September 23, 2022

Washington State Pharmacy Quality Assurance Commission

Commission Business Meeting Materials

SAFETY. QUALITY. INNOVATION.

Washington State Pharmacy Quality Assurance Commission
Sample Ancillary Personnel Utilization Plan

Overview

What is an AUP?

An Ancillary Personnel Utilization Plan (AUP) is a document that pharmacies licensed by the Pharmacy Quality Assurance Commission (commission) must submit to the commission for approval, prior to the utilization of pharmacy assistants or pharmacy technicians (RCW 18.64A.040 and RCW 18.64A.060).

What is an AUP required to include?

An AUP must contain information regarding how pharmacy assistants or pharmacy technicians will be utilized and supervised while working in the pharmacy, including explanations of delegated tasks, and the conditions under which pharmacy assistants or pharmacy technicians are expected to perform their tasks (WAC 246-945-410). All functions shall be listed in the AUP application. Specialized functions are no longer required to be submitted separately.

Who signs the AUP?

While an AUP must be approved by the commission, the responsible pharmacy manager maintains discretion regarding its implementation. Therefore, the AUP must be reviewed and signed by the responsible pharmacy manager before it is submitted to the commission for review. It is also important to note that the duties and responsibilities of the ancillary personnel are subject to the discretion of the supervising pharmacist on duty (WAC 246-945-315).

Where should Pharmacy Ancillary Utilization Applications be submitted?

The Pharmacy Ancillary Utilization Application, along with a completed, signed, and dated ancillary personnel utilization plan, and check or money order made payable to **Department of Health**, should be mailed to:

Department of Health
P.O. Box 1099
Olympia, WA 98507-1099

Please send any other documents not sent with the initial application to:

Pharmacy Quality Assurance Commission Credentialing
P.O. Box 47877
Olympia, WA 98504-7877

Washington State Pharmacy Quality Assurance Commission
Sample Ancillary Personnel Utilization Plan

Please retain a copy of your submitted AUP and Pharmacy Ancillary Utilization Application for your records.

When should an initial Pharmacy Ancillary Utilization Application and AUP be submitted?

Pharmacies that are applying for an initial license with an AUP and Pharmacy Ancillary Utilization Application, must submit them at least 60 days prior to a Pharmacy Commission business meeting.

Why has the commission issued a sample AUP? Is my pharmacy required to use the sample AUP?

The commission has provided this sample AUP as a tool to assist licensees in creating a plan for utilizing its pharmacy personnel. The use of the sample AUP is **not** required, however, pharmacies may choose to use it as a template and format it to meet their specific practice needs.

How do I use the sample AUP?

Your pharmacy may use the sample AUP to document the duties and responsibilities to be performed by ancillary personnel. Tables are provided for you to input the duties and responsibilities of both pharmacy technicians and pharmacy assistants. Appendix A contains additional tables should you require more space to complete your plan. Appendix B contains a supplemental list of potential duties and responsibilities that may be helpful to pharmacies as they prepare their AUPs. Note: Appendix B does not contain an exhaustive list. It is intended to function as a resource, but its use is not required.

Where can I find information regarding staffing and the supervision of pharmacy personnel?

The commission recognizes that many pharmacies face challenges related to adequate staffing. For reference, WAC 246-945-410 addresses sufficient staffing in the pharmacy. WAC 246-945-460 specifically addresses the staffing and supervision of pharmacy personnel, which the responsible pharmacy manager determines. Chapter 18.64A RCW addresses the duties of pharmacy technicians and assistants and limitations on practice. This is noted on the next page in **Definitions and Duties**.

Washington State Pharmacy Quality Assurance Commission
Sample Ancillary Personnel Utilization Plan

Definitions and Duties

"Pharmacy ancillary personnel" means pharmacy technicians and pharmacy assistants (RCW 18.64A.010(5)).

"Pharmacy technician" means: (a) A person who is enrolled in, or who has satisfactorily completed, a commission-approved training program designed to prepare persons to perform nondiscretionary functions associated with the practice of pharmacy; or (b) A person who is a graduate with a degree in pharmacy or medicine of a foreign school, university, or college recognized by the commission (RCW 18.64A.010(6)).

"Pharmacy assistant" means a person registered by the commission to perform limited functions in the pharmacy (RCW 18.64A.010(7)).

Scope of Practice:

"Pharmacy technicians" may assist in performing, under the supervision and control of a licensed pharmacist, manipulative, nondiscretionary functions associated with the practice of pharmacy and other such duties and subject to such restrictions as the commission may by rule adopt (RCW 18.64A.030(1)). Pharmacy technicians may not perform tasks identified by the commission as nondelegable in WAC 246-945-320.

"Pharmacy assistants" may perform, under the supervision of a licensed pharmacist, duties including, but not limited to, typing of prescription labels, filing, refiling, bookkeeping, pricing, stocking, delivery, nonprofessional phone inquiries, and documentation of third-party reimbursements and other such duties and subject to such restrictions as the commission may by rule adopt (RCW 18.64A.030(2)). A pharmacy assistant may also prepackage and label drugs for subsequent use in prescription dispensing operations; and count, pour, and label for individual prescriptions (WAC 246-945-315(3)). Pharmacy assistants may not perform any other pharmacy task other than those provided above.

Please also see WAC 246-945-315 for the Commission's rules on supervising and delegating tasks to pharmacy ancillary personnel.

Washington State Pharmacy Quality Assurance Commission
Sample Ancillary Personnel Utilization Plan

Ancillary Personnel Utilization Plan	
Duties and Responsibilities *To be completed by the applicant. Please fill in the duties and responsibilities of the **pharmacy technician(s)** in the fields below. While reviewing each entry, the responsible pharmacy manager may wish to use the right column to enter a checkmark or their initials for recordkeeping purposes.*	**Reviewed by the Responsible Pharmacy Manager**
T1.	
T2.	
T3.	
T4.	
T5.	
T6.	
T7.	
T8.	
T9.	
T10.	
T11.	
T12.	
T13.	
T14.	
T15.	
T16.	
T17.	
T18.	
T19.	
T20.	

Please see Appendix A if you need additional pages to complete the plan.

Responsible Pharmacy Manager Name:
Responsible Pharmacy Manager Signature:
Date:

Washington State Pharmacy Quality Assurance Commission
Sample Ancillary Personnel Utilization Plan

Ancillary Personnel Utilization Plan	
Duties and Responsibilities *To be completed by the applicant. Please fill in the duties and responsibilities of the **pharmacy assistant(s)** in the fields below. While reviewing each entry, the responsible pharmacy manager may wish to use the right column to enter a checkmark or their initials for recordkeeping purposes.*	**Reviewed by the Responsible Pharmacy Manager**
A1.	
A2.	
A3.	
A4.	
A5.	
A6.	
A7.	
A8.	
A9.	
A10.	
A11.	
A12.	
A13.	
A14.	
A15.	
A16.	
A17.	
A18.	
A19.	
A20.	

Please see Appendix A if you need additional pages to complete the plan.

Responsible Pharmacy Manager Name:
Responsible Pharmacy Manager Signature:
Date:

Appendix A

Additional Duties and Responsibilities

Duties and Responsibilities *To be completed by the applicant. Please fill in the duties and responsibilities of the **pharmacy technician(s)** in the fields below. While reviewing each entry, the responsible pharmacy manager may wish to use the right column to enter a checkmark or their initials for recordkeeping purposes.*	**Reviewed by the Responsible Pharmacy Manager**
T21.	
T22.	
T23.	
T24.	
T25.	
T26.	
T27.	
T28.	
T29.	
T30.	
T31.	
T32.	
T33.	
T34.	
T35.	
T36.	
T37.	
T38.	
T39.	
T40.	

Responsible Pharmacy Manager Name:
Responsible Pharmacy Manager Signature:
Date:

Appendix A

Additional Duties and Responsibilities

Duties and Responsibilities *To be completed by the applicant. Please fill in the duties and responsibilities of the **pharmacy assistant(s)** in the fields below. While reviewing each entry, the responsible pharmacy manager may wish to use the right column to enter a checkmark or their initials for recordkeeping purposes.*	**Reviewed by the Responsible Pharmacy Manager**
A21.	
A22.	
A23.	
A24.	
A25.	
A26.	
A27.	
A28.	
A29.	
A30.	
A31.	
A32.	
A33.	
A34.	
A35.	
A36.	
A37.	
A38.	
A39.	
A40.	

Responsible Pharmacy Manager Name:
Responsible Pharmacy Manager Signature:
Date:

Appendix B

Supplemental List of Potential Duties and Responsibilities
(Note: This is not an exhaustive list)
A, T = Assistants and technicians may perform
T = Only technicians may perform

Related to Prescription Intake

- Greets customers/patients arriving at the pharmacy. (A, T)
- Greets customers/patients calling the pharmacy and answers inquiries regarding
  a) The price of a prescription that has been filled and is ready for pick-up. (A, T)
  b) The pharmacy's hours of operation. (A, T)
  c) The number of refills remaining on a prescription. (A, T)
  d) The request to refill a medication when provided the prescription number. (A, T)
  e) The date a prescription medication will be returned to stock. (A, T)
  f) The date and time of a customer's/patient's vaccination appointment. (A, T)
  g) The availability of goods and services (may require directing the phone call to a pharmacist). (A, T)
- Handles calls to and/or from a prescriber's office regarding a customer's/patient's profile information that does not require interpretation (e.g., medication quantity, date last filled, and price). (A, T)
- Utilizes the pharmacy software system to enter prescription data electronically, print corresponding labels, scan stock bottles, and prepare prescriptions for verification by a licensed pharmacist. "Prepare" means a pharmacy technician sequesters a filled prescription in a basket, small tote, or on the pharmacy bench for the pharmacist to review. (T)
- May generate a label for a refill prescription only when there has been no change to the required elements of the prescription (WAC 246-945-010). (A, T)
- Provides vaccine screening forms for customers/patients to complete and for the pharmacist to review. (A, T)
- Receives and unpacks delivery totes containing supplies and drugs. (A, T)
- Accurately types prescription orders which are then checked and initialed by a licensed pharmacist. Reviews a customer's/patient's medication profile to retrieve specific information related to third-party billing, adjudication, medication refill frequency, and vaccination history, as directed by a licensed pharmacist. (T)
- Handles calls from a prescriber's office authorizing refills provided that no changes in the prescription are involved. (T)
- Following direction from a pharmacist, contacts a wholesaler or distributor to place or verify the status of an order. (A, T)

Appendix B

Supplemental List of Potential Duties and Responsibilities
(Note: This is not an exhaustive list)
A, T = Assistants and technicians may perform
T = Only technicians may perform

Related to Prescription Processing

- Obtains individually prepackaged, labeled medications for prescriptions. (T)
- Pours and counts out medication from a stock bottle. The count must be performed for individual prescriptions, under the direct supervision of a licensed pharmacist. The accuracy of the prescription's contents must be verified by a licensed pharmacist and noted by that pharmacist's initials on the prescription label. (A, T)
- Maintains assigned work area and equipment in clean and orderly condition, including the pharmacy counters and shelves. Protects secure patient information from plain view and disposal in common wastebaskets. (A, T)
- Medication reconstitution (i.e., restoration of the original form of medication previously altered for preservation and storage by addition of a specific quantity of distilled water or provided diluent requiring no calculation). In 100% of the cases, the accuracy of the technician's work is verified by a licensed pharmacist. The verification is documented by the licensed pharmacist's initials on the label(s) affixed to the verified reconstituted medication(s). (T)
- Files and retrieves various pharmacy records as required by the pharmacist, including order invoices and receipts. (A, T)

Related to Prescription Finalization

- Assists customers/patients waiting to check out at the pharmacy. (A, T)
- Calls customers/patients to let them know their medications are ready for pick-up. (A, T)
- Operates cash register and/or digital signature pad used to document prescription pick-up. (A, T)
- Hands out refills when specifically requested to do so by a pharmacist and when a pharmacist has determined that counseling is not necessary. (A, T)
- Systematically files completed prescriptions that have been verified and prepared by the pharmacist for customer/patient pick-up. (A, T)

Other Pharmacy Functions

- Prepares IV admixtures. (T)
- Fills unit dose cassettes. (T)
- Administers immunizations. (T)*

*Pharmacies and pharmacists who wish to use pharmacy technicians to administer medications or devices should submit an AUP that meets the standards identified in the Pharmacy Commission's Guidance Document: Ancillary Utilization Plans and Pharmacy Technician Administration.

Commission SBAR Communication

Agenda Item/Title: Pharmacy Assistants' Scope of Practice

Date SBAR Communication Prepared: September 6, 2022

Reviewer: T. Nomi Peaks

Link to Action Plan:

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

Situation: The Pharmacy Quality Assurance Commission (Pharmacy Commission) Pharmacy Practice Subcommittee met recently to discuss the topic of pharmacy assistants' scope of practice. It tasked Pharmacy Commission staff with combining the comments from the recent subcommittee meeting in an SBAR for the full commission to review at the September business meeting.

Background: Earlier this year, the Pharmacy Commission received an inquiry about whether a pharmacy assistant could stock an Automated Drug Dispensing Device (ADDD). Staff prepared and presented an SBAR (see attached) to the full commission regarding this topic, and the ensuing discussion generated additional considerations, including:

1) May a pharmacy assistant stock an ADDD?
2) May a pharmacy assistant stock medications outside of a pharmacy?
3) May a pharmacy assistant retrieve medications from pharmacy shelves to stock them outside of a pharmacy?
4) May a pharmacy assistant retrieve medications from pharmacy shelves to fill prescriptions inside a pharmacy?

To aid in addressing the questions above, the Pharmacy Practice Subcommittee was tasked with evaluating the guidance document, DOH 690-356 (Access to Drugs Stored Outside of the Pharmacy), to determine if modifications to the document's current language were needed.

Additionally, the subcommittee was asked to engage in stakeholdering to consider the viewpoints of those in support of, and those opposed to, pharmacy assistants retrieving (also referred to as "pulling") medications from pharmacy shelves to stock them outside of a pharmacy and to use in filling prescriptions.

Assessment:

The subcommittee did not recommend making changes to the guidance document, DOH 690-356. This is because the document refers to unlicensed employees of health care facilities who, as part of their job duties, must access drug products stored outside of the pharmacy. Pharmacy assistants are licensed professionals and guidance pertaining to their scope of practice would be unrelated to the document's overall intent. Additionally, pharmacy assistants' access to drugs stored outside of the pharmacy is captured in WAC 246-945-455.

Commission SBAR Communication

Regarding the topic of pharmacy assistants retrieving medications from pharmacy shelves for stocking and/or prescription filling purposes, commissioners and stakeholders offered the following feedback:

- *Perhaps we should consider that a pharmacy can put in its Ancillary Personnel Utilization Plan (AUP) that there is the technology that would allow a pharmacy assistant to do more specialized functions.*
- *A solution may be to enroll a pharmacy assistant in a pharmacy technician training program or accredited pharmacy technician school and attain the certification required to pull medications from the shelves.*
- *Perhaps a rule change is required to allow pharmacy assistants to use a pre-printed refill list (not for patient-specific prescriptions) to stock an ADDD. Barcode scanning would be required to open the ADDD for stocking, and the pharmacy assistant would pull the drug from the pharmacy shelves for the pharmacist to check before the pharmacy assistant stocks the ADDD.*
- *While working to modernize the rules, it is important to be conscious of the areas where we have to be careful and not support rulemaking that erodes away the technician; we stratify tasks based on education and experience for a reason.*
- *Pulling a drug from pharmacy shelving should be a part of the pharmacy assistant's scope of practice. Technology is available which helps assistants pull the right medications.*
- *There are checks in place in pharmacies that utilize advanced technology; multiple stops to make sure that medications are going in the right places…perhaps assistants could pull drugs with the right technology.*
- *If a pharmacy technician is thoroughly trained on drug recognition and drug strengths, and there is a lack of that training for pharmacy assistants…it might be that the assistants could pull the wrong drugs, and I do not think pulling by assistants was intended by the commission.*
- *There is concern that this may be chipping away at training requirements for pharmacy technicians…it is important not to replace skilled pharmacy technicians.*

Recommendation: Given the comments above, the Pharmacy Commission should determine next steps as it pertains to the following pharmacy tasks:

a. Pharmacy assistants stocking an ADDD.
b. Pharmacy assistants stocking medications outside of a pharmacy.
c. Pharmacy assistants retrieving medications from pharmacy shelves for the purpose of filling individual prescriptions.

The recommendation of Pharmacy Commission staff is that the Commission should engage in rulemaking if it believes pharmacy assistants should be authorized to perform these tasks. If the Commission does not believe pharmacy assistants should be authorized to perform these tasks then the Commission could do nothing, or issue an FAQ or article in the newsletter regarding this issue.

Follow-up Action: The commissioners will inform staff of appropriate follow-up action.

Commission SBAR Communication

Reviewed at the March 14, 2022 PQAC Business Meeting

Agenda Item/Title: Clarifying Question on the Utilization of Pharmacy Assistants to Replenish Automated Drug Distribution Devices (ADDDs).

Date SBAR Communication Prepared: March 14, 2022

Reviewer: Taifa "Nomi" Peaks, Pharmacist Consultant

Link to Action Plan:

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

Situation:

Pharmacy Quality Assurance Commission (commission) Staff requests the commission's guidance on pharmacy assistants and the replenishment of automated drug distribution devices (ADDDs).

Under the commission's new rules, does the replenishment of an ADDD fall under a pharmacy assistant's scope of practice? Does the act of stocking include stocking an ADDD?

Background:

For reference, language specific to the replenishment of ADDDs in the since-repealed WAC 246-874-040(2)(a)(i) only allowed a pharmacist, a pharmacy intern, or a pharmacy technician (under the supervision of a pharmacist) to perform this task. In July 2020, the new rules codified in Chapter 246-945 WAC superseded Chapter 246-874 WAC. The new rules do not distinguish if a pharmacy assistant may or may not replenish an ADDD.

RCW 18.64A.030(2) states, "'*Pharmacy assistants'" may perform, under the supervision of a licensed pharmacist, duties including, but not limited to, typing of prescription labels, filing, refiling, bookkeeping, pricing, stocking, delivery, nonprofessional phone inquiries, and documentation of third-party reimbursements and other such duties and subject to such restrictions as the commission may by rule adopt.*" Historically, the word stocking has been interpreted to refer to the act of stocking pharmacy shelves.

WAC 246-945-315(3) states, "*A pharmacist may delegate to a pharmacy assistant those functions defined in 18.64A.030 and the following: (a) Prepackage and label drugs for subsequent use in prescription dispensing operations; and (b) Count, pour, and label for individual prescriptions*." Customarily, pharmacists or pharmacy technicians retrieve the drugs that pharmacy assistants are tasked with prepackaging, counting, pouring, and labeling.

Commission SBAR Communication

Assessment:

The potential benefits of utilizing pharmacy assistants to replenish ADDDs include personnel support for those pharmacies burdened by staffing shortages, the opportunity for assistants to gain professional aptitude and confidence, and improved productivity for high-volume pharmacies. The potential challenges include establishing the appropriate ADDD training for assistants, estimating the impact on pharmacists' duties as they supervise the ADDD replenishment, and determining if that supervision may occur remotely.

While the new rules delineate tasks that may be assigned to a pharmacy assistant per a supervising pharmacist's discretion, they do not specifically address if the act of stocking encompasses the replenishment of an ADDD.

Recommendations:

Option 1: Clarify that stocking includes stocking an ADDD. Direct staff to draft FAQ clarifying the commission's interpretation of the word stocking in RCW 18.64A.030(2). Function will need to be included in commission-approved AUP. The use of an electronic verification system equipped with barcode scanning to stock an ADDD may be noted as a best practice that is subject to the discretion of the responsible pharmacy manager.

Option 2: Clarify that stocking does **not** include stocking an ADDD. Direct staff to draft FAQ or interpretive statement clarifying the commission's interpretation of the word stocking in RCW 18.64A.030(2).

Follow-up Action:

Staff will proceed with steps as necessary to implement the commission's decision.

BILL REQUEST - CODE REVISER'S OFFICE

PLEASE NOTE this is a prelimiary draft as it has not been approved by the Governor's Office.

BILL REQ. #: Z-0084.1/23

ATTY/TYPIST: MW:jlb

BRIEF DESCRIPTION: Protecting patients in facilities regulated by the department of health by establishing uniform enforcement tools.

AN ACT Relating to protecting patients in facilities regulated by the department of health by establishing uniform enforcement tools; amending RCW 18.46.010, 18.46.050, 18.46.130, 70.42.010, 70.42.130, 70.42.180, 70.127.010, 70.127.170, 70.127.213, 70.230.010, 70.230.070, 71.12.710, 71.12.500, 70.38.025, 70.38.111, 70.38.260, 70.170.020, 18.64.005, 18.64.011, 18.64.047, 18.64.165, 18.64A.020, 18.64A.060, 69.45.080, 69.43.100, 69.43.140, 69.50.302, 69.50.303, 69.50.304, 69.50.310, 69.50.320, and 69.41.080; reenacting and amending RCW 71.12.455, 71.24.025, and 71.24.037; adding a new section to chapter 18.46 RCW; adding new sections to chapter 70.42 RCW; adding new sections to chapter 70.127 RCW; adding a new section to chapter 70.230 RCW; adding a new section to chapter 71.12 RCW; adding a new section to chapter 71.24 RCW; adding new sections to chapter 18.64 RCW; adding a new section to chapter 69.38 RCW; adding a new section to chapter 69.45 RCW; repealing RCW 18.64.200, 18.64.390, and 69.50.305; and prescribing penalties.

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

Sec. 1. RCW 18.46.010 and 2000 c 93 s 30 are each amended to read as follows:

(1) "Birthing center" or "childbirth center" means any health facility, not part of a hospital or in a hospital, that provides

facilities and staff to support a birth service to low-risk maternity clients: PROVIDED, HOWEVER, That this chapter shall not apply to any hospital approved by the American College of Surgeons, American Osteopathic Association, or its successor.

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

(3) "Immediate jeopardy" means a situation in which the birthing center's noncompliance with one or more statutory or regulatory requirements has placed the health and safety of patients in its care at risk for serious injury, serious harm, serious impairment, or death.

(4) "Low-risk" means normal, uncomplicated prenatal course as determined by adequate prenatal care and prospects for a normal uncomplicated birth as defined by reasonable and generally accepted criteria of maternal and fetal health.

((~~(4)~~)) (5) "Person" means any individual, firm, partnership, corporation, company, association, or joint stock association, and the legal successor thereof.

Sec. 2. RCW 18.46.050 and 1997 c 58 s 823 are each amended to read as follows:

(1) ((~~The department may deny, suspend, or revoke a license in any case in which it finds that there has been failure or refusal to comply with the requirements established under this chapter or the rules adopted under it.~~

~~(2) The department shall immediately suspend the license of a person who has been certified pursuant to RCW 74.20A.320 by the department of social and health services as a person who is not in compliance with a support order or a residential or visitation order. If the person has continued to meet all other requirements for reinstatement during the suspension, reissuance of the license shall be automatic upon the department's receipt of a release issued by the department of social and health services stating that the person is in compliance with the order.~~

~~RCW 43.70.115 governs notice of a license denial, revocation, suspension, or modification and provides the right to an adjudicative proceeding but shall not apply to actions taken under subsection (2) of this section~~)) In any case in which the department finds that a birthing center has failed or refused to comply with the requirements of this chapter, the standards or rules adopted under this chapter, or other applicable state or federal statutes or rules regulating

birthing centers, the department may take one or more of the actions identified in this section, except as otherwise limited in this section.

(a) When the department determines the birthing center has previously been subject to an enforcement action for the same or similar type of violation of the same statute or rule, or has been given any previous statement of deficiency that included the same or similar type of violation of the same or similar statute or rule, or when the birthing center failed to correct noncompliance with a statute or rule by a date established or agreed to by the department, the department may impose reasonable conditions on a license. Conditions may include correction within a specified amount of time, training, or hiring a department-approved consultant if the birthing center cannot demonstrate to the department that it has access to sufficient internal expertise. If the department determines that the violations constitute immediate jeopardy, the conditions may be imposed immediately in accordance with subsection (2) of this section.

(b) In accordance with the authority the department has under RCW 43.70.095, the department may assess a civil fine of up to $3,000 per violation on a birthing center licensed under this chapter when the department determines the birthing center has previously been subject to an enforcement action for the same or similar type of violation of the same statute or rule, or has been given any previous statement of deficiency that included the same or similar type of violation of the same or similar statute or rule, or when the birthing center failed to correct noncompliance with a statute or rule by a date established or agreed to by the department.

(i) Proceeds from these fines may only be used by the department to offset costs associated with licensing and enforcement of birthing centers.

(ii) The department shall adopt in rules under this chapter specific fine amounts in relation to the severity of the noncompliance and at an adequate level to be a deterrent to future noncompliance.

(iii) If a birthing center is aggrieved by the department's action of assessing civil fines, the licensee has the right to appeal under RCW 43.70.095.

(c) The department may suspend a specific category or categories of services or care or birthing rooms within the birthing center as

related to the violation by imposing a limited stop service. This may only be done if the department finds that noncompliance results in immediate jeopardy.

(i) Prior to imposing a limited stop service, the department shall provide a birthing center written notification upon identifying deficient practices or conditions that constitute an immediate jeopardy. The birthing center shall have 24 hours from notification to develop and implement a department-approved plan to correct the deficient practices or conditions that constitute an immediate jeopardy. If the deficient practices or conditions that constitute immediate jeopardy are not verified by the department as having been corrected within the same 24-hour period, the department may issue the limited stop service.

(ii) When the department imposes a limited stop service, the birthing center may not provide the services in the category or categories subject to the limited stop service to any new or existing patients, unless otherwise allowed by the department, until the limited stop service is terminated.

(iii) The department shall conduct a follow-up inspection within five business days or within the time period requested by the birthing center if more than five business days is needed to verify the violation necessitating the limited stop service has been corrected.

(iv) The limited stop service shall be terminated when:

(A) The department verifies the violation necessitating the limited stop service has been corrected or the department determines that the birthing center has taken intermediate action to address the immediate jeopardy; and

(B) The birthing center establishes the ability to maintain correction of the violation previously found deficient.

(d) The department may suspend new admissions to the birthing center by imposing a stop placement. This may only be done if the department finds that noncompliance results in immediate jeopardy and is not confined to a specific category or categories of patients or a specific area of the birthing center.

(i) Prior to imposing a stop placement, the department shall provide a birthing center written notification upon identifying deficient practices or conditions that constitute an immediate jeopardy. The birthing center shall have 24 hours from notification to develop and implement a department-approved plan to correct the

deficient practices or conditions that constitute an immediate jeopardy. If the deficient practices or conditions that constitute immediate jeopardy are not verified by the department as having been corrected within the same 24-hour period, the department may issue the stop placement.

(ii) When the department imposes a stop placement, the birthing center may not admit any new patients until the stop placement is terminated.

(iii) The department shall conduct a follow-up inspection within five business days or within the time period requested by the birthing center if more than five business days is needed to verify the violation necessitating the stop placement has been corrected.

(iv) The stop placement shall be terminated when:

(A) The department verifies the violation necessitating the stop placement has been corrected or the department determines that the birthing center has taken intermediate action to address the immediate jeopardy; and

(B) The birthing center establishes the ability to maintain correction of the violation previously found deficient.

(e) The department may deny an application for a license or suspend, revoke, or refuse to renew a license.

(2) Except as otherwise provided, RCW 43.70.115 governs notice of actions taken by the department under subsection (1) of this section and provides the right to an adjudicative proceeding. Adjudicative proceedings and hearings under this section are governed by the administrative procedure act, chapter 34.05 RCW. The application for an adjudicative proceeding must be in writing, state the basis for contesting the adverse action, include a copy of the department's notice, be served on and received by the department within 28 days of the birthing center's receipt of the adverse notice, and be served in a manner that shows proof of receipt.

(3) When the department determines a licensee's noncompliance results in immediate jeopardy, the department may make the imposition of conditions on a licensee, a limited stop service, stop placement, or the suspension of a license effective immediately upon receipt of the notice by the licensee, pending any adjudicative proceeding.

(a) When the department makes the suspension of a license or imposition of conditions on a license effective immediately, a licensee is entitled to a show cause hearing before a presiding officer within 14 days of making the request. The licensee must

request the show cause hearing within 28 days of receipt of the notice of immediate suspension or immediate imposition of conditions. At the show cause hearing the department has the burden of demonstrating that more probably than not there is an immediate jeopardy.

(b) At the show cause hearing, the presiding officer may consider the notice and documents supporting the immediate suspension or immediate imposition of conditions and the licensee's response and shall provide the parties with an opportunity to provide documentary evidence and written testimony, and to be represented by counsel. Prior to the show cause hearing, the department shall provide the licensee with all documentation that supports the department's immediate suspension or imposition of conditions.

(c) If the presiding officer determines there is no immediate jeopardy, the presiding officer may overturn the immediate suspension or immediate imposition of conditions.

(d) If the presiding officer determines there is immediate jeopardy, the immediate suspension or immediate imposition of conditions shall remain in effect pending a full hearing.

(e) If the presiding officer sustains the immediate suspension or immediate imposition of conditions, the licensee may request an expedited full hearing on the merits of the department's action. A full hearing must be provided within 90 days of the licensee's request.

(4) When the department determines an alleged violation, if true, would constitute an immediate jeopardy, and the licensee fails to cooperate with the department's investigation of such an alleged violation, the department may impose an immediate stop placement, immediate limited stop service, or immediate suspension.

(a) When the department imposes an immediate stop placement, immediate limited stop service, or immediate suspension for failure to cooperate, a licensee is entitled to a show cause hearing before a presiding officer within 14 days of making the request. The licensee must request the show cause hearing within 28 days of receipt of the notice of an immediate stop placement, immediate limited stop service, or immediate suspension for failure to cooperate. At the show cause hearing the department has the burden of demonstrating that more probably than not the alleged violation, if true, would constitute an immediate jeopardy and the licensee failed to cooperate with the department's investigation.

(b) At the show cause hearing, the presiding officer may consider the notice and documents supporting the immediate stop placement, immediate limited stop service, or immediate suspension for failure to cooperate, and the licensee's response and shall provide the parties with an opportunity to provide documentary evidence and written testimony, and to be represented by counsel. Prior to the show cause hearing, the department shall provide the licensee with all documentation that supports the department's immediate action for failure to cooperate.

(c) If the presiding officer determines the alleged violation, if true, does not constitute an immediate jeopardy or determines that the licensee cooperated with the department's investigation, the presiding officer may overturn the immediate action for failure to cooperate.

(d) If the presiding officer determines the allegation, if true, would constitute an immediate jeopardy and the licensee failed to cooperate with the department's investigation, the immediate action for failure to cooperate shall remain in effect pending a full hearing.

(e) If the presiding officer sustains the immediate action for failure to cooperate, the licensee may request an expedited full hearing on the merits of the department's action. A full hearing must be provided within 90 days of the licensee's request.

NEW SECTION. **Sec. 3.** A new section is added to chapter 18.46 RCW to read as follows:

(1) The department may give written notice to cease and desist to any person whom the department has reason to believe is engaged in the unlicensed operation of a birthing center.

(2)(a) Except as otherwise provided in this section, the requirement to cease and desist unlicensed operation is effective 20 days after the person receives the notice.

(b) The department may make the date the action is effective sooner than 20 days after receipt when necessary to protect the public health, safety, or welfare. When the department does so, it shall state the effective date and the reasons supporting the effective date in the written notice to cease and desist.

(3) The person to whom the notice to cease and desist is issued may request an adjudicative proceeding to contest the notice. The adjudicative proceeding is governed by the administrative procedure

act, chapter 34.05 RCW. The request for an adjudicative proceeding must be in writing, state the basis for contesting the notice, include a copy of the notice, and be served on and received by the department within 20 days from the date the person receives the notice to cease and desist.

