

WSR 25-07-053

PROPOSED RULES

DEPARTMENT OF HEALTH

[Filed March 12, 2025, 2:18 p.m.]

Original Notice.

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

Title of Rule and Other Identifying Information: Amending outdated references to pharmacy quality assurance commission (PQAC) WAC sections in residential treatment facility, in-home services, ambulatory surgical facilities, and hospital licensing regulations.

The department of health (department) is proposing housekeeping amendments to the following WAC sections to fix incorrect references to PQAC rules:

- WAC 246-320-211 Pharmaceutical services for hospital licensing regulations.
- WAC 246-330-200 Pharmaceutical services for ambulatory surgical facilities.
- WAC 246-335-310 Definitions, 246-335-722 Pharmaceutical services, and 246-335-738 Pharmaceutical services area, sections for in-home services agencies.
- WAC 246-337-105 Medication management for residential treatment facilities.

Hearing Location(s): On May 6, 2025, at 12:00 p.m., virtual hearing. Register in advance for this webinar at https://us02web.zoom.us/webinar/register/WN_yDeZESnDT-Ocs3EQMPJRIg. After registering, you will receive a confirmation email containing information about joining the webinar. You may also submit comments in writing.

Date of Intended Adoption: May 13, 2025.

Submit Written Comments to: Julie Tomaro, Department of Health, P.O. Box 47850, Olympia, WA 98504-7850, email julie.tomaro@doh.wa.gov, <https://fortress.wa.gov/doh/policyreview/>, beginning the date and time of this filing, by May 6, 2025, at 11:59 p.m.

Assistance for Persons with Disabilities: Contact Julie Tomaro, phone 360-236-2937, TTY 711, email julie.tomaro@doh.wa.gov, by April 21, 2025.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: In 2021, PQAC filed WSR 21-05-054, completing a process of consolidating and reorganizing chapters of rule related to pharmacy under Title 246 WAC. During this process, there were a number of WAC chapters relating to pharmacy that were repealed and replaced by chapter 246-945 WAC. The reorganization of the pharmacy or PQAC rules into chapter 246-945 WAC resulted in facility WAC sections with out-of-date references to pharmacy WAC sections that were repealed and replaced by chapter 246-945 WAC.

In the proposed rules, the department has identified the appropriate new cross references in new PQAC chapter 246-945 WAC. WAC 246-337-105 includes a cross-reference to WAC 246-874-010, which defined automatic drug dispensing devices (ADDDs) in the prior version of the pharmacy rules. However, the definition for ADDDs was not carried over into the new pharmacy rules in chapter 246-945 WAC and as a result, there is no section to reference to for the definition of ADDDs. The department is proposing adding the definition of ADDDs that was in former WAC 246-874-010 into 246-337-105. The proposal updates WAC 246-377-105 without changing the effect of the rule as it existed when WAC 246-874-010 was in effect. The proposed change clarifies the

rule as it is not understandable in its current form with a reference to a rule, WAC 246-874-010, which no longer exists.

The purpose of this proposed rule making is to remove the citations to repealed pharmacy rules and replace them with the PQAC rules in chapter 246-945 WAC. The proposed amendments will ensure that the impacted facilities rules are accurate and reduce confusion for impacted facilities.

Reasons Supporting Proposal: Since 2021, the department has been working to update PQAC references across professions and facilities through rule making, as resources allow; however, not all impacted WAC sections have been updated. In October 2024, the department received a petition request for rule making that asked the department to update the pharmacy reference in WAC 246-320-211(1). The petitioner pointed out that the hospital licensing regulations pharmaceutical services section contained an obsolete reference, chapter 246-873 WAC, and requested that the department update the section to reference current PQAC rules in chapter 246-945 WAC.

The department accepted this petition and expanded the rule making to include five additional sections that still had references to the repealed pharmacy WAC sections. Amending the references in these rules to cite to relevant sections in chapter 246-945 WAC will accurately reflect the pharmacy requirements for each facility type.

Statutory Authority for Adoption: RCW 70.41.030, 70.127.130, 70.230.020, and 71.12.670.

Statute Being Implemented: RCW 70.41.030, 70.127.130, 70.230.020, and 71.12.670.

Rule is not necessitated by federal law, federal or state court decision.

Name of Proponent: Department of health, governmental.

