Title 20—DEPARTMENT OF COMMERCE AND INSURANCE
Division 2220—State Board of Pharmacy
Chapter 2—General Rules

PROPOSED AMENDMENT

20 CSR 2220-2.900 Class N: Health Care Facility Automated Dispensing *[and Storage]* **Systems.** The board is amending the title, deleting sections (1)–(6) and adding new sections (1)–(9).

PURPOSE: This amendment clarifies and updates supervision, technology, and operational requirements for Class N Health Care facility automated dispensing systems.

PURPOSE: This rule establishes [guidelines] ***licensing standards and requirements*** *for the use of* ***Class N*** *automated dispensing* [and storage] *systems* ***(Health Care Facility)****.*

[*(1) Automated dispensing and storage systems (hereafter referred to as automated system or system) are hereby defined to include, but are not limited to, mechanical systems that perform operations or activities, relative to the storage, packaging or dispensing of medications, and which collect, control, and maintain all transaction information. Such systems may be used in pharmacies and where a pharmacy permit exists, for maintaining patient care unit medication inventories or for a patient profile dispensing system, provided the utilization of such devices is under the supervision of a pharmacist. A pharmacist is not required to be physically present at the site of the automated pharmacy system if the system is supervised electronically by a pharmacist. In order to supervise the system within an ambulatory care setting, the pharmacist must maintain constant visual and auditory communication with the site and full control of the automated system must be maintained by the pharmacist and shall not be delegated to any other person or entity. Supervision of an automated refill patient self-service device requires that a pharmacist employed by the pharmacy by which the device is owned and operated be available at all times during operating hours of the pharmacy.*

(A) Documentation shall be maintained by the owner/operator of an automated system for the type of equipment, locations where all systems are located, identification of all persons accessing the automated system, the identity of persons stocking or restocking the system and the pharmacist responsible for checking the accuracy of medications stocked.

(B) Automated systems that are used within licensed health care facilities shall be used only in settings that ensure medication orders are reviewed by a pharmacist in accordance with established policies and procedures and laws governing the practice of pharmacy. A pharmacist shall control all operations of the automated system and approve the release of the initial dose of a prescription drug order. Subsequent doses from an approved prescription drug order may be removed from the automated system after this initial approval. Any change made in the

prescription drug order shall require a new approval by a pharmacist to release the drug.

(C) In ambulatory care settings, a pharmacist must input all information from a prescription or prescription drug order into the electronic data system utilized for the initiation of the dispensing of a drug at a remote site and maintain proper oversight over the entire dispensing process. A pharmacist shall be accessible at all times to respond to patient's or other health professionals' inquiries or requests pertaining to drugs dispensed through the use of the automated pharmacy system. No prescription shall be prepared or dispensed from a remote automated system unless it is from a prescriber providing clinical services at the same location. Labeling of drug containers must be in accordance with section 338.059, RSMo, and application of labels to containers must occur prior to release of the prepared prescription drug from the automated system. Labels shall contain both the name, address and phone number of the supervising pharmacy and the remote dispensing site.

(D) When automated systems are located at remote sites the central pharmacy responsible for the operation and supervision of a remote site must maintain separate and readily retrievable records of all transactions and prescriptions processed by each remote automated system. Remote automated sites must provide the name, address and toll free telephone number of the supervising pharmacy displayed on the automated dispensing system in a prominent location.

(E) Automated systems shall maintain adequate security systems and procedures to prevent unauthorized access or use and shall at all times maintain compliance with all state and federal drug laws including all controlled substance requirements and patient confidentiality laws.

1. *Any remote automated system that stocks controlled substances must maintain a perpetual inventory from each site.*
2. *Automated systems in ambulatory care settings must be located in an area that will provide adequate space for private consultations to occur and must only be installed within the same area utilized by the prescriber for the provision of clinical services.*
3. *Automated refill patient self-service devices must be physically attached to the pharmacy so that access to areas used to restock the device are only accessible through the pharmacy physical plant by pharmacy personnel.*

(F) Restocking of automated systems shall be done by registered technicians under the supervision of a pharmacist or by a pharmacist.

