For Stakeholder Comment - Shared Services, Remote Pharmacy Functions, and Automated Distribution Systems

Date Issued: 8/14/2026
Comments Due: 9/30/2026

In an effort to expand access to pharmacy services via technology, the Ohio Board of Pharmacy is proposing an update and expansion of its pharmacy technology-related rules. Included in this packet are the following 8 new rules:

4729:5-3-25 - Shared services and remote pharmacy functions. (NEW)

- 4729:5-3-25.1 - Central fill pharmacies. (NEW)
- 4729:5-3-25.2 - Remote prescription or medication order processing. (NEW)
- 4729:5-3-25.3 - Electronic Product Verification (NEW)

4729:5-3-17 - Automated distribution systems. (NEW)

- 4729:5-3-17.1 - Automated pharmacy systems. (NEW)
- 4729:5-3-17.2 - Automated drug storage systems. (NEW)
- 4729:5-3-17.3 - Self-service prescription kiosks. (NEW)

Comments on the proposed rules will be accepted until close of business on **September 30, 2026**. Please send all comments to the following email address: rulecomments@pharmacy.ohio.gov.

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4729:5-3-25 - Shared services and remote pharmacy functions. (NEW)

(RESCIND 4729:5-3-25)

(A) “Shared services and remote pharmacy functions” means any of the following:

(1) Operation of a central fill pharmacy in accordance with rule 4729:5-3-25.1 of the Administrative Code.

(2) Remote prescription or medication order processing in accordance with rule 4729:5-3-25.2 of the Administrative Code.

(3) Electronic product verification in accordance with rule 4729:5-3-25.3 of the Administrative Code.

(B) A terminal distributor of dangerous drugs providing shared services and remote pharmacy functions shall comply with all requirements of this rule, including all supplemental rules adopted thereunder.

4729:5-3-25.1 - Central fill pharmacies. (NEW)

(RESCIND 4729:5-9-02.13 and 4729:5-5-19)

(A) As used in this rule:

(1) "Central fill pharmacy" means a pharmacy licensed as a terminal distributor of dangerous drugs acting as an agent of an originating pharmacy to fill or refill a prescription or medication order. A central fill pharmacy may also be the originating pharmacy pursuant to rule 4729:5-3-25.1 of the Administrative Code.

(2) "Originating pharmacy" means a pharmacy licensed as a terminal distributor of dangerous drugs that uses a central fill pharmacy to fill or refill a prescription or medication order.

(3) “Positive identification” has the same meaning as in rule 4729:5-5-01 of the Administrative Code.

(B) A central fill pharmacy and originating pharmacy may process a request for the filling or refilling of a prescription or medication order received by an originating pharmacy only pursuant to the following requirements:

(1) The central fill pharmacy either has the same owner as the originating pharmacy or has a written contract with the originating pharmacy outlining the services to be provided and the responsibilities of each pharmacy in fulfilling the terms of the contract in compliance with federal and state law. The contract shall expressly state who is responsible for performing outpatient counseling requirements in accordance with rule 4729:5-5-09 of the Administrative Code.

(2) The central fill pharmacy shall maintain a record of all originating pharmacies, including name, address, terminal distributor of dangerous drugs license number, and, if applicable, drug enforcement administration registration number, for which it processes a request for the filling or refilling of a prescription or medication order received by the originating pharmacy. The record shall be made readily retrievable and maintained for a period of three years.

(3) The central fill pharmacy and originating pharmacy shall have access to common electronic files as part of a real time, online database or have appropriate technology to allow

secure access to sufficient information necessary or required to dispense or process the prescription or medication order.

(4) The originating pharmacy shall comply with the minimum required information for a patient profile prior to sending a prescription or medication order to the central fill pharmacy.

(a) For outpatient prescriptions the patient profile shall comply with rule 4729:5-5-07 of the Administration Code.

(b) For inpatient orders, the patient profile shall comply with rule 4729:5-9-02.5 of the Administrative Code.

(5) The originating pharmacy shall remain responsible for compliance with the dangerous drug dispensing requirements of Chapters 4729:5-5 and 4729:5-9 of the Administrative Code that are not assumed in writing by the central fill pharmacy.

(6) The originating pharmacy shall remain responsible for compliance the compounding requirements of Chapter 4729:7-2 of the Administrative Code that are not assumed in writing by the central fill pharmacy.

(7) The prescription label attached to the container shall contain the name and address of the originating pharmacy.

(a) The date on which the prescription or order was dispensed shall be the date on which the central fill pharmacy filled the prescription or order.

(b) For outpatient dispensing, if the originating pharmacy and the central fill pharmacy are not under common ownership, either of the following shall apply:

(i) The name of the central fill pharmacy shall be included on the medication label or an auxiliary label; or

(ii) A statement is included in the prescription information accompanying the dangerous drug that indicates a central fill pharmacy was used to fill the prescription and includes the name of the central fill pharmacy.

