Chapter 246-874 WAC
PHARMACY AND TECHNOLOGY

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WAC

WAC 246-874-010 Definitions. The following definitions apply to this chapter, unless the context clearly indicates otherwise:

(1) "ADDD" or "automated drug dispensing device" 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.

(2) "Blind count" means a physical inventory on the ADDD taken by a pharmacist or other Washington state credentialed health care professional acting within their scope of practice, as determined by the responsible manager, who performs a physical inventory without knowledge of or access to the quantities currently shown on electronic or other inventory systems.

(3) "Commission" means the Washington state pharmacy quality assurance commission.

(4) "Controlled substances" has the same meaning as defined in RCW 69.50.101.

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

(6) "Dispense" or "dispensing" means the interpretation of a prescription or order for a legend drug and, pursuant to that prescription or order, the proper selection, measuring, labeling, or packaging necessary to prepare that prescription or order for delivery. For purposes of part 1 of this chapter, dispensing by an ADDD does not include compounding.

(7) "Electronic verification system" means an electronic verification, bar code verification, radio frequency identification (RFID), weight verification, or similar electronic process that accurately verifies that medications have been properly dispensed by, labeled by, or loaded into an ADDD.

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

(9) "Override" means the process by which credentialed health care professionals, acting within their scopes of practice, are permitted to access and remove from an ADDD certain legend drugs, including controlled substances, prior to prospective drug utilization review and approval by a pharmacist.

(10) "Override list" means a list of medications, tailored to the health care facility based on the nature of care delivered, which are subject to retrieval without prospective drug utilization review.

(11) "Part 1" means WAC 246-874-020 through 246-874-070.

(12) "Pharmacist" has the same meaning as defined in RCW 18.64.011.

(13) "Pharmacy technician" has the same meaning as defined in RCW 18.64A.010.

(14) "Prospective drug utilization review" means the evaluation and approval of medication orders by a pharmacist prior to administration of the first dose.

(15) "Replenishment" includes checking stock, loading, unloading, filling and refilling of medications in the ADDD.

(16) "Responsible manager" has the same meaning as WAC 246-869-070, and is synonymous with WAC 246-865-060, 246-873-040, and 246-904-030.

(17) "Secure area" means that drugs are stored in a manner to prevent unmonitored access by unauthorized individuals.

(18) "Supervision" means overseen directly by a pharmacist, who is on the premises or indirectly by an electronic verification system for managing of ADDD inventory.

[Statutory Authority: RCW 18.64.005 and chapter 18.64 RCW. WSR 17-07-027, § 246-874-010, filed 3/7/17, effective 4/7/17.]

PART 1
AUTOMATED DRUG DISPENSING DEVICES

WAC 246-874-020 General applicability. (1) Part 1 sets the requirements for an ADDD managed by licensed pharmacies under chapter 18.64 RCW, health care entities as defined in RCW 18.64.011, health care facilities as defined in RCW 70.38.025, assisted living facilities as defined in RCW 18.20.020, nursing homes as defined in RCW 18.51.010, health maintenance organizations as defined in RCW 70.38.025, and public health centers as defined in RCW 70.40.020, and any other entity authorized by the commission, that choose to use them.

(2) Use of an ADDD that conforms to the requirements in part 1 does not require approval by the commission. Pharmacies, including nonresident pharmacies shall provide written notice on a form provided by the department of the physical address of the facilities where ADDDs they manage or serve are located.

(3) Previously approved facilities using ADDDs shall have one year from the effective date of (date will be added by the code reviser office) to comply with part 1.

(4) Nothing in part 1 is applicable to technology that solely counts or stores, kiosks, robots, emergency kits, supplemental dose kits, or automation for compounding, administration, or packaging.

[Statutory Authority: RCW 18.64.005 and chapter 18.64 RCW. WSR 17-07-027, § 246-874-020, filed 3/7/17, effective 4/7/17.]

WAC 246-874-025 Responsible manager designation requirement for an ADDD. Each pharmacy and facility using an ADDD shall designate a responsible manager, who is a pharmacist licensed in Washington state. The responsible manager is responsible for oversight of the ADDDs, and to assure that drugs are procured, stored, delivered, and dispensed in

compliance with all applicable state and federal statutes and regulations.

[Statutory Authority: RCW 18.64.005 and chapter 18.64 RCW. WSR 17-07-027, § 246-874-025, filed 3/7/17, effective 4/7/17.]

WAC 246-874-030 General requirements for an ADDD. (1) The pharmacy and any facility using an ADDD shall have written policies and procedures in place prior to any use of an ADDD. The responsible manager shall review the written policies and procedures at least annually and make the necessary revisions. The pharmacy or facility must document the required annual review and make the annual review available upon request by the commission or its designee. Electronic documents made available on a computer at the facility or pharmacy are permissible.

