

9/23/21

The following information is being provided pursuant to the requirements of Executive Order 2011-01K and Senate Bill 2 of the 129th General Assembly, which require state agencies, including the State of Ohio Board of Pharmacy, to draft rules in collaboration with stakeholders, assess and justify an adverse impact on the business community (as defined by S.B. 2), and provide an opportunity for the affected public to provide input on the following rule.

New:

- 4729-3-01 – Outlines the definition of “disqualifying offense” and the Board’s 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.

Amend:

- 4729:1-1-01 - Provides definitions section for the pharmacist division of the Ohio Administrative Code. The rule is amended to comply with HB 263 (133rd GA).
- 4729:1-2-02 - Provides the requirements for licensure by reciprocity. The rule is amended to comply with HB 263 (133rd GA).
- 4729:1-4-01 - Establishes the scope of disciplinary actions the Board of Pharmacy may impose on a pharmacist. The rule is amended to comply with HB 263 (133rd GA).
- 4729:1-4-02 - Establishes the requirements for when and how pharmacists should notify the Board of Pharmacy of violations of Ohio laws and rules. The rule is amended to comply with HB 263 (133rd GA).
- 4729:2-1-01 - Provides definitions section for the pharmacy intern division of the Ohio Administrative Code. The rule is amended to comply with HB 263 (133rd GA).
- 4729:2-4-01 - Establishes the scope of disciplinary actions the Board of Pharmacy may impose on pharmacy interns. The rule is amended to comply with HB 263 (133rd GA).
- 4729:2-4-02 - Establishes the requirements for when and how pharmacy interns should notify the Board of Pharmacy of violations of Ohio laws and rules. The rule is amended to comply with HB 263 (133rd GA).
- 4729:3-4-01 - Establishes the Board of Pharmacy's authority to impose disciplinary actions on a pharmacy technician trainee, registered pharmacy technician or certified pharmacy technicians. The rule is amended to comply with HB 263 (133rd GA).
- 4729:3-4-02 - Establishes the requirements for a pharmacy technician trainee, registered pharmacy technician or certified pharmacy technician to report a violation to the Board of Pharmacy. The rule is amended to comply with HB 263 (133rd GA).
- 4729:5-1-01 - Definition section for the division of the OAC pertaining to terminal distributors of dangerous drugs. The rule is amended to comply with HB 263 (133rd GA).
- 4729:5-2-01 - Defines the responsibilities and requirements for the responsible person under each classification of terminal distributor for dangerous drugs license. Unless

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otherwise approved by the Board, prohibits a terminal distributor from having a responsible person criminal convictions or administrative discipline. The rule is amended to comply with HB 263 (133rd GA).

- 4729:5-4-01 - Establishes the Board of Pharmacy's authority to impose disciplinary actions on a terminal distributor of dangerous drugs. The rule is amended to comply with HB 263 (133rd GA).
- 4729:6-1-01 - Provides the definitions for the drug distributor division of the Administrative Code. The rule is amended to comply with HB 263 (133rd GA).
- 4729:6-2-01 - Outlines the requirements for serving as the responsible person for an Ohio-licensed drug distributor. The rule is amended to comply with HB 263 (133rd GA).
- 4729:6-4-01 - Outlines the instances where the Board may impose a disciplinary action against a drug distributor. The rule is amended to comply with HB 263 (133rd GA).
- 4729:11-1-01 - Definition section for home medical equipment division. The rule is amended to comply with HB 263 (133rd GA).
- 4729:11-2-02 - Establishes the requirements for the designated representative on a home medical services license or certification of registration. The rule is amended to comply with HB 263 (133rd GA).
- 4729:11-4-01 - Establishes the Board of Pharmacy's authority to impose disciplinary actions on a home medical equipment provider. The rule is amended to comply with HB 263 (133rd GA).

Comments on the proposed rule will be accepted until close of business on October 7, 2021.

Please send all comments to the following email address: RuleComments@pharmacy.ohio.gov

In addition, please copy your comments to: CSIPublicComments@governor.ohio.gov

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Common Sense Initiative

Mike DeWine, Governor
Jon Husted, Lt. Governor

Sean McCullough, Director

Business Impact Analysis

Agency, Board, or Commission Name: State of Ohio Board of Pharmacy

Rule Contact Name and Contact Information: Cameron McNamee
Cameron.mcnamee@pharmacy.ohio.gov

Regulation/Package Title (a general description of the rules' substantive content):

Disqualifying Offenses for Application for Licensure or Registration

Rule Number(s): 4729-3-01, 4729:1-1-01, 4729:1-2-02, 4729:1-4-01, 4729:1-4-02, 4729:2-1-01, 4729:2-4-01, 4729:2-4-02, 4729:3-4-01, 4729:3-4-02, 4729:5-1-01, 4729:5-2-01, 4729:5-4-01, 4729:6-1-01, 4729:6-2-01, 4729:6-4-01, 4729:11-1-01, 4729:11-2-02, 4729:11-4-01

Date of Submission for CSI Review: 9/23/21

Public Comment Period End Date: 10/7/21

Rule Type/Number of Rules:

New/ 1 rules

No Change/ rules (FYR?)

Amended/ 18 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 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

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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):

- a. ☒ Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**
 - 4729:5-2-01 – This rule requires specific licensure for the responsible person on a terminal distributor license.
- b. ☒ Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**
 - 4729:1-1-01, 4729:1-2-02, 4729:1-4-01, 4729:1-4-02, 4729:2-4-01, 4729:2-4-02, 4729:3-4-01, 4729:3-4-02, 4729:5-1-01, 4729:5-2-01, 4729:5-4-01, 4729:6-1-01, 4729:6-2-01, 4729:6-4-01, 4729:11-1-01, 4729:11-2-02, 4729:11-4-01 - Violation of the rule may result in administrative licensure discipline for a pharmacist, pharmacy intern, pharmacy technician, terminal distributor of dangerous drugs, drug distributor, home medical equipment services provider. Discipline might include reprimand, suspension of a license, required course work, monetary penalty and/or revocation of a license.
- c. ☒ Requires specific expenditures or the report of information as a condition of compliance.**
 - 4729:1-1-01, 4729:2-1-01, 4729:5-1-01, 4729:6-1-01, 4729:11-1-01 - An application that is deemed abandoned will result in a forfeiture of the licensure fee (fees are for a two-year license).

Such fees are as follows:

- Pharmacists: \$250

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- Pharmacy Interns: \$45
- Pharmacy Technicians: \$50
- Drug Distributor: \$1,900 or \$2,000 (depending on the drugs sold)
- Terminal Distributor: \$320 or \$440 (depending on the drugs sold)
- Home Medical Equipment Registration: \$150 application fee, \$300 renewal fee
- Home Medical Equipment License: \$300 application fee, \$400 renewal fee
- 4729:1-2-02, 4729:5-2-01, 4729:6-2-01- Requires submission to a criminal records check.
- 4729:1-4-02: Establishes the requirements for when and how pharmacists should notify the Board of Pharmacy of violations of Ohio laws and rules. The regulation should have no adverse impact. This rule will require the reporting of suspected violations to the Board. The suspected violations may be reported using the Board's online compliant form, which takes approximately 10-15 minutes per submission. This requirement is unchanged from current rule.
- 4729:2-4-02: Establishes the requirements for when and how pharmacy interns should notify the Board of Pharmacy of violations of Ohio laws and rules. This rule will require the reporting of suspected violations to the Board. The suspected violations may be reported using the Board's online compliant form, which takes approximately 10-15 minutes per submission. This requirement is unchanged from current rule.
- 4729:3-4-02 - This will require notification to the Board if a technician observes a violation specified in the rule. Notification can be performed online and will take approximately 10-20 minutes to complete.
- 4729:5-2-01, 4729:6-2-01, 4729:11-2-02 – Requires reporting of a new responsible person or designated representative to the Board within 10 days.

d. ☐ 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.

New:

- 4729-3-01 – Outlines the definition of “disqualifying offense” and the Board’s 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.

