



Common Sense Initiative

Mike DeWine, *Governor*
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Business Impact Analysis

Agency, Board, or Commission Name: Ohio Board of Pharmacy_____

Rule Contact Name and Contact Information: Summer Reyburn,
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Regulation/Package Title (a general description of the rules' substantive content):

Disciplinary Actions and TDDD Definitions_____

Rule Number(s): 4729:5-4-01; 4729:6-1-01; 4729:6-4-01_____

Date of Submission for CSI Review: 4/17/2026_____

Public Comment Period End Date: 5/15/2026_____

Rule Type/Number of Rules:

New/___ rules

No Change/___ rules (FYR? ___)

Amended/ 3 rules (FYR? Y)

Rescinded/___ rules (FYR? ___)

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the

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Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Reason for Submission

- 1. R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

Which adverse impact(s) to businesses has the agency determined the rule(s) create?

The rule(s):

- Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**
- Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**
- Requires specific expenditures or the report of information as a condition of compliance.**
- Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**

Regulatory Intent

- 2. Please briefly describe the draft regulation in plain language.**

Please include the key provisions of the regulation as well as any proposed amendments.

- 4729:5-4-01 - Establishes the Board of Pharmacy’s authority to impose disciplinary actions on a terminal distributor of dangerous drugs. Adds possibility of sanctions to someone who transfers ownership and access to a facility to previous employee or agent of the person whose license was revoked or disciplined. Adds possibility of sanctions to someone who knowingly allows someone or a company access to drug stock if they have been denied the right to work in a similar facility, including anyone who has participated in the ownership of an entity that disregarded the laws and regulations of any state. Makes small grammatical changes.
- 4729:6-1-01 - Provides the definitions for the drug distributor division of the Administrative Code. Updated definition for positive identification to include a magnetic card reader, a bar code reader, or randomly generated questions for identification to consistently align with other Board of Pharmacy rule definitions.
- 4729:6-4-01 - Outlines the instances where the Board may impose a disciplinary action against a drug distributor. Updates references to the Federal Food, Drug, and Cosmetic Act. Adds possibility of sanctions to someone who transfers ownership and access to a facility to previous employee, family member/spouse, or agent of the person whose license was revoked or disciplined. Adds possibility of sanctions to someone who knowingly allows someone or a company access to drug stock if they have been denied the right to work in a similar facility, including anyone who has participated in the ownership of an entity that disregarded the laws and regulations of any state. Makes small grammatical changes.

3. Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.

The proposed rules are authorized by sections 4729.26 and 3719.28 of the Ohio Revised Code.

4. Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?

If yes, please briefly explain the source and substance of the federal requirement.

These rules do not implement a federal requirement.

- 5. If the regulation implements a federal requirement, but includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

Not applicable.

- 6. What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?**

Section 4729.26 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules governing the practice of pharmacy. Without these regulations the Board would not be able to provide definitions for the licensure and regulation of drug distributors and terminal distributors.

Section 3719.28 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules regarding the form and content of records to be kept by persons authorized to manufacture, distribute, dispense, conduct research in, prescribe, administer, or otherwise deal with controlled substances.

- 7. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**

The success of the regulations will be measured by having rules written in plain language, licensee compliance with the rules, and minimal questions from licensees regarding the provisions of the rules.

- 8. Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**

If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.

No.

Development of the Regulation

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9. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.

If applicable, please include the date and medium by which the stakeholders were initially contacted.

These rules were distributed for initial public comment by posting the rule package to the Board's proposed rules website between December 8, 2025 and January 15, 2026.

Prior to filing with CSI, the rules were reviewed and approved by the Board of Pharmacy.

10. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?

The Board received multiple comments on this rule package during the initial comment process for the two Disciplinary Actions rules (OAC 4729:5-4-01 and 4729:6-4-01). One comment recommended striking "in any capacity" and adding "actively participated" as well as adding back in a mention to having "access to drug stock" in (B)(26)(l) for 4729:5-4-01, which the Board agreed to update.

11. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?

Scientific data was not used to develop or review these rules.

12. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives? *Alternative regulations may include performance-based regulations, which define the required outcome, but do not dictate the process the regulated stakeholders must use to comply.*

As the regulations are essential to protecting the public's safety by ensuring uniform standards for the practice of pharmacy and distribution of dangerous drugs, the Ohio Board of Pharmacy did not consider any regulatory alternatives.

13. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

The Board of Pharmacy's Director of Policy and Communications reviewed the proposed rules to ensure that the regulations do not duplicate another Ohio Board of Pharmacy regulation.

14. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.

The rules will be posted on the Board of Pharmacy's web site; information concerning the rules will be included in materials e-mailed to licensees; and notices will be sent to associations, individuals, and groups. Board of Pharmacy staff are also available via phone or email to answer questions regarding implementation of the rules. In addition, the Board's compliance agents are trained to educate licensees on current and/or new regulations during on-site inspections.

Board of Pharmacy staff receive regular updates on rules via a monthly internal newsletter, biannual staff meetings featuring a regulatory update, mandatory all-day law reviews for new employees, email updates, webinars from the Director of Policy and Communications, and feedback from the Board's legal department for every citation submitted.

Adverse Impact to Business

15. Provide a summary of the estimated cost of compliance with the rule(s). Specifically, please do the following:

a. Identify the scope of the impacted business community, and

- Terminal distributors of dangerous drugs; and
- Distributors of dangerous drugs.

b. Quantify and identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance, etc.).

The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a

representative business. Please include the source for your information/estimated impact.

- 4729:5-4-01 – Violation of this rule may result in administrative licensure discipline for a terminal distributor of dangerous drugs. Discipline might include reprimand, suspension of a license, monetary fine (\$1,000) and/or revocation of a license.
- 4729:6-1-01 – An application that is deemed abandoned will result in a forfeiture of the licensure fee (fees are for a two-year license).
- 4729:6-4-01 – Violation of this rule may result in administrative licensure discipline for a distributor of dangerous drugs. Discipline might include reprimand, suspension of a license, monetary fine (\$2,500) and/or revocation of a license.

16. Are there any proposed changes to the rules that will reduce a regulatory burden imposed on the business community? Please identify. (*Reductions in regulatory burden may include streamlining reporting processes, simplifying rules to improve readability, eliminating requirements, reducing compliance time or fees, or other related factors*).

No.

17. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

The Board determined that the regulatory intent justifies the impact on business because the regulations protect and promote public safety by ensuring uniform licensing standards and definitions.

Regulatory Flexibility

18. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

These rules do not provide any exemptions or alternative means of compliance for small businesses. The law does not differentiate on the size of the business and therefore the regulation is uniform across Ohio.

19. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

The Ohio Board of Pharmacy does not fine licensees or impose penalties for first-time paperwork violations.

20. What resources are available to assist small businesses with compliance of the regulation?

Board of Pharmacy staff is available by telephone and e-mail to answer questions. Board staff members also provide presentations to groups and associations who seek updates on current regulations. Additionally, staff are trained to educate licensees on compliance with all Board of Pharmacy rules and regulations.

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 **the real property owner or** 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.** ~~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, with access to drug stock or any role in the purchasing, ordering, directing, or recommending of drug stock 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 actively participated 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. (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 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, with access to drug stock or any role in the purchasing, ordering, directing, or recommending of drug stock 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 actively participated 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 wholesaler 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.