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

PROPOSED RULE

20 CSR 2220-2.910 Class O: Automated Dispensing Systems (Ambulatory Care)

PURPOSE: This rule establishes licensing standards and requirements for Class O: Automated Dispensing Systems (Ambulatory Care).

(1) Definitions.

(A) "Ambulatory prescription dispensing system"—A Class O automated dispensing system (Class O ADS) used to process, verify, fill, label, and dispense a completed prescription/medication order for patient retrieval from the system using an electronic verification system.

(B) "Class O Automated Dispensing System": A pharmacy license classification which allows the use of an ambulatory prescription dispensing system or a prescription pick-up system as defined by this rule at a specific location. A Class O ADS does not include an automated system used for compounding medication, a Class N automated dispensing system, or an automated filling system governed by 20 CSR 2220-2.950.

(C) "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/prescriptions have been properly stocked, restocked, loaded, filled, dispensed, or labeled.

(D) "Prescription pick-up system"—A Class O ADS that allows a patient to obtain a filled, labeled, and pharmacist-verified prescription/medication order placed in the system by or on behalf of a Missouri licensed pharmacy for patient retrieval. A prescription pick-up system does not include a vacuum tube drug delivery system identified in 20 CSR 2220-2.800.

(E) "Supervising pharmacist"—A Missouri licensed pharmacist designated to supervise a Class O ADS while the system is in operation.

(2) Licensing. Applicants for a Class O ADS pharmacy permit classification must file an application on a form approved by the board and pay the applicable fee. A pharmacy Change of Classification application is required for currently licensed Missouri pharmacies opting to add a Class O ADS classification to their existing Missouri pharmacy permit. Application fees to add or obtain a Class O ADS pharmacy permit shall be waived for Class N ADS permit holders licensed on the effective date of this rule for a period of six (6) months from this rule's effective date.

(A) A Class O ADS permit may be used to operate all Class O ADSs located at the address designated on the permit. A Class O ADS may only be used by the permit holder, and may

not be used to dispense prescriptions/medication orders for multiple pharmacies.

(B) The appropriate pharmacy permit classification is required for any pharmacy activities under the board's jurisdiction that occur at the Class O ADS site other than operating the Class O ADS. Class O 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) To be eligible for licensure, a Class O ADS must be located within the permitted address of a Missouri licensed pharmacy where pharmacy services other than Class J Shared services, Class I Consultant services, or Class O ADS services are provided, or at an indoor location where healthcare services are regularly provided by a licensed healthcare provider at the same location. A Class O ADS must be located at an address recognized by the United States Postal Service and may not be located outside of a physical structure.

(D) Applicants may petition the board in writing to approve a Class O ADS at an alternative location to increase patient access to medication in an area where access to an ambulatory/community pharmacy is limited. Petition requests must include documentation or evidence demonstrating how the proposed Class O ADS location will expand patient access to medication and promote public health. The board will consider the following factors when determining petition requests:

1. The availability of pharmacy services in the proposed Class O ADS pharmacy area;
2. Benefits or risks to patient care;
3. Policies/procedures for ensuring adequate security;
4. The permit holder's ability to promptly access the Class O ADS in the event of an emergency, which shall be no more than thirty (30) minutes;
5. The applicant's experience and compliance history; and
6. Any other factor that may benefit or adversely impact public health.

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

(A) A sign must be conspicuously posted or electronically displayed on the Class O ADS that clearly identifies the permit holder's name, address, the system's hours of operation, and a telephone number for contacting the pharmacy during operational hours.

(B) A Missouri licensed pharmacist must be capable of being physically present at the approved Class O ADS location within thirty (30) minutes in the event of an emergency or other system malfunction.

(C) A video surveillance system must be in place that allows the pharmacy to physically view the Class O ADS and the Class O ADS site at all times. A video surveillance system is not required if a pharmacist is present on-site and able to view the Class O ADS at all times the system is accessible to the public.

(D) 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).

(E) At a minimum, temperatures in drug storage areas of the Class O ADS must be recorded

and reviewed daily. Alternatively, a continuous temperature monitoring system may be used to comply with this subsection, 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.

(F) The Class O ADS system must use an electronic verification system to electronically verify and ensure prescriptions/medication orders are properly dispensed to the correct patient. The electronic verification system(s) 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 Class O ADS occurs that changes or alters the dispensing or electronic verification process. Validation dates and results must be documented in writing and readily retrievable.

(G) The Class O ADS permit holder must regularly review system operations to ensure proper functioning. At a minimum, a Missouri-licensed pharmacist must visit and review Class O ADS operations weekly during the first month of system operations and monthly thereafter. The dates of the required weekly and monthly visits/reviews and the identity of the designated pharmacist must be documented and readily retrievable at the request of the board or the board's authorized designee. The permit holder shall remain responsible for Class O ADS services and ensuring proper functioning.

