



## **For Stakeholder Comment - Winter 2025-2026 Rules**

**Date Issued: 12/8/2025**

**Comments Due: 1/15/2026**

The following rules are being distributed for stakeholder comment as part of the Board's statutorily required 5-year rule review process:

- **Rule 4729:5-3-25 | Electronic product verification. (NEW)**
- **Rule 4729:5-4-01 | Disciplinary actions. (AMEND)** *(applies to terminal distributors of dangerous drugs)*
- **Rule 4729:6-4-01 | Disciplinary actions. (AMEND)** *(applies to drug distributors)*
- **Rule 4729:6-1-01 | Definitions - distributors of dangerous drugs. (AMEND)**
- **Rule 4729-3-01 | Disqualifying offenses. (AMEND)**
- **Rule 4729-5-01 | Recognized and approved schools of pharmacy. (AMEND)**

Comments on the proposed rules will be accepted until the close of business on **Thursday, January 15, 2026**. Please send all comments to the following email address:

[rulecomments@pharmacy.ohio.gov](mailto:rulecomments@pharmacy.ohio.gov)

**Rule 4729:5-3-25 | Electronic product verification. (NEW)**

(A) As used in this rule:

(1) "Electronic product verification" or "electronic verification" means the non-physical dispensation ("final check") of a drug by a pharmacist using an electronic verification system to verify the accuracy of the final contents of the prepared 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 remote prescription dispensing, 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 located in this state;

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

(4) Is a current employee of the pharmacy operating the electronic verification system.

(C) An electronic verification system shall allow the pharmacist to see an exact, clear, and unobstructed visual images of the filled prescription or medication order contents 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 dangerous drug or drug device and sufficient data retention capabilities to investigate any quality-related events.

(1) The system shall use barcoding technology to ensure the accuracy of prescriptions or orders verified 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 prescriptions or orders 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.

(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 medication or device;

(b) The full quantity of the filled prescription;

(c) Except as provided in paragraph (C)(4) 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; and

(d) Clear markings present on the pill or capsule, if applicable.

(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) Images associated with the verification and dispensing of a prescription or order shall be retained and become part of the patient's profile and maintained for one year from the date of verification.

(7) 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.

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

(9) 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.

(10) 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 verifications 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 the prescription or order 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, delivery, or storage.

(F) Except as provided for in this paragraph, a pharmacist shall not conduct electronic product verification of compounded drug preparations.

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

(2) At the completion of the compounding process and prior to release or dispensation, 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 pharmacists, pharmacy interns, and pharmacy technicians assisting the pharmacist with electronic final 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 electronic verification system.

(H) An electronic verification system shall be implemented and validated by an Ohio-licensed pharmacist prior to initial use to ensure proper functioning. The system shall be revalidated by an Ohio-licensed pharmacist in accordance with the pharmacy's policies and procedures at least once every six months.

(1) Proof of compliance with validation/revalidation requirements shall be documented by an Ohio-licensed pharmacist and maintained in a readily retrievable format for three years from the date of validation or revalidation.

(2) The records shall document the positive identification of the pharmacist performing 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) Only employees of the pharmacy, including a pharmacy chain, shall be permitted to conduct or assist with electronic final verification in accordance with this rule.

#### **Rule 4729:5-4-01 | Disciplinary actions. (AMEND)**

(A) The state board of pharmacy, in accordance with Chapter 119. of the Revised Code, may impose any one or more of the following sanctions on an **applicant or** person licensed as a terminal distributor of dangerous drugs for any of the causes set forth in paragraph (B) of this rule:

- (1) Suspend, revoke, restrict, limit, or refuse to grant or renew a license;
- (2) Reprimand or place the license holder on probation;
- (3) Impose a monetary penalty or forfeiture as set forth in section [4729.57](#) of the Revised Code.

