Ohio Administrative Code

Rule 4729:5-3-25 Electronic product verification.

Effective: August 19, 2026

(A) As used in this rule:

(1) "Electronic product verification" or "electronic verification" means the non-physical dispensation ("final check") of a drug or device by a pharmacist using an electronic verification system to verify the accuracy of the drug or device and affixed label prior to dispensing. Electronic final verification does not include the following:

(a) Operation of a remote dispensing pharmacy pursuant to Chapter 4729:5-18 of the Administrative Code;

(b) The practice of remote outpatient prescription processing pursuant to rule 4729:5-5-20 of the Administrative Code;

(c) The practice of remote medication order processing pursuant to rule 4729:5-9-02.14 of the Administrative Code;

(d) The practice of personally furnishing by a prescriber pursuant to division 4729:5 of the Administrative Code; or

(e) The dispensation of a drug or device from an automated pharmacy system pursuant to rule 4729:5-3-17 of the Administrative Code.

(2) "Electronic verification system" means a system that complies with the requirements set forth in this rule.

(B) For a pharmacist to engage in electronic product verification, the pharmacist shall:

(1) Be licensed as a pharmacist in this state.

(2) Physically practice in a pharmacy licensed as a terminal distributor of dangerous drugs that is:

(a) Located in this state; and

(b) Under the same common ownership and control.

(3) Complete the required training and competency evaluations in paragraph (G) of this rule.

(4) Be a current or contracted employee of the pharmacy operating the electronic verification system.

(C) An electronic verification system shall allow the pharmacist to see exact, clear, and unobstructed visual images of the drug or device being dispensed and the label affixed to the container. The system shall, at a minimum, have high-definition image resolution with variable viewing options to accurately and safely dispense a drug or device and sufficient data retention capabilities to investigate any quality-related events.

(1) The system shall use barcoding technology to ensure the accuracy of drugs or devices dispensed in accordance with this rule. Barcodes shall be scanned, and not manually typed, into the system. The board may waive or modify the barcode technology requirements listed in this paragraph if the electronic verification system can provide an alternative method to ensure the accuracy of drugs or devices dispensed in accordance with this rule.

(2) The system shall produce images that are high definition with image resolution of at least 300 pixels per inch and in full color.

(3) If multiple units are being dispensed, the pharmacist must be able to see and verify an image or images of each unit and each individual affixed label.

(4) The images shall contain the following to ensure the pharmacist is able to appropriately verify the prescription prior to dispensing:

(a) A clear image of the prescription label affixed to the drug or device;

(b) The full quantity of the filled prescription;

(c) Except as provided in paragraph (C)(5) of this rule, the medication stock bottle or container and label of a drug that has been returned to stock in accordance with rule 4729:5-5-22 of the Administrative Code used to fill the prescription, if applicable;

(d) Clear markings present on the drug being dispensed (e.g., tablets, capsules, etc.), if applicable; and

(e) A clear image of the following, if not otherwise captured or maintained in the pharmacy system:

(i) The drug's national drug code, as defined in 21 CFR 207.33 (April 1, 2026), or global trade item number; and

(ii) The drug's serial number, lot number, and expiration date.

(5) The board may waive or modify the requirements listed in paragraph (C)(4)(c) of this rule if the electronic verification system can provide an alternative method that accurately captures information from the medication stock bottle and/or container and label of a drug that has been returned to stock in accordance with rule 4729:5-5-22 of the Administrative Code.

(6) The system shall use stock images of the correct drug, including markings if applicable.

(7) Images associated with the electronic product verification shall be retained in a secure, uniform, and electronic format and maintained for one year from the date of verification. Images associated with electronic product verification shall be made readily retrievable.

(8) Use of an electronic verification system shall be terminated if the system is not properly functioning. Prior to resuming the use of the system, the pharmacy shall identify the root cause or causes of the malfunction and shall validate that the system is properly functioning.

(9) The electronic verification system shall be capable of clearly communicating that the pharmacist has verified the drug or device prior to sale or distribution.

