



STATE OF WASHINGTON
DEPARTMENT OF HEALTH

Olympia, Washington 98504

**PHARMACY TECHNOLOGY COMMITTEE
WORKGROUP MEETING**

Washington State Department of Health
Kent Regional Office
20425 72nd Avenue S, Building 2, Suite 319
Kent, WA 98032 Room #309

February 5, 2016

AGENDA

TOPIC	SCHEDULED TIME
I. Introductions	1:30 – 1:40 pm
II. Background information on preliminary draft of AMS rules, including comments received to date	1:40 – 2:00 pm
III. Discussion of preliminary draft & Public Comment	2:00 – 3:15 pm
IV. Discuss possible scheduling of next meeting	3:15 – 3:30 pm
V. Adjourn	3:30 pm

WAC 246-874-010 Definitions

- (1) "AMS" or "automated medication system" includes, but are not limited to, a mechanical system that performs operations or activities, related to the storage, counting, dispensing, or distribution of drugs, but does not include compounding or administration. An AMS shall collect, and maintain all transaction information, including but not limited to the identity of the individuals accessing the system, to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.
- (2) "Blind count" means a physical inventory on the AMS taken by a Washington state licensed health care practitioner who perform a hands-on count of inventory without knowledge of or access to the quantities currently shown on electronic or other inventory systems. The ability to access or the knowledge of the count of inventory eliminates the count from qualifying as a "blind count."
- (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, the proper selection, labeling and packaging of a legend drug, including controlled substances for delivery. For purposes of this chapter, dispensing by AMS does not include measuring or compounding.
- (7) "Diversion" means the possession, use, prescription for use, or distribution of legend drugs, including controlled substances, in any way other than for legitimate or therapeutic purposes.
- (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 AMS.
- (9) "Emergent medications" means drugs that are necessary for immediate lifesaving patient care to prevent death or serious impairment of health. The absence of such drugs could reasonably be expected to result in placing the patient's health in serious jeopardy;
- (10) "Interface" means a connection between two or more pieces of electronic equipment to allow communication between software systems.
- (11) "Immediate use" means the administration of emergent medications.
- (12) "Legend drugs" shall have the same meaning as defined in RCW 69.41.010(12).

- (13) "Override" shall mean the process by which appropriately licensed health care practitioners, consistent with their scopes of practice, are permitted to access and remove from AMS certain legend drugs, including controlled substances, prior to prospective drug utilization review and approval by a pharmacist. Only emergent medications may be subject to override.
- (14) "Override list" means a list of emergent medications, tailored to the health care facility based on the nature of care delivered, which are subject to retrieval without prospective drug utilization review.
- (15) "Pharmacist" means a person licensed by the Washington state pharmacy quality assurance commission to engage in the practice of pharmacy.
- (16) "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.
- (17) "Pharmacy technician" shall have the same meaning as defined in RCW 18.64A.010.
- (18) "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 emergent medications.
- (19) "Privilege List" means a record of functions that can be performed in the AMS based upon the various health care practitioner licensures and their scopes of practice in administering drugs.
- (20) "Repackaged" means the act of taking a finished drug product from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the drug. Repackaging also includes the act of placing the contents of multiple containers (e.g., vials) of the same finished drug product into one container, as long as the container does not include other ingredients. If a drug is

manipulated in any other way, including if the drug is reconstituted, diluted, mixed, or combined with another ingredient, that act is not considered repackaging.

- (21) “Replenishment” includes checking stock, loading, unloading, filling and refilling of medications in the AMS.

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WAC 246-874-020 General applicability.

This chapter sets the requirements for an AMS in licensed pharmacies, non-resident pharmacies, health care entities as defined in RCW 18.64.011(13), health care facilities as defined in RCW 70.38.025(6), health maintenance organizations as defined in RCW 70.38.025(7), public health centers as defined in RCW 70.40.020(5), and medical facilities as defined in RCW 70.40.020(7) that choose to use them. Use of an AMS that conforms to the following requirements does not require approval by the commission.

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

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

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WAC 246-874-030 Policies and procedures requirements for an AMS.

- (1) The pharmacy and any facility utilizing an AMS shall have written policies and procedures in place prior to any use of an AMS. 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 at all facility locations where the system is being used, as well as at the pharmacy of the PIC.
- (3) At a minimum, the policies and procedures shall address all of the following :
 - (a) A master list documenting:
 - (i) Name, and address where the AMS is located, and if multiple devices or multiple locations, all locations and device type;
 - (ii) AMS manufacture name, model, and serial numbers;
 - (iii) Facility license number where AMS is located and corresponding responsible pharmacy license number from which drugs are supplied;
 - (iv) Name of the PIC; and
 - (v) Description of how device is used.
 - (b) AMS system operation including, but not limited to a list of all drugs stocked in each respective machine and which drugs if any are subject to override.
 - (c) Maintenance, including manufacturer's schedules and recommendations for maintenance of the AMS and a plan for maintenance of all related documentation for the life of the device.
 - (d) Addresses all requirements set forth in WAC 246-874-021 – WAC 246-874-080.

WAC 246-874-040 Security requirements for AMS.

- (1) The PIC shall assure the device has an adequate security system and procedures for the AMS, 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.
- (2) The PIC shall have adequate security systems and procedures for the AMS, addressing access, including:
 - (a) Only those Washington state licensed health care practitioners, acting within their scope of practice, who are employed at the facility, shall access the AMS. At least a monthly check to ensure system access is limited to these individuals shall occur;
 - (b) Facility information technology employees or employees of similar title shall not have access to the drugs or privileges into the AMS unit containing the drugs; and
 - (c) 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 AMS only under the following conditions:
 - (i) Nursing programs shall provide students with orientation and practice experiences that include demonstration of competency of skills prior to utilizing an AMS;
 - (ii) Nursing programs, healthcare facilities, and pharmacies shall provide adequate training for students accessing AMS; and
 - (iii) 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; and
 - (d) Privilege list indicating:

- (i) Which health care practitioners can access AMS and list of specific privileges permitted within each type of practitioner's scope of practice; and
 - (ii) What specific privileges nursing students will have while enrolled in a Washington state nursing commission approved nursing program.
- (3) The AMS shall provide a mechanism to record the person accessing the device to fill, select, retrieve, inventory, or stock medications. Records shall be maintained and readily retrievable on-site;
- (4) System access for former employees shall be removed immediately;
- (5) Discharged patients shall be removed immediately;
- (6) Patient profiles added outside the normal admission discharge transfer process, shall be reconciled by a pharmacist no later than the next business day. On at least a daily basis, the PIC, or his or pharmacy designee, shall run an Added Patient, or equivalent, report to ensure reconciliation has occurred;
- (7) The PIC shall have the sole responsibility to:
 - (a) Assign, discontinue or change access to the system;
 - (b) Ensure that access to the medications comply with state and federal regulations; and
 - (c) Ensure that the AMS is stocked accurately and in accordance with established, written policies and procedures; and
- (8) Comply with applicable state and federal laws and regulations, including all state and federal laws and regulations pertaining to patient confidentiality; and
- (9) The PIC shall perform quarterly audits of compliance with the AMS policies and procedures.

WAC 246-874-050 Inventory control requirements for an AMS.

(1) Replenishment:

- (a) The PIC shall approve the AMS drug inventory;
- (b) The PIC shall implement procedures and maintain adequate records regarding use and accountability for legend drugs;
- (c) Replenishment of the AMS is reserved to a pharmacist, pharmacy intern, or a pharmacy technician under the supervision of a pharmacist;
 - (i) Pharmacy technicians checking the accuracy of a second pharmacy technician's medication selections to be replenished into AMS without a pharmacist final approval shall meet the criteria for specialized functions in WAC 246-901-035(1) and have documentation of the training on file in the pharmacy. All pharmacy technician specialized functions shall be approved by the commission prior to implementation;
 - (ii) All electronic verification system checking, or other approved technology, used in place of manual double-checking of the medications stocked in the AMS. shall be approved by the commission prior to implementation; and
- (d) Drugs placed in the AMS shall be in the manufacturer's original, sealed unit dose or unit-of-use packaging or in repackaged unit-dose containers in accordance with federal and state laws and regulations; and
- (e) If an AMS is utilized, drugs normally contained in a separate emergency kit or supplemental dose kit shall be stocked into the AMS. Only emergent medications defined on the override list may be accessed prior to receiving prospective approval from the pharmacist provided that the absence of the drugs would threaten the survival of the patient.

(2) Controlled substances: The PIC shall implement procedures and maintain adequate records regarding use and accountability of 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 or other legend drugs determined by the PIC shall be perpetually inventoried with a blind count by a Washington state licensed health care practitioner each time they are accessed in AMS;

- (ii) All controlled substances that are accessed for replenishment or removal in AMS shall have an inventory count performed at a minimum of once every 7 days by two authorized persons licensed to administer drugs. At least one of these persons shall be a licensed nurse; and
 - (iii) Controlled substances shall be stored in individually secured pockets or compartments within the AMS;
- (b) A record of medications replenished or inventoried including identification of the person accessing the AMS shall be readily retrievable and maintained by the PIC; and
- (c) 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 which involves pharmacy when necessary; 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 and the facility or nursing administration. 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;
 - (iii) If the AMS is located in a hospital, the PIC shall work with the nursing administration to resolve such report by the end of the shift.
- (3) Override:** Medications ordered that are defined on the override list may be removed prior to a pharmacist's prospective drug utilization review. The pharmacist shall perform retrospective drug utilization review on these medication orders within next business day.
- (4) Removed Medications** The AMS shall be capable of producing on-demand, a hard-copy record of distribution that shall show patient name, drug name and strength, dose removed, dose to be administered, date and time of removal from the device, and identity of person removing the drug. Records shall be readily retrievable and stored in accordance with state and federal laws and regulations for a minimum of 2 years.
- (5) Returned Medications:** A drug removed from a system but not administered to a patient may be returned to the AMS return bin or other area designated by the PIC only if the drug remains unopened, sealed, intact, and is properly stored. Records shall be readily

retrievable and stored in accordance with state and federal laws and regulations for a minimum of 2 years.

(6) Wasted Medications

- (a) The AMS shall be capable of producing on-demand, a hard-copy record of wastage that shall show patient name, drug name and strength, dose withdrawn, dose to be administered, date and time of withdrawal from the device, identity of person withdrawing the drug, the amount wasted, and the identity of the witness;
- (b) All controlled substances wasted shall have a witness licensed to administer drugs countersign the waste and it shall be documented and recorded in the AMS; and
- (c) Records shall be readily retrievable and stored in accordance with state and federal laws and regulations for the life of the device.

(7) Expired Medications:

- (a) There shall be a defined process for securing and accounting for expired medications.; and
- (b) On at least a monthly basis the PIC, or his or her pharmacy designee, shall run an expired drug report and appropriately manage medications soon to expire.

(8) A mechanism to record all medication Records shall be readily retrievable and stored in accordance with state and federal laws and regulations for the life of the device

(9) The AMS shall be interfaced with the medication order software system to prevent such removal of medications until the prospective drug utilization review and approval has occurred.

(10) Delivery Record:

- (a) Prior to removal of drugs from the pharmacy, a delivery record shall be generated for all drugs to be placed in the AMS which shall include the date; drug name; dosage form; and strength; quantity; health care entity; and a unique identifier for the specific device receiving drugs; and initials of pharmacist checking the list of drugs to be removed from the pharmacy and the records of distribution accuracy; and
- (b) At the time of loading medications into the AMS, the delivery record for all drugs shall be signed by a nurse or other person authorized to administer drugs from that specific device, and the record returned to the pharmacy.

WAC 246-874-060 Prospective Drug Utilization Review Requirement for AMS.

- (1) A pharmacist shall perform prospective drug utilization review of the prescription or medication order prior to any removal from the AMS, except if:
 - (a) The system is being used to provide access to emergent medications on override and only a quantity sufficient is removed to meet the immediate use of the patient;
 - (b) The drug is a subsequent dose from a previously reviewed drug order; or
 - (c) The prescriber controls the drug dispensing process when there is no delegation.
- (2) The hospital pharmacy shall provide twenty-four hour prospective drug utilization review services.

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WAC 246-874-070 Quality assurance process requirements for AMS.

Quality assurance process shall include but is not limited to:

- (1) Establishing a quality assurance program prior to implementation of a system and the supervision of an ongoing quality assurance program that monitors appropriate use and performance of a system which is evidenced by written policies and procedures;
- (2) Method for ensuring accurate replenishment of the AMS;
- (3) Method for reviewing override data and medication error data associated with AMS and identifying opportunities for improvement. On at least a daily basis the PIC, or his or her pharmacy designee, shall run an override or similar report to reconcile that prescriber's orders are matched against all controlled substances and legend drugs that have been dispensed subject to an override;
- (4) Procedures for conducting quality control checks for drug removal for accuracy;
- (5) Method to assign, discontinue or update authorized access to the AMS;
- (6) Maintain or have access to all records of documentation relating to the AMS being used for the life of the device or as otherwise required by law;
- (7) Establish a mechanism for securing and accounting for waste or unused; medications removed from the AMS according to policies and procedures, and existing state and federal law;
- (8) Use of the data collected to take action to ensure quality of care and make improvements to the AMS;
- (9) Method to detect failure of the AMS to operate correctly along with the documentation on the frequency of any failures and the repairs completed;
- (10) Reconciliation of inventory discrepancies within twenty-four (24) hours of discovery. Investigative reports shall be part of quality assurance reporting. On at least a daily basis, the PIC, or his or her pharmacy designee, shall run discrepancy reports to ensure appropriate resolution;
- (11) Method for maintaining uninterrupted drug supply and service during AMS system downtimes or breakdowns;
- (12) Procedures for recalls to include procedures to avoid mixing lot numbers of drugs added to the AMS; and
- (13) Documentation of the outcomes of the quality assurance activities.

Summary of Comments on AMS Draft Rule

Compiled from emailed stakeholder comments accepted through January 15th, 2016

	Comment	From	Response
	General-Overall Comment		
1	<p>I am wondering if the draft WAC 246-874 will replace WAC 246-872 or merely supplement it. If the two WAC chapters will co-exists, they appear to be redundant and/or conflicting. Also, if a facility is not included in the general applicability of WAC 246-874-020 (e.g. a dentist's office), then can/how would such an entity operate an AMS/ADDD? In other words, is the intent of the draft WAC to restrict the use of AMS to only those entities listed in WAC 246-874-020?</p>	<p>Nathan E. Deen, Assistant Attorney General Office of the Attorney General, Washington State University</p>	<p>To answer your first question, the draft language numbered as WAC 246-874 would replace current WAC 246-872. Which means we plan to repeal all current sections under WAC 246-872. We have not fully decided or confirmed whether we will make an entire new chapter, or simply create a new numbering scheme under WAC 246-872.</p> <p>Secondly, the intent of the draft is not to restrict use outside of the stated facilities. If a practitioner-prescriber is exclusively responsible for the drugs, i.e. ordering them from a wholesaler, possessing the DEA registration in his or her name if controlled substances are located there, accounting for the drugs via recordkeeping, etc., then the question of AMS use should be directed to the practitioner-prescriber's licensing authority, i.e. is the ownership, use, etc. of the AMS within the prescriber's scope of practice.</p> <p>If the practitioner-prescriber is working within a health care entity, and the health care entity purchases the drugs from a wholesaler, possesses the DEA registration, and is the responsible licensee for the accounting/recordkeeping regarding the drugs, then the AMS is subject to the regulations of the Pharmacy Commission.</p> <p>I hope this information is helpful. Please let me know if you have any further questions.</p>
2	<p>Finally, I'd like to suggest that there be a chapter containing a statement to the effect that "devices which contain private health information (PHI) are to have their electronic storage media completely erased or destroyed prior to removal from the facility." How many second-hand fax machines out there today continue to store, in their internal memory, PHI records that were transmitted electronically?</p> <p>I thank you for taking the time to review these comments and to consider them in the spirit that they are offered. I look forward to these future WACs becoming the cornerstone of the work being carried out by the other Technology Committee subcommittees in order to advance our profession more rapidly into a high-tech era.</p>	<p>Richard Molitor</p>	

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	Comment	From	Response
3	CVS Health believes that some of the requirements applicable to long-term care, medical facility or hospital technology may not appropriately apply to technology employed in a licensed pharmacy area.	Lauren Berton, PharmD, Director, Pharmacy Regulatory Affairs, CVS Health	
4	In closing, I value the approach that these proposed rules represent in attempting to “future proof” interpretation of new technologies as they enter the marketplace. However, the focus on AMS to include both profiled dispensing systems and electronic emergency kits without regard to the inherent differences that these contain is a concern. Thank you very much for working with stakeholders during this rulemaking process and considering my comments to the proposed rules.	Brian Beach, PharmD, CFO Kelley-Ross Pharmacy Group	
5	<p>Good morning</p> <p>We are considering the use of a fully automated, self-contained dispensing machine produced by Insty-Meds (www.instymeds.com) which licenses the machine as a wholesaler. Our intent is to have the machine help facilitate physician dispensing. I understand physician dispensing is allowed in Washington State and all the rules that go along with it.</p> <p>I cannot tell if the proposed rules would apply in this instance to this machine in a physician-dispensing setting. It appears the rules are aimed at units like Pyxis or Omnicell which are usually tied to a hospital pharmacy.</p> <p>Please help me understand the intent of the proposed rules.</p>	Nathan Lawless, RPh Manager, Clinical Pharmacy The Everett Clinic	<p>Thank you for your comments. The intent of the draft is regulate the use of automated medication systems in hospital, health care entity, pharmacy and similar settings as identified in the draft WAC 246-874-020.</p> <p>If a practitioner-prescriber is exclusively responsible for the drugs, i.e. ordering them from a wholesaler, possessing the DEA registration in his or her name if controlled substances are located there, accounting for the drugs via recordkeeping, etc., then the question of AMS use should be directed to the practitioner-prescriber’s licensing authority, i.e. is the ownership, use, etc. of the AMS within the prescriber’s scope of practice.</p> <p>If the practitioner-prescriber is working within a health care entity, and the health care entity purchases the drugs from a wholesaler, possesses the DEA registration, and is the responsible licensee for the accounting/recordkeeping regarding the drugs, then the AMS is subject to the regulations of the Pharmacy Commission.</p> <p>I hope this information is helpful. Please let me know if you have any further questions.</p>

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	Comment	From	Response
	<p>(CONT.) This “triple oversight” structure is unique to VTH Pharmacy. We provide pharmacy services for animals not humans. The strict application of all pharmacy laws and rules are problematic because such regulations are predicated on assumptions related to pharmacy operations inhuman health care settings.</p> <p>Our pharmacy plans to implement the CUBEX Automated Medication System to improve control of medications in areas that are currently using a manual cabinet-type system for floor stock medications. Authorization and use of medications from floor stock (manual cabinets or AMS) is legally provided by veterinarians or licensed veterinary technicians under current state and federal law. We will provide an additional level of quality control beyond what is required by law by assigning cabinet stocking decisions and higher level auditing duties to licensed pharmacy staff. Our initial installation of AMS units is planned for the surgical suites, the intensive care unit, and the large animal area.</p>	<p>Debra C. Sellon, DVM, PhD, Director, Veterinary Teaching Hospital – Washington State Univ.</p>	
General-Overall Comment - Additional Technology, Kiosks & Robots			
8	<p>Hope all is well. I have been serving on several of the technology rules committees, and understand from talking to Lisa Roberts that the process has changed dramatically. I have a question about the draft AMS rules. Is the intent that these will be the only automated dispensing rules? Or will there be other rules drafted to address patient accessible systems? I had proposed language to a couple of my committees addressing that type of technologies, and the language made its way into some of the early drafts (see attached). The proposed draft AMS rules are broad enough that they could include this type of technology, but if there are not going to be any additional rules proposed, I may offer a few comments to clarify that the AMS rules permit patient accessible systems in clinics, retail pharmacies, EDs and other locations where access to pharmacy services is needed. Thanks, and best wishes for a happy, healthy, and prosperous 2016.</p>	<p>Ed Rickert, Partner Quarles & Brady LLP</p>	<p>Good Afternoon, My understanding was that these kiosk type devices were not being addressed in this last Rule modification/revision that was sent out. But, there will be more discussion once stakeholder commentary is received and reviewed. I would definitely provide your thoughts and suggestions to the website Technologyrules@doh.wa.gov for consideration. Thank you and Happy New Year, Rich</p>

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	Comment	From	Response
9	<p>Asteres-automated prescription and OTC pickup kiosks: Under the proposed rules, a system such as ours falls under the definition of an AMS in WAC 246-874-010 (1). Under WAC 246-874-020 General applicability, our AMS conforms to the health care facility placement of such a unit however nonconformance with some of the specific requirements in WAC 246-874-040, WAC 246-874-050, WAC 246-874-060, and WAC 246-874-070 would require prior approval by the commission. Will there be a provision or method for a variance to the new rules? Currently, WAC 246-895-170 Variance and Procedure provides a mechanism for a manufacturer to submit documentation to the Commission for system approval. Unfortunately, the variance only applies to WAC 246-895-040 through WAC 246-895-160. I have also attached the current regulations for Wisconsin. I think they do a good job putting in requirements for the technology without being so specific that only certain types of AMS technology pertains. They have also included regulations for Remote Dispensing Sites which allows for the placement of the AMS in non-licensed buildings. Something like this will allow for expansion into sites such as correctional facilities, rehab centers, corporate sites and LTC while still maintaining oversight and control by the PQAC. Please don't hesitate to reach out with any additional comments or questions.</p>	Sara Lake, Marketing Manager and Regulatory Affairs, Asteres Inc.	In my telephone conversation with Sara, I suggested she email me her thoughts, and identify the sections she felt were not applicable to her product. I have included those comments in the body of this document by section.
10	CVS Health also would like the Commission and Technology Committee to consider whether the proposed rules adequately account for the various types of "in-pharmacy" technology (i.e., Parata, ScriptPro) that is used for "counting", "dispensing", or packaging of medication prior to final dispensing of a patient's prescription drug order.	Lauren Berton, PharmD, Director, Pharmacy Regulatory Affairs, CVS Health	
General-Overall Comment (Electronic Storage)			
11	I encourage the committee developing the proposed WAC's to consider language that supports the electronic storage of ADC (AMS) information. A central location of storage is common but is readily available on-site when needed. Please see attached for additional recommendations to the proposed WAC's.	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	