Name of Agency Personnel Responsible for Drafting, Implementation, and Enforcement: Julie Tomaro, 111 Israel Road S.E., Tumwater, WA 98501, 360-236-2937.

A school district fiscal impact statement is not required under RCW 28A.305.135.

A cost-benefit analysis is not required under RCW 34.05.328. RCW 34.05.328 (5)(b)(iv) exempts rules that only correct typographical errors or clarify language of a rule without changing its effect. The proposed amendments improve the clarity of the rules by updating incorrect and out-of-date references.

This rule proposal, or portions of the proposal, is exempt from requirements of the Regulatory Fairness Act because the proposal:

Is exempt under RCW 19.85.025(3) as the rules only correct typographical errors, make address or name changes, or clarify language of a rule without changing its effect.

Explanation of exemptions: The proposed changes correct typographical errors and clarify language of a rule without changing its effect.

Scope of exemption for rule proposal:

Is fully exempt.

March 12, 2025
Todd Mountin, PMP
Deputy Chief of Policy
for Jessica Todorovich, MS
Acting Secretary of Health

RDS-6154.1

AMENDATORY SECTION (Amending WSR 09-07-050, filed 3/11/09, effective 4/11/09)

WAC 246-320-211 Pharmaceutical services. This section assures patient pharmaceutical needs are met in a planned and organized manner.

Hospitals must:

- (1) Meet the requirements in chapter ((246-873)) 246-945 WAC; and
- (2) Establish and use a process for selecting medications based on evaluating their relative therapeutic merits, safety, and cost.

RDS-6155.1

AMENDATORY SECTION (Amending WSR 09-09-032, filed 4/7/09, effective 5/8/09)

WAC 246-330-200 Pharmaceutical services. This section assures patient pharmaceutical needs are met in a planned and organized manner. This section is consistent with the requirements for a health care entity license under RCW 18.64.450 and chapter ((246-904)) 246-945 WAC.

An ambulatory surgical facility must:

- (1) Only administer, dispense or deliver legend drugs and controlled substances to patients receiving care in the facility;
- (2) Assure drugs dispensed to patients are dispensed and labeled consistent with the requirements of RCW 18.64.246, and chapters 69.41 and 69.50 RCW;
- (3) Establish a process for selecting medications based on evaluating their relative therapeutic merits, safety, and cost; and
- (4) Designate a pharmacist consultant who is licensed in Washington state. The pharmacist consultant can be either employed or contracted by the facility. The pharmacist consultant is responsible for:
 - (a) Establishing policy and procedures related to:
 - (i) Purchasing, ordering, storing, compounding, delivering, dispensing and administering of controlled substances or legend drugs;
 - (ii) Assuring drugs are stored, compounded, delivered or dispensed according to all applicable state and federal rules and regulations;
 - (iii) Maintaining accurate inventory records and patient medical records related to the administration of controlled substances and legend drugs;
 - (iv) Maintaining any other records required by state and federal regulations;
 - (v) Security of legend drugs and controlled substances; and
 - (vi) Controlling access to controlled substances and legend drugs.
 - (b) Establishing a process for completing all forms for the purchase and order of legend drugs and controlled substances; and

(c) Establishing a method for verifying receipt of all legend drugs and controlled substances purchased and ordered by the ambulatory surgical facility.

RDS-6156.1

AMENDATORY SECTION (Amending WSR 18-06-093, filed 3/6/18, effective 4/6/18)

WAC 246-335-310 Definitions—General. The definitions in this section apply throughout this chapter unless the context clearly indicates otherwise:

(1) "Activities of daily living" or "ADL" means routine activities performed around the home or in the community and includes:

(a) "Ambulation" means how an individual moves between locations in their immediate living environment and how they move to and return from more distant areas. Assistance with ambulation includes supervising or guiding the client or patient when walking alone or with the help of a mechanical device such as a walker, assisting with difficult parts of walking such as climbing stairs, supervising or guiding the client or patient if they are able to propel a wheelchair, pushing of the wheelchair, and providing constant or standby physical assistance to the client or patient if totally unable to walk alone or with a mechanical device.

(b) "Bathing" means how an individual takes a full-body bath or shower, sponge bath, and transfers in and out of the tub or shower. Assistance with bathing includes supervising or guiding the client or patient to bathe, assisting the client or patient with difficult tasks such as getting in or out of the tub or shower, washing their back and other hard to reach areas, and completely bathing the client or patient if they are totally unable to wash themselves.