Amend:

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- 4729:1-1-01 - Provides definitions section for the pharmacist division of the Ohio Administrative Code. The rule is amended to comply with HB 263 (133rd GA).
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- 4729:5-2-01 - Defines the responsibilities and requirements for the responsible person under each classification of terminal distributor for dangerous drugs license. Unless otherwise approved by the Board, prohibits a terminal distributor from having a responsible person criminal convictions or administrative discipline. The rule is amended to comply with HB 263 (133rd GA).
- 4729:5-4-01 - Establishes the Board of Pharmacy's authority to impose disciplinary actions on a terminal distributor of dangerous drugs. The rule is amended to comply with HB 263 (133rd GA).
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- 4729:6-2-01 - Outlines the requirements for serving as the responsible person for an Ohio-licensed drug distributor. The rule is amended to comply with HB 263 (133rd GA).
- 4729:6-4-01 - Outlines the instances where the Board may impose a disciplinary action against a drug distributor. The rule is amended to comply with HB 263 (133rd GA).

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- 4729:11-1-01 - Definition section for home medical equipment division. The rule is amended to comply with HB 263 (133rd GA).
- 4729:11-2-02 - Establishes the requirements for the designated representative on a home medical services license or certification of registration. The rule is amended to comply with HB 263 (133rd GA).
- 4729:11-4-01 - Establishes the Board of Pharmacy's authority to impose disciplinary actions on a home medical equipment provider. The rule is amended to comply with HB 263 (133rd GA).

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, 3719.28, 9.78 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.***

The rules do not implement a federal requirement.

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

This rule exceeds federal requirements because licensure and regulation of pharmacists, interns, technicians, terminal distributors, and drug distributors is required pursuant to Chapter 4729. of the Revised Code.

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.

The purpose of the rules is to update the rules to comply with HB 263 (133rd GA). HB 263 prohibits a state licensing authority from refusing to issue a license to an individual based solely on being charged with or convicted of a criminal offense or based on a nonspecific qualification such as "moral turpitude" or lack of "moral character." (See ORC 9.78)

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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

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.

This rule package was distributed for initial public comment by posting the rule package to the Board's proposed rules website.

Prior to filing with CSI, the rule was 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 three comments on this rule package during the initial public comment process. The comments were not incorporated into the rule, as the comments did not comply with the requirements set forth in HB 263. For example, the commenters requested that references to moral character to be re-inserted.

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 this rule.

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?

As the modifications to the regulations are required by ORC 9.78, the State of Ohio Board of Pharmacy did not consider any regulatory alternatives.

13. Did the Agency specifically consider a performance-based regulation? Please explain.
Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.

The agency did not consider a performance-based regulation for this rule package, as these rules are being updated to reflect ORC 9.78. It is the Board's responsibility to ensure uniform practice standards across Ohio.

14. 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 rule to ensure that the regulations do not duplicate another State of Ohio Board of Pharmacy regulation.

15. 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 rule package will be posted on the Board of Pharmacy's web site, information concerning the rule 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 rule. 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

16. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

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

The rule package impacts the following:

- Pharmacists;
- Pharmacy technicians;
- Pharmacy interns;
- Terminal distributors of dangerous drugs;
- Wholesale distributors of dangerous drugs; and
- Home medical equipment services providers.

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

Violation of these rules may result in administrative discipline for a licensee. Discipline might include reprimand, denial of a license, suspension of a license, monetary fine and/or revocation of a license.

c. Quantify the expected adverse impact from the regulation.

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.

- 4729-3-01 – Outlines the definition of “disqualifying offense” and the Board’s 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. This rule is definitional and does not have an adverse impact.
- 4729:1-1-01, 4729:2-1-01, 4729:5-1-01, 4729:6-1-01, 4729:11-1-01: An application that is deemed abandoned will result in a forfeiture of the licensure fee (fees are for a two-year license).

Such fees are as follows:

- Pharmacists: \$250
- Pharmacy Interns: \$45
- Pharmacy Technicians: \$50
- Drug Distributor: \$1,900 or \$2,000 (depending on the drugs sold)
- Terminal Distributor: \$320 or \$440 (depending on the drugs sold)
- Home Medical Equipment Registration: \$150 application fee, \$300 renewal fee
- Home Medical Equipment License: \$300 application fee, \$400 renewal fee
- 4729:1-2-02: The rule requires applicants to meet state education requirements. Foreign applicants will also incur the costs of taking additional examinations. In addition, applicants must submit to a criminal records check.

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- 4729:1-4-01: Establishes the scope of disciplinary actions the Board of Pharmacy may impose on pharmacists. The regulation should have no adverse impact. Disciplinary action may result in a fine of up to \$500 per violation as well as other actions listed in question 14b of this rule
- 4729:1-4-02: Establishes the requirements for when and how pharmacists should notify the Board of Pharmacy of violations of Ohio laws and rules. The regulation should have no adverse impact. This rule will require the reporting of suspected violations to the Board. The suspected violations may be reported using the Board's online compliant form, which takes approximately 10-15 minutes per submission.
- 4729:2-4-01: Establishes the scope of disciplinary actions the Board of Pharmacy may impose on pharmacy interns. Disciplinary action may result in a fine of up to \$500 per violation as well as other actions listed in question 14b of this rule.
- 4729:2-4-02: Establishes the requirements for when and how pharmacy interns should notify the Board of Pharmacy of violations of Ohio laws and rules. This rule will require the reporting of suspected violations to the Board. The suspected violations may be reported using the Board's online compliant form, which takes approximately 10-15 minutes per submission.
- 4729:3-4-01 - Establishes the Board of Pharmacy's authority to impose disciplinary actions on a pharmacy technician trainee, registered pharmacy technician or certified pharmacy technicians. Violation of this section may result in administrative licensure discipline for a pharmacy technician. Discipline might include reprimand, suspension of a license, monetary fine (\$500) and/or revocation of a license.
- 4729:3-4-02 - Establishes the requirements for a pharmacy technician trainee, registered pharmacy technician or certified pharmacy technician to report a violation to the Board of Pharmacy. This will require notification to the Board if a technician observes a violation specified in the rule. Notification can be performed online and will take approximately 10-20 minutes to complete.
- 4729:5-1-01 – The rule defines an abandoned application. An applicant whose application is deemed abandoned forfeits their licensure fee (\$160 or \$220).
- 4729:5-2-01 – Provides the requirements for a Responsible Person under the different classifications of terminal distributors of dangerous drugs license. For pharmacies, this requires a request for approval if an individual wishes to serve as the Responsible Person at more than one location. This requires a submission of a form that takes approximately 15 minutes. Additionally, this rule will require a terminal distributor to ensure a responsible person has not violated any provision of the rule. This could result in increased costs to review the employees background (i.e. background checks, licensure searches, etc.).

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- 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 and/or revocation of a license.
- 4729:11-1-01- Definition section for home medical equipment division. This should not have an adverse impact as it is definitional.
- 4729:11-2-02- Establishes the requirements for licensure or certificate of operation for a home medical equipment provider, including renewal. Registration renewal costs \$300 biennially, licensure costs \$400 biennially. There are costs associated with accreditation. These requirements are unchanged from current rule.
- 4729:11-4-01- Establishes the Board of Pharmacy’s authority to impose disciplinary actions on a home medical equipment provider. These requirements are unchanged from current rule.

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.

Regulatory Flexibility

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

This rule does 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 State of 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.

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4729-3-01 Disqualifying offenses. (NEW)

(A) As used in agency 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).

Rule 4729:1-1-01 | Definitions - pharmacists. (AMEND)

As used in this division:

(A) "Abandoned application" means an application for a licensure pursuant to this division where the applicant fails to complete all application requirements within thirty days after being notified by the board. 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.

~~(B) "Act of moral turpitude" means an act or behavior that gravely violates moral sentiment or accepted moral standards of the community and is a morally culpable quality held to be present in some criminal offenses as distinguished from others.~~

~~(CB)~~ "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.

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

~~(ED)~~ "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.