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Rule Section - 010 - Definitions-General		
12	It seems like the intent here is to cover devices like Pyxis and Talyst for remote first does, or unit of use telepharmacy dispensing machines. However, the initial definition seems like it would also arc into covering robots inside a retail pharmacy that are packaging into vials or strips such as a Scriptpro or Parata.	Charles Ho, Harrison Medical Center
Rule Section - 010 (1) - Definitions - "AMS"		
13	This can very easily be confusion with Antimicrobial Stewardship that it is getting a lot of press lately. The main purpose of these machines is distribution or dispensing so maybe calling them ADM (Automated Distribution Machines) or ADC (Automated Drug Cabinets) could differentiate them a bit more. Does this system mean one device or multiple devices?	Xheni Waggoner, PharmD, Northwest Hospital & Medical Center, UWMedicine
14	Suggest add "remote" before storage	Xheni Waggoner, PharmD, Northwest Hospital & Medical Center, UWMedicine
15	Note: This definition excludes mechanical systems used for storing drugs in pharmacy areas. Just wanted to make sure that this definition does not include carousels or robots used just for drug storage in pharmacy for which only pharmacy staff have access to.	Xheni Waggoner, PharmD, Northwest Hospital & Medical Center, UWMedicine
16	the storage, counting, dispensing, or and distribution of drugs The challenge with this saying "or" this definition could be very far reaching and apply to other technology where this WAC may not apply (e.g. Carousel systems within a central hospital pharmacy, ScriptPro in a retail setting, etc.)	Julie Doung, PharmD, Pharmacy IT Coordinator, Northwest Hospital & Medical Center
17	Does this broad definition allow for technology/systems beyond ADDD? For example, does this cover prescription 'vending machines?' Please clarify.	Cindy Wilson, PharmD, Manager, Pharmacy 340B Program, CHI Franciscan Health

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	Comment	From	Response
18	<p>Automated medication system is new terminology and is too broad for the scope of the proposed WAC's (which tend to focus specifically on automated dispensing cabinets "ADC"). I propose that the WAC's focus on Automated Dispensing Cabinets. I support the use of nationally recognized terminology and discourage the use of definitions that are not nationally recognized and transferable to other states. Other definitions in the proposed WAC's should be reviewed against nationally recognized terminology.</p> <p>Also suggested amended language: "...accuracy, and accountability <u>quality assurance assessments</u>."</p>	<p>Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health</p>	
19	<p>We had several questions on the definition of automated medication systems in order to better understand the Commission's intent, and we hope that we can work together to discuss these questions through stakeholder meetings. It appears that the intent of this rule pertains to Pyxis or Pyxis-like devices that are used for nursing unit dispensing, but the definition included here for AMS would encompass other devices such as pill counters, Parata-like devices for filling prescriptions, pharmacy inventory/dispensing systems (e.g., Carousels and Robots), Electronic Controlled Substance Vault Systems (e.g., Pyxis C2 Safe) and repackaging equipment. We request that the Commission clarify the intent of this rule for us to better understand what these rules would apply to. The "but not limited" to language, in particular, opens up this rule to a very broad category of devices.</p> <p>Similarly, we are unsure whether this rule applies to both the retail (ambulatory) and hospital settings, or just the hospital setting. As written, it appears to be only applicable to the hospital setting, and we are unsure as to whether these rules apply to non-hospital-based settings, even though we understand from past comments from PQAC members that the desire is for these rules to effect practice beyond the hospital setting. We hope that the Commission will clarify the intent here so we can be sure that the rules as written can achieve the intended effects.</p> <p>Finally, we have some concerns that using the term "AMS" for these machines is confusing, as AMS is currently used to describe another common pharmacy term, Antimicrobial Stewardship. Use of a second meaning for this acronym would create confusion; we recommend that the Commission continue using the previous term, "automated drug dispensing devices" or ADDs, which is an already accepted abbreviation and we believe encompasses the intent of the rule.</p>	<p>Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health</p>	

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	Comment	From	Response
Rule Section 010 (2) - Definitions - "Blind Count"			
20	<p>The ability to access or the knowledge of the count of inventory eliminates the count from qualifying as a "blind count."</p> <p>Recommend elimination of this sentence. The "Blind Count" definition itself is readily published on the internet and recommend just sticking to it.</p>	Charles Ho, Harrison Medical Center	
21	<p>Suggested deletion. <i>The section is not applicable to prescription and OTC kiosks.</i></p> <p>Prescriptions in a delivery AMS are all patient specific.</p>	Sara Lake, Marketing Manager and Regulatory Affairs, Asteres Inc.	
Rule Section 010 (6) - Definitions - "Dispensing"			
22	<p>The definition of "dispensing" should be consistent with other definitions in RCW/WAC. If already defined, is it needed here?</p>	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
Rule Section 010 (8) - Definitions - "Electronic verification system"			
23	<p>Referring to the word "dispensed"</p> <p>Based on your definition in #6, should this be "delivered" or "distributed" instead?</p>		
Rule Section 010 (9) - Definitions - "Emergent medications"			
24	<p>"Emergent medications"</p> <p>What about antibiotics, for example, or pain medications? These are not life-saving classes of medications but waiting for pain medication causes suffering and delaying antibiotics will delay improvements in the patient's health status which may result in extended stays and worse clinical outcomes. This definition needs to provide included classes and excluded classes otherwise the inspectors will take it upon themselves to determine what constitutes an emergent med.</p>	Cheryl Pell, RPh Director of Pharmacy Management – Medication Review, Inc.	
25	<p>How does this apply to antibiotics or pain meds? Forcing patients to wait for pain medications because they aren't "lifesaving" will cause undue suffering that may cause further deleterious effects to a patient's health (elevated BP, RR, etc.). Antibiotics aren't immediately "lifesaving" per se, but how does delaying an antibiotic that has been screened against allergies/acceptable dose range benefit a patient?</p>	Lindsay Mckie PMH Medical Center	

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	Comment	From	Response
26	This definition needs to be broadened for clinical scenarios which are urgent and require immediate access to certain medications, but may not be 'lifesaving.' Critical access hospitals without 24hr pharmacy services need to be considered. Conditions such as severe nausea/vomiting, pain, etc. need to be addressed urgently. We have concerns that this takes away from the hospital's ability to treat a patient quickly when the provider has assessed and determined the urgency of the condition.	Cindy Wilson, PharmD, Manager, Pharmacy 340B Program, CHI Franciscan Health	
27	What is the intent of this definition?	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
28	Emergent Medications: To aid in providing optimum care in Nursing Facilities, medications that may not be considered emergent as outlined in the draft could not be in AMS or included an override list. Many medications that may not be considered emergent as defined in the draft are important to quality care. A patient's health can be potentially jeopardized with a delay of obtaining a medication without being considered 'life threatening' as indicated in the draft. Suggest indicating the Nursing Facility's Quality Assurance Committee with the Medical Director and Pharmacist be responsible for determining the AMS contents and exclude Nursing Facilities from these requirements.	Greg Milanich, PharmD, FASCP, AVP, Pharmacy Services, HCR ManorCare	
Rule Section 010 (11) - Definitions - "Immediate Use"			
29	Emergent medications may be administered more than once to prevent death or serious impairment of health. The definition of immediate is: occurring or done at once; instant. The definition of "Immediate use" should be defined as the shortest possible time between the order and the administration.	Cheryl Pell, RPh Director of Pharmacy Management – Medication Review, Inc. On behalf of one of her pharmacists (Mike)	
30	How does immediate use translate into emergent medications? This makes no sense at all. Immediate use, as it relates to a product, is a pharmaceutical that is acquired, compounded, etc., and is dispensed and administered to a patient in a short time frame. Immediate use defines the intent of the language but is not an accurate definition.	Cheryl Pell, RPh Director of Pharmacy Management – Medication Review, Inc. On behalf of herself and one of her pharmacists (Chris)	

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	Comment	From	Response
31	Actually, "immediate use" is more a description of a time frame rather than the act of administering a medication. This doesn't make any sense.	Lindsay Mckie PMH Medical Center	
32	Is this defined in RCW/WAC elsewhere?	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
Rule Section 010 (13) - Definitions - "Override"			
33	<p>"Override" I don't think that this decision should lie with the Commission. It should be decided by each facilities PIC along with input from the medical director/P&T recommendation. A saline flush is not and 'emergent' medication but I am certainly not going to require that an order for it be prospectively reviewed by a pharmacist before it can be removed from a pyxis machine. There are several drugs that are not emergent but relatively "harmless" and should be allowed to retrieve via override.</p> <p>And what about power outages and computer crashes? The medication is not "emergent" but the medication needs to be given in a timely manner. In these cases overrides need to be used as the interface between EHR and AMS is not intact.</p>	Cheryl Pell, RPh Director of Pharmacy Management – Medication Review, Inc. On behalf of herself and one of her pharmacists (Chris)	
34	<p>Consider adding this verbiage to ensure that medications are only removed upon receipt of an order and not just because they are on override.</p> <p>Suggested amended language: "Override" shall mean the process by which appropriately licensed health care practitioners, consistent with their scopes of practice, <u>upon receipt of medication order by prescriber</u> are permitted to access and remove from the AMS certain legend drugs, including controlled substances, prior to prospective drug utilization review and approval by a pharmacist. <u>Only emergent medications may be subject to override. Override of medications is only allowed if the time required for a pharmacist to review a new medication order would delay treatment leading to patient harm.</u>"</p> <p>Please consider adding this verbiage to allow for rapid dispensing of meds that impacts patient quality of life (nausea meds, pain meds, paralytics, sedation meds) upon receipt of med order. This verbiage is intended to minimize treatment delays and patient back up.</p>	Xheni Waggoner, PharmD, Northwest Hospital & Medical Center, UWMedicine	

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	Comment	From	Response
35	Why is the Commission trying to decide what a facility may consider acceptable for override? Isn't that a decision to be made between the PIC, the medical director, and P&T? Isn't this a bit of micromanaging from on high?	Lindsay Mckie PMH Medical Center	
36	Prior to prospective drug utilization review and approval by a "...pharmacist." Not applicable. Drugs in a delivery AMS are reviewed and approved PRIOR to being loaded.	Sara Lake, Marketing Manager and Regulatory Affairs, Asteres Inc.	
37	Assuming this relates to definition (9). Again, consideration needs to be made for urgent situations which require immediate access to medications. This is especially a factor in small facilities without 24 hour pharmacy. In our organization the override list is approved by P&T committee with provider input. It seems an overreach for there to be clinical restrictions in a WAC that prevents appropriate and timely treatment of urgent medical situations. Recommend it would be more appropriate for the PQAC to require the hospital have a process for determining what is on the override list, versus dictating clinical decision-making in a WAC.	Cindy Wilson, PharmD, Manager, Pharmacy 340B Program, CHI Franciscan Health	
38	Should be consistent with CMS or joint commission expectations. Suggested amended language: " ...Only emergent medications may be subject to override. <u>Medications for override dispensing will be defined by policy.</u> "	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
Rule Section - 010 (14) - Definitions - "Override list"			
39	Suggest deletion of "emergent"	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
Rule Section 010 (16) - Definitions - "PIC"			
40	There appear to be several different levels included and referenced here within the definition of PIC itself, and we believe the inclusion of director of pharmacy, staff pharmacist, and consultant pharmacists, for example, ultimately creates confusion as to who is ultimately accountable and responsible. Additionally, a PIC may have multiple roles, which then under this definition, may put multiple individuals in charge at any one point in time. We request that the Commission clarify this language. Additional, if AMS's are used, will need to include WAC 246-330-200 (4)(i-iv), requiring a "Consultant Pharmacist" oversight.	Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health	

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	Comment	From	Response
	Rule Section 010 (18) - Definitions - "Prospective drug utilization review"		
41	How is the Commission going to provide 24 hour pharmacist access? Is the Commission going to pay the small critical access hospitals for this 24 hour coverage that they mandate?	Cheryl Pell, RPh Director of Pharmacy Management – Medication Review, Inc. On behalf of one of her pharmacists (Mike)	
42	Suggested amended language: ... Prospective drug utilization review need not occur prior to administration of emergent medications <u>removed on override</u> .	Xheni Waggoner, PharmD, Northwest Hospital & Medical Center, UWMedicine	
43	Delete: "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 emergent medications"	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
44	(18)(b) Not every hospital is able to employ a pharmacist or telepharmacy 24 hours a day. How are CAHs going to have funds for this? Having an AMS allows hospitals to provide medications to patients when a pharmacist isn't available. If a hospital doesn't have an AMS, do they not have to have prospective order review? This doesn't make any sense. And the Charge nurse (per WAC) is allowed to enter the pharmacy and pull a med for patient administration before a pharmacist ever reviews the order. This can't go both ways.	Lindsay Mckie PMH Medical Center	
	Rule Section 010 (19) - Definitions - "Privilege list"		
45	"Privilege list" The meaning of this is not clear to me.	Sara Lake, Marketing Manager and Regulatory Affairs, Asteres Inc.	
46	Is this already defined by the licensed individual's scope of practice? Therefore, this is not needed.	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	

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	Comment	From	Response
	Rule Section 010 (20) - Definitions - "Repackaged"		
47	Is there a national standard for repackaging from ASHP or other source?	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
	Rule Section 010 (21) - Definitions - "Replenishment"		
48	Is this definition needed? Need to recognize that the functions listed could be performed by different licensed individuals (pharmacists vs. technician vs other licensed individual).	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
	Suggested New Definition		
49	<u>"Remove" or other terminology used by AMS systems means the act of drug dispensing by the AMS.</u> (Adding this definition as I see this terminology is used later on which can be ambiguous to readers if not predefined. Not all AMS use "Remove" as the function of drug dispensing. Recommend either add this definition, or refrain from using "Remove" as the term to describe drug dispensing by AMS).	Charles Ho, Harrison Medical Center	
	Rule Section 020 – General Applicability		
50	Questions: 1. Are vet schools exempt from these proposed rules because the facility is not defined in the listed RCWs? 2. Are health care facilities such as Residential Treatment Facilities exempt from these proposed rules if the facility has a Health Care Entity (HCE) license?	Karen Nishi Consultant Pharmacist CUBEX LLC	
51	I fully support the expansion of using automated drug dispensing devices in all practice settings. Any automated drug dispensing device is safer and more secure than a locked cabinet. The laws should encourage (but not require) the use of automated drug dispensing devices. I completely support the recognition that automated drug dispensing devices are a core component of pharmacy practice and don't require PQAC approval for their use. In many ways, automated drug dispensing devices have become the standard of practice.	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	

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	Comment	From	Response
52	As it's written, we believe that we could not put an automated dispensing machine/cabinet in an infusion suite that we operate under our home health license, as it is not a location that is separately licensed under any of these categories. Yet, use of a cabinet could open many doors for us in facilitating timely, efficient, safe, and secure medication access for ambulatory infusion patients. We hope to work with the Commission to understand whether there is a solution here so that use of AMS/ADD is allowable in our infusion suites under the home health license.	Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health	
Rule Section 021 - Pharmacist-in-Charge			
53	Question: If a freestanding surgery center were using an AMS to control and track medications used in their procedures, would the center then be required to designate a PIC?	Karen Nishi Consultant Pharmacist CUBEX LLC	
54	I'd like to recommended that the word "compounded" be removed from this section and, consider not allowing compounded medications to be stored in these devices without further discussion of just what types of drugs we're talking about. Are they parenteral products, ointments, etc.? Also I'd like to see included in this section a statement that the PIC is to inspect these devices daily (in keeping with the language of the QA section WAC 246-874-070(10))	Richard Molitor	
55	Suggested amended language: Each facility using an AMS...The PIC shall be responsible to assure that the drugs are procured , stored, compounded , delivered, and dispensed... Not sure why "compounded" will fall under the duties of the PIC as defined for AMS since this are mainly just distribution devices.	Xheni Waggoner, PharmD, Northwest Hospital & Medical Center, UWMedicine	
56	Suggested amended language: "Each facility using an AMS shall designate <u>have</u> a PIC," (based on definition above and the synonymous nature of the definition, "have" fits better. For instance, facilities with an existing director of pharmacy who is as PIC cannot designate another director of pharmacy. Or can change the sentence to read: "Each facility using an AMS shall have a PIC or a designee who is a pharmacist licensed in Washington state, for oversight ... "	Charles Ho, Harrison Medical Center	

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	Comment	From	Response
57	Is this PIC synonymous with the PIC or “responsible manager” of the entire pharmacy? Not reasonable to expect a director of pharmacy to manage the minutiae of the AMS system, need a different word or definitions to be clearer separating the AMS PIC from the responsible manager for the pharmacy.	Margie Hummel, PharmD, Pharmacist Informatics, Providence Health	
58	Is this the same PIC as we have that oversees the pharmacy currently and or can there be a different PIC for different areas under the same pharmacy license .	Roger Wolf, Administrative Director, Richard Paul, Manager II, Inpatient Pharmacy, Suzanne Dolbey, Manager, Informatic Systems, Virginia Mason Hospital & Seattle Medical Center	
59	PIC is defined elsewhere in RCW/WAC. The use of PIC must include “or designee.” This language is needed to maintain operation of the pharmacy. As written, I fear this could have a negative operational and financial impact on health care organizations. As written, the WAC implies a legislative mandate to employee pharmacists. In addition, the language implies a punitive approach to holding the PIC accountable. The current overall actions by PQAC toward PIC’s in the State of Washington is causing recruiting issues and is having a negative effect on the ability to train, promote, and encourage future leaders in the pharmacy profession.	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
60	Not needed. PIC defined in other RCW/WAC’s. Delete: “Each facility using an AMS shall designate a PIC, a pharmacist licensed in Washington state, for oversight of the use of these devices.”	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
61	We believe this section is redundant with current policy that there must be a PIC designated for each pharmacy. An additional requirement for a PIC specific to AMS operations would create confusion and inefficiency, and we believe the Commission’s intent was to ensure that the PIC already designated was also responsible for AMS operations within the pharmacy they are responsible for. We request that the Commission strike this section in favor of the current requirements.	Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health	

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Comment	From	Response
Rule Section 030 (1) - P&P Req. - Requiring written P&P, annual review of same.		
62	Suggested amended language: “...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.	Pharmacy Operations Manager, Northwest Hospital & Medical Center, UWMedicine
	Recommend deletion, that is a given.	
63	Suggested amended language: “ The pharmacy and Any”	Charles Ho, Harrison Medical Center
64	Considering how health systems operate, suggest modifying wording for policy review to simply state.....’shall be reviewed at least annually with necessary revisions made.....’ rather than specifying the review is by the PIC. The PIC is accountable for implementing.	Cindy Wilson, PharmD, Manager, Pharmacy 340B Program, CHI Franciscan Health
65	Delete: “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.	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health
	Already defined in WAC/RCW.	
66	Replenishment: Pharmacies providing AMS are typically offsite for Nursing Facilities. It can be argued that the greater need for AMS occurs when their Pharmacy is located a greater distance. It is not logistically reasonable to have a Pharmacist, pharmacy intern, or a pharmacy technician under the supervision of a pharmacist to replenish AMS. This requirement is not consistent with the National Association Board of Pharmacy (NAPB) Model Act’s intent. Suggest indicating that a licensed or registered nurse can replenish the AMS with reasonable safeguards such as blind counts and barcoding in Nursing Facilities or when the AMS is in settings that the pharmacy is offsite.	Greg Milanich, PharmD, FASCP, AVP, Pharmacy Services, HCR ManorCare
67	We hope that the Commission can clarify - are both the "AMS PIC" and director of pharmacy now required to review these policies and procedures annually?	Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health

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	Comment	From	Response
	Rule Section 030 (2) - P&P Req. - Location of P&P at all applicable locations		
68	Does facility locations means different units of the hospital where the pharmacy is located or is the hospital considered one location?	Xheni Waggoner, PharmD, Pharmacy Operations Manager, Northwest Hospital & Medical Center, UWMedicine	
69	Do we really need a paper copy of P&P in every unit that has an AMS when the P&P is online and available on every computer?	Lindsay Mckie PMH Medical Center	
70	Suggested amended language: “or can be readily accessed by the facility, as well as at the pharmacy of the PIC.” (What if a facility does not have a pharmacy? are they excluded from getting AMS, period? I recommend eliminating the need for pharmacy for as long as there is 1) good P&P, 2) an RPH designed to oversee the AMS as the PIC of the AMS, and 3) same rules applied to those facilities as if a pharmacy. This allows for more facilities to move towards AMS technology. The “readily accessible” clause allows for Centralized-multi-facility organizations to implement centralized P&P structure—mostly web-based access to P&P housed at the central location.)	Charles Ho, Harrison Medical Center	
71	Suggested amended language: “A current copy of all policies and procedures related to the use of the system shall be maintained at all facility locations where the system is being used, as well as at the pharmacy of the PIC, or readily retrievable <u>when requested.</u> ”	Julie Doung, PharmD, Pharmacy IT Coordinator, Northwest Hospital & Medical Center	
72	Regarding current copy of P&P – or available electronically	Roger Wolf, Administrative Director, Richard Paul, Manager II, Inpatient Pharmacy, Suzanne Dolbey, Manager, Informatic Systems, Virginia Mason Hospital & Seattle Medical Center	

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	Comment	From	Response
73	Clarify to allow for electronic version of P&P.	Cindy Wilson, PharmD, Manager, Pharmacy 340B Program, CHI Franciscan Health	
74	Suggested amended language: <u>Policies and procedures will be readily available at all locations where ADC (AMS) are used.</u> A current copy of all policies and procedures related to the use of the system shall be maintained at all facility locations where the system is being used, as well as the pharmacy of the PIC,	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
75	We request that the Commission adopt language allowing for documents to be readily accessible instead of requiring physical copies at each location – which would be very difficult to comply with given constraints on physical space. Suggested language: A current copy of all policies and procedures related to the use of the system shall be maintained at all facility locations where the system is being used, as well as at the pharmacy of the PIC. <u>readily available to all users in either electronic or paper form.</u>	Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health	
Rule Section 030 (3)- P&P Req. - Minimum standards for P&P-Master List			
76	So don't think these details need to be part of the actual policy but the policy should note where the information is located and who maintains. Thinking about the upcoming device reconfiguration post GHC transition how will we track?	Roger Wolf, Administrative Director, Richard Paul, Manager II, Inpatient Pharmacy, Suzanne Dolbey, Manager, Informatic Systems, Virginia Mason Hospital & Seattle Medical Center	