(c) "Body care" means how an individual performs applications of dressings and ointments or lotions to their body, trims their toenails, and applies lotion to their feet. Assistance with body care includes general skin care and the application of over-the-counter ointments or lotions. Body care excludes foot care for clients or patients who are diabetic or have poor circulation, and changing bandages or dressings when sterile procedures are required.

(d) "Dressing" means how an individual puts on, fastens, and takes off all items of clothing, including donning or removing a prosthesis. Assistance with dressing includes supervising or cueing the client or patient to dress and assisting them with difficult tasks such as putting on socks, pants, shoes, and fastening, zipping, or tying clothing related items.

(e) "Eating" means how an individual eats and drinks, regardless of skill. Assistance with eating includes supervising or guiding the client or patient when they are able to feed themselves, assisting with difficult tasks such as cutting food or buttering bread, and orally feeding the client or patient when they are unable to feed themselves.

(f) "Medication management" means how an individual ingests or applies medications or herbal supplements. Assistance with medication

management includes reminding, coaching, and handing medication containers to the client or patient.

(g) "Personal hygiene" means how an individual maintains their personal hygiene. Assistance with personal hygiene includes helping the client or patient with combing hair, brushing teeth, shaving, applying makeup, washing and drying face, trimming finger nails, applying nail polish, and menses care.

(h) "Positioning" means how an individual moves to and from a lying position, turns side to side, and positions their body while in bed, in a recliner, or other type of furniture. Assistance with positioning includes helping the client or patient to assume a desired position, helping with turning, and setting up for the client or patient to perform exercises or active range of motion. Positioning assistance may also include passive range of motion to maintain joint flexibility or prevent complications, such as contractures and pressure sores.

(i) "Toileting" means how an individual uses the toilet room, commode, bedpan, or urinal. Assistance with toileting includes helping the client or patient to and from the bathroom, assisting with bedpan routines, using incontinent briefs, cleaning after elimination, and assisting the client or patient on and off the toilet.

(j) "Transfer" means how an individual moves between surfaces such as to and from a bed, chair, wheelchair, or standing position. Assistance with transferring includes helping the client or patient with getting in and out of a bed or wheelchair or on and off the toilet or in and out of the bathtub. Transfer includes supervising or guiding the client or patient when they are able to transfer, providing steadying assistance, and helping the client or patient when they are able to assist in their own transfers. This does not include transfers when the client or patient is unable to assist in their own transfer or needs assistive devices unless specific training or skills verification has occurred consistent with agency policies and procedures.

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

(3) "Advanced directive" means a legal document in which a person specifies what actions should be taken for their health if they are no longer able to make decisions for themselves because of illness or incapacity. Advanced directives are not intended to guide the actions of emergency medical personnel.

(4) "Area agencies on aging" or "AAA" means an agency established under 42 U.S.C. chapter 35 and designated by the department of social and health services (DSHS) to contract for home care services on behalf of DSHS.

(5) "Authenticated" means a written signature or unique identifier verifying accuracy of information.

(6) "Back-up care" means substitute care for a client or patient arranged by the agency's administration when caregiving staff, aides, or health services cannot be provided as scheduled.

(7) "Client abandonment" or "patient abandonment" occur when an in-home services agency establishes a care relationship with a client or patient, as evidenced by signed admission forms and plan of care, and the agency ends the care relationship without referring to an appropriate alternative agency or caregiver, or not following applicable discharge requirements in WAC 246-335-420, 246-335-520, and 246-335-620.

(8) "Clinical judgment" means an interpretation or conclusion about a client or patient's needs, concerns, or health problems by a

physician licensed under chapter 18.57 or 18.71 RCW, a podiatric physician and podiatric surgeon licensed under chapter 18.22 RCW, an advanced registered nurse practitioner licensed under chapter 18.79 RCW, a registered nurse licensed under chapter 18.79 RCW, a physical therapist licensed under chapter 18.74 RCW, an occupational therapist licensed under chapter 18.59 RCW, or a speech and language therapist licensed under chapter 18.35 RCW. Clinical judgment includes the decision to take action or not, use or modify standard approaches, or improvise new ones as deemed appropriate by the client or patient's response.

(9) "Contractor" means a person who is self-employed who enters into agreement with an in-home services agency to provide client or patient care services or equipment.