(B) The board may impose the sanctions set forth in paragraph (A) of this rule for any of the following:

- (1) Making any false material statements in an application for a license or renewal of a license as a terminal distributor of dangerous drugs.
- (2) Violating any rule of the board.
- (3) Violating any provision of Chapter 4729. of the Revised Code.
- (4) Except as provided in section [4729.89](#) of the Revised Code, violating any provision of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, or Chapter 3715. of the Revised Code.
- (5) Violating any provision of the federal drug abuse control laws or Chapter 2925. or 3719. of the Revised Code.
- (6) Falsely or fraudulently promoting to the public a dangerous drug, except that nothing in this rule prohibits a terminal distributor of dangerous drugs from furnishing information concerning a dangerous drug to a health care provider or another licensed terminal distributor.
- (7) Ceasing to satisfy the qualifications of a terminal distributor of dangerous drugs set forth in section [4729.55](#) of the Revised Code.
- (8) Except as provided in division (C) of section [4729.57](#) of the Revised Code:

(a) Waiving the payment of all or any part of a deductible or copayment that an individual, pursuant to a health insurance or health care policy, contract, or plan that covers the services provided by a terminal distributor of dangerous drugs, would otherwise be required to pay for the services if the waiver is used as an enticement to a patient or group of patients to receive pharmacy services from that terminal distributor;

(b) Advertising that the terminal distributor will waive the payment of all or any part of a deductible or copayment that an individual, pursuant to a health insurance or health care policy, contract, or plan that covers the pharmaceutical services, would otherwise be required to pay for the services.

(9) Conviction of a felony.

(10) Violation of any restrictions placed by the state board of pharmacy on a license or violating any terms of a board order issued against the licensee.

(11) Exclusion from participation in medicare or a state health care program.

(12) Being denied a license or registration by the drug enforcement administration or appropriate issuing body of any state or jurisdiction.

(13) Being the subject of any of the following by the drug enforcement administration or licensing agency of any state or jurisdiction:

(a) A disciplinary action that resulted in the suspension or revocation of the person's license or registration; or

(b) A disciplinary action that was based, in whole or in part, on the person's inappropriate prescribing, dispensing, diverting, administering, storing, personally furnishing, compounding, supplying or selling a controlled substance or other dangerous drug.

(14) Commission of an act that constitutes a disqualifying offense, regardless of the jurisdiction in which the act was committed.

(15) Has been subject to any of the following:

(a) A finding by a court of the person's eligibility for intervention in lieu of conviction; or

(b) A finding by a court of the person's eligibility for treatment or intervention in lieu of conviction in another jurisdiction.



(16) Has been granted entry into a diversion program, deferred prosecution program, or the equivalent thereof.

(17) Is addicted to or abusing alcohol or drugs.

(18) Commission of an act that constitutes a misdemeanor that is related to, or committed in, the person's professional practice.

(19) Employs a responsible person that does not meet the requirements set forth in rule [4729:5-2-01](#) of the Administrative Code.

(20) The ownership of such entity has been transferred from a person whose license issued in accordance with Chapter 4729. of the Revised Code has been revoked or disciplined by the state board of pharmacy or any other professional licensing agency to a spouse, ~~or other~~ family member, **or previous employee or agent of the person whose license was revoked or disciplined.**

(21) The ownership of such facility has been transferred from a licensee whose license has been revoked or disciplined by the state board of pharmacy or any other professional licensing agency to another who employs **or contracts with** the former owner **or the spouse, family member, or previous employee or agent of the person whose license was revoked or disciplined.** ~~or who allows the former owner to be present within the physical confines of the location to be licensed.~~

(22) Except as provided in Chapter 3719. of the Revised Code, dispensing a sample drug as defined in rule [4729:6-3-08](#) of the Administrative Code.

(23) The method used by the terminal distributor to store, possess or distribute dangerous drugs poses serious harm to others.

(24) The furnishing of false or fraudulent information or omitting information on due diligence questionnaires and/or attestation documents regarding the purchase or receipt of dangerous drugs from manufacturers, repackagers, third-party logistics providers, outsourcing facilities, wholesale distributors or other terminal distributors.