(4)(a) If the department gives a person 20 days' notice to cease and desist and the person requests an adjudicative proceeding before its effective date, the department shall not implement the notice until the final order has been entered. The presiding or reviewing officer may permit the department to implement part or all of the notice while the proceedings are pending if the respondent causes an unreasonable delay in the proceeding, if the circumstances change so that implementation is in the public interest, or for other good cause.

(b) If the department gives a licensee less than 20 days' notice to cease and desist and the respondent timely files a request for an adjudicative proceeding, the department may implement the cease and desist on the effective date stated in the notice. The presiding or reviewing officer may order the department to stay implementation of part or all of the adverse action while the proceedings are pending if staying implementation is in the public interest or for other good cause.

(5) The department may assess a civil fine not exceeding $5,000 for each day a person operates a birthing center without a valid license.

(a) The department shall give written notice to the person against whom it assesses a civil fine.

(b) Except as otherwise provided in (c) and (d) of this subsection, the civil fine is due and payable 20 days after receipt.

(c) The person against whom the department assesses a civil fine has the right to request an adjudicative proceeding. The proceeding is governed by the administrative procedure act, chapter 34.05 RCW. The request must be in writing, state the basis for contesting the fine, include a copy of the notice, be served on and received by the department within 20 days of the person receiving the notice of civil fine, and be served in a manner which shows proof of receipt.

(d) If the person files a timely and sufficient request for adjudicative proceeding, the department shall not implement the fine until the final order has been served.

(6) Neither the issuance of a cease and desist order nor payment of a civil fine shall relieve the person so operating a birthing center without a license from criminal prosecution, but the remedy of a cease and desist order or civil fine shall be in addition to any criminal liability. A final notice to cease and desist is conclusive proof of unlicensed operation and may be enforced under RCW 7.21.060. This method of enforcement of the final notice to cease and desist or civil fine may be used in addition to, or as an alternative to, any provisions for enforcement of agency orders set out in chapter 34.05 RCW.

Sec. 4. RCW 18.46.130 and 2000 c 93 s 39 are each amended to read as follows:

(1) Notwithstanding the existence or use of any other remedy, the department may in the manner provided by law, upon the advice of the attorney general who shall represent the department in all proceedings, maintain an action in the name of the state for an injunction or other process against any person to restrain or prevent the advertisement, operation ((~~or~~)), maintenance, management, or opening of a birthing center not licensed under this chapter.

(2) The injunction shall not relieve the person operating a birth center without a license from criminal prosecution, or the imposition of a civil fine under section 3 of this act, but the remedy by injunction shall be in addition to any criminal liability or civil fine. A person that violates an injunction issued under this chapter shall pay a civil penalty, as determined by the court, of not more than $25,000, which shall be deposited in the department's local fee account. For the purpose of this section, the superior court issuing any injunction shall retain jurisdiction and the cause shall be continued, and in such cases the attorney general acting in the name of the state may petition for the recovery of civil penalties. All fines, forfeitures, and penalties collected or assessed by a court because of a violation of RCW 18.46.020 shall be deposited in the department's local fee account.

Sec. 5. RCW 70.42.010 and 1989 c 386 s 2 are each amended to read as follows:

Unless the context clearly requires otherwise, the definitions in this section apply throughout this chapter.

(1) "Department" means the department of health ((~~if enacted, otherwise the department of social and health services~~)).

(2) "Designated test site supervisor" means the available individual who is responsible for the technical functions of the test site and who meets the department's qualifications set out in rule by the department.

(3) "Immediate jeopardy" means a situation in which the medical test site's noncompliance with one or more statutory or regulatory requirements has placed the health and safety of patients in its care at risk for serious injury, serious harm, serious impairment, or death.

(4) "Person" means any individual, or any public or private organization, agent, agency, corporation, firm, association, partnership, or business.

((~~(4)~~)) (5) "Proficiency testing program" means an external service approved by the department which provides samples to evaluate the accuracy, reliability and performance of the tests at each test site.

((~~(5)~~)) (6) "Quality assurance" means a comprehensive set of policies, procedures, and practices to assure that a test site's results are accurate and reliable. Quality assurance means a total program of internal and external quality control, equipment preventative maintenance, calibration, recordkeeping, and proficiency testing evaluation, including a written quality assurance plan.

((~~(6)~~)) (7) "Quality control" means internal written procedures and day-to-day analysis of laboratory reference materials at each test site to insure precision and accuracy of test methodology, equipment, and results.

((~~(7)~~)) (8) "Test" means any examination or procedure conducted on a sample taken from the human body, including screening.

((~~(8)~~)) (9) "Test site" means any facility or site, public or private, which analyzes materials derived from the human body for the purposes of health care, treatment, or screening. A test site does not mean a facility or site, including a residence, where a test approved for home use by the federal food and drug administration is used by an individual to test himself or herself without direct supervision or guidance by another and where this test is not part of a commercial transaction.

Sec. 6. RCW 70.42.130 and 1989 c 386 s 14 are each amended to read as follows:

Under this chapter, and chapter 34.05 RCW, the department may place conditions on a license which limit or cancel a test site's authority to conduct any of the tests or groups of tests of any licensee who:

(1) Fails or refuses to comply with the requirements of this chapter ((~~or~~)), the rules or standards adopted under this chapter, or other applicable state or federal statutes or rules regulating medical test sites;

(2) Has knowingly or with reason to know made a false statement of a material fact in the application for a license or in any data attached thereto or in any record required by the department;

(3) Refuses to allow representatives of the department to examine any book, record, or file required by this chapter to be maintained;

(4) Willfully prevented, interfered with, or attempted to impede in any way the work of a representative of the department;

(5) Willfully prevented or interfered with preservation of evidence of a known violation of this chapter or the rules adopted under this chapter; or

(6) Misrepresented, or was fraudulent in, any aspect of the licensee's business.

NEW SECTION. **Sec. 7.** A new section is added to chapter 70.42 RCW to read as follows:

(1) The department may prohibit a specific category or categories of services within the medical test site as related to noncompliance with the requirements of this chapter or the standards or rules adopted under this chapter by imposing a limited stop service. This may only be done if the department finds that noncompliance results in immediate jeopardy.

(2) Prior to imposing a limited stop service, the department shall provide the medical test site a written notification upon identifying deficient practices or conditions that constitute an immediate jeopardy. The medical test site shall have 24 hours from notification to develop and implement a department-approved plan to correct the deficient practices or conditions that constitute an immediate jeopardy. If the deficient practices or conditions that constitute immediate jeopardy are not verified by the department as

having been corrected within the same 24-hour period, the department may issue the limited stop service.

(3) When the department imposes a limited stop service, the medical test site may not perform any new testing in the category or categories subject to the limited stop service until the limited stop service is terminated.

(4) The department shall conduct a follow-up inspection within five business days or within the time period requested by the medical test site if more than five business days is needed to verify the violation necessitating the limited stop service has been corrected.

(5) The limited stop service shall be terminated when:

(a) The department verifies the violation necessitating the limited stop service has been corrected or the department determines that the medical test site has taken intermediate action to address the immediate jeopardy; and

(b) The medical test site establishes the ability to maintain correction of the violation previously found deficient.

(6) Except as otherwise provided, RCW 43.70.115 governs notice of actions taken by the department under subsection (1) of this section and provides the right to an adjudicative proceeding. Adjudicative proceedings and hearings under this section are governed by the administrative procedure act, chapter 34.05 RCW. The application for an adjudicative proceeding must be in writing, state the basis for contesting the adverse action, include a copy of the department's notice, be served on and received by the department within 28 days of the medical test site's receipt of the adverse notice, and be served in a manner that shows proof of receipt.

(7) When the department determines a licensee's noncompliance results in immediate jeopardy, the department may make the imposition of conditions on a licensee, a limited stop service, or the suspension of a license effective immediately upon receipt of the notice by the licensee, pending any adjudicative proceeding.

(a) When the department makes the suspension of a license, limited stop service, or imposition of conditions on a license effective immediately, a licensee is entitled to a show cause hearing before a presiding officer within 14 days of making the request. The licensee must request the show cause hearing within 28 days of receipt of the notice of immediate suspension or immediate imposition of conditions. At the show cause hearing the department has the

burden of demonstrating that more probably than not there is an immediate jeopardy.

(b) At the show cause hearing, the presiding officer may consider the notice and documents supporting the immediate suspension, immediate limited stop service, or immediate imposition of conditions and the licensee's response and shall provide the parties with an opportunity to provide documentary evidence and written testimony, and to be represented by counsel. Prior to the show cause hearing, the department shall provide the licensee with all documentation that supports the department's immediate suspension, immediate limited stop service, or imposition of conditions.

(c) If the presiding officer determines there is no immediate jeopardy, the presiding officer may overturn the immediate suspension, immediate stop service, or immediate imposition of conditions.

(d) If the presiding officer determines there is immediate jeopardy, the immediate suspension, immediate limited stop service, or immediate imposition of conditions shall remain in effect pending a full hearing.

(e) If the presiding officer sustains the immediate suspension, immediate limited stop service, or immediate imposition of conditions, the licensee may request an expedited full hearing on the merits of the department's action. A full hearing must be provided within 90 days of the licensee's request.

(8) When the department determines an alleged violation, if true, would constitute an immediate jeopardy, and the licensee fails to cooperate with the department's investigation of such an alleged violation, the department may impose an immediate limited stop service or immediate suspension.

(a) When the department imposes an immediate limited stop service or immediate suspension for failure to cooperate, a licensee is entitled to a show cause hearing before a presiding officer within 14 days of making the request. The licensee must request the show cause hearing within 28 days of receipt of the notice of an immediate limited stop service or immediate suspension for failure to cooperate. At the show cause hearing the department has the burden of demonstrating that more probably than not the alleged violation, if true, would constitute an immediate jeopardy and the licensee failed to cooperate with the department's investigation.

(b) At the show cause hearing, the presiding officer may consider the notice and documents supporting the immediate limited stop service or immediate suspension for failure to cooperate, and the licensee's response and shall provide the parties with an opportunity to provide documentary evidence and written testimony, and to be represented by counsel. Prior to the show cause hearing, the department shall provide the licensee with all documentation that supports the department's immediate action for failure to cooperate.

(c) If the presiding officer determines the alleged violation, if true, does not constitute an immediate jeopardy or determines that the licensee cooperated with the department's investigation, the presiding officer may overturn the immediate action for failure to cooperate.

(d) If the presiding officer determines the allegation, if true, would constitute an immediate jeopardy and the licensee failed to cooperate with the department's investigation, the immediate action for failure to cooperate shall remain in effect pending a full hearing.

(e) If the presiding officer sustains the immediate action for failure to cooperate, the licensee may request an expedited full hearing on the merits of the department's action. A full hearing must be provided within 90 days of the licensee's request.

NEW SECTION. **Sec. 8.** A new section is added to chapter 70.42 RCW to read as follows:

(1) The department may give written notice to cease and desist to any person whom the department has reason to believe is engaged in the unlicensed operation of a medical test site.

(2)(a) Except as otherwise provided in this section, the requirement to cease and desist unlicensed operation is effective 20 days after the person receives the notice.

(b) The department may make the date the action is effective sooner than 20 days after receipt when necessary to protect the public health, safety, or welfare. When the department does so, it shall state the effective date and the reasons supporting the effective date in the written notice to cease and desist.

(3) The person to whom the notice to cease and desist is issued may request an adjudicative proceeding to contest the notice. The adjudicative proceeding is governed by the administrative procedure act, chapter 34.05 RCW. The request for an adjudicative proceeding

must be in writing, state the basis for contesting the notice, include a copy of the notice, and be served on and received by the department within 20 days from the date the person receives the notice to cease and desist.

(4)(a) If the department gives a person 20 days' notice to cease and desist and the person requests an adjudicative proceeding before its effective date, the department shall not implement the notice until the final order has been entered. The presiding or reviewing officer may permit the department to implement part or all of the notice while the proceedings are pending if the respondent causes an unreasonable delay in the proceeding, if the circumstances change so that implementation is in the public interest, or for other good cause.

(b) If the department gives a licensee less than 20 days' notice to cease and desist and the respondent timely files a request for an adjudicative proceeding, the department may implement the cease and desist on the effective date stated in the notice. The presiding or reviewing officer may order the department to stay implementation of part or all of the adverse action while the proceedings are pending if staying implementation is in the public interest or for other good cause.

(5) The department may assess a civil fine not exceeding $5,000 for each day a person operates a medical test site without a valid license.

(a) The department shall give written notice to the person against whom it assesses a civil fine.

(b) Except as otherwise provided in (c) and (d) of this subsection, the civil fine is due and payable 20 days after receipt.

(c) The person against whom the department assesses a civil fine has the right to request an adjudicative proceeding. The proceeding is governed by the administrative procedure act, chapter 34.05 RCW. The request must be in writing, state the basis for contesting the fine, include a copy of the notice, be served on and received by the department within 20 days of the person receiving the notice of civil fine, and be served in a manner which shows proof of receipt.

(d) If the person files a timely and sufficient request for adjudicative proceeding, the department shall not implement the fine until the final order has been served.

(6) Neither the issuance of a cease and desist order nor payment of a civil fine shall relieve the person so operating a medical test

site without a license from criminal prosecution, but the remedy of a cease and desist order or civil fine shall be in addition to any criminal liability. A final notice to cease and desist is conclusive proof of unlicensed operation and may be enforced under RCW 7.21.060. This method of enforcement of the final notice to cease and desist or civil fine may be used in addition to, or as an alternative to, any provisions for enforcement of agency orders set out in chapter 34.05 RCW.

Sec. 9. RCW 70.42.180 and 1989 c 386 s 19 are each amended to read as follows:

(1) Notwithstanding the existence or use of any other remedy, the department may, in the manner provided by law and upon the advice of the attorney general, who shall represent the department in the proceedings, maintain an action in the name of the state for an injunction or other process against any person to restrain or prevent the advertising, operating, maintaining, managing, or opening of a test site without a license under this chapter. It is a misdemeanor to own, operate, or maintain a test site without a license.

(2) The injunction shall not relieve the person operating a medical test site without a license from criminal prosecution, or the imposition of a civil fine under section 8 of this act, but the remedy by injunction shall be in addition to any criminal liability or civil fine. A person that violates an injunction issued under this chapter shall pay a civil penalty, as determined by the court, of not more than $25,000, which shall be deposited in the department's local fee account. For the purpose of this section, the superior court issuing any injunction shall retain jurisdiction and the cause shall be continued, and in such cases the attorney general acting in the name of the state may petition for the recovery of civil penalties. All fines, forfeitures, and penalties collected or assessed by a court because of a violation of RCW 70.42.020 shall be deposited in the department's local fee account.

Sec. 10. RCW 70.127.010 and 2011 c 89 s 13 are each amended to read as follows:

Unless the context clearly requires otherwise, the definitions in this section apply throughout this chapter.

(1) "Administrator" means an individual responsible for managing the operation of an agency.

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

(3) "Director of clinical services" means an individual responsible for nursing, therapy, nutritional, social, and related services that support the plan of care provided by in-home health and hospice agencies.

(4) "Family" means individuals who are important to, and designated by, the patient or client and who need not be relatives.

(5) "Home care agency" means a person administering or providing home care services directly or through a contract arrangement to individuals in places of temporary or permanent residence. A home care agency that provides delegated tasks of nursing under RCW 18.79.260(3)(e) is not considered a home health agency for the purposes of this chapter.

(6) "Home care services" means nonmedical services and assistance provided to ill, disabled, or vulnerable individuals that enable them to remain in their residences. Home care services include, but are not limited to: Personal care such as assistance with dressing, feeding, and personal hygiene to facilitate self-care; homemaker assistance with household tasks, such as housekeeping, shopping, meal planning and preparation, and transportation; respite care assistance and support provided to the family; or other nonmedical services or delegated tasks of nursing under RCW 18.79.260(3)(e).

(7) "Home health agency" means a person administering or providing two or more home health services directly or through a contract arrangement to individuals in places of temporary or permanent residence. A person administering or providing nursing services only may elect to be designated a home health agency for purposes of licensure.

(8) "Home health services" means services provided to ill, disabled, or vulnerable individuals. These services include but are not limited to nursing services, home health aide services, physical therapy services, occupational therapy services, speech therapy services, respiratory therapy services, nutritional services, medical social services, and home medical supplies or equipment services.

(9) "Home health aide services" means services provided by a home health agency or a hospice agency under the supervision of a registered nurse, physical therapist, occupational therapist, or speech therapist who is employed by or under contract to a home health or hospice agency. Such care includes ambulation and exercise, assistance with self-administered medications, reporting changes in

patients' conditions and needs, completing appropriate records, and personal care or homemaker services.

(10) "Home medical supplies" or "equipment services" means diagnostic, treatment, and monitoring equipment and supplies provided for the direct care of individuals within a plan of care.

(11) "Hospice agency" means a person administering or providing hospice services directly or through a contract arrangement to individuals in places of temporary or permanent residence under the direction of an interdisciplinary team composed of at least a nurse, social worker, physician, spiritual counselor, and a volunteer.

(12) "Hospice care center" means a homelike, noninstitutional facility where hospice services are provided, and that meets the requirements for operation under RCW 70.127.280.

(13) "Hospice services" means symptom and pain management provided to a terminally ill individual, and emotional, spiritual, and bereavement support for the individual and family in a place of temporary or permanent residence, and may include the provision of home health and home care services for the terminally ill individual.

(14) "Immediate jeopardy" means a situation in which the in-home services agency's noncompliance with one or more statutory or regulatory requirements has placed the health and safety of patients in its care at risk for serious injury, serious harm, serious impairment, or death.

(15) "In-home services agency" means a person licensed to administer or provide home health, home care, hospice services, or hospice care center services directly or through a contract arrangement to individuals in a place of temporary or permanent residence.

((~~(15)~~)) (16) "Person" means any individual, business, firm, partnership, corporation, company, association, joint stock association, public or private agency or organization, or the legal successor thereof that employs or contracts with two or more individuals.

((~~(16)~~)) (17) "Plan of care" means a written document based on assessment of individual needs that identifies services to meet these needs.

((~~(17)~~)) (18) "Quality improvement" means reviewing and evaluating appropriateness and effectiveness of services provided under this chapter.

((~~(18)~~)) (19) "Service area" means the geographic area in which the department has given prior approval to a licensee to provide home health, hospice, or home care services.

((~~(19)~~)) (20) "Social worker" means a person with a degree from a social work educational program accredited and approved as provided in RCW 18.320.010 or who meets qualifications provided in 42 C.F.R. Sec. 418.114 as it existed on January 1, 2012.

((~~(20)~~)) (21) "Survey" means an inspection conducted by the department to evaluate and monitor an agency's compliance with this chapter.

Sec. 11. RCW 70.127.170 and 2003 c 140 s 10 are each amended to read as follows:

((~~Pursuant to chapter 34.05 RCW and RCW 70.127.180(3), the department may deny, restrict, condition, modify, suspend, or revoke a license under this chapter or, in lieu thereof or in addition thereto, assess monetary penalties of a civil nature not to exceed one thousand dollars per violation, or require a refund of any amounts billed to, and collected from, the consumer or third-party payor in any case in which it finds that the licensee, or any applicant, officer, director, partner, managing employee, or owner of ten percent or more of the applicant's or licensee's assets~~)) The department is authorized to take any of the actions identified in section 12 of this act against an in-home services agency's license in any case in which it finds that the licensee:

(1) Failed or refused to comply with the requirements of this chapter ((~~or the~~)), standards or rules adopted under this chapter, or other applicable state or federal statutes or rules regulating the facility or agency;

(2) Was the holder of a license issued pursuant to this chapter that was revoked for cause and never reissued by the department, or that was suspended for cause and the terms of the suspension have not been fulfilled and the licensee has continued to operate;

(3) Has knowingly or with reason to know made a misrepresentation of, false statement of, or failed to disclose, a material fact to the department in an application for the license or any data attached thereto or in any record required by this chapter or matter under investigation by the department, or during a survey, or concerning information requested by the department;

(4) Refused to allow representatives of the department to inspect any book, record, or file required by this chapter to be maintained or any portion of the licensee's premises;

(5) Willfully prevented, interfered with, or attempted to impede in any way the work of any representative of the department and the lawful enforcement of any provision of this chapter. This includes but is not limited to: Willful misrepresentation of facts during a survey, investigation, or administrative proceeding or any other legal action; or use of threats or harassment against any patient, client, or witness, or use of financial inducements to any patient, client, or witness to prevent or attempt to prevent him or her from providing evidence during a survey or investigation, in an administrative proceeding, or any other legal action involving the department;

(6) Willfully prevented or interfered with any representative of the department in the preservation of evidence of any violation of this chapter or the rules adopted under this chapter;

(7) Failed to pay any civil monetary penalty assessed by the department pursuant to this chapter within ((~~ten~~)) 10 days after the assessment becomes final;

(8) Used advertising that is false, fraudulent, or misleading;

(9) Has repeated incidents of personnel performing services beyond their authorized scope of practice;

(10) Misrepresented or was fraudulent in any aspect of the conduct of the licensee's business;

(11) Within the last five years, has been found in a civil or criminal proceeding to have committed any act that reasonably relates to the person's fitness to establish, maintain, or administer an agency or to provide care in the home of another;

(12) Was the holder of a license to provide care or treatment to ill individuals, ((~~disabled, or~~)) vulnerable individuals, or individuals with disabilities that was denied, restricted, not renewed, surrendered, suspended, or revoked by a competent authority in any state, federal, or foreign jurisdiction. A certified copy of the order, stipulation, or agreement is conclusive evidence of the denial, restriction, nonrenewal, surrender, suspension, or revocation;

(13) Violated any state or federal statute, or administrative rule regulating the operation of the agency;

(14) Failed to comply with an order issued by the secretary or designee;

(15) Aided or abetted the unlicensed operation of an in-home services agency;

(16) Operated beyond the scope of the in-home services agency license;

(17) Failed to adequately supervise staff to the extent that the health or safety of a patient or client was at risk;

(18) Compromised the health or safety of a patient or client, including, but not limited to, the individual performing services beyond their authorized scope of practice;

(19) Continued to operate after license revocation, suspension, or expiration, or operating outside the parameters of a modified, conditioned, or restricted license;

(20) Failed or refused to comply with chapter 70.02 RCW;

(21) Abused, neglected, abandoned, or financially exploited a patient or client as these terms are defined in RCW 74.34.020;

(22) Misappropriated the property of an individual;

(23) Is unqualified or unable to operate or direct the operation of the agency according to this chapter and the rules adopted under this chapter;

(24) Obtained or attempted to obtain a license by fraudulent means or misrepresentation; or

(25) Failed to report abuse or neglect of a patient or client in violation of chapter 74.34 RCW.

NEW SECTION. **Sec. 12.** A new section is added to chapter 70.127 RCW to read as follows:

(1) When the department determines the in-home services agency has previously been subject to an enforcement action for the same or similar type of violation of the same statute or rule, or has been given any previous statement of deficiency that included the same or similar type of violation of the same or similar statute or rule, or when the in-home services agency failed to correct noncompliance with a statute or rule by a date established or agreed to by the department, the department may impose reasonable conditions on a license. Conditions may include correction within a specified amount of time, training, or hiring a department-approved consultant if the in-home services agency cannot demonstrate to the department that it has access to sufficient internal expertise. If the department

determines that the violations constitute immediate jeopardy, the conditions may be imposed immediately in accordance with subsection (5) of this section.

(2)(a) In accordance with the authority the department has under RCW 43.70.095, the department may assess a civil fine of up to $3,000 per violation on an in-home services agency licensed under this chapter when the department determines the in-home services agency has previously been subject to an enforcement action for the same or similar type of violation of the same statute or rule, or has been given any previous statement of deficiency that included the same or similar type of violation of the same or similar statute or rule, or when the in-home services agency failed to correct noncompliance with a statute or rule by a date established or agreed to by the department.

(b) Proceeds from these fines may only be used by the department to offset costs associated with licensing and enforcement of in-home services agencies.

(c) The department shall adopt in rules under this chapter specific fine amounts in relation to the severity of the noncompliance and at an adequate level to be a deterrent to future noncompliance.

(d) If a licensee is aggrieved by the department's action of assessing civil fines, the licensee has the right to appeal under RCW 43.70.095.

(3) The department may suspend a specific category or categories of services or care that the in-home services agency provides as related to the violation by imposing a limited stop service. This may only be done if the department finds that noncompliance results in immediate jeopardy.

(a) Prior to imposing a limited stop service, the department shall provide an in-home services agency written notification upon identifying deficient practices or conditions that constitute an immediate jeopardy. The in-home services agency shall have 24 hours from notification to develop and implement a department-approved plan to correct the deficient practices or conditions that constitute an immediate jeopardy. If the deficient practices or conditions that constitute immediate jeopardy are not verified by the department as having been corrected within the same 24-hour period, the department may issue the limited stop service.

(b) When the department imposes a limited stop service, the in-home services agency may not provide the services in the category or categories subject to the limited stop service to any new or existing individuals until the limited stop service is terminated.

(c) The department shall conduct a follow-up inspection within five business days or within the time period requested by the in-home services agency if more than five business days is needed to verify the violation necessitating the limited stop service has been corrected.

(d) The limited stop service shall be terminated when:

(i) The department verifies the violation necessitating the limited stop service has been corrected or the department determines that the in-home services agency has taken intermediate action to address the immediate jeopardy; and

(ii) The in-home services agency establishes the ability to maintain correction of the violation previously found deficient.

(4) The department may suspend new admissions to an in-home services agency that qualifies as a hospice care center by imposing a stop placement. This may only be done if the department finds that noncompliance results in immediate jeopardy and is not confined to a specific category or categories of services or care that the hospice care center provides.

(a) Prior to imposing a stop placement, the department shall provide an in-home services agency that qualifies as a hospice care center written notification upon identifying deficient practices or conditions that constitute an immediate jeopardy. The hospice care center shall have 24 hours from notification to develop and implement a department-approved plan to correct the deficient practices or conditions that constitute an immediate jeopardy. If the deficient practices or conditions that constitute immediate jeopardy are not verified by the department as having been corrected within the same 24-hour period, the department may issue the stop placement.

(b) When the department imposes a stop placement, the hospice care center may not admit any new patients until the stop placement is terminated.

(c) The department shall conduct a follow-up inspection within five business days or within the time period requested by the hospice care center if more than five business days is needed to verify the violation necessitating the stop placement has been corrected.

(d) The stop placement shall be terminated when:

(i) The department verifies the violation necessitating the stop placement has been corrected or the department determines that the hospice care center has taken intermediate action to address the immediate jeopardy; and

(ii) The hospice care center establishes the ability to maintain correction of the violation previously found deficient.

(5) The department may deny an application for a license or suspend, revoke, or refuse to renew a license.

NEW SECTION. **Sec. 13.** A new section is added to chapter 70.127 RCW to read as follows:

(1) Except as otherwise provided, RCW 43.70.115 governs notice of the imposition of conditions on a license, a limited stop service, stop placement, or the suspension, revocation, or refusal to renew a license and provides the right to an adjudicative proceeding. Adjudicative proceedings and hearings under this section are governed by the administrative procedure act, chapter 34.05 RCW. The application for an adjudicative proceeding must be in writing, state the basis for contesting the adverse action, include a copy of the department's notice, be served on and received by the department within 28 days of the licensee's receipt of the adverse notice, and be served in a manner that shows proof of receipt.

(2) When the department determines a licensee's noncompliance results in immediate jeopardy, the department may make the imposition of conditions on a licensee, a limited stop service, stop placement, or the suspension of a license effective immediately upon receipt of the notice by the licensee, pending any adjudicative proceeding.

(a) When the department makes the suspension of a license or imposition of conditions on a license effective immediately, a licensee is entitled to a show cause hearing before a presiding officer within 14 days of making the request. The licensee must request the show cause hearing within 28 days of receipt of the notice of immediate suspension or immediate imposition of conditions. At the show cause hearing the department has the burden of demonstrating that more probably than not there is immediate jeopardy.

(b) At the show cause hearing, the presiding officer may consider the notice and documents supporting the immediate suspension or immediate imposition of conditions and the licensee's response and shall provide the parties with an opportunity to provide documentary

evidence and written testimony, and to be represented by counsel. Prior to the show cause hearing, the department shall provide the licensee with all documentation that supports the department's immediate suspension or imposition of conditions.

(c) If the presiding officer determines there is no immediate jeopardy, the presiding officer may overturn the immediate suspension or immediate imposition of conditions.

(d) If the presiding officer determines there is immediate jeopardy, the immediate suspension or immediate imposition of conditions shall remain in effect pending a full hearing.

(e) If the presiding officer sustains the immediate suspension or immediate imposition of conditions, the licensee may request an expedited full hearing on the merits of the department's action. A full hearing must be provided within 90 days of the licensee's request.

(3) When the department determines an alleged violation, if true, would constitute an immediate jeopardy, and the licensee fails to cooperate with the department's investigation of such an alleged violation, the department may impose an immediate stop placement, immediate limited stop service, or immediate suspension.

(a) When the department imposes an immediate stop placement, immediate limited stop service, or immediate suspension for failure to cooperate, a licensee is entitled to a show cause hearing before a presiding officer within 14 days of making the request. The licensee must request the show cause hearing within 28 days of receipt of the notice of an immediate stop placement, immediate limited stop service, or immediate suspension for failure to cooperate. At the show cause hearing the department has the burden of demonstrating that more probably than not the alleged violation, if true, would constitute an immediate jeopardy and the licensee failed to cooperate with the department's investigation.

(b) At the show cause hearing, the presiding officer may consider the notice and documents supporting the immediate stop placement, immediate limited stop service, or immediate suspension for failure to cooperate, and the licensee's response and shall provide the parties with an opportunity to provide documentary evidence and written testimony, and to be represented by counsel. Prior to the show cause hearing, the department shall provide the licensee with all documentation that supports the department's immediate action for failure to cooperate.

(c) If the presiding officer determines the alleged violation, if true, does not constitute an immediate jeopardy or determines that the licensee cooperated with the department's investigation, the presiding officer may overturn the immediate action for failure to cooperate.

(d) If the presiding officer determines the allegation, if true, would constitute an immediate jeopardy and the licensee failed to cooperate with the department's investigation, the immediate action for failure to cooperate shall remain in effect pending a full hearing.

(e) If the presiding officer sustains the immediate action for failure to cooperate, the licensee may request an expedited full hearing on the merits of the department's action. A full hearing must be provided within 90 days of the licensee's request.

Sec. 14. RCW 70.127.213 and 2000 c 175 s 19 are each amended to read as follows:

(1) The department may ((~~issue a notice of intention to issue a~~)) give written notice to cease and desist ((~~order~~)) to any person whom the department has reason to believe is engaged in the unlicensed operation of an in-home services agency. ((~~The person to whom the notice of intent is issued may request an adjudicative proceeding to contest the charges. The request for hearing must be filed within twenty days after service of the notice of intent to issue a cease and desist order. The failure to request a hearing constitutes a default, whereupon the department may enter a permanent cease and desist order, which may include a civil fine. All proceedings shall be conducted in accordance with chapter 34.05 RCW.~~

~~(2) If the department makes a final determination that a person has engaged or is engaging in unlicensed operation of an in-home services agency, the department may issue a cease and desist order. In addition, the department may impose a civil fine in an amount not exceeding one thousand dollars for each day upon which the person engaged in unlicensed operation of an in-home services agency. The proceeds of such fines shall be deposited in the department's local fee account.~~

~~(3) If the department makes a written finding of fact that the public interest will be irreparably harmed by delay in issuing an order, the department may issue a temporary cease and desist order. The person receiving a temporary cease and desist order shall be~~

~~provided an opportunity for a prompt hearing. The temporary cease and desist order shall remain in effect until further order of the department. The failure to request a prompt or regularly scheduled hearing constitutes a default, whereupon the department may enter a permanent cease and desist order, which may include a civil fine.~~

~~(4) Neither the issuance of a cease and desist order nor payment of a civil fine shall relieve the person so operating an in-home services agency without a license from criminal prosecution, but the remedy of a cease and desist order or civil fine shall be in addition to any criminal liability. The cease and desist order is conclusive proof of unlicensed operation and may be enforced under RCW 7.21.060. This method of enforcement of the cease and desist order or civil fine may be used in addition to, or as an alternative to, any provisions for enforcement of agency orders set out in chapter 34.05 RCW.~~))

(2)(a) Except as otherwise provided in this section, the requirement to cease and desist unlicensed operation is effective 20 days after the person receives the notice.