(G) All events involving access to the contents of the automated system must be recorded electronically.

(H) No medication or device shall be returned directly to the system for reissue or reuse by a person not licensed or registered by the board of pharmacy.

(I) Quality assurance documentation for the use and performance of the automated systems shall be maintained for a minimum period of two (2) years and shall include at a minimum the following:

1. *Breach of security of the automated system;*
2. *Failure of the system to operate correctly along with the frequency of any failures*

and the necessary repairs completed;

3. *Tests completed to measure the effectiveness and accuracy of the system. every six (6) months and whenever any upgrade or change is made to the system.*

(J) Drugs that are repackaged for use in automated systems at remote locations must comply with 20 CSR 2220-2.130 Drug Repackaging requirements. Automated refill patient self-service devices must comply with all labeling and dispensing laws governing the provision of medication refills to patients. Products that are considered temperature sensitive or products that require further manipulation in order to be ready for use by a patient shall not be provided through patient self-service devices, unless the device has the capability to provide storage conditions in compliance with Food and Drug Administration (FDA) requirements.

(K) If an automated system uses removable cartridges or containers to hold drugs, the prepackaging of the cartridges or containers must occur at the pharmacy where the original inventory is maintained unless provided by a FDA approved repackager and who is licensed as a drug distributor. The prepackaged cartridges or containers may be sent to the automated system at remote locations to be loaded into the machine by registered technicians under the supervision of a pharmacist or by a pharmacist provided that—

1. *A pharmacist has verified the container has been properly filled and labeled;*
2. *The individual containers are transported to the automated system in a secure, tamper-evident container; and*
3. *The automated system utilizes technologies to ensure that the containers are accurately loaded in the automated system.*

(L) Any pharmacy that maintains an automated system for remote dispensing to ambulatory patients must maintain a video camera and audio system to provide for effective communication between pharmacy personnel and consumers. It must be a system that will allow for the appropriate exchange of oral as well as written communications to facilitate patient counseling as provided in 20 CSR 2220-2.190 and other matters involved in the correct transaction or provision of drugs.

1. *Video monitors used for the proper identification and communication with persons receiving prescription drugs shall be a minimum of twelve inches (12") wide and provided at both the pharmacy and remote location for direct visual contact between pharmacist and patient.*
2. *Both the video monitor and the audio system must be in good working order or operations utilizing the automated system shall cease until appropriate corrections or repairs are made to the system(s).*
3. *Backlighting or other factors that may inhibit video or audio performance must be taken into account when using such systems to identify recipients of prescription drugs. Positive identification of recipients must be made before any drug is delivered.*

(2) Each automated system shall maintain a manual of policies and procedures that, at a minimum, shall include the following:

(A) System operations that include specific and measurable accountability for safety, security, accuracy, patient confidentiality, access, data retention and retrieval,

downtime procedures, emergency first dose or refill patient self-service procedures, inspection of systems by pharmacy personnel, installation requirements, maintenance, medication security, quality assurance, inventory levels and control, staff education and training and system set-up and malfunction.

(B) Documentation by the automated system at remote locations for on-site patient administration and remote dispensing of medications that includes specific identification of patients, medications used along with dates and times the system is utilized.

(C) Effective procedures for securing and accounting for wasted medications or discarded medications.

(D) Access to and limits on access (security levels) to the automated system must be defined and must comply with applicable state and federal laws and regulations.

(3) The pharmacist-in-charge is responsible for the overall compliance of the automated system in the same manner as other pharmacy operations as outlined in 4 CSR 220-2.090. In addition, responsibilities will also include:

(A) Establishment of a quality assurance program prior to implementation of an automated system and the supervision of an ongoing quality assurance program that monitors appropriate use and performance of the automated system, which is evidenced by written policies and procedures developed by the pharmacy;

(B) Assign, discontinue or change access to the automated system;

(C) Assure that the automated system is in good working order and accurately provides the correct strength, dosage form and quantity of a drug prescribed while maintaining appropriate record keeping and security safeguards.

