.

(a) Seventy percent of amounts appropriated to the authority from the account shall be distributed to counties pursuant to the distribution formula adopted under this section. The authority, in consultation with the department of corrections, the Washington state association of counties, the Washington state association of drug court professionals, the superior court judges' association, the Washington association of prosecuting attorneys, representatives of the criminal defense bar, representatives of substance use disorder treatment providers, and any other person deemed by the authority to be necessary, shall establish a fair and reasonable methodology for distribution to counties of moneys in the criminal justice treatment account. County or regional plans submitted for the expenditure of formula funds must be approved by the panel established in (b) of this subsection.

(b) Thirty percent of the amounts appropriated to the authority from the account shall be distributed as grants for purposes of treating offenders against whom charges are filed by a county prosecuting attorney. The authority shall appoint a panel of representatives from the Washington association of prosecuting

attorneys, the Washington association of sheriffs and police chiefs, the superior court judges' association, the Washington state association of counties, the Washington defender's association or the Washington association of criminal defense lawyers, the department of corrections, the Washington state association of drug court professionals, and substance use disorder treatment providers. The panel shall review county or regional plans for funding under (a) of this subsection and grants approved under this subsection. The panel shall attempt to ensure that treatment as funded by the grants is available to offenders statewide.

(6) The county alcohol and drug coordinator, county prosecutor, county sheriff, county superior court, a substance abuse treatment provider appointed by the county legislative authority, a member of the criminal defense bar appointed by the county legislative authority, and, in counties with a drug court, a representative of the drug court shall jointly submit a plan, approved by the county legislative authority or authorities, to the panel established in subsection (5)(b) of this section, for disposition of all the funds provided from the criminal justice treatment account within that county. The submitted plan should incorporate current evidence-based practices in substance use disorder treatment. The funds shall be used solely to provide approved alcohol and substance ((~~abuse~~)) use disorder treatment pursuant to RCW 71.24.560 and treatment support services. No more than ten percent of the total moneys received under subsections (4) and (5) of this section by a county or group of counties participating in a regional agreement shall be spent for treatment support services.

(7) Counties are encouraged to consider regional agreements and submit regional plans for the efficient delivery of treatment under this section.

(8) Moneys allocated under this section shall be used to supplement, not supplant, other federal, state, and local funds used for substance abuse treatment.

(9) If a region or county uses criminal justice treatment account funds to support a therapeutic court, the therapeutic court must allow the use of all medications approved by the federal food and drug administration for the treatment of opioid use disorder as deemed medically appropriate for a participant by a medical professional. If appropriate medication-assisted treatment resources are not available or accessible within the jurisdiction, the health

care authority's designee for assistance must assist the court with acquiring the resource.

(10) Counties must meet the criteria established in RCW 2.30.030(3).

Sec. 28. RCW 71.24.585 and 2017 c 297 s 12 are each amended to read as follows:

((~~The state of Washington declares that there is no fundamental right to medication-assisted treatment for opioid use disorder.~~))

(1)(a) The state of Washington ((~~further~~)) declares that ((~~while medications used in the treatment of opioid use disorder are addictive substances, that they nevertheless have several legal, important, and justified uses and that one of their appropriate and legal uses is, in conjunction with other required therapeutic procedures, in the treatment of persons with opioid use disorder. The state of Washington recognizes as evidence-based for the management of opioid use disorder the medications approved by the federal food and drug administration for the treatment of opioid use disorder. Medication-assisted treatment should only be used for participants who are deemed appropriate to need this level of intervention. Providers must inform patients of all treatment options available. The provider and the patient shall consider alternative treatment options, like abstinence, when developing the treatment plan. If medications are prescribed, follow up must be included in the treatment plan in order to work towards the goal of abstinence.~~)) substance use disorders are medical conditions. Substance use disorders should be treated in a manner similar to other medical conditions by using interventions that are supported by evidence, including medications approved by the federal food and drug administration for the treatment of opioid use disorder. It is also recognized that many individuals have multiple substance use disorders, as well as histories of trauma, developmental disabilities, or mental health conditions. As such, all individuals experiencing opioid use disorder should be offered evidence-supported treatments to include federal food and drug administration approved medications for the treatment of opioid use disorders and behavioral counseling and social supports to address them. For behavioral health agencies, an effective plan of treatment for most persons with opioid use disorder integrates access to medications and psychosocial counseling and should be consistent with the American society of

addiction medicine patient placement criteria. Providers must inform patients with opioid use disorder or substance use disorder of options to access federal food and drug administration approved medications for the treatment of opioid use disorder or substance use disorder. Because some such medications are controlled substances in chapter 69.50 RCW, the state of Washington maintains the legal obligation and right to regulate the ((~~clinical~~)) uses of these medications in the treatment of opioid use disorder.

((~~Further,~~)) (b) The authority must work with other state agencies and stakeholders to develop value-based payment strategies to better support the ongoing care of persons with opioid and other substance use disorders.

(c) The department of corrections shall develop policies to prioritize services based on available grant funding and funds appropriated specifically for opioid use disorder treatment.

(2) The authority must promote the use of medication therapies and other evidence-based strategies to address the opioid epidemic in Washington state. Additionally, by January 1, 2020, the authority must prioritize state resources for the provision of treatment and recovery support services to inpatient and outpatient treatment settings that allow patients to start or maintain their use of medications for opioid use disorder while engaging in services.

(3) The state declares that the main goals of ((~~opiate substitution treatment is total abstinence from substance use for the individuals who participate in the treatment program, but recognizes the additional goals of reduced morbidity, and restoration of the ability to lead a productive and fulfilling life. The state recognizes that a small percentage of persons who participate in opioid treatment programs require treatment for an extended period of time. Opioid treatment programs shall provide a comprehensive transition program to eliminate substance use, including opioid use of program participants~~)) treatment for persons with opioid use disorder are the cessation of unprescribed opioid use, reduced morbidity, and restoration of the ability to lead a productive and fulfilling life.

(4) To achieve the goals in subsection (3) of this section, to promote public health and safety, and to promote the efficient and economic use of funding for the medicaid program under Title XIX of the social security act, the authority may seek, receive, and expend

alternative sources of funding to support all aspects of the state's response to the opioid crisis.

(5) The authority must partner with the department of social and health services, the department of corrections, the department of health, the department of children, youth, and families, and any other agencies or entities the authority deems appropriate to develop a statewide approach to leveraging medicaid funding to treat opioid use disorder and provide emergency overdose treatment. Such alternative sources of funding may include:

(a) Seeking a section 1115 demonstration waiver from the federal centers for medicare and medicaid services to fund opioid treatment medications for persons eligible for medicaid at or during the time of incarceration and juvenile detention facilities; and

(b) Soliciting and receiving private funds, grants, and donations from any willing person or entity.

(6)(a) The authority shall work with the department of health to promote coordination between medication-assisted treatment prescribers, federally accredited opioid treatment programs, substance use disorder treatment facilities, and state-certified substance use disorder treatment agencies to:

(i) Increase patient choice in receiving medication and counseling;

(ii) Strengthen relationships between opioid use disorder providers;

(iii) Acknowledge and address the challenges presented for individuals needing treatment for multiple substance use disorders simultaneously; and

(iv) Study and review effective methods to identify and reach out to individuals with opioid use disorder who are at high risk of overdose and not involved in traditional systems of care, such as homeless individuals using syringe service programs, and connect such individuals to appropriate treatment.

(b) The authority must work with stakeholders to develop a set of recommendations to the governor and the legislature that:

(i) Propose, in addition to those required by federal law, a standard set of services needed to support the complex treatment needs of persons with opioid use disorder treated in opioid treatment programs;

(ii) Outline the components of and strategies needed to develop opioid treatment program centers of excellence that provide fully integrated care for persons with opioid use disorder;

(iii) Estimate the costs needed to support these models and recommendations for funding strategies that must be included in the report;

(iv) Outline strategies to increase the number of waivered health care providers approved for prescribing buprenorphine by the substance abuse and mental health services administration; and

(v) Outline strategies to lower the cost of federal food and drug administration approved products for the treatment of opioid use disorder.

(7) State agencies shall review and promote positive outcomes associated with the accountable communities of health funded opioid projects and local law enforcement and human services opioid collaborations as set forth in the Washington state interagency opioid working plan.

(8) The authority must partner with the department and other state agencies to replicate effective approaches for linking individuals who have had a nonfatal overdose with treatment opportunities, with a goal to connect certified peer counselors with individuals who have had a nonfatal overdose.

(9) State agencies must work together to increase outreach and education about opioid overdoses to non-English-speaking communities by developing a plan to conduct outreach and education to non-English-speaking communities. The department must submit a report on the outreach and education plan with recommendations for implementation to the appropriate legislative committees by July 1, 2020.

NEW SECTION. **Sec. 29.** A new section is added to chapter 71.24 RCW to read as follows:

(1) Subject to funds appropriated by the legislature, the authority shall implement a pilot project for law enforcement assisted diversion which shall adhere to law enforcement assisted diversion core principles recognized by the law enforcement assisted diversion national support bureau, the efficacy of which have been demonstrated in peer-reviewed research studies.