(8) An originating outpatient pharmacy shall provide, upon the request of a patient or caregiver, the name and address of the central fill pharmacy and a contact phone number where the patient or caregiver can receive further assistance regarding prescriptions filled by a central fill pharmacy.

(9) The originating pharmacy shall maintain the original prescriptions or medication orders received for purposes of filing and record keeping as required by state and federal law, rules, and regulations.

(10) The central fill pharmacy shall maintain all original fill and refill requests received from the originating pharmacy and shall treat them as original and refill prescription or medication orders for purposes of filing and record keeping as required by state and federal law, rules, and regulations.

(11) The central fill pharmacy and originating pharmacy shall each maintain records to capture the positive identification of the licensed or registered individuals responsible for performing respective activities in accordance rule 4729:5-5-04 of the Administrative Code for outpatient prescriptions and rule 4729:5-9-02.3 of the Administrative Code for institutional medications orders.

(12) The central fill pharmacy and originating pharmacy shall adopt a written quality assurance program for pharmacy services in accordance with rule 4729:5-3-22 of the Administrative Code.

(C) Dangerous drugs may be returned by the originating pharmacy to the central fill pharmacy that originally filled the prescription or medication order for the express purpose of being returned to the central fill pharmacy's stock shelves in accordance with the following:

(1) The central fill pharmacy complies with the requirements of rule 4729:5-3-16 of the Administrative Code; and

(2) The originating and central fill pharmacy are under common ownership and control.

(D) An originating pharmacy may return dangerous drugs received by a central fill pharmacy to stock shelves in accordance with rule 4729:5-3-16 of the Administrative Code.

(E) For outpatient dispensing, a central fill pharmacy may dispense a prescription directly to a patient pursuant to the following requirements:

(1) A prospective drug utilization review is conducted pursuant to a written contract or agreement in accordance with rule 4729:5-5-08 of the Administrative Code;

(2) Patient counseling is provided pursuant to a written contract or agreement in accordance with rule 4729:5-5-09 of the Administrative Code;

(3) The dispensing is conducted in accordance with all other applicable state and federal laws, regulations and rules, including those specified 21 CFR Parts 1300, 1301, 1304, 1305 and 1306 (August 6, 2026).

(F) All written documentation required by this rule shall be maintained for three years from the date of execution or review and shall be made readily retrievable.

(G) Drugs that are repackaged or relabeled by a central fill pharmacy shall comply with the requirements of rule 4729:5-5-17 of the Administrative Code for outpatient prescriptions and rule 4729:5-9-02.12 for institutional medication orders.

4729:5-3-25.2 - Remote prescription or medication order processing. (NEW)

(RESCIND 4729:5-9-02.14, 4729:5-9-02.15, 4729:5-5-20, 4729:5-5-25)

(A) As used in this rule:

(1) "Direct supervision" and "personal supervision" have the same meaning as in rule 4729:2-1-01 of the Administrative Code and 4729:3-1-01 of the Administrative Code.

(2) "Remote prescription or order processing" means the processing of a prescription or medication order for an outpatient or institutional pharmacy licensed as a terminal distributor of dangerous drugs by a remote pharmacist or a remote technician or intern under the direct supervision or remote supervision of a pharmacist.

(a) Remote prescription or medication order processing does not include the dispensing of a drug, but may include, in accordance with the licensee or registrant's applicable scope of practice, the following:

(i) Receiving, interpreting, evaluating, clarifying, and verification of prescriptions.

(ii) Prescription or order entry, other data entry, performing prospective drug utilization review, interpreting clinical data, performing therapeutic interventions, and providing drug information services.

(b) The requirements of this rule shall be limited to the processing of prescriptions or medication order dispensed in or into this state.

(2) "Remote pharmacy intern" includes any of the following:

(a) If performing remote prescription or medication order processing in this state, a pharmacy intern shall comply with all of the following:

(i) Be an Ohio licensed pharmacy intern;

(ii) Be either employed or a contract employee of an Ohio-licensed pharmacy or remote pharmacy.

(iii) Processes prescriptions or medication orders from either:

(*a*) A remote site, which may include the intern's residence or other location where the pharmacist and the outpatient, institutional, or remote pharmacy can ensure the confidentiality and integrity of patient information; or

(*b*) On the premises of an Ohio-licensed remote pharmacy or pharmacy.

(b) If performing remote prescription or medication order processing outside of this state, a pharmacy intern shall comply with all of the following:

(i) Be licensed or registered in the state where the remote prescription or medication order processing is occurring.