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

(I) Notification of any dispensing error involving a Class O ADS that is dispensed to the patient must be submitted electronically or in writing to the board within ten (10) days of discovery. The required notification must include the date of the incident, patient name, description of the error, the applicable prescription/medication order number or unique identifier, and any corrective action taken.

(4) Standards of Operation. A Class O 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. Medication must be accurately dispensed and labeled.

(A) Medication may only be dispensed by a Class O ADS pursuant to a valid patient-specific prescription or medication order. A Class O ADS may not be used to dispense prescriptions/medication for multiple pharmacies.

(B) The Class O ADS must be supervised at all times it is in operation by a Missouri licensed pharmacist who is either physically present at the Class O ADS site or who is supervising via an electronic system that allows the pharmacist to adequately view the Class O ADS and supervise all Class O ADS activities. The required pharmacist supervision may not be delegated to an intern pharmacist.

1. The supervising pharmacist must maintain full operational control over the Class O ADS whenever the Class O ADS is in operation, and must be able to terminate or suspend Class O ADS operations when deemed necessary or appropriate.

2. The required electronic system must provide a continuous real-time video link to allow the supervising pharmacist to see the entire Class O ADS site. A two-way communication mechanism must also be available that allows communication between the supervising pharmacist and any technicians or intern pharmacists present on site. Medication may not be dispensed and the Class O ADS may not be operated if the required video link and audio communication are not fully functioning.
3. A supervising pharmacist may not supervise more than two (2) Class O ADSs at a time. The identity of the supervising pharmacist must be documented and maintained in the supervising pharmacy's records. Licensees may request a waiver of the supervision limit. The board will consider the factors in subsection (2)(D) when determining waiver requests.

(C) For Class O ADS prescription pick-up systems, only filled and labeled prescriptions that have been verified by a pharmacist may be loaded in or dispensed from the Class O ADS prescription pick-up system, except as otherwise authorized by law. The entire dispensing process must be fully automated after the prescription/medication order is loaded into the Class O prescription pick-up system. No manual manipulation of the prescription/medication order or the affixed label may occur after the prescription/medication order is stocked, restocked, or loaded in the Class O ADS prescription pick-up system.

(D) For Class O ADS ambulatory prescription dispensing systems, the entire prescription/medication order filling, dispensing, and labeling process must be automated and the required prescription/medication label must be affixed by the Class O ADS ambulatory prescription dispensing system prior to dispensing from the Class O ADS ambulatory prescription dispensing system. No manual manipulation of the prescription/medication order or the affixed label may occur after the automated filling process is initiated.

(E) Medication may not be dispensed via a Class O ADS if the patient or the patient's authorized designee requests not to use the Class O ADS.

(5) Patient Counseling. An offer to counsel must be made to the patient or the patient's authorized representative prior to a prescription or medication order being dispensed from a Class O ADS, except as otherwise required by law for Class R remote dispensing site pharmacies. The offer to counsel may be made verbally by authorized pharmacy staff or made electronically via the Class O ADS.

(A) Adequate space and equipment must be available to confidentially counsel patients. Live, real-time patient counseling must be provided if counseling is requested by the patient or otherwise required. If a pharmacist is not present on-site, two-way video and audio technology must be available that allows the pharmacist and patient to both view and communicate with each other. Medication may not be dispensed if the required video and audio technology is not fully functioning.

(B) Video monitors/screens used for patient counseling or communication must be a minimum of twelve inch (12") wide diagonally. Backlighting or other factors that may inhibit video performance must be taken into account when using video technology to counsel/communicate with patients.

(C) A sign must be conspicuously posted or continuously displayed electronically on the Class O ADS informing patients that a pharmacist will provide counseling either in-person or via the video/audio system on request. The sign must include clear instructions for requesting counseling and must be easily viewed and readable by the public.

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

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

(B) For Class O ADS prescription pick-up systems, a pharmacist must physically verify that prescriptions/medication orders have been properly loaded into the Class O ADS prescription pick-up system. The identity of the verifying pharmacist must be documented and maintained in the pharmacy's records. Alternatively, an electronic verification system may be used to verify that prescriptions/medication orders have been properly loaded into the Class O ADS prescription pick-up system, if no manual intervention with the prescription/medication order occurs after the electronic verification is completed. If authorized by a pharmacist, intern pharmacists, or pharmacy technicians may load a Class O ADS prescription pick-up system without a pharmacist present or additional pharmacist verification if:

1. An electronic verification system is used to verify the prescription/medication order has been properly loaded into the ADS system;
2. No manual intervention with the prescription/medication order occurs after the electronic verification required by this subsection, other than removing the prescription/medication order by authorized pharmacy staff for return/destruction; and
3. The electronic verification system has been validated and revalidated as required by section (3)(F). Validation dates and results must be documented in writing and readily retrievable.