~~(FE)~~ "Compounding" has the same meaning as defined in section 4729.01 of the Revised Code and agency 4729 of the Administrative Code.

~~(GF)~~ "Controlled substance" has the same meaning as in section 3719.01 of the Revised Code.

~~(HG)~~ "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

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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; 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.

~~(H)~~ "Dispense" means the final association of a drug with a 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.

~~(J) "Good moral character," pursuant to sections and of the Revised Code, means those virtues of a person which are generally recognized as beneficial to the public health, safety and welfare, or a pattern of behavior conforming to a profession's ethical standards and showing an absence of moral turpitude, including conduct consistent with justice, honesty, or morality.~~

~~(K)~~ "Interpret prescriptions," as used in section 4729.01 of the Revised Code, means the professional judgment of a pharmacist when reviewing a valid prescription order of a prescriber for a patient in accordance with the applicable requirements set forth in agency 4729 of the Administrative Code.

~~(L)~~ "Personal supervision" or "direct supervision" means a pharmacist shall be physically present in the pharmacy, or in the area where the practice of pharmacy is occurring, to provide personal review and approval of all professional activities.

~~(M)~~ "Pharmacist" means an individual who holds a valid pharmacist license in accordance with Chapter 4729. of the Revised Code.

~~(NL)~~ "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.

~~(OM)~~

(1) "Positive identification" means a method of identifying a person that does not rely solely 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 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.

~~(PN)~~ "Practice of pharmacy" has the same meaning as in division (B) of section [4729.01](#) of the Revised Code.

~~(QO)~~ "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.

~~(RP)~~ "Responsible person" has the same meaning as defined in rule [4729:5-2-01](#) of the Administrative Code.

~~(SQ)~~ "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

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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.

(~~TR~~) "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.

(~~US~~) "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.

(~~VT~~) "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.

(~~WU~~) "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 3719.121 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.

(~~XV~~) "Veteran" means anyone who is serving or has served under honorable conditions in any component of the armed forces, including the national guard and reserve.

Rule 4729:1-2-02 | Criteria for licensure by reciprocity. (AMEND)

(A) An applicant seeking licensure as a pharmacist by reciprocity shall comply with all the following:

(1) Be at least eighteen years of age.

~~(2) Be of good moral character and habits.~~

~~(3)~~ Obtain a degree in pharmacy from a school of pharmacy approved by the state board of pharmacy.

~~(4)~~ Have met the applicable practical experience requirements by either:

(a) Successfully graduating after December 31, 2006 with a doctor of pharmacy degree (Pharm.D.) from a school of pharmacy approved by the state board of pharmacy; or

(b) Obtaining a total of at least one thousand seven hundred and forty hours of documented supervised practical experience in Ohio or any other state or jurisdiction in which the credentials are at least the equivalent of those required by this state at the time the experience was obtained. If the reciprocating state or jurisdiction requires less than the required hours, the board may grant internship credit for practice as a pharmacist.

~~(5)~~ Hold an active license or registration to practice pharmacy, which is in good standing, in a state or jurisdiction in which the credentials are at least the equivalent of those required by this state. Certification of these credentials shall be filed on forms provided by the national association of boards of pharmacy (NABP) or similar forms recognized and approved by the board.

(B) An applicant who has met the requirements of the state or jurisdiction with which the applicant holds a certificate of good standing pursuant to a "Foreign Pharmacy Graduate Examination Commission (FPGEC)" certificate shall be required to establish proficiency in spoken English by providing evidence of the successful completion of the "Test of English as a Foreign Language, Internet-based test" (TOEFL iBT) pursuant to rule 4729:1-2-04 of the Administrative Code.

(C) Candidates who qualify for licensure by reciprocity shall personally appear before the full board within six months of the date that the application is filed with the board. Candidates who do not appear before the board within the six-month period must file a new application and fee for licensure by reciprocity, as the original application shall be deemed abandoned.

(D) Pursuant to section 4729.071 of the Revised Code, a candidate must submit electronic or ink fingerprint impressions for a criminal records check prior to receiving an initial license to practice as a pharmacist. A reciprocity candidate must submit fingerprint impressions no later than twelve months after the date the board receives the application materials. After twelve

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months, a candidate must submit a new application, the required fee, fingerprint impressions, and again personally appear before the board as described in this paragraph (C) of this rule.

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Rule 4729:1-4-01 | Disciplinary actions. (AMEND)

(A) As used in this rule:

(1) "Dishonesty" means any action by a licensee, registrant or applicant to include, but is not limited to, making any statement that deceives, misrepresents or misleads, or be a party to or an accessory to any fraudulent or deceitful practice or transaction in the practice of pharmacy or in the operation or conduct of a pharmacy.

(2) "Unprofessional conduct" has the same meaning as defined in division (C) of section 4729.16 of the Revised Code and shall also include conduct that is detrimental to the best interests of the public, including conduct that endangers the health, safety or welfare of a patient or client. Such conduct shall include, but not be limited to, the following acts: coercion, intimidation, harassment, sexual harassment, improper use of private health information, threats, degradation of character, indecent or obscene conduct, and theft.

~~(3) "Act involving moral turpitude" means an act or behavior that gravely violates moral sentiment or accepted moral standards of the community and is a morally culpable quality held to be present in some criminal offenses as distinguished from others.~~

(B)

(1) The state board of pharmacy, after notice and hearing in accordance with Chapter 119. of the Revised Code, may impose any one or more of the following sanctions on a pharmacist or applicant for a pharmacist license if the board finds the individual engaged in any of the conduct set forth in paragraph (B)(2) of this rule:

(a) Revoke, suspend, restrict, limit, or refuse to grant or renew a license;

(b) Reprimand or place the license holder on probation;

(c) Impose a monetary penalty or forfeiture not to exceed in severity any fine designated under the Revised Code for a similar offense, or in the case of a violation of a section of the Revised Code that does not bear a penalty, a monetary penalty or forfeiture of not more than five hundred dollars.

(2) The board may impose the sanctions listed in paragraph (B)(1) of this rule if the board finds a pharmacist or applicant for a pharmacist license:

(a) Has a criminal conviction for, judicial finding of guilt of, or plea of guilty to a disqualifying offense.~~Has been convicted of a felony.~~

(b) Engaged in dishonesty or unprofessional conduct in the practice of pharmacy.

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(c) Is addicted to or abusing alcohol or drugs or is impaired physically or mentally to such a degree as to render the pharmacist unfit to practice pharmacy.

~~(d) Has been convicted of a misdemeanor related to, or committed in, the practice of pharmacy.~~

(ed) Violated, conspired to violate, attempted to violate, or aided and abetted the violation of any of the provisions of Chapter 4729. of the Revised Code, sections 3715.52 to 3715.72 of the Revised Code, Chapter 2925., 3796., 3719. or 4752. of the Revised Code, or any rule adopted by the board under those provisions.

(fe) Permitted someone other than a pharmacist or pharmacy intern to practice pharmacy.

(gf) Knowingly lent the pharmacist's name to an illegal practitioner of pharmacy or had a professional connection with an illegal practitioner of pharmacy.

(hg) Divided or agreed to divide remuneration made in the practice of pharmacy with any other individual, including, but not limited to, any licensed health professional authorized to prescribe drugs or any owner, manager, or employee of a health care facility, residential care facility, or nursing home.

(ih) Violated the terms of a consult agreement entered into pursuant to section 4729.39 of the Revised Code.

(ji) Committed fraud, misrepresentation, or deception in applying for or securing a license issued by the board under this chapter or under Chapter 3796., 3715., 3719. or 4752. of the Revised Code.

(kj) Failed to comply with an order of the board or a settlement agreement.

~~(l) Committed an act involving moral turpitude that constitutes a misdemeanor or felony in this state, regardless of the jurisdiction in which the act was committed.~~

(mk) Violated any state or federal law, regulation or rule regardless of the jurisdiction in which the acts were committed, except for minor traffic violations such as parking violations, speeding tickets and violations such as failure to obey a red light, failure to use a turn signal or expired vehicle registration.