(D) Procedures used for notifying the board on a timely basis and other state and federal agencies, when warranted, of any breach of security which results in the unauthorized removal of drugs.

(4) Except where otherwise noted in this rule, all records specified must be retained as a part of the dispensing record of the pharmacy and in accordance with section 338.100, RSMo and board regulations governing the proper maintenance and retrieval of records.

(5) Pharmacies that maintain automated sites for dispensing drugs to ambulatory patients shall maintain a Class J: Shared Service classification on each pharmacy permit involved in such activity.

*(6) The supervising pharmacy shall have sufficient pharmacists on duty such that each pharmacist may supervise no more than three (3) remote sites that are simultaneously open to provide services. An exception to the supervision limit may be granted by the board in situations where the provider has documented a need for a pharmacist to supervise additional remote sites and has demonstrated that appropriate safeguards are in place to assure proper supervision of each remote site.**]***

(1) Definitions.

(A) "Class N: Automated dispensing system" (ADS)—An automated system located within a licensed health care facility used to dispense medication for resident patients of the facility pursuant to a patient-specific prescription or a medication order as defined by Chapter 338, RSMo, or a prescription drug order as defined by 20 CSR

2220-2.140. An automated dispensing system does not include an automated system used for compounding medication, a Class O automated dispensing system, or an automated filling system governed by 20 CSR 2220-2.950.

(B) "Electronic Verification System"—An electronic verification, bar code verification, weight verification, radio frequency identification (RFID), or similar electronic process or system process used to verify and ensure medication has been properly stocked, restocked, loaded, filled, dispensed, or labeled.

(C) "Licensed health care facility"—A health care facility licensed by or operated by the state of Missouri, or otherwise authorized by the state, to administer health care to resident patients in the ordinary course of business or professional practice.

(D) "Med pak"—A patient med pak as defined by 20 CSR 2220-2.145.

(2) Licensing. Applicants for a Class N (ADS) permit classification must file an application on a form approved by the board with the applicable fee, and submit proof that the proposed Class N ADS location qualifies as a licensed health care facility, as defined by this rule.

(A) A Class N ADS permit will be issued for the healthcare facility address designated on the application, and may be used to operate all Class N ADSs located at the board approved address. A Class N ADS must be located indoors at the permitted health care facility address and may not be located outside of the health care facility.

(B) The appropriate pharmacy permit classification is required for any pharmacy activities under the board's jurisdiction that occur at the Class N ADS site other than dispensing from an automated dispensing system. Class N ADS pharmacies must comply with all requirements applicable to any additional pharmacy permit classifications held by the pharmacy, including, but not limited to, all applicable security and staff supervision requirements. A Class J pharmacy permit is required for shared service activities, as provided in 20 CSR 2220-2.650.

(C) A Class N ADS permit is not required for automated dispensing systems used solely to provide medication for immediate administration by healthcare facility staff to resident patients in an emergency situation, as allowed by law or the healthcare facility's licensing agency.

(3) System requirements. A Class N ADS must be maintained in good working order and in a clean and sanitary manner. If applicable, a Class N ADS must be cleaned and disinfected on a regular basis using appropriate materials and agents.

(A) A Class N ADS must be validated by a properly qualified board licensee or appropriately supervised board registrant designated by the pharmacy to ensure the system is functioning properly prior to first use and prior to restarting the system after an unanticipated system shutdown or interruption. Additional validation must occur if any modification to the automated dispensing system occurs that changes or alters the dispensing or electronic verification process.

(B) Medication must be stored and maintained in a thermostatically controlled area within temperature and humidity requirements as provided in the Food and Drug Administration approved drug product labeling or the United States Pharmacopeia (USP).