(25) Retaliating against or disciplining an employee for filing a complaint with a board of pharmacy or other licensing body or reporting a violation of state or federal statute or any ordinance or regulation of a political subdivision that the employee's employer has authority

to correct. As used in this rule, retaliation or discipline of an employee includes, but is not limited to, the following:

- (a) Removing or suspending the employee from employment;
- (b) Withholding from the employee salary increases or employee benefits to which the employee is otherwise entitled;
- (c) Transferring or reassigning the employee;
- (d) Denying the employee a promotion that otherwise would have been received;
- (e) Reducing the employee in pay or position.

(26) Unless otherwise approved by the board, a terminal distributor knowingly: employs **or contracts with** a person; **has any agent, owner, partner, member, officer, director or manager of the applicant or person licensed as a terminal distributor of dangerous drugs; or if the applicant or licensee is a corporation or limited liability company, any shareholder directly or indirectly owning voting interests or membership interests in the corporation or limited liability company, who: with access to drug stock who:**

- (a) Has been denied the right to work in any facility by the state board of pharmacy as part of an official order of the board.
- (b) Has been denied the right to work in such a facility by another professional licensing agency as part of an official order of that agency.
- (c) Has committed an act that constitutes a disqualifying offense, regardless of the jurisdiction in which the act was committed.
- (d) Has committed an act that constitutes a misdemeanor or felony drug offense, except for a minor misdemeanor drug offense, regardless of the jurisdiction in which the act was committed.
- (e) Has been subject to any of the following:
  - (i) A finding by a court of the person's eligibility for intervention in lieu of conviction; or
  - (ii) A finding by a court of the person's eligibility for treatment or intervention in lieu of conviction in another jurisdiction.

(f) Has been granted entry into a diversion program, deferred prosecution program, or the equivalent thereof.

(g) Is addicted to or abusing alcohol or drugs.

(h) Has been excluded from participation in medicare or a state health care program.

(i) Has been denied a license or registration by the drug enforcement administration or appropriate issuing body of any state or jurisdiction.

(j) Has been the subject of any of the following by the drug enforcement administration or licensing agency of any state or jurisdiction:

(i) A disciplinary action that resulted in the suspension, probation, surrender or revocation of the person's license or registration; or

(ii) A disciplinary action that was based, in whole or in part, on the person's inappropriate prescribing, dispensing, diverting, administering, storing, securing, personally furnishing, compounding, supplying or selling a controlled substance or other dangerous drug.

(k) Has committed an act that constitutes a misdemeanor that is related to, or committed in, the ~~employee's~~ individual's professional practice.

**(l) Has participated in any capacity in the operation or ownership of an entity licensed by the board that has demonstrated a disregard for the laws or regulations of this state or any other state, including but not limited to, an entity that has been suspended, revoked, or disciplined by the board for violations of section 4729.51 of the Revised Code, the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, the federal drug abuse control laws, Chapter 2925., 3715., 3719., 4729. of the Revised Code, or any rule of the board.**

#### **Rule 4729:6-4-01 | Disciplinary actions.**

(A) The state board of pharmacy, in accordance with Chapter 119. of the Revised Code, may impose any one or more of the following sanctions on an **applicant or** person licensed as a distributor of dangerous drugs for any of the causes set forth in paragraph (B) of this rule:

- (1) Suspend, revoke, restrict, limit, or refuse to grant or renew a license;
- (2) Reprimand or place the license holder on probation;
- (3) Impose a monetary penalty or forfeiture as set forth in section [4729.56](#) of the Revised Code.