(nl) Has been disciplined by the state board of pharmacy pursuant to section 4729.16 of the Revised Code.

(on) 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.

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(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.

(~~p~~m) Failed to conform to prevailing standards of care of similar pharmacists under the same or similar circumstances, whether or not actual injury to a patient is established.

(~~q~~o) 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.

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

(~~s~~q) Cannot practice according to acceptable and prevailing standards of care by reason of mental illness or physical illness, including, but not limited to, physical deterioration that adversely affects cognitive, motor, or perceptive skills.

Rule 4729:1-4-02 | Duty to Report. (AMEND)

(A) As used in this rule:

(1) "Error in dispensing" or "prescription error" means an act or omission of clinical significance relating to the dispensing of a drug. An error in dispensing may be considered a violation of division

(A)(2) of section [3715.52](#) and section [3715.64](#) of the Revised Code.

(2) "Harm" means impairment of the physical, emotional, or psychological function or structure of the body and/or pain resulting therefrom.

(3) "Intervention" means a change in therapy or active medical/surgical treatment.

(4) "Intervention necessary to sustain life" means cardiovascular and respiratory support (e.g., CPR, defibrillation, intubation, etc.).

(5) "Reckless behavior" means a person who acts recklessly or who is reckless. A person acts recklessly when, with heedless indifference to the consequences, the person disregards a substantial and unjustifiable risk that the person's conduct is likely to cause a certain result or is likely to be of a certain nature. A person is reckless with respect to circumstances when, with heedless indifference to the consequences, the person disregards a substantial and unjustifiable risk that such circumstances are likely to exist.

(6) "Unprofessional conduct" has the same meaning as defined in paragraph (A) of rule [4729:1-4-01](#) of the Administrative Code.

(B) Pursuant to section [4729.10](#) of the Revised Code, a pharmacist who has knowledge, from direct observation or objective evidence, of violations described in paragraph (C) of this rule shall report such conduct to the state board of pharmacy.

(C) The following shall be reported to the board:

(1) Except as provided in paragraph (C)(1)(a) of this rule, conduct indicating an individual licensed or registered by the board is addicted to or is suspected to be abusing alcohol, drugs or other chemical substances or impaired physically or mentally to such a degree as to render the individual unfit to carry out their professional duties.

(a) A pharmacist shall not be required to report in accordance with this rule if the pharmacist becomes aware of any condition described in paragraph (C)(1) of this rule as a result of either:

(i) The pharmacist's treatment of the individual for the condition; or

(ii) The pharmacist having access to the individual's protected health information.

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(2) Except as provided in paragraph (H) of this rule, violations, attempts to violate, or aiding and abetting in the violation of any of the provisions of Chapters 4729., 4752., 3715., 3719., 3796., 2925., and 2913. of the Revised Code, or any rule adopted by the board under those provisions, by an individual or entity licensed or registered by the board.

(3) Conduct by a pharmacy technician trainee, registered pharmacy technician, certified pharmacy technician, pharmacy intern or pharmacist that constitutes unprofessional conduct or dishonesty as defined in rule 4729:1-4-01 of the Administrative Code.

(D)

(1) Pursuant to section 4729.23 of the Revised Code, the identity of the pharmacist making a report in accordance with this rule shall remain confidential.

(2) Notwithstanding the confidentiality provided in accordance with paragraph (D)(1) of this rule, a pharmacist may be required to testify in a disciplinary proceeding as to the conduct or violations listed in paragraph (C) of this rule without disclosing the pharmacist was the reporting individual.

(E) Reporting required in accordance with this rule shall be made in writing, either by mail, using the board's online complaint form (available on the board's web site: www.pharmacy.ohio.gov), or by telephone and shall include the following information:

(1) The name of the licensee, registrant or other individual who may have committed a violation listed in paragraph (C) of this rule;

(2) The violation which is believed to have occurred; and

(3) The date(s) of and place(s) of occurrence(s), if known.

(F) A licensed pharmacist shall notify the board of any of the following:

(1) Any criminal conviction for, judicial finding of guilt of, or plea of guilty to of a disqualifying offense within ten days after the date of conviction, ~~except for minor traffic violations such as parking violations, speeding tickets and violations such as failure to obey a red light, failure to use a turn signal or expired registration.~~

(2) The pharmacist is convicted of, plead guilty to, is subject to a judicial finding of eligibility for intervention in lieu of conviction in this state under section 2951.041 of the Revised Code or the equivalent thereof in another jurisdiction within ten days after the individual is deemed eligible.

(3) The pharmacist is granted entry into a diversion program, deferred prosecution program, or the equivalent thereof within ten days after the individual is granted entry into a program.

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(4) Any arrest for a felony within ten days after the arrest.

(G) A pharmacist shall notify the board of any disciplinary licensing or registration action taken by another state against the licensee within ten days of the notice action. This includes, but is not limited to, a disciplinary action that is stayed pending appeal.

(H) An error in dispensing shall not be required to be reported pursuant to paragraph (C) of this rule except when the error is the result of reckless behavior or unprofessional conduct and meets any of the following per the national coordinating council for "Medication Error Reporting and Prevention's Index for Categorizing Medication Errors" (2/20/2001):

(1) An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention;

(2) An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization;

(3) An error occurred that may have contributed to or resulted in permanent patient harm;

(4) An error occurred that required intervention necessary to sustain life; or

(5) An error occurred that may have contributed to or resulted in the patient's death.

(I) Pursuant to section [4729.10](#) of the Revised Code, in the absence of fraud or bad faith, a person who reports in accordance with this rule or testifies in any adjudication conducted under Chapter 119. of the Revised Code is not liable to any person for damages in a civil action as a result of the report or testimony.

Rule 4729:2-1-01 - Definitions - pharmacy interns. (AMEND)

(A) "Abandoned application" means an application for a licensure pursuant to this division where the applicant fails to complete all application requirements within thirty days after being notified by the board. 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.

~~(B) "Act of moral turpitude" means an act or behavior that gravely violates moral sentiment or accepted moral standards of the community and is a morally culpable quality held to be present in some criminal offenses as distinguished from others.~~

(C) "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.

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

(E) "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.

(F) "Compounding" has the same meaning as defined in section [4729.01](#) of the Revised Code and agency 4729. of the Administrative Code.

(G) "Controlled substance" has the same meaning as in section [3719.01](#) of the Revised Code.

(H) "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

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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.

(I) "Dispense" means the final association of a drug with a 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.

~~(J) "Good moral character" means those virtues of a person which are generally recognized as beneficial to the public health, safety and welfare, or a pattern of behavior conforming to a profession's ethical standards and showing an absence of moral turpitude, including conduct consistent with justice, honesty, or morality.~~

(K) "In good standing" means a preceptor to which all the following apply:

(1) Has not been denied the privilege of supervising interns by the board;

(2) Has not been denied a license, registration or certificate by any public agency or licensing agency;

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(3) Does not have a license, registration or certificate limited, suspended, or revoked by any public agency or licensing agency.

(L) "Personal supervision" or "direct supervision" means a pharmacist shall be physically present in the pharmacy, or in the area where the practice of pharmacy is occurring, to provide personal review and approval of all professional activities. The pharmacist providing personal supervision of an intern shall:

- (1) Be readily available to answer questions of the pharmacy intern;
- (2) Make appropriate in-process and end-process verifications of the activities of the pharmacy intern; and
- (3) Be fully responsible for the practice of the pharmacy intern.

(M) "Pharmacist" means an individual who holds a valid pharmacist license in accordance with Chapter 4729. of the Revised Code.

(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) "Preceptor" means an individual responsible for seeing that a pharmacy intern is properly supervised and exposed to all aspects of an internship program.

(1) A preceptor shall be either:

(a) A pharmacist who holds a license to practice pharmacy that is in good standing. Unless employed by a school of pharmacy, a preceptor shall have at least one year of practice experience as a licensed pharmacist.