(2) Under the pilot project, the authority must partner with the law enforcement assisted diversion national support bureau to award a

contract, subject to appropriation, for two or more geographic areas in the state of Washington for law enforcement assisted diversion. Cities, counties, and tribes may compete for participation in a pilot project.

(3) The pilot projects must provide for comprehensive technical assistance from law enforcement assisted diversion implementation experts to develop and implement a law enforcement assisted diversion program in the pilot project's geographic areas in a way that ensures fidelity to the research-based law enforcement assisted diversion model.

(4) The key elements of a law enforcement assisted diversion pilot project must include:

(a) Long-term case management for individuals with substance use disorders;

(b) Facilitation and coordination with community resources focusing on overdose prevention;

(c) Facilitation and coordination with community resources focused on the prevention of infectious disease transmission;

(d) Facilitation and coordination with community resources providing physical and behavioral health services;

(e) Facilitation and coordination with community resources providing medications for the treatment of substance use disorders;

(f) Facilitation and coordination with community resources focusing on housing, employment, and public assistance;

(g) Twenty-four hours per day and seven days per week response to law enforcement for arrest diversions; and

(h) Prosecutorial support for diversion services.

Sec. 30. RCW 71.24.590 and 2018 c 201 s 4045 are each amended to read as follows:

(1) When making a decision on an application for licensing or certification of a program, the department shall:

(a) Consult with the county legislative authorities in the area in which an applicant proposes to locate a program and the city legislative authority in any city in which an applicant proposes to locate a program;

(b) License or certify only programs that will be sited in accordance with the appropriate county or city land use ordinances. Counties and cities may require conditional use permits with reasonable conditions for the siting of programs. Pursuant to RCW

36.70A.200, no local comprehensive plan or development regulation may preclude the siting of essential public facilities;

(c) Not discriminate in its licensing or certification decision on the basis of the corporate structure of the applicant;

(d) Consider the size of the population in need of treatment in the area in which the program would be located and license or certify only applicants whose programs meet the necessary treatment needs of that population;

(e) Consider the availability of other certified opioid treatment programs near the area in which the applicant proposes to locate the program;

(f) Consider the transportation systems that would provide service to the program and whether the systems will provide reasonable opportunities to access the program for persons in need of treatment;

(g) Consider whether the applicant has, or has demonstrated in the past, the capability to provide the appropriate services to assist the persons who utilize the program in meeting goals established by the legislature in RCW 71.24.585. The department shall prioritize licensing or certification to applicants who have demonstrated such capability and are able to measure their success in meeting such outcomes;

(h) Hold one public hearing in the community in which the facility is proposed to be located. The hearing shall be held at a time and location that are most likely to permit the largest number of interested persons to attend and present testimony. The department shall notify all appropriate media outlets of the time, date, and location of the hearing at least three weeks in advance of the hearing.

(2) A county may impose a maximum capacity for a program of not less than three hundred fifty participants if necessary to address specific local conditions cited by the county.

(3) A program applying for licensing or certification from the department and a program applying for a contract from a state agency that has been denied the licensing or certification or contract shall be provided with a written notice specifying the rationale and reasons for the denial.

(4) Opioid treatment programs may order, possess, dispense, and administer medications approved by the United States food and drug administration for the treatment of opioid use disorder, alcohol use

disorder, tobacco use disorder, and reversal of opioid overdose. For an opioid treatment program to order, possess, and dispense any other legend drug, including controlled substances, the opioid treatment program must obtain additional licensure as required by the department, except for patient-owned medications.

(5) Opioid treatment programs may accept, possess, and administer patient-owned medications.

(6) Registered nurses and licensed practical nurses may dispense up to a thirty-one day supply of medications approved by the United States food and drug administration for the treatment of opioid use disorder to patients of the opioid treatment program, under an order or prescription and in compliance with 42 C.F.R. Sec. 8.12.

(7) For the purpose of this chapter, "opioid treatment program" means a program that:

(a) ((~~Dispensing a~~)) Engages in the treatment of opioid use disorder with medications approved by the ((~~federal~~)) United States food and drug administration for the treatment of opioid use disorder and ((~~dispensing medication for the~~)) reversal of opioid overdose; and

(b) ((~~Providing~~)) Provides a comprehensive range of medical and rehabilitative services.

Sec. 31. RCW 71.24.595 and 2018 c 201 s 4046 are each amended to read as follows:

(1) To achieve more medication options, the authority must work with the department and the authority's medicaid managed care organizations, to eliminate barriers and promote access to effective medications known to address opioid use disorders at state-certified opioid treatment programs. Medications include, but are not limited to: Methadone, buprenorphine, and naltrexone. The authority must encourage the distribution of naloxone to patients who are at risk of an opioid overdose.

(2) The department, in consultation with opioid treatment program service providers and counties and cities, shall establish statewide treatment standards for licensed or certified opioid treatment programs. The department shall enforce these treatment standards. The treatment standards shall include, but not be limited to, reasonable provisions for all appropriate and necessary medical procedures, counseling requirements, urinalysis, and other suitable tests as needed to ensure compliance with this chapter.

((~~(2)~~)) (3) The department, in consultation with opioid treatment programs and counties, shall establish statewide operating standards for certified opioid treatment programs. The department shall enforce these operating standards. The operating standards shall include, but not be limited to, reasonable provisions necessary to enable the department and counties to monitor certified or licensed opioid treatment programs for compliance with this chapter and the treatment standards authorized by this chapter and to minimize the impact of the opioid treatment programs upon the business and residential neighborhoods in which the program is located.

((~~(3)~~)) (4) The department shall analyze and evaluate the data submitted by each treatment program and take corrective action where necessary to ensure compliance with the goals and standards enumerated under this chapter. Opioid treatment programs are subject to the oversight required for other substance use disorder treatment programs, as described in this chapter.

NEW SECTION. **Sec. 32.** A new section is added to chapter 71.24 RCW to read as follows:

By October 1, 2019, the authority must work with the department, the accountable communities of health, and community stakeholders to develop a plan for the coordinated purchasing and distribution of opioid overdose reversal medication across the state of Washington. The plan must be developed in consultation with the University of Washington's alcohol and drug abuse institute and community agencies participating in the federal demonstration grant titled Washington state project to prevent prescription drug or opioid overdose.

NEW SECTION. **Sec. 33.** A new section is added to chapter 71.24 RCW to read as follows:

(1) The department, in coordination with the authority, must develop a strategy to rapidly deploy a response team to a local community identified as having a high number of fentanyl-related or other drug overdoses by the local emergency management system, hospital emergency department, local health jurisdiction, law enforcement agency, or surveillance data. The response team must provide technical assistance and other support to the local health jurisdiction, health care clinics, hospital emergency departments, substance use disorder treatment providers, and other community-based

organizations, and are expected to increase the local capacity to provide medication-assisted treatment and overdose education.

(2) The department and the authority must reduce barriers and promote medication treatment therapies for opioid use disorder in emergency departments and same-day referrals to opioid treatment programs, substance use disorder treatment facilities, and community-based medication treatment prescribers for individuals experiencing an overdose.

NEW SECTION. **Sec. 34.** A new section is added to chapter 71.24 RCW to read as follows:

(1) Subject to funds appropriated by the legislature, or approval of a section 1115 demonstration waiver from the federal centers for medicare and medicaid services, to fund opioid treatment medications for persons eligible for medicaid at or during the time of incarceration and juvenile detention facilities, the authority shall establish a methodology for distributing funds to city and county jails to provide medication for the treatment of opioid use disorder to individuals in the custody of the facility in any status. The authority must prioritize funding for the services required in (a) of this subsection. To the extent that funding is provided, city and county jails must:

(a) Provide medication for the treatment of opioid use disorder to individuals in the custody of the facility, in any status, who were receiving medication for the treatment of opioid use disorder through a legally authorized medical program or by a valid prescription immediately before incarceration; and

(b) Provide medication for the treatment of opioid use disorder to incarcerated individuals not less than thirty days before release when treatment is determined to be medically appropriate by a health care practitioner.

(2) City and county jails must make reasonable efforts to directly connect incarcerated individuals receiving medication for the treatment of opioid use disorder to an appropriate provider or treatment site in the geographic region in which the individual will reside before release. If a connection is not possible, the facility must document its efforts in the individual's record.

NEW SECTION. **Sec. 35.** A new section is added to chapter 74.09 RCW to read as follows:

(1) In order to support prevention of potential opioid use disorders, the authority must develop and recommend for coverage nonpharmacologic treatments for acute, subacute, and chronic noncancer pain and must report to the governor and the appropriate committees of the legislature, including any requests for funding necessary to implement the recommendations under this section. The recommendations must contain the following elements:

(a) A list of which nonpharmacologic treatments will be covered;

(b) Recommendations as to the duration, amount, and type of treatment eligible for coverage;

(c) Guidance on the type of providers eligible to provide these treatments; and

(d) Recommendations regarding the need to add any provider types to the list of currently eligible medicaid provider types.

(2) The authority must ensure only treatments that are evidence-based for the treatment of the specific acute, subacute, and chronic pain conditions will be eligible for coverage recommendations.

NEW SECTION. **Sec. 36.** A new section is added to chapter 41.05 RCW to read as follows:

A health plan offered to employees, school employees, and their covered dependents under this chapter issued or renewed on or after January 1, 2020, shall provide coverage without prior authorization of at least one federal food and drug administration approved product for the treatment of opioid use disorder in the drug classes opioid agonists, opioid antagonists, and opioid partial agonists.