(b) The department may make the date the action is effective sooner than 20 days after receipt when necessary to protect the public health, safety, or welfare. When the department does so, it shall state the effective date and the reasons supporting the effective date in the written notice to cease and desist.

(3) The person to whom the notice to cease and desist is issued may request an adjudicative proceeding to contest the notice. The adjudicative proceeding is governed by the administrative procedure act, chapter 34.05 RCW. The request for an adjudicative proceeding must be in writing, state the basis for contesting the notice, include a copy of the notice, and be served on and received by the department within 20 days from the date the person receives the notice to cease and desist.

(4)(a) If the department gives a person 20 days' notice to cease and desist and the person requests an adjudicative proceeding before its effective date, the department shall not implement the notice until the final order has been entered. The presiding or reviewing officer may permit the department to implement part or all of the notice while the proceedings are pending if the respondent causes an unreasonable delay in the proceeding, if the circumstances change so that implementation is in the public interest, or for other good cause.

(b) If the department gives a licensee less than 20 days' notice to cease and desist and the respondent timely files a request for an adjudicative proceeding, the department may implement the cease and desist on the effective date stated in the notice. The presiding or reviewing officer may order the department to stay implementation of part or all of the adverse action while the proceedings are pending if staying implementation is in the public interest or for other good cause.

(5) The department may assess a civil fine not exceeding $5,000 for each day a person operates an in-home services agency without a valid license.

(a) The department shall give written notice to the person against whom it assesses a civil fine.

(b) Except as otherwise provided in (c) and (d) of this subsection, the civil fine is due and payable 20 days after receipt.

(c) The person against whom the department assesses a civil fine has the right to request an adjudicative proceeding. The proceeding is governed by the administrative procedure act, chapter 34.05 RCW. The request must be in writing, state the basis for contesting the fine, include a copy of the notice, be served on and received by the department within 20 days of the person receiving the notice of civil fine, and be served in a manner which shows proof of receipt.

(d) If the person files a timely and sufficient request for adjudicative proceeding, the department shall not implement the fine until the final order has been served.

(6) Neither the issuance of a cease and desist order nor payment of a civil fine shall relieve the person so operating an in-home services agency without a license from criminal prosecution, but the remedy of a cease and desist order or civil fine shall be in addition to any criminal liability. A final notice to cease and desist is conclusive proof of unlicensed operation and may be enforced under RCW 7.21.060. This method of enforcement of the final notice to cease and desist or civil fine may be used in addition to, or as an alternative to, any provisions for enforcement of agency orders set out in chapter 34.05 RCW.

Sec. 15. RCW 70.230.010 and 2011 c 76 s 1 are each amended to read as follows:

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

(1) "Ambulatory surgical facility" means any distinct entity that operates for the primary purpose of providing specialty or multispecialty outpatient surgical services in which patients are admitted to and discharged from the facility within ((~~twenty-four~~)) 24 hours and do not require inpatient hospitalization, whether or not the facility is certified under Title XVIII of the federal social security act. An ambulatory surgical facility includes one or more surgical suites that are adjacent to and within the same building as, but not in, the office of a practitioner in an individual or group practice, if the primary purpose of the one or more surgical suites is to provide specialty or multispecialty outpatient surgical services, irrespective of the type of anesthesia administered in the one or more surgical suites. An ambulatory surgical facility that is adjacent to and within the same building as the office of a practitioner in an individual or group practice may include a surgical suite that shares a reception area, restroom, waiting room, or wall with the office of the practitioner in an individual or group practice.

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

(3) "General anesthesia" means a state of unconsciousness intentionally produced by anesthetic agents, with absence of pain sensation over the entire body, in which the patient is without protective reflexes and is unable to maintain an airway.

(4) "Immediate jeopardy" means a situation in which the ambulatory surgical facility's noncompliance with one or more statutory or regulatory requirements has placed the health and safety of patients in its care at risk for serious injury, serious harm, serious impairment, or death.

(5) "Person" means an individual, firm, partnership, corporation, company, association, joint stock association, and the legal successor thereof.

((~~(5)~~)) (6) "Practitioner" means any physician or surgeon licensed under chapter 18.71 RCW, an osteopathic physician or surgeon licensed under chapter 18.57 RCW, or a podiatric physician or surgeon licensed under chapter 18.22 RCW.

((~~(6)~~)) (7) "Secretary" means the secretary of health.

((~~(7)~~)) (8) "Surgical services" means invasive medical procedures that:

(a) Utilize a knife, laser, cautery, cryogenics, or chemicals; and

(b) Remove, correct, or facilitate the diagnosis or cure of a disease, process, or injury through that branch of medicine that treats diseases, injuries, and deformities by manual or operative methods by a practitioner.

Sec. 16. RCW 70.230.070 and 2007 c 273 s 8 are each amended to read as follows:

(1) The secretary may deny, suspend, or revoke the license of any ambulatory surgical facility in any case in which he or she finds the applicant or registered entity knowingly made a false statement of material fact in the application for the license or any supporting data in any record required by this chapter or matter under investigation by the department.

(2) ((~~The secretary shall investigate complaints concerning operation of an ambulatory surgical facility without a license. The secretary may issue a notice of intention to issue a cease and desist order to any person whom the secretary has reason to believe is engaged in the unlicensed operation of an ambulatory surgical facility. If the secretary makes a written finding of fact that the public interest will be irreparably harmed by delay in issuing an order, the secretary may issue a temporary cease and desist order. The person receiving a temporary cease and desist order shall be provided an opportunity for a prompt hearing. The temporary cease and desist order shall remain in effect until further order of the secretary. Any person operating an ambulatory surgical facility under this chapter without a license is guilty of a misdemeanor, and each day of operation of an unlicensed ambulatory surgical facility constitutes a separate offense.~~

~~(3) The secretary is authorized to deny, suspend, revoke, or modify a license or provisional license in any case in which it finds that there has been a failure or refusal to comply with the requirements of this chapter or the standards or rules adopted under this chapter. RCW 43.70.115 governs notice of a license denial, revocation, suspension, or modification and provides the right to an adjudicative proceeding.~~

~~(4) Pursuant to chapter 34.05 RCW, the secretary may assess monetary penalties of a civil nature not to exceed one thousand dollars per violation.~~)) The department is authorized to take any of the actions identified in this section against an ambulatory surgical facility's license or provisional license in any case in which it

finds that there has been a failure or refusal to comply with the requirements of this chapter or the standards or rules adopted under this chapter.

(3) When the department determines the ambulatory surgical facility has previously been subject to an enforcement action for the same or similar type of violation of the same statute or rule, or has been given any previous statement of deficiency that included the same or similar type of violation of the same or similar statute or rule, or when the ambulatory surgical facility failed to correct noncompliance with a statute or rule by a date established or agreed to by the department, the department may impose reasonable conditions on a license. Conditions may include correction within a specified amount of time, training, or hiring a department-approved consultant if the ambulatory surgical facility cannot demonstrate to the department that it has access to sufficient internal expertise. If the department determines that the violations constitute immediate jeopardy, the conditions may be imposed immediately in accordance with subsections (5) and (6) of this section.

(4)(a) In accordance with the authority the department has under RCW 43.70.095, the department may assess a civil fine of up to $7,500 per violation on an ambulatory surgical facility licensed under this chapter when the department determines the ambulatory surgical facility has previously been subject to an enforcement action for the same or similar type of violation of the same statute or rule, or has been given any previous statement of deficiency that included the same or similar type of violation of the same or similar statute or rule, or when the ambulatory surgical facility failed to correct noncompliance with a statute or rule by a date established or agreed to by the department.

(b) Proceeds from these fines may only be used by the department to offset costs associated with licensing and enforcement of ambulatory surgical facilities.

(c) The department shall adopt in rules under this chapter specific fine amounts in relation to the severity of the noncompliance and at an adequate level to be a deterrent to future noncompliance.

(d) If a licensee is aggrieved by the department's action of assessing civil fines, the licensee has the right to appeal under RCW 43.70.095.

(5) The department may suspend a specific category or categories of services or care or operating rooms or recovery rooms within the ambulatory surgical facility as related to the violation by imposing a limited stop service. This may only be done if the department finds that noncompliance results in immediate jeopardy.

(a) Prior to imposing a limited stop service, the department shall provide an ambulatory surgical facility written notification upon identifying deficient practices or conditions that constitute an immediate jeopardy. The ambulatory surgical facility shall have 24 hours from notification to develop and implement a department-approved plan to correct the deficient practices or conditions that constitute an immediate jeopardy. If the deficient practices or conditions that constitute immediate jeopardy are not verified by the department as having been corrected within the same 24-hour period, the department may issue the limited stop service.

(b) When the department imposes a limited stop service, the ambulatory surgical facility may not provide the services in the category or categories subject to the limited stop service to any new or existing individuals, unless otherwise allowed by the department, until the limited stop service is terminated.

(c) The department shall conduct a follow-up inspection within five business days or within the time period requested by the ambulatory surgical facility if more than five business days is needed to verify the violation necessitating the limited stop service has been corrected.

(d) The limited stop service shall be terminated when:

(i) The department verifies the violation necessitating the limited stop service has been corrected or the department determines that the ambulatory surgical facility has taken intermediate action to address the immediate jeopardy; and

(ii) The ambulatory surgical facility establishes the ability to maintain correction of the violation previously found deficient.

(6) The department may suspend new admissions to the ambulatory surgical facility by imposing a stop placement. This may only be done if the department finds that noncompliance results in immediate jeopardy and is not confined to a specific category or categories of patients or a specific area of the ambulatory surgical facility.

(a) Prior to imposing a stop placement, the department shall provide an ambulatory surgical facility written notification upon identifying deficient practices or conditions that constitute an

immediate jeopardy. The ambulatory surgical facility shall have 24 hours from notification to develop and implement a department-approved plan to correct the deficient practices or conditions that constitute an immediate jeopardy. If the deficient practices or conditions that constitute immediate jeopardy are not verified by the department as having been corrected within the same 24-hour period, the department may issue the stop placement.

(b) When the department imposes a stop placement, the ambulatory surgical facility may not admit any new patients until the stop placement is terminated.

(c) The department shall conduct a follow-up inspection within five business days or within the time period requested by the ambulatory surgical facility if more than five business days is needed to verify the violation necessitating the stop placement has been corrected.

(d) The stop placement shall be terminated when:

(i) The department verifies the violation necessitating the stop placement has been corrected or the department determines that the ambulatory surgical facility has taken intermediate action to address the immediate jeopardy; and

(ii) The ambulatory surgical facility establishes the ability to maintain correction of the violation previously found deficient.

(7) The department may deny an application for a license or suspend, revoke, or refuse to renew a license.

(8) Except as otherwise provided, RCW 43.70.115 governs notice of actions taken by the department under subsection (1) of this section and provides the right to an adjudicative proceeding. Adjudicative proceedings and hearings under this section are governed by the administrative procedure act, chapter 34.05 RCW. The application for an adjudicative proceeding must be in writing, state the basis for contesting the adverse action, include a copy of the department's notice, be served on and received by the department within 28 days of the licensee's receipt of the adverse notice, and be served in a manner that shows proof of receipt.

(a) When the department determines a licensee's noncompliance results in immediate jeopardy, the department may make the imposition of conditions on a licensee, a limited stop service, stop placement, or the suspension of a license effective immediately upon receipt of the notice by the licensee, pending any adjudicative proceeding.

(b) When the department makes the suspension of a license or imposition of conditions on a license effective immediately, a licensee is entitled to a show cause hearing before a presiding officer within 14 days of making the request. The licensee must request the show cause hearing within 28 days of receipt of the notice of immediate suspension or immediate imposition of conditions. At the show cause hearing the department has the burden of demonstrating that more probably than not there is an immediate jeopardy.

(c) At the show cause hearing, the presiding officer may consider the notice and documents supporting the immediate suspension or immediate imposition of conditions and the licensee's response and shall provide the parties with an opportunity to provide documentary evidence and written testimony, and to be represented by counsel. Prior to the show cause hearing, the department shall provide the licensee with all documentation that supports the department's immediate suspension or imposition of conditions.

(d) If the presiding officer determines there is no immediate jeopardy, the presiding officer may overturn the immediate suspension or immediate imposition of conditions.

(e) If the presiding officer determines there is immediate jeopardy, the immediate suspension or immediate imposition of conditions shall remain in effect pending a full hearing.

(f) If the presiding officer sustains the immediate suspension or immediate imposition of conditions, the licensee may request an expedited full hearing on the merits of the department's action. A full hearing must be provided within 90 days of the licensee's request.

(9) When the department determines an alleged violation, if true, would constitute an immediate jeopardy, and the licensee fails to cooperate with the department's investigation of such an alleged violation, the department may impose an immediate stop placement, immediate limited stop service, or immediate suspension.

(a) When the department imposes an immediate stop placement, immediate limited stop service, or immediate suspension for failure to cooperate, a licensee is entitled to a show cause hearing before a presiding officer within 14 days of making the request. The licensee must request the show cause hearing within 28 days of receipt of the notice of an immediate stop placement, immediate limited stop service, or immediate suspension for failure to cooperate.

(b) At the show cause hearing the department has the burden of demonstrating that more probably than not the alleged violation, if true, would constitute an immediate jeopardy and the licensee failed to cooperate with the department's investigation.

(c) At the show cause hearing, the presiding officer may consider the notice and documents supporting the immediate stop placement, immediate limited stop service, or immediate suspension for failure to cooperate, and the licensee's response and shall provide the parties with an opportunity to provide documentary evidence and written testimony, and to be represented by counsel. Prior to the show cause hearing, the department shall provide the licensee with all documentation that supports the department's immediate action for failure to cooperate.

(d) If the presiding officer determines the alleged violation, if true, does not constitute an immediate jeopardy or determines that the licensee cooperated with the department's investigation, the presiding officer may overturn the immediate action for failure to cooperate.

(e) If the presiding officer determines the allegation, if true, would constitute an immediate jeopardy and the licensee failed to cooperate with the department's investigation, the immediate action for failure to cooperate shall remain in effect pending a full hearing.

(f) If the presiding officer sustains the immediate action for failure to cooperate, the licensee may request an expedited full hearing on the merits of the department's action. A full hearing must be provided within 90 days of the licensee's request.

NEW SECTION. **Sec. 17.** A new section is added to chapter 70.230 RCW to read as follows:

(1) The department may give written notice to cease and desist to any person whom the department has reason to believe is engaged in the unlicensed operation of an ambulatory surgical facility.

(2)(a) Except as otherwise provided in this section, the requirement to cease and desist unlicensed operation is effective 20 days after the person receives the notice.

(b) The department may make the date the action is effective sooner than 20 days after receipt when necessary to protect the public health, safety, or welfare. When the department does so, it

shall state the effective date and the reasons supporting the effective date in the written notice to cease and desist.

(3) The person to whom the notice to cease and desist is issued may request an adjudicative proceeding to contest the notice. The adjudicative proceeding is governed by the administrative procedure act, chapter 34.05 RCW. The request for an adjudicative proceeding must be in writing, state the basis for contesting the notice, include a copy of the notice, and be served on and received by the department within 20 days from the date the person receives the notice to cease and desist.

(4)(a) If the department gives a person 20 days' notice to cease and desist and the person requests an adjudicative proceeding before its effective date, the department shall not implement the notice until the final order has been entered. The presiding or reviewing officer may permit the department to implement part or all of the notice while the proceedings are pending if the respondent causes an unreasonable delay in the proceeding, if the circumstances change so that implementation is in the public interest, or for other good cause.

(b) If the department gives a licensee less than 20 days' notice to cease and desist and the respondent timely files a request for an adjudicative proceeding, the department may implement the cease and desist on the effective date stated in the notice. The presiding or reviewing officer may order the department to stay implementation of part or all of the adverse action while the proceedings are pending if staying implementation is in the public interest or for other good cause.

(5) The department may assess a civil fine not exceeding $5,000 for each day a person operates an ambulatory surgical facility without a valid license.

(a) The department shall give written notice to the person against whom it assesses a civil fine.

(b) Except as otherwise provided in (c) and (d) of this subsection, the civil fine is due and payable 20 days after receipt.

(c) The person against whom the department assesses a civil fine has the right to request an adjudicative proceeding. The proceeding is governed by the administrative procedure act, chapter 34.05 RCW. The request must be in writing, state the basis for contesting the fine, include a copy of the notice, be served on and received by the

department within 20 days of the person receiving the notice of civil fine, and be served in a manner which shows proof of receipt.

(d) If the person files a timely and sufficient request for adjudicative proceeding, the department shall not implement the fine until the final order has been served.

(6) Neither the issuance of a cease and desist order nor payment of a civil fine shall relieve the person so operating an ambulatory surgical facility without a license from criminal prosecution, but the remedy of a cease and desist order or civil fine shall be in addition to any criminal liability. A final notice to cease and desist is conclusive proof of unlicensed operation and may be enforced under RCW 7.21.060. This method of enforcement of the final notice to cease and desist or civil fine may be used in addition to, or as an alternative to, any provisions for enforcement of agency orders set out in chapter 34.05 RCW.

Sec. 18. RCW 71.12.710 and 2020 c 115 s 3 are each amended to read as follows:

(1) In any case in which the department finds that a ((~~licensed psychiatric hospital~~)) private establishment has failed or refused to comply with ((~~applicable state~~)) the requirements of this chapter, the standards or rules adopted under this chapter, or other applicable state or federal statutes or ((~~regulations~~)) rules, the department may take one or more of the actions identified in this section, except as otherwise limited in this section.

(a) When the department determines the ((~~psychiatric hospital~~)) private establishment has previously been subject to an enforcement action for the same or similar type of violation of the same statute or rule, or has been given any previous statement of deficiency that included the same or similar type of violation of the same or similar statute or rule, or when the ((~~psychiatric hospital~~)) private establishment failed to correct noncompliance with a statute or rule by a date established or agreed to by the department, the department may impose reasonable conditions on a license. Conditions may include correction within a specified amount of time, training, or hiring a department-approved consultant if the ((~~hospital~~)) private establishment cannot demonstrate to the department that it has access to sufficient internal expertise.

(b)(i) In accordance with the authority the department has under RCW 43.70.095, the department may assess a civil fine of up to ((~~ten~~

~~thousand dollars~~)) $10,000 per violation, not to exceed a total fine of ((~~one million dollars~~)) $1,000,000, on a ((~~hospital~~)) private establishment licensed under this chapter when the department determines the ((~~psychiatric hospital~~)) private establishment has previously been subject to an enforcement action for the same or similar type of violation of the same statute or rule, or has been given any previous statement of deficiency that included the same or similar type of violation of the same or similar statute or rule, or when the ((~~psychiatric hospital~~)) private establishment failed to correct noncompliance with a statute or rule by a date established or agreed to by the department.

(ii) Proceeds from these fines may only be used by the department to provide training or technical assistance to ((~~psychiatric hospitals and~~)) private establishments or to offset costs associated with licensing ((~~psychiatric hospitals~~)) private establishments.

(iii) The department shall adopt in rules under this chapter specific fine amounts in relation to the severity of the noncompliance.

(iv) If a licensee is aggrieved by the department's action of assessing civil fines, the licensee has the right to appeal under RCW 43.70.095.

(c) ((~~In accordance with RCW 43.70.095, the department may impose civil fines of up to ten thousand dollars for each day a person operates a psychiatric hospital without a valid license. Proceeds from these fines may only be used by the department to provide training or technical assistance to psychiatric hospitals and to offset costs associated with licensing psychiatric hospitals.~~

~~(d)~~)) The department may suspend new admissions of a specific category or categories of patients as related to the violation by imposing a limited stop placement. This may only be done if the department finds that noncompliance results in immediate jeopardy.

(i) Prior to imposing a limited stop placement, the department shall provide a ((~~psychiatric hospital~~)) private establishment written notification upon identifying deficient practices or conditions that constitute an immediate jeopardy, and the ((~~psychiatric hospital~~)) private establishment shall have ((~~twenty-four~~)) 24 hours from notification to develop and implement a department-approved plan to correct the deficient practices or conditions that constitute an immediate jeopardy. If the deficient practices or conditions that constitute immediate jeopardy are not

verified by the department as having been corrected within the same ((~~twenty-four~~)) 24-hour period, the department may issue the limited stop placement.

(ii) When the department imposes a limited stop placement, the ((~~psychiatric hospital~~)) private establishment may not ((~~admit any new patients~~)) accept any new admissions in the category or categories subject to the limited stop placement until the limited stop placement order is terminated.

(iii) The department shall conduct a follow-up inspection within five business days or within the time period requested by the ((~~psychiatric hospital~~)) private establishment if more than five business days is needed to verify the violation necessitating the limited stop placement has been corrected.

(iv) The limited stop placement shall be terminated when:

(A) The department verifies the violation necessitating the limited stop placement has been corrected or the department determines that the ((~~psychiatric hospital~~)) private establishment has taken intermediate action to address the immediate jeopardy; and

(B) The ((~~psychiatric hospital~~)) private establishment establishes the ability to maintain correction of the violation previously found deficient.

((~~(c)~~)) (d) The department may suspend all new admissions to the ((~~psychiatric hospital~~)) private establishment by imposing a stop placement. This may only be done if the department finds that noncompliance results in immediate jeopardy and is not confined to a specific category or categories of patients or a specific area of the ((~~psychiatric hospital~~)) private establishment.

(i) Prior to imposing a stop placement, the department shall provide a ((~~psychiatric hospital~~)) private establishment written notification upon identifying deficient practices or conditions that constitute an immediate jeopardy, and the ((~~psychiatric hospital~~)) private establishment shall have ((~~twenty-four~~)) 24 hours from notification to develop and implement a department-approved plan to correct the deficient practices or conditions that constitute an immediate jeopardy. If the deficient practices or conditions that constitute immediate jeopardy are not verified by the department as having been corrected within the same ((~~twenty-four~~)) 24-hour period, the department may issue the stop placement.

(ii) When the department imposes a stop placement, the ((~~psychiatric hospital~~)) private establishment may not ((~~admit any~~

~~new patients~~)) accept any new admissions until the stop placement order is terminated.

(iii) The department shall conduct a follow-up inspection within five business days or within the time period requested by the ((~~psychiatric hospital~~)) private establishment if more than five business days is needed to verify the violation necessitating the stop placement has been corrected.

(iv) The stop placement order shall be terminated when:

(A) The department verifies the violation necessitating the stop placement has been corrected or the department determines that the ((~~psychiatric hospital~~)) private establishment has taken intermediate action to address the immediate jeopardy; and

(B) The ((~~psychiatric hospital~~)) private establishment establishes the ability to maintain correction of the violation previously found deficient.

((~~(f)~~)) (e) The department may suspend a specific category or categories of services within the private establishment as related to the violation by imposing a limited stop service. This may only be done if the department finds that noncompliance results in immediate jeopardy.

(i) Prior to imposing a limited stop service, the department shall provide a private establishment written notification upon identifying deficient practices or conditions that constitute an immediate jeopardy. The private establishment shall have 24 hours from notification to develop and implement a department-approved plan to correct the deficient practices or conditions that constitute an immediate jeopardy. If the deficient practices or conditions that constitute immediate jeopardy are not verified by the department as having been corrected within the same 24-hour period, the department may issue the limited stop service.

(ii) When the department imposes a limited stop service, the private establishment may not provide the services in the category or categories subject to the limited stop service to any new or existing individuals, unless otherwise allowed by the department, until the limited stop service is terminated.

(iii) The department shall conduct a follow-up inspection within five business days or within the time period requested by the private establishment if more than five business days is needed to verify the violation necessitating the limited stop service has been corrected.

(iv) The limited stop service shall be terminated when:

(A) The department verifies the violation necessitating the limited stop service has been corrected or the department determines that the private establishment has taken intermediate action to address the immediate jeopardy; and

(B) The private establishment establishes the ability to maintain correction of the violation previously found deficient.

(f) The department may suspend, revoke, or refuse to renew a license.

(2)(a) Except as otherwise provided, RCW 43.70.115 governs notice of the imposition of conditions on a license, a limited stop placement, stop placement, or the suspension, revocation, or refusal to renew a license and provides the right to an adjudicative proceeding. Adjudicative proceedings and hearings under this section are governed by the administrative procedure act, chapter 34.05 RCW. The application for an adjudicative proceeding must be in writing, state the basis for contesting the adverse action, including a copy of the department's notice, be served on and received by the department within ((~~twenty-eight~~)) 28 days of the licensee's receipt of the adverse notice, and be served in a manner that shows proof of receipt.

(b) When the department determines a licensee's noncompliance results in immediate jeopardy, the department may make the imposition of conditions on a licensee, a limited stop placement, stop placement, or the suspension of a license effective immediately upon receipt of the notice by the licensee, pending any adjudicative proceeding.

(i) When the department makes the suspension of a license or imposition of conditions on a license effective immediately, a licensee is entitled to a show cause hearing before a presiding officer within ((~~fourteen~~)) 14 days of making the request. The licensee must request the show cause hearing within ((~~twenty-eight~~)) 28 days of receipt of the notice of immediate suspension or immediate imposition of conditions. At the show cause hearing the department has the burden of demonstrating that more probably than not there is an immediate jeopardy.

(ii) At the show cause hearing, the presiding officer may consider the notice and documents supporting the immediate suspension or immediate imposition of conditions and the licensee's response and must provide the parties with an opportunity to provide documentary evidence and written testimony, and to be represented by counsel.

Prior to the show cause hearing, the department must provide the licensee with all documentation that supports the department's immediate suspension.

(iii) If the presiding officer determines there is no immediate jeopardy, the presiding officer may overturn the immediate suspension or immediate imposition of conditions.

(iv) If the presiding officer determines there is immediate jeopardy, the immediate suspension or immediate imposition of conditions shall remain in effect pending a full hearing.

(v) If the secretary sustains the immediate suspension or immediate imposition of conditions, the licensee may request an expedited full hearing on the merits of the department's action. A full hearing must be provided within ((~~ninety~~)) 90 days of the licensee's request.

(3) When the department determines an alleged violation, if true, would constitute an immediate jeopardy, and the licensee fails to cooperate with the department's investigation of such an alleged violation, the department may impose an immediate stop placement, immediate limited stop placement, immediate limited stop service, or immediate suspension.

(a) When the department imposes an immediate stop placement, immediate limited stop placement, immediate limited stop service, or immediate suspension for failure to cooperate, a licensee is entitled to a show cause hearing before a presiding officer within 14 days of making the request. The licensee must request the show cause hearing within 28 days of receipt of the notice of an immediate stop placement, immediate limited stop placement, immediate limited stop service, or immediate suspension for failure to cooperate. At the show cause hearing the department has the burden of demonstrating that more probably than not the alleged violation, if true, would constitute an immediate jeopardy and the licensee failed to cooperate with the department's investigation.

(b) At the show cause hearing, the presiding officer may consider the notice and documents supporting the immediate stop placement, immediate limited stop placement, immediate limited stop service, or immediate suspension for failure to cooperate, and the licensee's response and shall provide the parties with an opportunity to provide documentary evidence and written testimony, and to be represented by counsel. Prior to the show cause hearing, the department shall

provide the licensee with all documentation that supports the department's immediate action for failure to cooperate.

(c) If the presiding officer determines the alleged violation, if true, does not constitute an immediate jeopardy or determines that the licensee cooperated with the department's investigation, the presiding officer may overturn the immediate action for failure to cooperate.

(d) If the presiding officer determines the allegation, if true, would constitute an immediate jeopardy and the licensee failed to cooperate with the department's investigation, the immediate action for failure to cooperate shall remain in effect pending a full hearing.

(e) If the presiding officer sustains the immediate action for failure to cooperate, the licensee may request an expedited full hearing on the merits of the department's action. A full hearing must be provided within 90 days of the licensee's request.

Sec. 19. RCW 71.12.455 and 2020 c 115 s 6 are each reenacted and amended to read as follows:

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

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

(2) "Elopement" means any situation in which an admitted patient of a ((~~psychiatric hospital~~)) private establishment who is cognitively, physically, mentally, emotionally, and/or chemically impaired wanders, walks, runs away, escapes, or otherwise leaves a ((~~psychiatric hospital~~)) private establishment or the grounds of a ((~~psychiatric hospital~~)) private establishment prior to the patient's scheduled discharge unsupervised, unnoticed, and without the staff's knowledge.

(3) "((~~Establishment~~)) Private establishment," "establishment," and "institution" mean:

(a) Every private or county or municipal hospital, including public hospital districts, ((~~sanitariums,~~)) homes, ((~~psychiatric~~)) behavioral health hospitals, residential treatment facilities, or other places receiving or caring for any person with ((~~mental illness, mentally incompetent person, or chemically dependent person~~)) a behavioral health or substance use disorder; and

(b) Beginning January 1, 2019, facilities providing pediatric transitional care services.

(4) "Immediate jeopardy" means a situation in which the ((~~psychiatric hospital's~~)) private establishment's noncompliance with one or more statutory or regulatory requirements has placed the health and safety of patients in its care at risk for serious injury, serious harm, serious impairment, or death.

(5) "Pediatric transitional care services" means short-term, temporary, health and comfort services for drug exposed infants according to the requirements of this chapter and provided in an establishment licensed by the department ((~~of health~~)).

(6) "((~~Psychiatric~~)) Behavioral health hospital" means an establishment caring for any person with mental illness or substance use disorder excluding acute care hospitals licensed under chapter 70.41 RCW, state psychiatric hospitals established under chapter 72.23 RCW, and residential treatment facilities as defined in this section.

(7) "Residential treatment facility" means an establishment in which ((~~twenty-four~~)) 24-hour on-site care is provided for the evaluation, stabilization, or treatment of residents for substance use, mental health, co-occurring disorders, or for drug exposed infants.

(8) "Secretary" means the secretary of the department of health.

(9) "Technical assistance" means the provision of information on the state laws and rules applicable to the regulation of ((~~psychiatric~~)) behavioral health hospitals, the process to apply for a license, and methods and resources to avoid or address compliance problems. Technical assistance does not include assistance provided under chapter 43.05 RCW.

(10) "Trained caregiver" means a noncredentialed, unlicensed person trained by the establishment providing pediatric transitional care services to provide hands-on care to drug exposed infants. Caregivers may not provide medical care to infants and may only work under the supervision of an appropriate health care professional.

Sec. 20. RCW 71.12.500 and 2000 c 93 s 25 are each amended to read as follows:

The department ((~~of health~~)) may at any time examine ((~~and ascertain how far~~)) a licensed private establishment ((~~is conducted in compliance with this chapter, the rules adopted under this chapter, and the requirements of the license therefor. If the interests of the patients of the establishment so demand, the~~

~~department may, for just and reasonable cause, suspend, modify, or revoke any such license. RCW 43.70.115 governs notice of a license denial, revocation, suspension, or modification and provides the right to an adjudicative proceeding.~~)) to determine whether it has failed or refused to comply with the requirements of this chapter, the standards or rules adopted under this chapter, or other applicable state or federal statutes or rules regulating private establishments.