(C) At a minimum, temperatures in drug storage areas of the ADS must be recorded and reviewed daily. Alternatively, a continuous temperature monitoring system may be used if the system maintains ongoing documentation of temperature recordings that promptly alerts pharmacy staff when temperatures are outside of the required range and provides the amount of variance.

(D) An ongoing and documented quality assurance program must be established to monitor the performance of the automated dispensing system. The quality assurance program must include procedures for handling and reporting dispensing errors, system malfunctions, and other compliance concerns.

(E) A pharmacist must reconcile a sample size of medication dispensed/removed from a Class N ADS on a quarterly basis to verify authorization for dispensing. The required sample size must be identified in the pharmacy's policies and procedures. Proof of compliance with this subsection and the review date(s) must be maintained and documented in the pharmacy's records.

(4) Standards of Operation. A Class N ADS must be safely and properly operated at all times in compliance with applicable state and federal laws, including, but not limited to, all applicable controlled substance laws.

(A) A Class N ADS may only be used in settings that ensure prescriptions and medication/drug orders are reviewed by a pharmacist. Only staff of the licensed health care facility may remove or obtain medications from a Class N ADS for patient use. Patients may not obtain medication directly from the automated dispensing system.

(B) Medication may only be dispensed by a Class N ADS pursuant to a valid prescription or medication/drug order. A prospective drug utilization review must be conducted for initial and changed prescriptions and medication/drug orders, as required by 20 CSR 2220-2.195. Policies and procedures must be in place for reviewing medication dispensing for compliance with this subsection, including, but not limited to, policies and procedures for terminating discontinued prescriptions and medication/drug orders and as needed prescriptions and medication/drug orders to prevent unauthorized dispensing.

(C) A pharmacist must control all operations of the ADS and approve the release of the initial dose, except in cases of emergency dispensing for immediate administration to a patient as authorized by law. Subsequent doses from an approved prescription or medication/drug order may be removed from the ADS by healthcare staff in accordance with the pharmacy's policies and procedures, provided a pharmacist must approve the release of subsequent dose(s) if any change in the prescription or medication/drug order occurs. Subsequent doses of patient-specific labeled prescriptions must comply with subsection (4)(D) of this rule.

(D) For ADSs that dispense a patient specific labeled prescription or medication/drug order, pharmacist verification of the final drug product and label may be satisfied if:

1. A pharmacist reviews and verifies the prescription or medication/drug order and the patient information used to initiate the dispensing process prior to dispensing;

2. The entire dispensing process is fully automated from the time the process is initiated until a completed, sealed, and properly labeled medication container is

produced that is ready for dispensing. Required labels must be affixed to the container prior to release of the medication from the automated dispensing system. No manual manipulation of the prescription container or label may occur after the medication is released; and

3. An electronic verification system is used to ensure the correct label has been affixed and the correct medication and medication strength, dosage form, and quantity have been dispensed.

(E) Labeled prescription containers provided to patients must be labeled in accordance with applicable statutory and regulatory requirements, and must contain the name, address and telephone number of the Class N ADS permit holder. Med paks dispensed by a Class N ADS must comply with all applicable provisions of 20 CSR 2220-2.145, regardless if given to the patient.

(F) In addition to 20 CSR 2220-2.080 and other prescription record-keeping requirements, the following information must be documented and readily retrievable for all prescriptions and medication/drug orders removed from the system:

1. The patient's name or other unique identifier;

2. The date and time the medication is removed;

3. The medication, dosage strength, and quantity removed; and

4. The identity or other unique identifier of the authorized healthcare staff member removing the medication.

(5) Supervision. A Class N ADS must be supervised by a Missouri licensed pharmacist who is readily accessible physically or electronically to monitor system activities and respond to inquiries or requests (e.g., on call). Electronic technology must allow the pharmacist to adequately monitor and supervise Class N ADS operations. The pharmacist supervision required by this section may not be delegated to an intern pharmacist.