NEW SECTION. **Sec. 37.** A new section is added to chapter 48.43 RCW to read as follows:

For health plans issued or renewed on or after January 1, 2020, a health carrier shall provide coverage without prior authorization of at least one federal food and drug administration approved product for the treatment of opioid use disorder in the drug classes opioid agonists, opioid antagonists, and opioid partial agonists.

NEW SECTION. **Sec. 38.** A new section is added to chapter 74.09 RCW to read as follows:

Upon initiation or renewal of a contract with the authority to administer a medicaid managed care plan, a managed health care system shall provide coverage without prior authorization of at least one

federal food and drug administration approved product for the treatment of opioid use disorder in the drug classes opioid agonists, opioid antagonists, and opioid partial agonists.

NEW SECTION. **Sec. 39.** A new section is added to chapter 28A.210 RCW to read as follows:

(1) For the purposes of this section:

(a) "High school" means a school enrolling students in any of grades nine through twelve;

(b) "Opioid overdose reversal medication" has the meaning provided in RCW 69.41.095;

(c) "Opioid-related overdose" has the meaning provided in RCW 69.41.095; and

(d) "Standing order" has the meaning provided in RCW 69.41.095.

(2)(a) For the purpose of assisting a person at risk of experiencing an opioid-related overdose, a high school may obtain and maintain opioid overdose reversal medication through a standing order prescribed and dispensed in accordance with RCW 69.41.095.

(b) Opioid overdose reversal medication may be obtained from donation sources, but must be maintained and administered in a manner consistent with a standing order issued in accordance with RCW 69.41.095.

(c) A school district with two thousand or more students must obtain and maintain at least one set of opioid overdose reversal medication doses in each of its high schools as provided in (a) and (b) of this subsection. A school district that demonstrates a good faith effort to obtain the opioid overdose reversal medication through a donation source, but is unable to do so, is exempt from the requirement in this subsection (2)(c).

(3)(a) The following personnel may distribute or administer the school-owned opioid overdose reversal medication to respond to symptoms of an opioid-related overdose pursuant to a prescription or a standing order issued in accordance with RCW 69.41.095: (i) A school nurse; (ii) a health care professional or trained staff person located at a health care clinic on public school property or under contract with the school district; or (iii) designated trained school personnel.

(b) Opioid overdose reversal medication may be used on school property, including the school building, playground, and school bus, as well as during field trips or sanctioned excursions away from

school property. A school nurse or designated trained school personnel may carry an appropriate supply of school-owned opioid overdose reversal medication on field trips or sanctioned excursions.

(4) Training for school personnel who have been designated to distribute or administer opioid overdose reversal medication under this section must meet the requirements for training described in section 40 of this act and any rules or guidelines for such training adopted by the office of the superintendent of public instruction. Each high school is encouraged to designate and train at least one school personnel to distribute and administer opioid overdose reversal medication if the high school does not have a full-time school nurse or trained health care clinic staff.

(5)(a) The liability of a person or entity who complies with this section and RCW 69.41.095 is limited as described in RCW 69.41.095.

(b) If a student is injured or harmed due to the administration of opioid overdose reversal medication that a practitioner, as defined in RCW 69.41.095, has prescribed and a pharmacist has dispensed to a school under this section, the practitioner and pharmacist may not be held responsible for the injury unless he or she acted with conscious disregard for safety.

NEW SECTION. **Sec. 40.** A new section is added to chapter 28A.210 RCW to read as follows:

(1) For the purposes of this section:

(a) "Opioid overdose reversal medication" has the meaning provided in RCW 69.41.095; and

(b) "Opioid-related overdose" has the meaning provided in RCW 69.41.095.

(2)(a) To prevent opioid-related overdoses and respond to medical emergencies resulting from overdoses, by January 1, 2020, the office of the superintendent of public instruction, in consultation with the department of health and the Washington state school directors' association, shall develop opioid-related overdose policy guidelines and training requirements for public schools and school districts.

(b)(i) The opioid-related overdose policy guidelines and training requirements must include information about: The identification of opioid-related overdose symptoms; how to obtain and maintain opioid overdose reversal medication on school property issued through a standing order in accordance with section 39 of this act; how to obtain opioid overdose reversal medication through donation sources;

the distribution and administration of opioid overdose reversal medication by designated trained school personnel; free online training resources that meet the training requirements in this section; and sample standing orders for opioid overdose reversal medication.

(ii) The opioid-related overdose policy guidelines may: Include recommendations for the storage and labeling of opioid overdose reversal medications that are based on input from relevant health agencies or experts; and allow for opioid-related overdose reversal medications to be obtained, maintained, distributed, and administered by health care professionals and trained staff located at a health care clinic on public school property or under contract with the school district.

(c) In addition to being offered by the school, training on the distribution or administration of opioid overdose reversal medication that meets the requirements of this subsection (2) may be offered by nonprofit organizations, higher education institutions, and local public health organizations.

(3)(a) By March 1, 2020, the Washington state school directors' association must collaborate with the office of the superintendent of public instruction and the department of health to either update existing model policy or develop a new model policy that meets the requirements of subsection (2) of this section.

(b) Beginning with the 2020-21 school year, the following school districts must adopt an opioid-related overdose policy: (a) School districts with a school that obtains, maintains, distributes, or administers opioid overdose reversal medication under section 39 of this act; and (b) school districts with two thousand or more students.

(c) The office of the superintendent of public instruction and the Washington state school directors' association must maintain the model policy and procedure on each agency's web site at no cost to school districts.

(4) Subject to the availability of amounts appropriated for this specific purpose, the office of the superintendent of public instruction shall develop and administer a grant program to provide funding to public schools with any of grades nine through twelve and public higher education institutions to purchase opioid overdose reversal medication and train personnel on the administration of opioid overdose reversal medication to respond to symptoms of an

opioid-related overdose. The office must publish on its web site a list of annual grant recipients, including award amounts.

Sec. 41. RCW 28A.210.260 and 2017 c 186 s 2 are each amended to read as follows:

(1) Public school districts and private schools which conduct any of grades kindergarten through the twelfth grade may provide for the administration of oral medication, topical medication, eye drops, ear drops, or nasal spray, of any nature to students who are in the custody of the school district or school at the time of administration, but are not required to do so by this section, subject to the following conditions:

((~~(1)~~)) (a) The board of directors of the public school district or the governing board of the private school or, if none, the chief administrator of the private school shall adopt policies which address the designation of employees who may administer oral medications, topical medications, eye drops, ear drops, or nasal spray to students, the acquisition of parent requests and instructions, and the acquisition of requests from licensed health professionals prescribing within the scope of their prescriptive authority and instructions regarding students who require medication for more than fifteen consecutive school days, the identification of the medication to be administered, the means of safekeeping medications with special attention given to the safeguarding of legend drugs as defined in chapter 69.41 RCW, and the means of maintaining a record of the administration of such medication;

((~~(2)~~)) (b) The board of directors shall seek advice from one or more licensed physicians or nurses in the course of developing the foregoing policies;

((~~(3)~~)) (c) The public school district or private school is in receipt of a written, current and unexpired request from a parent, or a legal guardian, or other person having legal control over the student to administer the medication to the student;

((~~(4)~~)) (d) The public school district or the private school is in receipt of ((~~(a)~~)): (i) A written, current and unexpired request from a licensed health professional prescribing within the scope of his or her prescriptive authority for administration of the medication, as there exists a valid health reason which makes administration of such medication advisable during the hours when school is in session or the hours in which the student is under the

supervision of school officials((~~,~~)); and ((~~(b)~~)) (ii) written, current and unexpired instructions from such licensed health professional prescribing within the scope of his or her prescriptive authority regarding the administration of prescribed medication to students who require medication for more than fifteen consecutive workdays;

((~~(5)~~)) (e) The medication is administered by an employee designated by or pursuant to the policies adopted pursuant to (a) of this subsection ((~~(1) of this section~~)) and in substantial compliance with the prescription of a licensed health professional prescribing within the scope of his or her prescriptive authority or the written instructions provided pursuant to (d) of this subsection ((~~(4) of this section~~)). If a school nurse is on the premises, a nasal spray that is a legend drug or a controlled substance must be administered by the school nurse. If no school nurse is on the premises, a nasal spray that is a legend drug or a controlled substance may be administered by a trained school employee or parent-designated adult who is not a school nurse. The board of directors shall allow school personnel, who have received appropriate training and volunteered for such training, to administer a nasal spray that is a legend drug or a controlled substance. After a school employee who is not a school nurse administers a nasal spray that is a legend drug or a controlled substance, the employee shall summon emergency medical assistance as soon as practicable;

((~~(6)~~)) (f) The medication is first examined by the employee administering the same to determine in his or her judgment that it appears to be in the original container and to be properly labeled; and

((~~(7)~~)) (g) The board of directors shall designate a professional person licensed pursuant to chapter 18.71 RCW or chapter 18.79 RCW as it applies to registered nurses and advanced registered nurse practitioners, to delegate to, train, and supervise the designated school district personnel in proper medication procedures;