(2) The pharmacy or facility must maintain a current copy of all policies and procedures related to the use of the ADDD and make them available within the pharmacy or facility where the ADDD is located and make available upon request to the commission or its designee. Electronic documents made available on a computer at the facility or pharmacy are permissible.

(3) The policies and procedures must include, but are not limited to:

(a) All sections of part 1;

(b) User privileges based upon user type;

(c) Criteria for selection of medications subject to override and an override list approved by the pharmacy or facility's pharmacy and therapeutics committee or equivalent committee;

(d) Diversion prevention procedures; and

(e) Record retention and retrieval requirements that adhere to all state and federal laws and regulations. Records must be retained for a minimum of two years.

(4) An ADDD shall collect and maintain all transaction information including, but not limited to, the identity of the individuals accessing the system and identity of all personnel loading the ADDD, to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability. The pharmacy or facility must maintain all records of transactions and make available upon request to the commission or its designee. Electronic documents made available on a computer at the facility or pharmacy are permissible.

(5) Inventory control.

(a) Authorized personnel must place drugs into the ADDD in the manufacturer's original sealed unit dose or unit-of-use packaging, in repackaged unit-dose containers, or in other suitable containers to support patient care and safety, and in accordance with federal and state laws and regulations;

(b) When applicable, patient owned medications that have been properly identified and approved for use per the facility's policies, may be stored in accordance with policies for safe and secure handling of medication practices.

(6) The responsible manager may designate a Washington state credentialed health care professional acting within their scope of practices as a designee to perform tasks in part 1. The responsible manager shall retain all professional and personal responsibility for any assisted tasks performed by personnel under his or her responsibility, as shall the pharmacy employing such personnel.

[Statutory Authority: RCW 18.64.005 and chapter 18.64 RCW. WSR 17-07-027, § 246-874-030, filed 3/7/17, effective 4/7/17.]

WAC 246-874-040 Security and safety requirements for ADDD. (1) The responsible manager shall ensure adequate security systems and procedures for the ADDD, addressing access, including:

(a) A system by which secure access of users is obtained by such methods as biometrics or some other secure technology; and

(b) Prevention of unauthorized access or use, including:

(i) System access for former employees, or individuals whose access or privileges have been changed or terminated, must be removed immediately or inactivated upon notification; and

(ii) Discharged patients shall have patient profiles removed from the ADDD as soon as possible but no later than twelve hours from notification of the discharge.

(2) The responsible manager or designee shall assign, discontinue, or change user access and types of drug privileges for accessing an ADDD. Access to the ADDD must be limited to those Washington state credentialed health care professionals acting within their scope of practice. Access to the ADDD by facility information technology employees or employees of similar title must be properly restricted and addressed in policies and procedures.

(a) Replenishment of medications in an ADDD is reserved to:

(i) A pharmacist, pharmacy intern, or a pharmacy technician under the supervision of a pharmacist; or

(ii) A Washington state licensed registered nurse or licensed practical nurse may replenish an ADDD using an electronic verification system, that ensures exact placement of secured compartments into the ADDD;

(b) Pharmacists must provide an independent double check of all medications to be distributed to an ADDD in the absence of an approved specialized function or electronic verification system used in stocking an ADDD. A pharmacy technician that meets the criteria for specialized functions in WAC 246-901-035(1) may also provide the independent double check in place of a pharmacist. Electronic verification system checking or other approved technology may be used in place of an independent manual double check.

(3) A pharmacist shall perform prospective drug utilization review and approve each medication order, except if:

(a) The drug is a subsequent dose from a previously reviewed drug order;

(b) The prescriber is in the immediate vicinity and controls the drug dispensing process;

(c) The system is being used to provide access to medications on override and only a quantity sufficient to meet the immediate need of the patient is removed; or

(d) When twenty-four hour pharmacy services are not available.

(4) When twenty-four hour pharmacy services are not available, a pharmacist shall perform retrospective drug utilization review within six hours of the pharmacy being open, except when a dispensed override medication is a one-time dose or order for discharged patients.

(5) The pharmacist shall reconcile and review all medication orders added to a patient's profile outside of the facility's normal admission discharge transfer process and procedures, no later than the next business day.

(6) Medications or devices may only be returned directly to the ADDD for reissue or reuse consistent with policy and procedures for safe and secure medication processes, which include, but are not limited to:

(a) Medications or devices stored in unsecured patient specific bins, matrices, or open pockets, such as home medications or multiple use patient specific bottles may be returned to an ADDD so long as adequate controls are in place to ensure proper return. Controlled substances cannot be returned to unsecured patient specific bins, matrices, or open pockets.

(b) Medications stored in patient specific containers may not be returned to general stock for reuse.