(A) If applicable, a two-way audio communication system must be in place to allow pharmacy technicians or intern pharmacists present at the Class N ADS pharmacy to effectively communicate with the supervising pharmacist. The Class N ADS may not be operated if the electronic or communication technology required by this section is unavailable or not in working order unless a pharmacist is onsite.

(6) Stocking/Restocking. Medication must be securely stocked, loaded, and reloaded in a Class N ADS in a manner that protects against theft and diversion, and in compliance with 20 CSR 2220-2.010.

(A) Only board licensees or registrants may stock, load, or restock a Class N ADS, as authorized by the pharmacy's policies and procedures.

(B) A pharmacist must physically verify that medication has been properly stocked, restocked, and loaded into a Class N ADS. Alternatively, an electronic verification system may be used to verify that medication or medication containers have been properly stocked, restocked, and loaded into the device, if no manual intervention with the medication or medication container after the electronic verification occurs other than healthcare staff retrieving medication or medication being removed by authorized pharmacy staff for return/destruction.

(C) If authorized by a pharmacist, intern pharmacists, or pharmacy technicians may

stock, restock, or load manufacturer unit of use packages and repacked containers previously verified by a pharmacist into a Class N ADS without a pharmacist present or additional pharmacist verification, if an electronic verification system is used to verify the manufacturer unit of use packages and repacked containers have been correctly stocked, restocked, or loaded. No manual intervention with the manufacturer unit of use package or repacked container may occur after the electronic verification required by this subsection, other than removing the manufacturer unit of use package or repacked containers by authorized health care facility staff for dispensing or return/destruction.

(D) Return to stock medication may be returned and reused as authorized by 20 CSR 2220-3.040 or 20 CSR 2220-2.145 governing multi-med dispensing. No medication shall be returned directly to the Class N ADS for reissue or reuse by a person not licensed or registered by the Board of Pharmacy.

(E) The following documentation must be maintained and readily retrievable:

1. **The name, strength, and quantity of the medication stocked, loaded, restocked, or removed from the ADS system;**
2. **The date and time medication is stocked, loaded, restocked, or removed from the ADS system;**
3. **The identity of individuals stocking, loading, restocking, or removing medication in the ADS system; and**
4. **The identity of the pharmacist responsible for verifying the contents of any repacked containers stocked, restocked, or loaded into the ADS system, if applicable.**

(7) Security. Adequate security and supervision must be maintained at all times to prevent medication theft and diversion and unauthorized access to or use of the Class N ADS. A Class N ADS must also comply with all security provisions of 20 CSR 2220-2.010. Confidential records and Class N data must be securely maintained to prevent unauthorized access to, and unauthorized storage/transfer of, confidential information.

(A) A Class N ADS must be securely placed, locked, and maintained inside the physical building of the licensed health care facility in a manner that prevents theft, diversion, and unauthorized access or medication removal.

(B) A Class N ADS must have an alarm mechanism that promptly alerts a designated member of the pharmacy's staff in the event of a security breach or unauthorized access to the system.

(C) Authorized access to the Class N ADS must be defined in the pharmacy's policies and procedures. The permit holder must be able to stop or change access to the Class N ADS as deemed necessary or appropriate.

(D) A perpetual inventory must be maintained for each Class N ADS that stocks controlled substances that is reconciled by pharmacy staff on a monthly basis.

(E) Class N ADS permit holders must maintain current policies and procedures for handling and investigating confirmed or suspected security breaches and medication losses or diversion, including, but not limited to, an escalation policy/procedure for addressing inventory discrepancies and policies/procedures for terminating system operations in the event of a security breach, inventory discrepancy, suspected

loss/diversion, or unauthorized access to, or loss of patient confidential information.

(F) Security breaches of the Class N ADS must be immediately investigated. Use/operation of the Class N ADS must immediately cease until the security breach has been rectified and proper security is restored. Any security breach of the Class N ADS must be documented and reported to the board in writing within three (3) business days of discovery.