(B) The board may impose the sanctions set forth in paragraph (A) of this rule for any of the following:

- (1) Making any false material statements in an application for licensure or licensure renewal under section [4729.52](#) of the Revised Code.
- (2) Violating any federal, state, or local drug law; any provision of Chapter 2925., 3715., 3719., or 4729. of the Revised Code; or any rule of the board.
- (3) A conviction of a felony.
- (4) Commission of an act that constitutes a disqualifying offense, regardless of the jurisdiction in which the act was committed.
- (5) Failing to satisfy the qualifications for licensure under section [4729.53](#) of the Revised Code or the rules of the board or ceasing to satisfy the qualifications after the license is granted or renewed.
- (6) Falsely or fraudulently promoting to the public a drug that is a controlled substance included in schedule I, II, III, IV, or V, except that nothing in this rule prohibits a drug distributor from furnishing information concerning a controlled substance to a health care provider or licensed terminal distributor.
- (7) ~~Violating any provision of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), United States Code Title 21 (10/22/2017).~~ **Violating any provision of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C. 301.**

- (8) Failing to comply with the requirements of rule [4729:6-3-05](#) of the Administrative Code.
- (9) Conducting the sale of a suspicious order without conducting an independent analysis prior to completing a sale to determine whether the reported drugs are likely to be diverted from legitimate channels in accordance with rule [4729:6-3-05](#) of the Administrative Code.
- (10) Commission of a crime of moral turpitude as defined in section [4776.10](#) of the Revised Code.
- (11) Violation of any restrictions placed by the state board of pharmacy on a license or violating any terms of a board order issued against the licensee.
- (12) Exclusion from participation in Medicare or a state health care program.
- (13) Being denied a license or registration by the drug enforcement administration or appropriate issuing body of any state or jurisdiction.
- (14) Being the subject of any of the following by the drug enforcement administration or licensing agency of any state or jurisdiction:
  - (a) A disciplinary action that resulted in the suspension or revocation of the person's license or registration; or
  - (b) A disciplinary action that was based, in whole or in part, on the person's inappropriate prescribing, dispensing, diverting, administering, storing, personally furnishing, compounding, supplying or selling a controlled substance or other dangerous drug.
- (15) Has been subject to any of the following:
  - (a) A finding by a court of the person's eligibility for intervention in lieu of conviction; or
  - (b) A finding by a court of the person's eligibility for treatment or intervention in lieu of conviction in another jurisdiction.
- (16) Has been granted entry into a diversion program, deferred prosecution program, or the equivalent thereof.
- (17) Is addicted to or abusing alcohol or drugs.
- (18) Commission of an act that constitutes a misdemeanor that is related to, or committed in, the person's professional practice.

(19) Employs a responsible person that does not meet the requirements set forth in rule [4729:6-2-01](#) of the Administrative Code.

(20) Retaliating against or disciplining an employee for filing a complaint with a board of pharmacy or other licensing body or reporting a violation of state or federal statute or any ordinance or regulation of a political subdivision that the employee's employer has authority to correct. As used in this rule, retaliation or discipline of an employee includes, but is not limited to, the following:

- (a) Removing or suspending the employee from employment;
- (b) Withholding from the employee salary increases or employee benefits to which the employee is otherwise entitled;
- (c) Transferring or reassigning the employee;
- (d) Denying the employee a promotion that otherwise would have been received;
- (e) Reducing the employee in pay or position.

(21) The method used by the drug distributor to store, possess or distribute dangerous drugs poses serious harm to others.

(22) The ownership of such entity has been transferred from a person whose license issued in accordance with Chapter 4729. of the Revised Code has been revoked or disciplined by the state board of pharmacy or any other state or federal professional licensing or regulatory agency to a spouse, ~~or other~~ family member, **or previous employee or agent of the person whose license was revoked or disciplined.**

(23) The ownership of such facility has been transferred from a licensee whose license has been revoked or disciplined by the state board of pharmacy or any other state or federal professional licensing or regulatory agency to another who employs **or contracts with** the former owner **or the spouse, family member, or previous employee or agent of the person whose license was revoked or disciplined.** ~~or who allows the former owner to be present within the physical confines of the location to be licensed.~~

(24) Unless otherwise approved by the board, a distributor knowingly: employs **or contracts with** a person; **has any agent, owner, partner, member, officer, director or manager of**