(10) Prior to dispensing, a pharmacist shall review and authorize overrides performed by a pharmacy technician or pharmacy intern of any technologically generated errors, warnings, alerts, or exceptions related to system functionality or verification/accuracy. Documentation of the pharmacist's review and authorization must be captured using electronic positive identification and maintained for three years from the date of review in a readily retrievable format.

(11) A pharmacist shall not be required to conduct electronic product verification if, in the pharmacist's professional judgement, the system, personnel, or processes employed by the pharmacy present a danger to the health and safety of patients.

(D) All electronic product verification shall be documented using an electronic form of positive identification in accordance with rule 4729:5-5-04 or rule 4729:5-9-02.3 of the Administrative Code.

(E) No further manipulation of a drug or device shall occur after the pharmacist's electronic verification is complete other than applying the required container lid or seal. Manipulation does not include preparing a finished prescription/medication order for mailing, sale, delivery, or storage.

(F) Except as provided for in this paragraph, a pharmacist shall not conduct electronic product verification of compounded drug preparations. A pharmacist may utilize electronic product verification as part of the compounding process as follows:

(1) The pharmacist complies with all applicable requirements of this rule.

(2) Only components used for compounded drug preparations may be verified by a pharmacist using an electronic verification system.

(3) Reconstituted drug products (ex. stock solutions) may be used or manipulated for compounding after the pharmacist's electronic verification is complete.

(4) At the completion of the compounding process and prior to release or dispensation, sale, or distribution, the compounded drug preparation shall be visually inspected by a pharmacist in person to determine whether the physical appearance of the drug is as expected (e.g., free of inappropriate visible particulates or other foreign matter, discoloration, or other defects) and that the container closure integrity is in compliance with all applicable United States Pharmacopeia chapters referenced in rule 4729:7-1-01 of the Administrative Code. A pharmacist shall document this verification using positive identification.

(G) All pharmacy personnel utilizing an electronic final verification system must be trained and competent to perform the duties assigned and have a documented initial assessment of competency using the pharmacy's electronic verification system. Additional documented assessments shall be required in the event of a substantive change to the system's functionality or in the event of a major system update.

(H) An electronic verification system shall be implemented and validated by the vendor or manufacturer with oversight by an Ohio-licensed pharmacist prior to initial use to ensure proper functioning. The system shall be validated in accordance with the pharmacy's policies and procedures at least annually and upon the addition of new processes or material system changes.

(1) Validation is a documented process established by the terminal distributor of dangerous drugs that proves the electronic verification system consistently operates according to its intended use, specifications, and requirements of this rule.

(2) Proof of compliance with validation requirements shall be documented by the vendor or manufacturer and maintained in a readily retrievable format for three years from the date of validation or revalidation.

(3) The records shall document the positive identification of the pharmacist responsible for overseeing the required validation, date(s) performed, and the results of the validation.

(I) Pharmacies using an electronic verification system as authorized by this rule shall maintain an ongoing and documented quality assurance system that monitors the performance of the electronic verification system to ensure proper and accurate functioning in accordance with rule 4729:5-3-22 of the Administrative Code. The quality assurance system shall also include procedures for reporting system malfunctions.

(J) Pharmacies utilizing an electronic verification system pursuant to this rule shall maintain and implement written policies and procedures governing all aspects of electronic verification activities. Such policies and procedures shall be maintained in a readily retrievable format and shall include, but are not limited to, the following:

(1) Staff training and competency assessments;

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

(3) Validation and revalidation of electronic verification technology to ensure proper functioning; and

(4) System maintenance, including any routine or preventive maintenance.

(K) Pharmacies using an electronic verification system shall comply with all applicable record keeping requirements pursuant to rule 4729:5-5-04 or rule 4729:5-9-02.3 of the Administrative Code.

(L) A pharmacy licensed as a terminal distributor of dangerous drugs that is engaged in electronic product verification shall comply with all minimum standards for the operation of a pharmacy, including rule 4729:5-5-02 of the Administrative Code and all supplemental rules adopted thereunder.