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

PROPOSED RULE

20 CSR 2220-2.012 Technology Assisted Prescription/Medication Order Verification (Intern Pharmacists and Pharmacy Technicians)

PURPOSE: This rule establishes requirements for pharmacy technicians/intern pharmacists performing technology assisted prescription/medication order verification under the supervision of a pharmacist.

(1) Definitions.
- (A) "Authorized intern pharmacist"—An individual who holds a current and active Missouri intern pharmacist license and has completed employer approved training in technology assisted verification using the pharmacy's approved technology assisted verification system.
- (B) "Authorized pharmacy technician"—A currently registered Missouri pharmacy technician who—
  1. Holds an active pharmacy technician certification issued by a certification entity accredited by the National Commission for Certifying Agencies;
  2. Has completed employer approved training in technology assisted verification using the pharmacy's approved technology assisted verification system; and
  3. Has assisted in the practice of pharmacy as a registered/licensed pharmacy technician in the state of Missouri or another U.S. state or territory for a minimum of one (1) year.
- (C) "Technology Assisted Verification" (TAV)—The process of verification of the final prescription or medication order and affixed label by an authorized pharmacy technician or authorized intern pharmacist using a technology assisted verification system that complies with this rule.
- (D) "Technology Assisted Verification System" (TAVS)—An electronic system that utilizes barcode technology or another electronic process/method to electronically verify the final medication prescription or medication order has been properly dispensed and to electronically verify the prescription/medication order has been properly labeled for the correct patient.

(2) Pharmacy Technicians/Intern Pharmacists. A Missouri-licensed pharmacist may allow an authorized pharmacy technician or authorized intern pharmacist to verify the final prescription/medication order using a TAVS if:
- (A) The medication is a non-controlled substance and will be dispensed in the original manufacturer's unopened unit of use package, or the non-controlled medication has been repackaged in compliance with 20 CSR 2220-2.130 and previously verified by a pharmacist;
- (B) The authorized pharmacy technician or intern pharmacist is under the supervision of a Missouri-licensed pharmacist who is physically present within the dispensing area and able to provide immediate assistance. A current list of pharmacy technicians/intern

pharmacists authorized to perform TAV must be maintained at the pharmacy along with proof of the required training and competency assessment;

(C) The authorized pharmacy technician/intern pharmacist is competent to perform the duties assigned and has completed a documented initial and annual assessment of competency using the pharmacy's approved TAVS. A pharmacist may not simultaneously supervise a total of more than two (2) pharmacy technicians or intern pharmacists performing TAV as authorized by this rule. The pharmacist-in-charge may petition the board to increase the number of supervised technicians/intern pharmacists for good cause;

(D) A pharmacist verifies the accuracy of prescription/medication order data entry prior to dispensing and completes a prospective drug utilization review. The identity of the verifying pharmacist must be recorded in the pharmacy's records as required by 20 CSR 2220-2.080;

(E) The TAVS is used to verify the proper prescription label has been affixed to the correct manufacturer unit of use package or repacked container for the correct patient. The identity of the authorized pharmacy technician or intern pharmacist performing the TAV and the supervising pharmacist must be documented in the pharmacy's records; and

(F) No manual manipulation of the prescription/medication order occurs after the TAV occurs. For purposes of this rule, manual intervention does not include preparing a finished prescription/medication order for mailing, delivery, or storage.

(3) Technology Requirements. Technology assisted verification systems must be maintained in good working order, and must verify prescriptions/medication orders and the affixed labels with one-hundred percent (100%) accuracy. Use of the TAVS must be terminated and the root cause identified and corrected if a verification error is detected. Only a pharmacist shall be authorized to initiate the operation of a TAVS or override any technology generated errors, warnings, alerts, or exceptions related to TAVS functioning or medication verification/accuracy.

(A) The TAVS must be implemented and validated by a pharmacist prior to initial use to confirm the technology's accuracy and correctness. At a minimum, the TAVS must complete one thousand (1,000) consecutive product verifications during the initial validation process with a one-hundred percent (100%) accuracy rate. A pharmacist must audit one-hundred percent (100%) of product verifications completed during the initial validation process before dispensing and confirm accuracy. The required pharmacist audit may not be delegated to an intern pharmacist or a pharmacy technician.

(B) A pharmacist must conduct daily random quality testing on a sample size of prescriptions verified by the TAVS. The required sample size shall not be less than two percent (2%) of prescriptions/medication orders verified via the TAVS on the last day of system operation. Use of the TAVS must be terminated and the root cause identified and corrected if quality testing results show less than one-hundred percent (100%) accuracy.

(C) A TAVS must be revalidated by a pharmacist in accordance with the pharmacy's policies and procedures.

(D) The required revalidation process must include a sampling of prescriptions/medication order verifications by the TAVS using a sample size that is sufficient to confirm the technology is properly and accurately functioning. A pharmacist must audit and verify one-hundred percent (100%) accuracy of the sampled verifications prior to further use of the TAVS. The required pharmacist audit may not be delegated to an intern pharmacist

or a pharmacy technician.

(E) Proof of compliance with validation, revalidation, and testing requirements must be documented and maintained in the pharmacy's records, including, but not limited to the name, initials, or identification code(s) of the pharmacist performing the required validation/testing, and validation/testing date(s) and results.

(5) Quality Assurance. Pharmacies using TAV as authorized by this rule must maintain an ongoing and documented quality assurance system that monitors the performance of the TAVS and the TAV process to ensure proper and accurate functioning. The quality assurance system must include procedures for reporting dispensing errors, system malfunctions, or other compliance concerns. Notification of any dispensing error involving a TAV that reaches the patient must be submitted to the board electronically or in writing within ten (10) days of discovery. The required notification must include the date of the incident, patient name, the technician or intern pharmacist who performed the TAV, a description of the error, the applicable prescription/medication order number or unique identifier, and the supervising pharmacist of record.

(6) Policies and Procedures. Pharmacies using TAV must maintain current, written policies and procedures governing all aspects of technology assisted verification activities, including, but not limited to:

(A) Staff training and competency assessments;

(B) Operation of the required quality assurance system, including, reporting, investigating, and addressing errors, system malfunctions, and other quality assurance issues;

(C) Testing, validation, and revalidation of the TAVS to ensure proper functioning; and

(D) System maintenance, including, any routine or preventative maintenance.

(7) Recordkeeping. Records required by this rule must be maintained by the pharmacy electronically or in writing for a minimum of two (2) years. Records must be made available for inspection or copying, and produced to the board or the board's authorized designee upon request.

(8) Applicability. Compliance with this rule is not required if a pharmacist physically verifies the final prescription/medication order and the affixed label before dispensing. Final prescription/medication order verification for a Class R Remote Dispensing Site pharmacy must comply with 20 CSR 2220-2.680.

AUTHORITY: sections 338.140, and 338.210, RSMo Supp. 2020 and sections 338.240, 338.280, and 338.400, RSMo 2016. Original rule filed: February 9, 2022.

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

PRIVATE COST: This proposed rule will not cost private entities more than five hundred dollars ($500) in the aggregate.

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.*