((~~(8)(a) For the purposes of this section, "parent-designated adult" means a volunteer, who may be a school district employee, who receives additional training from a health care professional or expert in epileptic seizure care selected by the parents, and who provides care for the child consistent with the individual health plan.~~

((~~(b)~~)) (h) To be eligible to be a parent-designated adult, a school district employee not licensed under chapter 18.79 RCW must file, without coercion by the employer, a voluntary written, current, and unexpired letter of intent stating the employee's willingness to be a parent-designated adult. If a school employee who is not licensed under chapter 18.79 RCW chooses not to file a letter under this section, the employee shall not be subject to any employer reprisal or disciplinary action for refusing to file a letter. A parent-designated adult must be a volunteer, who may be a school district employee, who receives additional training from a health care professional or expert in epileptic seizure care selected by the parents, and who provides care for the child consistent with the individual health plan; and

((~~(9)~~)) (i) The board of directors shall designate a professional person licensed under chapter 18.71, 18.57, or 18.79 RCW as it applies to registered nurses and advanced registered nurse practitioners, to consult and coordinate with the student's parents and health care provider, and train and supervise the appropriate school district personnel in proper procedures for care for students with epilepsy to ensure a safe, therapeutic learning environment. Training may also be provided by an epilepsy educator who is nationally certified. Parent-designated adults who are school employees are required to receive the training provided under this subsection. Parent-designated adults who are not school employees must show evidence of comparable training. The parent-designated adult must also receive additional training as established in (h) of this subsection ((~~(8)(a) of this section~~)) for the additional care the parents have authorized the parent-designated adult to provide. The professional person designated under this subsection is not responsible for the supervision of the parent-designated adult for those procedures that are authorized by the parents((~~;~~)).

((~~(10)~~)) (2) This section does not apply to:

(a) Topical sunscreen products regulated by the United States food and drug administration for over-the-counter use. Provisions related to possession and application of topical sunscreen products are in RCW 28A.210.278; and

(b) Opioid overdose reversal medication. Provisions related to maintenance and administration of opioid overdose reversal medication are in section 39 of this act.

Sec. 42. RCW 28A.210.270 and 2013 c 180 s 2 are each amended to read as follows:

(1) In the event a school employee administers oral medication, topical medication, eye drops, ear drops, or nasal spray to a student pursuant to RCW 28A.210.260 in substantial compliance with the prescription of the student's licensed health professional prescribing within the scope of the professional's prescriptive authority or the written instructions provided pursuant to RCW 28A.210.260((~~(4)~~)) (1)(d), and the other conditions set forth in RCW 28A.210.260 have been substantially complied with, then the employee, the employee's school district or school of employment, and the members of the governing board and chief administrator thereof shall not be liable in any criminal action or for civil damages in their individual or marital or governmental or corporate or other capacities as a result of the administration of the medication.

(2) The administration of oral medication, topical medication, eye drops, ear drops, or nasal spray to any student pursuant to RCW 28A.210.260 may be discontinued by a public school district or private school and the school district or school, its employees, its chief administrator, and members of its governing board shall not be liable in any criminal action or for civil damages in their governmental or corporate or individual or marital or other capacities as a result of the discontinuance of such administration: PROVIDED, That the chief administrator of the public school district or private school, or his or her designee, has first provided actual notice orally or in writing in advance of the date of discontinuance to a parent or legal guardian of the student or other person having legal control over the student.

NEW SECTION. **Sec. 43.** A new section is added to chapter 28B.10 RCW to read as follows:

(1) For the purposes of this section:

(a) "Opioid overdose reversal medication" has the meaning provided in RCW 69.41.095; and

(b) "Opioid-related overdose" has the meaning provided in RCW 69.41.095.

(2) By the beginning of the 2019-20 academic year, a public institution of higher education with a residence hall housing at least one hundred students must develop a plan: (a) For the maintenance and administration of opioid overdose reversal medication

in and around the residence hall; and (b) for the training of designated personnel to administer opioid overdose reversal medication to respond to symptoms of an opioid-related overdose. The training may utilize free online training resources including, but not limited to, the free online training resources identified as appropriate for public schools in section 40 of this act. The plan may identify: The ratio of residents to opioid overdose reversal medication doses; the designated trained personnel, who may include residence hall advisers; and whether the designated trained personnel covers more than one residence hall.

(3) The state board for community and technical colleges shall assist an individual community or technical college with applying for grants or donations to obtain opioid overdose reversal medication at no cost or at a discount.

NEW SECTION. **Sec. 44.** (1) Section 15 of this act expires January 1, 2021.

(2) Section 16 of this act takes effect January 1, 2021.

NEW SECTION. **Sec. 45.** If specific funding for the purposes of this act, referencing this act by bill or chapter number, is not provided by June 30, 2019, in the omnibus appropriations act, this act is null and void.

Passed by the Senate April 26, 2019.
Passed by the House April 26, 2019.
Approved by the Governor May 8, 2019.
Filed in Office of Secretary of State May 13, 2019.

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WAC 246-945-162 Pharmacist license qualifications. (1) In addition to the requirements in RCW 18.64.080, an applicant for a pharmacist license who holds a baccalaureate degree in pharmacy or a doctor of pharmacy degree from a commission accredited school or college of pharmacy shall submit documentation of education and practice experience as follows:

(a) An applicant who graduated before July 1, 2020, whose official transcripts confer or award a baccalaureate of pharmacy or doctorate of pharmacy degree shall provide certification of at least fifteen hundred pharmacy internship hours in accordance with WAC 246-945-163.

(b) An applicant who graduates after July 1, 2020, whose official transcripts confer or award a doctorate of pharmacy is deemed to have satisfied the pharmacy practice experience and education requirements for licensure without documentation of internship hours.

(2) An applicant for a pharmacist license whose academic training in pharmacy is from institutions in foreign countries shall:

(a) Achieve certification by FPGEC including:

(i) Passing FPGEE;

(ii) Passing required TOEFL iBT;

(b) Provide official transcripts or diploma that shows a baccalaureate of pharmacy or doctorate of pharmacy degree is awarded or conferred; and

(c) Certification of a minimum of fifteen hundred pharmacy internship hours in accordance with WAC 246-945-163.

(3) An applicant for a pharmacist license shall take and pass pharmacist licensure examinations as defined in WAC 246-945-165.

~~(4) An applicant for a pharmacist license shall provide proof of completion of seven hours of AIDS education as required in chapter 246-12 WAC, Part 8. The applicant is exempt from this requirement if they are a graduate of a commission accredited school or college of pharmacy because the curriculum satisfies this requirement.~~

[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, § 246-945-162, filed 6/1/20, effective 7/1/20.]

WAC 246-945-200 Pharmacy assistants. (1) To become registered as a pharmacy assistant an applicant shall submit an application to the commission that meets the requirements of chapter 246-12 WAC, Part 2.

~~(2) An initial applicant shall complete four hours of AIDS education as required in chapter 246-12 WAC, Part 8.~~

(2~~3~~) The supervising pharmacist, shall instruct the pharmacy assistant regarding their scope of practice.

(3~~4~~) To renew a registration a pharmacy assistant shall submit an application to the commission with the applicable fees in accordance with chapter 246-907 WAC.

[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, § 246-945-200, filed 6/1/20, effective 7/1/20.]

WAC 246-945-205 Pharmacy technician certification. (1) An applicant for a pharmacy technician certification shall be eighteen years of age and hold a high school diploma or GED.

(2) To be issued a certification as a pharmacy technician an applicant shall meet the qualifications in RCW 18.64A.020, and:

(a) Provide proof of completion of eight hours of guided study of Washington state and federal pharmacy law. The law study shall be done in coordination and oversight of a Washington licensed pharmacist.

~~(b) Provide proof of four hours of AIDS education as required in chapter 246-12 WAC, Part 8, the applicant is exempt if they have completed a commission-approved training program whose program materials on file with the commission office document four hours of AIDS education.~~

(b~~c~~) Provide proof of successful completion of a commission-approved pharmacy-technician training program WAC 246-945-215. Acceptable documentation includes:

(i) On-the-job training program. Successful completion of didactic and practice experience signed by the program director on a form provided by the commission; or

(ii) Formal academic or college programs. Official transcripts of completion of a diploma or certificate program at

a pharmacy technician school or a two-year associate degree program, which shall include evidence of practice training hours; or

(iii) Certificate of Release or Discharge from Active Duty, DD214 documenting evidence of pharmacy technician training provided by a branch of the federal armed services.

(d) Pass a national certification examination approved by the commission within one year of completing a commission-approved training program and applying for certification, unless otherwise authorized by the commission.

(3) An applicant who is a graduate of a foreign school, university or college of pharmacy or medicine, whose professional degree program is approved by the commission shall complete the following:

(a) If English is not the primary language, the applicant shall take and pass TOEFL iBT;

(b) Complete five hundred twenty hours of supervised experience under the supervision of a licensed pharmacist with training hours reported using forms provided by the commission; and

(c) Pass a national certification examination approved by the commission.

(4) An out-of-state pharmacy technician applicant must meet the same requirements as a pharmacy technician trained in Washington state.

[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, § 246-945-205, filed 6/1/20, effective 7/1/20.]

WAC 246-945-001 Definitions. The definitions in chapters 18.64 and 18.64A RCW and those in this section apply throughout this chapter unless otherwise stated.

