

Chapter 246-874
(Pharmacy and Technology)

Part 1
Automated Drug Dispensing Devices

NEW SECTION

WAC 246-874-010 Definitions

The following definitions apply throughout Part 1 of this chapter, unless the context clearly indicates otherwise:

- (1) "ADDD" or "automated drug dispensing device" includes, but are 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, but does not include technology that solely counts or stores, kiosks, robots, emergency kits, supplemental dose kits, or automation for compounding or administration.
- (2) "Blind count" means a physical inventory on the ADDD taken by a Washington state licensed pharmacist or other qualified health care professional acting within their scope of practice, as determined by the PIC who performs a physical of 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" shall have the same meaning as defined in RCW 69.50.101(e).
- (5) "Department" means the Washington state department of health.
- ~~(6)~~ (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 this part, dispensing by ADDD does not include compounding.
- ~~(6)~~ (7) "Direct supervision" means a pharmacist who provides guidance to pharmacy personnel and evaluation of pharmacy tasks, is on the premises, and is quickly and easily available.
- ~~(7)~~ (8) "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, labeled by or loaded into an ADDD.
- ~~(8)~~ (9) "Legend drugs" shall have the same meaning as defined in RCW 69.41.010(12).
- ~~(9)~~ (10) "Override" shall mean the process by which appropriately licensed health care professionals, consistent with their scopes of practice, are permitted to access and remove from ADDD certain legend drugs, including controlled substances, prior to prospective drug

utilization review and approval by a pharmacist. Only emergency medications may be subject to override.

~~(10)~~(11) "Override list" means a list of emergency 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)~~(12) "Pharmacist" means a person licensed by the Washington state pharmacy quality assurance commission to engage in the practice of pharmacy.

~~(12)~~(13) "Pharmacist -in-charge" (PIC) means a pharmacist who has the responsibility for ensuring compliance with all laws and regulations governing the operation of their respective pharmacy, and is synonymous with "responsible manager" in WAC 246-869-070, director of pharmacy or pharmacist designee in WAC 246-873-040, director of pharmaceutical services, staff pharmacist or consultant pharmacist in WAC 246-865-060, and pharmacist in-charge in WAC 246-904-030.

~~(13)~~(14) "Pharmacy technician" shall have the same meaning as defined in RCW 18.64A.010.

~~(14)~~(15) "Prospective drug utilization review" means the evaluation and approval of medication orders prior to administration of the first dose by a Washington state licensed pharmacist to:

- (a) Ensure patient safety by intercepting prescribing errors; and
 - (b) Ensure the right of every patient to twenty-four hour pharmacist access and care.
- Prospective drug utilization review need not occur prior to administration of emergency medications.

~~(16)~~ "Replenishment" includes checking stock, loading, unloading, filling and refilling of medications in the ADDD.

~~(15)~~(17) "Secure area" means that drugs are stored in a manner to prevent unmonitored access by unauthorized individuals.

WAC 246-874-020 General applicability.

(1) This ~~part~~Part sets the requirements for an ADDD in licensed pharmacies, health care entities as defined in RCW 18.64.011(13), health care facilities as defined in RCW 70.38.025(6), assisted living facilities as defined in RCW 18.20.020(2), nursing homes as defined in RCW 18.51.010(3), health maintenance organizations as defined in RCW 70.38.025(7), and public health centers as defined in RCW 70.40.020(5) that choose to use them.

(2) Use of an ADDD that conforms to the requirements in this Part does not require approval by the commission. Pharmacies, including non-resident pharmacies shall provide written notice on a form provided by the department of the physical address of the facilities where ADDDs are located.

(3) Nothing in this Part is applicable to technology that solely counts or stores, kiosks, robots, emergency kits, supplemental dose kits, or automation for compounding or administration.

NEW SECTION

WAC 246-874-021 Pharmacist-in-charge designation requirement for an ADDD.

Each pharmacy and facility using an ADDD shall designate a pharmacist-in-charge (PIC), a pharmacist who shall be licensed in Washington state. The PIC shall be responsible for oversight of the se devices ADDDs, and to assure that drugs are procured, stored, delivered and dispensed in compliance with all applicable state and federal statutes and regulations.

WAC 246-874-030 General requirements for an ADDD.

- (1) The pharmacy and any facility utilizing an ADDD shall have written policies and procedures in place prior to any use of an ADDD. The PIC shall review the written ~~Written~~ policies and procedures ~~shall be reviewed~~ at least annually by the PIC, with and make necessary revisions ~~made~~. The required annual review shall be documented and made available upon request by the commission or its designee.
- (2) A current copy of all policies and procedures related to the use of the system shall be maintained and available within the pharmacy or facility where the ADDD is located. Electronic documents made available on a computer at the facility or pharmacy are permissible.
- (3) At a minimum, the policies and procedures shall address all of the following:
 - (a) All sections of the Part;
 - (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 ~~plan~~ 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, 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. Records of transactions shall be maintained and readily available on request.
- (5) Inventory Control

~~The PIC with the pharmacy and therapeutics or equivalent committee shall approve the ADDD drug inventory;~~

- ~~(a) (a) Drugs placed in the ADDD shall be 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 are in accordance with federal and state laws and regulations;~~
- ~~(b) (b) When applicable, patient owned medications, which remain in the original prescription bottle, that have been properly identified, and have been approved for use per the facility's policies, may be stored in an ADDD in a specific bin or compartment or otherwise segregated may be stored in accordance with policies for safe and secure handling of medication practices.~~

~~(6) The PIC may designate a pharmacist designee to perform tasks in this Part. The PIC 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.~~

Comment [tw1]: Taken from WAC 246-863-095 – Pharmacist's professional responsibilities.

