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

PROPOSED RULE

20 CSR 2220-2.011 Electronic Final Product Verification (Pharmacists)

PURPOSE: This rule establishes requirements for electronic final product verification by a pharmacist using qualifying technology.

(1) Pharmacist verification. A Missouri licensed pharmacist may use an electronic verification system to verify the accuracy of a final prescription/medication order, provided:
   (A) The electronic verification system allows the pharmacist to see an exact, clear, and unobstructed visual image of the filled prescription/medication order contents and the label affixed to the container. If multiple units are being dispensed, the pharmacist must be able to see and verify an image of each unit and each individual affixed label. A mechanism must be in place to record or communicate the pharmacist's verification approval;
   (B) The identity of the pharmacist responsible for verifying the final product is documented in the pharmacy's records as required by 20 CSR 2220-2.080;
   (C) Pharmacy technicians and intern pharmacists assisting the pharmacist with electronic verification must be trained and competent to perform the duties assigned and have a documented initial and annual assessment of competency using the pharmacy's approved electronic verification system;
   (D) No further manipulation of the prescription/medication order occurs after the pharmacist's electronic verification is complete other than applying the required container lid or seal. For purposes of this section, manipulation does not include preparing a finished prescription/medication order for mailing, delivery, or storage; and
   (E) Except as otherwise provided by law, compounded preparations cannot be verified via an electronic verification system. Compounded preparations must be personally verified by a pharmacist.

(2) Technology Requirements. Electronic verification systems must be maintained in good working order, and must provide a clear, unobstructed visual image of the filled prescription/medication order contents and the affixed label for each individual prescription or medication order. Use of the electronic verification system must be terminated if the system is not properly functioning and the root cause identified and corrected before further use. Only a pharmacist shall be authorized to override any technology generated errors, warnings, alerts, or exceptions related to system functioning or medication verification/accuracy.
   (A) The electronic verification system must be implemented and validated by a pharmacist prior to initial use to confirm proper functioning. The system must be revalidated by a pharmacist in accordance with the pharmacy's policies and procedures.
   (B) Proof of compliance with validation/revalidation requirements must be documented and maintained in the pharmacy's records, including, but not limited to the identity of the

pharmacist performing the required validation/testing, and validation/testing date(s) and results.

(3) Quality Assurance. Pharmacies using an electronic verification system as authorized by this rule must maintain an ongoing and documented quality assurance system that monitors the performance of the electronic verification system and the electronic assisted verification process to ensure proper and accurate functioning. The quality assurance system must include procedures for reporting dispensing errors and system malfunctions.

(4) Policies and Procedures. Pharmacies utilizing an electronic verification system pursuant to this rule must maintain current, written policies and procedures governing all aspects of electronic-assisted verification activities, including, but not limited to:
(A) Staff training and competency assessments;
(B) Operation of the quality assurance system, including, reporting, investigating and addressing errors, system malfunctions, and other quality assurance issues;
(C) Testing, validation, and revalidation of electronic verification technology to ensure proper functioning; and
(D) System maintenance, including, any routine or preventative maintenance.

(5) Recordkeeping. Except as otherwise provided herein, records required by this rule must be maintained electronically or in writing by the pharmacy 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.

(6) The provisions of this rule do not modify, amend, or supersede any provisions of law governing pharmacy technician or intern pharmacist supervision requirements.

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.*