NEW SECTION. **Sec. 21.** A new section is added to chapter 71.12 RCW to read as follows:

(1) The department may give written notice to cease and desist to any person whom the department has reason to believe is engaged in the unlicensed operation of a private establishment.

(2)(a) Except as otherwise provided in this section, the requirement to cease and desist unlicensed operation is effective 20 days after the person receives the notice.

(b) The department may make the date the action is effective sooner than 20 days after receipt when necessary to protect the public health, safety, or welfare. When the department does so, it shall state the effective date and the reasons supporting the effective date in the written notice to cease and desist.

(3) The person to whom the notice to cease and desist is issued may request an adjudicative proceeding to contest the notice. The adjudicative proceeding is governed by the administrative procedure act, chapter 34.05 RCW. The request for an adjudicative proceeding must be in writing, state the basis for contesting the notice, include a copy of the notice, and be served on and received by the department within 20 days from the date the person receives the notice to cease and desist.

(4)(a) If the department gives a person 20 days' notice to cease and desist and the person requests an adjudicative proceeding before its effective date, the department shall not implement the notice until the final order has been entered. The presiding or reviewing officer may permit the department to implement part or all of the notice while the proceedings are pending if the respondent causes an unreasonable delay in the proceeding, if the circumstances change so that implementation is in the public interest, or for other good cause.

(b) If the department gives a licensee less than 20 days' notice to cease and desist and the respondent timely files a request for an adjudicative proceeding, the department may implement the cease and desist on the effective date stated in the notice. The presiding or reviewing officer may order the department to stay implementation of part or all of the adverse action while the proceedings are pending if staying implementation is in the public interest or for other good cause.

(5) The department may assess a civil fine not exceeding $5,000 for each day a person operates a private establishment without a valid license.

(a) The department shall give written notice to the person against whom it assesses a civil fine.

(b) Except as otherwise provided in (c) and (d) of this subsection, the civil fine is due and payable 20 days after receipt.

(c) The person against whom the department assesses a civil fine has the right to request an adjudicative proceeding. The proceeding is governed by the administrative procedure act, chapter 34.05 RCW. The request must be in writing, state the basis for contesting the fine, include a copy of the notice, be served on and received by the department within 20 days of the person receiving the notice of civil fine, and be served in a manner which shows proof of receipt.

(d) If the person files a timely and sufficient request for adjudicative proceeding, the department shall not implement the fine until the final order has been served.

(6) Neither the issuance of a cease and desist order nor payment of a civil fine shall relieve the person so operating a private establishment without a license from criminal prosecution, but the remedy of a cease and desist order or civil fine shall be in addition to any criminal liability. A final notice to cease and desist is conclusive proof of unlicensed operation and may be enforced under RCW 7.21.060. This method of enforcement of the final notice to cease and desist or civil fine may be used in addition to, or as an alternative to, any provisions for enforcement of agency orders set out in chapter 34.05 RCW.

Sec. 22. RCW 70.38.025 and 2000 c 175 s 22 are each amended to read as follows:

When used in this chapter, the terms defined in this section shall have the meanings indicated.

(1) "Board of health" means the state board of health created pursuant to chapter 43.20 RCW.

(2) "Capital expenditure" is an expenditure, including a force account expenditure (i.e., an expenditure for a construction project undertaken by a nursing home facility as its own contractor) which, under generally accepted accounting principles, is not properly chargeable as an expense of operation or maintenance. Where a person makes an acquisition under lease or comparable arrangement, or through donation, which would have required review if the acquisition had been made by purchase, such expenditure shall be deemed a capital expenditure. Capital expenditures include donations of equipment or facilities to a nursing home facility which if acquired directly by such facility would be subject to certificate of need review under the provisions of this chapter and transfer of equipment or facilities for less than fair market value if a transfer of the equipment or facilities at fair market value would be subject to such review. The cost of any studies, surveys, designs, plans, working drawings, specifications, and other activities essential to the acquisition, improvement, expansion, or replacement of any plant or equipment with respect to which such expenditure is made shall be included in determining the amount of the expenditure.

(3) "Continuing care retirement community" means an entity which provides shelter and services under continuing care contracts with its members and which sponsors or includes a health care facility or a health service. A "continuing care contract" means a contract to provide a person, for the duration of that person's life or for a term in excess of one year, shelter along with nursing, medical, health-related, or personal care services, which is conditioned upon the transfer of property, the payment of an entrance fee to the provider of such services, or the payment of periodic charges for the care and services involved. A continuing care contract is not excluded from this definition because the contract is mutually terminable or because shelter and services are not provided at the same location.

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

(5) "Expenditure minimum" means, for the purposes of the certificate of need program, ((~~one million dollars~~)) $1,000,000 adjusted by the department by rule to reflect changes in the United States department of commerce composite construction cost index; or a

lesser amount required by federal law and established by the department by rule.

(6) "Health care facility" means hospices, hospice care centers, hospitals, ((~~psychiatric~~)) behavioral health hospitals, nursing homes, kidney disease treatment centers, ambulatory surgical facilities, and home health agencies, and includes such facilities when owned and operated by a political subdivision or instrumentality of the state and such other facilities as required by federal law and implementing regulations, but does not include any health facility or institution conducted by and for those who rely exclusively upon treatment by prayer or spiritual means in accordance with the creed or tenets of any well-recognized church or religious denomination, or any health facility or institution operated for the exclusive care of members of a convent as defined in RCW 84.36.800 or rectory, monastery, or other institution operated for the care of members of the clergy. In addition, the term does not include any nonprofit hospital: (a) Which is operated exclusively to provide health care services for children; (b) which does not charge fees for such services; and (c) if not contrary to federal law as necessary to the receipt of federal funds by the state.

(7) "Health maintenance organization" means a public or private organization, organized under the laws of the state, which:

(a) Is a qualified health maintenance organization under Title XIII, section 1310(d) of the Public Health ((~~Services [Service]~~)) Service Act; or

(b)(i) Provides or otherwise makes available to enrolled participants health care services, including at least the following basic health care services: Usual physician services, hospitalization, laboratory, X-ray, emergency, and preventive services, and out-of-area coverage; (ii) is compensated (except for copayments) for the provision of the basic health care services listed in (b)(i) to enrolled participants by a payment which is paid on a periodic basis without regard to the date the health care services are provided and which is fixed without regard to the frequency, extent, or kind of health service actually provided; and (iii) provides physicians' services primarily (A) directly through physicians who are either employees or partners of such organization, or (B) through arrangements with individual physicians or one or more groups of physicians (organized on a group practice or individual practice basis).

(8) "Health services" means clinically related (i.e., preventive, diagnostic, curative, rehabilitative, or palliative) services and includes alcoholism, drug abuse, and mental health services and as defined in federal law.

(9) "Health service area" means a geographic region appropriate for effective health planning which includes a broad range of health services.

(10) "Person" means an individual, a trust or estate, a partnership, a corporation (including associations, joint stock companies, and insurance companies), the state, or a political subdivision or instrumentality of the state, including a municipal corporation or a hospital district.

(11) "Provider" generally means a health care professional or an organization, institution, or other entity providing health care but the precise definition for this term shall be established by rule of the department, consistent with federal law.

(12) "Public health" means the level of well-being of the general population; those actions in a community necessary to preserve, protect, and promote the health of the people for which government is responsible; and the governmental system developed to guarantee the preservation of the health of the people.

(13) "Secretary" means the secretary of health or the secretary's designee.

(14) "Tertiary health service" means a specialized service that meets complicated medical needs of people and requires sufficient patient volume to optimize provider effectiveness, quality of service, and improved outcomes of care.

(15) "Hospital" means any health care institution which is required to qualify for a license under RCW 70.41.020((~~(2)~~)) (8); or as a ((~~psychiatric~~)) behavioral health hospital under chapter 71.12 RCW.

Sec. 23. RCW 70.38.111 and 2021 c 277 s 1 are each amended to read as follows:

(1) The department shall not require a certificate of need for the offering of an inpatient tertiary health service by:

(a) A health maintenance organization or a combination of health maintenance organizations if (i) the organization or combination of organizations has, in the service area of the organization or the service areas of the organizations in the combination, an enrollment

of at least ((~~fifty thousand~~)) 50,000 individuals, (ii) the facility in which the service will be provided is or will be geographically located so that the service will be reasonably accessible to such enrolled individuals, and (iii) at least ((~~seventy-five~~)) 75 percent of the patients who can reasonably be expected to receive the tertiary health service will be individuals enrolled with such organization or organizations in the combination;

(b) A health care facility if (i) the facility primarily provides or will provide inpatient health services, (ii) the facility is or will be controlled, directly or indirectly, by a health maintenance organization or a combination of health maintenance organizations which has, in the service area of the organization or service areas of the organizations in the combination, an enrollment of at least ((~~fifty thousand~~)) 50,000 individuals, (iii) the facility is or will be geographically located so that the service will be reasonably accessible to such enrolled individuals, and (iv) at least ((~~seventy-five~~)) 75 percent of the patients who can reasonably be expected to receive the tertiary health service will be individuals enrolled with such organization or organizations in the combination; or

(c) A health care facility (or portion thereof) if (i) the facility is or will be leased by a health maintenance organization or combination of health maintenance organizations which has, in the service area of the organization or the service areas of the organizations in the combination, an enrollment of at least ((~~fifty thousand~~)) 50,000 individuals and, on the date the application is submitted under subsection (2) of this section, at least ((~~fifteen~~)) 15 years remain in the term of the lease, (ii) the facility is or will be geographically located so that the service will be reasonably accessible to such enrolled individuals, and (iii) at least ((~~seventy-five~~)) 75 percent of the patients who can reasonably be expected to receive the tertiary health service will be individuals enrolled with such organization;

if, with respect to such offering or obligation by a nursing home, the department has, upon application under subsection (2) of this section, granted an exemption from such requirement to the organization, combination of organizations, or facility.

(2) A health maintenance organization, combination of health maintenance organizations, or health care facility shall not be exempt under subsection (1) of this section from obtaining a certificate of need before offering a tertiary health service unless:

(a) It has submitted at least ((~~thirty~~)) 30 days prior to the offering of services reviewable under RCW 70.38.105(4)(d) an application for such exemption; and

(b) The application contains such information respecting the organization, combination, or facility and the proposed offering or obligation by a nursing home as the department may require to determine if the organization or combination meets the requirements of subsection (1) of this section or the facility meets or will meet such requirements; and

(c) The department approves such application. The department shall approve or disapprove an application for exemption within ((~~thirty~~)) 30 days of receipt of a completed application. In the case of a proposed health care facility (or portion thereof) which has not begun to provide tertiary health services on the date an application is submitted under this subsection with respect to such facility (or portion), the facility (or portion) shall meet the applicable requirements of subsection (1) of this section when the facility first provides such services. The department shall approve an application submitted under this subsection if it determines that the applicable requirements of subsection (1) of this section are met.

(3) A health care facility (or any part thereof) with respect to which an exemption was granted under subsection (1) of this section may not be sold or leased and a controlling interest in such facility or in a lease of such facility may not be acquired and a health care facility described in (1)(c) which was granted an exemption under subsection (1) of this section may not be used by any person other than the lessee described in (1)(c) unless:

(a) The department issues a certificate of need approving the sale, lease, acquisition, or use; or

(b) The department determines, upon application, that (i) the entity to which the facility is proposed to be sold or leased, which intends to acquire the controlling interest, or which intends to use the facility is a health maintenance organization or a combination of health maintenance organizations which meets the requirements of (1)(a)(i), and (ii) with respect to such facility, meets the requirements of (1)(a)(ii) or (iii) or the requirements of (1)(b)(i) and (ii).

(4) In the case of a health maintenance organization, an ambulatory care facility, or a health care facility, which ambulatory or health care facility is controlled, directly or indirectly, by a

health maintenance organization or a combination of health maintenance organizations, the department may under the program apply its certificate of need requirements to the offering of inpatient tertiary health services to the extent that such offering is not exempt under the provisions of this section or RCW 70.38.105(7).

(5)(a) The department shall not require a certificate of need for the construction, development, or other establishment of a nursing home, or the addition of beds to an existing nursing home, that is owned and operated by a continuing care retirement community that:

(i) Offers services only to contractual members;

(ii) Provides its members a contractually guaranteed range of services from independent living through skilled nursing, including some assistance with daily living activities;

(iii) Contractually assumes responsibility for the cost of services exceeding the member's financial responsibility under the contract, so that no third party, with the exception of insurance purchased by the retirement community or its members, but including the medicaid program, is liable for costs of care even if the member depletes his or her personal resources;

(iv) Has offered continuing care contracts and operated a nursing home continuously since January 1, 1988, or has obtained a certificate of need to establish a nursing home;

(v) Maintains a binding agreement with the state assuring that financial liability for services to members, including nursing home services, will not fall upon the state;

(vi) Does not operate, and has not undertaken a project that would result in a number of nursing home beds in excess of one for every four living units operated by the continuing care retirement community, exclusive of nursing home beds; and

(vii) Has obtained a professional review of pricing and long-term solvency within the prior five years which was fully disclosed to members.

(b) A continuing care retirement community shall not be exempt under this subsection from obtaining a certificate of need unless:

(i) It has submitted an application for exemption at least ((~~thirty~~)) 30 days prior to commencing construction of, is submitting an application for the licensure of, or is commencing operation of a nursing home, whichever comes first; and

(ii) The application documents to the department that the continuing care retirement community qualifies for exemption.

(c) The sale, lease, acquisition, or use of part or all of a continuing care retirement community nursing home that qualifies for exemption under this subsection shall require prior certificate of need approval to qualify for licensure as a nursing home unless the department determines such sale, lease, acquisition, or use is by a continuing care retirement community that meets the conditions of (a) of this subsection.

(6) A rural hospital, as defined by the department, reducing the number of licensed beds to become a rural primary care hospital under the provisions of Part A Title XVIII of the Social Security Act Section 1820, 42 U.S.C., 1395c et seq. may, within three years of the reduction of beds licensed under chapter 70.41 RCW, increase the number of licensed beds to no more than the previously licensed number without being subject to the provisions of this chapter.

(7) A rural health care facility licensed under RCW 70.175.100 formerly licensed as a hospital under chapter 70.41 RCW may, within three years of the effective date of the rural health care facility license, apply to the department for a hospital license and not be subject to the requirements of RCW 70.38.105(4)(a) as the construction, development, or other establishment of a new hospital, provided there is no increase in the number of beds previously licensed under chapter 70.41 RCW and there is no redistribution in the number of beds used for acute care or long-term care, the rural health care facility has been in continuous operation, and the rural health care facility has not been purchased or leased.

(8) A rural hospital determined to no longer meet critical access hospital status for state law purposes as a result of participation in the Washington rural health access preservation pilot identified by the state office of rural health and formerly licensed as a hospital under chapter 70.41 RCW may apply to the department to renew its hospital license and not be subject to the requirements of RCW 70.38.105(4)(a) as the construction, development, or other establishment of a new hospital, provided there is no increase in the number of beds previously licensed under chapter 70.41 RCW. If all or part of a formerly licensed rural hospital is sold, purchased, or leased during the period the rural hospital does not meet critical access hospital status as a result of participation in the Washington rural health access preservation pilot and the new owner or lessor applies to renew the rural hospital's license, then the sale,

purchase, or lease of part or all of the rural hospital is subject to the provisions of this chapter.

(9)(a) A nursing home that voluntarily reduces the number of its licensed beds to provide assisted living, licensed assisted living facility care, adult day care, adult day health, respite care, hospice, outpatient therapy services, congregate meals, home health, or senior wellness clinic, or to reduce to one or two the number of beds per room or to otherwise enhance the quality of life for residents in the nursing home, may convert the original facility or portion of the facility back, and thereby increase the number of nursing home beds to no more than the previously licensed number of nursing home beds without obtaining a certificate of need under this chapter, provided the facility has been in continuous operation and has not been purchased or leased. Any conversion to the original licensed bed capacity, or to any portion thereof, shall comply with the same life and safety code requirements as existed at the time the nursing home voluntarily reduced its licensed beds; unless waivers from such requirements were issued, in which case the converted beds shall reflect the conditions or standards that then existed pursuant to the approved waivers.

(b) To convert beds back to nursing home beds under this subsection, the nursing home must:

(i) Give notice of its intent to preserve conversion options to the department of health no later than ((~~thirty~~)) 30 days after the effective date of the license reduction; and

(ii) Give notice to the department of health and to the department of social and health services of the intent to convert beds back. If construction is required for the conversion of beds back, the notice of intent to convert beds back must be given, at a minimum, one year prior to the effective date of license modification reflecting the restored beds; otherwise, the notice must be given a minimum of ((~~ninety~~)) 90 days prior to the effective date of license modification reflecting the restored beds. Prior to any license modification to convert beds back to nursing home beds under this section, the licensee must demonstrate that the nursing home meets the certificate of need exemption requirements of this section.

The term "construction," as used in (b)(ii) of this subsection, is limited to those projects that are expected to equal or exceed the expenditure minimum amount, as determined under this chapter.

(c) Conversion of beds back under this subsection must be completed no later than four years after the effective date of the license reduction. However, for good cause shown, the four-year period for conversion may be extended by the department of health for one additional four-year period.

(d) Nursing home beds that have been voluntarily reduced under this section shall be counted as available nursing home beds for the purpose of evaluating need under RCW 70.38.115(2) (a) and (k) so long as the facility retains the ability to convert them back to nursing home use under the terms of this section.

(e) When a building owner has secured an interest in the nursing home beds, which are intended to be voluntarily reduced by the licensee under (a) of this subsection, the applicant shall provide the department with a written statement indicating the building owner's approval of the bed reduction.

(10)(a) The department shall not require a certificate of need for a hospice agency if:

(i) The hospice agency is designed to serve the unique religious or cultural needs of a religious group or an ethnic minority and commits to furnishing hospice services in a manner specifically aimed at meeting the unique religious or cultural needs of the religious group or ethnic minority;

(ii) The hospice agency is operated by an organization that:

(A) Operates a facility, or group of facilities, that offers a comprehensive continuum of long-term care services, including, at a minimum, a licensed, medicare-certified nursing home, assisted living, independent living, day health, and various community-based support services, designed to meet the unique social, cultural, and religious needs of a specific cultural and ethnic minority group;

(B) Has operated the facility or group of facilities for at least ((~~ten~~)) 10 continuous years prior to the establishment of the hospice agency;

(iii) The hospice agency commits to coordinating with existing hospice programs in its community when appropriate;

(iv) The hospice agency has a census of no more than ((~~forty~~)) 40 patients;

(v) The hospice agency commits to obtaining and maintaining medicare certification;

(vi) The hospice agency only serves patients located in the same county as the majority of the long-term care services offered by the organization that operates the agency; and

(vii) The hospice agency is not sold or transferred to another agency.

(b) The department shall include the patient census for an agency exempted under this subsection (10) in its calculations for future certificate of need applications.

(11) To alleviate the need to board psychiatric patients in emergency departments and increase capacity of hospitals to serve individuals on ((~~ninety~~)) 90-day or ((~~one hundred eighty~~)) 180-day commitment orders, for the period of time from May 5, 2017, through June 30, 2023:

(a) The department shall suspend the certificate of need requirement for a hospital licensed under chapter 70.41 RCW that changes the use of licensed beds to increase the number of beds to provide psychiatric services, including involuntary treatment services. A certificate of need exemption under this subsection (11)(a) shall be valid for two years.

(b) The department may not require a certificate of need for:

(i) The addition of beds as described in RCW 70.38.260 (2) and (3); or

(ii) The construction, development, or establishment of a ((~~psychiatric~~)) behavioral health hospital licensed as an establishment under chapter 71.12 RCW that will have no more than ((~~sixteen~~)) 16 beds and provide treatment to adults on ((~~ninety~~)) 90 or ((~~one hundred eighty~~)) 180-day involuntary commitment orders, as described in RCW 70.38.260(4).

(12)(a) An ambulatory surgical facility is exempt from all certificate of need requirements if the facility:

(i) Is an individual or group practice and, if the facility is a group practice, the privilege of using the facility is not extended to physicians outside the group practice;

(ii) Operated or received approval to operate, prior to January 19, 2018; and

(iii) Was exempt from certificate of need requirements prior to January 19, 2018, because the facility either:

(A) Was determined to be exempt from certificate of need requirements pursuant to a determination of reviewability issued by the department; or

(B) Was a single-specialty endoscopy center in existence prior to January 14, 2003, when the department determined that endoscopy procedures were surgeries for purposes of certificate of need.

(b) The exemption under this subsection:

(i) Applies regardless of future changes of ownership, corporate structure, or affiliations of the individual or group practice as long as the use of the facility remains limited to physicians in the group practice; and

(ii) Does not apply to changes in services, specialties, or number of operating rooms.

(13) A rural health clinic providing health services in a home health shortage area as declared by the department pursuant to 42 C.F.R. Sec. 405.2416 is not subject to certificate of need review under this chapter.

Sec. 24. RCW 70.38.260 and 2021 c 277 s 2 are each amended to read as follows:

(1) For a grant awarded during fiscal years 2018 and 2019 by the department of commerce under this section, hospitals licensed under chapter 70.41 RCW and ((~~psychiatric~~)) behavioral health hospitals licensed as establishments under chapter 71.12 RCW are not subject to certificate of need requirements for the addition of the number of new psychiatric beds indicated in the grant. The department of commerce may not make a prior approval of a certificate of need application a condition for a grant application under this section. The period during which an approved hospital or ((~~psychiatric~~)) behavioral health hospital project qualifies for a certificate of need exemption under this section is two years from the date of the grant award.

(2)(a) Until June 30, 2023, a hospital licensed under chapter 70.41 RCW is exempt from certificate of need requirements for the addition of new psychiatric beds.

(b) A hospital that adds new psychiatric beds under this subsection (2) must:

(i) Notify the department of the addition of new psychiatric beds. The department shall provide the hospital with a notice of exemption within ((~~thirty~~)) 30 days; and

(ii) Commence the project within two years of the date of receipt of the notice of exemption.

(c) Beds granted an exemption under RCW 70.38.111(11)(b) must remain psychiatric beds unless a certificate of need is granted to change their use or the hospital voluntarily reduces its licensed capacity.

(3)(a) Until June 30, 2023, a ((~~psychiatric~~)) behavioral health hospital licensed as an establishment under chapter 71.12 RCW is exempt from certificate of need requirements for the one-time addition of up to 30 new psychiatric beds devoted solely for 90-day and 180-day civil commitment services and for the one-time addition of up to 30 new voluntary psychiatric beds or involuntary psychiatric beds for patients on a 120 hour detention or 14-day civil commitment order, if the hospital makes a commitment to maintain a payer mix of at least ((~~fifty~~)) 50 percent medicare and medicaid based on a calculation using patient days for a period of five consecutive years after the beds are made available for use by patients, if it demonstrates to the satisfaction of the department:

(i) That its most recent two years of publicly available fiscal year-end report data as required under RCW 70.170.100 and 43.70.050 reported to the department by the ((~~psychiatric~~)) behavioral health hospital, show a payer mix of a minimum of ((~~fifty~~)) 50 percent medicare and medicaid based on a calculation using patient days; and

(ii) A commitment to maintaining the payer mix in (a) of this subsection for a period of five consecutive years after the beds are made available for use by patients.

(b) A ((~~psychiatric~~)) behavioral health hospital that adds new psychiatric beds under this subsection (3) must:

(i) Notify the department of the addition of new psychiatric beds. The department shall provide the ((~~psychiatric~~)) behavioral health hospital with a notice of exemption within ((~~thirty~~)) 30 days; and

(ii) Commence the project within two years of the date of receipt of the notice of exemption.

(c) Beds granted an exemption under RCW 70.38.111(11)(b) must remain the types of psychiatric beds indicated to the department in the original exemption application unless a certificate of need is granted to change their use or the ((~~psychiatric~~)) behavioral health hospital voluntarily reduces its licensed capacity.

(4)(a) Until June 30, 2023, an entity seeking to construct, develop, or establish a ((~~psychiatric~~)) behavioral health hospital licensed as an establishment under chapter 71.12 RCW is exempt from

certificate of need requirements if the proposed ((~~psychiatric~~)) behavioral health hospital will have no more than ((~~sixteen~~)) 16 beds and dedicate a portion of the beds to providing treatment to adults on ((~~ninety~~)) 90 or ((~~one hundred eighty~~)) 180-day involuntary commitment orders. The ((~~psychiatric~~)) behavioral health hospital may also provide treatment to adults on a 120 hour detention or 14-day involuntary commitment order.

(b) An entity that seeks to construct, develop, or establish a ((~~psychiatric~~)) behavioral health hospital under this subsection (4) must:

(i) Notify the department of the addition of construction, development, or establishment. The department shall provide the entity with a notice of exemption within ((~~thirty~~)) 30 days; and

(ii) Commence the project within two years of the date of receipt of the notice of exemption.

(c) Entities granted an exemption under RCW 70.38.111(11)(b)(ii) may not exceed ((~~sixteen~~)) 16 beds unless a certificate of need is granted to increase the ((~~psychiatric~~)) behavioral health hospital's capacity.

(5) This section expires June 30, 2025.

Sec. 25. RCW 71.24.025 and 2021 c 302 s 402 are each reenacted and amended to read as follows:

Unless the context clearly requires otherwise, the definitions in this section apply throughout this chapter.

(1) "988 crisis hotline" means the universal telephone number within the United States designated for the purpose of the national suicide prevention and mental health crisis hotline system operating through the national suicide prevention lifeline.

(2) "Acutely mentally ill" means a condition which is limited to a short-term severe crisis episode of:

(a) A mental disorder as defined in RCW 71.05.020 or, in the case of a child, as defined in RCW 71.34.020;

(b) Being gravely disabled as defined in RCW 71.05.020 or, in the case of a child, a gravely disabled minor as defined in RCW 71.34.020; or

(c) Presenting a likelihood of serious harm as defined in RCW 71.05.020 or, in the case of a child, as defined in RCW 71.34.020.

(3) "Alcoholism" means a disease, characterized by a dependency on alcoholic beverages, loss of control over the amount and

circumstances of use, symptoms of tolerance, physiological or psychological withdrawal, or both, if use is reduced or discontinued, and impairment of health or disruption of social or economic functioning.

(4) "Approved substance use disorder treatment program" means a program for persons with a substance use disorder provided by a treatment program licensed or certified by the department as meeting standards adopted under this chapter.

(5) "Authority" means the Washington state health care authority.

(6) "Available resources" means funds appropriated for the purpose of providing community behavioral health programs, federal funds, except those provided according to Title XIX of the Social Security Act, and state funds appropriated under this chapter or chapter 71.05 RCW by the legislature during any biennium for the purpose of providing residential services, resource management services, community support services, and other behavioral health services. This does not include funds appropriated for the purpose of operating and administering the state psychiatric hospitals.

(7) "Behavioral health administrative services organization" means an entity contracted with the authority to administer behavioral health services and programs under RCW 71.24.381, including crisis services and administration of chapter 71.05 RCW, the involuntary treatment act, for all individuals in a defined regional service area.

(8) "Behavioral health aide" means a counselor, health educator, and advocate who helps address individual and community-based behavioral health needs, including those related to alcohol, drug, and tobacco abuse as well as mental health problems such as grief, depression, suicide, and related issues and is certified by a community health aide program of the Indian health service or one or more tribes or tribal organizations consistent with the provisions of 25 U.S.C. Sec. 1616l and RCW 43.71B.010 (7) and (8).

(9) "Behavioral health provider" means a person licensed under chapter 18.57, 18.71, 18.71A, 18.83, 18.205, 18.225, or 18.79 RCW, as it applies to registered nurses and advanced registered nurse practitioners.

(10) "Behavioral health services" means mental health services as described in this chapter and chapter 71.36 RCW and substance use disorder treatment services as described in this chapter that, depending on the type of service, are provided by licensed or

certified behavioral health agencies, behavioral health providers, or integrated into other health care providers.

(11) "Child" means a person under the age of ((~~eighteen~~)) 18 years.

(12) "Chronically mentally ill adult" or "adult who is chronically mentally ill" means an adult who has a mental disorder and meets at least one of the following criteria:

(a) Has undergone two or more episodes of hospital care for a mental disorder within the preceding two years; or

(b) Has experienced a continuous ((~~psychiatric~~)) behavioral health hospitalization or residential treatment exceeding six months' duration within the preceding year; or

(c) Has been unable to engage in any substantial gainful activity by reason of any mental disorder which has lasted for a continuous period of not less than ((~~twelve~~)) 12 months. "Substantial gainful activity" shall be defined by the authority by rule consistent with Public Law 92-603, as amended.

(13) "Clubhouse" means a community-based program that provides rehabilitation services and is licensed or certified by the department.

(14) "Community behavioral health program" means all expenditures, services, activities, or programs, including reasonable administration and overhead, designed and conducted to prevent or treat substance use disorder, mental illness, or both in the community behavioral health system.

(15) "Community behavioral health service delivery system" means public, private, or tribal agencies that provide services specifically to persons with mental disorders, substance use disorders, or both, as defined under RCW 71.05.020 and receive funding from public sources.

(16) "Community support services" means services authorized, planned, and coordinated through resource management services including, at a minimum, assessment, diagnosis, emergency crisis intervention available ((~~twenty-four~~)) 24 hours, seven days a week, prescreening determinations for persons who are mentally ill being considered for placement in nursing homes as required by federal law, screening for patients being considered for admission to residential services, diagnosis and treatment for children who are acutely mentally ill or severely emotionally or behaviorally disturbed discovered under screening through the federal Title XIX early and

periodic screening, diagnosis, and treatment program, investigation, legal, and other nonresidential services under chapter 71.05 RCW, case management services, psychiatric treatment including medication supervision, counseling, psychotherapy, assuring transfer of relevant patient information between service providers, recovery services, and other services determined by behavioral health administrative services organizations.

(17) "Consensus-based" means a program or practice that has general support among treatment providers and experts, based on experience or professional literature, and may have anecdotal or case study support, or that is agreed but not possible to perform studies with random assignment and controlled groups.

(18) "County authority" means the board of county commissioners, county council, or county executive having authority to establish a behavioral health administrative services organization, or two or more of the county authorities specified in this subsection which have entered into an agreement to establish a behavioral health administrative services organization.

(19) "Crisis call center hub" means a state-designated center participating in the national suicide prevention lifeline network to respond to statewide or regional 988 calls that meets the requirements of RCW 71.24.890.

(20) "Crisis stabilization services" means services such as 23-hour crisis stabilization units based on the living room model, crisis stabilization units as provided in RCW 71.05.020, triage facilities as provided in RCW 71.05.020, short-term respite facilities, peer-run respite services, and same-day walk-in behavioral health services, including within the overall crisis system components that operate like hospital emergency departments that accept all walk-ins, and ambulance, fire, and police drop-offs.

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

(22) "Designated crisis responder" has the same meaning as in RCW 71.05.020.

(23) "Director" means the director of the authority.

(24) "Drug addiction" means a disease characterized by a dependency on psychoactive chemicals, loss of control over the amount and circumstances of use, symptoms of tolerance, physiological or psychological withdrawal, or both, if use is reduced or discontinued, and impairment of health or disruption of social or economic functioning.

(25) "Early adopter" means a regional service area for which all of the county authorities have requested that the authority purchase medical and behavioral health services through a managed care health system as defined under RCW 71.24.380((~~(6)~~)) (7).

(26) "Emerging best practice" or "promising practice" means a program or practice that, based on statistical analyses or a well established theory of change, shows potential for meeting the evidence-based or research-based criteria, which may include the use of a program that is evidence-based for outcomes other than those listed in subsection (27) of this section.