(ii) Be either employed or a contract employee of a pharmacy or remote pharmacy who holds a nonresident pharmacy license in accordance with Chapter 4729:5-8 of the Administrative Code.

(iii) Processes prescriptions or medication orders from either:

(*a*) A remote site, which may include the pharmacy intern's residence or other location where the pharmacist and the nonresident pharmacy or remote pharmacy can ensure the confidentiality and integrity of patient information;

(*b*) On the premises of an Ohio-licensed remote pharmacy or nonresident pharmacy.

(c) A remote pharmacy intern may only perform remote prescription or medication order processing activities that fall within the intern's applicable scope of practice.

(2) "Remote pharmacy" includes either:

(a) A pharmacy, including a nonresident pharmacy, licensed as a terminal distributor of dangerous drugs that dispenses dangerous drugs; or

(b) A pharmacy licensed as a limited category II terminal distributor of dangerous drugs that does not stock, own, or dispense any dangerous drugs and whose sole business consists of entry, review, and/or verification of prescriptions or medication orders and consulting services under contract for a licensed pharmacy in this state.

(c) A remote pharmacy does not include a remote dispensing pharmacy as defined in Chapter 4729:5-18 of the Administrative Code.

(3) "Remote pharmacist" includes any of the following:

(a) If performing remote prescription or medication order processing in this state, a pharmacist shall comply with all of the following:

(i) Be an Ohio licensed pharmacist;

(ii) Be either employed or a contract employee of an Ohio-licensed pharmacy or remote pharmacy.

(iii) Processes prescriptions or medication orders from either:

(*a*) A remote site, which may include the pharmacist's residence or other location where the pharmacist and the outpatient, institutional, or remote pharmacy can ensure the confidentiality and integrity of patient information; or

(*b*) On the premises of an Ohio-licensed remote pharmacy or pharmacy.

(b) If performing remote prescription or medication order processing outside of this state, a pharmacist shall comply with all of the following:

(i) Be licensed or registered in the state where the remote prescription or medication order processing is occurring.

(ii) Be either employed or a contract employee of a pharmacy or remote pharmacy who holds a nonresident pharmacy license in accordance with Chapter 4729:5-8 of the Administrative Code.

(iii) Processes prescriptions or medication orders from either:

(*a*) A remote site, which may include the pharmacist's residence or other location where the pharmacist and the nonresident pharmacy or remote pharmacy can ensure the confidentiality and integrity of patient information;

(*b*) On the premises of an Ohio-licensed remote pharmacy or nonresident pharmacy.

(4) "Remote supervision" means that a pharmacist directs and controls the actions of remote technicians and remote interns through the use of technology that ensures a supervising pharmacist can meet the requirements of this rule. A pharmacist providing remote supervision shall:

(a) Be readily available to answer questions of a remote technician or remote pharmacy intern; and

(b) Be fully responsible for the practice and accuracy of the remote technician or remote pharmacy intern.

(5) "Remote technician" includes any of the following:

(a) If performing remote prescription or medication order processing in this state, a pharmacy technician shall comply with all of the following:

(i) Be registered as an Ohio certified pharmacy technician, registered pharmacy technician, or pharmacy technician trainee.

(ii) Be either employed or a contract employee of an Ohio-licensed pharmacy or remote pharmacy.

(iii) Processes prescriptions or medication orders from either:

(*a*) A remote site, which may include the technician's residence or other location where the pharmacist and the outpatient, institutional, or remote pharmacy can ensure the confidentiality and integrity of patient information; or

(*b*) On the premises of an Ohio-licensed remote pharmacy or pharmacy.

(b) If performing remote prescription or medication order processing outside of this state, a pharmacy technician shall comply with all of the following:

(i) Be licensed or registered in the state where the remote prescription or medication order processing is occurring, or if working in a state that has not yet implemented a technician registration process, has received training and is working as a pharmacy technician in accordance with of the laws and regulations of their state of practice.

(ii) Be either employed or a contract employee of an Ohio-licensed pharmacy or remote pharmacy.

(iii) Processes prescriptions or medication orders from either:

(*a*) A remote site, which may include the technician's residence or other location where the technician and the nonresident pharmacy or remote pharmacy can ensure the confidentiality and integrity of patient information; or

(*b*) On the premises of an Ohio-licensed remote pharmacy or pharmacy.

(c) A nonresident pharmacy shall be responsible for ensuring all actions performed by an unregistered or unlicensed remote technician comply with the requirements of this rule.

(d) A remote technician may only perform remote prescription or medication order processing activities that fall within the technician's applicable scope of practice.

(B) A pharmacist, pharmacy intern, or pharmacy technician shall only be permitted to conduct remote prescription or medication order processing within the United States, to include the District of Columbia, the Commonwealth of Puerto Rico or a territory or insular possession subject to the jurisdiction of the United States.