(1) "ACPE" means accreditation council for pharmacy education.

(2) "Active ingredient" means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of humans or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in that drug product in a modified form intended to furnish the specified activity or effect.

(3) "Adulterated" refers to a drug that was produced and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with WAC 246-945-550 as to safety and has the identity and strength, and

meets the quality and purity characteristics, which it purports or is represented to possess.

(4) "Animal control agency" means any agency authorized by law to euthanize or destroy animals; to sedate animals prior to euthanasia or to engage in chemical capture of animals.

(5) "Approved legend drugs" means any legend drug approved by the commission for use by registered humane societies or animal control agencies for the sole purpose of sedating animals prior to euthanasia, when necessary, and for use in chemical capture programs.

(6) "Audit trail" means all materials and documents required for the entire process of filling a prescription, which shall be sufficient to document or reconstruct the origin of the prescription, and authorization of subsequent modifications of that prescription.

(7) "Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

(8) "Blood component" means that part of the blood separated by physical or mechanical means.

(9) "Central fill pharmacy" means a pharmacy contracting with an originating pharmacy, or having the same owner as an originating pharmacy, that provides centralized prescription filling on behalf of the originating pharmacy pursuant to these rules.

(10) "Chemical capture program" means wildlife management programs registered under RCW 69.41.080 and 69.50.320 to use approved legend drugs and controlled substance for chemical capture. Chemical capture includes immobilization of individual animals in order for the animals to be moved, treated, examined, or for other legitimate purposes.

(11) "Collaborative drug therapy agreement" or "CDTA" means a written guideline or protocol previously established and approved by a practitioner authorized to prescribe drugs that enables a pharmacist to exercise prescriptive authority.

(12) "Controlled substances" has the same meaning as RCW 69.50.101.

(13) "Controlled substance wholesaler" means a wholesaler licensed under RCW 18.64.046 to possess and sell controlled

substances to a licensed pharmacy or other legally licensed or authorized person.

(14) "Commission" means the pharmacy quality assurance commission.

(15) "Counterfeit" means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.

(16) "CPE" means continuing pharmacy education accredited by the ACPE.

(17) "Consultation" means:

(a) A communication or deliberation between a pharmacist and a patient, a patient's agent, or a patient's health care provider in which the pharmacist uses professional judgment to provide advice about drug therapy.

(b) A method by which the pharmacist meets patient information requirements as set forth in WAC 246-945-325.

(18) "Credential" means a license, certification, or registration under the chapters specified in RCW 18.130.040 issued to a person to practice a regulated health care profession. Whether the credential is a license, certification, or registration is determined by the law regulating the profession.

(19) "DEA" means the United States Drug Enforcement Administration.

(20) "Delegated tasks" means tasks that are performed pursuant to a pharmacist's direction, without the exercise of the pharmacy ancillary personnel's own judgment and discretion, and which do not require the pharmacy ancillary personnel's to exercise the independent professional judgment that is the foundation of the practice of the profession of pharmacy.

(21) "Department" means the Washington state department of health.

(22) "Dose" means the amount of drug to be administered at one time.

(23) "Drug(s) of concern" are those drugs identified by the commission as demonstrating a potential for abuse by all professionals licensed to prescribe, dispense, or administer such substances in this state.

(24) "Drug price advertising" means the dissemination of nonpromotional information pertaining to the prices of legend or prescription drugs.

(25) "Drug product" means a finished dosage form (e.g., tablet, capsule, solution) that contains an active drug ingredient generally, but not necessarily, in association with inactive ingredients. The term also includes a finished dosage form that does not contain an active ingredient but is intended to be used as a placebo.

(26) "Drug sample" means a unit of prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

(27) "Drug standard and information sources" means industry recognized reference and resources.

(28) "Drug storage area" means an area where legend drugs, controlled substances, or other restricted items are stored, compounded, or dispensed.

(29) "Drug utilization review" includes, but is not limited to, the following activities:

(a) Evaluation of prescriptions and patient records for known allergies, rational therapy-contraindications, appropriate dose, and route of administration and appropriate directions for use;

(b) Evaluation of prescriptions and patient records for duplication of therapy;

(c) Evaluation of prescriptions and patient records for interactions between drug-drug, drug-food, drug-disease, and adverse drug reactions; and

(d) Evaluation of prescriptions and patient records for proper utilization, including over- or under-utilization, and optimum therapeutic outcomes.

(30) "Electronic means" means an electronic device used to send, receive, and/or store prescription information, including computers, facsimile machines, etc.

(31) "Electronic signature" means an electronic sound, symbol, or process attached to or logically associated with a contract or other record and executed or adopted by a person with the intent to sign the record.

(32) "Enrolled student" means a student who has accepted an offer of admission in writing and the student has made the appropriate deposit securing admission to an accredited school or college of pharmacy.

(33) "Equivalent manager" means an individual authorized to act on behalf of a pharmaceutical firm not licensed as a pharmacy to serve as the primary contact for the department and is responsible for managing the facility operations which includes, but is not limited to, actively involved in and aware of the daily operations of the facility.

(34) "Export wholesaler" means any wholesaler authorized by the commission to export legend drugs and nonprescription (OTC) drugs to foreign countries.

(35) "FDA" – United States Food and Drug Administration.

(36) "Full-line wholesaler" means a drug wholesale distributor that is licensed under RCW 18.64.046 to possess and

sell legend drugs, controlled substance and nonprescription drugs to a licensed pharmacy or other legally licensed or authorized person.

(37) "FPGEC" means foreign pharmacy graduate examination committee.

(38) "FPGEE" means foreign pharmacy graduate equivalency examination.

(39) "Generic substitution" means the act of switching between a branded drug and its therapeutically equivalent generic version.

(40) "HIPAA" means Health Insurance Portability and Accountability Act.

(41) "Hospital" means any institution licensed under chapter 70.41 or 71.12 RCW or designated under RCW 72.23.020.

(42) "Hospital pharmacy" means that portion of a hospital licensed under RCW 18.64.043 which is engaged in the manufacture, production, preparation, dispensing, sale, or distribution of drugs, components, biologicals, chemicals, devices and other materials used in the diagnosis and treatment of injury, illness and diseases.

(43) "Hospital pharmacy associated clinic" or "HPAC" means an individual practitioner's office or multipractitioner clinic owned, operated, or under common control of a parent hospital or health system, where the physical address of the office or clinic is identified on a hospital pharmacy license.

(44) "Immediate supervision" means supervision by a pharmacist who is immediately available at all times the delegated tasks are being performed; who is aware of delegated tasks being performed; and who provides personal assistance, direction and approval throughout the time the delegated tasks are being performed.

(a) "Immediately available" means the pharmacist and pharmacy ancillary personnel or interns are on the same physical premises, or if not, technology is used to enable real time, two-way communications between the pharmacist and ~~technician(s)~~pharmacy ancillary personnel and interns.

(b) Use of technology: A pharmacist, as an adjunct to assist in the immediate supervision of the pharmacy ancillary personnel or intern, may employ technological means to communicate with or observe the pharmacy ancillary personnel or

intern. A pharmacist shall make certain all applicable state and federal laws including, but not limited to, confidentiality, are fully observed when employing technological means of communication and observation. If technology is being used to provide immediate supervision of pharmacy ancillary personnel or intern such technology shall be sufficient to provide the personal assistance, direction and approval required to meet the standard of practice for the delegated tasks.

(45) "Inoperable" means a credential status indicating that an individual cannot practice because he or she is not actively participating or enrolled in a required training program when this condition is a requirement of the credential. Inoperable status is not the result of enforcement action. The health care professional can resume practice when appropriately enrolled in a required training program and the credential is reactivated.

(46) "Internal test assessment" means, but is not limited to, conducting those tests of quality assurance necessary to ensure the integrity of the test.

(47) "Investigational drug" means any article drug that has an investigational drug application (INDA) that has been approved by the FDA.

(48) "Key party" means immediate family members and others who would be reasonably expected to play a significant role in the health care decisions of the patient or client and includes, but is not limited to, the spouse, domestic partner, sibling, parent, child, guardian and person authorized to make health care decisions of the patient or client.

(49) "Law enforcement" means any general or limited authority Washington peace officer or federal law enforcement officer or tribal officer.

(50) "License transfer" means the process used by licensed pharmacists to transfer their existing pharmacist license to Washington using NABP's Electronic Licensure Transfer Program® (e-LTP™).

(51) "Lot" means a batch or a specific identified portion of a batch having uniform character and quality within specified limits, or in the case of a drug product produced by continuous process, it is a specific identified amount produced in a unit

of time or quantity in a manner that assures it is having uniform character and quality within specified limits.

(52) "Manual signature" means a printed or wet signature.

(53) "Misbranded" applies to all drugs the package or label of which bears any statement, design or device regarding such article or the ingredients or substances contained therein which is false or misleading in any particular way, and drug product which is falsely branded as to the state, territory or country in which it is manufactured or produced.

(54) "NABP" means the National Association of Boards of Pharmacy.

(55) "NDC" means National Drug Code.

(56) "Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services.

(57) "Nuclear pharmacist" means a pharmacist licensed under RCW 18.64.080 who holds an endorsement that meets the requirements of WAC 246-945-180.