(C) For Class O ADS ambulatory prescription dispensing systems, an electronic verification system must be used to verify that medication or medication containers have been properly stocked, restocked, and loaded into the Class O ADS ambulatory prescription dispensing system. 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 O ADS ambulatory prescription dispensing system without a pharmacist present or additional pharmacist verification if:

1. An electronic verification system is used to verify the medication has been correctly stocked, restocked, or loaded;
2. No manual intervention with the manufacturer unit of use package or repacked container occurs after the required electronic verification required by this subsection occurs, other than removing the manufacturer unit of use package or repacked container by authorized pharmacy staff for return/destruction; and
3. The electronic verification system has been validated and revalidated as required by section (3)(F). Validation dates and results must be documented in writing and readily retrievable.

(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 a Class O 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 date and time prescriptions/medication orders are stocked, loaded, restocked, and removed from the Class O ADS system;
2. The date and time medications are stocked, loaded, restocked, and removed from the Class O ADS system;
3. The identity of individuals stocking, loading, restocking, or removing prescriptions/medication orders and medication in the system; and
4. For Class O ADS ambulatory prescription dispensing systems, the identity of the pharmacist responsible for verifying the contents of any manufacturer unit of use packages and repacked containers stocked, restocked, or loaded into the Class O ADS ambulatory prescription dispensing system by an intern pharmacist or pharmacy technician without a pharmacist present.

(7) Security. Adequate security and supervision must be maintained to prevent medication theft and diversion and unauthorized access to or use of the Class O ADS. Class O ADS permit holders must comply with all security provisions of this rule and 20 CSR 2220-2.010. Confidential records must be securely maintained to prevent unauthorized access to, and unauthorized storage/transfer of, confidential information.

(A) A Class O ADS must be securely placed, locked, and maintained at the address licensed by the board in a manner that prevents theft, diversion, or unauthorized access, or medication removal. Authorized access to the Class O ADS must be defined in the permit holder's policy and procedures.

(B) In addition to the requirements of section (8), written policies and procedures must be in place to immediately access, secure, remove, and store medication in the event of an emergency or security breach.

(C) The Class O ADS must have an alarm mechanism that promptly alerts a designated member(s) of the pharmacy's staff in the event of a security breach or unauthorized access to the Class O ADS. For Class O ADS' located outside of a Missouri licensed pharmacy, the alarm must also alert local law enforcement in the event of a security breach or unauthorized access to the Class O ADS, if available. Additionally, a Board licensee or registrant located in Missouri must have the authority to access and suspend operations of the Class O ADS if necessary.

(D) Confirmed or suspected security breaches of the Class O ADS must be immediately investigated. If confirmed, use/operation of the Class O ADS must immediately cease until the security breach has been rectified and proper security is restored. All security breaches of the Class O ADS must be documented and reported to the board in writing within three (3) business days of discovery.

(E) 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.

(F) A perpetual inventory must be maintained for each Class O ambulatory prescription dispensing system stocking controlled substances that is reconciled by pharmacy staff on a monthly basis.

(8) Policies and Procedures. Class O permit holders must maintain current and accurate written policies and procedures governing all aspects of Class O ADS activities, including but not limited to—
(A) Staff education and training;
(B) Maintaining the Class O 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 O ADS system access;
(E) Filling, stocking, restocking, and loading the Class O ADS;
(F) Removing expired, adulterated, misbranded, or recalled medication;
(G) Temperature monitoring and documentation;
(H) Prescription processing, verification, and recordkeeping;
(I) Patient counseling;
(J) Ensuring cleanliness and sanitary operation of the Class O ADS 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 and restarting Class O ADS 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 O ADS access and terminating Class O ADS operations in the event of a confirmed or suspected security breach, inventory discrepancy, suspected loss/diversion, loss of patient confidential information, and unauthorized access to the Class O ADS;
(N) Receiving, handling, documenting, and investigating alarm notifications/alerts in the event of a security breach of the Class O ADS;
(O) Conducting routine and preventive system validation and maintenance of the Class O ADS;
(P) Quality assurance;
(Q) Handling, investigating, and reporting dispensing errors;
(R) Recordkeeping; and
(S) Data retention and retrieval.

(9) Records.
(A) Class O permit holders must maintain readily retrievable records of all Class O ADS transactions, including, but not limited to, all prescriptions and medication orders processed and/or dispensed by the Class O ADS and records of all medication stocked in or removed from the Class O ADS.
(B) Prescriptions and medication orders dispensed from a Class O ADS must be separately identifiable in the pharmacy's prescription records and individually retrievable from other prescriptions/medication orders maintained by the pharmacy. This requirement also applies to any Class J pharmacy dispensing prescriptions via a Class O ADS.

(C) Except as otherwise provided by this rule or other applicable law, all records required by this rule must be maintained for 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. 2022, and section 338.280, RSMo, 2016. Original rule filed Sept. 6, 2023.

PUBLIC COST: This proposed rule 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 one million one hundred ten thousand seven hundred twenty dollars ($1,110,720) 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 rule 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.*