(C) A pharmacy may outsource prescription or medication order processing to a remote pharmacy provided the pharmacies are either:

(1) Under common ownership or control; or

(2) The pharmacy has entered into a written contract or agreement with a remote pharmacy that outlines the services to be provided and the responsibilities and accountabilities of each party to the contract or agreement in compliance with federal and state statutes, rules, and regulations. The pharmacy and remote pharmacy shall maintain a copy of the contract or agreement in a readily retrievable manner for inspection and review by an agent, inspector, or employee of the board.

(D) A pharmacy utilizing remote prescription or medication order processing shall ensure that all remote pharmacists, interns, and technicians providing such services have been trained on

the pharmacy's policies and procedures relating to prescription or medication order processing. The training of each pharmacist, intern, and technician shall be documented.

(1) The pharmacy and the remote pharmacy shall jointly develop a procedure to communicate changes in policies and procedures related to prescription or medication order processing.

(2) A terminal distributor of dangerous drugs may utilize one training program for all pharmacies under the terminal distributor's common ownership and control.

(E) A pharmacy utilizing remote pharmacists, interns, and technicians shall maintain or have access to a record of the following:

(1) The name of each pharmacist, intern, and technician engaged in remote prescription or medication order processing;

(2) The address of each location where a remote pharmacist, intern, or technician will be providing remote prescription processing services;

(3) Evidence of current licensure, registration, or certification in the state where the remote pharmacist, intern, or technician is performing remote prescription or medication order processing.

(F) The pharmacy shall ensure that any remote pharmacist, intern, or technician shall have secure electronic access to the pharmacy's patient information system and to other electronic systems that the on-site pharmacist has access to when the pharmacy is open.

(G) The remote pharmacist must be able to contact the prescriber issuing a prescription or medication order to discuss any concerns identified during the pharmacist's review of patient information and the prescription or order. A procedure must be in place to communicate any problems identified with the prescriber and the pharmacy.

(H) Each remote entry record must comply with all record keeping requirements for pharmacies, including capturing the positive identification of the remote pharmacist, interns, and technicians involved in the review and verification of the prescription or medication order.

(I) A pharmacy utilizing remote prescription or medication order processing is responsible for maintaining records of all prescriptions or orders entered into their information system, including those entered by a remote pharmacist, intern, or technician. The system shall have the ability to audit the activities of remote pharmacists, interns, and technicians.

(J) A pharmacy utilizing remote prescription or medication order processing services shall develop and implement a policy and procedure manual. A remote pharmacy shall maintain a copy of those portions of the policy and procedure manual that relate to the remote pharmacy's operations. Each manual shall include the following:

(1) The responsibilities of the pharmacy and the remote pharmacy;

(2) List of the names, addresses, telephone numbers, and all license numbers of the pharmacies, pharmacists, pharmacy interns, and technicians involved in remote prescription processing; and

(3) Policies and procedures for:

(a) Protecting the confidentiality and integrity of patient information;

(b) Ensuring that no patient information is duplicated, downloaded, or removed from the pharmacy's patient information system;

(c) Maintaining appropriate records of each pharmacist, intern, and technician involved in prescription processing;

(d) Complying with federal and state statutes, rules, and regulations;

(e) Reviewing written policies and procedures at least every three years, or upon the implementation of a significant change of written policies and procedures, and documentation of the review; and

(f) Annually reviewing the competencies of pharmacists, interns, and technicians providing remote prescription or medication order processing.

4729:5-3-25.3 – Electronic Product Verification (NEW)

(RESCIND 4729:5-3-25)

NOTE: The Board is not proposing any significant changes compared to the existing rule. The only notable changes are cross references to other rules that are proposed to be moved in this rule package [see paragraph (A)(1)].

(A) As used in this rule:

(1) "Electronic product verification" or "electronic verification" means the nonphysical 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 prescription or medication order processing pursuant to rule 4729:5-3-17.2 of the Administrative Code;

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

(d) The dispensation of a drug or device from an automated pharmacy system pursuant to rule 4729:5-3-17.1 of the Administrative Code.

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

(3) "Positive identification" has the same meaning as in rule 4729:5-5-01 of the Administrative Code.

(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 (March 5, 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.

4729:5-3-17 - Automated distribution systems. (NEW)

(A) “Automated distribution systems” means any of the following:

(1) An automated pharmacy system in accordance with rule 4729:5-3-17.1 of the Administrative Code.

(2) An automated drug storage system in accordance with rule 4729:5-3-17.2 of the Administrative Code.

(3) A self-service prescription kiosk in accordance with rule 4729:5-3-17.3 of the Administrative Code.

B) A terminal distributor of dangerous drugs operating an automated distribution system shall comply with all requirements of this rule, including all supplemental rules adopted thereunder.