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	Comment	From	Response
	Rule Section 030 (3)(a)(i) - P&P Req. - Minimum standards for P&P-Name, locations of devices		
77	<p>“Name, and address...”</p> <p>This does NOT make sense. The console will state how many AMS there are and device type. Also, the AMS may be moved at any time to provide better patient care.</p>	<p>Cheryl Pell, RPh Director of Pharmacy Management – Medication Review, Inc. On behalf of herself one of her pharmacists (Mike)</p>	
78	<p>This is kind of redundant, don’t you think?</p>	<p>Lindsay Mckie PMH Medical Center</p>	
79	<p>Suggested to delete “serial numbers”</p> <p>(Not sure about the importance of serial#. If a device is damaged and replaced by vendor or naturally replaced on scheduled maintenance for those Leased contracts, it’d be very difficult tracking serial numbers and those numbers do not impact the system operations in any way, shape, or form for as long as it’s the same device and model. Recommend not pursue Serial Number listing. This causes P&Ps to be constantly updated with every device maintenance. And the Board may not have the most updated P&P. And the Board will be required to constantly update serial #s)</p>	<p>Charles Ho, Harrison Medical Center</p>	
80	<p>Suggested amended language: ...”multiple locations, <u>list all specific locations and device type</u>;</p>	<p>Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health</p>	
81	<p>Policies and Procedures are only updated periodically; keeping this AMS information up-to-date at all times could add significant administrative burden. We believe the intent of the Commission is to ensure easy access to this information at any point in time, and therefore, think that the policies and procedures could instead reference to the master AMS listing, as this is a more dynamic list in most facilities.</p>	<p>Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health</p>	

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	Comment	From	Response
	Rule Section 030 (3)(a)(ii) - P&P Req. - Minimum standards for P&P-AMS manufacture information		
82	How will the model and serial number in a policy help in the use/safety/operation of the AMS device? Why is this necessary?	Cheryl Pell, RPh Director of Pharmacy Management - Medication Review, Inc. On behalf of herself and one of her pharmacists (Chris)	
83	This information is located on each AMS unit. How is documenting this going to make the use/safety/security any better? Are we worried that someone has come and secretly replaced one in the dead of the night while everyone sleeps?	Lindsay Mckie PMH Medical Center	
84	What does this level of detail provide in terms of medication safety or diversion prevention? As systems are expanded or machines fail, serial numbers may change. Is it useful to include this in a written policy, versus having the records on hand?	Margie Hummel, PharmD, Pharmacist Informaticist, Providence Health	
85	What value or usefulness does this add, especially including serial numbers in the policy? The pharmacy already maintains this separately. This creates another location to upkeep this data. In 20 years of AMS experience we have never needed this in a policy. Recommend removing and simply stating it must be produced if requested upon inspection.	Cindy Wilson, PharmD, Manager, Pharmacy 340B Program, CHI Franciscan Health	
86	Suggested amended language: "AMS manufacture name, <u>device type</u> , <u>model</u> , and <u>serial numbers</u> , and <u>unique device identifier</u> ;	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
	Rule Section 030 (3)(a)(iii) - P&P Req. - Minimum standards for P&P-Facility license		
87	Delete.	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	

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	Comment	From	Response
Rule Section 030 (3)(a)(iv) - P&P Req. - Minimum standards for P&P-Name of PIC			
88	PIC changes, usual approach to policy is to refer to a title, not a specific name of a person.	Margie Hummel, PharmD, Pharmacist Informaticist, Providence Health	
89	It is typically not recommended to include people's names in a policy but rather just the title. This name is already designated as the PIC/Responsible pharmacist to PQAC.	Cindy Wilson, PharmD, Manager, Pharmacy 340B Program, CHI Franciscan Health	
90	Not needed. Defined by license.	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
91	<p>Again, we believe that requiring this information in the policies and procedures isn't practical to comply with; instead, we suggest allowing the policies and procedures to refer to PIC by job title or position assignment, not by pharmacist name, as keeping specific names of individuals within the policies and procedures will be fraught with errors and upkeep issues. Along with the current requirement that each PIC be listed with PQAC itself, we believe this would follow the intent of the Commission, which is for information regarding the PIC for each location (and therefore, for AMS operations) is readily available at any point in time. Additionally, adding position and title of the Director of Pharmacy would fold-in non-hospital-based settings.</p> <p>Suggested language would read: <u>"Position and title of the PIC, or director of pharmacy, or consultant pharmacist"</u></p>	Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health	
Rule Section 030(3)(a)(v) - P&P Req. - Minimum standards for P&P-Description of how device is used			
92	Does this really ask for the description of how the device is used? Please see definition section. This needs to be removed.	Cheryl Pell, RPh Director of Pharmacy Management - Medication Review, Inc. On behalf of herself one of her pharmacists (Mike)	

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	Comment	From	Response
93	What do they mean by “description of how device is used”?	Cheryl Pell, RPh Director of Pharmacy Management – Medication Review, Inc. On behalf of herself and one of her pharmacists (Chris)	
94	Ummm...by nature, these things dispense drugs. Is there any other necessary description?	Lindsay Mckie PMH Medical Center	
95	As stated in 021....Each facility using an AMS shall designate a PIC, a pharmacist licensed in Washington state, for oversight of the use of these devices. The PIC shall be responsible to assure that the drugs are procured, stored, compounded, delivered and dispensed in compliance with all applicable state and federal statutes and regulations.	Roger Wolf, Administrative Director, Richard Paul, Manager II, Inpatient Pharmacy, Suzanne Dolbey, Manager, Informatic Systems, Virginia Mason Hospital & Seattle Medical Center	
96	Suggested amended language: “...how devices <u>is</u> <u>are</u> used.”	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
97	We are unsure what the Commission means by the requirement for a “description of how the device is used” in policies and procedures, and request that the Commission clarify. We would be unsure of how to comply as written. What is the intent of including this?	Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health	

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	Comment	From	Response
	Rule Section 030(3)(b) – P&P Req. - AMS system operation including, but not limited to list of all drugs stocked in each respective machine and [which are override]		
98	Probably the most ridiculous statement so far. The medications are added and removed from the AMS on almost a daily basis. Do the people making these requirements work in a real setting?	Cheryl Pell, RPh Director of Pharmacy Management – Medication Review, Inc. On behalf of herself one of her pharmacists (Mike)	
99	Does this mean that every time a drug is added a new report has to be generated and placed in the P&P manual?	Cheryl Pell, RPh Director of Pharmacy Management – Medication Review, Inc. On behalf of herself and one of her pharmacists (Chris)	
100	I really feel that there needs to be a definitive understanding amongst stakeholders and regulators as to just what an “override” category should be. Otherwise there’s just a lot of abuse potential here. Certainly some cardiac drugs, antipsychotics, and maybe antibiotics are appropriate for inclusion into this category but leaving this list in the hands of the facility may result in the categorization of bisacodyl suppositories as “override-eligible” if not appropriately regulated. Also with the availability of after hours pharmacy services (telepharmacy, an emerging practice type) now providing pharmacist order-entry and profile review these “override” lists should be very small indeed.	Richard Molitor	Does the definition of “override” take care of this concern?
101	The list of medications stored in each device may change daily depending on what medications patients are at home. Having a printed list that gets outdated daily is not feasible. For example our hospital has 40 some Pyxis machines and each can hold up to 300 – 400 drugs. Consider adding requirement for the list of drugs to be readily retrievable as supposed to part of policies and procedures.	Xheni Waggoner, PharmD, Pharmacy Operations Manager, Northwest Hospital & Medical Center, UWMedicine	
102	So, every time we add a new med to stock we need to print out a new list and add it to P&P? Again, this seems a bit excessive. And by a bit, I mean A LOT.	Lindsay Mckie PMH Medical Center	

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	Comment	From	Response
106	Inventory in each machine changes DAILY, maintaining a list in a policy would be impossible. The current inventory of each machine is available within the AMS operating system. This should be changed to state that a list of drugs available by override is maintained, and delete the piece about the list of drugs stocked in each machine.	Margie Hummel, PharmD, Pharmacist Informaticist, Providence Health	
107	List suggests paper documentation versus available electronically. Need to define "List"	Roger Wolf, Administrative Director, Richard Paul, Manager II, Inpatient Pharmacy, Suzanne Dolbey, Manager, Informatic Systems, Virginia Mason Hospital & Seattle Medical Center	
108	Suggested amended language: <u>"A list of medications in each ADC (AMS) will be maintained. If the list of medications is stored electronically, a description of how to produce a hard copy of the ADC (AMS) medication list will be outlined. AMS system operation including, but not limited to, a list of all drugs stocked in each respective machine and which drugs if any are subject to override."</u>	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
109	The list of drugs stocked in an AMS is dynamic, this list changes routinely depending on patient treatments, the "list of all drugs stocked in each respective machine" should not be part of the policy and procedure.	Gail Bunker, PharmD, TG/AH Pharmacy Operations Manager, Multicare Health System	
110	An AMS inventory is dynamic and policies are very static. An average hospital has approximately 3,000 possible drugs on formulary, and over the course of any given week, 20 drugs could have easily been moved in to or out of the machines. We request that the Commission strike this language.	Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health	
Rule Section 030 - P&P (NEW SECTION SUGGESTION)			
111	The ADC (AMS) will be programmed with a list of medications deemed appropriate for override access.	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	

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	Comment	From	Response
	Rule Section 030(3)(c) - P&P Req. - Maintenance plans		
112	Not needed. These AMSs are rented and the contract has maintenance.	Cheryl Pell, RPh Director of Pharmacy Management – Medication Review, Inc. On behalf of herself one of her pharmacists (Mike)	We are merely asking that documentation to be included in the P&P, or located in the same area, and retrievable.
113	These devices are rented and come with a maintenance contract. It isn't necessary for this to be in a P&P manual.	Cheryl Pell, RPh Director of Pharmacy Management – Medication Review, Inc. On behalf of herself and one of her pharmacists (Chris)	
114	Not sure what this means. “and a plan for maintenance of all related documentation” Suggested deletion of phrase.	Xheni Waggoner, PharmD, Pharmacy Operations Manager, Northwest Hospital & Medical Center, UWMedicine	
115	These are rented and already on a maintenance contract. Why would we need to have this?	Lindsay Mckie PMH Medical Center	
116	Why is this necessary in the policy? It already exists in the vendor contract/service agreement. Perhaps simply state it must be producible upon inspection if requested rather than maintaining it within the policy.	Cindy Wilson, PharmD, Manager, Pharmacy 340B Program, CHI Franciscan Health	
117	Suggested amended language: <u>ADC will be maintained in accordance with the manufacturer's recommendations.</u> Maintenance, including manufacturer's schedules and recommendations for maintenance of the AMS and a plan for maintenance of all related documentation for the life of the device.	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	

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	Comment	From	Response
118	<ul style="list-style-type: none"> • Is the intent of this requirement is to ensure equipment is inspected and functional? If so, the draft language should change to reflect this and specific details should not be required in the policy and procedure. • Preventative Maintenance on AMS equipment is required by contract with the vendor, why are specific details of the manufacturer’s maintenance schedules and recommendations required in policy? The policy should merely state, Preventative Maintenance shall occur per vendor requirements. • What does “a plan for maintenance of all related documentation for the life of the device” refer to? Is this is referring to tracking specific maintenance requirements on a particular AMS? This level of detail should not be required within the policy. • Suggestion, “Preventative Maintenance shall occur annually per vendor requirements.” 	Gail Bunker, PharmD, TG/AH Pharmacy Operations Manager, Multicare Health System	
119	Add “readily retrievable” or “available to all parties” language to allow for this documentation to be accessed electronically, rather than require a physical copy at each location. Change: “the life of the device” to “while device is in use”.	Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health	
Rule Section 030 (3)(d) - P&P Req. - Address all requirements further set out.			
120	Technical correction – it appears that the proposed rules end at 070.	Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health	
Rule Section - 040 (1) - Security Req. - Requires the PIC to have security and procedures in place			
121	I’d suggest the first sentence read: “The PIC shall assure the device has an adequate location, security system and procedures for the AMS...” (inserting the word “location”).	Richard Molitor	
122	Suggested amended language: The PIC ADC shall assure the device has <u>have</u> an adequate security system and procedures for the AMS ADC including:”	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	

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	Comment	From	Response
	Rule Section 040 (1)(a) - Security Req. - Secure access of AMS		
123	“biometrics” – Why call this out as this is potentially current day language and technology. Change this to “a secured system where one can be tracked.”	Roger Wolf, Administrative Director, Richard Paul, Manager II, Inpatient Pharmacy, Suzanne Dolbey, Manager, Informatic Systems, Virginia Mason Hospital & Seattle Medical Center	
124	Suggested amended language: “A system by which secure access of <u>individual</u> users is obtained by such methods as biometrics or some other secure technology, ”	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
125	While we agree that use of biometrics is ideal for security, not all technology includes biometrics as an option and/or the specific biometric may not be compatible with specific users requiring the use of passwords or other methods of security. We are also unsure of the Commissions intent regarding use of the term 'secure technology'; we believe this requirement is too specific and should simply state the system has a security process for ensuring the identity of the user to prevent unauthorized access of the device.	Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health	
	Rule Section 040 (2) - Security Req. - Requirements for security and prodcares - regarding access		
126	Suggested amended language: The PIC shall have a Adequate security...	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
	Rule Section 040 (2)(a) - Security Req. - Allowing only WA licensed health care practitioners, w/in scope to access AMS		
127	I'd like to recommend inspections weekly instead of monthly to minimize the impact and potential diversion.	Richard Molitor	
128	Why is there a need for “at least a monthly check to ensure system access is limited” if I have processed in place to strictly limit access and have oversight to all access? Then in (9) why quarterly audits of compliance with AMS policies and procedures – same reason as above	Traci Mitchell, PharmD, MHA, Pharmacy Services Manager Evergreen Health Monroe	

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	Comment	From	Response
129	<p>“Only those [WA] state licensed health care practitioners...”</p> <p>Does the “Commission” have any idea what this entails? I agree that a check is needed, but not “at least a monthly check.” I wish the members of the Commission would spend some time in a hospital setting and try to implement some of these requirements.</p>	<p>Cheryl Pell, RPh Director of Pharmacy Management – Medication Review, Inc.; On behalf of herself one of her pharmacists (Mike)</p>	
130	<p>Monthly is excessive.</p>	<p>Cheryl Pell, RPh Director of Pharmacy Management – Medication Review, Inc.; On behalf of herself and one of her pharmacists (Chris)</p>	
131	<p>There are instances that supplies (as supposed to drugs) are stored in Pyxis machine with unlicensed personal needing access to them. Adding this proposed verbiage will allow for this exception.</p> <p>“...at the facility, shall <u>have access to the AMS for the purpose of removing drugs.</u>”</p>	<p>Xheni Waggoner, PharmD, Pharmacy Operations Manager, Northwest Hospital & Medical Center, UWMedicine</p>	
132	<p>Monthly is excessive. We don’t have that kind of time.</p>	<p>Lindsay Mckie PMH Medical Centerv</p>	
133	<p>A monthly check is too frequent, will be impossible to comply for all but the smallest facilities.</p>	<p>Margie Hummel, PharmD, Pharmacist Informaticist, Providence Health</p>	
134	<p>“licensed health care practitioners” – Not defined who this is. I believe you are saying non-licensed, non-pharmacy personnel.</p> <p>“Monthly check” This seems excessive to check monthly. Should be in one’s P&P how they will handle those that are no longer employed</p>	<p>Roger Wolf, Administrative Director, Richard Paul, Manager II, Inpatient Pharmacy, Suzanne Dolbey, Manager, Informatic Systems, Virginia Mason Hospital & Seattle Medical Center</p>	

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	Comment	From	Response
135	Need clarification of what constitutes a check. Access is authorized by HR and the education department. HR notifies the system administrator when employees are terminated. Their access is deleted at that time if applicable. Does this satisfy the rule?	Craig Travis, Pharmacist Mason General Hospital	
136	<ul style="list-style-type: none"> • The PIC should be allowed to delegate the monthly check of access to the system. • (4) also states System access for former employees shall be removed immediately 	Gail Bunker, PharmD, TG/AH Pharmacy Operations Manager, Multicare Health System	
137	<p>Pharmacy staff are not usually employed at the facility and the inventory of medications in the AMS belongs to the pharmacy until they are removed for resident use. It is not reasonable to prohibit pharmacy staff from accessing the AMS and their inventory.</p> <p>Suggested language:</p> <p>“Only those Washington state licensed health care practitioners, acting within their scope of practice, and pharmacy staff approved by the PIC, shall access the AMS.”</p>	Lynn Whitmore, RN, MS, Nurse Consultant, Senior Care Pharmacy of the West	
Rule Section 040(2)(b) - Security Req. - Restricts IT or similar employees from accessing AMS			
138	<p>Suggest deletion of whole point.</p> <p>Not sure that this need to be listed as unauthorized access since 2a above already addresses what authorized user means.</p>	Xheni Waggoner, PharmD, Pharmacy Operations Manager, Northwest Hospital & Medical Center, UWMedicine	
139	<p>Suggested amended language:</p> <p>“Facility information technology employees ... system for the purpose of servicing and supporting the AMS system, access to the drugs or privileges into the AMS unit containing the drugs;”</p> <p>(This language is essential for large multi-site hospital systems that utilize centralized IT system for support. I do recognize and support that IT personnel may not physically access into drug storage. But we do need to allow them into the data system to support the machines and maintain it when it breaks.)</p>	Charles Ho, Harrison Medical Center	
140	<p>“Facility information technology employees or employees of similar title Non-licensed-employees shall not have access to the drugs or privileges into in the ADC AMS unit containing the drugs; and”</p>	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	

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	Comment	From	Response
141	As written, this rule excludes IT Pharmacy Analysts whom are also licensed pharmacists or technicians. We suggest that instead, the Commission use inclusionary language rather than exclusionary, as otherwise, the list of whom should NOT have access to AMS's will need to be updated and may not be complete as the field evolves. To that effect, we urge the Commission to strike part b), as the intent is really encompassed in part a) – which lists who IS able to access AMS devices.	Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health	
Rule Section 040(2)(c) - Security Req. - Nursing student language			
142	This section is mostly not applicable. But, nurses in some circumstances may access a delivery AMS when assisting a discharge patient in picking up their prescriptions when leaving the hospital.	Sara Lake, Marketing Manager and Regulatory Affairs, Asteres Inc.	
143	Suggested amended language: If a A facility <u>may</u> provides a clinical opportunity for nursing students enrolled in an <u>Washington state</u> accredited nursing commission program approved nursing programs-ADC, nursing students may access to the AMS ADC only under the following conditions:"	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
144	We agree with the Commissions intent to ensure that students have adequate and proper training to operate AMS devices. However, we believe the requirements placed on nursing schools as written in this section to train for and have policies on the use of AMS is problematic and could possibly harm patients. Nursing schools send students to multiple facilities and those facility will have different policies and different equipment. This will result in confusion by the students which could result in errors. In addition, this could result in complications for the PIC when trying to confirm this education has occurred, or resolve the conflicts between multiple entities. Suggested language: We believe (i) should be struck. We believe that (ii) should be changed to 'Healthcare facilities shall provide adequate training for students accessing AMS: and'. We believe that (iii) should be changed to 'Health care facilities shall have policies and procedures that direct the use AMS by nursing students to provide medications administration safely, including policies and procedures for'.	Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health	

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	Comment	From	Response
145	<ul style="list-style-type: none"> • Section (i) should be removed. The PIC should not have procedures for Nursing program orientation, this is a redundant requirement since (ii) states students will receive AMS training • If a healthcare facility or pharmacy provides adequate AMS training for students, there should be no further obligation to track Nursing Program orientation, Section (ii) should be sufficient. • Separate policies for nursing students should not be required under Section (iii), nursing students are obligated to operate the AMS per the facility AMS policy. • Medication errors including near misses and alleged diversions are tracked at a system-level and include students. There should not be separate tracking for students, “(C) Reporting of student medication errors, near misses and alleged diversion” should be eliminated. 	Gail Bunker, PharmD, TG/AH Pharmacy Operations Manager, Multicare Health System	
Rule Section 040(2)(c)(i) - Security Req. - Nursing Students			
146	Suggested amended language: “Nursing programs ADC shall provide students with Orientation and practice...”	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
Rule Section 040(2)(c)(ii) - Security Req. - Nursing Students			
147	Isn't this a facilities decision allowing nursing students to do clinicals, rather than the Commissions? Since when is the nursing administration of medications monitored by the Pharmacy Commission? None of this section should be here – this is facility-based.	Lindsay Mckie PMH Medical Center	
148	Delete	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
Rule Section 040(2)(c)(iii) - Security Req. - Nursing Students			
149	Why is nursing administration of medications being addressed by the Commission? How does the Commission propose to monitor this? This entire section should be managed by the hospital that is allowing a nursing student to do their clinicals there	Cheryl Pell, RPh Director of Pharmacy Management – Medication Review, Inc.; On behalf of herself and one of her pharmacists (Chris)	

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	Comment	From	Response
150	The nursing commission approved nursing programs ADC, health care facilities, and pharmacies shall Have policies and procedures for nursing students to provide medication administration safely, including policies and procedures for:	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
Rule Section 040(2)(c)(iii)(A)-(B) - Security Req. - Nursing Students			
151	Delete.	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
Rule Section 040(2)(c)(iii)(C) - Security Req. - Nursing Students			
152	Why is this called out specifically in this WAC? Certainly a facility would train/orient nursing students to med administration with or without an AMS used. Along the same line, why is there a specific requirement to report med errors, near misses, alleged diversion? These would be necessary whether an AMS is in use or not where nursing students are participating in med administration.	Cindy Wilson, PharmD, Manager, Pharmacy 340B Program, CHI Franciscan Health	
Rule Section 040(2)(d) - Security Req. - Privilege list			
153	Add point under privilege list: <u>Which hospital employees can access AMS and list of specific privileges (access to drug removal/inventory should NOT be a privilege)</u>	Xheni Waggoner, PharmD, Pharmacy Operations Manager, Northwest Hospital & Medical Center, UWMedicine	
154	Not applicable. Section (c) and (d) are very specific. How about something more general? Example: The stocking of all medications in the automated dispensing system shall be accomplished by qualified personnel under no less than the general supervision of a licensed pharmacist; except that when an automated dispensing system is located within a pharmacy the supervision must be direct.	Sara Lake, Marketing Manager and Regulatory Affairs, Asteres Inc.	
155	Again list suggests paper what about "list or ability to display electronically"	Roger Wolf, Administrative Director, Richard Paul, Manager II, Inpatient Pharmacy, Suzanne Dolbey, Manager, Informatic Systems, Virginia Mason Hospital & Seattle Medical Center	