**the applicant or person licensed as a distributor of dangerous drugs; or if the applicant or licensee is a corporation or limited liability company, any shareholder directly or indirectly owning voting interests or membership interests in the corporation or limited liability company, who: with access to drug stock who:**

- (a) Has been denied the right to work in any facility by the state board of pharmacy as part of an official order of the board.
- (b) Has been denied the right to work in such a facility by another professional licensing agency as part of an official order of that agency.
- (c) Has committed an act that constitutes a disqualifying offense, regardless of the jurisdiction in which the act was committed.
- (d) Has committed an act that constitutes a misdemeanor or felony drug offense, except for a minor misdemeanor drug offense, regardless of the jurisdiction in which the act was committed.
- (e) Has been subject to any of the following:
  - (i) A finding by a court of the person's eligibility for intervention in lieu of conviction; or
  - (ii) A finding by a court of the person's eligibility for treatment or intervention in lieu of conviction in another jurisdiction.
- (f) Has been granted entry into a diversion program, deferred prosecution program, or the equivalent thereof.
- (g) Is addicted to or abusing alcohol or drugs.
- (h) Has been disciplined by the state board of pharmacy pursuant to Chapter 4729. of the Revised Code, except for a disciplinary action related to the failure to timely obtain continuing education required pursuant to agency 4729 of the Administrative Code.
- (i) Has been excluded from participation in medicare or a state health care program.
- (j) Has been denied a license or registration by the drug enforcement administration or appropriate issuing body of any state or jurisdiction.

(k) Has been the subject of any of the following by the drug enforcement administration or licensing agency of any state or jurisdiction:

(i) A disciplinary action that resulted in the suspension, probation, surrender or revocation of the person's license or registration; or

(ii) A disciplinary action that was based, in whole or in part, on the person's inappropriate prescribing, dispensing, diverting, administering, storing, securing, personally furnishing, compounding, supplying or selling a controlled substance or other dangerous drug.

(l) Has committed an act that constitutes a misdemeanor that is related to, or committed in, the **employee's individual's** professional practice.

**(m) Has participated in any capacity in the operation or ownership of an entity licensed by the board that has demonstrated a disregard for the laws or regulations of this state or any other state, including but not limited to, an entity that has been suspended, revoked, or disciplined by the board for violations of section 4729.51 of the Revised Code, the “Federal Food, Drug, and Cosmetic Act,” 52 Stat. 1040 (1938), 21 U.S.C.A. 301, the federal drug abuse control laws, Chapter 2925., 3715., 3719., 4729. of the Revised Code, or any rule of the board.**



## **Rule 4729:6-1-01 | Definitions - distributors of dangerous drugs. (AMEND)**

As used in this division:

(A) "Distributor of dangerous drugs" or "drug distributor" means the following persons licensed in accordance with section [4729.52](#) of the Revised Code:

(1) Wholesale distributors of dangerous drugs, including:

(a) Brokers; and

(b) Virtual wholesalers.

(2) Manufacturers of dangerous drugs.

(3) Outsourcing facilities.

(4) Third-party logistics providers.

(5) Repackagers of dangerous drugs.

(B) "Abandoned application" means an application submitted for licensure in accordance with this division that meets the criteria in paragraph (B)(1) of this rule. An applicant forfeits all fees associated with an abandoned application. The board shall not be required to act on any abandoned application and the application may be destroyed by board staff. If the application is abandoned, the applicant shall be required to reapply for licensure, submit the required fee, and comply with the licensure requirements in effect at the time of reapplication.

(1) An application shall be deemed abandoned if any of the following apply:

(a) An applicant fails to demonstrate compliance with rule [4729:6-2-01](#) of the Administrative Code and the applicable licensing rules pursuant to this division within ninety days of receipt of a completed application. The applicant may submit a request to the executive director or the director's designee for a one-time, ninety-day extension.

(b) An applicant fails to complete all application requirements within thirty days after being notified of the incomplete application by the board.