(b) A person who is of good moral character and is qualified to direct the practical experience in the area approved by the director of licensing pursuant to rule [4729:2-2-05](#) of the Administrative Code.

(2) A person may serve as the preceptor for more than one intern.

(3) Except as provided in paragraph (O)(4) of this rule, the number of interns engaged in the practice of pharmacy at any time is limited to not more than two for each pharmacist on duty, unless otherwise approved by the board.

(4) The number of pharmacy interns engaged in the administration of immunizations at any time is limited to not more than six for each pharmacist providing personal supervision.

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(5) A preceptor must report to the board on the progress and aptitude of an intern when requested by the director of licensing.

(P)

(1) "Positive identification" means a method of identifying a person that does not rely solely 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 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.

(Q) "Practical experience affidavit" is a form provided by the state board of pharmacy used to submit evidence of practical experience for internship credit pursuant to rule [4729:2-2-06](#) of the Administrative Code.

(R) "Practice of pharmacy" has the same meaning as in division (B) of section [4729.01](#) of the Revised Code.

(S) "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.

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(T) "Responsible person" has the same meaning as defined in rule [4729:5-2-01](#) of the Administrative Code.

(U) "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.

(V) "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.

(W) "School of pharmacy" has the same meaning as a college of pharmacy or a department of pharmacy of a university, which has been recognized and approved by the state board of pharmacy in accordance with rule [4729-5-01](#) of the Administrative Code.

(X) "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.

(Y) "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.

(Z) "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 [3719.121](#) 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.

(AA) "Veteran" means anyone who is serving or has served under honorable conditions in any component of the armed forces, including the national guard and reserve.

Rule 4729:2-4-01 | Disciplinary actions. (AMEND)

(A) As used in this rule:

(1) "Dishonesty" means any action by a licensee, registrant or applicant to include, but is not limited to, making any statement that deceives, misrepresents or misleads, or be a party to or an accessory to any fraudulent or deceitful practice or transaction in the practice of pharmacy or in the operation or conduct of a pharmacy.

(2) "Unprofessional conduct" has the same meaning as defined in division (C) of section 4729.16 of the Revised Code and shall also include conduct that is detrimental to the best interests of the public, including conduct that endangers the health, safety or welfare of a patient or client. Such conduct shall include, but not be limited to, the following acts: coercion, intimidation, harassment, sexual harassment, improper use of private health information, threats, degradation of character, indecent or obscene conduct, and theft.

~~(3) "Act involving moral turpitude" means an act or behavior that gravely violates moral sentiment or accepted moral standards of the community and is a morally culpable quality held to be present in some criminal offenses as distinguished from others.~~

(B)

(1) The state board of pharmacy, after notice and hearing in accordance with Chapter 119. of the Revised Code, may impose any one or more of the following sanctions on a pharmacy intern or applicant for a pharmacy intern license if the board finds the individual engaged in any of the conduct set forth in paragraph (B)(2) of this rule:

(a) Revoke, suspend, restrict, limit, or refuse to grant or renew a license;

(b) Reprimand or place the license holder on probation;

(c) Impose a monetary penalty or forfeiture not to exceed in severity any fine designated under the Revised Code for a similar offense, or in the case of a violation of a section of the Revised Code that does not bear a penalty, a monetary penalty or forfeiture of not more than five hundred dollars.

(2) The board may impose the sanctions listed in paragraph (B)(1) of this rule if the board finds a pharmacy intern or applicant for a pharmacy intern license:

~~(a) Has a criminal conviction for, judicial finding of guilt of, or plea of guilty to a disqualifying offenseHas been convicted of a felony.~~

(b) Engaged in dishonesty or unprofessional conduct in the practice of pharmacy.

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(c) Is addicted to or abusing alcohol or drugs or is impaired physically or mentally to such a degree as to render the pharmacy intern unfit to practice pharmacy.

~~(d) Has been convicted of a misdemeanor related to, or committed in, the practice of pharmacy.~~

(ed) Violated, conspired to violate, attempted to violate, or aided and abetted the violation of any of the provisions of Chapter 4729. of the Revised Code, sections 3715.52 to 3715.72 of the Revised Code, Chapter 2925., 3796., 3719. or 4752. of the Revised Code, or any rule adopted by the board under those provisions.

(fe) Knowingly lent the pharmacy intern's name to an illegal practitioner of pharmacy or had a professional connection with an illegal practitioner of pharmacy.

(gf) Divided or agreed to divide remuneration made in the practice of pharmacy with any other individual, including, but not limited to, any licensed health professional authorized to prescribe drugs or any owner, manager, or employee of a health care facility, residential care facility, or nursing home.

(hg) Committed fraud, misrepresentation, or deception in applying for or securing a license issued by the board under this chapter or under Chapter 3796., 3715., 3719. or 4752. of the Revised Code.

(ih) Failed to comply with an order of the board or a settlement agreement.

~~(j) Committed an act involving moral turpitude that constitutes a misdemeanor or felony in this state, regardless of the jurisdiction in which the act was committed.~~

(ki) Violated any state or federal law, regulation or rule regardless of the jurisdiction in which the acts were committed, except for minor traffic violations such as parking violations, speeding tickets and violations such as failure to obey a red light, failure to use a turn signal or expired vehicle registration.

(lj) Has been disciplined by the state board of pharmacy pursuant to section 4729.16 of the Revised Code.

(mk) 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.

(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.

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(nl) Failed to conform to prevailing standards of care of similar pharmacy interns under the same or similar circumstances, whether or not actual injury to a patient is established.

(en) 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.

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

(qo) Cannot practice according to acceptable and prevailing standards of care by reason of mental illness or physical illness, including, but not limited to, physical deterioration that adversely affects cognitive, motor, or perceptive skills.

Rule 4729:2-4-02 | Duty to report. (AMEND)

(A) As used in this rule:

"Error in dispensing" or "prescription error" means an act or omission of clinical significance relating to the dispensing of a drug. An error in dispensing may be considered a violation of division (A)(2) of section 3715.52 and section 3715.64 of the Revised Code.

(B) Pursuant to section 4729.10 of the Revised Code, a pharmacy intern who has knowledge, from direct observation or objective evidence, of violations described in paragraph (C) of this rule shall report such conduct to the state board of pharmacy.

(C) The following shall be reported to the board:

(1) Except as provided in paragraph (C)(1) of this rule, conduct indicating an individual licensed or registered by the board is addicted to or is suspected to be abusing alcohol, drugs or other chemical substances or impaired physically or mentally to such a degree as to render the individual unfit to carry out their professional duties.

A pharmacy intern shall not be required to report in accordance with this rule if the intern becomes aware of any condition described in paragraph (C)(1) of this rule as a result of either:

(a) The intern's treatment of the individual for the condition; or

(b) The intern having access to the individual's protected health information.

(2) Except as provided in paragraph (H) of this rule, violations, attempts to violate, or aiding and abetting in the violation of any of the provisions of Chapters 4729., 3715., 3719., 2925., and 2913. of the Revised Code, or any rule adopted by the board under those provisions, by an individual licensed or registered by the board.

(3) Conduct by a pharmacy technician trainee, registered pharmacy technician, certified pharmacy technician, pharmacy intern or pharmacist that constitutes unprofessional conduct or dishonesty as defined in rule 4729:2-4-01 of the Administrative Code.

(D)

(1) Pursuant to section 4729.23 of the Revised Code, the identity of the pharmacy intern making a report in accordance with this rule shall remain confidential.

(2) Notwithstanding the confidentiality provided in accordance with paragraph (D) (1) of this rule, a pharmacy intern may be required to testify in a disciplinary proceeding as to the conduct or violations listed in paragraph (C) of this rule without disclosing the intern was the reporting individual.

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(E) Reporting required in accordance this rule shall be made in writing, either by mail, using the board's online complaint form (available on the board's web site: www.pharmacy.ohio.gov), or by telephone and shall include the following information:

- (1) The name of the licensee, registrant or other individual who may have committed a violation listed in paragraph (C) of this rule;
- (2) The violation which is believed to have occurred; and
- (3) The date(s) of and place(s) of occurrence(s), if known.