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156	ADC use will be limited to scope of practice by licensed individual who has access, Privilege list indicating: Delete the remaining privilege list section	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
Rule Section 040(2)(d)(i) - Security Req. - Requires privilege list to identify practioners and scope			
157	Does this mean individual names, or their role or title (e.g. MDs will have XYZ, RN will have ABC, pharmacists vs. specific names)? Specific names will be too difficult to maintain.	Margie Hummel, PharmD, Pharmacist Informaticist, Providence Health	
158	Is this a list of all professionals accessing the device or of providers with prescriptive authority dispensing medication?	Craig Travis, Pharmacist Mason General Hospital	
Rule Section 040(3) - Security Req. - Requires record of persons accessing machine for pretty much all reasons, and those record to be on-site			
159	Suggested amended language: "Records shall be maintained and readily retrievable on-site;" (For large multi-site facilities, the records may not be maintained "on-site" per se by is always accessible on-site. Recommend focus on <u>readily retrievable</u> and not the physical location of storage. Most likely storage is held in a Data Center facility under very strict access control and includes seismic, electronic, and fire protections such as halon gas suppression system and independently gridded power generators).	Charles Ho, Harrison Medical Center	
160	Too specific. Example: All events involving the contents of the AMS must be recorded electronically. Records shall be maintained by the pharmacy and be available to the board. Records shall include: The time and location of the system accessed. Identification of the individual accessing the system. Type of transaction. Name, strength, dosage form and quantity of the drug accessed. Name of the patient for whom the drug was ordered. Such additional information as the managing pharmacist may deem necessary.	Sara Lake, Marketing Manager and Regulatory Affairs, Asteres Inc.	
161	Suggested amended language: "The AMS-ADC shall...maintained and readily retrievable on-site; "	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	

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162	To allow for electronic record-keeping, we suggest that the Commission strike “shall be maintained” and “on-site”. There is also a question as to the length of time that records shall be maintained; we recommend the standard practice of two years throughout. Please see section comments below on 246-874-050 (6) (c) for our concerns with the language “for the life of the machine”, which we believe would apply to this section as well.	Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health	
Rule Section 040(4) - Security Req. - System removal of former employees - immediately			
163	Delete “former” and replace with “termed”	Xheni Waggoner, PharmD, Pharmacy Operations Manager, Northwest Hospital & Medical Center, UWMedicine	
164	Define “immediately”.	Lindsay Mckie PMH Medical Center	
165	Suggested amended language: “System access for former employees shall be removed immediately <u>within 48 hours by PIC; and</u> ” The changes that Genoa is proposing will allow our pharmacies to remain compliant and at the same time it will require us to increase our hours per week to include pharmacist hours on a Saturday which increases our cost to do business. Nevertheless, we are willing to do it in order to accommodate.	Christy M. Barr, RPh, Regional VP of Operations – Western Division, Genoa, A QoL Healthcare Company	
166	Suggested amended language: “System access for former employees shall be removed immediately <u>in accordance to the organizations IT security policy;</u> ”	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
167	As noted in 246-874-040 (2)(a) we believe this also needs to address non employed employees. In addition, we request that the Commission adopt language in this section for reasonable operating process in these cases, and suggest that a more reasonable timeline would be within 5 working days of dismissal from the facility.	Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health	

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	Comment	From	Response
168	Former Employee Access and Discharge Patients: The draft indicates that former employee access and discharged patients need to be immediately removed from the AMS. This would not be reasonable because these functions are typically limited to select users. Suggest indicating one business day instead of immediately.	Greg Milanich, PharmD, FASCP, AVP, Pharmacy Services, HCR ManorCare	
Rule Section 040(5) - Security Req. - System removal of discharged patients - immediately			
169	Suggested amended language: “Discharged patients shall be removed immediately <u>within 48 hours by PIC</u> ” The changes that Genoa is proposing will allow our pharmacies to remain compliant and at the same time it will require us to increase our hours per week to include pharmacist hours on a Saturday which increases our cost to do business. Nevertheless, we are willing to do it in order to accommodate.	Christy M. Barr, RPh, Regional VP of Operations – Western Division, Genoa, A QoL Healthcare Company	
170	“discharged patients ...immediately” Again, the Commission has no idea. I see situations where admitting selects a predetermined discharge date. I agree that discharged patients need to be removed from the AMS, but a 72 hour window will prevent many issues and increase patient care.	Cheryl Pell, RPh Director of Pharmacy Management – Medication Review, Inc.; On behalf of herself one of her pharmacists (Mike)	
171	Current WAC states 12 hours. Immediately is not feasible.	Cheryl Pell, RPh Director of Pharmacy Management – Medication Review, Inc.; On behalf of herself and one of her pharmacists (Chris)	
172	Again, define “immediately”. Per the current WAC, this is 12 hours. “Immediately” is not reasonable or feasible.	Lindsay Mckie PMH Medical Center	
173	Not applicable.	Sara Lake, Marketing Manager and Regulatory Affairs, Asteres Inc.	
174	“Immediately” needs clarification – most hospitals leave the patient in for a couple of hours to facilitate 1) erroneous discharges from EMR and 2) return/waste if patient administered medication immediately prior to discharge.	Margie Hummel, PharmD, Pharmacist Informaticist, Providence Health	

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	Comment	From	Response
175	Removing discharged patients immediately may prevent users from documenting waste of controlled substances. Recommend a broader time frame of 24 hours more at least end of shift.	Craig Travis, Pharmacist Mason General Hospital	
176	The facility needs a short window of time post discharge to allow for any return of medications to the AMS.	Cindy Wilson, PharmD, Manager, Pharmacy 340B Program, CHI Franciscan Health	
177	Suggested amended language: "Discharged patients shall be removed immediately <u>in an appropriate timeframe that allows normal discharge processes to occur;</u> "	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
178	Discharging of a patient in an electronic sense maybe different from physically leaving a facility. We request that the Commission adopt language that allows for a delay in the system to allow for multiple reasons, such as the wasting of a controlled substance. We believe this should be changed to 24 hours, which we believe our facilities, including nursing homes, would be able to comply with.	Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health	
Rule Section 040(6) - Security Req. - Added Patient report, and requiring patient profiles outside ADT to be reconciled next business day			
179	There's a conflict with "reconciliation" needing to occur by the next "business" day but PIC review of reconciliation must occur "daily". I'd like to recommend that the reconciliation occur by the next calendar day, not the next business day, again noting that after hours services could handle this operation of their service to the facility.	Richard Molitor	
180	"Patient profiles..." What is with these unattainable small windows? Do the members of the Commission work seven days a week? Do the members of the commission work on Saturday or Sunday? What did the members of the Commission do on Christmas?	Cheryl Pell, RPh Director of Pharmacy Management - Medication Review, Inc.; On behalf of herself one of her pharmacists (Mike)	

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181	This will be extremely cumbersome for hospitals to manage on a daily basis and nearly impossible for hospitals that do not employ a pharmacist.	Cheryl Pell, RPh Director of Pharmacy Management – Medication Review, Inc.; On behalf of herself and one of her pharmacists (Chris)	
182	Is concerning to me – the SOLE RESPONSIBILITY of the PIC to ensure the AMS is accurately stocked. If I am a non-PIC pharmacist that checks the AMS fill incorrectly, I am exempt from being the responsible pharmacist? The PIC would be held liable?	Cheryl Pell, RPh Director of Pharmacy Management – Medication Review, Inc.; On behalf of herself and one of her pharmacists (Chris)	
183	Why is Pharmacy now handling admissions? There are other departments better suited to running this information to ground. And, if a hospital does not have a daily pharmacist, how are they going to fulfill this requirement?	Lindsay Mckie PMH Medical Center	
184	<p>Suggested deleting this point. (Part 1 of 2) Patient profiles added outside the normal admission discharge transfer process, shall be reconciled by a pharmacist no later than the next business day. On at least a daily basis, the PIC, or his or pharmacy designee, shall run an Added Patient, or equivalent, report to ensure reconciliation has occurred;</p> <p>(This is not achievable by some systems in the market where the data merging can only occur after patient’s discharge or errors could result because of the merge and the system may show duplicated orders. Merging profiles is not an essential step in clinical practice as long as when profiled patients are added by ADT system after the emergent situation has passed and the clinicians use the profiled patients. When this happens, the previously added temporary patient serves as records only and largely for billing thereafter. There is more risk to merging the records than benefits if rushed.)</p>	Charles Ho, Harrison Medical Center	

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	Comment	From	Response
	<p>(CONT.) I recommend the following language instead: (Part 2 of 2) Patients added outside of Admission, Discharge, and Transfer (ADT) system are known as Temporary Patients or Added Patients which are created by an AMS user directly to the AMS and outside of the Facility's registration process. Use of these patients shall be limited to urgent or emergent circumstances only as approved by the facility's written P&P, and the facility's PIC or designee has a defined mechanism to review all temporarily added patients. The PIC or designee must review these patients within 1 business day after they have been added into the AMS, and these temporarily added patients must not be used as soon as the same patient has been added to the AMS by the standard ADT process. The temporarily added patients must be merged with the ADT added patients as early as the AMS is capable of performing.</p> <p>The intent to review and to protect (and restrict) temporary patient use can be achieved by the above. And a mechanism can be developed to oversee the use of the temporary patients without rushing to merge data. The goal is to use Profiled patients. This can be achieved by the above language.</p>	<p>Charles Ho, Harrison Medical Center</p>	
185	<p>Suggested amended language: "Patient profiles added outside the normal admission discharge transfer process, shall be reconciled by a pharmacist no later than the next business day. On at least a daily basis, the PIC, or his or pharmacy designee, shall run an Added Patient, or equivalent, a report to ensure reconciliation has occurred;"</p>	<p>Julie Doung, PharmD, Pharmacy IT Coordinator, Northwest Hospital & Medical Center</p>	
186	<p>Many places do not have the resources to perform this function that quickly. Reviewing a sample would be more feasible than reconciling every single patient added.</p>	<p>Margie Hummel, PharmD, Pharmacist Informaticist, Providence Health</p>	
187	<p>"reconciled by a pharmacist no later than the next business day"</p> <p>What about by a pharmacy technician as they are often times overseeing this part of the AMS system. In addition the next business day for a hospital is usually the next day and this is not always possible depending on staffing. "The facility should have a system in place to identify newly added patients and should be reconciled as soon as possible"</p>	<p>Roger Wolf, Administrative Director, Richard Paul, Manager II, Inpatient Pharmacy, Suzanne Dolbey, Manager, Informatic Systems, Virginia Mason Hospital & Seattle Medical Center</p>	

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	Comment	From	Response
188shall be reconciled by a pharmacist [add or designee] no later than the next business day..... In many facilities the AMS daily activity is monitored by a skilled technician or pharmacist under the supervision of a pharmacist or the PIC.	Cindy Wilson, PharmD, Manager, Pharmacy 340B Program, CHI Franciscan Health	
189	Suggested amended language: "Patient profiles added outside the normal admission discharge transfer process, shall be reconciled by a pharmacist no later than the next business day. On at least a daily basis, the PIC, or his or her pharmacy designee, shall run an Added Patient, or equivalent, report to ensure reconciliation has occurred; "	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
190	We request clarification on the terms "patient profile" and "reconciliation", and hope to work with the Commission on understanding the intent of this language in order to ensure it has the desired effect, and whether having a pharmacist review is necessary.	Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health	
Rule Section 040(7) - Security Req. - PIC sole responsibility			
191	Based on experience, keeping track of all users and setting up access for all users in a community hospital (nurses, students, pharmacy staff) is an enormous task that it will not be practical for the PIC to manage on a day to day basis. This should be a delegated task. Suggested language: "The PIC <u>or their delegate</u> shall have the sole responsibility to:"	Xheni Waggoner, PharmD, Pharmacy Operations Manager, Northwest Hospital & Medical Center, UWMedicine	
192	Suggested amended language: The PIC <u>or designee</u> shall have the sole responsibility to...	Charles Ho, Harrison Medical Center	
193	Suggested amended language: The PIC <u>and/or designee</u> shall have the sole responsibility to: In many circumstances, either the director or the manager would be the person ensuring b and c but would not be the same person performing maintenance on the access to the system. Depending on availability of the PIC, there may be a need for access outside of the PIC hours especially for 24 hours facilities so adding a designee would help.	Julie Doung, PharmD, Pharmacy IT Coordinator, Northwest Hospital & Medical Center	

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	Comment	From	Response
194	See above comment about defining a PIC, this should be PIC or designee, the director of pharmacy of a facility larger than critical access does not have the time to be responsible for this and should be able to designate this function. The PICs responsibility is to establish criteria for who may have access and what that access should be, not actually do it.	Margie Hummel, PharmD, Pharmacist Informaticist, Providence Health	
195	Should include designee language. Typically IT oriented medical professional monitor access.	Craig Travis, Pharmacist Mason General Hospital	
196	Suggested deletion of entire section.	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
197	<ul style="list-style-type: none"> • Most hospitals have a Pyxis Administrator that assists with user access this should not be the sole responsibility of the PIC. Delegation of these activities to a Pyxis Administrator or designee needs to be allowed considering healthcare facilities such as our have 5000+ AMS users. • Suggested change “Sole” responsibility should change to, “ The PIC is responsible for AMS security and ensures medication access complies with state and federal regulation. The PIC provides oversight to the Pyxis Administrator or designee to assign, discontinue or change access to the system and to ensure the AMS is stocked accurately according to policies and procedures. 	Gail Bunker, PharmD, TG/AH Pharmacy Operations Manager, Multicare Health System	
Rule Section 040(7)(a) - Security Req. - PIC sole responsibility-assign, discontinue, change access			
198	Assigning users to the system could be a full time job by itself.	Xheni Waggoner, PharmD, Pharmacy Operations Manager, Northwest Hospital & Medical Center, UWMedicine	
199	This should not be the sole responsibility of the PIC. It is appropriate to designate select skilled and supervised personnel, such as a Lead Tech or a pharmacist to maintain users in the AMS. The PIC should have oversight of the process.	Cindy Wilson, PharmD, Manager, Pharmacy 340B Program, CHI Franciscan Health	

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	Comment	From	Response
200	This should not be the sole responsibility of the PIC. It is appropriate to designate select skilled and supervised personnel, such as a Lead Tech or a pharmacist to maintain users in the AMS. The PIC should have oversight of the process.	Cindy Wilson, PharmD, Manager, Pharmacy 340B Program, CHI Franciscan Health	
201	<p>We believe that in a large institution, requiring that the PIC be solely responsible for assigning access to the system does not allow for appropriate flexibility to manage appropriate AMS use with other PIC responsibilities. It is not unheard of to have 75 new users, removed, or changed accesses in a week. While we agree that the number of people that have access to this responsibility needs to be limited, we think it does not need to be done solely by the PIC. We therefore request that (a) is stricken here, which would allow for this to be a delegated function by the PIC. In addition, we think this language should be moved up to the policies and procedures section WAC 246-874-030 (3).</p> <p>Additionally, the term stating PIC has “sole responsibility” brings forward the confusion of WAC 246-874-010 (16), as a large hospital or institution may have multiple PIC’s per the draft WAC.</p>	Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health	
Rule Section 040(7)(b) - Security Req. - PIC sole responsibility-ensure access to meds comply w/ law			
202	Stated already in WAC 246-874-021 under PIC - AMS section.	Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health	
Rule Section 040(7)(c) - Security Req. - PIC sole responsibility-ensure stocking of AMS			
203	So, again, only the PIC is responsible? No one else can add users to the AMS? No one else can stock meds? What is this really trying to say?	Lindsay Mckie PMH Medical Center	
204	A delivery AMS is not stocked. State that the AMS is ‘maintained’ or ‘managed’.	Sara Lake, Marketing Manager and Regulatory Affairs, Asteres Inc.	

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	Comment	From	Response
	Rule Section 040(8) - Security Req. - Comply with all laws regarding patient confidentiality		
205	We believe that the HIPPA laws that are in place address this issue. Deleting this section would avoid confusion and redundancy in WAC, as all other laws are assumed to be in place and don't need to be included in this rule.	Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health	
	Rule Section 040(9) - Security Req. - PIC perform quarterly reports		
206	“The PIC...quarterly audits...” What is the commissions expectation here? Quarterly? Really?	Cheryl Pell, RPh Director of Pharmacy Management – Medication Review, Inc.; On behalf of herself and one of her pharmacists (Chris)	
207	I'd like to recommend more frequent review (monthly vs. quarterly) to more rapidly respond to diversion or other non-compliant activities which may be occurring.	Richard Molitor	
208	Not sure why this requirement is under the security requirement section. Consider moving this to the Quality Assurance Audit Section.	Xheni Waggoner, PharmD, Pharmacy Operations Manager, Northwest Hospital & Medical Center, UWMedicine	
209	The PIC shall <u>assure performance of quarterly compliance</u> audits of compliance with the AMS policies and procedures The PIC may not be the persone performing audits.	Roger Wolf, Administrative Director, Richard Paul, Manager II, Inpatient Pharmacy, Suzanne Dolbey, Manager, Informatic Systems, Virginia Mason Hospital & Seattle Medical Center	

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	Comment	From	Response
210	Suggested amended language: “The PIC shall perform quarterly <u>Quarterly</u> audits of compliance with the AMS ADC policies and procedures <u>will be performed.</u> ”	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
211	<ul style="list-style-type: none"> • Please provide an example of best practice on how quarterly audits of compliance with AMS policies and procedures should be performed. • Suggested change, the language should be changed to “The PIC is responsible for ensuring quarterly audits are performed” . The language as written would indicate that the PIC needs to personally perform the audits. This needs to be a delegable task. 	Gail Bunker, PharmD, TG/AH Pharmacy Operations Manager, Multicare Health System	
212	Quarterly audits would be excessive here and would create redundancies in processes. In addition, the term “audit” here is undefined. If adopted as-is, we are concerned that this could be too widely applied and meaningless. We believe that annual audits that could coincide with policy review and renewal would be more reasonable and would follow the Commission’s intent, and we hope to work with the Commission, through further stakeholder meetings, to understand the expected scope of these audits so that it’s clear to all parties what is involved and expected.	Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health	
Rule Section 050 - Inventory Control Req. - PIC approves AMS drug inventory			
213	There seems to be an opportunity here to make the description broader to allow flexibility while preserving safe medication storage and access to include, if the organization wishes, to include products that are multiuse, but patient specific.	Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health	
214	Not applicable. Delivery AMS do not keep a drug inventory. They are filled with patient specific prescriptions that have been filled by pharmacy staff and verified by a pharmacist. No applicable for delivery AMS. Example: All containers of medications stored in the AMS shall be packaged and labeled in accordance with state and federal law. All aspects of handling controlled substances shall meet the requirements of all state and federal law. The AMS shall provide a mechanism for securing an accounting for medications removed from and subsequently returned to the AMS, in accordance with state and federal law.	Sara Lake, Marketing Manager and Regulatory Affairs, Asteres Inc.	

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	Comment	From	Response
Rule Section 050(1)(a) - Inventory Control Req. - PIC implements procedures and maintains records-legend drugs			
215	Delete section (regarding PIC approval of inventory)	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
216	What does PIC 'AMS inventory approval' entail? This has the potential, as written, to add administrative time to the PIC role without a clear added security benefit that we're aware of. We request that the Commission strike part a, as inventory is dynamic.	Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health	
Rule Section 050(1)(c) - Inventory Control Req. - Replenishment of AMS is reserved to a pharmacist,			
217	Add language: Replenishment of the AMS is reserved to a pharmacist, pharmacy intern, pharmacy technician <u>or a trained and licensed Washington state health care practitioner approved by the PIC.</u>	Karen Nishi Consultant Pharmacist CUBEX LLC	
218	Suggested amended language: " Replenishment of the <u>The PIC or licensed designee is responsible AMS ADC replenishment...</u> " Delete remainder of subsection.	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
219	CVS Health generally supports and applauds the Pharmacy Quality Assurance Commission (the "Commission") on the proposed changes drafted by the Technology Committee to amend these rules to correspond with current industry standards in Long-Term Care Settings. However, CVS Health respectfully requests additional revisions under proposed rule WAC 246-874-050. Specifically we request that the Commission allow a licensed nurse to not only have access to but replenish the AMS and allow a medication not administered to a patient be returned to the AMS by a pharmacist, pharmacy technician, pharmacy intern or a licensed nurse. Suggested amended language: "Replenishment of the AMS is reserved to a pharmacist, pharmacy intern, or a pharmacy technician, or a licensed nurse in a licensed health care facility under the supervision of a pharmacist;"	Lauren Berton, PharmD, Director, Pharmacy Regulatory Affairs, CVS Health	

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	Comment	From	Response
220	<p>I was surprised and disappointed that the draft rules do not allow a nurse to restock (replenish) an AMS located off site from the pharmacy. Allowing the nurse to replenish an AMS was recommended in the response to the statutory recommendations submitted by WHCA/WSPA (attachment 1 & 2). Though I was not a participant in the PQAC ADDD technology subcommittee, my colleague provided their recommendations that also support nurse replenishment (attachment 3). Our pharmacists checks and approves all medication cartridges, cassettes or containers to be placed in the device prior to delivery. Compared to a manual tackle box (currently used as e-kits), AMS are safer, provide better documentation, prevent diversion and have security measures to control access. We service the entire state of Washington from a single location. Requiring a pharmacy employee to restock the device is not feasible. For reference, Minnesota and North Carolina have regulations supporting this practice.</p>	<p>Teri Ferreira, RPh, General Manager, Consonus Pharmacy</p>	
221	<p>I was disappointed that the draft rules do not contemplate a nurse to restock (replenish) an AMS. Allowing the nurse to replenish an AMS was recommended by the Technology Committee sub-groups representing both LTC and ADDDS/Robotics (attachment 1). Moreover, in response to the statutory recommendations submitted by WHCA/WSPA, the Commission recommended allowing a nurse to restock an AMS (attachment 2 & 3). LTC pharmacies employ bar code scanning, RFID or other similar technologies to assure accuracy and integrity of the restocking process. A pharmacist checks and approves all medication cartridges, cassettes or containers to be placed in the device prior to delivery. Compared to a manual tackle box (currently used as e-kits), AMS are safer, provide better documentation, prevent diversion and have security measures to control access. Requiring a pharmacy employee to restock the device in a rural area may not be feasible and LTC pharmacies may decide to pull these units; replacing them with less safe and less secure manual tackle boxes. For reference, Minnesota and North Carolina have regulations supporting this practice.</p>	<p>Scott Hancock, President of Pharmacy Services, Propac Pharmacy</p>	
222	<p>One of the advantages of the draft rule language is the broad definition of “replenishment” which includes activities both pharmacy staff and nurses may perform under their scope of practice. Draft WAC 246-874-010 definition: “Replenishment includes checking stock, loading unloading, filling and refilling of medications in the AMS.</p> <p>Pharmacists, pharmacy interns and pharmacy technicians currently check stock, fill and refill medications and do cycle counts for the AMS. Facility nurses load and unload the pharmacy-filled containers in the AMS and do cycle counts with security requirements in place for controlled substances (witnesses and blind counts).</p>	<p>Lynn Whitmore, RN, MS, Nurse Consultant, Senior Care Pharmacy of the West</p>	