NEW SECTION

WAC 246-874-040 Security and safety requirements for ADDD.

- (1) The PIC 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 shall be removed immediately upon notification; and
 - (ii) Discharged patients shall have patient profiles removed from the ADDD as soon as possible but no later than 12 hours from notification of the discharge.
- (2) The PIC or licensed pharmacy designee shall assign, discontinue, or change user access and types of drug privileges to the ADDD. Access to the ADDD shall be limited to those Washington state licensed health care practitioners 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 a pharmacist, pharmacy intern, or a pharmacy technician under the direct supervision of a pharmacist or as approved by the Commission under WAC 246-901-100, a nurse may replenish an

ADDD utilizing an electronic verification barcoding system, which ensures exact placement of secured compartments into the ADDD;

- (b) Pharmacy technicians checking the accuracy of a second pharmacy technician's medication selections to be replenished into an ADDD without a pharmacist's final approval shall meet the criteria for specialized functions in WAC 246-901-~~034035~~(1) and have documentation of training on file. All technician specialized functions shall be approved by the commission prior to implementation.
 - (c) The pharmacy commission may approve electronic verification system checking or other approved technology used in place of manual double-checking of the medications stocked in the ADDD. Such pharmacy commission approval shall be done prior to implementation of such technology. ~~Electronic verification system checking, or other approved technology may be used in place of manual double checking of medication stocking of the ADDDs.~~
- (3) A pharmacist shall perform prospective drug utilization review and approve each medication order prior to dispensing of a drug 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; or
 - (c) The system is being used to provide access to emergency medications on override and only a quantity sufficient to meet the immediate need of the patient is removed. Only medications needed to prevent death or severe adverse health consequences may be designated as emergency medications. Except for acute care settings, a pharmacist shall perform retrospective drug utilization review in this case within 24 hours.
- (4) Patient profiles added outside the normal admission discharge transfer process, shall be reconciled by a pharmacist no later than the next business day.
- (5) No medication or device shall be returned directly to the ADDD for reissue or reuse unless appropriate technological safeguards are in place and used during the return process to ensure accurate inventory return.
- (a) Medications stored in patient specific bins 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.

Comment [tw2]: Changed to reflect current practice, which requires commission approval of these systems.

Sepi asked for this to be clarified, Gordon and Lisa R. both feel the electronic verification systems are specialized functions and should require approval from the commission.

- (b) Medications stored in patient specific containers may not be returned to general stock for reuse.
- (6) The PIC 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.
- (7) An ADDD used in an assisted living facility must be located in a secure area, with both the area where the ADDD is located and the ADDD are locked when not in use.

NEW SECTION

WAC 246-874-050 Accountability requirements for an ADDD.

- (1) The ADDD 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 PIC 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, including but not limited to:
 - (i) Controlled substances shall be perpetually inventoried with a blind count by a Washington state licensed pharmacist or other qualified health care professional acting within their scope of practice, as determined by the PIC each time they are accessed in an ADDD; except for controlled substances in one unit dose packaging dispensed from an ADDD to the practitioner per transaction, and access the rest of the controlled substance inventory is restricted.
 - (ii) All controlled substances that are accessed for replenishment or removal in an ADDD shall have an inventory count performed at a minimum of once every 7 days by two authorized persons licensed to handle drugs; and
 - (iii) Controlled substances shall be stored in individually secured pockets or compartments within the ADDD. Storage in “matrix” drawers or open pocket drawers is prohibited.
 - (b) Controlled substance discrepancy monitoring and resolution, which includes:

- (i) The PIC shall work with the facility or nursing administration to maintain an ongoing medication discrepancy resolution and medication monitoring process; and
 - (ii) A discrepancy report shall be generated for each discrepancy in the count of a drug on hand in the device. Each such report shall be resolved by the PIC or pharmacist designee and the facility or nursing administration or nurse designee. If there is an unresolved discrepancy after seventy-two (72) hours of the time the discrepancy was discovered, ~~or and~~ if determined to be a theft or a significant loss of drugs, the PIC shall report to the commission and the federal Drug Enforcement Administration as required by federal law;
- (3) Wasted controlled substances.
- (a) The ADDD shall be capable of producing a hard-copy report of wastage that shall show patient name, drug name and strength, dose withdrawn, date and time of waste, the amount wasted, and the identity of the person wasting and the witness;
 - (b) All controlled substances wasted shall have a witness, who is licensed to administer or dispense drugs, both the person wasting and the witness must countersign the waste and it shall be recorded in the ADDD.

NEW SECTION

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 system, which is evidenced by written policies and procedures. The PIC 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 for drug removal for accuracy;
- (3) Method for reviewing override data and medication error data associated with ADDD and identifying opportunities for improvement.

NEW SECTION

WAC 246-874-100 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 utilizing an ADDD;
- (2) Nursing programs, healthcare 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 policies and procedures for:
 - (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.

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