(27) "Evidence-based" means a program or practice that has been tested in heterogeneous or intended populations with multiple randomized, or statistically controlled evaluations, or both; or one large multiple site randomized, or statistically controlled evaluation, or both, where the weight of the evidence from a systemic review demonstrates sustained improvements in at least one outcome. "Evidence-based" also means a program or practice that can be implemented with a set of procedures to allow successful replication in Washington and, when possible, is determined to be cost-beneficial.

(28) "Immediate jeopardy" means a situation in which the licensed or certified behavioral health agency's noncompliance with one or more statutory or regulatory requirements has placed the health and safety of patients in its care at risk for serious injury, serious harm, serious impairment, or death.

(29) "Indian health care provider" means a health care program operated by the Indian health service or by a tribe, tribal organization, or urban Indian organization as those terms are defined in the Indian health care improvement act (25 U.S.C. Sec. 1603).

((~~(29)~~)) (30) "Intensive behavioral health treatment facility" means a community-based specialized residential treatment facility for individuals with behavioral health conditions, including individuals discharging from or being diverted from state and local hospitals, whose impairment or behaviors do not meet, or no longer meet, criteria for involuntary inpatient commitment under chapter 71.05 RCW, but whose care needs cannot be met in other community-based placement settings.

((~~(30)~~)) (31) "Licensed or certified behavioral health agency" means:

(a) An entity licensed or certified according to this chapter or chapter 71.05 RCW;

(b) An entity deemed to meet state minimum standards as a result of accreditation by a recognized behavioral health accrediting body recognized and having a current agreement with the department; or

(c) An entity with a tribal attestation that it meets state minimum standards for a licensed or certified behavioral health agency.

((~~(31)~~)) (32) "Licensed physician" means a person licensed to practice medicine or osteopathic medicine and surgery in the state of Washington.

((~~(32)~~)) (33) "Long-term inpatient care" means inpatient services for persons committed for, or voluntarily receiving intensive treatment for, periods of ((~~ninety~~)) 90 days or greater under chapter 71.05 RCW. "Long-term inpatient care" as used in this chapter does not include: (a) Services for individuals committed under chapter 71.05 RCW who are receiving services pursuant to a conditional release or a court-ordered less restrictive alternative to detention; or (b) services for individuals voluntarily receiving less restrictive alternative treatment on the grounds of the state hospital.

((~~(33)~~)) (34) "Managed care organization" means an organization, having a certificate of authority or certificate of registration from the office of the insurance commissioner, that contracts with the authority under a comprehensive risk contract to provide prepaid health care services to enrollees under the authority's managed care programs under chapter 74.09 RCW.

((~~(34)~~)) (35) "Mental health peer-run respite center" means a peer-run program to serve individuals in need of voluntary, short-term, noncrisis services that focus on recovery and wellness.

((~~(35)~~)) (36) Mental health "treatment records" include registration and all other records concerning persons who are receiving or who at any time have received services for mental illness, which are maintained by the department of social and health services or the authority, by behavioral health administrative services organizations and their staffs, by managed care organizations and their staffs, or by treatment facilities. "Treatment records" do not include notes or records maintained for personal use by a person providing treatment services for the

entities listed in this subsection, or a treatment facility if the notes or records are not available to others.

((~~(36)~~)) (37) "Mentally ill persons," "persons who are mentally ill," and "the mentally ill" mean persons and conditions defined in subsections (2), (12), ((~~(44)~~)) (45), and ((~~(45)~~)) (46) of this section.

((~~(37)~~)) (38) "Mobile rapid response crisis team" means a team that provides professional on-site community-based intervention such as outreach, de-escalation, stabilization, resource connection, and follow-up support for individuals who are experiencing a behavioral health crisis, that shall include certified peer counselors as a best practice to the extent practicable based on workforce availability, and that meets standards for response times established by the authority.

((~~(38)~~)) (39) "Recovery" means a process of change through which individuals improve their health and wellness, live a self-directed life, and strive to reach their full potential.

((~~(39)~~)) (40) "Research-based" means a program or practice that has been tested with a single randomized, or statistically controlled evaluation, or both, demonstrating sustained desirable outcomes; or where the weight of the evidence from a systemic review supports sustained outcomes as described in subsection (27) of this section but does not meet the full criteria for evidence-based.

((~~(40)~~)) (41) "Residential services" means a complete range of residences and supports authorized by resource management services and which may involve a facility, a distinct part thereof, or services which support community living, for persons who are acutely mentally ill, adults who are chronically mentally ill, children who are severely emotionally disturbed, or adults who are seriously disturbed and determined by the behavioral health administrative services organization or managed care organization to be at risk of becoming acutely or chronically mentally ill. The services shall include at least evaluation and treatment services as defined in chapter 71.05 RCW, acute crisis respite care, long-term adaptive and rehabilitative care, and supervised and supported living services, and shall also include any residential services developed to service persons who are mentally ill in nursing homes, residential treatment facilities, assisted living facilities, and adult family homes, and may include outpatient services provided as an element in a package of services in a supported housing model. Residential services for

children in out-of-home placements related to their mental disorder shall not include the costs of food and shelter, except for children's long-term residential facilities existing prior to January 1, 1991.

((~~(41)~~)) (42) "Resilience" means the personal and community qualities that enable individuals to rebound from adversity, trauma, tragedy, threats, or other stresses, and to live productive lives.

((~~(42)~~)) (43) "Resource management services" mean the planning, coordination, and authorization of residential services and community support services administered pursuant to an individual service plan for: (a) Adults and children who are acutely mentally ill; (b) adults who are chronically mentally ill; (c) children who are severely emotionally disturbed; or (d) adults who are seriously disturbed and determined by a behavioral health administrative services organization or managed care organization to be at risk of becoming acutely or chronically mentally ill. Such planning, coordination, and authorization shall include mental health screening for children eligible under the federal Title XIX early and periodic screening, diagnosis, and treatment program. Resource management services include seven day a week, ((~~twenty-four~~)) 24 hour a day availability of information regarding enrollment of adults and children who are mentally ill in services and their individual service plan to designated crisis responders, evaluation and treatment facilities, and others as determined by the behavioral health administrative services organization or managed care organization, as applicable.

((~~(43)~~)) (44) "Secretary" means the secretary of the department of health.

((~~(44)~~)) (45) "Seriously disturbed person" means a person who:

(a) Is gravely disabled or presents a likelihood of serious harm to himself or herself or others, or to the property of others, as a result of a mental disorder as defined in chapter 71.05 RCW;

(b) Has been on conditional release status, or under a less restrictive alternative order, at some time during the preceding two years from an evaluation and treatment facility or a state mental health hospital;

(c) Has a mental disorder which causes major impairment in several areas of daily living;

(d) Exhibits suicidal preoccupation or attempts; or

(e) Is a child diagnosed by a mental health professional, as defined in chapter 71.34 RCW, as experiencing a mental disorder which

is clearly interfering with the child's functioning in family or school or with peers or is clearly interfering with the child's personality development and learning.

((~~(45)~~)) (46) "Severely emotionally disturbed child" or "child who is severely emotionally disturbed" means a child who has been determined by the behavioral health administrative services organization or managed care organization, if applicable, to be experiencing a mental disorder as defined in chapter 71.34 RCW, including those mental disorders that result in a behavioral or conduct disorder, that is clearly interfering with the child's functioning in family or school or with peers and who meets at least one of the following criteria:

(a) Has undergone inpatient treatment or placement outside of the home related to a mental disorder within the last two years;

(b) Has undergone involuntary treatment under chapter 71.34 RCW within the last two years;

(c) Is currently served by at least one of the following child-serving systems: Juvenile justice, child-protection/welfare, special education, or developmental disabilities;

(d) Is at risk of escalating maladjustment due to:

(i) Chronic family dysfunction involving a caretaker who is mentally ill or inadequate;

(ii) Changes in custodial adult;

(iii) Going to, residing in, or returning from any placement outside of the home, for example, ((~~psychiatric~~)) behavioral health hospital, short-term inpatient, residential treatment, group or foster home, or a correctional facility;

(iv) Subject to repeated physical abuse or neglect;

(v) Drug or alcohol abuse; or

(vi) Homelessness.

((~~(46)~~)) (47) "State minimum standards" means minimum requirements established by rules adopted and necessary to implement this chapter by:

(a) The authority for:

(i) Delivery of mental health and substance use disorder services; and

(ii) Community support services and resource management services;

(b) The department of health for:

(i) Licensed or certified behavioral health agencies for the purpose of providing mental health or substance use disorder programs and services, or both;

(ii) Licensed behavioral health providers for the provision of mental health or substance use disorder services, or both; and

(iii) Residential services.

((~~(47)~~)) (48) "Substance use disorder" means a cluster of cognitive, behavioral, and physiological symptoms indicating that an individual continues using the substance despite significant substance-related problems. The diagnosis of a substance use disorder is based on a pathological pattern of behaviors related to the use of the substances.

((~~(48)~~)) (49) "Tribe," for the purposes of this section, means a federally recognized Indian tribe.

Sec. 26. RCW 71.24.037 and 2019 c 446 s 23 and 2019 c 325 s 1007 are each reenacted and amended to read as follows:

(1) The secretary shall license or certify any agency or facility that: (a) Submits payment of the fee established under RCW 43.70.110 and 43.70.250; and (b) submits a complete application that demonstrates the ability to comply with requirements for operating and maintaining an agency or facility in statute or rule((~~; and (c) successfully completes the prelicensure inspection requirement~~)).

(2) The secretary shall establish by rule minimum standards for licensed or certified behavioral health agencies that must, at a minimum, establish: (a) Qualifications for staff providing services directly to persons with mental disorders, substance use disorders, or both; (b) the intended result of each service; and (c) the rights and responsibilities of persons receiving behavioral health services pursuant to this chapter and chapters 71.34 and ((~~chapter~~)) 71.05 RCW. The secretary shall provide for deeming of licensed or certified behavioral health agencies as meeting state minimum standards as a result of accreditation by a recognized behavioral health accrediting body recognized and having a current agreement with the department.

(3) ((~~The department shall review reports or other information alleging a failure to comply with this chapter or the standards and rules adopted under this chapter and may initiate investigations and enforcement actions based on those reports.~~

~~(4) The department shall conduct inspections of agencies and facilities, including reviews of records and documents required to be maintained under this chapter or rules adopted under this chapter.~~

~~(5) The department may suspend, revoke, limit, restrict, or modify an approval, or refuse to grant approval, for failure to meet the provisions of this chapter, or the standards adopted under this chapter. RCW 43.70.115 governs notice of a license or certification denial, revocation, suspension, or modification and provides the right to an adjudicative proceeding.~~

~~(6)~~)) No licensed or certified behavioral health ((~~service provider~~)) agency may advertise or represent itself as a licensed or certified behavioral health ((~~service provider~~)) agency if approval has not been granted or has been denied, suspended, revoked, or canceled.

((~~(7)~~)) (4) Licensure or certification as a behavioral health ((~~service provider~~)) agency is effective for one calendar year from the date of issuance of the license or certification. The license or certification must specify the types of services provided by the behavioral health ((~~service provider~~)) agency that meet the standards adopted under this chapter. Renewal of a license or certification must be made in accordance with this section for initial approval and in accordance with the standards set forth in rules adopted by the secretary.

((~~(8)~~)) (5) Licensure or certification as a licensed or certified behavioral health ((~~service provider~~)) agency must specify the types of services provided that meet the standards adopted under this chapter. Renewal of a license or certification must be made in accordance with this section for initial approval and in accordance with the standards set forth in rules adopted by the secretary.

((~~(9)~~)) (6) The department shall develop a process by which a provider may obtain dual licensure as an evaluation and treatment facility and secure withdrawal management and stabilization facility.

((~~(10)~~)) (7) Licensed or certified behavioral health ((~~service providers~~)) agencies may not provide types of services for which the licensed or certified behavioral health ((~~service provider~~)) agency has not been certified. Licensed or certified behavioral health ((~~service providers~~)) agencies may provide services for which approval has been sought and is pending, if approval for the services has not been previously revoked or denied.

((~~(11) The department periodically shall inspect licensed or certified behavioral health service providers at reasonable times and in a reasonable manner.~~

~~(12) Upon petition of the department and after a hearing held upon reasonable notice to the facility, the superior court may issue a warrant to an officer or employee of the department authorizing him or her to enter and inspect at reasonable times, and examine the books and accounts of, any licensed or certified behavioral health service provider refusing to consent to inspection or examination by the department or which the department has reasonable cause to believe is operating in violation of this chapter.~~

~~(13)~~)) (8) The department shall maintain and periodically publish a current list of licensed or certified behavioral health ((~~service providers~~)) agencies.

((~~(14) Each licensed or certified behavioral health service provider shall file with the department or the authority upon request, data, statistics, schedules, and information the department or the authority reasonably requires. A licensed or certified behavioral health service provider that without good cause fails to furnish any data, statistics, schedules, or information as requested, or files fraudulent returns thereof, may have its license or certification revoked or suspended.~~

~~(15) The authority shall use the data provided in subsection (14) of this section to evaluate each program that admits children to inpatient substance use disorder treatment upon application of their parents. The evaluation must be done at least once every twelve months. In addition, the authority shall randomly select and review the information on individual children who are admitted on application of the child's parent for the purpose of determining whether the child was appropriately placed into substance use disorder treatment based on an objective evaluation of the child's condition and the outcome of the child's treatment.~~

~~(16) Any settlement agreement entered into between the department and licensed or certified behavioral health service providers to resolve administrative complaints, license or certification violations, license or certification suspensions, or license or certification revocations may not reduce the number of violations reported by the department unless the department concludes, based on evidence gathered by inspectors, that the licensed or certified~~

~~behavioral health service provider did not commit one or more of the violations.~~

~~(17) In cases in which a behavioral health service provider that is in violation of licensing or certification standards attempts to transfer or sell the behavioral health service provider to a family member, the transfer or sale may only be made for the purpose of remedying license or certification violations and achieving full compliance with the terms of the license or certification. Transfers or sales to family members are prohibited in cases in which the purpose of the transfer or sale is to avoid liability or reset the number of license or certification violations found before the transfer or sale. If the department finds that the owner intends to transfer or sell, or has completed the transfer or sale of, ownership of the behavioral health service provider to a family member solely for the purpose of resetting the number of violations found before the transfer or sale, the department may not renew the behavioral health service provider's license or certification or issue a new license or certification to the behavioral health service provider.~~))

NEW SECTION. **Sec. 27.** A new section is added to chapter 71.24 RCW to read as follows:

(1) The department shall review reports or other information alleging a failure to comply with this chapter or the standards and rules adopted under this chapter and may initiate investigations and enforcement actions based on those reports.

(2) The department shall conduct inspections of licensed or certified behavioral health agencies, including reviews of records and documents required to be maintained under this chapter or rules adopted under this chapter.

(3) Each licensed or certified behavioral health agency shall file with the department or the authority upon request data, statistics, schedules, medical records, and other information the department or the authority reasonably requires. A licensed or certified behavioral health agency that without good cause fails to furnish any data, statistics, schedules, or information as requested, or files fraudulent returns thereof, may have its license or certification revoked or suspended.

(4) The authority shall use the data provided in subsection (3) of this section to evaluate each program that admits children to inpatient substance use disorder treatment upon application of their

parents. The evaluation shall be done at least once every 12 months. In addition, the authority shall randomly select and review the information on individual children who are admitted on application of the child's parent for the purpose of determining whether the child was appropriately placed into substance use disorder treatment based on an objective evaluation of the child's condition and the outcome of the child's treatment.

(5) Any settlement agreement entered into between the department and licensed or certified behavioral health agencies to resolve administrative complaints, license or certification violations, license or certification suspensions, or license or certification revocations may not reduce the number of violations reported by the department unless the department concludes, based on evidence gathered by inspectors, that the licensed or certified behavioral health agency did not commit one or more of the violations.

(6) In cases in which a licensed or certified behavioral health agency that is in violation of licensing or certification standards attempts to transfer or sell the behavioral health agency to a family member, the transfer or sale may only be made for the purpose of remedying license or certification violations and achieving full compliance with the terms of the license or certification. Transfers or sales to family members are prohibited in cases in which the purpose of the transfer or sale is to avoid liability or reset the number of license or certification violations found before the transfer or sale. If the department finds that the owner intends to transfer or sell, or has completed the transfer or sale of, ownership of the behavioral health agency to a family member solely for the purpose of resetting the number of violations found before the transfer or sale, the department may not renew the behavioral health agency's license or certification or issue a new license or certification to the behavioral health provider.

(7) In any case in which the department finds that a licensed or certified behavioral health agency has failed or refused to comply with the requirements of this chapter or the standards or rules adopted under this chapter, the department may take one or more of the actions identified in this section, except as otherwise limited in this section.

(a) When the department determines the licensed or certified behavioral health agency has previously been subject to an enforcement action for the same or similar type of violation of the

same statute or rule, or has been given any previous statement of deficiency that included the same or similar type of violation of the same or similar statute or rule, or when the licensed or certified behavioral health agency failed to correct noncompliance with a statute or rule by a date established or agreed to by the department, the department may impose reasonable conditions on a license. Conditions may include correction within a specified amount of time, training, or hiring a department-approved consultant if the licensed or certified behavioral health agency cannot demonstrate to the department that it has access to sufficient internal expertise.

(b)(i) In accordance with the department's authority under RCW 43.70.095, the department may assess a civil fine of up to $3,000 per violation on a licensed or certified behavioral health agency when the department determines the licensed or certified behavioral health agency has previously been subject to an enforcement action for the same or similar type of violation of the same statute or rule, or has been given any previous statement of deficiency that included the same or similar type of violation of the same or similar statute or rule, or when the licensed or certified behavioral health agency failed to correct noncompliance with a statute or rule by a date established or agreed to by the department.

(ii) Proceeds from these fines may only be used by the department to provide training or technical assistance to licensed or certified behavioral health agencies and to offset costs associated with licensing, certification, or enforcement of behavioral health agencies.

(iii) The department shall adopt in rules under this chapter specific fine amounts in relation to the severity of the noncompliance and at an adequate level to be a deterrent to future noncompliance.

(iv) If a licensee is aggrieved by the department's action of assessing civil fines, the licensee has the right to appeal under RCW 43.70.095.

(c) The department may suspend new intake or admission of a specific category or categories of individuals receiving behavioral health services as related to the violation by imposing a limited stop placement. This may only be done if the department finds that noncompliance results in immediate jeopardy.

(i) Prior to imposing a limited stop placement, the department shall provide a licensed or certified behavioral health agency

written notification upon identifying deficient practices or conditions that constitute an immediate jeopardy, and the licensed or certified behavioral health agency shall have 24 hours from notification to develop and implement a department-approved plan to correct the deficient practices or conditions that constitute an immediate jeopardy. If the deficient practices or conditions that constitute immediate jeopardy are not verified by the department as having been corrected within the same 24-hour period, the department may issue the limited stop placement.

(ii) When the department imposes a limited stop placement, the licensed or certified behavioral health agency may not accept any new individuals in the category or categories subject to the limited stop placement until the limited stop placement is terminated.

(iii) The department shall conduct a follow-up inspection within five business days or within the time period requested by the licensed or certified behavioral health agency if more than five business days is needed to verify the violation necessitating the limited stop placement has been corrected.

(iv) The limited stop placement shall be terminated when:

(A) The department verifies the violation necessitating the limited stop placement has been corrected or the department determines that the licensed or certified behavioral health agency has taken intermediate action to address the immediate jeopardy; and

(B) The licensed or certified behavioral health agency establishes the ability to maintain correction of the violation previously found deficient.

(d) The department may suspend a specific category or categories of behavioral health services as related to the violation by imposing a limited stop service. This may only be done if the department finds that noncompliance results in immediate jeopardy.

(i) Prior to imposing a limited stop service, the department shall provide a licensed or certified behavioral health agency written notification upon identifying deficient practices or conditions that constitute an immediate jeopardy. The licensed or certified behavioral health agency shall have 24 hours from notification to develop and implement a department-approved plan to correct the deficient practices or conditions that constitute an immediate jeopardy. If the deficient practices or conditions that constitute immediate jeopardy are not verified by the department as

having been corrected within the same 24-hour period, the department may issue the limited stop service.

(ii) When the department imposes a limited stop service, the licensed or certified behavioral health agency may not provide the services in the category or categories subject to the limited stop service to any new or existing individuals, unless otherwise allowed by the department, until the limited stop service is terminated.

(iii) The department shall conduct a follow-up inspection within five business days or within the time period requested by the licensed or certified behavioral health agency if more than five business days is needed to verify the violation necessitating the limited stop service has been corrected.

(iv) The limited stop service shall be terminated when:

(A) The department verifies the violation necessitating the limited stop service has been corrected or the department determines that the licensed or certified behavioral health agency has taken intermediate action to address the immediate jeopardy; and

(B) The licensed or certified behavioral health agency establishes the ability to maintain correction of the violation previously found deficient.

(e) The department may suspend, revoke, or refuse to renew a license.

(8)(a) Except as otherwise provided, RCW 43.70.115 governs notice of the imposition of conditions on a license, a limited stop placement, limited stop service, or the suspension, revocation, or refusal to renew a license and provides the right to an adjudicative proceeding. Adjudicative proceedings and hearings under this section are governed by the administrative procedure act, chapter 34.05 RCW. The application for an adjudicative proceeding must be in writing, state the basis for contesting the adverse action, include a copy of the department's notice, be served on and received by the department within 28 days of the licensee's receipt of the adverse notice, and be served in a manner that shows proof of receipt.

(b) When the department determines a licensee's noncompliance results in immediate jeopardy, the department may make the imposition of conditions on a licensee, a limited stop placement, limited stop service, or the suspension of a license effective immediately upon receipt of the notice by the licensee, pending any adjudicative proceeding.

(i) When the department makes the suspension of a license or imposition of conditions on a license effective immediately, a licensee is entitled to a show cause hearing before a presiding officer within 14 days of making the request. The licensee must request the show cause hearing within 28 days of receipt of the notice of immediate suspension or immediate imposition of conditions. At the show cause hearing the department has the burden of demonstrating that more probably than not there is an immediate jeopardy.

(ii) At the show cause hearing, the presiding officer may consider the notice and documents supporting the immediate suspension or immediate imposition of conditions and the licensee's response and shall provide the parties with an opportunity to provide documentary evidence and written testimony, and to be represented by counsel. Prior to the show cause hearing, the department shall provide the licensee with all documentation that supports the department's immediate suspension.

(iii) If the presiding officer determines there is no immediate jeopardy, the presiding officer may overturn the immediate suspension or immediate imposition of conditions.

(iv) If the presiding officer determines there is immediate jeopardy, the immediate suspension or immediate imposition of conditions shall remain in effect pending a full hearing.

(v) If the secretary sustains the immediate suspension or immediate imposition of conditions, the licensee may request an expedited full hearing on the merits of the department's action. A full hearing must be provided within 90 days of the licensee's request.

(9) When the department determines an alleged violation, if true, would constitute an immediate jeopardy, and the licensee fails to cooperate with the department's investigation of such an alleged violation, the department may impose an immediate limited stop placement, immediate limited stop service, or immediate suspension.

(a) When the department imposes an immediate limited stop placement, immediate limited stop service, or immediate suspension for failure to cooperate, a licensee is entitled to a show cause hearing before a presiding officer within 14 days of making the request. The licensee must request the show cause hearing within 28 days of receipt of the notice of an immediate limited stop placement, immediate limited stop service, or immediate suspension for failure

to cooperate. At the show cause hearing the department has the burden of demonstrating that more probably than not the alleged violation, if true, would constitute an immediate jeopardy and the licensee failed to cooperate with the department's investigation.

(b) At the show cause hearing, the presiding officer may consider the notice and documents supporting the immediate limited stop placement, immediate limited stop service, or immediate suspension for failure to cooperate, and the licensee's response and shall provide the parties with an opportunity to provide documentary evidence and written testimony, and to be represented by counsel. Prior to the show cause hearing, the department shall provide the licensee with all documentation that supports the department's immediate action for failure to cooperate.

(c) If the presiding officer determines the alleged violation, if true, does not constitute an immediate jeopardy or determines that the licensee cooperated with the department's investigation, the presiding officer may overturn the immediate action for failure to cooperate.

(d) If the presiding officer determines the allegation, if true, would constitute an immediate jeopardy and the licensee failed to cooperate with the department's investigation, the immediate action for failure to cooperate shall remain in effect pending a full hearing.

(e) If the presiding officer sustains the immediate action for failure to cooperate, the licensee may request an expedited full hearing on the merits of the department's action. A full hearing must be provided within 90 days of the licensee's request.

Sec. 28. RCW 70.170.020 and 2022 c 197 s 1 are each amended to read as follows:

As used in this chapter:

(1) "Department" means department of health.

(2) "Hospital" means any health care institution which is required to qualify for a license under RCW 70.41.020(8); or as a ((~~psychiatric~~)) behavioral health hospital under chapter 71.12 RCW.

(3) "Secretary" means secretary of health.

(4) "Charity care" means medically necessary hospital health care rendered to indigent persons when third-party coverage, if any, has been exhausted, to the extent that the persons are unable to pay for

the care or to pay deductibles or coinsurance amounts required by a third-party payer, as determined by the department.

(5) "Indigent persons" are those patients or their guarantors who qualify for charity care pursuant to RCW 70.170.060(5) based on the federal poverty level, adjusted for family size, and who have exhausted any third-party coverage.

(6) "Third-party coverage" means an obligation on the part of an insurance company, health care service contractor, health maintenance organization, group health plan, government program, tribal health benefits, or health care sharing ministry as defined in 26 U.S.C. Sec. 5000A to pay for the care of covered patients and services, and may include settlements, judgments, or awards actually received related to the negligent acts of others which have resulted in the medical condition for which the patient has received hospital health care service. The pendency of such settlements, judgments, or awards must not stay hospital obligations to consider an eligible patient for charity care.

(7) "Special studies" means studies which have not been funded through the department's biennial or other legislative appropriations.

Sec. 29. RCW 18.64.005 and 2022 c 240 s 15 are each amended to read as follows:

The commission shall:

(1) Regulate the practice of pharmacy and enforce all laws placed under its jurisdiction;

(2) Prepare or determine the nature of, and supervise the grading of, examinations for applicants for pharmacists' licenses;

(3) Establish the qualifications for licensure of pharmacists or pharmacy interns;

(4) Conduct hearings for the revocation or suspension of licenses, permits, registrations, certificates, or any other authority to practice granted by the commission, which hearings may also be conducted by an administrative law judge appointed under chapter 34.12 RCW or a presiding officer designated by the commission. The commission may authorize the secretary, or their designee, to serve as the presiding officer for any disciplinary proceedings of the commission ((~~authorized under this chapter~~)). The presiding officer shall not vote on or make any final decision in cases pertaining to standards of practice or where clinical expertise

is necessary. All functions performed by the presiding officer shall be subject to chapter 34.05 RCW;

(5) Issue subpoenas and administer oaths in connection with any hearing, or disciplinary proceeding held under this chapter or any other chapter assigned to the commission;

(6) Assist the regularly constituted enforcement agencies of this state in enforcing all laws pertaining to drugs, controlled substances, and the practice of pharmacy, or any other laws or rules under its jurisdiction;

(7) Promulgate rules for the dispensing, distribution, wholesaling, and manufacturing of drugs and devices and the practice of pharmacy for the protection and promotion of the public health, safety, and welfare. Violation of any such rules shall constitute grounds for ((~~refusal~~)) denial of an application, assessment of a civil fine, imposition of a limited stop service, imposition of reasonable conditions, suspension, ((~~or~~)) revocation, or modification of licenses or any other authority to practice issued by the commission;

(8) Adopt rules establishing and governing continuing education requirements for pharmacists and other licensees applying for renewal of licenses under this chapter;

(9) Be immune, collectively and individually, from suit in any action, civil or criminal, based upon any disciplinary proceedings or other official acts performed as members of the commission. Such immunity shall apply to employees of the department when acting in the course of disciplinary proceedings;

(10) Suggest strategies for preventing, reducing, and eliminating drug misuse, diversion, and abuse, including professional and public education, and treatment of persons misusing and abusing drugs;

(11) Conduct or encourage educational programs to be conducted to prevent the misuse, diversion, and abuse of drugs for health care practitioners and licensed or certified health care facilities;

(12) Monitor trends of drug misuse, diversion, and abuse and make periodic reports to disciplinary boards of licensed health care practitioners and education, treatment, and appropriate law enforcement agencies regarding these trends;

(13) Enter into written agreements with all other state and federal agencies with any responsibility for controlling drug misuse, diversion, or abuse and with health maintenance organizations, health care service contractors, and health care providers to assist and

promote coordination of agencies responsible for ensuring compliance with controlled substances laws and to monitor observance of these laws and cooperation between these agencies. The department of social and health services, the department of labor and industries, and any other state agency including licensure disciplinary boards, shall refer all apparent instances of over-prescribing by practitioners and all apparent instances of legend drug overuse to the department. The department shall also encourage such referral by health maintenance organizations, health service contractors, and health care providers;

(14) Whenever the workload of the commission requires, request that the secretary appoint pro tempore members. While serving as members pro tempore persons have all the powers, duties, and immunities, and are entitled to the emoluments, including travel expenses, of the commission.

Sec. 30. RCW 18.64.011 and 2021 c 78 s 1 are each amended to read as follows:

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

(1) "Administer" means the direct application of a drug or device, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject.

(2) "Business licensing system" means the mechanism established by chapter 19.02 RCW by which business licenses, endorsed for individual state-issued licenses, are issued and renewed utilizing a business license application and a business license expiration date common to each renewable license endorsement.

(3) "Chart order" means a lawful order for a drug or device entered on the chart or medical record of an inpatient or resident of an institutional facility by a practitioner or his or her designated agent.

(4) "Closed door long-term care pharmacy" means a pharmacy that provides pharmaceutical care to a defined and exclusive group of patients who have access to the services of the pharmacy because they are treated by or have an affiliation with a long-term care facility or hospice program, and that is not a retailer of goods to the general public.

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

(6) "Compounding" means the act of combining two or more ingredients in the preparation of a prescription. Reconstitution and

mixing of (a) sterile products according to federal food and drug administration-approved labeling does not constitute compounding if prepared pursuant to a prescription and administered immediately or in accordance with package labeling, and (b) nonsterile products according to federal food and drug administration-approved labeling does not constitute compounding if prepared pursuant to a prescription.

(7) "Controlled substance" means a drug or substance, or an immediate precursor of such drug or substance, so designated under or pursuant to the provisions of chapter 69.50 RCW.

(8) "Deliver" or "delivery" means the actual, constructive, or attempted transfer from one person to another of a drug or device, whether or not there is an agency relationship.

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

(10) "Device" means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (a) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or other animals, or (b) to affect the structure or any function of the body of human beings or other animals.

(11) "Dispense" means the interpretation of a prescription or order for a drug, biological, or device and, pursuant to that prescription or order, the proper selection, measuring, compounding, labeling, or packaging necessary to prepare that prescription or order for delivery.

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

(13) "Drug" and "devices" do not include surgical or dental instruments or laboratory materials, gas and oxygen, therapy equipment, X-ray apparatus or therapeutic equipment, their component parts or accessories, or equipment, instruments, apparatus, or contrivances used to render such articles effective in medical, surgical, or dental treatment, or for use or consumption in or for mechanical, industrial, manufacturing, or scientific applications or purposes. "Drug" also does not include any article or mixture covered by the Washington pesticide control act (chapter 15.58 RCW), as enacted or hereafter amended, nor medicated feed intended for and used exclusively as a feed for animals other than human beings.

(14) "Drugs" means:

(a) Articles recognized in the official United States pharmacopoeia or the official homeopathic pharmacopoeia of the United States;

(b) Substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or other animals;

(c) Substances (other than food) intended to affect the structure or any function of the body of human beings or other animals; or

(d) Substances intended for use as a component of any substances specified in (a), (b), or (c) of this subsection, but not including devices or their component parts or accessories.

