Chapter 246-874

(Pharmacy and Technology)

Part 1

Automated Drug Dispensing Devices

NEW SECTION

WAC 246-874-010 Definitions

The following definitions apply to WAC 246-874-010 through WAC 246-874-070, 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 licensed health care professional acting within their scope of practice, but 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 licensed health care professional acting within their scope of practice, determined by the PIC 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 this part, dispensing by 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, 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 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.

(10) “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) “Part” means Part 1 of chapter 246-874 WAC.

(12) "Pharmacist" means a person who is licensed under chapter 18.64 RCW by the commission to engage in the practice of pharmacy.

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

(14) “PIC” or “pharmacist-in-charge” 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 WAC 246-869-070, WAC 246-873-040, WAC 246-865-060, and WAC 246-904-030.

(15) “Prospective drug utilization review” means the evaluation and approval of medication orders prior to administration of the first dose by a 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.

(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.

NEW SECTION

WAC 246-874-020 General applicability.

(1) This Part sets the requirements for an ADDD managed by licensed pharmacies under RCW 18.64, 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, 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 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) Previously approved facilities using ADDDs shall have one year from the effective date of (provided by Code Reviser) to comply with this part.

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

NEW SECTION

WAC 246-874-025 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 is licensed in Washington state. The PIC 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.

NEW SECTION

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 PIC shall review the written policies and procedures at least annually and make necessary revisions. The pharmacy or facility must document the required annual review and make available upon request by the commission or its designee.

(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. 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 this 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 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. The pharmacy or facility must maintain and make readily available on request all records of transaction.

(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 are in accordance with federal and state laws and regulations;

(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 accordance with policies for safe and secure handling of medication practices.

(6) The PIC may designate a pharmacy 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.

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 twelve 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 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 a pharmacist, pharmacy intern, a pharmacy technician under the supervision of a pharmacist, or a nurse may replenish an ADDD using an electronic verification system, that 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 246-901-035 and have documentation of training on file. All technician specialized functions must be approved by the commission prior to implementation.

(c) 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 of the pharmacy being open.

(4) The pharmacist shall reconcile patient profiles added outside the normal admission discharge transfer process, no later than the next business day.

(5) Medication 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 patient specific bins, matrix, or open pockets, excluding controlled substances, 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.

(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 the area where the ADDD is located and the ADDD 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) All controlled substances must be perpetually inventoried with a blind count by a pharmacist or other licensed health care professional acting within their scope of practice, determined by the PIC, each time they are accessed in an ADDD; except for controlled substances dispensed in dose specific amounts by an ADDD to a licensed health care professional acting within their scope of practice without access to the remaining controlled substance inventory.

(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 seven days by two authorized persons licensed to handle drugs; and

(iii) Controlled substances must 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 must be generated for each transaction where the count of a drug on hand in the device, does not reflect actual inventory. Each report must be resolved by the PIC or pharmacy designee and the facility or nursing administration or nurse designee. If there is an unresolved discrepancy after seventy-two (72) hours from the time the discrepancy was discovered, 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) A hard-copy report of wastage 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 sign the waste and must 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 ADDD, 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 246-874-070 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, healthcare facilities, and pharmacies shall provide adequate training for students accessing ADDDs; 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.