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

(11) "Directed plan of correction" means a plan developed by the department, based on a current statement of deficiencies and a licensee's survey history, which specifies the corrective actions the licensee must take and time frames in which those actions are to be completed.

(12) "Document" means the process of recording information relating to client or patient care verified by signature or unique identifier, title, and date.

(13) "DSHS" means the Washington state department of social and health services.

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

(15) "Health care professional" means an individual who provides health or health-related services within the individual's authorized scope of practice and who is licensed, registered or certified under Title 18 RCW.

(16) "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.

(17) "In-home services category" means home care, home health, hospice, or hospice care center services.

(18) "Instrumental activities of daily living" or "IADL" means routine activities performed around the home or in the community and includes:

(a) "Meal preparation" means how an individual prepares their meals. Assistance with meal preparation includes planning meals for clients or patients, cooking, assembling ingredients, setting out food, utensils, and cleaning up after meals.

(b) "Ordinary housework" means how an individual performs ordinary work around the house. Assistance with ordinary housework includes washing dishes and cookware, dusting, vacuuming, mopping, making bed, tidying up, laundry, taking out garbage, or other like activities.

(c) "Essential shopping" means how an individual completes shopping tasks to meet their health and nutritional needs. Assistance with essential shopping includes trips in the local area to shop for food, medical necessities and household items required specifically for a client or patient's health, maintenance, or well-being. Shopping assistance can be done with a client or patient or on their behalf. Within the context of IADL services, essential shopping does not include client or patient transfer assistance.

(d) "Wood supply" means how an individual supplies their home with wood when wood is used as the sole source of fuel for heating or cooking. Assistance with wood supply includes splitting, stacking, carrying wood, or other like activities.

(e) "Travel to medical services" means how an individual travels by vehicle, bus, or taxi to a physician's office or clinic in the local area to obtain medical diagnosis or treatment. Assistance with travel to medical services includes driving the client or patient yourself, or traveling as a support person in a personal vehicle, bus, or taxi. Within the context of IADL services, travel to medical services does not include client or patient transfer assistance.

(f) "Managing finances" means how an individual manages their personal finances. Assistance with managing finances includes helping the client or patient to pay bills, balance checkbook, or other like activities.

(g) "Telephone use" means how an individual makes and receives telephone calls and text messages. Assistance with telephone use includes bringing a phone to the client or patient, helping with dialing numbers, helping with sending and retrieving text messages, helping with general phone operation, or other like activities.

(19) "Licensee" means the person to whom the department issues the in-home services license.

(20) "Managed care plan" means a plan controlled by the terms of the reimbursement source.

(21) "Mandatory reporter" means an administrator, authorizing practitioner, director of clinical services, health care professional, home care aide, home health aide, medical director, licensed nurse, social worker, supervisor of direct care services, therapist, therapy assistant, volunteer, or other individuals associated with an in-home services agency.

(22) "Medication self-administration with assistance" means reminding or coaching the client or patient to take their medication, handing the medication container to the client or patient, opening the medication container, using an enabler, or placing the medication in the hand of the client or patient, along with other assistance, as defined by the pharmacy quality assurance commission in chapter ~~((246-888))~~ 246-945 WAC.

(23) "Minimum health care credentialing" or "minimum credentialing" means the minimum credential level necessary to provide safe and quality care to adequately meet the care needs of clients and patients:

(a) For home care agencies, minimum health care credentialing is a certified home care aide or higher credential. Minimum health care credentialing is not required for long-term care workers who meet the exemption criteria in chapter 246-980 WAC;

(b) For home health and hospice agencies, minimum health care credentialing is a certified nursing assistant or higher level health care credential necessary to meet patient care needs.

(24) "Nonmedical services" means ADL and IADL tasks which do not require clinical judgment and are ordinarily performed by the client or patient, which if not for the client or patient's functional, physical, or mental limitation(s), would be completed independently by the client or patient, or family.

(25) "Nursing assistant certified" means an individual certified as a nursing assistant under chapter 18.88A RCW.

(26) "Nursing assistant registered" means an individual registered as a nursing assistant under chapter 18.88A RCW.