4729:5-3-17.1 - Automated pharmacy systems. (NEW)

(RESCIND 4729:5-3-17)

(A) As used in this rule:

(1) "Automated pharmacy system" means a mechanical system that performs operations or activities, other than administration, relative to storage, packaging, compounding, dispensing, or distribution of dangerous drugs that collects, controls, and maintains transaction information and records. An automated pharmacy system does not include any of the following:

(a) An "automated drug storage system" as defined in rule 4729:5-17.2 of the Administrative Code.

(b) A “self-service prescription kiosk” as defined in rule 4729:5-3-19 of the Administrative Code.

(c) A “remote dispensing pharmacy” or “telepharmacy system” pursuant to chapter 4729:5-18 of the Administrative Code.

(d) An electronic system used as part of “electronic product verification” in accordance with rule 4729:5-3-25.3 of the Administrative Code.

(2) "Dispense" means the final association of a drug with a particular patient pursuant to a prescription, drug order, or other lawful order of a prescriber and the professional judgment of and the responsibility for interpreting, preparing, compounding, labeling, and packaging a specific drug.

(a) In the case of an automated pharmacy system that dispenses dangerous drugs without the final association by a pharmacist, the system shall capture the positive identification of the pharmacist authorizing the patient specific prescription in the system prior to its dispensation.

(b) Nothing in this paragraph shall prohibit an automated pharmacy system from being utilized to restock an automated drug storage systems.

(3) "Positive identification" has the same meaning as in rule 4729:5-5-01 of the Administrative Code.

(4) "Tamper evident" means a package, storage container, or other physical barrier that is sealed or secured in such a way that access to the drugs stored within is not possible without leaving visible proof that such access has been attempted or made.

(B) An automated pharmacy system shall be reviewed by the board prior to its implementation by the terminal distributor of dangerous drugs.

(1) The board shall receive a request from the responsible person on the terminal distributor of dangerous drugs license.

(2) Upon notification, the board shall evaluate the system to determine if it meets the requirements of this rule.

(C) An automated pharmacy system shall be located on the premises of a licensed terminal distributor of dangerous drugs where existing medical or pharmaceutical services are provided.

(D) Approval of all automated pharmacy systems shall be site-specific.

(E) The automated pharmacy 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.

(F) In the case of an automated pharmacy system that dispenses dangerous drugs without the final association by a pharmacist, the board shall approve the system to determine if it meets the requirements of this rule.

(1) The responsible person of the licensed terminal distributor of dangerous drugs shall be required to have a pharmacist verify for accuracy all dangerous drugs dispensed by the system for a continuous forty-five-day period.

(2) The responsible person shall compile metrics, using a form developed by the board, documenting the performance of the system during this period. The accuracy metrics during the forty-five-day pharmacy review period shall be no less than ninety-nine and nine hundred eighty-five thousandths (99.985) per cent.

(3) The terminal distributor of dangerous drugs shall implement a quality assurance program to determine continued appropriate use of the automated pharmacy system.

(a) The quality assurance program shall monitor the performance of the automated pharmacy system, ensure the system is in good working order and accurately prepares the correct strength, dosage form, and quantity of the drug prescribed or ordered.

(b) The quality assurance program shall consist of a review of all dispensed prescriptions over the daily operational hours of the automated pharmacy system as follows:

(i) For automated pharmacy systems that dispense less than 10,000 dosage units per day, at least five percent of all dispensed prescriptions.

(ii) For automated pharmacy systems that dispense more than 10,000 dosage units per day, at least two percent of all dispense prescriptions.

(G) All records maintained in accordance with this rule, including documentation of quality assurance metrics, shall be readily retrievable and maintained for period of three years.

(H) If an automated pharmacy system that dispenses dangerous drugs in accordance with paragraph (A)(2)(a) of this rule selects an incorrect drug, the terminal distributor shall immediately institute a one hundred percent pharmacist verification of all drugs dispensed. The one hundred percent verification procedure shall continue until such time as the terminal distributor can document that the cause of the error has been identified and addressed and that the system is no longer making errors.

(I) A registered or certified pharmacy technician, pharmacy technician trainee, pharmacy intern, or nurse licensed in accordance with Chapter 4723. of the Revised Code may stock an automated pharmacy system provided that:

(1) Except as provided in paragraph (I)(2) of this rule, the container, canister, or other dangerous drug storage device being stocked by the technician, trainee, intern, or nurse is tamper-evident and is verified by a pharmacist and documented using positive identification.

(2) Pharmacist verification requirements in paragraph (I)(1) of this rule do not apply if all the following are met:

(a) The container, canister, or other dangerous drug storage device being stocked is properly identified by barcode or other secondary information system, which has been verified by a pharmacist to ensure the proper drug is placed into and recognized as the correct drug by the system.