(F) A licensed pharmacy intern shall notify the board of any of the following:

- (1) Any criminal conviction for, judicial finding of guilt of, or plea of guilty to of a disqualifying offense within ten days after the date of conviction, except for minor traffic violations such as parking violations, speeding tickets and violations such as failure to obey a red light, failure to use a turn signal or expired vehicle registration.
- (2) The intern is convicted of, plead guilty to, is subject to a judicial finding of eligibility for intervention in lieu of conviction in this state under section [2951.041](#) of the Revised Code or the equivalent thereof in another jurisdiction within ten days after the individual is deemed eligible.
- (3) The intern is granted entry into a diversion program, deferred prosecution program, or the equivalent thereof within ten days after the individual is granted entry into a program.
- (4) Any arrest for a felony within ten days after the arrest.

(G) A pharmacy intern shall notify the board of any disciplinary licensing or registration action taken by another state against the licensee within ten days of the notice action. This includes, but is not limited to, a disciplinary action that is stayed pending appeal.

(H) An error in dispensing shall not be required to be reported to the board in accordance with this rule.

(I) Pursuant to section [4729.10](#) of the Revised Code, in the absence of fraud or bad faith, a person who reports in accordance with this rule or testifies in any adjudication conducted under Chapter 119. of the Revised Code is not liable to any person for damages in a civil action as a result of the report or testimony.

Rule 4729:3-4-01 | Disciplinary actions. (AMEND)

(A) As used in this rule:

(1) "Dishonesty" means any action by a licensee, registrant or applicant to include, but is not limited to, making any statement that deceives, misrepresents or misleads, or be a party to or an accessory to any fraudulent or deceitful practice or transaction in the practice of pharmacy or in the operation or conduct of a pharmacy.

(2) "Unprofessional conduct" means conduct that is detrimental to the best interests of the public, including conduct that endangers the health, safety or welfare of a patient or client. Such conduct shall include, but not be limited to, the following acts: coercion, intimidation, harassment, sexual harassment, improper use of private health information, threats, degradation of character, indecent or obscene conduct, and theft.

~~(3) "Act involving moral turpitude" means an act or behavior that gravely violates moral sentiment or accepted moral standards of the community and is a morally culpable quality held to be present in some criminal offenses as distinguished from others.~~

(B) The state board of pharmacy, after notice and hearing in accordance with Chapter 119. of the Revised Code, may impose one or more of the following sanctions on a pharmacy technician trainee, registered pharmacy technician, certified pharmacy technician or applicant for such registration if the board finds the individual engaged in any of the conduct set forth in paragraph (C) of this rule:

(1) Revoke, suspend, restrict, limit, or refuse to grant or renew a registration;

(2) Reprimand or place the holder of the registration on probation;

(3) Impose a monetary penalty or forfeiture not to exceed in severity any fine designated under the Revised Code for a similar offense, or in the case of a violation of a section of the Revised Code that does not bear a penalty, a monetary penalty or forfeiture as specified in section [4729.96](#) of the Revised Code.

(C) The board may impose the sanctions listed in paragraph (B) of this rule if the board finds a pharmacy technician trainee, registered pharmacy technician, certified pharmacy technician or applicant for such registration:

(1) Has engaged in any of the conduct specified in division (A)(2) of section [4729.96](#) of the Revised Code.

(2) Violated any state or federal law or rule regardless of the jurisdiction in which the acts were committed, except for minor traffic violations such as parking violations, speeding tickets and violations such as failure to obey a red light, failure to use a turn signal or expired registration.

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(3) Has been disciplined by the state board of pharmacy pursuant to section 4729.96 of the Revised Code.

(4) Has been 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, probation, surrender or revocation of the person's license or registration.

(b) 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.

(5) 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.

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

~~(7) Committed an act involving moral turpitude that constitutes a misdemeanor or felony in this state, regardless of the jurisdiction in which the act was committed.~~

(87) Cannot conduct authorized activities according to acceptable and prevailing standards of care by reason of mental illness or physical illness, including, but not limited to, physical deterioration that adversely affects cognitive, motor, or perceptive skills.

(98) Engaged in dishonesty or unprofessional conduct.

Rule 4729:3-4-02 | Duty to report. (AMEND)

(A) As used in this rule:

"Error in dispensing" or "prescription error" means an act or omission of clinical significance relating to the dispensing of a drug. An error in dispensing may be considered a violation of division (A)(2) of section [3715.52](#) and section [3715.64](#) of the Revised Code.

(B) Pursuant to section [4729.10](#) of the Revised Code, a pharmacy technician trainee, registered pharmacy technician or certified pharmacy technician who has knowledge, from direct observation or objective evidence, of violations described in paragraph (C) of this rule shall report such conduct to the board.

(C) The following shall be reported to the board:

(1) Except as provided in paragraph (C)(1)(a) of this rule, conduct indicating an individual licensed or registered by the board is addicted to or is suspected to be abusing alcohol, drugs or other chemical substances or impaired physically or mentally to such a degree as to render the individual unfit to carry out their professional duties.

(a) A registrant shall not be required to report in accordance with this rule if the registrant becomes aware of any condition described in paragraph (C)(1) of this rule as a result of either:

(i) The registrant is involved in the treatment of the individual for the condition; or

(ii) The registrant having access to the individual's protected health information.

(2) Except as provided in paragraph (H) of this rule, violations, attempts to violate, or aiding and abetting in the violation of any of the provisions of Chapters 4729., 3715., 3719., 2925., and 2913. of the Revised Code, or any rule adopted by the board under those provisions, by an individual licensed or registered by the board.

(3) Conduct by a pharmacy technician trainee, registered pharmacy technician, certified pharmacy technician, pharmacy intern or pharmacist that constitutes unprofessional conduct or dishonesty as defined in rule [4729:3-4-01](#) of the Administrative Code.

(D)

(1) Pursuant to section [4729.23](#) of the Revised Code, the identity of the registrant making a report in accordance with this rule shall remain confidential.

(2) Notwithstanding the confidentiality provided in accordance with paragraph (D)(1) of this rule, a registrant may be required to testify in a disciplinary proceeding as to the conduct or

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violations listed in paragraph (C) of this rule without disclosing the registrant was the reporting individual.

(E) Reporting required in accordance with paragraph (C) this rule shall be made in writing, either by mail or using the board's complaint form (available on the board's web site: www.pharmacy.ohio.gov), or by telephone and include the following information:

- (1) The name of the licensee or registrant or other individual who may have committed a violation listed in paragraph (C) of this rule;
- (2) The violation which is believed to have occurred; and
- (3) The date(s) of and place(s) of occurrence(s), if known.

(F) An individual registered pursuant to this division shall notify the board of any of the following:

- (1) Any criminal conviction for, judicial finding of guilt of, or plea of guilty to ~~of~~ a disqualifying offense within ten days after the date of conviction, except for minor traffic violations such as parking violations, speeding tickets and violations such as failure to obey a red light, failure to use a turn signal or expired registration.
- (2) The registrant is convicted of, plead guilty to, is subject to a judicial finding of eligibility for intervention in lieu of conviction in this state under section [2951.041](#) of the Revised Code or the equivalent thereof in another jurisdiction within ten days after the individual is deemed eligible.
- (3) The registrant is granted entry into a diversion program, deferred prosecution program, or the equivalent thereof within ten days after the individual is granted entry into a program.
- (4) Any arrest for a felony within ten days after the arrest.
- (5) For a certified pharmacy technician, failure to maintain a current pharmacy technician certification from an organization that has been recognized by the board.

(G) An individual registered pursuant to this division shall notify the board of any disciplinary licensing or registration action taken by another state against the registrant within ten days of the notice of action. This includes, but is not limited to, a disciplinary action that is stayed pending appeal.

(H) An error in dispensing shall not be required to be reported pursuant to paragraph (C) of this rule.