(c) An applicant that fails to demonstrate compliance with appropriate security and control rules pursuant to this division of the Administrative Code. The applicant may submit a request to the executive director or the director's designee for a one-time, ninety-day extension.

(2) An application shall not be deemed abandoned if the application is subject to any of the following:

(a) An administrative proceeding; or

(b) If there is discipline pending against the applicant.

(C) "Access to drug stock" includes not only physical access, but also any influence over the handling of dangerous drugs such as purchases, inventories, issuance of medical orders, etc. It does not include employees or contractors such as maintenance, janitorial, information technology or other staff that may need limited supervised access to areas where dangerous drugs or drug enforcement administration controlled substance order forms are stored.

(D) "Addicted to or abusing alcohol or drugs" means the chronic and habitual use of alcohol or the use of a drug of abuse as defined in section [3719.011](#) of the Revised Code by an individual to the extent that the individual no longer can control the individual's use of alcohol or drugs, the individual is physically or psychologically dependent on alcohol or drugs, or the individual's use or abuse of alcohol or drugs endangers the health, safety, or welfare of the individual or others.

(E) "Adulterated drug" includes a dangerous drug to which any of the following applies:

(1) A compounded dangerous drug if it exceeds the assigned beyond-use date.

(2) Meets any of the requirements described in section [3715.63](#) of the Revised Code.

(3) Is beyond the expiration date as stated by the manufacturer, repackager, or distributor in its labeling. This does not apply to expired drugs that are donated pursuant to sections [3715.88](#) to [3715.92](#) of the Revised Code.

(4) Is not stored, dispensed or personally furnished according to the requirement of the federal act as indicated in the product labeling.

(F) "Board of pharmacy" or "board" means the state board of pharmacy established under Chapter 4729. of the Revised Code.

(G) "Broker" means any person engaged in the marketing, offering, or contracting for wholesale distribution and sale of dangerous drugs in or into Ohio who does not take physical possession of the dangerous drugs. A broker shall be licensed as a wholesale distributor pursuant to section [4729.52](#) of the Revised Code with a broker classification.

(H) "Business day" means any day other than Saturday, Sunday or a holiday recognized by the state of Ohio on which the offices of the board of pharmacy are not open for business.

(I) "Dangerous drug" has the same meaning as in section [4729.01](#) of the Revised Code.

(J) "Disciplinary action," unless otherwise stated in this division, means any of the following by the drug enforcement administration or licensing agency of any state or jurisdiction, regardless of whether the action occurred by formal proceeding, consent, settlement, or other agreement:

(1) An action to revoke, suspend, restrict, limit, or refuse to grant or renew a license, registration, or certification;

(2) A summary or emergency suspension of a license, registration or certification, of any length, and any subsequent revision to the action;

(3) An administrative fine or money penalty, taken as a result of a formal proceeding, to include any fine or money penalty connected to the delivery of health care services or taken in conjunction with other adverse licensure, registration or certification actions, such as revocation, suspension, censure, reprimand or probation;

(4) An action to reprimand or place the license, registration, or certification holder on probation;

(5) The issuance of a corrective action plan only if such issuance is in conjunction with other adverse licensure, registration or certification actions, such as revocation, suspension, reprimand, probation or surrender;

(6) The withdrawal of a renewal application for licensure, registration or certification while under investigation;

(7) The non-renewal of a license, registration or certification while under investigation or to avoid an investigation;

(8) The surrender or other relinquishment of a license, registration or certification in lieu of a formal sanction against a person's license, registration, or certificate, whether permanent or temporary;

(9) In lieu of an adverse licensure, registration or certification action, a licensing agency issues a consent order in which a person agrees not to re-apply for a license, registration, or certification in the future;

(10) An enforceable agreement not to practice or to be placed into inactive or other equivalent status while under investigation or in exchange for not conducting an investigation.

(K) "Manufacturer of dangerous drugs" or "manufacturer" means a person, other than a pharmacist or prescriber, that meets the following criteria:

(1) Meets the definition of a manufacturer pursuant in section 21 U.S. Code Section 360 eee (11/27/2013); and

(2) Manufactures dangerous drugs and who is engaged in the sale or distribution of dangerous drugs in or into Ohio.