(58) "Originating pharmacy" means a pharmacy that receives a prescription from a patient, the patient's agent, or a prescriber, outsources prescription filling or processing

functions to another pharmacy, and ultimately dispenses the prescription drug or device to the patient or the patient's agent. This does not include pharmacies engaged in shared pharmacy services in accordance with RCW 18.64.570.

(59) "Over-the-counter drugs" or "OTC" means "nonlegend" or "nonprescription" drugs, and any drugs which may be lawfully sold without a prescription.

(60) "Over-the-counter only wholesaler" means any wholesaler licensed under RCW 18.64.046 to possess and sell OTC drugs to any outlets credentialed for resale.

(61) "Pharmaceutical firm" means a business engaged in the dispensing, delivering, distributing, manufacturing, or wholesaling of prescription drugs or devices within or into Washington state.

(62) "Pharmacy intern" means a person who is registered with the commission under RCW 18.64.080(3) as a pharmacy intern.

(63) "Pharmacy services" means any services provided that meet the definition of the practice of pharmacy, RCW 18.64.011.

(64) "Plan of correction" is a proposal devised by the applicant or credential holder that includes specific corrective

actions that must be taken to correct identified unresolved deficiencies with time frames to complete them.

(65) "Precursor drugs" as defined in chapter 69.43 RCW.

(66) "Prescription drug" means any drug, including any biological product required by federal statute or regulation to be dispensed only by a prescription, including finished dosage forms and bulk drug substances subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act.

(67) "Protocol" means a written set of procedures, steps or guidance.

(68) "Radiopharmaceutical service" means, but is not limited to:

(a) The preparing, compounding, dispensing, labeling, and delivery of radiopharmaceuticals;

(b) The participation in radiopharmaceutical selection and radiopharmaceutical utilization reviews;

(c) The proper and safe storage and distribution of radiopharmaceuticals;

(d) The maintenance of radiopharmaceutical quality assurance;

(e) The responsibility for advising, where necessary or where regulated, of therapeutic values, hazards and use of radiopharmaceuticals; or

(f) The offering or performing of those acts, services, operations or transactions necessary in the conduct, operation management and control of a nuclear pharmacy.

(69) "Radiopharmaceutical" means any substance defined as a drug in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any nonradioactive reagent kit or nuclide generator which is intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides. The term "radioactive drug" includes a "radioactive biological product."

(70) "Radiopharmaceutical quality assurance" means, but is not limited to, the performance of appropriate chemical, biological and physical tests on radiopharmaceuticals and the interpretation of the resulting data to determine their

suitability for use in humans and animals, including internal test assessment authentication of product history and the keeping of proper records.

(71) "Readily retrievable" means a record that is kept by automatic data processing systems or other electronic, mechanized, or written recordkeeping systems in such a manner that it can be separated out from all other records in a reasonable time.

(72) "Reverse distributor" means a pharmaceutical wholesaler that receives drugs for destruction, return credit, or otherwise disposes of drugs received from a registrant that holds a credential to dispense or possess drugs.

(73) "Secretary" means the secretary of the Washington state department of health.

(74) "Strength" means:

(a) The concentration of the drug product; and/or

(b) The potency, that is, the therapeutic activity of the drug product as indicated by appropriate laboratory tests or by adequately developed and controlled clinical data.

(75) "U.S. jurisdiction" means a state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, or a territory or insular possession subject to the jurisdiction of the United States.

(76) "USP" means the United States Pharmacopeia.

(77) "Therapeutic substitution" means the act of dispensing an alternative drug that is believed to be therapeutically similar but may be chemically different, in a different category, or with different pharmacokinetic properties. This substitution is based on the premise that the substituted drug will provide similar clinical efficacy, desired outcome, and safety profile.

(78) "TOEFL iBT" means an internet based test which measures the ability to use and understand English. It evaluates the combined use of reading, listening, speaking and writing skills.

(79) "Virtual manufacturer" means an individual or facility that sells his or her own prescription drugs, but never physically possesses the drugs.

(80) "Virtual wholesaler" means an individual or facility that sells a prescription drug and/or device, but never physically possesses the product.

(81) "Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

(a) The sale, purchase, or trade of a drug, an offer to sell, purchase or trade a drug, or the dispensing of a drug pursuant to a prescription;

(b) The lawful distribution of drug samples by manufacturers' representatives or distributors' representatives;

(c) The sale, purchase, or trade of blood and blood components intended for transfusion;

(d) Intracompany sales, being defined as any transaction or transfer between any division, subsidiary, parent and/or affiliated or related company under the common ownership and control of a corporate entity, unless such transfer occurs between a wholesale distributor and a health care entity or practitioner; or

(e) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons, for purposes of this section, "emergency medical reasons" includes transfers of prescription drugs by retail pharmacy to another retail pharmacy or practitioner to alleviate a temporary shortage, except that the gross dollar value of such transfers shall not exceed five percent of the total prescription drug sale revenue of either the transferor or transferee pharmacy during any twelve consecutive month period.

[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, § 246-945-001, filed 6/1/20, effective 7/1/20.]

WAC 246-945-011 Prescription validity. (1) Prior to dispensing and delivering a prescription, a pharmacist shall verify its validity.

(2) A prescription shall be considered invalid if:

(a) At the time of presentation, the prescription shows evidence of alteration, erasure, or addition by any person other than the person who wrote it;

(b) The prescription does not contain the required information as provided in WAC 246-945-010;

(c) The prescription is expired; or

(d) The prescription is for a controlled substance and does not comply with the requirements in RCW 69.50.308.

(3) A prescription is considered expired when:

(a) The prescription is for a controlled substance listed in Schedule II through V and the date of dispensing is more than six months after the prescription's date of issue.

(b) The prescription is for a noncontrolled legend drug or OTC~~'s~~ and the date of dispensing is more than twelve months after the prescription's date of issue.

[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, § 246-945-011, filed 6/1/20, effective 7/1/20.]

WAC 246-945-063 Precursor definitions. The definitions in this section apply to WAC 246-945-065 through 246-945-088.

(1) "~~Registered~~ Restricted product" means any nonprescription product containing any detectable quantity of ephedrine, pseudoephedrine, and phenylpropanolamine or their salts or isomers, or salts of isomers.

(2) "Retailer" means a pharmacy licensed by, or shopkeeper or itinerant vendor registered with, the department of health under chapter 18.64 RCW that sells, dispenses, or otherwise provides restricted products to purchasers.

(3) "Sale" means the transfer, selling, or otherwise furnishing of any restricted product to any person.

[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, § 246-945-063, filed 6/1/20, effective 7/1/20.]

WAC 246-945-590

Wholesaler—Policies and procedures.

Wholesalers shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, transport, and shipping and wholesale distribution of drugs, including policies and procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories. Wholesalers shall include the following in their written policies and procedures:

(1) A procedure to be followed for handling recalls and withdrawals of drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:

(a) Any action initiated at the request of FDA or any other federal, state, or local law enforcement or other government agency, including the commission; or

(b) Any volunteer action by the manufacturer to remove defective or potentially defective drugs from the market.

(2) A procedure to ensure that wholesalers prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of a strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

(3) A procedure to ensure that any outdated drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed in accordance with federal and state laws, including all necessary documentation and the appropriate witnessing. This procedure shall provide for written documentation of the disposition of outdated drugs.

(4) A procedure for the destruction of outdated drugs in accordance with federal and state laws.

(5) A procedure for the disposing and destruction of containers, labels, and packaging to ensure that the containers, labels, and packaging cannot be used in counterfeiting activities, including all necessary documentation, and the appropriate witnessing of the destruction of any labels, packaging, immediate containers, or containers in accordance with all applicable federal and state requirements.

OPTION 1:

(6) A procedure for identifying, investigating, and reporting significant drug inventory discrepancies involving counterfeit, suspect of being counterfeit, contraband, or suspect of being contraband, in the inventory and reporting of such discrepancies ~~as required~~ to the FDA, commission, and~~/or~~, as applicable, the DEA ~~appropriate federal or state agency~~ upon discovery of such discrepancies.

OPTION 2:

(6) A procedure for identifying, investigating, and reporting significant drug inventory discrepancies involving counterfeit, suspect of being counterfeit, contraband, or suspect of being contraband, in the inventory and reporting of such discrepancies ~~as required~~ to the FDA, commission, ~~and/~~or, as applicable, the DEA ~~appropriate federal or state agency~~ upon discovery of such discrepancies.

(7) A procedure for reporting criminal or suspected criminal activities involving the inventory of drug(s) as required to the commission, FDA, and if applicable, DEA.

(8) Procedures addressing:

(a) The design and operation of the suspicious order monitoring and reporting system;

(b) Mandatory annual training for staff responsible for identifying and reporting suspicious orders and potential diversion activities. Such training must include the following:

(i) The wholesaler's suspicious order monitoring system;

(ii) The process to collect all relevant information on customers in accordance with WAC **246-960-330**; and

(iii) The requirement and process for submission of suspicious order and information on customers who engage in potential diversion activities.

(9) A procedure for timely responding to customers who submit purchase orders for patients with emergent needs.