(I) Pursuant to section [4729.10](#) of the Revised Code, in the absence of fraud or bad faith, a person who reports in accordance with this rule or testifies in any adjudication conducted under Chapter 119. of the Revised Code is not liable to any person for damages in a civil action as a result of the report or testimony.

Rule 4729:5-1-01 | Definitions. (AMEND)

As used in this division:

(A) "Terminal distributor of dangerous drugs" or "terminal distributor" means a person who is engaged in the sale of dangerous drugs at retail, or any person, other than a manufacturer, repackager, outsourcing facility, third-party logistics provider, wholesale distributor, or pharmacist, who has possession, custody, or control of dangerous drugs for any purpose other than for that person's own use and consumption.

(1) A terminal distributor of dangerous drugs includes pharmacies, hospitals, nursing homes, and laboratories and all other persons who procure dangerous drugs for sale or other distribution by or under the supervision of a pharmacist, licensed health professional authorized to prescribe drugs or any other person authorized by the board of pharmacy.

(2) A terminal distributor shall comply with the provisions set forth in this division.

(B) "Abandoned application" means an application submitted for licensure that meets the criteria set forth 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 complete all application requirements within thirty days after being notified of the incomplete application by the board.

(b) An applicant for a terminal distributor of dangerous drugs that fails to demonstrate compliance with rule [4729:5-2-01](#) of the Administrative Code. The applicant may submit a request to the director of licensing for a one-time, ninety-day extension.

(c) An applicant for a terminal distributor of dangerous drugs 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 director of licensing 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.

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(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, IT or other staff that may need limited supervised access to areas where dangerous drugs or D.E.A. controlled substance order forms are kept.

~~(D) "Act of moral turpitude" means an act or behavior that gravely violates moral sentiment or accepted moral standards of the community and is a morally culpable quality held to be present in some criminal offenses as distinguished from others.~~

~~(ED)~~ "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.

~~(FE)~~ "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.

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

~~(HG)~~ "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.

~~(H)~~ "Campus," as used to describe a type of terminal distributor of dangerous drugs license issued pursuant to section 4729.54 of the Revised Code, means an establishment or place consisting of multiple buildings where dangerous drugs are stored that are located on a contiguous plot of land. All such buildings and stocks of dangerous drugs shall be under common ownership and control.

~~(J)~~ "Certified diabetes educator," as used in Chapters 3719. and 4729. of the Revised Code, means a person who has been certified to conduct diabetes education by the "National Certification Board for Diabetes Educators" (NCBDE).

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~~(KJ)~~ "Controlled substance" has the same meaning as in section 3719.01 of the Revised Code.

~~(LK)~~ "Dangerous drug" has the same meaning as in section 4729.01 of the Revised Code.

~~(ML)~~ "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.

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~~(NM)~~ "Distributor of dangerous drugs" or "drug distributor" means the following persons licensed in accordance with section 4729.52 of the Revised Code and division 4729:6 of the Administrative 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.

~~(ON)~~ "Inpatient" means any person who receives drugs for use while within an institutional facility.

~~(PO)~~ "Outpatient" means any person who receives drugs for use outside of an institutional facility.

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

~~(RQ)~~ "Personally furnish" or "personally furnishing" means the final association of a drug with a patient by a prescriber prior to providing the drug to a patient for use outside the prescriber's practice setting.

~~(SR)~~ "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.

~~(TS)~~ "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.

~~(UT)~~ "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

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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.

~~(YU)~~ "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.

~~(WV)~~ "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.

~~(XW)~~ "Sample" means a drug or pharmaceutical preparation that would be hazardous to health or safety if used without the supervision of a licensed health professional authorized to prescribe drugs, or a drug of abuse, and that, at one time, had been placed in a container plainly marked as a sample by a manufacturer.

~~(YX)~~ "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.

~~(ZY)~~ "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.

~~(AAZ)~~ "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 [4729.571](#) 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.

~~(BBAA)~~ "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 4729:5-2-01 | Responsible Person - Terminal Distributor. (AMEND)

(A) Except as provided in paragraph (B) of this rule, for a pharmacy licensed as a terminal distributor of dangerous drugs:

(1) Only a pharmacist may be the responsible person whose name appears on the terminal distributor of dangerous drugs license for a pharmacy as defined in division (A) of section 4729.01 of the Revised Code. A pharmacist shall be the responsible person for no more than one such pharmacy or campus unless granted permission in accordance with paragraph (G) of this rule.

(2) The responsible person shall be responsible for the practice of the profession of pharmacy, including, but not limited to, the supervision and control of dangerous drugs as required in division

(B) of section 4729.55 of the Revised Code, adequate safeguards as required in division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs and maintaining all drug records otherwise required.

(3) The person to whom the terminal distributor of dangerous drugs license has been issued and all pharmacists on duty are responsible for compliance with all state and federal laws, regulations, and rules governing the distribution of drugs and the practice of pharmacy.

(B) For an institutional pharmacy licensed as a terminal distributor of dangerous drugs:

(1) Only a pharmacist licensed under section 4729. of the Revised Code may be the responsible person whose name appears on the terminal distributor of dangerous drugs license for an institutional pharmacy. A pharmacist shall be the responsible person for no more than one such pharmacy or campus unless granted permission in accordance with paragraph (G) of this rule.

(2) The responsible person shall be responsible for all of the following:

(a) The practice of the profession of pharmacy performed within the institutional facility, including, but not limited to, the supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, adequate safeguards as required in division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs and maintaining all drug records otherwise required.

(b) The development, implementation, supervision, and coordination of all services provided by the institutional pharmacy.

(c) In conjunction with the appropriate interdisciplinary committees, the development of written policies and procedures which are consistent with this division of the Administrative Code and other applicable federal and state laws, regulations and rules governing the legal distribution of drugs, adherence to these policies and procedures in order to provide for the safe distribution of

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drugs in all areas of the institutional facility, and making readily retrievable a current copy of these written policies and procedures.

(3) The person to whom the terminal distributor of dangerous drugs license has been issued and all pharmacists on duty are responsible for compliance with all state and federal laws, regulations, and rules governing the distribution of drugs and the practice of pharmacy.

(C) For locations licensed as a category III terminal distributor of dangerous drugs with a pain management classification under section [4729.552](#) of the Revised Code:

(1) Only a physician authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery may be the responsible person whose name appears on the category III terminal distributor of dangerous drugs with a pain management classification license as defined in section [4729.552](#) of the Revised Code. A physician shall be the responsible person for no more than one such location unless granted permission in accordance with paragraph (G) of this rule. A physician shall not be designated the responsible person for a location licensed as a category III terminal distributor of dangerous drugs with a pain management classification unless the physician will be physically present at the location for a sufficient amount of time to provide adequate supervision.

(2) The responsible person shall submit to a criminal records check in accordance with section [4776.02](#) of the Revised Code.

(3) The responsible person for locations licensed as a category III terminal distributor of dangerous drugs with a pain management classification under section [4729.552](#) of the Revised Code must meet one of the following requirements:

(a) Hold current subspecialty certification in pain management by the American board of medical specialties, or hold a current certificate of added qualification in pain management by the American osteopathic association bureau of osteopathic specialists;

(b) Hold current subspecialty certification in hospice and palliative medicine by the American board of medical specialties, or hold a current certificate of added qualification in hospice and palliative medicine by the American osteopathic association bureau of osteopathic specialists;

(c) Hold current board certification by the American board of pain medicine;

(d) Hold current board certification by the American board of interventional pain physicians; or

(e) Hold current board certification in anesthesiology, psychiatry, neurology, physical medicine and rehabilitation, occupational medicine, or rheumatology by the American board of medical specialties or hold current primary certification in anesthesiology, psychiatry, neurology, physical medicine and rehabilitation, occupational medicine, or rheumatology by the American osteopathic association bureau of osteopathic specialists.

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(4) The person to whom the category III terminal distributor of dangerous drugs license with a pain management clinic classification has been issued, the responsible person and all licensed health professionals practicing at that location are responsible for compliance with all state and federal laws, regulations, and rules governing the operation of a pain management clinic and prescribing of controlled substances.