(27) "Nurse delegation" means the process, as described in RCW 18.79.260 (3)(e), WAC 246-840-910 through 246-840-970, and 246-980-130, a registered nurse takes to transfer the performance of selected nursing tasks in selected situations to competent nursing assistants or home care aides. The registered nurse delegating the task retains the responsibility and accountability for the nursing care of the client or patient. Except for the delegation of the administration of insulin by injection for the purpose of caring for individuals with diabetes, nurse delegation does not include delegating the administration of medications by injection, sterile procedures, and central line maintenance.

(28) "Occupational exposure" means reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of the employee's duties.

(29) "One-time visit" means a single visit by one individual to provide home care, home health, or hospice services with no predictable need for continuing visits, not to exceed (~~twenty-four~~) 24 hours.

(30) "On-site" means the location where client or patient services are provided.

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

(32) "Personnel" means individuals employed and compensated by the licensee.

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

(34) "Plan of correction" means a licensee authored document based on a statement of deficiencies, and includes specific corrective actions that must be taken to correct identified deficiencies to include, but not be limited to:

(a) How the deficiency will be or was corrected;

(b) What measures or monitors will be put in place to ensure the deficient practice does not recur;

(c) Who is responsible for the correction; and

(d) When each deficiency will be corrected.

(35) "Physician orders for life sustaining treatment" or "POLST" means a set of medical orders intended to guide emergency medical personnel in the initial treatment for persons with advanced life limiting illness based on their current medical condition and goals. The POLST form is not a living will or advanced directive but a physician order that communicates the details of those documents.

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

(37) "Range of motion" or "ROM" means the extent or limit to which a part of the body can be moved around a joint or a fixed point; the totality of movement a joint is capable of doing. ROM exercises are active or passive movements to assess, maintain, or restore the motion of joints in the body. Active and passive ROM are defined as:

(a) "Active range of motion" means independent exercises performed by an individual to restore or maintain their joint function to its optimal range (may require cuing or reminders by an agency worker).

(b) "Passive range of motion" means exercises performed by a trained individual to restore or maintain an individual's joint func-

tion to its optimal range when they are unable to independently move their joint. Passive ROM involves performing movements to each joint only to the extent the joint is able to move. Passive ROM, for either restoration or maintenance purposes, may be performed by home health agencies, hospice agencies, and hospice care centers following the established program. Passive range of motion, for maintenance purposes only, may be performed by home care agencies.

(38) "Record" means all documented information, regardless of its characteristics, media, physical form, and the manner in which it is recorded or stored.

(39) "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.

(40) "Statement of deficiencies" means a survey or investigation report completed by the department identifying one or more violations of chapter 70.127 RCW or this chapter. The report clearly identifies the specific law or rule that has been violated along with a description of the reasons for noncompliance.

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

(42) "Vital signs" means clinical measurements, specifically pulse rate, temperature, respiration rate, and blood pressure that indicate the state of a client or patient's essential body functions.

(43) "Volunteer" means an individual who provides direct care to a client or patient and who:

(a) Is not compensated by the in-home services licensee;

(b) May be reimbursed for personal mileage incurred to deliver services; and

(c) Is considered a mandatory reporter.

Volunteers providing services to vulnerable persons are considered permissive reporters and are subject to the mandatory reporting laws in chapters 74.34 and 26.44 RCW.

(44) "Vulnerable person" means a person:

(a) (~~Sixty~~) 60 years of age or older who has the functional, mental, or physical inability to care for himself or herself;

(b) Found incapacitated under chapter 11.88 RCW;

(c) Who has a developmental disability as defined under RCW 71A.10.020;

(d) Admitted to any facility; or

(e) Receiving services from home care, home health, or hospice agencies licensed or required to be licensed under chapter 70.127 RCW.

AMENDATORY SECTION (Amending WSR 18-06-093, filed 3/6/18, effective 4/6/18)

WAC 246-335-722 Pharmaceutical services. The licensee must ensure that all pharmaceutical services are provided consistent with chapter ((246-865)) 246-945 WAC and the following requirements:

(1) Pharmaceutical services must be available ((~~twenty-four~~)) 24 hours per day to provide medications and supplies through a licensed pharmacy;

(2) A licensed pharmacist must provide sufficient on-site consultation to ensure that medications are ordered, prepared, disposed, secured, stored, accounted for and administered in accordance with the policies of the center and chapter ((246-865)) 246-945 WAC;