(b) The utilization of a barcode, electronic verification, or similar verification process shall require an initial quality assurance validation by a pharmacist and shall be followed by a quarterly quality assurance review by a pharmacist. All barcodes utilized by automated pharmacy systems shall be scanned, and not manually typed, into the system.

(3) The positive identification of the individual stocking the system is documented.

(4) A pharmacist is fully responsible for all activities conducted by the technician, technician trainee, intern, or nurse.

(5) A pharmacist must be immediately available to answer questions or discuss the stocking of an automated pharmacy system.

(6) A registered pharmacy technician or pharmacy technician trainee shall be acting under the personal supervision of a pharmacist.

(I) A pharmacist shall be physically present at the terminal distributor of dangerous drugs to provide supervision of the automated pharmacy system when operational in a hospital, outpatient pharmacy, or institutional pharmacy. This requirement does not apply to automated pharmacy systems operating in the following locations:

(1) A long-term care facility, including a nursing home or a residential care facility as defined in rule 4729:5-9-01 of the Administrative Code; or

(2) A terminal distributor of dangerous drugs that is not a hospital, outpatient pharmacy, or institutional pharmacy where supervision is provided by a prescriber.

(J) All dangerous drugs within an automated pharmacy system shall be maintained in a clean and orderly condition. Automated systems shall be maintained at temperatures which will ensure the integrity of the drugs as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling.

(K) All automated pharmacy systems that store or maintain drugs requiring temperature control (e.g., drugs that are required to be refrigerated or frozen) shall comply with the applicable temperature monitoring and record keeping requirements of either:

(1) Chapter 4729:5-9 of the Administrative Code for institutional pharmacies; or

(2) Chapter 4729:5-5 of the Administrative Code for outpatient pharmacies.

(L) All personnel utilizing an automated pharmacy system must be trained and competent to perform the duties assigned and have a documented initial assessment of competency using the automated pharmacy 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.

(M) Automated pharmacy systems that dispense outpatient prescriptions directly to a patient or patient’s caregiver utilizing an electronic system to capture the final association by a pharmacist of this rule shall:

(1) Comply with the applicable requirements of this rule.

(2) Not perform the packaging of any dangerous drug or device, except for labeling. All drugs or devices dispensed for outpatient use shall be prepackaged in existing tamper-evident containers that contain standard dosing regimens determined by the terminal distributor of dangerous drugs.

(3) Provide clear instructions on how to use the machine in English, braille, and, in accordance with the terminal distributor's policies, any other language spoken by the primary patient population served by the automated pharmacy system.

(4) Prominently display notification that patient counseling is available pursuant to rule 4729:5-5-09 of the Administrative Code. Counseling shall be immediately available to any patient or caregiver that requests it via telephone, videoconference, or another accessible option for those experiencing hearing loss.

(a) Instructions on how to contact a pharmacist via toll-free telephone shall be displayed by on the system and must also be printed on the customer receipt or included with the patient instructions.

(b) The system shall provide the ability for the pharmacist or the terminal distributor of dangerous drugs operating the system to require patient counseling before the system dispenses the drug or device.

(5) Be operated by one or more Ohio licensed pharmacists practicing in the state of Ohio that are employed by or under contract with the terminal distributor of dangerous drugs.

(6) Allow the pharmacist to see an exact, clear, and unobstructed visual image or 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.

(7) Produce images for pharmacist review that are high definition with image resolution of at least 300 pixels per inch and in full color.

(8) Maintain all images associated with the dispensing process in a secure, uniform, and electronic format for one year from the date of verification. Such images shall be made readily retrievable.

(9) Be capable of clearly communicating that the pharmacist has verified the drug or device prior to sale or distribution.

(10) Employ a method of two-factor authentication to identify a patient or caregiver of the patient to ensure the prescription is delivered from the automated pharmacy system only to its intended recipient.

(11) Not dispense any of the following:

(a) Controlled substances.

(b) Any hazardous drug, except for conventionally manufactured hazardous drugs that are tablets or capsules that do not require any further manipulation other than counting or repackaging.

(c) New prescriptions for pediatric drug that require dose measuring or reconstitution.

(12) Implement a back-up process to ensure uninterrupted access for patients in the event the system is malfunctioning. The process shall ensure that the patient's prescription is transferred to the pharmacy of the patient's choice during system malfunction.

(13) Meet the following security requirements:

(a) Is electronically protected against unauthorized access;

(b) Be bolted to the floor or installed in a wall;

(c) Be constructed in such manner as to prevent tampering, break-in and theft of inventory; and

(d) Is able to either:

(i) Sound an alarm if a break-in is attempted; or

(ii) Transmit a notification to on-site security if a break-in is attempted.