Commission SBAR Communication

Agenda Item/Title: Retired Active Pharmacist Credential

Date SBAR Communication Prepared: Nov 16, 2020

Reviewer:

Link to Action Plan:

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

Situation: (Briefly describe the current situation. Give a clear, succinct overview of pertinent issues)
Allowing for continued application of Governor Inslee's proclamation to permit pharmacist with retired license status to practice during the declared emergency.

Background: (Briefly state the pertinent history):

- On March 26, 2020, Governor Inslee signed proclamation 20-32 (currently in force until midnight December 7, 2020 #20-32.9) *Department of Health – Healthcare Worker Licensing* (4) Licensed health professional rules restricting the practice of retired active licenses to help increase the number of healthcare workers available to meet needs of patients and to address the COVID's impact on the healthcare systems.

  This proclamation included a provision that allows a pharmacist with a retired pharmacist license status to practice pharmacy. The proclamation waived "shall not be authorized to practice pharmacy and" from WAC 246-863-080(2) Retired Pharmacist license. WAC 246-863-080 read:

The holder of a retired pharmacist license ~~shall not be authorized to practice pharmacy and~~ need not comply with the continuing education requirements of chapter 246-861 WAC.

- With the adoption and implementation of the chapter 246-945 WAC the retired pharmacist license status rules were repealed effective July 1, 2020. *Retired pharmacist licenses seeking renewal during this time were expired with no option for renewal. Status Reason(internal): Retired Not Renewed*

Credential Prefix	Credential Subcategory	Credential Type	Status	Status Reason	# of Credentials
PHRM		Pharmacist License	RETIRED	NOT PRACTICING	178
				Totals:	**178**

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

The Governor's proclamation 20-32 waives specific regulatory obligations or limitation that may prevent Washington State's healthcare system from meeting the demands for healthcare staffing during the pandemic.

Commission SBAR Communication

To meet the intent, the Commission is asked to consider authorizing emergency rules for a retired active pharmacist license status providing the ability to practice pharmacy in emergent or intermittent circumstances as defined in the draft rule, which is included in this packet.

(Emergency rules when immediate adoption of a rule is necessary for the preservation of the public health, safety, or general welfare, and that observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the public interest. Emergency Rules are effective for 120 day upon filing.)

Recommendation: (What actions are you asking the commission to take? What do you want to happen next?
Approve proposed emergency rules for retired active pharmacist license/credentials status with or without revisions.

Other considerations

- If the pandemic/proclamation 20-32 is extended beyond the adoption of new fee rules will a retired active pharmacist credential be issues without a fee, or until such time that fee rules are adopted? Pending fee rules do not establish a fee for a retired active pharmacist credential.
- Will current retired pharmacist credentials be converted to retired active or upon request?
- If requested, can a retired pharmacist credential be renewed if it expired after July 1, 2020 but before the adoption of emergency rules?

For future agenda: Consider exploring permanent rules for retired active pharmacist license status, if desired.

Follow-up Action: Staff to file necessary rulemaking documentation with the code reviser's office and distribute notice via GovDelivery.

Additional information:
ACTIVE RETIRED

Pharmacist statute

- RCW 18.64.205– Authority to issue active retired pharmacist credential.

Department of Health rules

- WAC 246-12-120 How to obtain a retired active credential
- WAC 246-12-130 How to renew a retired active credential
- WAC 246-12-140 How to return to active status from retired active status

Dental

- WAC 246-817-230 Dentist retired active status.

Medical

- WAC 246-919-480 Retired active license.

Veterinary

- WAC 246-933-305 Retired active credential.

Nursing
- WAC 246-840-125 Retired active credential. Registered or Licensed Practical Nurse (includes ARNP)

Psychologists
- WAC 246-924-500 Retired active credential

Osteopathic physician
- WAC 246-853-235 Retired active credential

NEW SECTION

WAC 246-945-XXX Retired active pharmacist license status.

(1) A pharmacist may apply for a retired active pharmacist license status if they:

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

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

(c) Pay a fee as specified in WAC 246-907-030.

(2) The holder of a retired pharmacist license shall practice only in emergent or intermittent circumstances. "Emergent" includes, but is not be limited to, earthquakes, floods, times of declared war or other states of emergency. "Intermittent" means no more than a total of ninety days each year in Washington state.

(3) To renew a retired active pharmacist license, the holder shall comply with WAC 246-12-130, WAC 246-861-090 and WAC 246-907-030.

(4) The holder of a retired active pharmacist license may return to an active pharmacist license by complying with WAC 246-12-140 and WAC 246-907-030.

Commission SBAR Communication

Agenda Item/Title: Foreign Trained Pharmacist – Licensure requirements

Date SBAR Communication Prepared: 11/25/2020

Reviewer:

Link to Action Plan:

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

Situation: (Briefly describe the current situation. Give a clear, succinct overview of pertinent issues)
With the adoption/implementation of chapter 246-945 WAC and the repeal of WAC 246-863-040 and policy/procedure #45 the internship hours required for foreign trained pharmacists to qualify for a Washington license has changed. Staff is requesting guidance from the Commission regarding internship hours for applicants in this category who have applied prior to July 1, 2020.

This special consideration was initiated by applicants applying under the Foreign Pharmacist Graduate process.

Background: (Briefly state the pertinent history):
This document is attempting to account for several different scenarios for which applicants may fall within the application/licensure process to ensure the commission has a comprehensive overview as it considers its guidance.

Relevant Rules:
There are no statutes specific to foreign trained pharmacists.

Former Standards
WAC 246-863-040 (3) Applicants whose academic training in pharmacy has been obtained from institutions in foreign countries and whose credentials are such that no further education is necessary must earn a total of 1500 intern hours before licensure. The applicant must earn at least 1200 intern hours before taking the full board examination: Provided, That the board may, for good cause shown, waive the required 1500 hours.

Policy Procedure #45 Internship Hours *(Required by Foreign Trained Pharmacist) rescinded August 2020*
A graduate of a foreign pharmacy school or university or a graduate of a Canadian school of pharmacy is required to receive certification from the Foreign Pharmacy Graduate Examination Committee and must earn intern hours in the United States prior to licensure. The number of hours required is based on the score received on the Foreign Pharmacy Graduate Equivalency Examination using the schedule below:

FPGEE Score	Intern Hours
75-90	1500 – at least 1200 hours earned prior to the NAPLEX/MPJE examinations
91-105	1000 – at least 800 hours earned prior to the NAPLEX/MPJE examinations
106-120	500 – all hours earned prior to the NAPLEX/MPJE examinations
Over 120	300 – all hours earned prior to the NAPLEX/MPJE examinations.

Commission SBAR Communication

Before earning hours, a foreign-trained pharmacist must hold a Washington State pharmacist intern registration. Internship hours are reported to the Commission using the *Preceptor Evaluation and Certification of Experience* form and the *Intern Site Evaluation* form.

Current Standards
WAC 246-945-162 Pharmacist license qualification.

(2) An applicant for a pharmacist license whose academic training in pharmacy is from institutions in foreign countries shall:

(a) Achieve certification by FPGEC including:

(i) Passing FPGEE;

(ii) Passing required TOEFL iBT;

(b) Provide official transcripts or diploma that shows a baccalaureate of pharmacy or doctorate of pharmacy degree is awarded or conferred; and

(c) Certification of a minimum of fifteen hundred pharmacy internship hours in accordance with WAC 246-945-163.

(3) An applicant for a pharmacist license shall take and pass pharmacist licensure examinations as defined in WAC 246-945-165.

- **WAC 246-945-163 – Certification of internship hours**
- **WAC 246-945-165 - Pharmacist licensure and jurisprudence examinations**

Statistics *(approximates)*

- 33 Intern registrations issued before July 1, 2020 – *Active Status*
  Note, original issue dates for the 33 active pharmacy interns range between 2007 thru 2020.
  - **Category 1** – Fifteen previously qualified under policy 45 for reduced hours – FPGEE scores between 91 -120 and over
    a. Five have met the reduced internship hours – pending licensure exams
    b. Ten have either reported zero hours. (Hours must be certified before a pharmacist license is issued; however, once all hours are received the applicant can be authorized to test. Hours are certified by receipt of *Supervising Pharmacist Evaluation and Certification of Experience* form and the *Intern Site Evaluation* form.)
  - **Category 2** - 18 applicants not effected by rule change - FPGEE scores between 75-90 required 1500; however, the rule does not provide early testing at 1200 hours
- **Category 3**–Foreign Pharmacist Graduates with pending, expired or closed pharmacy intern registrations and/or pending or closed pharmacist applications filed before July 1, 2020. Numbers unknown at this time. *Closed Status-A credential status for a healthcare professional application that remains deficient of required documentation or fees for 60 to 335 days depending on the specific credential type as determined by the profession.*

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

1. Can the Pharmacy Commission deny a pharmacist license applicant who fails to meet the requirements in WAC 246-945-162 and have applied on or after July 1, 2020? ***Yes***

Commission SBAR Communication

2. Can the Pharmacy Commission grant a waiver of pharmacy internship hours under WAC 246-863-040 and policy #45 for an applicant whose academic training in pharmacy is from an institution in a foreign country and who applied for a **pharmacist license** before July 1, 2020. ***Yes. (see legal analysis)***

3. Can the Pharmacy Commission grant a waiver of pharmacy internship hours under WAC 246-863-040 and policy #45 for an applicant whose academic training in pharmacy is from an institution in a foreign country and who has earned and certified internship hours as a registered intern under policy #45 before July 1, 2020, but had not yet applied for a pharmacist license? ***Perhaps*** *– knowing that applicants often wait to file the pharmacist application until after meeting the requirements, if the Pharmacy Commission considers this option it must set clear and specific qualifications to whom this scenario will apply.*

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

Options 1: Foreign Pharmacist graduated who have applied for a Washington Pharmacist license before July 1, 2020 are granted a waiver and shall meet the internship hours as required under WAC 246-863-040 and policy #45.