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	Comment	From	Response
	<p>(CONT.) When nurses load a container of medication into the AMS, they are placing a sealed container that was labeled, filled or refilled at the pharmacy and checked by a pharmacist into a locked cabinet (AMS). This is no different than what happens when nurses receive medications from the pharmacy for traditional emergency kits. With a traditional emergency kit, nurses receive a sealed plastic box from the pharmacy and place it into a locked cabinet. Suggested language:</p> <p><u>“Replenishment of the AMS to include checking stock, filling, refilling, loading and unloading the AMS is done by a pharmacist, pharmacy intern, or a pharmacy technician under the supervision of a pharmacist. Loading, unloading and accounting for medications in the AMS shall be done by Washington State licensed health care practitioners, approved by the facility and the PIC, acting within their scope of practice.”</u></p>	Lynn Whitmore, RN, MS, Nurse Consultant, Senior Care Pharmacy of the West	
223	<p>The draft rules don't allow the restocking (referred to as replenishment) of AMS by nurses. Does section (1) (c)(ii) of draft WAC 246-874-050 open the door for nurses if an approved verification system is used? Also attached are the Technology Committee recommendations for restocking. Committee language from Draft 8:</p> <p>“The checking and stocking of medications in the automated mediation system is reserved to a pharmacist, pharmacy intern, or a pharmacy technician at the pharmacy location and by other licensed healthcare professionals at pharmacy-owned equipment locations off-site.”</p> <p>4...The stocking and restocking of all medications in the Off-Site Facility System shall be performed by a Washington State licensed pharmacist and/or a Washington State certified pharmacy technician and/or a Washington State licensed health care professional based on approved facility protocols. A pharmacist must conduct final checks of work performed by a pharmacy technician or licensed health care professional.</p>	Forward from unknown 2 by Karen Nishi Consultant Pharmacist CUBEX LLC	
224	<p>The two big issues remain: 1) allowing a nurse to restock is critical, especially in remote areas 2) full-blown interfaces that require prospective DUR and override systems should not be required for electronic e-kits...my two cents.</p>	Forward from unknown 2 by Karen Nishi Consultant Pharmacist CUBEX LLC	
225	<p>I was hoping this was intended for mostly acute care settings but it mentions supplemental drug supplies so the intent must be to include LTC. The biggest issues include:</p> <p>-Restocking can't be done by a nurse</p>	Forward from unknown 3 by Karen Nishi Consultant Pharmacist CUBEX LLC	

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	Comment	From	Response
226	<p>I would like to comment on two very important points:</p> <ul style="list-style-type: none"> • Allowing, with appropriate safeguards and pharmacist oversight, nurses to restock an AMS • Allowing a nurse to access emergency medication prior to pharmacist review 	Scott Hancock, President of Pharmacy Services, Propac Pharmacy	
Rule Section 050(1)(c)(ii) - Inventory Control Req. - Electronic verification systems-to be approved by commission			
227	<p>Electronic double check systems are superior at preventing misloading of a machine compared to tech check tech which is superior to a pharmacist filling a machine, so we question whether it would be worth the Commission's time to require PQAC approval of each instance. If the intent of the Commission is to ultimately protect the public, we recommend that the Commission articulate a rule that will make this technology be the norm rather than the exception.</p> <p>Suggested language: : 'Electronic verification systems that use a medication identifier code to verify and control loading, filling and restocking of a AMS may be use to in place of manual double check so long as a pharmacist is responsible for assigning and matching the identifier code in AMS and interfaced systems and multiple like drugs are either attached together by the drug manufacturer ing or packaging process or attached together and verified as the same drug through the checking process described in 246-874-050 (10) (a); and'. We then recommend that "medication identifier code" be added to the definitions section as: "an alphanumeric code that is matched to a medication to read and identify that medication to an AMS. The code must be attached to each individual dose of medication."</p>	Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health	
228	See definition of electronic verification system...so the fact that we utilize scan on refill requires prior approval by the Commission?	Cheryl Pell, RPh Director of Pharmacy Management – Medication Review, Inc.; On behalf of herself and one of her pharmacists (Chris)	
229	Really? So, scan on refill into the AMS is wrong without Commission approval? This is an electronic double-check of verified meds. We're not ok with that?	Lindsay Mckie PMH Medical Center	
230	<p>Does this mean that even if a manufacturer has a tried and true method for accomplishing a second check electronically (e.g. Carefusion Pyxis system has a scanning system in place) that each facility must get approval to use it? What kind of back log would that create?</p> <p>Seems a system could be approved by the Commission and as long as a facility is using an approved system, what is the benefit of getting it separately reviewed for a specific facility?</p>	Margie Hummel, PharmD, Pharmacist Informaticist, Providence Health	

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231	<p>Regarding “electronic verification” And or if the technology is approved by PQAC for the company in question making the technology. Once the company that makes the technology gets it approved by PQAC we should be able to implement the technology without additional approval. Why do both.</p>	<p>Roger Wolf, Administrative Director, Richard Paul, Manager II, Inpatient Pharmacy, Suzanne Dolbey, Manager, Informatic Systems, Virginia Mason Hospital & Seattle Medical Center</p>	
232	<p>Electronic verification systems for AMSs utilize various forms of electronic verification, bar code scanning, RFID, weight verification or similar electronic processes to accurately certify that medications have been properly loaded into an AMS. With use of this type of technology, CVS Health requests that licensed nurses be added as an individual who can replenish the AMS and language that permits medication not administered to a patient be returned to the AMS by a pharmacist, pharmacy intern, pharmacy technician or a licensed nurse. Furthermore, current AMS technology accounts for all access points into an automated system including but not limited to auditable logs which document each authorized individual’s access into the AMS.</p> <p>Suggested amended language: “Returned medications: A drug removed from a system but not administered to a patient may be returned to the AMS return bin or other area designated by the PIC by a pharmacist, pharmacy intern, pharmacy technician or a licensed nurse only if the drug remains unopened, sealed, intact, and is properly stored.”</p>	<p>Lauren Berton, PharmD, Director, Pharmacy Regulatory Affairs, CVS Health</p>	
Rule Section 050(1)(d) - Inventory Control Req. - Packaging of drugs placed in AMS			
233	<p>Does this account for products purchased from a 503B Compounding Facility since they are not manufacturers ? Also USP 797 compliant compounded batches are placed in Pyxis machines for expedient delivery to patient. Not having the ability to place these types of products in AMS puts timely patient care in jeopardy. There are also multiple dose containers put in AMS (i.e. insulin vials). As long as the pharmacy has policies/procedures in place to ensure accurate dispensing/administration, the need to be this prescriptive on what can go in the machine is diminished.</p> <p>Suggested deleting language.</p>	<p>Xheni Waggoner, PharmD, Pharmacy Operations Manager, Northwest Hospital & Medical Center, UWMedicine</p>	

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234	Based upon the definition of drugs that are included in this section, it sounds like compounded products are not included in AMS. There are items like compounded narcotic PCA bags that are stored in AMS in our facility and this does not address them.	Julie Doung, PharmD, Pharmacy IT Coordinator, Northwest Hospital & Medical Center	
235	Not all drugs placed in AMS are unit of use. MDV,MDI's, etc	Roger Wolf, Administrative Director, Richard Paul, Manager II, Inpatient Pharmacy, Suzanne Dolbey, Manager, Informatic Systems, Virginia Mason Hospital & Seattle Medical Center	
236	Change AMS to ADC	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
237	Limiting this to 'unit dose' or 'unit-of-use' will limit the technology, thus excluding any chance at expanding to 'central fill' or 'prescription dispensing' technology (like ED dispensing machines, Carousels, Robots and CS Safes). Again, this rule could be applied to central pharmacy dispensing systems (robot and carousel).	Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health	

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	Rule Section 050(1)(e) - Inventory Control Req. - Emergency kits and supplemental dose kits - stored in AMS		
238	<p>I was quite confused reading through this. While I am hopeful it is not, I believe their intent is to combine the both the ADD current rules and LTC using them for ekits. They are two different distinct processes. All medications in an electronic ekit are considered emergent in the fact that they either must be given right away or prior to the delivery from the pharmacy.</p> <p>I agree with the bullet points below – as written, it would be almost impossible for us to utilize this safer technology thereby forcing us to use tackle boxes. As Karen pointed out on the commission call last week, why would we have stricter rules for EMS than tackle boxes? Maybe they are planning to not allow tackle boxes as emergency kits? About 4 years ago at a WSPA meeting, a comment was made by the board that they were hoping to do away with tackle boxes altogether as ekits. The comments at that time was that would be unfair business practices as smaller pharmacies cannot afford EMS.</p>	<p>Forward from unknown 1 by Karen Nishi Consultant Pharmacist CUBEX LLC</p>	
239	<p>The draft does not contemplate using AMS for emergency box use. Please see the attached recommendations by the Technology Committee. The Committee recommended that “non-profile” driven systems (i.e. e-kits) would not require prior or concomitant RPH review to gain access for administration. In contrast, the draft rules require) prior to removal. This is not current SOP. This requires a more robust interface and creation of an override list.</p> <p>Committee language from Draft #8</p> <p>“These non-profile driven systems do not require prior or concomitant pharmacist review of medication order/prescriptions in order to gain access to the system for medication administration.1</p> <p>1This type of system may include, but is not limited to, kiosks, night drug cabinets, emergency drug kits, or floor stock/first dose cabinets, and is used to dispense medication directly to a patient or to an authorized healthcare practitioner for immediate distribution to the patient. Such systems may be used by pharmacies, for maintaining patient care unit medication inventories. A pharmacist is not required to be physically present at the site of the automated dispensing or distribution and storage system if the system is managed by a pharmacist.”</p>	<p>Forward from unknown 2 by Karen Nishi Consultant Pharmacist CUBEX LLC</p>	

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	Comment	From	Response
240	<p>I was hoping this was intended for mostly acute care settings but it mentions supplemental drug supplies so the intent must be to include LTC. The biggest issues include:</p> <ul style="list-style-type: none"> -Pharmacist's review must be conducted before a medication is removed unless designated as emergent AND can't have a supplemental medications if an AMS is used 	<p>Forward from unknown 3 by Karen Nishi Consultant Pharmacist CUBEX LLC</p>	
241	<p>The acuity of Nursing Facilities has greatly increased over the last five years with the acuity being very similar to hospitals ten years ago excluding invasive and diagnostic procedures. Unlike hospitals, servicing Pharmacies providing medications are usually offsite. The distance can be 3-4 hours away. Nursing Facilities rely on emergency and supplemental dose kits to enable timely medication administration after patients are admitted or for new medication orders especially for time sensitive therapies such as antibiotics and pain medications. This is permitted under WAC 246-865-030. Nursing Facilities typically receive their new admissions during non-business hours including evenings, weekends, and holidays adding to the reliance of supplemental and emergency dose kits to provide quality care to the residents of Washington residing in Nursing Facilities. Supplemental and emergency dose kits are traditionally stored in 'tackle boxes' with no technology support. This has worked fine for decades but AMS offers a superior mechanism with increased accountability and decreased potential for medication errors. Nursing Facilities using AMS with reasonable requirements should be an option. If the draft would go into effect as written, it would be challenging to comply in the Nursing Facility setting resulting in not being able to take advantage of the technology that an AMS can provide.</p>	<p>Greg Milanich, PharmD, FASCP, AVP, Pharmacy Services, HCR ManorCare</p>	
242	<p>The approach of the revisions to this rule is a decent one: expanding the overall scope and definition of an AMS to allow for future technological advances and offerings to the industry without the need of constant updates and exceptions to the rules. One instance where the revision needs to be re-addressed is regarding the use of emergency kits in extended care facilities (nursing homes) as listed under WAC 246-865-030. (listed further in document)</p>	<p>Brian Beach, PharmD, CFO Kelley-Ross Pharmacy Group</p>	

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	Comment	From	Response
243	<p>I am a member of the Technology Committee as well as a stakeholder providing input for the long term care statutory language drafted and submitted by WHCA/WSPA. I thank you for the opportunity to provide comments on the AMS draft rules. Emergency boxes and AMS devices, often utilized solely as e-kits in LTC, are critical for ensuring safety and timely access to medications for patients in the long term care community. I would like to limit my comments to the utilization of automated medication systems as e-kits.</p> <p>I believe there is no argument that an AMS provides improved patient care and safety as well as better accountability and security compared to manual e-kits. I urge you to consider these comments and look forward to continued work with the Commission and Department of Health. This collaborative effort is truly appreciated by long term care residents and community.</p>	<p>Scott Hancock, President of Pharmacy Services, Propac Pharmacy</p>	
244	<p>Thank you for the opportunity to offer comments on the draft rules proposed for the use of Automated Medication Systems (AMS) in long term care settings. I have stakeholder interest in these proposed rules as a licensed registered nurse in Washington state working in the long term care arena. My professional nursing experience is extensive, including years working for the Department of Social and Health Services as a long term care Nurse Consultant and nursing home surveyor. Through this work, I have become very familiar with Washington Administration Code and federal regulations governing long term care. At the present time, I provide pharmacy nurse consultation services to eight long term care facilities located in both urban and rural areas of Washington. A number of these facilities currently use an AMS as their emergency kit.</p> <p>Unlike hospitals, a skilled nursing facility (SNF) typically receives medications from a pharmacy located off-site. The servicing pharmacy is a separate organization whose staff are not employed by the SNF. Admissions to the SNF occur seven days a week at all hours of the day and it is important for medications to be available in a timely manner to ensure safe quality care for the comfort and well-being of residents. The way this is accomplished in SNFs is with an emergency kit, which is either a traditional plastic tackle box kit or AMS. One of the significant advantages of an AMS versus the traditional emergency kits is security. Automated systems offer real time tracking and control of the medications in the facility. They also electronically monitor staff access and usage which is helpful in identifying potential compliance issues. Traditional tackle box kits do not provide that level of accountability or security. If the draft rules are passed as written, the pharmacy I work for will have no choice but to remove AMS cabinets from the Washington SNFs currently using them and replace them with the tackle box kits.</p>	<p>Lynn Whitmore, RN, MS, Nurse Consultant, Senior Care Pharmacy of the West</p>	

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	Comment	From	Response
245	Not quite sure I understand this section. Are they saying that emergency kits (crash carts), RSI kits, cardiac kits are not allowed anymore and these drugs have to be stocked in AMS only? At one of my hospitals, we have cardiac kits that are located in the emergency bay so that the nurse doesn't have to leave the patient alone	Cheryl Pell, RPh Director of Pharmacy Management – Medication Review, Inc.; On behalf of herself and one of her pharmacists (Chris)	
246	Add language: ...absence of the drugs would threaten the survival <u>or health</u> of the patient.”	Karen Nishi Consultant Pharmacist CUBEX LLC	
247	I am not sure I understand the intent of section (1)(e) of draft WAC 246-874-050. This seems to prevent using a “supplemental” tackle box e-kit if also using an AMS. The most obvious example would be refrigerator e-kits not stored in the AMS. This is not current SOP. Those of us with Cubex or other devices also have manual refrigerator kits or other kits necessary to care for patients.	Forward from unknown 2 by Karen Nishi Consultant Pharmacist CUBEX LLC	
248	Does this section imply that there could not be any crash carts, malignant hyperthermia carts, or anaphylaxis kits in the hospital? Per Joint Commission Standard MM.03.01.03 emergency medications need to be readily accessible in the patient care areas. While keeping them in the AMS device is fairly easily accessible – it is not as easily accessible as from a locked crash cart. Highly recommend removing this restrictive language.	Xheni Waggoner, PharmD, Pharmacy Operations Manager, Northwest Hospital & Medical Center, UWMedicine	
249	This isn't ok. At all. Emergency kits (crash carts), RSI kits, cardiac kits aren't allowed? These meds must be stocked in the AMS? That's garbage. So, the order has to be entered, then the nurse waits for the order to cross over the electronic abyss to a pharmacist, then back to the nurse, then...and this has taken 5-10 minutes and the patient needs a nitro tab? Really?	Lindsay Mckie PMH Medical Center	

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	Comment	From	Response
250	<p>Suggested deleting whole point. If an AMS is utilized, drugs normally contained in a separate emergency kit or supplemental dose kit shall be stocked into the AMS. Only emergent medications defined on the override list may be accessed prior to receiving prospective approval from the pharmacist provided that the absence of the drugs would threaten the survival of the patient.</p> <p>(This is not achievable and is dangerous. By this language, after AMS implementation, all crash carts (defined as kit supply of drugs outside of pharmacy) and rapid-sequence intubation kits (often associated with a crash cart) must be stocked into the AMS. This is not feasible by size or cart design, and dangerous because AMS has a chance of malfunctioning (mechanical, electrical, or otherwise); and under stress it has been proven/shown by major AMS companies that Biometrics tend to fail under these circumstances (sweat, adrenaline, etc.). This delays the users from accessing the AMS—or worse completely prevents access to AMS if AMS should fail mechanically or electrically. This language would jeopardize patient safety.</p>	Charles Ho, Harrison Medical Center	
251	<p>I support that PIC s shall evaluate the quantity and continuation of existing kits, carts, and drug supplies originally outside of AMS for opportunity to be moved into AMS. The Board can easily request each facility/PIC during the approval process (ADDD approval) to explain how would AMS benefit the reduction of free-standing kits and carts, and if a review has taken place to reduce those free-standing kits. However, approval should still be granted without prejudice since in some scenarios and in some facilities the free-standing kit (say Crash Cart) just cannot be replaced by an ASM. Crash Cart or any boxed kits are not subject to electrical or mechanical failures like an AMS is.</p>		
252	<p>So according to this section, Crash Carts or other emergent boxes are no longer allowed and must be stored in the AMS? This isn't a good solution to a critical situation where meds are readily needed and there is no time to run to a AMS devise to pull medications.</p>	Julie Doung, PharmD, Pharmacy IT Coordinator, Northwest Hospital & Medical Center	
253	<p>Does this apply to code carts? The purpose of such kits is that the time it takes to remove everything from an AMS could make the difference in a patient survival. Also, electronic systems have downtime, they need these back up kits for that event.</p>	Margie Hummel, PharmD, Pharmacist Informaticist, Providence Health	

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254	What about Code carts, OR medications that do not go through a prospective approval process. Anesthesia carts etc. This precludes health systems from taking care of patients in emergent situations.	Roger Wolf, Administrative Director, Richard Paul, Manager II, Inpatient Pharmacy, Suzanne Dolbey, Manager, Informatic Systems, Virginia Mason Hospital & Seattle Medical Center	
255	This language sounds as though it would be applicable to crash carts. If so this needs a great deal of clarification. Our AMS model would create a significant barrier in a code situation. If this is not the intent clarification of what an emergency or supplemental dose constitutes is needed.	Craig Travis, Pharmacist Mason General Hospital	
256	The use of emergency kits outside the AMS needs to be vetted with stakeholders. Does this mean the facility cannot stock medications in a crash cart? Malignant hyperthermia cart? Rapid intubation kit or pain block kit used by anesthesia (in which the LIP is using the kit and administering medications in urgent medical situations)? Does this mean there cannot be emergency medications for allergic reactions in procedure rooms outside the AMS? The desire of the PQAC to determine what constitutes an 'emergent medication' is highly concerning. This section is another attempt to limit access to medications for our patients. Recommend this also be vetted with a provider stakeholder group.	Cindy Wilson, PharmD, Manager, Pharmacy 340B Program, CHI Franciscan Health	
257	Delete entire subsection.	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	

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	Comment	From	Response
258	<p>An emergency kit is a critical component of providing timely access to medications to residents in extended care facilities (nursing homes) and is currently allowed under WAC 246-865-030. Long Term Care Pharmacies have provided emergency kits in non-electronic format (manual tackle boxes) since initiation of rule and in electronic format since the early 1990's under the guidelines of this WAC.</p> <p>Over the past 10 years, there has been confusion amongst stakeholders as inspectors were inspecting electronic ekits as ADDD's (WAC 246-872), not ekits (WAC 246-865-030). The difference is an ADDD is used for dispensing daily orders (i.e. in hospitals instead of unit dose carts), whereas ekits are for use off- site and used only for emergencies when medications cannot be obtained from a pharmacy in a timely manner.</p>	Teri Ferreira, RPh, General Manager, Consonus Pharmacy	
259	<p>The proposed rules do not take into consideration the differences between on-site and off-site AMS (previously defined in the rules as ADDD) used as electronic ekits. Our pharmacy would not be able to comply with the rules as written; therefore we would have to remove the electronic ekits (AMS as defined in the proposed rule) and replace with a less safe and less secure manual tackle box e-kit system.</p> <p>I would like to recommend the following changes to the proposed rules in order for us to continue to use the AMS as an electronic e-kit in the nursing homes we service:</p> <ul style="list-style-type: none"> • Allowing, with appropriate safeguards and pharmacist oversight, nurses to restock an AMS • Allowing a nurse to access emergency medication prior to pharmacist review • Removal of an override list for AMS used as e-kits located off site from pharmacy 	Teri Ferreira, RPh, General Manager, Consonus Pharmacy	
260	<p>Supplemental Dose Kit: The draft indicates that supplemental dose kits cannot be used if an AMS is used in a Nursing Facility. Not all needed medications can be kept in an AMS. For example, refrigerated medications and bulkier items.</p>	Greg Milanich, PharmD, FASCP, AVP, Pharmacy Services, HCR ManorCare	

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	Comment	From	Response
261	<p>Emergency kits have been utilized in extended care facilities since the early 1990's initially as non-electronic formats ("tackle boxes") and more recently as electronic systems (Pyxis, FirstDose, One Dose). These emergency kits serve a critical role in insuring timely access to medications for patients who are in need.</p> <p>The proposed rules do not address the off-site use of AMS as an electronic emergency kit, but rather focus on the use as a patient profiled, day-to-day medication storage and dispensing tool for nursing staff, similar to how such devices might be used in a Health-System environment. As written, my pharmacy would not be able to comply with the proposed rules and would need to convert these to less safe and secure "tackle box" emergency kits.</p>	<p>Brian Beach, PharmD, CFO Kelley-Ross Pharmacy Group</p>	
262	<p>I would like to propose that the draft rules be amended to address electronic emergency kits as separate systems from those historically interpreted as Automated Drug Dispensing Devices. This would allow electronic emergency kits to serve as a non-profiled access point for nurses to care for patients in need with appropriate oversight and safeguards in place through policies and procedures enacted through a pharmaceutical services committee at each facility.</p> <p>Today, these electronic systems allow for immediate notification of removal of medications and, in most cases, special codes to access controlled substances to ensure that valid, appropriate prescriptions have been issued by a prescriber and received by a pharmacist in the care of the patient in question. This practice has been supported by the PQAC ADDD Technology subcommittee and is documented in attachment 1.</p>	<p>Brian Beach, PharmD, CFO Kelley-Ross Pharmacy Group</p>	