(15) "Health care entity" means an organization that provides health care services in a setting that is not otherwise licensed by the state to acquire or possess legend drugs. Health care entity includes a freestanding outpatient surgery center, a residential treatment facility, and a freestanding cardiac care center. "Health care entity" does not include an individual practitioner's office or a multipractitioner clinic, regardless of ownership, unless the owner elects licensure as a health care entity. "Health care entity" also does not include an individual practitioner's office or multipractitioner clinic identified by a hospital on a pharmacy application or renewal pursuant to RCW 18.64.043.

(16) "Hospice program" means a hospice program certified or paid by medicare under Title XVIII of the federal social security act, or a hospice program licensed under chapter 70.127 RCW.

(17) "Institutional facility" means any organization whose primary purpose is to provide a physical environment for patients to obtain health care services including, but not limited to, services in a hospital, long-term care facility, hospice program, mental health facility, drug abuse treatment center, residential habilitation center, or a local, state, or federal correction facility.

(18) "Labeling" means the process of preparing and affixing a label to any drug or device container. The label must include all information required by current federal and state law and pharmacy rules.

(19) "Legend drugs" means any drugs which are required by any applicable federal or state law or regulation to be dispensed on prescription only or are restricted to use by practitioners only.

(20) "Long-term care facility" means a nursing home licensed under chapter 18.51 RCW, an assisted living facility licensed under chapter 18.20 RCW, or an adult family home licensed under chapter 70.128 RCW.

(21) "Manufacture" means the production, preparation, propagation, compounding, or processing of a drug or other substance or device or the packaging or repackaging of such substance or device, or the labeling or relabeling of the commercial container of such substance or device, but does not include the activities of a practitioner who, as an incident to his or her administration or dispensing such substance or device in the course of his or her professional practice, personally prepares, compounds, packages, or labels such substance or device. "Manufacture" includes the distribution of a licensed pharmacy compounded drug product to other state licensed persons or commercial entities for subsequent resale or distribution, unless a specific product item has approval of the commission. The term does not include:

(a) The activities of a licensed pharmacy that compounds a product on or in anticipation of an order of a licensed practitioner for use in the course of their professional practice to administer to patients, either personally or under their direct supervision;

(b) The practice of a licensed pharmacy when repackaging commercially available medication in small, reasonable quantities for a practitioner legally authorized to prescribe the medication for office use only;

(c) The distribution of a drug product that has been compounded by a licensed pharmacy to other appropriately licensed entities under common ownership or control of the facility in which the compounding takes place; or

(d) The delivery of finished and appropriately labeled compounded products dispensed pursuant to a valid prescription to alternate delivery locations, other than the patient's residence, when requested by the patient, or the prescriber to administer to the patient, or to another licensed pharmacy to dispense to the patient.

(22) "Manufacturer" means a person, corporation, or other entity engaged in the manufacture of drugs or devices.

(23) "Nonlegend" or "nonprescription" drugs means any drugs which may be lawfully sold without a prescription.

(24) "Person" means an individual, corporation, government, governmental subdivision or agency, business trust, estate, trust, partnership or association, or any other legal entity.

(25) "Pharmacist" means a person duly licensed by the commission to engage in the practice of pharmacy.

(26) "Pharmacy" means every place properly licensed by the commission where the practice of pharmacy is conducted.

(27) "Poison" does not include any article or mixture covered by the Washington pesticide control act (chapter 15.58 RCW), as enacted or hereafter amended.

(28) "Practice of pharmacy" includes the practice of and responsibility for: Interpreting prescription orders; the compounding, dispensing, labeling, administering, and distributing of drugs and devices; the monitoring of drug therapy and use; the initiating or modifying of drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs; the participating in drug utilization reviews and drug product selection; the proper and safe storing and distributing of drugs and devices and maintenance of proper records thereof; the providing of information on legend drugs which may include, but is not limited to, the advising of therapeutic values, hazards, and the uses of drugs and devices.

(29) "Practitioner" means a physician, dentist, veterinarian, nurse, or other person duly authorized by law or rule in the state of Washington to prescribe drugs.

(30) "Prescription" means an order for drugs or devices issued by a practitioner duly authorized by law or rule in the state of Washington to prescribe drugs or devices in the course of his or her professional practice for a legitimate medical purpose.

(31) "Secretary" means the secretary of health or the secretary's designee.

(32) "Shared pharmacy services" means a system that allows a participating pharmacist or pharmacy pursuant to a request from another participating pharmacist or pharmacy to process or fill a prescription or drug order, which may include but is not necessarily limited to preparing, packaging, labeling, data entry, compounding for specific patients, dispensing, performing drug utilization reviews, conducting claims adjudication, obtaining refill

authorizations, reviewing therapeutic interventions, or reviewing chart orders.

(33) "Wholesaler" means a corporation, individual, or other entity which buys drugs or devices for resale and distribution to corporations, individuals, or entities other than consumers.

(34) "Directed plan of correction" means a plan devised by the commission that includes specific corrective actions that must be taken to correct identified unresolved deficiencies with time frames to complete them.

(35) "Immediate jeopardy" means a situation in which a licensee's noncompliance with one or more statutory or regulatory requirements has placed the health and safety of individuals or animals at risk for serious injury, serious harm, serious impairment, or death.

(36) "License," "licensing," and "licensure" shall be deemed equivalent to the terms "approval," "credential," "certificate," "certification," "permit," and "registration".

(37) "Plan of correction" means a proposal devised by the applicant or licensee that includes specific corrective actions that must be taken to correct identified unresolved deficiencies with the time frames to complete them.

(38) "Statement of deficiency" means a written statement of the deficiencies completed by the commission, or its designee, identifying one or more violations of law. The report clearly identifies the specific law or rule that has been violated along with a description of the reasons for noncompliance.

NEW SECTION. **Sec. 31.** A new section is added to chapter 18.64 RCW to read as follows:

This section governs the denial of an application for a license or the suspension, revocation, or modification of a license issued by the commission. This section does not govern actions taken under chapter 18.130 RCW.

(1) The commission shall give written notice of the denial of an application for a license to the applicant or their agent. The form, contents, and service of the notice shall comply with this chapter and the procedural rules adopted by the commission.

(2) The commission shall give written notice of revocation, suspension, or modification of a license to the licensee or their agent. The form, contents, and service of the notice shall comply with this chapter and the procedural rules adopted by the commission.

(3) Except as otherwise provided in this chapter, revocation, suspension, or modification is effective 28 days after the licensee or the agent receives the notice.

(a) The commission may make the date the action is effective later than 28 days after receipt. If the commission does so, it shall state the effective date in the written notice given to the licensee or their agent.

(b) The commission may make the date the action is effective sooner than 28 days after receipt when necessary to protect the public health, safety, or welfare. When the commission does so, it shall state the effective date and the reasons supporting the effective date in the written notice given to the licensee or their agent.

(4) Except for licensees suspended for noncompliance with a child support order under chapter 74.20A RCW, a license applicant or licensee who is aggrieved by a commission denial, revocation, suspension, or modification has the right to an adjudicative proceeding. The proceeding is governed by the administrative procedure act, chapter 34.05 RCW. The form, contents, and service of the application for an adjudicative hearing must comply with this chapter and with the procedural rules adopted by the commission and must be served on and received by the commission within 28 days of the applicant or licensee receiving the notice.

(5)(a) If the commission gives a licensee 28 or more days' notice of revocation, suspension, or modification and the licensee files an appeal before its effective date, the commission shall not implement the adverse action until the final order has been entered. The commission may implement part or all of the adverse action while the proceedings are pending if the appellant causes an unreasonable delay in the proceeding, if the circumstances change so that implementation is in the public interest, or for other good cause.

(b) If the commission gives a licensee less than 28 days' notice of revocation, suspension, or modification and the licensee timely files a sufficient appeal, the commission may implement the adverse action on the effective date stated in the notice. The commission may stay implementation of part or all of the adverse action while the proceedings are pending if staying implementation is in the public interest or for other good cause.

(6) If the commission issues a written notice of revocation, suspension, or modification of a license and the licensee timely

files an appeal, the commission may accept the surrender of the licensee's license. A licensee that surrenders their license may not petition for reinstatement of their surrendered license.

NEW SECTION. **Sec. 32.** A new section is added to chapter 18.64 RCW to read as follows:

This section governs the assessment of a civil fine against a licensee issued by the commission. This section does not govern actions taken under chapter 18.130 RCW.

(1) The commission shall give written notice to the licensee or their agent against whom it assesses a civil fine. The form, contents, and service of the notice shall comply with this chapter and the procedural rules adopted by the commission.

(2) Except as otherwise provided in subsection (4) of this section, the civil fine is due and payable 28 days after receipt by the licensee or their agent. The commission may make the date the fine is due later than 28 days after receipt by the licensee or their agent. When the commission does so, it shall state the date the fine is due in the written notice given to the licensee against whom it assesses the fine.

(3) The licensee against whom the commission assesses a civil fine has the right to an adjudicative proceeding. The proceeding is governed by the administrative procedure act, chapter 34.05 RCW. The form, contents, and service of the application for an adjudicative hearing must comply with this chapter and the procedural rules adopted by the commission and must be served on and received by the commission within 28 days of the licensee receiving the notice.

(4) If the licensee files a timely and sufficient appeal, the commission shall not implement the action until the final order has been served. The commission may implement part or all of the action while the proceedings are pending if the appellant causes an unreasonable delay in the proceeding, if the circumstances change so that implementation is in the public interest, or for other good cause.

NEW SECTION. **Sec. 33.** A new section is added to chapter 18.64 RCW to read as follows:

This section does not govern actions taken under chapter 18.130 RCW.

(1) The commission is authorized to take any of the actions identified in this section against licenses, registrations, permits, or other credentials or approvals issued by the commission under this chapter and chapters 18.64A, 69.38, 69.41, 69.43, 69.45, and 69.50 RCW in any case in which it finds the licensee has failed or refused to comply with any state or federal statute or administrative rule regulating the license in question including, but not limited to, Title 69 RCW, this chapter, chapter 18.64A RCW, and administrative rules adopted by the commission, except as otherwise limited in this section.

(a) When the commission determines a licensee has previously been subject to an enforcement action for the same or similar type of violation of the same or similar statute or rule, or has been given any previous statement of deficiency that included the same or similar type of violation of the same or similar statute or rule, or when the licensee failed to correct noncompliance with a statute or rule by a date established or agreed to by the commission, the commission may impose reasonable conditions on a license. Conditions may include correction within a specified amount of time, a directed plan of correction, training, or hiring a commission-approved consultant if the licensee cannot demonstrate to the commission that it has access to sufficient internal expertise. If the commission determines the violations constitute immediate jeopardy, the conditions may be imposed immediately in accordance with subsection (2)(b) of this section.

(b)(i) In accordance with the commission's authority under section 32 of this act, the commission may assess a civil fine of up to $10,000 per violation, not to exceed a total fine of $1,000,000, on a licensee when the commission determines the licensee has previously been subject to an enforcement action for the same or similar type of violation of the same or similar statute or rule, or has been given any previous statement of deficiency that included the same or similar type of violation of the same or similar statute or rule, or when a licensee failed to correct noncompliance with a statute or rule by a date established or agreed to by the commission.

(ii) Proceeds from these fines may only be used by the commission to provide training or technical assistance to licensees and to offset costs associated with licensing and enforcement.

(iii) The commission shall adopt in rules under this chapter to establish specific fine amounts in relation to the severity of the

noncompliance and at an adequate level to be a deterrent to future noncompliance.

(iv) If a licensee is aggrieved by the commission's action of assessing civil fines, the licensee has the right to appeal under section 32 of this act.

(c) The commission may restrict the ability of a licensee to engage in a specific service related to a violation by imposing a limited stop service. This may only be done if the commission finds that noncompliance results in immediate jeopardy.

(i) Prior to imposing a limited stop service, the commission shall provide a licensee written notification upon identifying deficient practices or conditions that constitute an immediate jeopardy. The licensee shall have 24 hours from notification to develop and implement a commission-approved plan to correct the deficient practices or conditions that constitute an immediate jeopardy. If the deficient practices or conditions that constitute immediate jeopardy are not verified by the commission as having been corrected within the same 24-hour period, the commission may issue the limited stop service.

(ii) When the commission imposes a limited stop service, the licensee may not provide the services subject to the limited stop service, unless otherwise allowed by the commission, until the limited stop service order is terminated.

(iii) The commission shall conduct a follow-up inspection within five business days or within the time period requested by the licensee if more than five business days is needed to verify the violation necessitating the limited stop service has been corrected.

(iv) The limited stop service shall be terminated when:

(A) The commission verifies the violation necessitating the limited stop service has been corrected or the commission determines that the licensee has taken intermediate action to address the immediate jeopardy; and

(B) The licensee establishes the ability to maintain correction of the violation previously found deficient.

(d) The commission may deny an application, or suspend, revoke, or modify a license.

(2)(a) Except as otherwise provided, sections 31 and 32 of this act govern notices of actions taken by the commission under subsection (1) of this section and provides the right to an adjudicative proceeding. Adjudicative proceedings and hearings under

this section are governed by the administrative procedure act, chapter 34.05 RCW.

(b) When the commission determines a licensee's noncompliance results in immediate jeopardy, the commission may make the imposition of conditions on a licensee, a limited stop service, or the suspension or modification of a license effective immediately upon receipt of the notice by the licensee, pending any adjudicative proceeding.

(i) When the commission makes the suspension of a license or imposition of conditions on a license effective immediately, a licensee is entitled to a show cause hearing before a hearing panel of the commission within 14 days of making the request. The licensee must request the show cause hearing within 28 days of receipt of the notice. At the show cause hearing the commission has the burden of demonstrating that more probably than not there is an immediate jeopardy.

(ii) At the show cause hearing, the commission may consider the notice and documents supporting the immediate imposition of conditions on a licensee, a limited stop service, or the suspension or modification of a license, and the licensee's response, and shall provide the parties with an opportunity to provide documentary evidence and written testimony, and to be represented by counsel. Prior to the show cause hearing, the commission shall provide the licensee with all documentation that supports the commission's immediate imposition of conditions on a licensee, a limited stop service, or suspension or modification of a license.

(iii) If the hearing panel of the commission determines there is no immediate jeopardy, the hearing panel of the commission may overturn the immediate suspension or immediate imposition of conditions.

(iv) If the hearing panel of the commission determines there is immediate jeopardy, the immediate suspension or immediate imposition of conditions shall remain in effect pending a full hearing.

(v) If the commission sustains the immediate suspension or immediate imposition of conditions, the licensee may request an expedited full hearing on the merits. A full hearing must be provided within 90 days of the licensee's request, unless otherwise stipulated by the parties.

(3) The commission may only take action under subsection (1) of this section against a nonresident pharmacy for failure to comply

with any requirement of RCW 18.64.350 through 18.64.400, unless the nonresident pharmacy's conduct caused injury to a resident of this state and the conduct resulted in adverse action against the nonresident pharmacy by the regulatory or licensing agency in the state in which the nonresident pharmacy is located.

NEW SECTION. **Sec. 34.** A new section is added to chapter 18.64 RCW to read as follows:

This section does not govern actions taken under chapter 18.130 RCW.

(1) A licensee whose license has been suspended under this chapter may petition the commission for reinstatement after an interval as determined by the commission in the order. The commission shall hold hearings on the petition. The commission may deny the petition or may order reinstatement of the licensee's license. The commission may impose terms and conditions in the order of reinstatement.

(2) A licensee whose license has been suspended for noncompliance with a support order or visitation order under RCW 74.20A.320 may petition for reinstatement at any time by providing the commission a release issued by the department of social and health services stating that the person is in compliance with the order. If the person has continued to meet all other requirements for reinstatement during the suspension, the commission shall automatically reissue the person's license upon receipt of the release, and payment of a reinstatement fee, if any.

NEW SECTION. **Sec. 35.** A new section is added to chapter 18.64 RCW to read as follows:

The uniform disciplinary act, chapter 18.130 RCW, governs unlicensed practice of persons required to obtain a license under this chapter.

Sec. 36. RCW 18.64.047 and 2013 c 19 s 10 are each amended to read as follows:

(1) Any itinerant vendor or any peddler of any nonprescription drug or preparation for the treatment of disease or injury, shall pay a registration fee determined by the secretary on a date to be determined by the secretary as provided in RCW 43.70.250 and

43.70.280. The department may issue a registration to such vendor on an approved application made to the department.

(2) Any itinerant vendor or peddler who shall vend or sell, or offer to sell to the public any such nonprescription drug or preparation without having registered to do so as provided in this section, is guilty of a misdemeanor and each sale or offer to sell shall constitute a separate offense.

(3) In event the registration fee remains unpaid on the date due, no renewal or new registration shall be issued except upon compliance with administrative procedures, administrative requirements, and fees determined as provided in RCW 43.70.250 and 43.70.280. This registration shall not authorize the sale of legend drugs or controlled substances.

(4) An itinerant vendor may purchase products containing any detectable quantity of ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers only from a wholesaler licensed by the department under RCW 18.64.046 or from a manufacturer licensed by the department under RCW 18.64.045. The commission shall issue a warning to an itinerant vendor who violates this subsection, and may suspend or revoke the registration of the vendor for a subsequent violation.

(5) An itinerant vendor who has purchased products containing any detectable quantity of ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers, in a suspicious transaction as defined in RCW 69.43.035, is subject to the following requirements:

(a) The itinerant vendor may not sell any quantity of ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers, if the total monthly sales of these products exceed ((~~ten~~)) 10 percent of the vendor's total prior monthly sales of nonprescription drugs in March through October. In November through February, the vendor may not sell any quantity of ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers, if the total monthly sales of these products exceed ((~~twenty~~)) 20 percent of the vendor's total prior monthly sales of nonprescription drugs. For purposes of this section, "monthly sales" means total dollars paid by buyers. ((~~The commission may suspend or revoke the registration of an itinerant vendor who violates this subsection.~~))

(b) The itinerant vendor shall maintain inventory records of the receipt and disposition of nonprescription drugs, utilizing existing inventory controls if an auditor or investigator can determine compliance with (a) of this subsection, and otherwise in the form and manner required by the commission. The records must be available for inspection by the commission or any law enforcement agency and must be maintained for two years. The commission may suspend or revoke the registration of an itinerant vendor who violates this subsection. For purposes of this subsection, "disposition" means the return of product to the wholesaler or distributor.

Sec. 37. RCW 18.64.165 and 2016 c 81 s 10 are each amended to read as follows:

((~~The commission shall have the power to refuse, suspend, or revoke the license of any manufacturer, wholesaler, pharmacy, shopkeeper, itinerant vendor, peddler, poison distributor, health care entity, or precursor chemical distributor~~)) In addition to any other grounds, the commission may take action against a license issued under this chapter and chapters 18.64A, 69.38, 69.41, 69.43, 69.45, and 69.50 RCW, except nonresident pharmacies, upon proof that:

(1) The license was procured through fraud, misrepresentation, or deceit;

(2) Except as provided in RCW 9.97.020, the licensee has violated or has permitted any employee to violate any of the laws of this state or the United States relating to drugs, controlled substances, cosmetics, or nonprescription drugs, or has violated any of the rules and regulations of the commission or has been convicted of a felony.

Sec. 38. RCW 18.64A.020 and 2013 c 19 s 33 are each amended to read as follows:

(1)(a) The commission shall adopt, in accordance with chapter 34.05 RCW, rules fixing the classification and qualifications and the educational and training requirements for persons who may be employed as pharmacy technicians or who may be enrolled in any pharmacy technician training program. Such rules shall provide that:

(i) Licensed pharmacists shall supervise the training of pharmacy technicians;

(ii) Training programs shall assure the competence of pharmacy technicians to aid and assist pharmacy operations. Training programs shall consist of instruction and/or practical training; and

(iii) Pharmacy technicians shall complete continuing education requirements established in rule by the commission.

(b) Such rules may include successful completion of examinations for applicants for pharmacy technician certificates. If such examination rules are adopted, the commission shall prepare or determine the nature of, and supervise the grading of the examinations. The commission may approve an examination prepared or administered by a private testing agency or association of licensing authorities.

(2) The commission may disapprove or revoke approval of any training program for failure to conform to commission rules. In the case of the disapproval or revocation of approval of a training program by the commission, a hearing shall be conducted in accordance with ((~~RCW 18.64.160~~)) section 31 of this act, and appeal may be taken in accordance with the administrative procedure act, chapter 34.05 RCW.

Sec. 39. RCW 18.64A.060 and 2013 c 19 s 38 are each amended to read as follows:

No pharmacy licensed in this state shall utilize the services of pharmacy ancillary personnel without approval of the commission.

Any pharmacy licensed in this state may apply to the commission for permission to use the services of pharmacy ancillary personnel. The application shall be accompanied by a fee and shall comply with administrative procedures and administrative requirements set pursuant to RCW 43.70.250 and 43.70.280, shall detail the manner and extent to which the pharmacy ancillary personnel would be used and supervised, and shall provide other information in such form as the secretary may require.

The commission may approve or reject such applications. In addition, the commission may modify the proposed utilization of pharmacy ancillary personnel and approve the application as modified. Whenever it appears to the commission that pharmacy ancillary personnel are being utilized in a manner inconsistent with the approval granted, the commission may withdraw such approval. In the event a hearing is requested upon the rejection of an application, or upon the withdrawal of approval, a hearing shall be conducted in accordance with ((~~chapter 18.64 RCW, as now or hereafter amended,~~)) section 31 of this act and appeal may be taken in accordance with the administrative procedure act, chapter 34.05 RCW.

NEW SECTION. **Sec. 40.** A new section is added to chapter 69.38 RCW to read as follows:

Chapter 18.64 RCW governs the denial of licenses and the discipline of persons licensed under this chapter. The uniform disciplinary act, chapter 18.130 RCW, governs unlicensed practice of persons required to obtain a license under this chapter.

Sec. 41. RCW 69.45.080 and 2013 c 19 s 84 are each amended to read as follows:

(1) The manufacturer is responsible for the actions and conduct of its representatives with regard to drug samples.

(2) ((~~The commission may hold a public hearing to examine a possible violation and may require a designated representative of the manufacturer to attend.~~

~~(3) If a manufacturer fails to comply with this chapter following notification by the commission, the commission may impose a civil penalty of up to five thousand dollars. The commission shall take no action to impose any civil penalty except pursuant to a hearing held in accordance with chapter 34.05 RCW.~~

~~(4)~~)) Chapter 18.64 RCW governs the denial of licenses and the discipline of persons registered under this chapter.

(3) Specific drug samples which are distributed in this state in violation of this chapter, following notification by the commission, shall be subject to seizure following the procedures set out in RCW 69.41.060.

NEW SECTION. **Sec. 42.** A new section is added to chapter 69.45 RCW to read as follows:

The uniform disciplinary act, chapter 18.130 RCW, governs unlicensed practice of persons required to obtain a registration under this chapter.

Sec. 43. RCW 69.43.100 and 2013 c 19 s 74 are each amended to read as follows:

((~~The pharmacy quality assurance commission shall have the power to refuse, suspend, or revoke the permit of any manufacturer or wholesaler~~)) In addition to any other grounds, the pharmacy quality assurance commission may take action against a permit issued under this chapter upon proof that:

(1) The permit was procured through fraud, misrepresentation, or deceit;

(2) The permittee has violated or has permitted any employee to violate any of the laws of this state relating to drugs, controlled substances, cosmetics, or nonprescription drugs, or has violated any of the rules and regulations of the pharmacy quality assurance commission.

Sec. 44. RCW 69.43.140 and 2013 c 19 s 78 are each amended to read as follows:

(1) ((~~In addition to the other penalties provided for in this chapter or in chapter 18.64 RCW, the pharmacy quality assurance commission may impose a civil penalty, not to exceed ten thousand dollars for each violation, on any licensee or registrant who has failed to comply with this chapter or the rules adopted under this chapter. In the case of a continuing violation, every day the violation continues shall be considered a separate violation~~)) Chapter 18.64 RCW governs the denial of permits and the discipline of permits issued under this chapter. The uniform disciplinary act, chapter 18.130 RCW, governs unlicensed practice of persons required to obtain a permit under this chapter.

(2) The pharmacy quality assurance commission may waive ((~~the suspension or revocation of a license or registration~~)) action taken under chapter 18.64 RCW against a permit issued under this chapter ((~~18.64 RCW, or waive any civil penalty under this chapter,~~)) if the ((~~licensee or registrant~~)) permittee establishes that he or she acted in good faith to prevent violations of this chapter, and the violation occurred despite the licensee's or registrant's exercise of due diligence. In making such a determination, the pharmacy quality assurance commission may consider evidence that an employer trained employees on how to sell, transfer, or otherwise furnish substances specified in RCW 69.43.010(1) in accordance with applicable laws.

Sec. 45. RCW 69.50.302 and 2013 c 19 s 98 are each amended to read as follows:

(a) Every person who manufactures, distributes, or dispenses any controlled substance within this state or who proposes to engage in the manufacture, distribution, or dispensing of any controlled substance within this state, shall obtain annually a registration

issued by the ((~~department~~)) commission in accordance with the commission's rules.

(b) A person registered by the ((~~department~~)) commission under this chapter to manufacture, distribute, dispense, or conduct research with controlled substances may possess, manufacture, distribute, dispense, or conduct research with those substances to the extent authorized by the registration and in conformity with this Article.

(c) The following persons need not register and may lawfully possess controlled substances under this chapter:

(1) An agent or employee of any registered manufacturer, distributor, or dispenser of any controlled substance if the agent or employee is acting in the usual course of business or employment. This exemption shall not include any agent or employee distributing sample controlled substances to practitioners without an order;

(2) A common or contract carrier or warehouse operator, or an employee thereof, whose possession of any controlled substance is in the usual course of business or employment;

(3) An ultimate user or a person in possession of any controlled substance pursuant to a lawful order of a practitioner or in lawful possession of a substance included in Schedule V.

(d) The commission may waive by rule the requirement for registration of certain manufacturers, distributors, or dispensers upon finding it consistent with the public health and safety. Personal practitioners licensed or registered in the state of Washington under the respective professional licensing acts shall not be required to be registered under this chapter unless the specific exemption is denied pursuant to ((~~RCW 69.50.305~~)) sections 31 and 33 of this act for violation of any provisions of this chapter.

(e) A separate registration is required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances.

(f) The department, at the direction of the commission, may inspect the establishment of a registrant or applicant for registration in accordance with rules adopted by the commission.

Sec. 46. RCW 69.50.303 and 2013 c 19 s 99 are each amended to read as follows:

(a) The ((~~department~~)) commission shall register an applicant to manufacture ((~~or~~)), distribute, dispense, or conduct research with

controlled substances included in RCW 69.50.204, 69.50.206, 69.50.208, 69.50.210, and 69.50.212 unless the commission determines that the issuance of that registration would be inconsistent with the public interest. In determining the public interest, the commission shall consider the following factors:

(1) maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, research, or industrial channels;

(2) compliance with applicable state and local law;

(3) promotion of technical advances in the art of manufacturing controlled substances and the development of new substances;

(4) any convictions of the applicant under any laws of another country or federal or state laws relating to any controlled substance;

(5) past experience in the manufacture or distribution of controlled substances, and the existence in the applicant's establishment of effective controls against diversion of controlled substances into other than legitimate medical, scientific, research, or industrial channels;

(6) furnishing by the applicant of false or fraudulent material in any application filed under this chapter;

(7) suspension or revocation of the applicant's federal registration to manufacture, distribute, or dispense controlled substances as authorized by federal law; and

(8) any other factors relevant to and consistent with the public health and safety.

(b) Registration under subsection (a) of this section does not entitle a registrant to manufacture or distribute controlled substances included in Schedule I or II other than those specified in the registration.

(c) Practitioners must be registered, or exempted under RCW 69.50.302(d), to dispense any controlled substances or to conduct research with controlled substances included in Schedules II through V if they are authorized to dispense or conduct research under the law of this state. The commission need not require separate registration under this Article for practitioners engaging in research with nonnarcotic substances included in Schedules II through V where the registrant is already registered under this Article in another capacity. Practitioners registered under federal law to conduct research with substances included in Schedule I may conduct

research with substances included in Schedule I within this state upon furnishing the commission evidence of that federal registration.

(d) A manufacturer or distributor registered under the federal Controlled Substances Act, 21 U.S.C. Sec. 801 et seq., may submit a copy of the federal application as an application for registration as a manufacturer or distributor under this section. The commission may require a manufacturer or distributor to submit information in addition to the application for registration under the federal act.

Sec. 47. RCW 69.50.304 and 2013 c 19 s 100 are each amended to read as follows:

(a) ((~~A~~)) This chapter and chapter 18.64 RCW govern the denial of registrations and the discipline of registrations issued under RCW 69.50.303. The uniform disciplinary act, chapter 18.130 RCW, governs unlicensed practice of persons required to obtain a registration under this chapter.

(b) In addition to any other grounds, the commission may take action against the registration, or exemption from registration, under RCW 69.50.303 to manufacture, distribute, ((~~or~~)) dispense, or conduct research with a controlled substance ((~~may be suspended or revoked by the commission~~)) upon finding that the registrant has:

(1) furnished false or fraudulent material information in any application filed under this chapter;

(2) been convicted of a felony under any state or federal law relating to any controlled substance;

(3) had the registrant's federal registration suspended or revoked and is no longer authorized by federal law to manufacture, distribute, ((~~or~~)) dispense, or conduct research with controlled substances; or

(4) committed acts that would render registration under RCW 69.50.303 inconsistent with the public interest as determined under that section.

((~~(b)~~)) (c) The commission may limit revocation or suspension of a registration to the particular controlled substance or schedule of controlled substances, with respect to which grounds for revocation or suspension exist.

((~~(c)~~)) (d) If the commission suspends or revokes a registration, all controlled substances owned or possessed by the registrant at the time of suspension or the effective date of the revocation order may be placed under seal. No disposition may be made of substances under

seal until the time for taking an appeal has elapsed or until all appeals have been concluded unless a court, upon application, orders the sale of perishable substances and the deposit of the proceeds of the sale with the court. Upon a revocation order becoming final, all controlled substances may be forfeited to the state.

((~~(d)~~)) (e) The ((~~department~~)) commission may seize or place under seal any controlled substance owned or possessed by a registrant whose registration has expired or who has ceased to practice or do business in the manner contemplated by the registration. The controlled substance must be held for the benefit of the registrant or the registrant's successor in interest. The ((~~department~~)) commission shall notify a registrant, or the registrant's successor in interest, who has any controlled substance seized or placed under seal, of the procedures to be followed to secure the return of the controlled substance and the conditions under which it will be returned. The ((~~department~~)) commission may not dispose of any controlled substance seized or placed under seal under this subsection until the expiration of ((~~one hundred eighty~~)) 180 days after the controlled substance was seized or placed under seal. The costs incurred by the ((~~department~~)) commission in seizing, placing under seal, maintaining custody, and disposing of any controlled substance under this subsection may be recovered from the registrant, any proceeds obtained from the disposition of the controlled substance, or from both. Any balance remaining after the costs have been recovered from the proceeds of any disposition must be delivered to the registrant or the registrant's successor in interest.

((~~(e)~~)) (f) The ((~~department~~)) commission shall promptly notify the drug enforcement administration of all orders restricting, suspending, or revoking registration and all forfeitures of controlled substances.

Sec. 48. RCW 69.50.310 and 2013 c 19 s 104 are each amended to read as follows:

On and after September 21, 1977, a humane society and animal control agency may apply to the ((~~department~~)) commission for registration pursuant to the applicable provisions of this chapter for the sole purpose of being authorized to purchase, possess, and administer sodium pentobarbital to euthanize injured, sick, homeless, or unwanted domestic pets and animals. Any agency so registered shall

not permit a person to administer sodium pentobarbital unless such person has demonstrated adequate knowledge of the potential hazards and proper techniques to be used in administering this drug.