Option 2: Foreign Pharmacist graduated are granted a waiver and shall meet the internship hours as required under WAC 246-863-040 and policy #45 if

a. The applicant applied for a Washington Pharmacist license before July 1, 2020 shall meet the internship hours as required under WAC 246-863-040 and policy #45; or
b. The applicant was issued a Washington Pharmacy Intern registration and whose required internship hours are earned and/or certified in compliance with policy #45 before July 1, 2020, and who has applied for a Washington pharmacist license on or before March 1, 2021.

Option 2a
2 applicants meet this criterion

Option 2b
3 applicants meet these criteria

Option 3: Foreign Pharmacist graduated are granted a waiver and shall meet the internship hours as required under WAC 246-863-040 and policy #45 if:

a. The applicant applied for a Washington Pharmacist license before July 1, 2020 shall meet the internship hours as required under WAC 246-863-040 and policy #45; or
b. The applicant was issued a Washington Pharmacy Intern registration and whose required internship hours are earned and/or certified and has applied for a Washington pharmacist license on or before March 1, 2021.

Note: Option 3a is the same as Option 1 and 2a.

Option 3b
10 applicants meet these criteria

Additional Issue:
Policy #45 allowed for foreign pharmacist graduates to sit for the NAPLEX and MPJE before all required internship hours were completed/certified.

Does the Commission wish to continue this practice for foreign pharmacist graduates, authorizing applicants to test after completing 1200 of the required 1500 hours? NABP will not let a pharmacist applicant sit for the NAPLEX until he or she has graduated. This or another restriction does not apply

to foreign pharmacist graduates – authorization is determined by the state commission/board of pharmacy.

Follow-up Action: Notify OCS of the Commission's decision. Draft a communication to notify applicants who are impacted by the Commission's decision.

Pharmacy Quality Assurance Commission
POLICY/PROCEDURE

Title:	Internship Hours	**Number:**	45
Reference:	RCW 18.64.080 and WAC 246-858-020; WAC 246-863-040		
Contact:	Executive Director		
Effective Date:	October 19, 2018		
Supersedes:	December 11, 2014 version Policy 41 Verification of Out-of-State Internship Hours; Policy 33 Intern Hours for Foreign Trained Pharmacist; and Policy 31 Foreign Students as Interns		
Approved:	Chairperson, Pharmacy Quality Assurance Commission		

POLICY STATEMENT: Verification of Out-of-State Internship Hours:
required for licensure. As a result, several state boards are no longer certifying intern/externship hours.

Current rules require that the out-of-state boards of pharmacy certify internship/practical experience toward the fulfillment of a minimum of fifteen-hundred (1500) hours required for licensure as a pharmacist in Washington State. If a state board no longer certifies internship hours, the Commission will accept verification of the hours earned by written notification from the respective school or college of pharmacy upon graduation.

POLICY STATEMENT: Additional 300 Intern Hours for Washington Pharmacy Students
Washington state pharmacy students will continue to report three-hundred (300) hours of non-curriculum based practice experience to the Commission. Students will report the three-hundred (300) hours earned in Washington or another state using the *Preceptor Evaluation and Certification of Experience* form and the *Intern Site Evaluation* form.

POLICY STATEMENT: Intern Hours Required by Foreign Trained Pharmacist
A graduate of a foreign pharmacy school or university or a graduate of a Canadian school of pharmacy is required to receive certification from the Foreign Pharmacy Graduate Examination Committee and must earn intern hours in the United States prior to licensure. The number of hours required is based on the score received on the Foreign Pharmacy Graduate Equivalency Examination using the schedule below:

FPGEE Score	Intern Hours
75-90	1500 – at least 1200 hours earned prior to the NPLEX/MPJE examinations
91-105	1000 – at least 800 hours earned prior to the NPLEX/MPJE examinations
106-120	500 – all hours earned prior to the NPLEX/MPJE examinations
Over 120	300 – all hours earned prior to the NPLEX/MPJE examinations.

Before earning hours, a foreign-trained pharmacist must hold a Washington State pharmacist intern registration. Internship hours are reported to the Commission using the *Preceptor Evaluation and Certification of Experience* form and the *Intern Site Evaluation* form.

POLICY STATEMENT: Foreign Trained Pharmacist enrolled or graduate of an ACPE PharmD Program

A foreign-trained pharmacist enrolled in a college or school of pharmacy accredited by the Accreditation Council for Pharmacy Education is not required to provide a FPGEC certificate or take and pass the FPGEE as it applies to an intern registration. In addition the conferred PharmD degree meets the educational requirements for application for pharmacist license by examination. The required number of hours and reporting process mirrors those required for licensure by examination. Qualifying internship hours must be earned under in a state or territory of the United States.

POLICY STATEMENT: Foreign Students as Interns

A person attending a foreign pharmacy school who desires to come to Washington to gain practical experience must have approval of the commission prior to registration as an intern. Hours worked while an ~~intern~~ under this special commission allowance will not ~~count~~ towards any subsequent internship requirement should the ~~intern~~ decide to become a pharmacist ~~in~~ Washington using Foreign Pharmacy Graduate Examination Committee certification.

At a minimum, the following must be submitted to the commission for review:

1. Name and educational background of prospective intern,
2. Reason for wanting Washington internship experience,
3. Name of pharmacist to be supervising internship,
4. Length of internship and pharmacy(ies) to be training sites, and
5. Detailed information as to what the intern will be expected to do, e.g., observation, filling prescriptions, hospital rounds, etc.

This policy is effective until the rule or this policy is amended or vacated.

Commission SBAR Communication

Agenda Item/Title: **Access to Drugs Stored Outside the Pharmacy by Unlicensed Staff**

Date SBAR Communication Prepared: November 13, 2020

Reviewer:

Link to Action Plan:

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

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

Licensed hospital pharmacies allow staff members who are not licensed health care professionals to access drugs that are stored outside of the pharmacy. The new pharmacy rules do not permit unlicensed staff to access drugs stored outside of the pharmacy (*see* WAC 246-945-455(1)(c)).

Background: (Briefly state the pertinent history):

The new pharmacy rules contain a requirement that if a pharmacy stores drugs outside of the pharmacy then access to the drugs must be "limited to health care professionals licensed under the chapters specified in RCW 18.130.040 acting within their scope, and nursing students as provided in WAC 246-945-450" (*see* WAC 246-945-455(1)(c)). This requirement was added to reduce diversion of drugs that are not stored within the pharmacy.

Based on its statutory definition, the term "drugs" includes over-the-counter (OTC) drugs, non-controlled legend drugs, and controlled substances (*see* RCW 18.64.011(14)). As a result, the new rule (cited above) restricts access to OTCs, non-controlled legend drugs, and controlled substances stored outside the pharmacy to licensed health care professionals and nursing students.

Licensed health care professionals acting with their scope of practice may access drugs stored outside the pharmacy. RCW 18.130.040 provides the list of disciplining authorities whose professions may access drugs stored outside the pharmacy. This does not mean that all licensed health care professionals can access drugs. Instead, the individual must be a licensed health care professional and must be acting within their scope of practice. The only exception to this requirement is for nursing students.

There are some hospital pharmacies who permit unlicensed staff to access legend drugs and OTCs stored outside of the pharmacy. This includes access to, among other things, IV fluids e.g., normal saline, lactated ringers, and D5W. These hospital pharmacies would like to continue this practice notwithstanding the new rule.

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

The practice of hospital pharmacies permitting unlicensed staff to access legend drugs and OTCs stored outside of the pharmacy is not permitted by the Commission's rules (*see* WAC 246-945-455(1)(c)). The current rule language does not permit exceptions for unlicensed staff members to access drugs stored outside the pharmacy unless they are a nursing student. All individuals (except nursing students) who access drugs stored outside the pharmacy must be appropriately licensed and acting with their scope of practice. In addition, there is no exception for unlicensed staff to access OTCs or "low-risk" legend drugs stored outside the pharmacy. To comply with the rule, the hospital could register these unlicensed staff members as pharmacy assistants.

The Commission would need to amend its rule to allow unlicensed staff to access legend drugs and OTCs stored outside of the pharmacy.

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

Commission SBAR Communication

The Pharmacy Commission could consider some or all of the following:

1. Recommending that hospital pharmacies stop permitting unlicensed staff from accessing legend drugs and OTCs stored outside of the pharmacy until the unlicensed staff obtain a valid credential. For example, the unlicensed staff could obtain a pharmacy assistant credential.

2. The Commission can consider rulemaking to allow flexibility for pharmacies to allow access to drugs stored outside the pharmacy to unlicensed staff members by amending WAC 246-945-455(1)(c).

3. The Commission can also consider other solutions not yet identified.