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263	<p>There is currently no interface requirement for manual tackle boxes. Nurses can access manual kits as necessary to provide for prompt patient care. Likewise, the pharmacist is not required to input a prescription, in real time, in order for the nurse to access a manual tackle box. Conversely, the proposed AMS rules would require a robust interface and real-time data entry. While I support prospective pharmacist review for automated systems intended to dispense daily orders, I feel that automated systems used as e-kits should not be subject to real-time data entry and review. During on-call periods, the draft rules would require the pharmacist to return to the pharmacy and input the order; a process that could take several hours while a patient awaits critical medication that is already on site. LTC pharmacies may replace current AMS units with tackle boxes in order to provide better patient care. I respect the idea of an override list. However, it is difficult to define life-threatening or emergent. It depends on the family, patient, physician, nurse and the pharmacy. In my opinion, “emergency” does not necessarily mean life threatening, but addresses a patient in critical need of pain control, antibiotics or a routine medication for diabetes control or hypertension. Facilities have a federal requirement to administer medications in a timely fashion and patients deserve timely administration of all medications. The ADDD Technology subcommittee recommendations are included as attachment 4.</p>	<p>Scott Hancock, President of Pharmacy Services, Propac Pharmacy</p>	
264	<p>This section appears to be using a restrictive definition of supplemental dose kits that would actually be a barrier to medication access, becoming a patient safety issue. As we read it, there does not seem to be an exception process for code carts or emergency carts. We also question whether we would be in violation if a facility doesn’t have the capacity to store all drugs in the AMS such as IVs and other medications delivered to nursing units that are otherwise appropriately secured – does it become an “all or nothing” decision? To solve this issue, we request that this section is struck.</p>	<p>Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health</p>	
Rule Section 050 (2)(a)(i) - Inventory Control Req. - Perpetual inventory of controlled substances or legend drugs by blind count; each time one is accessed			
265	<p>Suggested amended language: Controlled substances or other legend drugs determined by the PIC shall be perpetually inventoried with a blind count by a Washington state licensed health care practitioner each time they are accessed in AMS <u>except in circumstances where drugs are loaded as single-use dispensing drawers</u></p>	<p>Julie Doung, PharmD, Pharmacy IT Coordinator, Northwest Hospital & Medical Center</p>	
266	<p>Replace AMS with ADC.</p>	<p>Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health</p>	

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	Comment	From	Response
267	<p>While we support this practice, as written, this section would require perpetual inventory for all controlled substances used in AMS – which we believe is an expansion of state law on controlled substances (currently only CII drugs require perpetual inventory by state law) and will create a double standard of practice between AMS and non-AMS care areas. Further, we question whether all automated machines have the ability to do this. We suggest that the Commission add language to clarify that this applies <u>“If a user has access to more than a single dose, then</u> controlled substances or other legend drugs determined by the PIC shall be perpetually inventoried...”</p>	<p>Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health</p>	
Rule Section 050 (2)(a)(ii) - Inventory Control Req. - All controlled substances accessed for replenishment or removal shall have an inventory count performed a minimum of every 7			
268	<p>I was hoping this was intended for mostly acute care settings but it mentions supplemental drug supplies so the intent must be to include LTC. The biggest issues include: -Controlled substances need to be inventoried weekly</p>	<p>Forward from unknown 3 by Karen Nishi Consultant Pharmacist CUBEX LLC</p>	
269	<p>Why must there be an inventory count every 7 days when AMSs keep perpetual inventories of all medications and we resolve all discrepancies. This is more strict than the current rule and really impacts patient care when nurses are tied up at a machine: Current WAC 246-872-040(3)(b) All controlled substances activities must comply with requirements of state and federal laws. The responsible pharmacist must have a system in place to verify the accuracy of controlled substance counts. Once in place, the counting system no longer requires compliance with WAC 246-873-080 (7)(h). The process for securing and accounting for returned or wasted medication is defined.</p>	<p>Traci Mitchell, PharmD, MHA Pharmacy Services Manager Evergreen Health Monroe</p>	
270	<p>So let me get this straight...we have a perpetual inventory of all controlled substances and a blind count requirement yet they have to be inventoried at least every 7 days? This requirement was removed in the latest rendition. Why is it being put back in place?</p>	<p>Cheryl Pell, RPh Director of Pharmacy Management – Medication Review, Inc.; On behalf of herself and one of her pharmacists (Chris)</p>	<p>Latest rendition is likely Draft #8</p>

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271	Amend language: "All controlled substances that are accessed for replenishment or removal in AMS shall have ((an inventory count performed at a minimum of once every 7 days by two authorized persons licensed to administer drugs. At least one of these persons shall be a licensed nurse)) a discrepancy report run each shift. Any discrepancies will be resolved within 24 hours"	Karen Nishi Consultant Pharmacist CUBEX LLC	
272	Would there be value in having the responsible individual rotated on a routing basis as a means to minimize the risk of diversion?	Richard Molitor	
273	Consider adding this verbiage to allow: "...every 7 days by two authorized persons licensed to <u>dispense/administer/handle controlled drugs substances</u> . At least one of these persons shall be a licensed nurse, <u>pharmacist or pharmacy technician</u> ; and"	Xheni Waggoner, PharmD, Pharmacy Operations Manager, Northwest Hospital & Medical Center, UWMedicine	
274	Wondering if it is necessary for at least one of these people be a licensed RN. What if 2 pharmacy staff members-tech or pharmacist-do the inventory?	Liz Verbrugge, PharmD, BCPS, Pharmacy Manager, PeaceHealth St. John Medical Center	Current draft language states "...two authorized persons licensed to administer drugs. At least one of these persons shall be a licensed nurse;" I'm not sure what this comment is referring to.
275	This requirement was removed from the WAC the last time it was rewritten. Why are we putting it back in? We already have perpetual inventory and blind counts.	Lindsay Mckie PMH Medical Center	
276	"two authorized persons authorized to access controlled substances. licensed to administer drugs. At least one of these persons shall be a licensed nurse; and" (Given staffing, it should be more beneficial to allow any other licensed personnel (who are authorized to access CS) to conduct this witnessed-inventory process. I, as a PIC, should be allowed to perform this inventory with an MD if situation warrants it. Or perhaps with another RPH. The goal is to detect diversion early by having witnessed-inventory process routinely. This detection can occur with any two persons and not just with a nurse. The quantity count is what sets off the diversion alert and not the user classification. In fact, if RNs are the routine users of one AMS, it might be beneficial to have some NON-RNs perform this inventory from time to time just in case the RNs were the ones diverting CS. I recommend eliminate the requirement on of which licensure type to perform the inventory).	Charles Ho, Harrison Medical Center	

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277	<p>What about controlled medications that are not accessed that often. Does this also mean that you would need to have an nurse come down to the pharmacy to do the controlled substance count on the controlled substances kept in the pharmacy in and AMS machine? I would remove this entire section ii. Why do we need to do an inventory count when we already have a blind count function involved with every transaction.</p>	<p>Roger Wolf, Administrative Director, Richard Paul, Manager II, Inpatient Pharmacy, Suzanne Dolbey, Manager, Informatic Systems, Virginia Mason Hospital & Seattle Medical Center</p>	
278	<p>Suggested amended language: “...removal in AMS ADC shall have an inventory... At least one of these persons shall be a licensed nurse; and”</p>	<p>Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health</p>	
279	<p>Weekly Controlled Substance Reconciliation: This is not warranted when users are required to indicate a blind count and a system for appropriate discrepancy resolution since a reconciliation is completed every time a medication is accessed.</p>	<p>Greg Milanich, PharmD, FASCP, AVP, Pharmacy Services, HCR ManorCare</p>	
280	<ul style="list-style-type: none"> • If Anesthesia “A-Carts” are considered an AMS nursing staff do not have access to these machines. Typically, pharmacy staff completes the inventory on these machines, therefore the language, “At least one of these persons shall be a licensed nurse” would not apply to Anesthesia AMS Carts • Pharmacy technicians are not licensed to administer drugs but should be allowed to assist with controlled substance inventories. • Language should be expanded to include providers, pharmacists, pharmacy techs and other licensed healthcare personal where medication administration is allowed within their scope of practice. 	<p>Gail Bunker, PharmD, TG/AH Pharmacy Operations Manager, Multicare Health System</p>	
281	<p>We believe that every 7 days is too often for AMS devices that are located in the pharmacy, but believe the Commissions intent is to have a specific inventory process when these devises are in the nursing unit. We therefore suggest that the language be changed to: “All controlled substances that are accessed for replenishment or removal in all nursing-unit based AMS shall have an inventory count performed at a minimum of once every 7 days by two authorized persons licensed to administer drugs. At least one of these persons shall be a licensed nurse;”</p>	<p>Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health</p>	

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	Comment	From	Response
Rule Section 050 (2)(a)(iii) - Inventory Control Req. - Requires controlled substances to be stored in individual pockets or compartments			
282	Some of our controlled substances dispensers are only accessible by pharmacy personnel. They dispense the medication on a per order individual basis and thus that access restriction provides a higher level of security. I would suggest language detailing that periodic counts be required for medications such that the entire contents of the device for a given medication are accessible by staff when issuing a dose.	Craig Travis, Pharmacist Mason General Hospital	
283	Suggested amended language: “ Storage of Controlled controlled substances shall meet the criteria of being double locked be stored in individually secured pockets or compartments within the AMS ADC; ”	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
284	We suggest that a similar augmentation be made as in the above, to read: “Controlled substances shall be stored in individually secured pockets or compartments within the <u>nursing-unit or OR/procedural based</u> AMS”	Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health	
Rule Section 050 (2)(b) - Inventory Control Req. - Requires record of medications replenished or inventoried including identifying			
285	Consider revising to:...shall be readily reviewed, retrievable and maintained by the PIC.	Richard Molitor	
286	This is already covered in the previous section for all drugs WAC 246-874-040. Suggested deletion.	Xheni Waggoner, PharmD, Pharmacy Operations Manager, Northwest Hospital & Medical Center, UWMedicine	
287	...shall be maintained by the AMS and readily retrievable by the PIC. readily retrievable and maintained by the PIC; and (minor sentence change to reduce ambiguity. It was reading like the PIC must personally maintain records of AMS accessing history. Usually the record is kept within the AMS server and the PIC readily retrieves it from wherever the server is located). All electronically based, nowadays.	Charles Ho, Harrison Medical Center	
288	Replace AMS with ADC, suggested amended language: “...shall be readily retrievable and maintained by the PIC; and ”	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	

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	Rule Section 050 (2)(c)(i) - Inventory Control Req. - Controlled substance discrepancy reports-requires PIC and facility/nursing admin to maintain discrepancy resolution and		
289	The individual creating the discrepancy should resolve the discrepancy; nursing created discrepancies should be resolved by nursing, pharmacy created discrepancies should be resolved by pharmacy. The PIC should provide oversight of controlled substance monitoring and discrepancy resolution. The PIC should not be actively involved with resolution of each discrepancy.	Gail Bunker, PharmD, TG/AH Pharmacy Operations Manager, Multicare Health System	
290	Consider adding this verbiage to allow for single dose dispensing. Some available systems (i.e. Pyxis Anesthesia Stations, only dispense the requested dose at a time, so the user does not have access to the entire inventory – therefore they cannot complete a blind count. “This process is exempt when the drugs are dispensed as single unit or single dose.”	Xheni Waggoner, PharmD, Pharmacy Operations Manager, Northwest Hospital & Medical Center, UWMedicine	
291	Suggested amended language: “The PIC <u>or designee</u> shall work...”	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
	Rule Section 050 (2)(c)(ii) - Inventory Control Req. - Controlled substance discrepancy reports-generation of report for each discrepancy, resolution of discrepancy, and mandatory		
292	“A discrepancy report...” Wow...that is a whole weekend. Some nurses work for 3 days and have 4 days off. How is this going to work? What about if the discrepancy was created before the person went on vacation? Again, I ask why such a short window? Does the Commission understand the different work schedules?	Cheryl Pell, RPh Director of Pharmacy Management – Medication Review, Inc.; On behalf of herself one of her pharmacists (Mike)	
293	If I cannot resolve a discrepancy of a single lorazepam 1 mg tablet, I am supposed to notify the Board? Or will this only occur if there is a “significant loss” as the law currently requires	Cheryl Pell, RPh Director of Pharmacy Management – Medication Review, Inc.; On behalf of herself and one of her pharmacists (Chris)	

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294	Override – This is NOT going to happen. I am at one hospital one day a week and will not return for 7 days. The Commission has not clue.	Cheryl Pell, RPh Director of Pharmacy Management – Medication Review, Inc.; On behalf of herself one of her pharmacists (Mike)	
295	Consider adding the verbiage to be consistent with the federal regulation/law. ...such report shall be resolved by the PIC (<u>or his designee</u>)...if determined to be a theft or a <u>significant</u> loss...	Xheni Waggoner, PharmD, Pharmacy Operations Manager, Northwest Hospital & Medical Center, UWMedicine	
296	Are we looking at “significant losses” as is currently required by law, or for one tablet that can’t be located?	Lindsay Mckie PMH Medical Center	
297	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 and the facility or nursing administration. 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;	Charles Ho, Harrison Medical Center	
298	(Some “discrepancies” are classified as discrepancies by AMS but not necessarily a discrepancy despite that there is a paper report. For example, a nurse counted 4 pieces of CS when there should be 5 pieces. That’s a discrepancy. Later on two other nurses inventoried the pocket and both confirmed that there were indeed 5 pieces, so the first nurse simply miscounted and indicated 4 pieces. In many AMS this situation is a defined discrepancy with report but there is <u>no CS loss</u> . The opposite can happen too that the nurse indicated 6 pieces of CS when there were only 5 pieces, proven by two other nurses under a Blind Count inventory verification. Again, a miscount.	Charles Ho, Harrison Medical Center	

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299	<p>(CONT.) This type of discrepancy should NOT require the PIC to personally resolve—in fact, this type of discrepancy—aka miscount—happens very, very, very, very routinely. A nurse very easily miscounts since there could be many loose pills in a pocket and sometimes a pill gets stuck in the corner of the pocket or it gets sandwiched between other pills. Even I the pharmacist has, from time to time, miscounted and had to recount again. Miscounts (as a discrepancy) shouldn't burden the PIC or pharmacy to resolve. As long as two other licensed individuals can both verify that there was just a miscount, this type of discrepancy is considered resolved and without further action necessary. I recommend the following language instead to meet the intent here:</p>	Charles Ho, Harrison Medical Center	
300	<p>Any reported discrepancy must be reviewed by two or more licensed persons authorized to access the discrepant drug and satisfactory resolution must be achieved within 72 hours upon discrepancy discovery where no loss of controlled substance can be positively confirmed by the reviewers. This resolution shall be documented and be readily retrievable by the PIC. Any discrepancy that cannot be resolved after 72 hours from its discovery, or when a theft of the discrepant drug has been determined, the PIC shall report this discrepancy to the Drug Enforcement Administration as required by federal law.</p>	Charles Ho, Harrison Medical Center	
301	<p>Most discrepancies are generated and resolved by nursing staff who are required to document a resolution with a witness. These are reviewed and the PIC maintains oversight of the process. The language needs to include the opportunity for the PIC or designee, nursing staff/management, facility leadership (sometimes a provider creates and resolves a discrepancy in period/procedure settings). This part of the language is too narrow.</p> <p>Regarding the requirement to report discrepancies which are not resolved within 72 hours, this is burdensome to the organization and will be a waste of resources. While most discrepancies are resolved within 72 hours, some are not. Many staff work rotating shifts and may be needed to help resolve a discrepancy but are not necessarily back on shift within 72 hours or they are unreachable when off shift. Reporting requirement should align with what already exists: known thefts/diversion and significant loss.</p>	Cindy Wilson, PharmD, Manager, Pharmacy 340B Program, CHI Franciscan Health	

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	Comment	From	Response
302	<p>Suggested amended language: A discrepancy Discrepancies will be resolved in a timely manner (not to exceed 72 hours). 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 and the facility or nursing administration. If there is an unresolved discrepancy after seventy two (72) hours of the time the discrepancy was discovered, or</p> <p>(iii)(NEW) If determined to be a theft or a loss of drugs <u>are identified</u>, the PIC <u>or designee</u> shall report to the commission and the federal Drug Enforcement Administration as required by federal law;"</p>	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
303	<p>Our experience is that 72 hours is too short for this turnaround, as these processes can involve staff that are part-time or go on paid leave. We request that this be changed to "within 72 hours if possible, but no longer than two weeks" instead, which would allow access to necessary staff schedules.</p>	Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health	
Rule Section 050 (2)(c)(iii) - Inventory Control Req. - Requires hospitals discrepancy reports and resolution to be with nursing admin by end of shift.			
304	<p>What is to be done if the hospital-based discrepancy can't be resolved by the end of the next shift? Does it need to be reported to PQAC and DEA?</p>	Richard Molitor	
305	<p>This is not consistent with the 72 hour rule above. Consider having one standard for resolving discrepancies to reduce confusion. Maybe 24 hour for both (also end of shift could be a different time depending on facility, day of the week etc.).</p>	Xheni Waggoner, PharmD, Pharmacy Operations Manager, Northwest Hospital & Medical Center, UWMedicine	
306	<p>This isn't always possible. Not all nursing administration and PIC's keep the same hours.</p>	Lindsay Mckie PMH Medical Center	
307	<p>If the AMS is located in a hospital, the PIC shall work with the nursing administration to resolve such report by the end of the shift. (Following the recommended language above (paragraph ii), paragraph iii is no longer necessary as it may take longer than end-of-shift to resolve a discrepancy. For example, a discrepancy is discovered 5 minutes before shift-ends; it may require additional time to resolve before 5 minutes is up, or if discrepancy is discovered at 3 AM, the PIC may not be on-site, on a Sunday. Paragraph ii process is more robust and more comprehensive. However, I recommend we add the following for paragraph iii) :</p>	Charles Ho, Harrison Medical Center	

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	Comment	From	Response
	<p>(CONT.) If the AMS is used by a hospital, the Department of Pharmacy and the PIC shall work collaboratively with Nursing Administration on all matters pertaining to drug discrepancies and their resolutions.</p> <p>(The reason I wrote “used by a hospital” instead of “located in a hospital” is because there are outpatient services located inside hospitals that do not belong to the hospital. Frequently, outpatient imaging services or independent HCEs may locate within a hospital building but are not owned by, operated by, or are a part of the hospital.)</p>	Charles Ho, Harrison Medical Center	
308	<p><i>Relating to facility leadership language</i></p> <p>Not all AMS devices are only used by nurses. We have some that are exclusively used by Anesthesiologists.</p>	Julie Doung, PharmD, Pharmacy IT Coordinator, Northwest Hospital & Medical Center	
309	Whose shift?	Margie Hummel, PharmD, Pharmacist Informaticist, Providence Health	
310	PIC or designee.....again, many facilities effectively utilize pharmacists and skilled technicians to resolve discrepancies. Refer to the above comment regarding requirement to report.	Cindy Wilson, PharmD, Manager, Pharmacy 340B Program, CHI Franciscan Health	
311	<p>Suggested amended language:</p> <p>(iv) (New number) If the AMS <u>ADC</u> is located in a hospital, the PIC <u>or designee</u>...</p>	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
312	We request that the Commission strike this language, as this duty of the PIC is implied. According to the role and function of the PIC, they would work with whoever was involved, so we believe this section is redundant. Furthermore, the definition of “shift” is difficult to align across facilities and care settings, making this rule very difficult to comply with without adding a role to the PIC that is not already implied.	Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health	

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	Comment	From	Response
	Rule Section 050 (3) - Inventory Control Req. - Override-allowing drugs on override list to be remove with prosepctive drug utilization review,		
313	This requirement will not be able to be met by facilities who don't employ a pharmacist or have telepharmacy. What happens on the weekend? The WAC allowing after hours removal states that the retrospective review should happen as soon as feasible. This is a conflict.	Cheryl Pell, RPh Director of Pharmacy Management – Medication Review, Inc., On behalf of herself and one of her pharmacists (Chris)	
314	Consider removing the word “business” in the override review, again due to the availability of after-hours services.	Richard Molitor	
315	This isn't possible if a facility doesn't have telepharmacy or 24 hour pharmacist coverage. The existing WAC states retrospective review should happen as soon as feasible. A CAH may only have a pharmacist a day or two a week, and may not be on consecutive business days.	Lindsay Mckie PMH Medical Center	
316	(See my added definition above. Define “Remove” as act of dispensing or refrain from using this terminology. Can be ambiguous. And “Remove” is proprietary to Pyxis. Omnicell calls it “Dispense Drugs”. MedSelect uses a green button that says “Continue” which is nested under the Dispense function side-bar on the right hand side. Recommend do not use terminology exclusive to one AMS vendor despite Pyxis being the most common AMS, or just use the word “dispense” here.)	Charles Ho, Harrison Medical Center	
317	Suggested amended language: “Override: Medications ordered that are defined on the override list may be removed prior to a pharmacist’s prospective drug utilization review. The pharmacist shall perform retrospective drug utilization review on these medication orders within the next business day <u>unless said pharmacy is closed for the ensuing 24-hour period after the dispensing has occurred, in which case such review shall occur within 48 hours of such dispensing.</u> ”	Christy M. Barr, RPh, Regional VP of Operations – Western Division, Genoa, A QoL Healthcare Company	
318	Delete. Overall we fill that sections 3 thru 10 should be removed from this document as these are items that should be in one's p&p. Better defining this section would be helpful. Overall I don't think that this much detail needs to be included. There are some areas of the hospital setting i.e. OR's, Procedural care areas that use and override function on all medications but the orders are not reviewed. Maybe we need to define override vs. non-override machines.	Roger Wolf, Administrative Director, Richard Paul, Manager II, Inpatient Pharmacy, Suzanne Dolbey, Manager, Informatic Systems, Virginia Mason Hospital & Seattle Medical Center	