(14) Continuously monitored and recorded by one or more video cameras. The video camera(s) shall provide one hundred percent video coverage of the system. Camera recordings shall be maintained for at least ninety days and shall be made readily available upon request by an agent, officer, or inspector of the board. The location where the automated pharmacy system is maintained shall have adequate lighting to produce clear digitally recorded and still picture production.

(N) An automated pharmacy system shall have security to prevent unauthorized individuals from accessing or obtaining dangerous drugs and include safeguards to detect the diversion of dangerous drugs. Except as provided for in paragraph (M)(13) of this rule, this shall include the use of tamper-evident containers, canisters, or other storage devices.

(O) All records kept by an automated pharmacy system shall comply with the applicable record keeping requirements of division 4729:5 of the Administrative Code and shall capture all events involving the contents of the system.

(P) Except as authorized under Chapter 4729:5-21 of the Administrative Code, an automated pharmacy system shall not be used to personally furnish dangerous drugs.

4729:5-3-17.2 - Automated drug storage systems. (NEW)

(RESCIND 4729:5-9-03.4)

(A) As used in this rule:

(1) "Automated drug storage system" means a mechanical system used for the secure storage of dangerous drugs that collects, controls, and maintains transaction information and records. All automated drug storage systems utilized by a terminal distributor of dangerous drug shall comply with the requirements of this rule.

(2) "Positive identification" has the same meaning as in rule 4729:5-5-01 of the Administrative Code.

(3) "Medications removed on override function" or "override medications" has the same meaning as in rule 4729:5-9-01 of the Administrative Code.

(B) Except as provided in paragraph (C) of this rule, the electronic system used to access all drugs within the automated drug storage system shall have an electronic timeout of one hundred twenty seconds of inactivity.

(C) For an automated drug storage system used exclusively for administering anesthesia drugs that is under the immediate supervision of a licensed healthcare provider authorized to administer such drugs, the electronic system used to access all drugs within the automated drug storage system shall have an electronic timeout of no more than sixty minutes of inactivity, unless an alternative method to ensure the security of the drug stock is approved by the board.

(D) A terminal distributor of dangerous drugs shall maintain an electronic record that documents access to the automated drug storage system.

(1) The record shall include the names, titles, and positive identification of all personnel accessing medications, date and time of access, the name and quantity of drugs obtained, and the name of the patient, when applicable.

(2) All records maintained in accordance with this rule shall be readily retrievable and maintained for period of three years.

(E) An automated drug storage system shall have security to prevent unauthorized individuals from accessing or obtaining dangerous drugs, including safeguards to detect and deter the diversion of dangerous drugs.

(F) A terminal distributor of dangerous drugs shall develop and implement the following policies and procedures with respect to an automated drug storage system:

(1) For patient-specific administration, a description of the types of medications removed on override function that will be reviewed for clinical suitability and the frequency of the reviews by the terminal distributor of dangerous drugs. All reviews shall be documented by the terminal distributor of dangerous drugs, and all documentation shall be maintained for three years in a readily retrievable manner.

(2) An audit process to deter and detect drug diversion.

(3) A process to track access to medication override access, including keys.

(4) Inspection of the system to ensure proper utilization and replacement of the drug supply.

(G) All policies and procedures required in accordance with paragraph (F) of this rule shall be maintained in a readily retrievable manner.

4729:5-3-17.3 - Self-service prescription kiosks. (NEW)

(RESCIND 4729:5-9-03.5)

(A) As used in this rule:

(1) "Hazardous drug" means any drug listed in table one on the national institute for occupational safety and health's list of antineoplastic and other hazardous drugs in healthcare settings as referenced in rule 4729:7-1-01 of the Administrative Code.

(2) "Self-service prescription kiosk" or "kiosk" means a self-service kiosk or locker for the pickup of new or refill prescriptions at a location licensed as a terminal distributor of dangerous drugs where existing medical or pharmaceutical services are provided.

(B) A self-service prescription kiosk shall be located inside of the premises of a terminal distributor of dangerous drugs.

(1) A self-service prescription kiosk shall not be located within a ten-mile radius of a pharmacy that serves the public as an outpatient pharmacy unless the kiosk is located at any of the following locations:

(a) A federally qualified health center or federally qualified health center look-alike, as defined in section 3701.047 of the Revised Code;

(b) At an institutional facility for the purpose only for facility employees and their family members; or

(c) A board approved location, based on a demonstration of need, that meets the standards established in paragraph (B)(2) of this rule.

(2) A terminal distributor of dangerous drugs may submit a request to the board, in a manner determined by board, to allow a self-service prescription kiosk located within a ten-mile radius of an outpatient pharmacy if the proposed self-service prescription kiosk is located in census block that is medium-high (0.5-0.75) or high (greater than 0.75) based upon the social vulnerability index (SVI) as designated by the board's Ohio pharmacy access dashboard (accessible via www.pharmacy.ohio.gov).

