Explanations of changes made to preliminary draft proposed rule regarding Automated Drug Dispensing Devices.

On February 5th, 2016 a stakeholder meeting was held to discuss a preliminary draft rule which attempted to update the rules around the use of automated drug distribution devices. At that meeting it was discussed that the draft distributed was too prescriptive and had a number of other unworkable flaws. Stakeholders, including the three commissioners in attendance, agreed the rule needed to be higher level and more global in nature.

Staff agreed to revisit the draft language. Stakeholders suggested that the preliminary draft could possibly be used as a template or guidance document for the rule, but overall needed more work. After discussion with the Sepi Soleimanpour, chair of the technology subcommittee, direction was given to draft the preliminary proposed rule as ADDD specific.

The ultimate goal will be to create a new chapter (as contemplated in the CR-101) relating to "Technology and Pharmacy". In that chapter there will be a general umbrella language rule regarding technology use in the practice of pharmacy, with other sections broken out to address specific technologies. The ADDDs rule would be the first specific breakout.

As a result of this direction, the attached draft is similar to the original preliminary draft distributed but has had changes made. Below please find a description of changes made.

The editing process began by looking at the following documents:

1. Current WAC 246-872
2. Draft #8, the most recent draft circulated by the technology workgroup;
3. The preliminary draft released on 12/30/15 and discussed on 2/5/16;
4. Draft language and comments from committee member commissioners; and
5. Guidelines and research from American Society of Health-System Pharmacists (ASHP) and the Institute for Safe Medication Practices (ISMP), and other states.

The rule as it is currently written appears to embody the spirit and guidance of both the ASHP and ISMP. Information was then taken from the documents and consolidated into the attached draft.

Section	Comments/Changes
Generally	Removed number references until we can identify where this rule will be placed in the current WAC numbering system.
Definition of ADDDs	- Changed back to ADDD rather than automated medication systems "AMS". The preliminary proposed rule language is specific to ADDDs while AMS is a more comprehensive of technology systems. - Added language to exclude certain technologies, making it more clear this rule only applies to ADDDs. - Removed "An ADDD shall collect, and maintain all transaction information, including … accountability." Definitions are not supposed to have enforceable

	requirements in them. Similar language was moved to general requirements section.
Definition of "Blind count"	- Replaced "hands on count of" with "physical"; - Clarified the count can be made by a WA licensed pharmacist or health care professional, as determined by the PIC, acting within their scope of practice. - Per commissioner input deleted "The ability to access or the knowledge of the count of inventory eliminates the count from qualifying as a 'blind count'."
Definition of "Dispensing"	Commissioners mentioned the definition may be problematic and should possibly be reserved for people dispensing. Changed the definition to be in alignment with statutory definition, RCW 69.41.010(5).
Definition of "Diversion"	After discussion, staff felt this definition was not needed, and reasonable understood in the profession.
Definition of "Emergency medications"	Replaced "emergent" with "emergency" but for the time being removed this definition, and inserted language regarding emergency medications as qualifying language after override in the Safety & Security Section (3)(c)
Definition of "Immediate use"	Definition removed, since emergency medications were qualified later in the document, staff felt this definition was no longer necessary since term was not used elsewhere in the preliminary proposed rule.
Definition of Privilege List	Definition no longer required. Reworded and placed in general requirements as necessary under policy and procedure requirement.
Definition of "Repackager" and "Repackaged"	Initially staff added a definition for "repackager", but later determined these definitions might not be necessary since repackaging is an industry understood term.
General Applicability Section	- Added language to require pharmacies and non-resident pharmacies to inform the commission of the locations of ADDDs they are stocking. The purpose of this language will help inspectors know what facilities have an ADDD machine so they can adequately prepare for their inspections. - Clarified the facilities the rule applies too. - Added clarifying language that this rule is solely applicable to ADDDs machines and called out specific technologies the rule does not