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	Comment	From	Response
319	The facility should have a process to monitor overrides, but to require every order to be retrospectively reviewed is onerous in a large facility and does not add quality, value or increase safety. Recommend rewording to require a QA process that is defined by the facility and can be reviewed upon inspection.	Cindy Wilson, PharmD, Manager, Pharmacy 340B Program, CHI Franciscan Health	
320	Delete Override subsection – this is irrelevant. Bedside barcoding is the critical step requiring a proactive pharmacist review.	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
321	The proposed rule calls for an override list to use in life –threatening or emergent situations. This does not make sense for an AMS used as an emergency kit for reasons noted above- not all emergency kits are electronic; and the fact that all medications in an ekit are considered emergent. Current rules (WAC 246-865-030) indicate the emergency kit list shall be determined by the pharmaceutical services committee.. and shall consider the number of residents to be served and their potential need for emergency medications. How do you define life-threatening or emergent? Our patients deserve to receive all medications in a timely manner, whether new or maintenance therapy. In fact, federal regulations require this in nursing homes and will cite the facility during survey if there is delay in any medication therapy. Emergency kits play a critical role in starting or maintaining medication therapy until medication can arrive from the pharmacy timely.	Teri Ferreira, RPh, General Manager, Consonus Pharmacy	
322	We believe this is redundant to section 246-874-060, and request that the Commission strike section 3 here in favor of the language in 060 to avoid confusion and redundancy.	Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health	
Rule Section 050 (4) - Inventory Control Req. - Removed medications records			
323	The all station events report doesn't not provide information on what dose is to be given the patient and to my knowledge, there is no way to get this information on to a report. The AMS documents that a Lisinopril 10mg tablet was removed but has no way of "knowing" that the patients dose was only 5mg.	Cheryl Pell, RPh Director of Pharmacy Management – Medication Review, Inc., On behalf of herself and one of her pharmacists (Chris)	

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	Comment	From	Response
324	<p>These can be printed and stored in hard copy format, but the records are not maintained by the system for 2 years. And how does the AMS know the dose to be administered? That's in the order, not in the AMS. The machine doesn't know that the patient only needs to have half of a 25mg metoprolol, it just knows that 1 tab of 25mg was dispensed.</p>	<p>Lindsay Mckie PMH Medical Center</p>	
325	<p>Suggested amended language: Removed Dispensed Medications The AMS shall be capable of producing on-demand, a hard-copy record of distribution that shall show patient name, drug name and strength, dose removed, dose to be administered, date and time of removal from the device, and identity of person dispensing removing the drug. Records shall be readily retrievable and stored in accordance with state and federal laws and regulations for a minimum of 2 years.</p>	<p>Charles Ho, Harrison Medical Center</p>	
326	<p>Delete. Overall we feel that sections 3 thru 10 should be removed from this document as these are items that should be in one's p&p.</p> <p>Regarding: "Records shall be readily retrievable and stored in accordance with state and federal laws and regulations for a minimum of 2 years" Please note that this language is used inconsistently in this legislation as in other instances you say "Records shall be readily retrievable and stored in accordance with state and federal laws and regulations for the life of the device". This language should be consistent throughout</p>	<p>Roger Wolf, Administrative Director, Richard Paul, Manager II, Inpatient Pharmacy, Suzanne Dolbey, Manager, Informatic Systems, Virginia Mason Hospital & Seattle Medical Center</p>	
327	<p>Replace AMS with ADC</p>	<p>Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health</p>	
328	<p>We request that the Commission provides clarity that electronic storage is acceptable rather than physical, printed copies.</p>	<p>Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health</p>	

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	Comment	From	Response
	Rule Section 050 (5) - Inventory Control Req. - returned medications records		
329	<p>Suggested amended language: Returned Medications: A drug removed dispensed from AMS a system but not administered to a patient may be returned to the AMS return bin or other area per the designated method of returning as approved by the PIC only if the drug remains unopened, sealed, intact, and is properly stored. Records shall be readily retrievable and stored in accordance with state and federal laws and regulations for a minimum of 2 years.</p>	Charles Ho, Harrison Medical Center	
330	<p>(Not all drug fit inside a return bin. Some drugs may need to be restocked back to AMS because there's only 1 piece available and the drug is packaged in a bulky box which will not fit a return bin (e.g. tPA, TNK, glucagon, a 250 mL bag of pressor drip for emergency use). Therefore, on a case-by-case basis for each drug the PIC needs to review and approve the method of returning. This is especially true for <u>refrigerated</u> drugs. Returns must be made promptly into the refrigerator. Any other fashion will render the drug wasted due to inappropriate temperature of storage. Recommend language change to reflect that each drug's return method is approved by PIC. Minimal requirement is unopened, sealed, intact, etc.)</p>	Charles Ho, Harrison Medical Center	
331	Delete. Overall we feel that sections 3 thru 10 should be removed from this document as these are items that should be in one's p&p.	Roger Wolf, Administrative Director, Richard Paul, Manager II, Inpatient Pharmacy, Suzanne Dolbey, Manager, Informatic Systems, Virginia Mason Hospital & Seattle Medical Center	
332	Replace AMS with ADC	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	

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	Comment	From	Response
	Rule Section 050 (6) - Inventory Control Req. - Wasted Medications		
333	<p>Does this imply that all medication waste needs to be documented? For example wasting of a partially used heparin drip? Would recommend adding verbiage that this only applies to controlled substances and move this to section (2) Controlled Substances. Would also recommend moving the entire Section (2) Controlled Substances to the end of WAC 246-875-050 for better reading flow.</p> <p>Move this entire section under Controlled Substances Section.</p>	Xheni Waggoner, PharmD, Pharmacy Operations Manager, Northwest Hospital & Medical Center, UWMedicine	
334	Delete. Overall we fill that sections 3 thru 10 should be removed from this document as these are items that should be in one's p&p.	Roger Wolf, Administrative Director, Richard Paul, Manager II, Inpatient Pharmacy, Suzanne Dolbey, Manager, Informatic Systems, Virginia Mason Hospital & Seattle Medical Center	
335	Replace AMS with ADC	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
	Rule Section 050 (6)(a) - Inventory Control Req. - Report requirements for wasted meds		
336	We are not sure this technology is broadly available today; as written, this may be too inflexible. We encourage the Commission to explore this further with stakeholders.	Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health	
	Rule Section 050 (6)(b) - Inventory Control Req. - Controlled substance waste-witness requirement		
337	<p>We encourage the Commission to allow for other systems as long as there's retrievable documentation; limiting this to the AMS may be too restrictive. For examples, nursing homes document wasting differently.</p> <p>Suggested language: "All controlled substances wasted shall have a witness licensed to administer drugs countersign the waste and it shall be documented and recorded in the AMS or in another readily retrievable format;"</p>	Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health	

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	Comment	From	Response
	Rule Section 050 (6)(c) - Inventory Control Req. - Records retrieval in accordance w/state & fed. Law		
338	Consider amending the sentence "...for the life of the device <u>and its software</u> ..."	Richard Molitor	
339	"...for the life of the device." (Recommend a set duration on par with paper records. Paper records are not maintained for life. AMS should not bear a higher burden when the same is not required for paper records. Likewise should a device fail sooner (say, 6 months), the records requirement should not be reduced to 6 months only. The requirement should be equal to that of a paper record or consistent with other records requirement in the other parts of the WAC. Example, dispensing records only required 2 years (equivalent to paper)	Charles Ho, Harrison Medical Center	
340	Why is the record storage and retrieval for the life of the device, rather than 2 years as required in other regulation, including DEA? This requirement should align with the others (see also 246-873-080)	Cindy Wilson, PharmD, Manager, Pharmacy 340B Program, CHI Franciscan Health	
341	Suggested amended language: "Records shall be readily retrievable... <u>a minimum of 2 years</u> the life of the device. "	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
342	Staff licensed to handle medications such as pharmacy technicians and Imaging technicians should be allowed to countersign for wastage.	Gail Bunker, PharmD, TG/AH Pharmacy Operations Manager, Multicare Health System	
343	The current rule for retention of CS records is two years; we urge the Commission to align these timelines with the current two years, and to strike the language "for the life of the machine". Some machines may last for 10 years or more – causing inordinate amounts of record-keeping which we don't believe is the intent of the Commission.	Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health	

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	Comment	From	Response
Rule Section 050 (7) - Inventory Control Req. - Expired medications			
344	Delete. Overall we feel that sections 3 thru 10 should be removed from this document as these are items that should be in one's p&p.	Roger Wolf, Administrative Director, Richard Paul, Manager II, Inpatient Pharmacy, Suzanne Dolbey, Manager, Informatic Systems, Virginia Mason Hospital & Seattle Medical Center	
Rule Section 050 (7)(a) - Inventory Control Req. - Requiring process for dealing with expired meds			
345	Consider defining the expiration date of a drug to be the first of the month when not specifically stated by the manufacturer.	Richard Molitor	
346	Consider changing to proposed verbiage for further clarity and brevity. There shall be a defined process for securing, <u>accounting and managing soon to expire and expired medications stored in the AMS</u> and accounting for expired medications; and (b) On at least a monthly basis the PIC, or his or her pharmacy designee, shall run an expired drug report and appropriately manage medications soon to expire.	Xheni Waggoner, PharmD, Pharmacy Operations Manager, Northwest Hospital & Medical Center, UWMedicine	
347	Suggested amended language: There shall be a defined process for securing and accounting for expired medications; and to remove expired medications from AMS, and	Charles Ho, Harrison Medical Center	
Rule Section 050 (7)(b) - Inventory Control Req. - Requires monthly report on expired or about to expire meds			
348	On at least a monthly basis the PIC, or his or her pharmacy designee, shall run an expired drug report and appropriately manage medications soon to expire. (The word Remove used here is defined as "eliminate". Another reason why the word "remove" is ambiguous and should be clarified in this entire proposal because it's sometimes used to describe an AMS function, other times used to literally mean "remove." The recommended change intent is: There shall be a process defined by the PIC to remove expired medications out of the AMS. Period. There shouldn't be a need to mandate how it is done per facility or per PIC. No expired drugs. Period. PIC to figure it out.)	Charles Ho, Harrison Medical Center	

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	Comment	From	Response
349	Monthly review for outdates and it implies that expiration dates need to be indicated in the AMS when items are restocked/stocked	Forward from unknown 3 by Karen Nishi Consultant Pharmacist CUBEX LLC	
350	Suggested amended language: “...the PIC, or his or her pharmacy designee, ...”	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
351	We question whether every machine has the capability to do this – we encourage the Commission to explore.	Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health	
Rule Section 050 (8) - Inventory Control Req. - Records retrieval in accordance w/state & fed. Law			
352	This conflicts with the previously mentioned recordkeeping requirement of two years.	Xheni Waggoner, PharmD, Pharmacy Operations Manager, Northwest Hospital & Medical Center, UWMedicine	
353	Suggested amended language: “...system to prevent such removal dispense of medications until the prospective drug utilization review and approval has occurred except in areas of a facility where non-prospective review of medications prior to dispensing or non-interfacing to ordering software has been approved by the Commission.” (Need to allow this language. Areas such as OR, Cath Lab, Intraoperative areas, or Anesthesia Systems (another Pyxis device) are all designed to be non-profiled. Without this exception in place, all operating rooms and cath labs will require pharmacist review of orders. This can be mortally dangerous to the patients.	Charles Ho, Harrison Medical Center	

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	Comment	From	Response
354	<p>Board can easily adopt process to approve or not approve an area for non-profiled operation. Facility can present their case for approval.</p> <p>Anesthesia station is not interfaced to ordering software because in an operating room, when a drug is needed during an operation the drug is administered immediately without going through an ordering software.</p> <p>The recommended exception (above) is reflective of current actual practice in operating rooms and cath labs.)</p>	Charles Ho, Harrison Medical Center	
355	Delete. Overall we feel that sections 3 thru 10 should be removed from this document as these are items that should be in one's p&p.	Roger Wolf, Administrative Director, Richard Paul, Manager II, Inpatient Pharmacy, Suzanne Dolbey, Manager, Informatic Systems, Virginia Mason Hospital & Seattle Medical Center	
356	Same as above regarding time for record storage and retrieval. This should align with other requirements/regulations, not the life of the device. We would assume if we changed AMS vendor we would still need to have records for the prior 2 years. Facilities should not be held to something longer than what is required in all other regulations, including DEA.	Cindy Wilson, PharmD, Manager, Pharmacy 340B Program, CHI Franciscan Health	
357	Suggested amended language: "A mechanism to record all medication Records <u>transactions and</u> shall be readily retrievable and stored in accordance with state and federal laws and regulations for the life of the device <u>minimum of 2 years.</u> "	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
358	We request that the Commission strike this section, as it is redundant to other references to record-keeping. We will also echo our earlier comment that all records retention policies should be aligned to the current two years.	Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health	

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	Comment	From	Response
Rule Section 050 (9) - Inventory Control Req. - Require AMS interface software			
359	The two big issues remain: 1) allowing a nurse to restock is critical, especially in remote areas 2) full-blown interfaces that require prospective DUR and override systems should not be required for electronic e-kits...my two cents.	Forward from unknown 2 by Karen Nishi Consultant Pharmacist CUBEX LLC	
360	I was hoping this was intended for mostly acute care settings but it mentions supplemental drug supplies so the intent must be to include LTC. The biggest issues include: -Must have interface with dispensing system	Forward from unknown 3 by Karen Nishi Consultant Pharmacist CUBEX LLC	
361	This is going to be the killer for CAH's who have a different EHR in their emergency room than they do on the inpatient side. I have a hospital that uses T-system in their ED and CPSI on the in-patient side. There cannot be an interface with two separate EHR's. This is a reality for many small hospitals. How is a small hospital in this situation supposed to be able to financially comply with this requirement if it is not in their budget to purchase the new EHR?	Cheryl Pell, RPh Director of Pharmacy Management – Medication Review, Inc., On behalf of herself and one of her pharmacists (Chris)	
362	Amend language: “The AMS shall be may be interfaced ...”	Karen Nishi Consultant Pharmacist CUBEX LLC	
363	This isn't going to work for a lot of CAHs. Not every hospital has the same EHR in ED and in the rest of the facility. The AMS can't interface with both.	Lindsay Mckie PMH Medical Center	
364	Suggested amended language: “The AMS shall be interfaced with the medication order software system <u>where possible</u> to prevent such” There are areas like the OR where verbal orders are given when orders are changed during the procedure or surgery. The AMS devises must allow for flexibility in these areas. Maybe suggest for increased frequency of audits and governance for areas with no interface?	Julie Doung, PharmD, Pharmacy IT Coordinator, Northwest Hospital & Medical Center	
365	“...until the prospective drug utilization review and approval has occurred.” I don't understand this portion of number 9. The AMS is interfaced with the pharmacy management system to monitor and manage the system, but there is no drug utilization review.	Sara Lake, Marketing Manager and Regulatory Affairs, Asteres Inc.	

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	Comment	From	Response
366	On another note these rule changes will require a significant investment by Genoa to replace all of the current automated machines with new equipment in order to meet the security requirements because the rules dictate that the automated systems not be autonomous but be interfaced with the pharmacy software system. This will result in thousands of dollars per month in additional cost of doing business which can become a burden to provide appropriate services.	Christy M. Barr, RPh, Regional VP of Operations – Western Division, Genoa, A QoL Healthcare Company	
367	Delete. Overall we feel that sections 3 thru 10 should be removed from this document as these are items that should be in one's p&p.	Roger Wolf, Administrative Director, Richard Paul, Manager II, Inpatient Pharmacy, Suzanne Dolbey, Manager, Informatic Systems, Virginia Mason Hospital & Seattle Medical Center	
368	Replace AMS with ADC. Not all sites have this capability, but I would argue a free standing ADC is better than a locked cabinet any day and every day.	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
369	There is currently no interface requirement for manual tackle boxes. Nurses can access manual kits as necessary to provide for prompt patient care. Likewise, the pharmacist is not required to input a prescription, in real time, in order for the nurse to access a manual tackle box. Conversely, the proposed AMS rules would require a robust interface and real-time data entry. While I support prospective pharmacist review for automated systems intended to dispense daily orders, I feel that automated systems used as e-kits should not be subject to real-time data entry and review. During on-call periods, the draft rules would require the pharmacist to return to the pharmacy and input the order; a process that could take several hours while a patient awaits critical medication that is already on site. The PQAC ADDD Technology subcommittee support non-profile driven systems for AMS used as ekits [see committee language below].	Teri Ferreira, RPh, General Manager, Consonus Pharmacy	

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	Comment	From	Response
	<p>(CONT.) Language Draft #8 from Technology Subcommittee: “Automated Dispensing or Distribution Storage System” includes, but is not limited to, a mechanical system controlled by a computer system and managed by a pharmacist that performs operations or activities relative to the storage, packaging, labeling and dispensing and collects, controls, and maintains all transaction information. These profile driven systems require that medication orders/prescriptions be reviewed by the pharmacist for appropriateness, dosage, and contraindications prior to, or concomitantly with, being entered into the system, and before access is allowed into the system for medication administration.¹</p> <p>¹This type of system may include, but is not limited to, kiosks, night drug cabinets, emergency drug kits, or floor stock/first does cabinets, and is used to dispense medication directly to a patient or to an authorized healthcare practitioner for immediate distribution to the patient. Such systems may be used by pharmacies, for maintaining patient care unit medication inventories. A pharmacist is not required to be physically present at the site of the automated dispensing or distribution and storage system if the system is managed by a pharmacist.”</p>	<p>Teri Ferreira, RPh, General Manager, Consonus Pharmacy</p>	
370	<p>Pharmacist Prospective Drug Utilization Review: Pharmacies servicing Nursing Facilities are not open 24 / 7/ 365 so all medications would be included on an override list. This may not be consistent with the intent. Suggest indicating a retrospective drug utilization review will occur within one business day</p>	<p>Greg Milanich, PharmD, FASCP, AVP, Pharmacy Services, HCR ManorCare</p>	
371	<p>We urge the Commission to strike this language. Not all systems can be integrated, and this assumes profile machines are being used as well. We believe the intent of this section is covered in normal operating processes.</p>	<p>Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health</p>	
Rule Section 050 (10) - Inventory Control Req. - Delivery record			
372	<p>This is very prescriptive and not necessary in a hospital setting. A differentiation must be made. It is difficult to figure out the intent of this particular regulation and what this achieves.</p>	<p>Xheni Waggoner, PharmD, Pharmacy Operations Manager, Northwest Hospital & Medical Center, UWMedicine</p>	

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	Comment	From	Response
373	This actually defeats the AMS. To use AMS electronically means no paperwork to be transported to and from pharmacy. Goal is to move to all electronic and all AMS systems today already keep this delivery records in an electronic form: names, date, time, locations, drugs, quantity, when, how, etc.) This entire paragraph turns off AMS and moves pharmacy back to paper system because the written language actually described a current pharmacy-nursing scenario who is not NOT on AMS. Everything intended to be captured is already within a typical AMS system via electronic record available on-demand.	Charles Ho, Harrison Medical Center	
374	Delete. Overall we fill that sections 3 thru 10 should be removed from this document as these are items that should be in one's p&p. Not sure why this is in the legislation. Not all pharmacies work off a list to fill the machines. In addition why would we need an RN to sign off after we have filled the machine. One object of using the machine is to prevent this interaction from happening, but at the same time having the medications available for our patients when they want them. Pulling an RN away from patient care activities on a regular basis is not very patient focused.	Roger Wolf, Administrative Director, Richard Paul, Manager II, Inpatient Pharmacy, Suzanne Dolbey, Manager, Informatic Systems, Virginia Mason Hospital & Seattle Medical Center	
Rule Section 050 (10)(a) - Inventory Control Req. - Requires a delivery record for drugs removed from a pharmacy			
375	"initials of pharmacist checking" The system already records the user that refilled a machine and who checked it, what benefit is there to this extra step? Many facilities use a tech check tech system or an electronic verification, at the machine rather than in the pharmacy. Checking at the machine is safer, as there is nothing guaranteeing that what was checked in the pharmacy made it to the correct station or pocket. Additionally, not all loads occur based on the AMS system generated list, as patient's needs dictate, one drug might be loaded in a machine based on a label generated from the EMR or just a verbal discussion and decision of the pharmacist on duty.	Margie Hummel, PharmD, Pharmacist Informaticist, Providence Health	
376	Are these delivery records intended to be retained by the facility? All refill/load/replenish transactions are recorded on the AMS. Keeping a delivery record would be a huge amount of paper to retain, especially at large facilities. What is the purpose? What is the value? What is meant by 'the records of distribution accuracy?' This requirement adds inefficiency to the process. Recommend removal.	Cindy Wilson, PharmD, Manager, Pharmacy 340B Program, CHI Franciscan Health	

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	Comment	From	Response
377	<p>Can this delivery record be generated and stored electronically?</p> <p>Suggested amended language: "...all drugs placed in the AMS ADC which shall include the date; drug name; dosage form; and strength; quantity; health care entity; and a unique identifier for the specific device receiving drugs; and initials <u>documentation of pharmacist licensed individual approved to checking the list of drugs to be removed from the pharmacy and the records of distribution accuracy; and</u>"</p>	<p>Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health</p>	
378	<p>The double check could be performed by a specialized tech function, not only pharmacist.</p>	<p>Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health</p>	
379	<p>Subsections (a) & (b)</p> <ul style="list-style-type: none"> • Pharmacies that meet criteria for specialized functions in WAC 246-90-035 should be allowed to have certified technician-check-technicians check the controlled substances removed from pharmacy for AMS delivery. • Pharmacies with a CII-Safe have the capability to generate receipt reports for controlled substances delivered to AMS units. Pharmacies with such capabilities should not require a nurse signature upon delivery. 	<p>Gail Bunker, PharmD, TG/AH Pharmacy Operations Manager, Multicare Health System</p>	
Rule Section 050 (10)(b) - Inventory Control Req. - Delivery record shall be signed by a nurse or other person authorized to administer drugs from that specific AMS			
380	<p>if the medications have been checked by a pharmacist WHY are we requiring that a nurse sign the delivery record????? They are not watching the technician refill the machine. if we are requiring scan on refill WHY are we requiring that a nurse sign the delivery list?? So if a pharmacist refills medications, which happens in CAH's, the pharmacist has to have a nurse sign the delivery record? This section should be deleted.</p>	<p>Cheryl Pell, RPh Director of Pharmacy Management – Medication Review, Inc., On behalf of herself and one of her pharmacists (Chris)</p>	
381	<p>I am confused about what the purpose is of having a delivery record signed by nurse. What are they signing for? Are they witnessing that the drugs are loaded in the Pyxis? We have electronic records that can tell us this.</p>	<p>Liz Verbrugge, PharmD, BCPS, Pharmacy Manager, PeaceHealth St. John Medical Center</p>	