(3) If the location that operates a self-service prescription kiosk has an on-site pharmacy, the kiosk shall be located in the immediate proximity of the pharmacy, unless otherwise approved by the board.

(C) A self-service prescription kiosk shall be:

(1) Of sufficient size and weight or shall be physically secured to prevent unauthorized removal.

(2) Constructed in such manner as to prevent tampering, break-in, or theft of inventory.

(3) Able to either:

(a) Sound an alarm if a break-in is attempted; or

(b) Transmit a notification to on-site security if a break-in is attempted.

(4) Continuously monitored and recorded by one or more video cameras. The video camera(s) shall provide one hundred percent video coverage of the system. Camera recordings shall be maintained for at least ninety days and shall be made readily available upon request by an agent, officer, or inspector of the board. The location where the self-service kiosk is maintained shall have adequate lighting to produce clear digitally recorded and still picture production.

(5) Prohibit access to the kiosk system and its contents by unauthorized personnel and maintain confidentiality of the patient information.

(D) Only a dangerous drug prescription dispensed by the terminal distributor-owned pharmacy may be provided to the patient or patient's caregiver via a self-service kiosk. A kiosk shall not provide any of the following:

(1) Controlled substances.

(2) Any hazardous drug, except for conventionally manufactured hazardous drugs that are tablets or capsules that do not require any further manipulation other than counting or repackaging.

(3) New prescriptions for pediatric drug that require dose measuring or reconstitution.

(4) Any prescriptions requiring mandatory patient counseling as part of a risk evaluation and mitigation strategy (REMS) in accordance with 21 USC 355-1 (August 1, 2026).

(E) All drugs and devices in a kiosk shall be maintained in a clean and orderly condition. Kiosks shall be maintained at temperatures which will ensure the integrity of the drugs as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling.

(F) Dangerous drugs stored in a kiosk that are not picked up by a patient may be returned to stock shelves in accordance with rule 4729:5-3-16 of the Administrative Code.

(G) A kiosk shall only be stocked by a terminal distributor employed pharmacist, pharmacy intern, certified pharmacy technician, registered pharmacy technician, or pharmacy technician trainee.

(H) A dispensing pharmacy described in paragraph (D) of this rule shall maintain a record keeping system that will provide accountability for proper receipt of all prescriptions provided to a patient or patient's caregiver via a self-service kiosk.

(I) A kiosk shall employ a method of two-factor authentication to identify a patient or caregiver of the patient to ensure the prescription is provided from the kiosk to its intended recipient.

(J) The pharmacy shall capture the consent of the patient to use the kiosk before the pharmacy dispenses the drugs or devices.

(K) The pharmacy shall determine patient eligibility to use the prescription kiosks, including assessment of language barriers, cognitive impairments, age, and disabilities requiring assistance.

(L) Prominently display notification that patient counseling is available pursuant to rule 4729:5-5-09 of the Administrative Code. Counseling shall be immediately available to any patient or caregiver that requests it via telephone, videoconference, or another accessible option for those experiencing hearing loss.

(1) Instructions on how to contact a pharmacist via toll-free telephone must be displayed by the kiosk and must also be printed on the customer receipt or included with the patient instructions.

(2) If the patient requests counseling when the pharmacy is closed or unavailable, the system shall record the request, and a pharmacist shall contact the patient and provide counseling within twenty-four hours of receiving the request.

(3) The system shall provide the ability for the pharmacist to force counseling before the system dispenses the drug or device.

(M) The kiosk shall have clear instructions on how to use the kiosk in English, braille, and, in accordance with the terminal distributor's policies, any other language spoken by the primary patient population served by the self-service kiosk.

(N) A self-service prescription kiosk 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 self-service kiosk 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.

(O) The terminal distributor of dangerous drugs shall maintain and implement the following policies and procedures that, at a minimum, include the following:

(1) Patient eligibility and selection criteria;

(2) Patient confidentiality;

(3) Patient counseling;

(4) Data retention and retrieval;

(5) Downtime procedures;

(6) Inspection of kiosks by pharmacy personnel;

(7) Maintenance;

(8) Quality assurance;

(9) Inventory control;

(10) Drug security;

(11) Staff education and training; and

(12) System set up, validation, and troubleshooting.

(P) The policies and procedures required in accordance with paragraph (O) of this rule shall be made available to all pharmacies that service the self-service kiosk.

(Q) A terminal distributor of dangerous drugs shall implement a quality assurance program for the operation of self-service prescription kiosk. The program shall include, but is not limited to, a review of the following:

(1) Complaints received;

(2) Medication errors;

(3) Mechanical and system failures or issues; and

(4) Drug security.