(7) The responsible manager shall ensure a method is in place to address breach of security of the ADDD including, but not limited to:

(a) Tracking of malfunction and failure of the ADDD to operate correctly; and

(b) Downtime procedures in the event of a disaster or power outage that interrupts the ability of the pharmacy to provide services.

(8) An ADDD used in an assisted living facility must be located in a secure area. The area where the ADDD is located and the ADDD shall be locked when not in use.

[Statutory Authority: RCW 18.64.005 and chapter 18.64 RCW. WSR 17-07-027, § 246-874-040, filed 3/7/17, effective 4/7/17.]

WAC 246-874-050 Accountability requirements for an ADDD. (1) The facility shall have a mechanism for securing and accounting for wasted, discarded, expired, or unused medication removal from the ADDD according to policies and procedures and existing state and federal laws and regulations.

(2) The responsible manager shall implement procedures and maintain adequate records regarding use and accountability of legend drugs, including controlled substances, in compliance with state and federal laws and regulations including, but not limited to:

(a) A system to verify the accuracy of controlled substance counts shall include:

(i) Controlled substances must be perpetually inventoried with a blind count each time they are accessed in an ADDD; except for controlled substances dispensed in dose specific amounts by an ADDD to a Washington state credentialed health care professional acting within their scope of practice without access to the remaining controlled substance inventory; or

(ii) All controlled substances that are accessed for replenishment in an ADDD shall have an inventory count performed at that time. When replenishment or removal has not occurred, an inventory count shall occur at a minimum, once every seven days by two authorized persons licensed to handle drugs.

(b) Controlled substances must be stored in individually secured pockets or compartments within the ADDD. Storage in "matrix" drawers or open pocket drawers is prohibited.

(c) Facilities using a closed canister system must have a system to verify the accuracy of controlled substance counts by perpetual inventory that is regularly reviewed and reconciled by pharmacy staff.

(d) Controlled substance discrepancy monitoring and resolution, which includes:

(i) The responsible manager shall work with the facility or nursing administration to maintain an ongoing medication discrepancy resolution and medication monitoring process; and

(ii) A discrepancy report must be generated for each transaction where the count of a drug on hand in the device, does not reflect actual inventory. All resolved and open discrepancies must be reviewed by the responsible manager or designee within seven calendar days; and

(iii) Comply with all state and federal Drug Enforcement Administration reporting requirements.

(3) Wasted controlled substances. All controlled substances wasted shall have a witness, who is a Washington state credentialed health care professional, acting within their scope of practice; the record of waste shall be authenticated by both persons. A waste record must be readily retrievable in the ADDD, electronic health record, or as a hard copy report in accordance with the facility's policies and procedures. The report of waste shall include patient name, drug name, drug strength, date and time of waste, the amount wasted, and the identity of the person wasting and the witness. Waste records must be maintained for a minimum of two years.

[Statutory Authority: RCW 18.64.005 and chapter 18.64 RCW. WSR 17-07-027, § 246-874-050, filed 3/7/17, effective 4/7/17.]

WAC 246-874-060 Quality assurance process requirements for ADDD. Each pharmacy and facility shall establish and maintain a quality assurance and performance program that monitors performance of the ADDD, which is evidenced by written policies and procedures that are made readily available on request to the commission or its designee. Electronic documents made available on a computer at the facility or pharmacy are permissible. The responsible manager shall perform annual audits of compliance with all ADDD policies and procedures. The quality assurance program shall include, but is not limited to:

(1) Method for ensuring accurate replenishment of the ADDD;

(2) Procedures for conducting quality control checks of drug removal for accuracy;

(3) Method for reviewing override data and medication error data associated with ADDD and identifying opportunities for improvement.

[Statutory Authority: RCW 18.64.005 and chapter 18.64 RCW. WSR 17-07-027, § 246-874-060, filed 3/7/17, effective 4/7/17.]

WAC 246-874-070 Nursing students ADDD access. If a facility provides a clinical opportunity for nursing students enrolled in a Washington state nursing commission approved nursing program, a nursing student may access the ADDD only under the following conditions:

(1) Nursing programs shall provide students with orientation and practice experiences that include demonstration of competency of skills prior to using an ADDD;

(2) Nursing programs, health care facilities, and pharmacies shall provide adequate training for students accessing ADDD; and

(3) The nursing commission approved nursing programs, health care facilities, and pharmacies shall have policies and procedures for nursing students to provide medication administration safely, including:

(a) Access and administration of medications by nursing students based on student competencies;

(b) Orientation of students and faculty to policies and procedures related to medication administration and distribution systems; and

(c) Reporting of student medication errors, near misses and alleged diversion.

[Statutory Authority: RCW 18.64.005 and chapter 18.64 RCW. WSR 17-07-027, § 246-874-070, filed 3/7/17, effective 4/7/17.]