(L) "Outsourcing facility" means a facility that is engaged in the compounding and sale of sterile drugs and is registered as an outsourcing facility with the United States food and drug administration.

(M) "Person" has the same meaning as in division (S) of section [4729.01](#) of the Revised Code and includes any individual member, regardless of the percentage of ownership, of any partnership, association, limited liability company or corporation.

(N) "Place on probation" means to take action against a license, for a period of time determined by the board, which imposes conditions or other requirements, or suspends or otherwise restricts some or all of the activities in which the licensee may engage.

(O)

(1) "Positive identification" means a method of identifying a person that does not rely on the use of a private personal identifier such as a password, but must use a secure means of identification that includes any of the following:

(a) A manual signature on a hard copy record;

- (b) A magnetic card reader;
- (c) A bar code reader;
- (d) A biometric method;
- (e) A proximity badge reader;
- (f) A board approved system of randomly generated personal questions;
- (g) A printout of every transaction that is verified and manually signed within a reasonable period of time by the individual who performed the action requiring positive identification. The printout must be maintained for three years and made readily retrievable; or
- (h) Other effective methods for identifying individuals that have been approved by the board.

**~~(2) A method of positive identification relying on a magnetic card reader, a bar code reader, a proximity badge reader, or randomly generated questions for identification must also include a private personal identifier, such as a password, for entry into a secure mechanical or electronic system. A method relying on a magnetic card reader, a bar code reader, a proximity badge reader, or randomly generated questions for identification must also include a private personal identifier.~~**

(P) "Readily retrievable" means that records maintained in accordance with this division shall be kept in such a manner that, upon request, they can be produced for review no later than three business days to an agent, officer, or inspector of the board.

(Q) "Refuse to grant or renew" means to deny original or continued licensure for a period of at least twenty-four months. After twenty-four months, or such period of time as the individual board order may require, a person licensed by the board or a person seeking to attain such status by licensure, and whose license the state board of pharmacy has refused to grant or renew, may make application to the board for issuance of a new license. A person that seeks to attain such status by licensure, whose license the state board of pharmacy has refused to grant or renew, must meet all requirements established by the board in rule and as may be set forth in the person's board order.

(R) "Repackager of dangerous drugs" or "repackager" means a person that meets the following:

(1) Repacks and relabels dangerous drugs for sale or distribution; and

(2) Is required to register with the United States food and drug administration to engage in the repackaging or relabeling of dangerous drugs.

(S) "Reverse distribute" or "reverse distribution" means to acquire dangerous drugs for the purpose of any of the following:

(1) Return to a manufacturer or entity authorized by the manufacturer to accept returns on the manufacturer's behalf; or

(2) Destruction or disposal.

(T) "Revoke" means to take action against a license rendering such license void and such license shall not be reissued. Revoke is an action that is permanent against the licensee.

(U) "Sale" or "sell" includes any transaction made by any person, whether as principal proprietor, agent, or employee, to do or offer to do any of the following: deliver, distribute, broker, exchange, gift or otherwise give away, or transfer, whether the transfer is by passage of title, physical movement, or both.

The shipment of dangerous drugs to a reverse distributor in this state licensed as a wholesale distributor of dangerous drugs in accordance with section [4729.52](#) of the Revised Code for the sole purpose of destruction or disposal of dangerous drugs, does not constitute a sale and does not require the person, if located outside of the state of Ohio, shipping the dangerous drugs to the reverse distributor to possess an Ohio license in accordance with Chapter 4729. of the Revised Code.

(V) "State" means a state of the United States, the District of Columbia, the Commonwealth of Puerto Rico or a territory or insular possession subject to the jurisdiction of the United States.

(W) "Suspend" means to take action against a license rendering such license without force and effect for a period of time as determined by the state board of pharmacy. The board may require that an individual whose license or registration has been suspended may not be employed by or work in a facility licensed by the state board of pharmacy to possess or distribute dangerous drugs during such period of suspension.