The ((~~department~~)) commission may issue a limited registration to carry out the provisions of this section. ((~~The commission shall promulgate such rules as it deems necessary to insure strict compliance with the provisions of this section. The commission may suspend or revoke registration upon determination that the person administering sodium pentobarbital has not demonstrated adequate knowledge as herein provided. This authority is granted in addition to any other power to suspend or revoke registration as provided by law.~~)) Chapter 18.64 RCW governs the denial of licenses and the discipline of registrations issued under this chapter. The uniform disciplinary act, chapter 18.130 RCW, governs unlicensed practice of persons required to obtain a registration under this chapter.

Sec. 49. RCW 69.50.320 and 2013 c 19 s 106 are each amended to read as follows:

The department of fish and wildlife may apply to the ((~~department of health~~)) commission for registration pursuant to the applicable provisions of this chapter to purchase, possess, and administer controlled substances for use in chemical capture programs. The department of fish and wildlife must not permit a person to administer controlled substances unless the person has demonstrated adequate knowledge of the potential hazards and proper techniques to be used in administering controlled substances.

The ((~~department of health~~)) commission may issue a limited registration to carry out the provisions of this section. The commission may adopt rules to ensure strict compliance with the provisions of this section. The commission, in consultation with the department of fish and wildlife, must by rule add or remove additional controlled substances for use in chemical capture programs. ((~~The~~)) Chapter 18.64 RCW governs the denial of licenses and the discipline of registrations issued under this chapter. The uniform disciplinary act, chapter 18.130 RCW, governs unlicensed practice of persons required to obtain a registration under this chapter. In addition to any other grounds, the commission ((~~shall~~)) may suspend or revoke a registration issued under this chapter upon determination that the person administering controlled substances has not demonstrated adequate knowledge as required by this section.

((~~This authority is granted in addition to any other power to suspend or revoke registration as provided by law.~~))

Sec. 50. RCW 69.41.080 and 2013 c 19 s 57 are each amended to read as follows:

Humane societies and animal control agencies registered with the ((~~pharmacy quality assurance~~)) commission under chapter 69.50 RCW and authorized to euthanize animals may purchase, possess, and administer approved legend drugs for the sole purpose of sedating animals prior to euthanasia, when necessary, and for use in chemical capture programs. For the purposes of this section, "approved legend drugs" means those legend drugs designated by the commission by rule as being approved for use by such societies and agencies for animal sedating or capture and does not include any substance regulated under chapter 69.50 RCW. Any society or agency so registered shall not permit persons to administer any legend drugs unless such person has demonstrated to the satisfaction of the commission adequate knowledge of the potential hazards involved in and the proper techniques to be used in administering the drugs.

The commission shall promulgate rules to regulate the purchase, possession, and administration of legend drugs by such societies and agencies and to insure strict compliance with the provisions of this section. Such rules shall require that the storage, inventory control, administration, and recordkeeping for approved legend drugs conform to the standards adopted by the commission under chapter 69.50 RCW to regulate the use of controlled substances by such societies and agencies. ((~~The~~)) Chapter 18.64 RCW governs the denial of licenses and the discipline of registrations issued under chapter 69.50 RCW. The uniform disciplinary act, chapter 18.130 RCW, governs unlicensed practice of persons required to obtain a registration under this chapter. In addition to any other grounds, the commission may suspend or revoke a registration issued under chapter 69.50 RCW upon a determination by the commission that the person administering legend drugs has not demonstrated adequate knowledge as herein provided. ((~~This authority is granted in addition to any other power to suspend or revoke a registration as provided by law.~~))

NEW SECTION. **Sec. 51.** The following acts or parts of acts are each repealed:

(1) RCW 18.64.200 (Refusal, suspension, and revocation of other licenses—Appeal procedure) and 2013 c 19 s 15, 1963 c 38 s 11, & 1909 c 213 s 11;

(2) RCW 18.64.390 (Nonresident pharmacies—Violations—Penalties) and 2013 c 19 s 23 & 1991 c 87 s 5; and

(3) RCW 69.50.305 (Procedure for denial, suspension, or revocation of registration) and 2013 c 19 s 101 & 1971 ex.s. c 308 s 69.50.305.

--- END ---

September 23, 2022 Business Meeting – Agenda Item 2.3 – Uniform Facility Enforcement Framework

PAGE 91 of the draft Z-draft, starting at line 6
NEW SECTION. **Sec. 34**. A new section is added to chapter 18.64 to read as follows:
This section does not govern actions taken under chapter **18.130** RCW.
(1) A licensee whose license has been suspended under this chapter may petition the commission for reinstatement after an interval as determined by the commission in the order. The commission shall hold hearings on the petition**. The Commission** ~~and~~ may deny the petition or may order reinstatement **of the licensee's license. The Commission may** ~~and~~ impose terms and conditions ~~issue an~~ **in the** order of reinstatement.

PAGE 97 of the draft Z-draft, starting at line 22
RCW 69.50.302(d):
(d) The commission may waive by rule the requirement for registration of certain manufacturers, distributors, or dispensers upon finding it consistent with the public health and safety. Personal practitioners licensed or registered in the state of Washington under the respective professional licensing acts shall not be required to be registered under this chapter unless the specific exemption is denied pursuant to ~~RCW 69.50.305~~ **Section 15 and 17** for violation of any provisions of this chapter.

STATE OF WASHINGTON

DEPARTMENT OF HEALTH

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NOTICE OF ADOPTION OF A POLICY STATEMENT

Title of Policy Statement: Enforcement of USP Chapters <800> and <825> | Policy Statement 65.3

Issuing Entity: Pharmacy Quality Assurance Commission

Subject Matter: This policy clarifies the Pharmacy Quality Assurance Commission's approach to United States Pharmacopeia (USP) chapters <800> and <825> as it relates to WAC 246-945-100 and RCW 18.64.270(2).

Effective Date: April 1, 2022

Contact Person: Lindsay Trant
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OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: April 11, 2022
TIME: 10:03 AM

WSR 22-09-018

Department of Health
Pharmacy Quality Assurance Commission

Policy Statement

Revised – 10/18/11

Title:	Enforcement of USP Chapters <800> and <825>	*Number: 65.3*
References:	RCW 18.64.270(2); WAC 246-945-016, WAC 246-945-017, WAC 246-945-100, and WAC 246-945-490; United States Pharmacopeia Chapters <795>, <797>, <800>, and <825>; Commission Policy #60.1	
Contact:	Lindsay Trant, Interim Deputy Director	
Phone:	(360) 236-4946	
Email:	wspqac@doh.wa.gov	
Effective Date:	April 1, 2022	
Supersedes:	Policy 65.2 effective October 1, 2021	
Approved By:	Teri Ferreira, RPh, Pharmacy Quality Assurance Commission Chair	

This policy clarifies the Pharmacy Quality Assurance Commission's (commission) approach to United States Pharmacopeia (USP) chapters <800> (USP 800) and <825> (USP 825) as it relates to WAC 246-945-100 and RCW 18.64.270(2).

At its March 24, 2022 business meeting, the commission voted to continue its position that it will not find deficiencies or take enforcement action against its licensees for failure to comply with USP 800 through September 30, 2022.

Compliance requirements for USP 825 began October 1, 2021 where applicable, per WAC 246-945-100 and RCW 18.64.270(2).

When appropriate, the commission will revisit its use of enforcement discretion for USP 800. Any decision to modify the commission's use of enforcement discretion for USP 800 will be during an open public meeting before September 30, 2022.

The commission will consider extending its use of enforcement discretion for USP 800 if USP has not made the revised USP chapters <795> (USP 795) and <797> (USP 797) official. Additionally, if USP makes the revised USP 795 and USP 797 official prior to September 30, 2022, the commission will consider whether to extend its use of enforcement discretion for an additional period of time.

Standards for hazardous drug compounding were supposed to be eliminated in the initial proposed revision to USP 797 and only exist in USP 800. The delay in formal adoption or release

of an updated revision draft for USP 797 has created some direct conflicts between the two chapters. The commission has considered and may revisit the delayed enforcement of USP 800 until the revised USP 795 and USP 797 are official to avoid licensees being subject to USP standards that conflict with each other. For those licensees who choose to become early adopters of USP 800, the commission's approach to the discrepancies between USP 797 and USP 800 can be found in a separate policy statement (#60.1), "Regulation of the Handling of Hazardous Drugs" available on the commission's website. Policy Statement #60.1 also explains adherence to the Washington State Department of Labor and Industries' (L&I) General Occupational Health Standards rules on Hazardous Drugs (WAC 296-62-500 *et al).*

Table of PQAC's Enforcement Discretion Timeline	
USP Chapters	Enforcement Discretion
USP 800	October 1, 2020 – September 30, 2022
USP 825	October 1, 2020 – September 30, 2021
Revised USP 795 and 797	N/A; Revised Chapters have not been released
Current USP 795 and 797	These chapters will continue to be enforced.

Note: Please see Policy #60.1 regarding direct conflicts between USP 797 and USP 800.

In 2013, the Washington State Legislature adopted standards set by USP as the standards pharmacies must meet when sterile or non-sterile compounding. RCW 18.64.270(2) states, "Any medicinal products that are compounded for patient administration or distribution to a licensed practitioner for patient use or administration shall, at a minimum, meet the standards of the official United States pharmacopeia as it applies to nonsterile products and sterile administered products." As a result, the commission has enforced standards published by USP for sterile and non-sterile compounding since 2014.

The commission's new rule chapter (chapter 246-945 WAC) went into effect on July 1, 2020. This chapter rewrite took place over two and half years and included extensive collaboration with interested parties.

The new chapter includes enforcement of USP standards in accordance with RCW 18.64.270(2). Specifically, WAC 246-945-100 Compounding minimum standards requires that licensees comply with USP chapters 795, 797, 800, and 825. There are additional requirements for labeling compounded products in WAC 246-945-016 and WAC 246-945-017. WAC 246-945-490(3) and (4) also require nuclear pharmacies to prepare, compound, and dispense radiopharmaceuticals in accordance with the standards in USP 825.

The commission recognizes there are discrepancies between USP 797 and USP 800 in its current form; however, its approach to these discrepancies as well as adherence to L&I's rules on Hazardous Drugs (WAC 296-62-500 *et al)* is established in a separate policy statement (#60.1), "Regulation of the Handling of Hazardous Drugs" available on the commission's website.

If USP makes the revised USP 795 and USP 797 official prior to September 30, 2022 the commission will consider whether to extend its use for enforcement discretion on USP 800 for an additional period of time to allow licensees to comply with all applicable USP chapters at a future open public meeting.

Commission SBAR Communication

Agenda Item/Title: Regulatory Framework Applicable to White Bagging

Date SBAR Communication Prepared: September 6, 2022

Reviewer: T. Nomi Peaks

Link to Action Plan:

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

Situation:

The purpose of this SBAR is to discuss the Pharmacy Commission's (commission) regulatory framework applicable to pharmacies engaging in the practice of white bagging.

Background:

White bagging refers to the "distribution of patient-specific medication(s) from a pharmacy, typically a specialty pharmacy, to the physician's office, hospital, or clinic for administration."[1] "White bagging" is distinct from "brown bagging" and "clear bagging."

"Brown bagging" refers to the "dispensing of medication(s) from a pharmacy (typically a specialty pharmacy) directly to a patient, who then transports the medication(s) to the physician's office for administration."[2]

"Clear bagging" is a practice in which a specialty pharmacy that is under shared common ownership with a clinician, is reimbursed for distributing patient-specific medication(s) to that clinician, who is then reimbursed for administering the medication(s).[3]

Note: these terms will be utilized in subsequent paragraphs sans quotation marks.

The regulatory and safety concerns of white bagging, brown bagging, and clear bagging have been discussed at previous commission meetings and at the most recent compounding subcommittee meeting in July. The potential impact of these practices on patient care was also considered. The outcome of those discussions was that the staff draft an SBAR that examines two questions:

1) Are licensed pharmacies permitted to distribute medications via white bagging?

[1] (nabp.pharmacy)
[2] (nabp.pharmacy)
[3] Based on a presentation by Dr. Kyle Robb, ASHP, *Summary of Recent State Legislation to Address Payer Mandated White Bagging*, 2021.

2) If they are, what laws and rules apply to licensees of the commission who engage in white bagging?

Assessment:

Commission staff reviewed current Washington State laws and rules and determined that it is likely lawful for licensees of the commission to distribute medications via white bagging. Additionally, there are no laws or rules that specifically regulate the distribution of medications via white bagging, but any licensee of the commission engaged in white bagging would need to comply with any other applicable laws and rules that apply to distribution of medications. While there are no laws or rules that specifically regulate the distribution of medications via white bagging in Washington State, there are also no laws or rules that specifically prohibit the practice.

Recommendation:

The preliminary analysis of state regulations related to the practice of white bagging as defined above has yielded several recommendations for the commission:

1. Consider additional analyses to address regulatory concerns specific to:
    a. White bagging and repackaging.
    b. White bagging and wholesale distribution.
    c. White bagging and the delivery of controlled substances.
    d. White bagging and compliance with federal regulations, including the Drug Supply Chain Security Act (DSCSA).
    e. White bagging and appropriate labeling.
    f. White bagging and questions surrounding medication ownership.
    g. White bagging and measures to ensure product integrity.
2. Consider investigating current actions by other state boards of pharmacy related to white bagging.
3. Consult with the Office of the Insurance Commissioner (OIC) and the Health Care Authority (HCA) to understand their current positions and goals, if any, related to white bagging, as the commission recognizes that white bagging is typically payer mandated. From these consultations, the Commission could discuss whether rulemaking is desirable.

4. Consider legislative action. The Legislative Subcommittee raised this topic as one to consider for the 2024 Legislative Session. If so, the commission would need to isolate a legislative request within its regulatory reach for staff to start researching.

Follow-up Action: The commission will direct staff regarding follow-up action.

Department of Health
Pharmacy Quality Assurance Commission

Guidance Document

Revised – 10/18/11

Title:	Pharmacy Lockers for Filled Prescription Pick-up	*Number:* G004
References:	WAC 246-945-415 and WAC 246-945-455	
Contact:	Marlee B. O'Neill, Executive Director, Pharmacy Quality Assurance Commission	
Phone:	360-236-4700	
Email:	WSPQAC@doh.wa.gov	
Effective Date:	September 23, 2022	
Supersedes:	N/A	
Approved By:	Teri Ferreira, RPh, Pharmacy Quality Assurance Commission Chair	

The Pharmacy Quality Assurance Commission (commission) interprets its laws and rules to permit pharmacies to use pharmacy-owned lockers to deliver filled prescriptions for non-controlled drugs, without the lockers being included as part of the pharmacy's license. Pharmacies should be aware of specific laws and rules that apply to the delivery of filled prescriptions for non-controlled drugs, including WAC 246-945-415(1) which requires pharmacies to take appropriate measures when delivering filled prescriptions to ensure product integrity and receipt by the patient or patient's agent.

During its July 2022 business meeting, the commission reviewed whether a licensed pharmacy could deliver filled prescriptions for non-controlled drugs to lockers owned and operated by that pharmacy. As part of its review, the commission decided its laws and rules:

- Permit pharmacies to use pharmacy-owned lockers to deliver filled prescriptions for non-controlled drugs.
- Do not require pharmacy-owned lockers used to deliver filled prescriptions for non-controlled drugs to be annexed or within the licensed pharmacy space.
- Do not require pharmacies to comply with WAC 246-945-455 if they deliver filled prescriptions for non-controlled drugs to pharmacy-owned lockers.

This guidance only applies to filled prescriptions for non-controlled drugs, and to lockers that are owned and operated by the pharmacy. Additionally, the commission will require pharmacies who deliver filled prescriptions for non-controlled drugs to pharmacy-owned lockers to comply with all applicable laws and rules applicable to the delivery of filled prescriptions for non-controlled drugs, which includes the requirement that pharmacies take appropriate measures when delivering filled prescriptions to ensure product integrity and receipt by the patient or the patient's agent (WAC 246-945-415(1)).

https://doh.wa.gov/licenses-permits-and-certificates/professions-new-renew-or-update/pharmacy-commission/commission-information

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Committee	Commission Members
Recurring	
Budget committee • HELMS	**Chair**: Patrick Gallaher **Members**: Judy Guenther, Williams Hayes, Helen Jung, Ken Kenyon **Staff lead**: PQAC Executive Director and Finance Officer
Legislative committee	**Chair**: William Hayes **Members**: Hawkins DeFrance, Craig Ritchie, Matthew Ray, Chair, Vice Chair **Staff lead**: Rules and Legislative Consultant
Strategic planning committee • FDA MOU • Self-Inspection Worksheets • Whitebagging	**Chair**: Jerrie Allard **Members**: Ann Wolken, Matthew Ray, Chair **Staff lead:** Program Manager
Ad Hoc	
Compounding committee • **FDA MOU** • **Self-inspection worksheets** • **White bagging**	**Chair**: Hawkins DeFrance **Members**: Ken Kenyon, Uyen Thorstensen **Staff lead**: Pharmacist Consultant
Facility subcommittee • HPACs committee • Suspicious orders • Facility enforcement authority	**Chair**: Ken Kenyon **Members**: Teri Ferreira, William Hayes, Helen Jung, Jerrie Allard **Staff lead**: Craig Ritchie
Pharmacy Practice Committee • Misfill and Pharmacy Work Condition Workgroup • Sunrise review • CDTA WMC Committee (Teri) • Sample AUP review	**Chair**: Ken Kenyon **Members**: Teri Ferreira, William Hayes, Helen Jung, Jerrie Allard **Staff lead**: Craig Ritchie

Approved March 24, 2022

2020

Plan-19

Pharmacy Quality Assurance Commission's 2019 Novel Coronavirus (COVID-19) Response Packet

'A Live Plan'

The Pharmacy Quality Assurance Commission (Commission) is issuing Plan-19 in response to the 2019 Novel Coronavirus (COVID-19) public health emergency.

For questions regarding this document, please contact the Commission at COVID19.PQAC@doh.wa.gov.

For questions regarding COVID-19, please visit the Washington State Department of Health's COVID-19 webpage at https://www.doh.wa.gov/Emergencies/Coronavirus.

January 22, 2021

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Introduction and Requests

The Commission has received a number of inquiries and questions related to the Commission's response to the COVID-19 pandemic.

COVID-19 refers to the "coronavirus disease 2019", a respiratory disease that has now spread to more than 100 locations globally, including the United States. In response to the COVID-19 outbreak, on January 30, 2020, the International Health Regulations Emergency Committee at the World Health Organization (WHO) declared a "public health emergency of international concern."[1] On February 29, 2020, the Governor issued a proclamation declaring a State of Emergency in all counties in the state of Washington due to the outbreak of COVID-19.[2] On March 13, 2020, the President of the United States declared a national emergency for the United States of America.[3]

Different parts of the country are seeing varied activity related to COVID-19. The duration and severity of each phase can vary depending on the characteristics of the virus and the public health response.[4]

There has now been broad sweeping action to help 'flatten the curve' in Washington state and nationwide to stop the spread of the virus and to help not overburden the healthcare system.

The Commission aims to continuously update Plan-19 to communicate their position on questions and inquiries it receives.

[1] https://www.who.int/news-room/detail/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-%282005%29-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-%282019-ncov%29
[2] https://www.governor.wa.gov/news-media/inslee-issues-covid-19-emergency-proclamation.
[3] https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/
[4] https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/summary.html

Impacts of COVID-19 on Compounding

Licensees of the Commission are required to comply with United States Pharmacopeia (USP) Chapters <795> and <797> (*see* RCW 18.64.270(2)). The Commission also permits its licensees to become early adopters of USP Chapter <800>.

On March 11, 2020, the Commission's Compounding Subcommittee met to discuss the impacts of COVID-19 on pharmacy compounding operations. The Commission heard from multiple licensees that compliance with USP Chapters has become incredibly challenging due to the supply chain disruptions with personal protective equipment (PPE) and cleaning supplies.

On March 17, 2020, as part of its special meeting, the Commission stated that **it would not find licensees deficient or take enforcement action against its licensees for failure to comply with USP Chapters caused by COVID-19**. If a licensee finds that it is unable to meet the standards in applicable USP Chapters due to COVID-19 Commission expects the licensee to:

1. Create a plan that documents the deviation from standard practice and workflow,
2. Follow the best practices recommendation contained below as it relates to PPE conservation, PPE shortages, and cleaning supply shortages, and
3. Engage with the licensee's infection prevention team (if any) to discuss adoption of modified workflows and standards in the face of COVID-19.

This position will only affect a licensee's standing with the Commission and does not affect obligations a licensee may owe to other local, state or federal regulators e.g. United States Food and Drug Administration and United States Drug Enforcement Administration.

This position will take effect immediately and will remain effective until the Commission withdraws this position at an open public meeting or until the Governor issues a proclamation declaring the termination of the state of emergency declared by Proclamation 20-05, as amended by any subsequent amendatory proclamations, whichever is earlier.

Best Practice Recommendations

PPE Conservation

- Reduce the frequency of compounding staff exiting the compounding area that would require donning of new PPE.
- Reduce unnecessary traffic into the compounding area by non-compounding personnel.
- Reuse PPE, when operationally feasible.
- Do not reuse facemasks or other PPE, if:
    - Visibly soiled
    - Moist
    - Contaminated
    - Wet or damaged and rendered non-usable
- Limit six-month sterile compounding recertification to conserve garb supplies to compounding personnel only.
- Purchase premix sterile products as a means of limiting necessity of compounding.

PPE Shortages

- Continue to utilize and maintain environmental controls such as clean rooms and hoods to optimize sterile compounding environments.

- Continue to work with institution's leadership and emergency responders purchase more PPE.
- Reserve remaining PPE for hazardous and batch-compounding operations
- Develop plans for compounding in lieu of or with minimal PPE. Plans should be supportive of quality and safety first, for example:
    - Re-use of non-soiled PPE
    - Working under "immediate-use" level compounding provision (n/a for medium or high risk level compounding), if applicable or Immediate-use level compounding may not apply in all settings i.e., long term care facilities
    - Working under "high-risk" level compounding conditions (which includes compounding ***without*** appropriate PPE) and decreasing BUD accordingly
    - Further limiting what may be compounded
- Increasing emphasis on technique
- Resource requests should go through **your emergency preparedness coalition.**
    - Eastern WA: REDI Coalition; 24/7 duty officer number 509-362-0041; general email is hcc@srhd.org
    - Western WA: Northwest Healthcare Response Network; 24/7 duty officer 425-988-2897; general e-mail: info@nwhrn.org
    - Southwest WA: Southwest Healthcare Preparedness Coalition; 24/7 duty officer phone: 800-259-0195; general e-mail is: swhpp@sw-ems.org

Cleaning Supply Shortage

- Increase emphasis on excellent hand hygiene, if surgical gel unavailable (e.g., hand hygiene with every glove change)
- Identify alternative cleaning agents

Outpatient and Retail Pharmacy Operation Recommendations

On March 17, 2020, the Commission adopted the following recommendations related to outpatient and retail pharmacy operations during the COVID-19 outbreak.

Retail and Outpatient pharmacists and pharmacies have a large role in the provision of public health services during a pandemic. Pharmacists and ancillary staff will continue to be on the front line of health care for patients. As we are beginning to see in other countries with directives of limited social interaction and varying degrees of quarantine, retail pharmacies and grocery vendors remain operational to ensure continuity of minimum services. The Commission wants to provide recommendations for operational safety during this pandemic.

There has been a great deal of unspecific direction to the retail pharmacy work environment. Common questions such as 'Am I or my staff at significant risk to contract the virus?' or 'Am I doing everything I can to limit the risk of exposure to my patients?' arise as conscientious caregivers work to assess the risk of Covid-19 in our work environment. The Commission recommends the following:

Step-by-Step

1. **Assess the Risk**

According to the CDC, exposure risk categories are broken into high, medium and low. Each aligns with a particular recommendation of PPE (personal protective equipment). Brief interactions with a patient regardless of whether the patient is wearing a facemask or not is considered low risk and does not require PPE. Examples of brief interactions include ringing patients up at the register, short consults at the consult window or counter and briefly entering a patient consult room but not having direct physical contact with the patient or the patient's secretions/excretions. Pharmacy staff that walk by a patient or who have no direct contact with the patient, or their secretions/excretions are considered to have no identifiable risk (CDC, 2020)[1]. Assess the physical layout of your pharmacy with these CDC exposure risk categories in mind and consider modifications to minimize risk. If a staff member does experience known community exposure, they should have their exposure risk assessed according to CDC guidance (https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html#table1) and contact your organization's occupational health program or your local health department.

2. **Clean the work/patient area frequently**

Perform routine environmental cleaning of all frequently touched surfaces in the workplace such as register/consult counters, pin pad and payment devices, workstations, and doorknobs. Use the cleaning agents that are usually used in these areas and follow the directions on the label. No additional disinfection beyond routine cleaning is recommended at this time. Provide disposable wipes so that commonly used surfaces (such as doorknobs, keyboards, desk areas) can be wiped down by employees before each use (CDC, 2020)[2].

3. Create effective social distancing

"***Social distancing has proven to be one of the most, if not the most effective ways to slow and lessen the impact of an epidemic like this,"*** said Fred Hutch oncologist and public health researcher Dr. Gary Lyman (Fred Hutch, 2020)[3].

Social distancing refers to maintaining adequate distance between yourself and another person to reduce the risk of breathing in droplets that are produced when an infected person coughs or sneezes, ideally six (6) feet. In the community pharmacy setting, social distancing measures may include discouraging patients from hovering near the pharmacy counter, closing or limiting access to the waiting rooms or rearrange or remove seating, and encouraging distance between patients standing in line. According to Duke University, "*It's recommended to maintain at least six (6) feet of distance from people and stay out of public places. Symptoms of COVID-19 can take up to 14 days to appear.*" (DUHS, 2020)[4].

Deploy any technology that allows your patients to enter and leave the pharmacy quickly. Texting prescription completion alerts or allowing patients to pay in advance and pick up at a non-register line window/counter both may be helpful. For those pharmacies that do not deliver prescriptions, consider mailing prescriptions exclusively to your elderly patients.

4. Maximize the use of your drive thru lanes or curbside, if available

A drive thru minimizes direct in-person interaction with pharmacy staff. This may be an ideal method to maintain patient services in a safe and effective manner. Minimize the use of cash transactions, whenever possible.

5. Wear gloves if hand sanitizer is in short supply

This will be important for the staff that are handling cash, credit cards or the old prescription bottles that are handed over the counter to enter the prescription refill number. Hand sanitizer products will become increasingly unavailable. Washing your hands between each ring-up or consult while attending to the normal parade of pharmacy duties is difficult. Change your gloves frequently throughout the day.

6. Implement the universal use of face coverings

Pharmacists and pharmacy technicians should always wear a facemask while they are in the pharmacy for source control. Medical or surgical facemasks are generally preferred over cloth face coverings for healthcare professionals (HCP) for source control.

The outpatient and retail pharmacies in Washington State play a critical role in this public health crisis. The Commission encourages you to practice safely in service of your patients during this pandemic. There will be difficult days ahead and the Commission is resolved to assist you in the care of your patients and of our professionals.

References:
CDC (2020, March 7th). Interim U.S. Guidance for Risk Assessment of Public Health Management of Healthcare Personnel with Potential Exposure in a Healthcare Setting to Patients with Coronavirus

Disease. (COVID-19). Retrieved from https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html#table1

CDC (2020, February 26th). Interim guidance for businesses and employers to plan and respond to 2019 coronavirus disease 2019 (COVID-19), February 2020. Retrieve from https://stacks.cdc.gov/view/cdc/85488

Mapes, Diane/Fred Hutch News Service (2020, March 12th) Stopping a pandemic in its tracks calls for cooperation, patience, handwashing and, yes, isolation. We can do it. Retrieved from https://www.fredhutch.org/en/news/center-news/2020/03/covid19---social-distancing--in-seattle-and-beyond.html

Duke University Health System (2020). Help Prevent the Spread of Covid –19. Retrieved from https://www.dukehealth.org/covid-19-update

ref: CDC (2020, June 28th). Guidance for Pharmacies. Retrieved from https://www.cdc.gov/coronavirus/2019-ncov/hcp/pharmacies.html

COVID-19 Testing Information as it Relates to the Practice of Pharmacy in Washington State

Pharmacist Scope of Practice in WA State:

As part of its business meeting on April 24, 2020, the Pharmacy Quality Assurance Commission (PQAC) clarified some of the following as it relates to Washington licensed pharmacists ordering, administering and reporting results of COVID-19 testing to patients:

- **Screening for patients receiving COVID-19 tests** – A pharmacist or pharmacy intern, under the supervision of a pharmacist, may conduct this screening. It is not within the scope of practice for a Pharmacy Technician to perform discretionary functions. A Pharmacy Technician may only perform screening elements to the extent that could be described as non-discretionary function(s). If the screening includes any form of discretionary decision-making, these decisions must be reserved to the pharmacist or pharmacy intern. Pharmacy assistants cannot conduct screening.
- **Ordering COVID-19 tests** – PQAC will not take enforcement action against pharmacists who order COVID-19 tests consistent with the "Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity under the PREP Act" issued by the U.S. Department of Health and Human Services on April 8, 2020. PQAC will be maintaining this position until it is withdrawn at an open public meeting or Governor Jay Inslee issues a proclamation terminating the state of emergency declared by Proclamation 20-05 as amended.
- **Administering COVID-19 tests** – Pharmacists may administer COVID-19 tests. How to administer test: https://www.doh.wa.gov/Emergencies/NovelCoronavirusOutbreak2020COVID19/HealthcareProviders
- **Reporting COVID-19 test results**- Pharmacists may not diagnose a patient with COVID-19, unless the diagnosis is permitted under the terms of a collaborative drug therapy agreement (CDTA). In the absence of a CDTA, if a pharmacist communicates the COVID-19 test results, the pharmacist shall only provide the results of the COVID-19 test and recommend the patient contact their primary health care provider.

Lab Certification and Requirements:

- Pharmacists in WA need to obtain certification of waiver from the WA State Department of Health indicating they are conducting CLIA waived tests. Under the HHS guidance, only COVID-19 tests with FDA Emergency Use Authorization (EUA) for use in waived settings can be used under a certificate of waiver.
- The Certification of Waiver Medical Test Sites Application link: https://www.doh.wa.gov/portals/1/Documents/Pubs/505038.pdf

- The rules for Medical Test Sites can be found in Chapter 246-338 WAC: https://apps.leg.wa.gov/WAC/default.aspx?cite=246-338
- A “medical test site” is a laboratory that must meet the requirements for notifiable conditions to report in the Washington Disease Reporting System (WDRS). Chapter 246-101 WAC https://apps.leg.wa.gov/WAC/default.aspx?cite=246-101
- Consider contracting with a health care provider who orders tests and reports via the Washington Disease Reporting System (WDRS) to comply with notifiable condition requirements.
- Employers need to ensure that employees performing the COVID-19 test have sufficient personal protective equipment (PPE) and comply with COVID-19 test manufacturer’s specific manual of instruction. PPE information here: https://www.doh.wa.gov/Emergencies/NovelCoronavirusOutbreak2020COVID19/HealthcareProviders
- For questions regarding the application process, you may contact the Medical Test Site Program LQA@doh.wa.gov

Biomedical Waste Requirements:

- Proper disposal of biomedical waste generated from the COVID-19 testing is critical and necessary due to the infections nature of the coronavirus.More COVID-19 Information and Resources

Stay up-to-date on the current COVID-19 situation in Washington, Governor Inslee’s proclamations, symptoms, how it spreads, and how and when people should get tested. See our Frequently Asked Questions for more information.