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	Comment	From	Response
382	NO NO NO NO NO NO NO NO. I can't say NO enough. Why would I, as a PHARMACIST need to have a NURSE verify the meds that I'm filling into the AMS? Is a nurse going to just check the drug order for me? This is complete and total garbage. This should be deleted. Does anyone really think a nurse is going to have the time to just stand patiently by and watch a technician or pharmacist refill the machine? Why do we need this? The order has been checked by a PHARMACIST prior to leaving the pharmacy. There are other controls to avoid diversion besides wasting everyone's time this way.	Lindsay Mckie PMH Medical Center	
383	I'm unclear of the intention of this but I don't find this method effective in assuring that medications were loaded. The loading activity would likely have occurred without the witnessing of the nurse so the signing of the form would be a formality and no guarantee that the load did not happen.	Julie Doung, PharmD, Pharmacy IT Coordinator, Northwest Hospital & Medical Center	
384	Not applicable. Reports are maintained for prescriptions leaving the pharmacy and being loaded into the AMS. If the system is outside of a hospital, there isn't necessarily a nurse on-site.	Sara Lake, Marketing Manager and Regulatory Affairs, Asteres Inc.	
385	Nursing does not have time to oversee this pharmacy function. As above, facilities have checking mechanisms in place, what additional benefit is there to having a nurse do this? Pharmacy has no way to mandate that a nurse will be available for this function every time a drug is loaded or refilled.	Margie Hummel, PharmD, Pharmacist Informaticist, Providence Health	
386	This is highly burdensome and unnecessary to require a nurse to stop patient care, double check the delivery record and sign off for all drugs being replenished. The AMS records the transaction and many utilize barcode technology. Is it really safer and higher quality care for patients to pull the nurse from the bedside to do this? Recommend removal of this requirement.	Cindy Wilson, PharmD, Manager, Pharmacy 340B Program, CHI Franciscan Health	
387	Delete subsection	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
388	We urge the Commission to strike this language; in order to operationalize this as written, we do not see any added value in having a nurse on a unit sign this delivery unless they were to stand there while the machine is loaded, which we believe would be a tremendous waste of healthcare resources. This also appears to be redundant to the electronic record that will be generated with the refill.	Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health	

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	Comment	From	Response
Rule Section 060 - Prospective Drug Utilization Review			
389	I was hoping this was intended for mostly acute care settings but it mentions supplemental drug supplies so the intent must be to include LTC. The biggest issues include: Pharmacist's review must be conducted before a medication is removed unless designated as emergent AND can't have a supplemental medications if an AMS is used	Forward from unknown 3 by Karen Nishi, Consultant Pharmacist, CUBEX LLC	
390	No applicable for delivery type AMS.	Sara Lake, Marketing Manager and Regulatory Affairs, Asteres Inc.	
391	First off I believe this is repetitive. Second this would preclude the use of AMS in the OR's, Procedure areas, anesthesia etc.	Roger Wolf, Administrative Director, Richard Paul, Manager II, Inpatient Pharmacy, Suzanne Dolbey, Manager, Informatic Systems, Virginia Mason Hospital & Seattle Medical Center	
392	Delete.	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
393	Pharmacist Prospective Drug Utilization Review: Pharmacies servicing Nursing Facilities are not open 24 / 7/ 365 so all medications would be included on an override list. This may not be consistent with the intent. Suggest indicating a retrospective drug utilization review will occur within one business day	Greg Milanich, PharmD, FASCP, AVP, Pharmacy Services, HCR ManorCare	

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	Comment	From	Response
394	<p>We want to bring to your attention, and suggest a revision, to the Prospective Drug Utilization Review section of the proposed rules. Healthcare providers use the Lynx Mobile system for dispensing medications. When the provider places the order for medications in the Electronic Health Record, Drug Utilization Review is performed at that time. These orders are electronically transferred to the AMS upon approval by the provider. We would like clarification, and I've provided some suggested language below.</p> <p>Suggested amended language: Add subsection (d) <u>"The provider has previously performed drug utilization review at the time of ordering the medication."</u></p>	Lindsay Lanagan, Manager, State Government Relations, McKesson Specialty Health	
Rule Section 060(1) - Prospective Drug Utilization Review - Requires prospective DUR on all prescription orders			
395	<p>Suggested amended language: A pharmacist shall perform prospective drug utilization review of the prescription or medication order prior to removal from the AMS <u>any user retrieving the ordered medications from the AMS for the purpose of administration</u>, except if:</p>	Charles Ho, Harrison Medical Center	
Rule Section 060(1)(a) - Prospective DUR - Exception for prospective DUR - AMS is being used for emergent drugs, on the override list			
396	<p>Amend language: "The system is being used to provide access to emergent medications xxxxxxxx xxxxxx xxxxx ..."</p>	Karen Nishi Consultant Pharmacist CUBEX LLC	
397	<p>The system is being used to provide access to emergent medications on override and only a quantity sufficient <u>sufficient quantity</u> is removed to meet the immediate use of the patient;</p>	Charles Ho, Harrison Medical Center	
398	<p>Suggested language: "The system is being used to provide access to emergent medications on override and only a quantity sufficient is removed <u>in a quantity sufficient</u> to meet the immediate use of the patient;</p>	Xheni Waggoner, PharmD, Pharmacy Operations Manager, Northwest Hospital & Medical Center, UWMedicine	

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	Comment	From	Response
	Rule Section 060(1)(c) - Prospective DUR - Exception for prescriber controlled AMS		
399	<p>Consider adding this verbiage to be consistent with Joint Commission Medication Management Standard MM.05.01.01 “A pharmacist reviews the appropriateness of all medication orders for medication orders to be dispensed in the hospital”. Joint Commission allows for an exception in the Emergency Department, Diagnostic Imaging and emergent situations. In addition, these medication systems are also used in procedural areas by prescribers themselves and in OR suites for immediate use for the patient during surgery/procedure so pharmacy is not involved with reviewing all medications needed for a surgery or procedure case.</p> <p>Suggested amended language: The prescriber controls the drug dispensing process when there is no delegation. If procedural areas, the medications are ordered by a licensed independent practitioner (LIP) and are to be administered by staff who are permitted to do so in accordance with law and regulation. While the LIP is not required to remain at bedside when the medication is administered, they must be available to provide immediate intervention should a patient experience an adverse drug event.</p>	<p>Xheni Waggoner, PharmD, Pharmacy Operations Manager, Northwest Hospital & Medical Center, UWMedicine</p>	
400	<p>The term “controls” is vague here – please clarify. Additionally, we request that the Commission add a subsection (d) that would read: <u>“The prescriber controls administration of the medication.”</u> Without this language, limiting excluded review to physician dispensing is too restrictive, as there are areas in the hospital such as surgery where the physician does not control the ‘dispensing’; rather they control the administration, and dispensing from AMS is incidental to the physician controlled administration and there is no value in retrospective review. We believe the added language we’ve suggested would clarify and help achieve the intent of the rule.</p>	<p>Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health</p>	

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	Comment	From	Response
Rule Section 060(1)(d) - Prospective Drug Utilization Review - SUGGESTED NEW SECTION			
401	<p>Suggest adding a new subsection (d): <u>The system is being used in an area of the facility approved by the Commission to be non-prospectively reviewed prior to drug dispensing or non-interfacing to the medication ordering software.</u> (The same exception language must be applied here as well. "Prescriber controlled drug dispensing process without delegation" is insufficient. Example: Surgeon calls out drug order STAT and tells a surgical nurse to get it STAT and give it STAT to stop a bleed. Is that delegation? Should prospective-review take place here?)</p>	Charles Ho, Harrison Medical Center	
Rule Section 060(2) - Prospective DUR - Requiries hospital pharmacies to provide 24-hour prospective DUR			
402	Does the Commission have grant money to give all the smaller hospitals money to be able to provide this service?	Cheryl Pell, RPh Director of Pharmacy Management – Medication Review, Inc., On behalf of herself one of her pharmacists (Mike)	
403	Does the PQAC have funds somewhere to help hospitals pay for this requirement?	Cheryl Pell, RPh Director of Pharmacy Management – Medication Review, Inc., On behalf of herself and one of her pharmacists (Chris)	
404	Again, because every CAH can afford to have 24 hours pharmacy access. This doesn't happen in the real world, unfortunately.	Lindsay Mckie PMH Medical Center	
405	States that the hospital will provide 24-hour prospective drug review. Should this actually say "provide or contract, with a third-party service, for 24-hour prospective drug review" to be consistent with the spirit of prospective drug review?	Richard Molitor	

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	Comment	From	Response
406	<p>(I do support this for the pharmacy profession. However, this language here is mutually in conflict with earlier language where pharmacists are allowed within next business day to review overridden medications. If a hospital pharmacy is 24/7 and prospective review is in effect, it mutually conflicts with other non-prospectively reviewed scenarios including when and where a pharmacy is closed at night. All medications are essentially on override during closed hours, to which a pharmacist may retrospectively review those within the next business day.</p> <p>I can see the intent here but perhaps better achieved by modifying other WAC sections such as "Hospital Pharmacy")</p>	Charles Ho, Harrison Medical Center	
407	<p>This will be a burden for those pharmacies not operating 24 hours a day.</p> <p>Suggested amended language: The hospital pharmacy shall provide twenty-four hour prospective drug utilization review services, <u>unless said pharmacy is closed for the ensuing 24-hour period after the dispensing has occurred, in which case such review shall occur within 48 hours of such dispensing.</u></p>	Christy M. Barr, RPh, Regional VP of Operations – Western Division, Genoa, A QoL Healthcare Company	
408	<p>Is this really feasible at this point for all facilities in the state? All CAH have 24 hour prospective review? This could be a barrier for some sites. AMS without prospective review is still safer than no AMS and no review. Recommend assessing whether this is realistic and appropriate.</p>	Cindy Wilson, PharmD, Manager, Pharmacy 340B Program, CHI Franciscan Health	
409	<p>We are concerned that this 24-hour requirement would be impossible for some facilities to adhere to, such as critical access pharmacies. We urge the Commission to strike this language.</p>	Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health	
Rule Section 070 (1) - Quality Assurance - Requires a quality assurance program to be established			
410	<p>Consider amending the sentence to read "Establishing a quality assurance program prior to implementation of an approved system..." Too often the PQAC is called upon to give retroactive approval to systems and protocols which have not undergone prior scrutiny. This needs to stop. Having language like this throughout future regulations helps make it more likely that organizations will comply with our regulations instead of surreptitiously implementing systems that give them an unfair upper hand over local competition.</p>	Richard Molitor	

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411	This entire section can be limited to one or two points as once again these should be called out in your P&P.	Roger Wolf, Administrative Director, Richard Paul, Manager II, Inpatient Pharmacy, Suzanne Dolbey, Manager, Informatic Systems, Virginia Mason Hospital & Seattle Medical Center	
Rule Section 070 (2) - Quality Assurance - Requires method to ensure accurate replenishment			
412	Delivery type AMS is not replenished. Prescriptions are patient specific.	Sara Lake, Marketing Manager and Regulatory Affairs, Asteres Inc.	
413	Replace AMS with ADC	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
Rule Section 070 (3) - Quality Assurance - Requires method to review override data; daily report on override and reconciliation requirement			
414	“...shall run override...”This is NOT going to happen. This commission talks about providing patient care, yet if this is approved, all I will be doing is running reports. This should say that at least twice a month...	Cheryl Pell, RPh Director of Pharmacy Management – Medication Review, Inc., On behalf of herself one of her pharmacists (Mike)	
415	This is extremely cumbersome to require on a daily basis for any hospital but especially for hospitals that do not employ a pharmacist every day.	Cheryl Pell, RPh Director of Pharmacy Management – Medication Review, Inc., On behalf of herself and one of her pharmacists (Chris)	

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	Comment	From	Response
416	Amend language: “...On at least a daily basis the PIC, or his or her pharmacy designee, shall xxxx xxxxxx xxxx reconcile that prescriber’s orders are matched against all controlled substances and legend drugs that have been dispensed subject to <u>policies and procedures</u> .”	Karen Nishi Consultant Pharmacist CUBEX LLC	
417	Amend the second sentence to read: “On at least a <u>daily</u> basis the PIC...” to be consistent with other sections of this WAC.	Richard Molitor	
418	There isn’t time for this on a daily basis, let alone more than once a day. And there are reasons that we have override lists.	Lindsay Mckie PMH Medical Center	
419	Suggested amended language: “... On at least a daily basis <u>Within the next business day</u> the PIC, or his or her pharmacy designee” (To be consistent with earlier section where pharmacists are allowed within next business day to review overridden drugs. Or are we presuming all AMS locations are 24/7 operations – or staffed by pharmacy 7 days a week (to achieve this requirement of “on a daily basis”)?	Charles Ho, Harrison Medical Center	
420	Not applicable to delivery AMS.	Sara Lake, Marketing Manager and Regulatory Affairs, Asteres Inc.	
421	Daily review of all overrides is burdensome and does not add value/safety. A sample would be reasonable and appropriate. As stated previously there can be a process to determine what is on override and a QA process to monitor. It is not appropriate for the PQAC or investigators to make clinical judgments regarding what is appropriate to be on override as long as the facility has a process that includes pharmacists and providers to make these determinations.	Cindy Wilson, PharmD, Manager, Pharmacy 340B Program, CHI Franciscan Health	
422	Suggested amended language: “Method for reviewing override...AMS ADC... On at least daily basis the PIC, or his or her pharmacy designee, shall run an override or similar report to reconcile that prescriber’s orders are matched against all controlled substances and legend drugs that have been dispensed subject to an override;	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	

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	Comment	From	Response
423	We believe the intent of the Commission is to set guidelines to ensure that entities are regularly monitoring override data and medication error data to ensure that nefarious and unlawful behavior is caught. However, as currently written, the Commission would require review of every individual override, which we believe is excessive given its legitimate use in normal operations. This should instead be focused on identifying trends in overrides by medications, areas, etc. We suggest that to solve this, the statement that begins with 'on at least a daily basis' should be struck.	Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health	
Rule Section 070 (4) - Quality Assurance - Quality control checks			
424	Please further define what the expectation here is	Cheryl Pell, RPh Director of Pharmacy Management - Medication Review, Inc., On behalf of herself and one of her pharmacists (Chris)	
425	Suggested amended language: "Procedures for conduction quality <u>assurance activities</u> control checks <u>for associated with</u> drug removal for accuracy ;	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
Rule Section 070 (5) - Quality Assurance - Method to assign, discontieue or update access to AMS			
426	Redundant – found in section 7 of WAC 246-874-040	Sara Lake, Marketing Manager and Regulatory Affairs, Asteres Inc.	
427	Replace AMS with ADC	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
Rule Section 070 (6) - Quality Assurance - Maintain records for life of device			
428	Amend second sentence to read: "Maintain or have access to all records of documentation relating to the AMS being used for the life of the device, <u>it's software</u> , or as otherwise required by law;"	Richard Molitor	
429	Suggested amended language: Maintain or have access to all records of documentation relating to the AMS being used for the life of the device or as otherwise required by law;	Charles Ho, Harrison Medical Center	

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	Comment	From	Response
430	This appears to conflict with prior statements. Record retention should be consistently applied. To state 'for the life of the device' or in this case 'the life of the device or as otherwise required by law' simply adds to confusion. Using 'life of the device' is not a reasonable way to determine length of record retention. Is it the life of a device or the life of the software running it, or something else? Other regulations state 2 years; please apply this consistently.	Cindy Wilson, PharmD, Manager, Pharmacy 340B Program, CHI Franciscan Health	
431	Suggested amended language: "Maintain or have access to all records of documentation relating to the AMS <u>ADC</u> being used for the life of the device <u>a minimum of 2 years...</u> "	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
432	Record retention for the life of the machine is excessive and serves no purpose – as mentioned earlier, we urge the Commission to align record retention requirements which are currently set at two years; this would match controlled substance record retention requirements.	Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health	
Rule Section 070 (7) - Quality Assurance - Procedures for accounting/securing wasted medications			
433	Not applicable.	Sara Lake, Marketing Manager and Regulatory Affairs, Asteres Inc.	
434	Replace AMS with ADC.	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
Rule Section 070 (8) - Quality Assurance - Use of data collected to ensure quality or care and make improvements			
435	Replace AMS with ADC.	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
Rule Section 070 (9) - Quality Assurance - Method to detect AMS failure to operate - documentation of frequency of failure and repairs made			
436	Replace AMS with ADC.	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	

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	Comment	From	Response
Rule Section 070 (10) - Quality Assurance - Reconciliation of inventory discrepancies w/in 24 hrs - daily discrepancy reports			
437	See Comment on (3) from Mike Why two different time frames? Either way, I am unable to complete this. I am only at the hospital one day a week and then go to the next hospital.	Cheryl Pell, RPh Director of Pharmacy Management – Medication Review, Inc., On behalf of herself one of her pharmacists (Mike)	
438	again, very cumbersome for a hospital to do this on a daily basis when they don't have a pharmacist in house more than once a week. Reconciliation of inventory discrepancies??...including why my saline flush count is off? The PIC or designee will be doing nothing all day but running discrepancy reports. We currently have our AMS set to autoresolve non controlled substance discrepancies. Shouldn't this be a decision of the hospital and not the Commission?	Cheryl Pell, RPh Director of Pharmacy Management – Medication Review, Inc., On behalf of herself and one of her pharmacists (Chris)	
439	Add: "Reconciliation of <u>controlled substance</u> inventory..."	Xheni Waggoner, PharmD, Pharmacy Operations Manager, Northwest Hospital & Medical Center, UWMedicine	
440	Suggested amended language: "Reconciliation of inventory discrepancies within twenty-four (24) <u>72</u> hours of discovery. Investigative reports shall be part of quality assurance reporting. On at least a daily basis, the PIC,..." (Earlier section gave 72 hours. Again on daily basis—will all facility that implements AMS be 24/7? Perhaps on daily basis during business days?)	Charles Ho, Harrison Medical Center	
441	Suggested amended language: "Reconciliation of <u>narcotic</u> inventory discrepancies within twenty-four (24) hours of..."	Julie Doung, PharmD, Pharmacy IT Coordinator, Northwest Hospital & Medical Center	

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442	This implies all meds not just controlled substances.	Roger Wolf, Administrative Director, Richard Paul, Manager II, Inpatient Pharmacy, Suzanne Dolbey, Manager, Informatic Systems, Virginia Mason Hospital & Seattle Medical Center	
443	Suggest deleting whole subsection and replacing with “Discrepancy analysis”	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
444	<ul style="list-style-type: none"> • The Quality assurance process requirements for AMS are too proscriptive, the previous Automated Drug Distribution Devices WAC 246-872 quality assurance requirements were sufficient. Each organization should be given latitude to develop a quality assurance program to meet the intent of the WAC. • Regarding (10), inventory amounts in the AMS vary due to a variety of reasons and non-controlled substance discrepancy amounts are generally low. Facilities with AMS should be allowed to evaluate how they address reconciliation of non-controlled substance inventories. An investigation should not be required for each discrepancy in an AMS. 	Gail Bunker, PharmD, TG/AH Pharmacy Operations Manager, Multicare Health System	
445	While we support the intent of the Commission to identify problem behaviors, we believe that reconciliation of every inventory discrepancy is excessive and may actually hinder staff from identifying problem trends, as they would become bogged down in paperwork. This requirement should instead be focused on identifying trends. A requirement to monitor and trend would have more value in identifying unauthorized removals of inventory so that you can see the forest through the trees. A requirement to reconcile all controlled substance discrepancies is reasonable and most likely already a standard process for all sites that use AMS. We also believe that 24 hours is not a reasonable time limit to resolve, as typically the discrepancy is discovered on the next transaction, and the time frame can be such that involved parties are not available. Two work weeks is a reasonable period of time to resolve, as is stated in our earlier comments.	Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health	

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	Comment	From	Response
	Rule Section 070 (11) - Quality Assurance - Procedures around downtime and breakdowns		
446	Suggested amended language: “Method for maintaining uninterrupted drug supply and service during Analysis of AMS-ADC system downtimes or breakdowns; and	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
	Rule Section 070 (12) - Quality Assurance - Recall procedures - lot mixing		
447	I am not following this requirement. If we have a recall, we check the AMS stock and look for any lot number that is included in the recall. Are they saying that when a drug is refilled, we can't mix the lot numbers?	Cheryl Pell, RPh Director of Pharmacy Management – Medication Review, Inc., On behalf of herself and one of her pharmacists (Chris)	
448	Suggested amended language: “Procedures for <u>handling recalls of drugs stored in these devices.</u> To include procedures to avoid mixing lot numbers of drugs added to the AMS; and	Xheni Waggoner, PharmD, Pharmacy Operations Manager, Northwest Hospital & Medical Center, UWMedicine	
449	We can't mix lots now? It's not enough that we compare lot numbers to recalls when we get them? Seriously? Gee, Cardinal/McKesson/AmeriSource, you can only send me one lot number at a time now.	Lindsay Mckie PMH Medical Center	
450	Suggested amended language: Procedures for recalls to include procedures to avoid mixing lot numbers of drugs added to the AMS; and <u>mechanism to locate and remove affected lots from the AMS, and</u> (Not mixing lots is an ideal statue but not practical or realistic in the field. AMS all have limited space/pockets, and a hospital's purchasing volume and turn around speed often result in multiple lots of the same drugs multiplied by multiple manufacturers due to rampant drug shortages. The goal is to eliminate any affected lots as soon as recalled. The burden should not be on the stocking individual lots to individual pockets. Again—ideal but not a realistic scenario.	Charles Ho, Harrison Medical Center	

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451	(CONT.) Typical recall process: a PIC can push a button and cease the dispensing of any drug (say, metoprolol and all metoprolols), and send designees to inspect that drug everywhere it is stocked. Dispensing is resumed once the pocketful has been inspected to contain no recalled lot of metoprolol. There is no need to separate each lot into each different pocket.)	Charles Ho, Harrison Medical Center	
452	It is not reasonable to expect that lot numbers will be kept separate in the device. The same manufacturer produces varying lot numbers over time. To separate all these is burdensome and takes up valuable space in the device, thereby limiting the overall inventory. Each device would end up with multiple pockets of the same drug. This would also increase errors (inadvertent mixing of lot numbers) while adding no value to the process or safety to the patient. Additionally with ongoing shortages requiring constant changes in inventory to maintain medication supply for patients, it is not reasonable to separate by lot number.	Cindy Wilson, PharmD, Manager, Pharmacy 340B Program, CHI Franciscan Health	
453	Delete subsection.	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	
454	We request that the Commission strike this language; to comply with this requirement, we would have to initiate a new drawer for each lot number to prevent lot-number mix-ups, but this is not a pragmatic solution as there is limited space with AMS. Additionally, systems don't currently track which patients get which lot numbers; this would require the development of a new system to track, without clear evidence that this is necessary for patient safety. We urge the Commission to strike everything after "procedures for recalls."	Lauren Platt, State Advocacy Program Manager-WA, Government & Public Affairs-Providence Health	
Rule Section 070 (13) - Quality Assurance - Requires documentation of all quality assurance activities			
455	Would become subsection (12). Suggested amended language: " <u>Maintain</u> documentation of the outcomes of the quality assurance activities.	Glenn Adams, PharmD, Senior VP of Ancillary Services, Confluence Health	