(G) Any confirmed or suspected medication diversion/theft must be immediately investigated. Medication diversion/theft must be reported to the board in writing within three (3) business days of discovery.

(8) Policies and Procedures. Class N ADS permit holders must maintain current and accurate written policies and procedures governing all aspects of Class N ADS activities, including but not limited to—

(A) Staff education and training;

(B) Maintaining the Class N ADS and the accompanying electronic verification process in good working order;

(C) Maintaining and protecting system data and confidential information;

(D) Granting, restricting, or terminating Class N ADS system access;

(E) Filling, stocking, restocking, and loading the Class N ADS;

(F) Removing expired, adulterated, misbranded, or recalled medication;

(G) Temperature monitoring and documentation;

(H) Prescription processing, verification, and recordkeeping, including, handling/termination of discontinued prescriptions and medication/drug orders and as needed prescriptions and medication/drug orders to prevent unauthorized dispensing;

(I) Patient counseling, if applicable;

(J) Ensuring cleanliness and sanitary operation of the device and preventing cross-contamination of cells, cartridges, containers, cassettes, or packages;

(K) Emergency response procedures, including, but not limited to, addressing power outages, and terminating system operations;

(L) Monitoring medication inventory to prevent diversion, theft, or loss, including an escalation policy/procedure for addressing inventory discrepancies;

(M) Security requirements, including, policies/procedures for authorizing Class N ADS system access and terminating Class N ADS system operations in the event of a security breach;

(N) Handling and investigating inventory discrepancies, suspected loss/diversion, or unauthorized access to or loss of patient confidential information;

(O) Receiving, handling, documenting, and investigating alarm notifications/alerts in the event of a security breach or unauthorized access to the Class N ADS, as referenced in section (8);

(P) Conducting routine and preventive system validation and maintenance;

(Q) Quality assurance;

(R) Handling, investigation, and reporting dispensing errors;

(S) Recordkeeping; and

(T) Data retention and retrieval.

(9) Records.

(A) Class N permit holders must maintain readily retrievable records of all Class N ADS transactions, including, but not limited to, all prescriptions and medication/drug orders processed and/or dispensed by the Class N ADS and records of all medication stocked in or removed from the Class N ADS.

(B) Prescriptions and medication/drug orders dispensed from a Class N ADS must be separately identifiable in the pharmacy's prescription records and individually retrievable from other prescriptions and medication/drug orders dispensed by the pharmacy. This requirement also applies to any Class J pharmacy dispensing prescriptions or medication/drug orders via a Class N ADS.

(C) Except as otherwise provided by this rule or other applicable law, all records required by this rule must be maintained a minimum of two (2) years and readily retrievable on request of the board or a board authorized designee. Records maintained at a pharmacy must be produced immediately or within two (2) hours of a request from the board or the board's authorized designee, or by making a computer terminal available to the inspector for immediate use to review the records requested. Records not maintained at a pharmacy must be produced within three (3) business days of a board request.

*AUTHORITY: sections **338.140,** 338.210 and 338.220, RSMo Supp. [2006] **2022** and [338.140 and] **section** 338.280, RSMo [2000] **2016**.* This rule originally filed as 4 CSR 220-2.900. Original rule filed Nov. 1, 2000, effective June 30, 2001. For intervening history, please consult the **Code of State Regulations**. Amended: Filed Sept. 6, 2023.*

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the aggregate.

PRIVATE COST: The board estimates private fiscal costs of forty-five thousand dollars ($45,000) annually, recurring over the life of the rule as reflected in the accompanying fiscal note.

*NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the Missouri Board of Pharmacy, PO Box 625, 3605 Missouri Boulevard, Jefferson City, MO 65102, by facsimile at (573) 526-3464, or via email at pharmacy@pr.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this rule in the **Missouri Register**. No public hearing is scheduled.*