The risk of COVID-19 is not connected to race, ethnicity or nationality. Stigma will not help to fight the illness. Share accurate information with others to keep rumors and misinformation from spreading.

- WA State Department of Health 2019 Novel Coronavirus Outbreak (COVID-19)
- WA State Coronavirus Response (COVID-19)
- Find Your Local Health Department or District
- CDC Coronavirus (COVID-19)
- Stigma Reduction Resources
- CDC Symptoms

Have more questions about COVID-19? Call our hotline: **1-800-525-0127.** For interpretative services, **press #** when they answer and **say your language**. (Open from 6 a.m. to 10 p.m.) For questions about your own health, COVID-19 testing, or testing results, please contact your health care provider.

Delivery of Prescription Medications Outside of a Pharmacy by Pharmacists, Pharmacy Technicians, or Pharmacy Assistants

The Commission interprets existing laws and rules to permit a pharmacist, pharmacy technician, or pharmacy assistant to deliver ***prescribed non-controlled medications*** to a patient, or the patient's agent, outside the physical confines of a pharmacy e.g. a pharmacist delivers prescribed non-controlled medication to the patient's home.

The commission also interprets existing laws and rules to permit a pharmacist, pharmacy technician, or pharmacy assistant to deliver ***prescribed controlled medications*** to the ultimate user (the patient who has been prescribed the medication or a member of the patient's household) outside the physical confines of a pharmacy e.g. a pharmacist delivers prescribed controlled medications to the patient at their home.

When a pharmacy technician or pharmacy assistant is delivering prescribed drugs outside the physical confines of a pharmacy, the pharmacy technician must work under the supervision and control of a pharmacist.

When pharmacists, pharmacy technicians, or pharmacy assistants are delivering prescribed drugs outside the physical confines of a pharmacy, the pharmacist must still make a written offer of patient counseling, along with contact information for the pharmacist and information about the medication.

This position only reflects the Commission's understanding of the laws and rules it enforces and does not affect obligations a pharmacist, pharmacy technician or pharmacy assistant may owe to other local, state or federal regulators e.g. United States Food and Drug Administration and United States Drug Enforcement Administration.

Commission Acts on Hand Sanitizer

The Pharmacy Commission (Commission) has received several inquiries and innovative collaborative concepts related to the manufacturing of alcohol-based hand sanitizer in light of the present public health emergency posed by COVID-19.

*Pursuant to the Commission's discussion and vote during the Special Meet*ing, March 27, 2020,
the commission will not refer or take enforcement actions against licensees or pharmacies that accept donated or manufactured hand sanitizer (using USP and/or non-USP grade ingredients) without obtaining a manufacturer license for consumer use and for health care personnel for the duration of the public health emergency.

Pursuant to the Commission's discussion and vote during the Special Meeting, March 27, 2020,
the commission will not refer or take enforcement actions against individuals or businesses that accept donated or manufactured hand sanitizer (using USP and/or non-USP grade ingredients) without obtaining a manufacturer license, pharmacy license, or shopkeeper registration for consumer use and for health care personnel for the duration of the public health emergency. The hand sanitizer should be in a manner that is consistent with the guidance issued by the United States Food and Drug Administration (FDA) or the United States Pharmacopeia on preparing alcohol-based hand sanitizer.

The Commission will provide an update when this position no longer effective or applicable. The Commission thanks everyone for their patience and doing their part in providing the best care possible during these unprecedented times.

Non-resident Pharmacies

Policy Statement
For nonresident pharmacies who are required to ***renew*** their nonresident pharmacy licenses ***by May 31, 2020***, the Pharmacy Commission will treat a letter from an approved inspection program, that complies with the criteria below, as meeting the requirement in RCW 18.64.360(1)(b)(i) and (ii) of providing an inspection report conducted by an approved inspection program within the last two years. The letter from the approved inspection program must state: (1) an inspection of the nonresident pharmacy has not been conducted within the last two years, and (2) an inspection cannot be conducted at this time because of the COVID-19 pandemic. A list of approved inspection programs can be found here.

This statement does not affect obligations of applicants for nonresident pharmacy licenses. These applicants will still need to provide an inspection report conducted by an inspection program approved by the Pharmacy Commission that has been issued within two years. A letter that meets the criteria in the paragraph above will not be acceptable for new applicants of nonresident pharmacy licenses.

Background
The Pharmacy Commission has had regulatory authority over nonresident pharmacies that operate in Washington since 1991 (*see* Pharmacies – Licensing of Nonresident Pharmacies, Laws of 1991, ch. 87). RCW 18.64.350 through RCW 18.64.420 delineates the Pharmacy Commission's regulatory authority for nonresident pharmacies. The Pharmacy Commission can take enforcement action, among other things, when a nonresident pharmacy fails to comply with any requirement of RCW 18.64.350 through RCW 18.64.400 (*see* RCW 18..64.390).

As part of the 2019 legislative session, the Legislature passed HB 1412 and amended RCW 18.64.360(1)(b) to require nonresident pharmacies to submit a copy of an inspection report as part of their initial application and renewal. The inspection had to be conducted by "an inspection program approved by the commission as having substantially equivalent standards to those of the commission" and the inspection report must have been "issued within two years of application or renewal." RCW 18.64.360(1)(b)(i) and (ii). The Pharmacy Commission has issued a directive identifying those inspection programs that conduct inspections based on equivalent standards to those of the commission.

Due to the COVID-19 pandemic, nonresident pharmacies have informed the Pharmacy Commission they will be unable to meet the requirement to provide a copy of an inspection report because in-person inspections are not currently being conducted. At its April 24, 2020, business meeting the Pharmacy Commission discussed this issue and stated that for nonresident pharmacies who are required to renew their nonresident pharmacy licenses by May 31, 2020, the Pharmacy Commission will treat a letter, that meets the criteria below, from an approved inspection program as meeting the requirement in RCW 18.64.360(1)(b)(i) and (ii) of providing an inspection report conducted by an approved inspection program within the last two years. The letter from the approved inspection program must state: (1) an inspection of the nonresident pharmacy has not been conducted within the last two years, and (2) an inspection cannot be conducted at this time because of the COVID-19 pandemic. This action does not affect obligations of applicants for nonresident pharmacy licenses. These applicants will still need to provide an inspection report conducted by an inspection program approved by the Pharmacy Commission that has been issued within two years.

Commission Frequently Asked Questions (FAQs)

If proclamation 30-32 (Department of Health – Healthcare Worker Licensing) expires, can pharmacy technicians continue to engage in remote medication order processing without being under the "immediate supervision" of a pharmacist?

No. If proclamation 30-32 (Department of Health – Healthcare Worker Licensing) expires, pharmacy technicians must perform tasks under the "immediate supervision" of a pharmacist. Before the Pharmacy Commission's new rules become effective on July 1, pharmacies who allow for remote supervision of pharmacy technicians should comply with the relevant requirements in chapter 246-901 WAC and the Pharmacy Commission's Technology and Service Guidelines. On July 1, 2020, when the Pharmacy Commission's new rules become effective, pharmacies should ensure that pharmacy technicians are under the "immediate supervision" of a pharmacist as defined in WAC 246-945-001(44).

Proclamation 30-32 (Department of Health – Healthcare Worker Licensing) waived and suspended the requirement that pharmacy technicians be under the "**immediate"** supervision of a pharmacist in WAC 246-901-010(11), WAC 246-901-020(1), and WAC 246-901-040.

Emergency proclamations issued by the Governor expire after thirty (30) days unless extended by the legislature and if the legislature is not in session, a proclamation may be extended in writing by the leadership of the senate and house of representatives (see RCW 43.06.220). Proclamation 30-32 was originally set to expire on April 25, 2020, but was subsequently extended by the leadership of the state legislature (otherwise known as the "four corners") on three occasions. The current extension (Proclamation 20-32.3) is set to expire on June 17, 2020. If the proclamation expires, then the word "immediate" will no longer be waived and suspended. The Pharmacy Commission does not have authority to extend the proclamation.

Does the Uniform Controlled Substances Act (RCW 69.50) restrict the quantity of controlled substances that may be prescribed?

The Uniform Controlled Substances Act (UCSA), RCW 69.50, does not limit the quantity of controlled substances (including those drugs listed in Schedule II) that may be prescribed. However, prescribers, and pharmacists, should be aware of specific prescribing laws that may apply to their profession. For example, a number of prescribing boards and commissions have specific laws and rules applicable to prescriptions for opioids.

The USCA does prohibit refills for a drug listed in Schedule II (*see* RCW 69.50.308(d)). The USCA also prohibits filling of a prescription for a drug listed in Schedule II more than six months after the date the prescription was issued (*see* RCW 69.50.308(d)).

The USCA prohibits more than five refills of a prescription for a drug listed in Schedule III, IV, or V (*see* RCW 69.50.308(g)).

No. In addition, there are no limits to prescribing controlled substances for health care providers during COVID-19 as long as the provider follow the rules regarding opioid prescribing. In addition, the USCA prohibits filling or refilling of a prescription for a drug listed in Schedule III, IV, or V, more than six months after the date issued by the prescriber (*see* RCW 69.50.308(g)).

Note: the Pharmacy Commission cannot guarantee that prescriptions of controlled substances for any quantity will be covered by a patient's prescription drug benefit.

Can hospital pharmacies permit discharge of patients with albuterol that does not meet outpatient-labelling standards?
The Commission will not find licensees deficient or take enforcement action against its licensees for failure to discharge patients with albuterol that does not meet outpatient-labelling standards.

This position will take effect immediately and will remain effective until the Commission withdraws this position at an open public meeting or until the Governor issues a proclamation declaring the termination of the state of emergency declared by Proclamation 20-05, as amended by any subsequent amendatory proclamations, whichever is earlier.

This position will only affect a licensee's standing with the Commission and does not affect obligations a licensee may owe to other local, state or federal regulators e.g. United States Food and Drug Administration and United States Drug Enforcement Administration.

Can a prescription for a substance included in Schedule II be dispensed upon the oral prescription of a practitioner?
A substance included in Schedule II may be dispensed upon the oral prescription of a prescriber in an emergency (RCW 69.50.308(c)). An emergency exists "when the immediate administration of the drug is necessary for proper treatment and no alternative treatment is available, and further, it is not possible for the [prescriber] to provide a written or electronic prescription for the drug at that time" (WAC 246-887-020(6)).

At its special meeting on April 3, 2020, the Commission stated that whether an emergency situation exists pursuant to the laws cited above is a determination made by the prescriber and pharmacist based on the individual facts of a particular medical situation. Further, and in agreement with the position taken by the United States Drug Enforcement Administration (DEA), while an emergency situation does not necessarily exist with regard to every prescription for a substance included in Schedule II issued during the COVID-19 state of emergency, the determination must still be made by prescribers and pharmacists on a case-by-case basis.

How does the waiver of pharmacy license of location extend to controlled substances and DEA registration requirements? What is the turnaround for the temporary registration?
Please send your contact information to Drug Enforcement Administration (DEA) Supervisory Diversion Investigator Craig Tom at craig.w.tom@usdoj.gov. Have your temporary location information, state licenses numbers, and Tax Identification Number readily available."
DEA is working with temporary sites to get them DEA Registrations as quickly as possible to avoid lapse in treatment, please have all of your Washington State controlled substance credentials ready to expedite the process.

For DEA COVID-19 information and latest updates on changes and exceptions to DEA rules: https://www.deadiversion.usdoj.gov/coronavirus.html

What is the Commission position on temporary closures of pharmacies?
There is really no role for the Pharmacy Commission when a pharmacy chooses to close temporarily. The pharmacy is still under the jurisdiction of the Commission and applicable laws and rules do apply even if the pharmacy is temporarily closed e.g. WAC 246-869-020 that requires a pharmacy to have adequate security for its drug supplies and records.

We recommend posting your differential hours for patients.

Should My Pharmacy Remain Open?
The Commission does not have authority to close businesses or pharmacies solely as a result of COVID-19. We encourage you to review the Washington State Coronavirus Response What's Open and Closed, Governor issued emergency proclamations, and follow the guidelines from the Centers for Disease Control and Prevention. Check with your local county health department to determine what activities are also considered essential and non-essential. Please check our website for the most up-to-date info on Washington's response to COVID-19 at www.doh.wa.gov/coronavirus.

Can pharmacy technicians perform order entry from a remote location?
Yes, a pharmacy technician may perform order entry from a remote location as long as they are under the supervision and control of a pharmacist. Licensees should familiarize themselves with the Commission's Technology and Services Guidelines #62 when implementing processes and procedures that allow remote supervision of pharmacy technicians by pharmacists.

During COVID-19, what are the signature requirements for delivery of prescribed medications?
Effective 03/31/2020, The Health Care Authority is temporarily removing the requirement to obtain a signature from the Medicaid client or the client's designee upon receipt of pharmacy products dispensed and delivered directly to a client. In response to the current public health emergency surrounding the outbreak of the Coronavirus disease (COVID-19), along with the Governor of Washington's emergency proclamations related to COVID-19, Washington Administrative Code 182-530-5000(e)(i) has been updated to allow delivery of pharmacy products without signature from the client or the client's designee in order to avoid unnecessary contact between the client and the delivery person.

During the COVID-19, am I required to make customers sign a logbook to purchase over-the-counter pseudoephedrine products?
Yes. A signature to purchase pseudoephedrine (without a prescription) is required as part of the Combat Methamphetamine Epidemic Act of 2005. See **21 U.S.C. 830**(e)(1)(A). The Assistant Administrator is not authorized to make an exception to a statutory requirement.

DEA understands the concern that requiring a signature for purchase of pseudoephedrine could undermine public health efforts to combat the spread of the coronavirus. If a customer is worried about using a stylus or pen at the pharmacy, the pharmacy could provide the customer with gloves, a sterilized stylus/pen, or sterilize the stylus/pen after each use at the request of the customer.

Can pharmacies and health care entities manufacture hand sanitizer without obtaining a manufacturer license?
Pursuant to the Governor's Emergency Proclamation 20-36, pharmacies and health care entities can manufacture and distribute hand sanitizer without any additional licensure.

Can individuals or business entities manufacture hand sanitizer for distribution to the public without obtaining a manufacturer license or shopkeeper registration?
Pursuant to the Governor's Emergency Proclamation 20-36, individuals or business entities that manufacture hand sanitizer for distribution to the public in a manner can do so without obtaining a manufacturer license or shopkeeper registration.

Will the Pharmacy Commission find licensees deficient or take enforcement action against licensees whose CDTAs expire during the COVID-19 pandemic?

Pharmacists may prescribe drugs under the terms of a collaborative drug therapy agreement (CDTA) entered into with a prescriber (*see* RCW 18.64.011(28)). Amongst other requirements, a CDTA is required to contain "[a] time period not to exceed 2 years during which the [CDTA] will be in effect" (*see* WAC 246-863-100((2)(b)).

On April 10, 2020, as part of its special meeting, the Pharmacy Commission stated that it would not find licensees deficient or take enforcement action against its licensees for prescribing under an expired CDTA if the cause for the failure to renew the CDTA was the COVID-19 pandemic. This position took effect immediately and will remain effective until the Pharmacy Commission withdraws this position at an open public meeting or until the governor issues a proclamation declaring the termination of the state of emergency declared by Proclamation 20-05, as amended by any subsequent amendatory proclamations, whichever is earlier.

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Does a pharmacist have the ability to independently order a COVID-19 tests?
Yes, the Commission adopted HHS's policy "HHS Statements on Authorizing Licensed Pharmacists to Order and Administer COVID-19 Tests" and the Commission will exercise prosecutorial discretion for those pharmacist engaging in COVID-19 testing.

Does a pharmacist have the ability to administer a COVID-19 tests?
Yes, pharmacists are allowed to administer tests, including COVID-19 tests. This falls under their scope of practice identified in RCW 18.64.011(28) which states "Practice of pharmacy" includes the practice of and responsibility for: Interpreting prescription orders; the compounding, dispensing, labeling, administering, and distributing of drugs and devices; the monitoring of drug therapy and use; the initiating or modifying of drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs; the participating in drug utilization reviews and drug product selection; the proper and safe storing and distributing of drugs and devices and maintenance of proper records thereof; the providing of information on legend drugs which may include, but is not limited to, the advising of therapeutic values, hazards, and the uses of drugs and devices."

Are retail and community pharmacist required to complete the Sterile Compounding Self-Inspection Worksheet: USP 797 – Sterile Compounding Addendum?
No. At the April 24, 2020 Pharmacy Commission business meeting, the Commission voted to not require the completion of the Sterile Compounding Self-Inspection forms in the retail and community pharmacist setting, when a pharmacist is engaged in low-risk compounding under the immediate use exemption.

Can a pharmacy use transportation network companies (TNCs) such as Uber, Lyft, or Postmates to deliver a patient's prescription medication?
Possibly--Under Washington law, a TNC could transport a patient's prescription medication if they are a "common carrier" or "contract carrier" (see RCW 69.41.030(1) and RCW 60.50.302(c)(2)). If a TNC is a "common carrier" or "contract carrier" the TNC would have to obtain a permit from the Washington State Utilities and Transportation Commission (UTC) unless they are exempt.

Pharmacies should contact the UTC to verify the status of a "common carrier" or "contract carrier". The contact information for the UTC can be found here, and a searchable database of common carriers can be found here.

Pharmacies should consider other applicable laws and other regulators e.g. United States Drug Enforcement Administration, before using TNCs to ship a patient's prescription medications. For example, the DEA has stated registrants are responsible for selecting common or contract carriers that will provide adequate security against in-transit losses or thefts.

Governor's Proclamations Waiving and Suspending Laws and Rules

Proclamation 20-36.10 *(effective until termination of the state of emergency pursuant to RCW 43.06.210, or until rescinded, whichever occurs first)*

On Dec. 9, 2021 Gov. Inslee modified Proclamation 20-36 to give pharmacies the flexibility they will need to store and access COVID-19 vaccines and treatments in locations outside of their pharmacies..

Proclamation waivers to allow off-site storage by pharmacies

The new waivers permit pharmacies to store outside of the pharmacy's main licensed location COVID-19 vaccines and drugs for treating COVID-19 for which the U.S. Food and Drug Administration has issued an emergency use authorization, license, or other approval.

Pharmacists may authorize non-pharmacy staff members to access the areas where these vaccines and drugs are stored without having to immediately supervise the non-pharmacy employees while they are doing so.

For instance, a hospital pharmacy may store COVID-19 vaccines in a hospital lab's ultra-cold freezer. Lab staff members may continue accessing the freezer and the area where the freezer is located without having to be immediately supervised by a pharmacist. Another example is that a retail pharmacy may partner with a private, independent lab or other enterprise to store vaccines in their freezers, and the staff of that lab or other enterprise will not have to be supervised by a pharmacist.

Pharmacies may store COVID-19 vaccines and drugs in locations outside of the pharmacy; however, current pharmacy standards still apply to store the vaccines and drugs in a facility with adequate security to protect them from unauthorized access, acquisition, or use.

Redistributing vaccines

Redistribution of COVID-19 vaccines to facilitate quick and effective vaccination, and to alleviate temporary shortages to aid in ending the COVID-19 pandemic, will be permitted. This qualifies as being done for emergency medical reasons. Redistribution of COVID-19 vaccines and treatments among pharmacies, health care facilities, and health care practitioners will not constitute wholesaling under the current law.

Commingled storage of vaccines and laboratory materials and specimens

Because ultra-cold freezer space is scarce, COVID-19 vaccines may need to be stored in the same freezer unit as laboratory materials and specimens. Unless the FDA's emergency use authorization for a COVID-19 vaccine prohibits it, the Pharmacy Quality Assurance Commission and the Department of Health – as the regulating agencies for pharmacies, medical test sites (laboratories), and hospitals – will permit commingled storage of COVID-19 vaccines and laboratory materials and specimens. The state will apply the standard in the CDC "Pink Book,"

which requires potentially contaminated laboratory items (e.g., blood, urine, and stool) to be properly contained and stored below vaccines to avoid contamination from drips or leaks**.**

Ancillary Utilization Plans

Pharmacies will not need Commission approval to utilize pharmacy technicians and assistants. Pharmacies that currently do have approval to utilize pharmacy technicians and assistants will also be able to utilize pharmacy technicians and assistants in a manner that is currently inconsistent with their approved AUP. In addition, pharmacy technicians can engage in specialized functions (IV admixture and unit-dose checking) without approval of the Commission.

While the approval of an AUP and specialized functions has been waived and suspended, pharmacy technicians and assistants will need to act within their statutory scope of practice and pharmacies/pharmacists remain responsible for actions taken by pharmacy technicians and assistants acting under their supervision.

License of Location - waived.

The "license of location" requirement for pharmacies has been waived and suspended. Consequently, pharmacies may store drugs outside of the physical confines of the pharmacy. Instead pharmacies could store drugs in other locations e.g. temporary pharmacy space that are not licensed. The pharmacy will still be responsible for drugs it stores outside of the physical confines of the pharmacy.

Differential Hours - waived.

Pharmacies do not need to notify the Commission thirty days before commencing differential hours. Pharmacies will also not need to undergo Commission inspection before commencing differential hours. This will affect pharmacies located within mercantile (retail) establishments

Hand Sanitizer - waived.

All persons engaged in the manufacture and distribution of hand sanitizer to the public, may do so without obtaining a manufacturer license or shopkeeper registration. This includes both entities licensed by the Commission, and those that are not licensed by the Commission.

Proclamation 20-32.11 *(effective until termination of the state of emergency pursuant to RCW 43.06.210, or until rescinded, whichever occurs first**)***

"Immediate" supervision of technicians - waived.

On March 26, 2020, the governor issued a proclamation waiving WAC 246-901-010(11), WAC 246-901-020(1) – the following language only: "immediate", and WAC 246-901-040 – the following language only: "immediate". This proclamation waives the requirement that a pharmacy technician or pharmacy technician trainee be under the ***immediate*** supervision of a pharmacist.

While the waiver is in effect, pharmacy technicians will only be required to act under the "supervision and control of a pharmacist" pursuant to RCW 18.64A.030(1). The Pharmacy Commission understands "supervision and control of a pharmacist" to mean that a pharmacist is readily available to a pharmacy technician or pharmacy technician trainee. This does include, but is not limited to, a pharmacist that is readily available via technology e.g. telephone or instant messaging service.

The proclamation does not remove the responsibility of a pharmacy or pharmacist for acts performed by pharmacy technicians or pharmacy technician trainees under their supervision (RCW 18.64A.080). In addition, the proclamation does not remove the requirement that a pharmacist must be on-site when employees of a pharmacy are engaged in sterile compounding (WAC 246-871-040).

Examples: Working remotely with technology, COVID-19 testing sites with access to pharmacists.

Retired Pharmacist license – waived.

The governor waived language in the retired pharmacist rule, which would allow a pharmacist with a retired pharmacist credential to practice pharmacy. The proclamation waived the following language from the rule: "shall not be authorized to practice pharmacy and".

Continuing Education Requirements for Pharmacist - waived.

This waiver removes the requirement for a pharmacist seeking reinstatement or reactivation of an expired license to provide proof of 15 continuing education hour for the last two most recent years.

This waiver removes the requirement to complete the equivalent of 1.5 continuing education unit (equal to fifteen contact hours) of continuing education for renewing a pharmacist license.

This waiver removes the requirement of a pharmacist to complete the three hours of suicide training from the department of health's model list with content related to imminent harm via lethal means, during the first full continuing education reporting period after initial licensure.
Waives CE requirements for **reactivating expired credential** if expired less than one renewal cycle.

Seven hours of HIV/AIDS training for pharmacist – waived.

This waiver removes the requirement for pharmacist applicants to complete seven hours of HIV/AIDS training for initial licensure.

Continuing Education Requirements for Pharmacy Technicians- waived

This waiver removes the requirement for pharmacy technicians to complete the minimum of ten continuing education hours or 1.0 continuing education unit (CEU), with one hour in pharmacy law, every renewal cycle following their first certification renewal.
Waives CE requirements for **reactivating expired credential** if expired less than one renewal cycle.

Four hours of HIV/AIDS training for pharmacy technicians and pharmacy assistants – waived.

This waiver removes the requirement for pharmacy technician and assistant applicants to complete 4-hours of HIV/AIDS training for initial licensure. Resources

Proclamation 20-59.8 *(effective until termination of the state of emergency pursuant to RCW 43.06.210, or until rescinded, whichever occurs first)*

Temporary Practice Permits for new graduates.

Proclamation 20.59 waives and suspends portions of the licensing and administrative statutes and rules relating to the issuance of Temporary Practice Permits (TPP) for healthcare workers who have recently graduated from professional health care programs in dentistry, pharmacy, and dental hygiene; and sets criteria for expiration and practice limits for the TPP.

USP Letter	2020-03-13 USP letter to state BOPs_
Hand Sanitizer	For pharmacists, pharmacies, and health care entities: https://www.fda.gov/media/136118/download, https://www.usp.org/sites/default/files/usp/document/about/public-policy/usp-covid19-handrub.pdf For persons or entities not currently licensed or registered with the Commission: https://www.fda.gov/media/136289/download, https://www.usp.org/sites/default/files/usp/document/about/public-policy/usp-covid19-handrub.pdf
American Red Cross CPR Provisional Certification	https://www.redcross.org/take-a-class/coronavirus-information/provisional-certification

Commission SBAR Communication

Agenda Item/Title: Monitoring of Drug Therapy: Pharmacists Conducting Health Screenings and Point-of-Care Testing

Date SBAR Communication Prepared: 9/7/2022

Reviewer: Commission Staff

Link to Action Plan:

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

Situation: (Brief Description)

Over the last two years, Pharmacy Quality Assurance Commission (commission) staff have received questions related to the ability of pharmacists to conduct point-of-care (POC) testing and perform health screenings. Specifically, whether it is within the scope of practice for a pharmacist to conduct POC testing and perform health screenings related to a condition the individual has not received a diagnosis for and has not been prescribed any medication to treat.

Background: (Briefly state the pertinent history):

Commission staff have heard that conducting POC testing and performing health screenings on individuals related to a condition the individual has not received a diagnosis for and has not been prescribed any medication to treat is within the scope of practice for a pharmacist because it amounts to the "monitoring of drug therapy."

The scope of practice of a pharmacist is delineated in statute. A pharmacist is permitted to engage in the "practice of pharmacy" (RCW 18.64.011(25)). The Legislature has defined the "practice of pharmacy" to include:

> the practice of and responsibility for: Interpreting prescription orders; the compounding, dispensing, labeling, administering, and distributing of drugs and devices; the monitoring of drug therapy and use; the initiating or modifying of drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs; the participating in drug utilization reviews and drug product selection; the proper and safe storing and distributing of drugs and devices and maintenance of proper records thereof; the providing of information on legend drugs which may include, but is not limited to, the advising of therapeutic values, hazards, and the uses of drugs and devices.

RCW 18.64.011(28).

The Commission has further explained in rule that, in the absence of a collaborative drug therapy agreement (CDTA), "monitoring of drug therapy and use" shall mean:

> a review of the drug therapy regimen of patients by a pharmacist for the purpose of evaluating or rendering advice to the prescribing practitioner or patient regarding the patients drug therapy. Monitoring of drug therapy includes, but is not limited to, the evaluation of the patient through history taking, physical examination, ordering, administering or reviewing laboratory tests, imaging, and social evaluation related to an existing diagnosis and drug therapies for optimization of drug therapy.

WAC 246-945-355.

Taken in aggregate, the Commission's statute and rule does not permit pharmacists from independently engaging in POC testing and health screenings related to a condition an individual has not received a diagnosis for and has not been prescribed any medication to treat, unless the pharmacist is acting pursuant to the terms of a CDTA or other standing order or protocol developed by an interdisciplinary team that includes a prescribing practitioner.

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

Commission staff have concluded that based on current law, pharmacists are authorized to engage in POC testing and health screenings as part of their scope without a CDTA or protocol; however, it must be related to an existing diagnosis and drug therapy as stated in WAC 246-945-355.

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

The commission can reaffirm its rule (WAC 246-945-355) as being in line with the parameters placed in statute and provide licensees with the following clarification:

Pursuant to the terms of a collaborative drug therapy agreement (CDTA), or other standing order or protocol developed by an interdisciplinary team that includes a prescribing practitioner, a pharmacist can:

- Screen individuals for previously undiagnosed acute and chronic conditions and provide a report of the results to the individual;
- Monitor an individual's diagnosed condition, regardless of whether the individual takes medication to treat the diagnosed condition, and report the outcome of monitoring to the patient; and
- Perform CLIA-waived point-of-care testing, interpret the results of this testing, and make recommendations for care to the patient.

In the absence of a CDTA, or other standing order or protocol, a pharmacist can:

- Monitor an individual's diagnosed condition and report the outcome of the monitoring to the individual or prescribing practitioner so long as the individual takes medication to treat their diagnosed condition; and

- Perform CLIA-waived point-of-care testing, interpret the results of this testing, and make recommendations for care to the patient or prescribing practitioner if the individual has received a diagnosis and been prescribed medication to treat the diagnosed condition and the pharmacist is monitoring the individual's drug therapy.

In the absence of a CDTA, or other standing order or protocol, a pharmacist cannot:

- Screen individuals for previously undiagnosed acute and chronic conditions and provide the individual with a report;
- Monitor an individual's diagnosed condition if they have not been prescribed medication to treat the diagnosed condition; and
- Perform CLIA-waived point-of-care testing, interpret the results of this testing, and make recommendations for care to the individual if they do not have a related diagnosis and prescribed medication.

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

Staff will follow-up as determined by the commission.

Pharmacy Quality Assurance Commission
2021-23 Budget & Fund Balance Overview
For the Period of July 1, 2021 through June 30, 2022

Health Professions Account Beginning Fund Balance on July 1, 2021	2,493,136
Revenue To-Date	10,854,403
21-23 HELMS Assessment To-Date	785,167
Expenses To-Date	5,931,823
Health Professions Account Fund Balance as of June 30, 2022	6,630,549

REVENUE	ESTIMATED REVENUE	ACTUAL REVENUE	VARIANCE	% OF ESTIMATED
To-Date	10,571,068	10,854,403	283,335	102.7%
Biennium Total	19,608,317			55.36%

EXPENSES - Health Professions Account	TOTAL BIEN BUDGET	BUDGET TO-DATE	EXPENSES TO-DATE	VARIANCE TO-DATE	VARIANCE TO-DATE %
Staff Salaries and Benefits	2,444,277	2,444,277	2,364,583	79,694	3.3%
Commission Pay	20,400	20,400	4,947	15,453	75.8%
Professional Service Contracts	7,728	7,728	485	7,243	93.7%
Attorney General Support	212,867	212,867	215,482	(2,615)	-1.2%
Goods and Services	45,000	45,000	19,353	25,647	57.0%
Travel	29,425	29,425	29,776	(351)	-1.2%
IT Equipment	14,328	14,328	10,298	4,030	28.1%
WA Recovery Assist. Prog. for Pharmacy (WRAPP)	67,476	67,476	84,126	(16,650)	-24.7%
Intra-Agency Charges - Discipline	783,658	783,658	578,744	204,914	26.1%
Intra-Agency Charges - Credentialing	1,576,275	1,576,275	1,081,782	494,493	31.4%
Intra-Agency Charges - Other	313,106	313,106	269,775	43,331	13.8%
Total Direct Costs	**5,514,540**	**5,514,540**	**4,659,353**	**855,187**	**15.5%**
Agency Indirect Costs	1,946,851	920,301	757,707	162,594	17.7%
Division Indirect Costs	1,300,332	614,645	514,763	99,882	16.3%
Total Indirect Costs	**3,247,183**	**1,534,946**	**1,272,470**	**262,476**	**17.1%**
Grand Total	**8,761,723**	**7,049,486**	**5,931,823**	**1,117,663**	**15.9%**

ACTUAL/PROJECTED FUND ACTIVITY