- (3) Medications must be administered only by individuals authorized to administer medications;
- (4) Medications may be self-administered in accordance with ((WAC 246-865-060 (7)(f))) chapter 246-945 WAC;
- (5) Drugs for external use must be stored apart from drugs for internal use;
- (6) Poisonous or caustic medications and materials including housekeeping and personal grooming supplies must show proper warning or poison labels and must be stored safely and separately from other medications and food supplies;
- (7) The hospice care center must maintain an emergency medication kit appropriate to the needs of the center;
- (8) Medications brought into the hospice care center by patients to be administered by an appropriate health care professional while in the center must be specifically ordered by an authorizing practitioner and must be identified by a pharmacist or licensed nurse with pharmacist consultation prior to administration;
- (9) Drugs requiring refrigeration must be kept in a separate refrigeration unit;
- (10) Schedule II through IV controlled substances must be:
 - (a) Kept in a separate keyed storage unit;
 - (b) When heat sensitive, be kept in a locked refrigeration unit;and
 - (c) When no longer needed by the patient, disposed of in compliance with chapter ((246-865)) 246-945 WAC;
- (11) In addition to the requirements in subsection (10) of this section, schedule III and IV controlled substances must be:
 - (a) Stored apart from other drugs; or
 - (b) Stored on a separate shelf, drawer, or compartment with schedule II controlled substances;
- (12) The hospice care center must provide for continuation of drug therapy for patients when temporarily leaving the center in accordance with ((WAC 246-865-070)) chapter 246-945 WAC;
- (13) If planning to use an automated drug distribution device, the hospice care center must first receive pharmacy quality assurance commission approval; and
- (14) If planning to provide pharmacy services beyond the scope of services defined in this section, the hospice care center must comply with the requirements for a licensed pharmacy in chapter ((246-869)) 246-945 WAC.

AMENDATORY SECTION (Amending WSR 18-06-093, filed 3/6/18, effective 4/6/18)

- WAC 246-335-738 Pharmaceutical services area.** (1) Pharmaceutical services area(s) must be accessible only to authorized personnel.
- (2) A hospice care center must provide pharmacy services area(s) consistent with ((WAC 246-865-050)) chapter 246-945 WAC which include adequate space for:
 - (a) A work counter;
 - (b) A handwash sink;
 - (c) A soap and paper towel dispenser;
 - (d) Drug storage units constructed of metal, solid wood, or plywood which provide:
 - (i) Locked storage for all drugs;

- (ii) Separate keyed storage for Schedule II through IV controlled substances;
 - (iii) Segregated storage for each patient's drugs;
 - (e) A lockable refrigerator for storage of heat sensitive drugs;
- and
- (f) Other storage needed according to the hospice care center's functional program.

RDS-6159.1

AMENDATORY SECTION (Amending WSR 18-06-092, filed 3/6/18, effective 4/16/18)

WAC 246-337-105 Medication management. The licensee is responsible for implementing policies and procedures for the control and appropriate use of all drugs within the RTF in accordance with all applicable state and federal regulations. The policies and procedures to implement this section must be developed, approved, and reviewed by a health care prescriber and the RTF administrator, and must be consistent with this chapter.

(1) Procurement. Timely procurement of drugs must be achieved in one or more of the following ways:

(a) A pharmacy licensed under chapter 18.64 RCW provides resident specific drugs by prescription order to the RTF;

(b) A prescriber purchases drugs from a licensed wholesaler and is responsible for the drugs;

(c) The RTF is listed as a hospital pharmacy associated clinic under a hospital pharmacy license in accordance with chapter 18.64 RCW and applicable rules adopted by the Washington state pharmacy quality assurance commission;

(d) The RTF holds a health care entity license under chapter 18.64 RCW and purchases drugs consistent with chapter ((246-904)) 246-945 WAC; and

(e) The resident brings his or her prescribed medication with them to the RTF.

(2) Storage and security.

(a) Storage of drugs must include limits on access to drugs to those staff authorized to assist, administer, or dispense drugs and addresses security, safety, sanitation, temperature, light, moisture and ventilation, and hand washing facilities. All drugs must be stored in accordance with United States pharmacopoeia standards and designated storage locations are constructed in accordance with WAC 246-337-126.