	apply too.
PIC Section	Restructured the language in hopes of making it clearer that there **does not** need to be a PIC assigned specifically for ADDDs.
Policy and Procedures Section	Changed the title to "General requirements for an ADDD."
General requirement section	- Changed language in (2) to clarify where the policies and procedures should be located, and allowing the electronic documentation of P&Ps. - Additionally, the minimum requirements were written to provide more clarity, and less prescription. - Added some language previously found in inventory control. - Added language allowing for the storing of patient owned medications. - Removed any redundant language.
Security Requirements	Changed the title to "Security and Safety Requirements"
Security and Safety	The prevention of unauthorized use now includes the removal of former employees, immediately upon notification, and discharged patients timeline was changed from immediately to 12 hours. This was to reflect current rule. - Clarified replenishment standard; - Included the ability for RNs and LPNs to replenish in LTC settings for ekits and supplemental dose kits, as allowing in current SB 6203. - Language was changed to allow electronic verification systems without commission approval needed. - Moved prospective/retrospective drug utilization review to this section.
Consolidation and deletion Inventory control sections	Consolidated these requirements into the Security and Safety section, and created a section specific to Controlled Substances in ADDDs. Deleted language regarding: - Override - Removed Medications - Returned Medications - Wasted Medications - Expired Medications - Interfacing requirement - Delivery Record - Language regarding e-kit and

	supplemental dose kit restrictions (deleted entirely) Removed, returned, wasted, and expired medications were consolidated into general language and can be found in general requirements. Override was moved to requirement of prospective drug utilization review. Interface and delivery record were completely deleted, at stakeholder and commissioner request do to workability issues.
Accountability Req.	- In the inventory replenishment count of controlled substances every 7 days it was suggested that the authorized personal should be licensed to handle <u>not</u> solely administer. - Changed language regarding persons to perform blind count to align with addition in definition. - Added language restricting use of matrix drawers for controlled substances. - Added language to address breach of security, including tracking of malfunctions, and downtime procedures.
Removed separate section on prospective drug utilization review	Consolidated in Security and Safety.
Quality Assurance	Revised the entire section, per commissioner input.
Added Nursing student ADDD access language	This was done to isolate the language agreed to by PQAC and NCQAC.

Part 1

Automated Drug Dispensing Devices

WAC 246-XXX-XXX Definitions

(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, 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) "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" shall have the same meaning as defined in RCW 69.41.010(12).

(9) "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) "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) "Pharmacist" means a person licensed by the Washington state pharmacy quality assurance commission to engage in the practice of pharmacy.

(12) “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) "Pharmacy technician" shall have the same meaning as defined in RCW 18.64A.010.

(14) “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.

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

WAC 246-XXX-XXX General applicability.

(1) This 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) choose to use them.

(2) Use of an ADDD that conforms to the following requirements does not require approval by the commission. Pharmacies, including non-resident pharmacies shall inform the commission of the location of all ADDDS which they are stocking.

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

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

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

WAC 246-XXX-XXX 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. Written policies and procedures shall be reviewed at least annually by the PIC, with 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 part 1 of this chapter;

(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; 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

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

(b) 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 other suitable containers to support patient care and safety and are in accordance with federal and state laws and regulations;

(c) When applicable, patient owned medications, which remain in the original prescription bottle, that have been properly identified, and approved for use per the facilities policies, may be stored in an ADDD in a patient specific bin.

WAC 246-XXX-XXX 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 discharge.

(2) The PIC 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 supervision of a pharmacist;

(b) In long term care facilities, a registered nurse or licensed practical nurse operating under appropriate direction and supervision by a pharmacist may replenish an ADDD being utilized as an emergency kit or supplemental dose kit, as defined in chapter 246-865 WAC, to provide for safe and timely patient access. Pharmacists shall ensure the qualified nurses are properly trained to carry out this function.

(c) 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 246-901-034(1) and have documentation of training on file. All technician specialized functions shall be approved by the commission prior to implementation.

(d) 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 administration 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 is removed to meet the immediate need of the patient. Only medications needed to prevent death or severe adverse health consequences may be designated as emergency medications. 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.

(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 ADD, 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.

WAC 246-XXX-XXX 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 dispensed from an ADDD in a fashion that only (1) unit-dose package is

given to the practitioner per transaction when requested by the practitioner. This fashion of dispensing must give the practitioner access to that one (1) unit-dose package only and not the rest of the 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 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 not permitted.

(b) Discrepancy monitoring and appropriate discrepancy 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 if determined to be a theft or a 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 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, licensed to administer drugs, countersign the waste and it shall be recorded in the ADDD.

WAC 246-XXX-XXX 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 quarterly 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.

WAC 246-XXX-XXX Nursing students ADDD access.

If a facility provides a clinical opportunity for nursing students enrolled in a Washington state nursing commission approved nursing programs, nursing students 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.