(X) "Summary suspension" means to take immediate action against a license without a prior hearing rendering such license without force and effect for a period of time as indicated in section [4729.561](#) of the Revised Code. The board may suspend a license issued pursuant to Chapter 4729. of the Revised Code by utilizing a telephone conference call to review the allegations and take a vote.

(Y) "Third-party logistics provider" means a person that provides or coordinates warehousing or other logistics services pertaining to dangerous drugs including distribution, on behalf of a manufacturer, wholesale distributor, or terminal distributor of dangerous drugs, but does not take ownership of the drugs or have responsibility to direct the sale or disposition of the drugs.

(Z) "Virtual wholesaler" or "virtual wholesaler distributor" means any person engaged in wholesale distribution of dangerous drugs in or into Ohio who has title but does not take physical possession of the dangerous drugs. A virtual wholesale distributor shall be licensed as a wholesale distributor pursuant to section [4729.52](#) of the Revised Code with a virtual wholesale distributor classification.

(AA) "Wholesale distributor of dangerous drugs" or "wholesale distributor" means a person engaged in the sale of dangerous drugs at wholesale or the reverse distribution of dangerous drugs and includes any agent or employee of such a person authorized by the person to engage in the sale of dangerous drugs at wholesale.

(BB) "Wholesale sale" and "sale at wholesale" mean any sale in which the purpose of the purchaser is to resell the article purchased or received by the purchaser.

### **Rule 4729-3-01 | Disqualifying offenses. (AMEND)**

(A) As used in **agency Chapter** 4729 of the Administrative Code, "disqualifying offense" means a criminal offense that is contained in the list adopted pursuant to paragraph (B) of this rule, and any existing or former criminal offense that is substantially equivalent to those explicitly contained in the list under municipal ordinances or laws of this state, any other state, or the United States, as required by division (B) of section [9.79](#) of the Revised Code.

(B) The board of pharmacy shall issue a resolution providing the list of specific criminal offenses for which a conviction, judicial finding of guilt, or plea of guilty may disqualify an individual from obtaining an initial license or registration issued by the board.

(C) The resolution shall be updated as necessary and shall be made available on the board's web site ([www.pharmacy.ohio.gov](http://www.pharmacy.ohio.gov)).

(D) For the purposes of enforcing **agency Chapter** 4729, ~~and 3796~~ of the Administrative Code, a certified copy of a plea of guilty to, or a judicial finding of guilt of any crime in a court of competent jurisdiction is conclusive proof of the commission of all of the elements of that crime.



**Rule 4729-5-01 | Recognized and approved schools of pharmacy. (AMEND)**

(A) Pursuant to section [4729.08](#) of the Revised Code, the state board of pharmacy recognizes and approves all pharmacy programs or schools of pharmacy that have candidate or accreditation status with the accreditation council for pharmacy education (A.C.P.E.). The board, by resolution, reserves the right to:

- (1) Deny the recognition or approval of a pharmacy program or school of pharmacy that meets A.C.P.E. candidate or accreditation status; or
- (2) Recognize or approve a pharmacy program or school of pharmacy that does not meet A.C.P.E. candidate or accreditation status.

(B) For the purpose of satisfying the requirements of division (C) of section [4729.08](#) of the Revised Code, graduates of a school of pharmacy located outside the United States shall establish educational equivalency by obtaining a "Foreign Pharmacy Graduate Examination **Commission Committee** (FPGEC)" certificate, and by establishing proficiency in spoken English by obtaining the minimum scores required by rule [4729:1-2-04](#) of the Administrative Code on the "Test of English as a Foreign Language, Internet-based test (TOEFL iBT)."

(C) The term "United States," as used in paragraph (B) of this rule, shall be deemed to include all states of the United States, the District of Columbia, the Commonwealth of Puerto Rico or a territory or insular possession subject to the jurisdiction of the United States.