(b) Automated drug dispensing devices (ADDDs). For the purposes of this section, an ADDD (~~has the same meaning as defined in WAC 246-874-010~~) includes, but is not limited to, a mechanical system controlled remotely by a pharmacist that performs operations or activities, related to the storage, counting, and dispensing of drugs to a credentialed health care professional consistent with their scope of practice. "ADDD" does not include technology that solely counts or stores, kiosks, robots, emergency kits, supplemental dose kits, or automation for compounding, administration, or packaging. ADDDs may be used to store drugs if:

(i) The ADDD is leased or owned by a prescriber who maintains sole responsibility for the drugs;

(ii) The RTF holds a health care entity license under chapter 18.64 RCW and complies with chapter ~~((s 246-874 and 246-904))~~ 246-945 WAC; or

(iii) The RTF is operated in connection with a licensed hospital and complies with chapter ~~((246-874))~~ 246-945 WAC and rules of the pharmacy quality assurance commission governing hospital pharmacy associated clinics.

(3) Inventory of stock drugs. The licensee shall document:

(a) Receipt and disposal of all drugs;

(b) Inventory of legend drugs;

(c) Inventory of controlled substances biennially, including:

(i) Keep all controlled substance records for a minimum of two years;

(ii) Have two authorized staff verify shift counts of controlled substances when transfer of accountability occurs. If an ADDD is used, staff must follow the policies and procedures developed for the ADDD; and

(iii) Report to the Washington state pharmacy quality assurance commission if the controlled substance counts or inventory indicate disappearances or unaccounted for discrepancies of controlled substances in accordance with ~~((WAC 246-873-080 and 246-887-020))~~ chapter 246-945 WAC, and 21 C.F.R. Sec. 1301.76(b).

(4) Prescribing and administering drugs.

(a) An organized system must be established and maintained that ensures accuracy in receiving, transcribing and implementing orders for medication administration that ensures residents receive the correct medication, dosage, route, time, and reason.

(b) An authorized health care prescriber shall sign all written orders for legend drugs, controlled substances and vaccines. Orders, including telephone or verbal orders for legend drugs, controlled substances and vaccines must be signed as soon as possible, but no later than ~~((seventy-two))~~ 72 hours after the telephone or verbal order has been issued.

(c) If using electronic prescribing, prescribers shall comply with RCW 69.50.312, chapter ~~((246-870))~~ 246-945 WAC, and 21 C.F.R. Sec. 1311(c).

(d) A prescriber shall approve the use of self-administered non-prescription drugs. Staff shall provide the nonprescription drugs according to prescriber instructions.

(e) A prescriber shall:

(i) Develop an approved list of nonprescription drugs acceptable for residents that includes the parameters of use for each drug; and

(ii) Review and approve the list annually.

(f) The licensee shall address the way(s) medications are administered including:

(i) Staff-administered medication in which licensed staff operating within their scope of practice remove the drug from the container and provide it to the resident for ingestion or otherwise administer the drug to the resident;

(ii) Observed self-administration of medication in which residents obtain their container of medication from a supervised and secure storage area, remove the dose needed, ingest or otherwise take the medication as directed on the label while being observed by staff;

(iii) Independent self-administration of medication in which residents obtain their container of medication from either a supervised

and secure storage area or from their personal belongings, remove the dose needed, ingest or otherwise take the medication as directed on the label without being observed by staff; or

(iv) Involuntary antipsychotic medication administration consistent with WAC 388-865-0570.

(g) Medication administration errors, adverse effects, and side effects must be reported and addressed;

(h) The licensee shall develop a policy and procedure for:

(i) The use, receipt, storage and accountability for residents receiving methadone from an outpatient methadone clinic, if applicable; and

(ii) Drugs given to a resident on temporary leave from the RTF.

(5) Documentation. All medications administered, observed being self-administered, or involuntarily administered must be documented on the medication administration record, including:

(a) Name and dosage of the medication;

(b) Parameters of use;

(c) Date the medication order was initiated;

(d) Date the medication order was discontinued;

(e) Time of administration;

(f) Route;

(g) Staff or resident initials indicating medication was administered, or observed being self-administered;

(h) Notation if medication was refused, held, wasted or not administered or observed being self-administered;

(i) Allergies; and

(j) Resident response to medication when given "as needed."

(6) RTF staff must have available to them a current established drug reference resource.

(7) For the purposes of this section:

(a) Controlled substance has the same meaning as defined in RCW 69.50.101; and

(b) Legend drugs has the same meaning as defined in RCW 69.41.010.