(D) For locations licensed as a category III terminal distributor of dangerous drugs with an office-based opioid treatment classification under section [4729.553](#) of the Revised Code:

(1) Only a physician or certified nurse practitioner who meets the following may be the responsible person whose name appears on the category III terminal distributor of dangerous drugs with an office-based opioid treatment classification license as defined in section [4729.553](#) of the Revised Code:

(a) The physician is authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery or the certified nurse practitioner is designated as a certified nurse practitioner in accordance with section [4723.42](#) of the Revised Code and rules adopted by the board of nursing; and

(b) The physician or certified nurse practitioner possesses a waiver to prescribe or personally furnish buprenorphine under the Drug Addiction Treatment Act of 2000 (DATA 2000) (2/20/2017).

(2) The responsible person shall submit to a criminal records check in accordance with section [4776.02](#) of the Revised Code.

(3) A physician or certified nurse practitioner shall not be designated the responsible person for a location licensed as a category III terminal distributor of dangerous drugs with an office-based opioid treatment classification unless the physician or certified nurse practitioner will be physically present at the location for at least fifteen hours per week. If the facility is not open more than fifteen hours per week, the minimum amount of on-site supervision shall be at least fifty per cent of the total hours the facility is open, as reported to the board by the licensee on the application. Any changes to the licensee's hours of operation shall be reported to the board, in a manner determined by the board, within three business days.

(a) The hour requirements of this paragraph do not apply if either:

(i) The responsible person is unable to meet the requirements due to a documented illness or emergency and there is another physician or certified nurse ~~practitioner~~[practitioner](#) on-site who meets the requirements of paragraph (C)(1) of this rule who can provide on-site supervision in accordance with the requirements described in this paragraph. The physician or certified nurse practitioner shall assume all responsibilities for compliance with this rule in the absence of the responsible person.

(ii) The location is closed for a state or federal holiday or other documented reason.

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(4) The person to whom the category III terminal distributor of dangerous drugs license with an office-based opioid treatment classification has been issued, the responsible person and all licensed health professionals practicing at that location are responsible for compliance with all state and federal laws, regulations, and rules regulating the operation of an office-based opioid treatment facility and prescribing of controlled substances.

(E) For all locations licensed as a terminal distributor of dangerous drugs:

(1) A location licensed as a terminal distributor of dangerous drugs must have a responsible person at all times.

(2) When there is a change of responsible person, the state board of pharmacy shall be notified within ten days of the effective date of the appointment of the new responsible person in a manner determined by the board. For a limited terminal distributor of dangerous drugs license, the notification shall include a drug list required in accordance with agency 4729 of the Administrative Code.

(3) A complete inventory, pursuant to 21 CFR 1304.11 of the Code of Federal Regulations (9/9/2014) and rule [4729:5-3-07](#) of the Administrative Code, shall be taken of the controlled substances on hand by the new responsible person on the effective date of the change of responsible person. The new responsible person shall be responsible for completing and maintaining this inventory record at the location licensed as a terminal distributor of dangerous drugs.

(4) The responsible person to whom the terminal distributor of dangerous drugs license has been issued and all licensed health professionals on duty are responsible for compliance with all state and federal laws, regulations, and rules governing the distribution of dangerous drugs.

(5) A responsible person must be physically present at the location for a sufficient amount of time to provide supervision and control of dangerous drugs on-site.

(6) The responsible person shall be responsible for ensuring the terminal distributor of dangerous drugs requirements are met, including, but not limited to, the supervision and control of dangerous drugs as required in division (B) of section [4729.55](#) of the Revised Code, adequate safeguards as required in division (C) of section [4729.55](#) of the Revised Code, security and control of dangerous drugs and maintaining all drug records otherwise required.

(7) The board of pharmacy shall issue a resolution providing the credential types required for the responsible person of each classification/business type of terminal distributor of dangerous drugs license. Only individuals that meet the credentials specified may be the responsible person for that classification/business type. The resolution shall be updated as necessary and shall be made available on the board's web site (www.pharmacy.ohio.gov).

(F) Unless otherwise approved by the board, a terminal distributor shall not have a responsible person who:

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(1) 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.

(2) Has been denied the right to work in such a facility by another professional licensing board/agency as part of an official order of that board/agency.

(3) Has committed an act that constitutes a disqualifying offense, ~~misdemeanor theft offense~~, regardless of the jurisdiction in which the act was committed.

~~(4) Has committed an act that constitutes a misdemeanor drug offense, except for a minor misdemeanor drug offense, regardless of the jurisdiction in which the act was committed.~~

~~(5) Has committed an act that constitutes a felony, regardless of the jurisdiction in which the act was committed.~~

(64) 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.

~~(75)~~ Has been granted entry into a diversion program, deferred prosecution program, or the equivalent thereof.

~~(86)~~ Cannot practice according to acceptable and prevailing standards of care by reason of mental illness or physical illness, including, but not limited to, physical deterioration that adversely affects cognitive, motor, or perceptive skills.

~~(97)~~ Is addicted to or abusing alcohol or drugs.

~~(108)~~ Has been excluded from participation in medicare or a state health care program.

~~(119)~~ Has been denied a license or registration by the drug enforcement administration or appropriate issuing body of any state or jurisdiction.

~~(1210)~~ Has been 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, probation, surrender or revocation of the person's license or registration; or

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(b) 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.

~~(13) Has committed an act that constitutes a misdemeanor that is related to, or committed in, the employee's professional practice.~~

~~(14) Has committed an act of moral turpitude that constitutes a felony or misdemeanor, regardless of the jurisdiction in which the act was committed.~~

(G) Written requests for being a responsible person at more than one location pursuant to this rule must be submitted to the state board of pharmacy in a manner determined by the board. The executive director or the directors designee shall have the authority to temporarily approve or deny a request for being a responsible person at more than one location for a period not to exceed sixty days. The full board will review requests the executive director or the directors designee has temporarily approved at the next scheduled board meeting. A terminal distributor of dangerous drugs whose request has been denied either by the executive director, the director's designee or the board will be provided with a written explanation of denial and allowed one opportunity to resubmit its request to address the identified concerns. The board may impose conditions on all approved requests, including requirements that requests be submitted for reapproval at intervals determined by the board.

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 a 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) Commission of an act of moral turpitude that constitutes a felony or misdemeanor, regardless of the jurisdiction in which the act was committed.~~

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

~~(16) Commission of an act that constitutes a misdemeanor drug offense, except for a minor misdemeanor drug offense, regardless of the jurisdiction in which the act was committed.~~

~~(17)~~ 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.

~~(18)~~ Has been granted entry into a diversion program, deferred prosecution program, or the equivalent thereof.

~~(19)~~ Is addicted to or abusing alcohol or drugs.

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~~(2018)~~ Commission of an act that constitutes a misdemeanor that is related to, or committed in, the person's professional practice.

~~(2119)~~ Employs a responsible person that does not meet the requirements set forth in rule [4729:5-2-01](#) of the Administrative Code.

~~(2220)~~ 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.

~~(2321)~~ 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 physical confines of the location to be licensed.

~~(2422)~~ 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.

~~(2523)~~ The method used by the terminal distributor to store, possess or distribute dangerous drugs poses serious harm to others.

~~(2624)~~ 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.

~~(2726)~~ Unless otherwise approved by the board, a terminal distributor knowingly employs a person with access to drug stock who:

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(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 ~~misdemeanor~~ ~~theft~~ 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 committed an act that constitutes a felony, regardless of the jurisdiction in which the act was committed.~~

(f) 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.

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

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

(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 professional practice.

Rule 4729:6-1-01 | Definitions. (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 director of licensing 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 director of licensing 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:

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(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) "Act of moral turpitude" means an act or behavior that gravely violates moral sentiment or accepted moral standards of the community and is a morally culpable quality held to be present in some criminal offenses as distinguished from others.~~

~~(E)~~ "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.

~~(F)~~ "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.

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

~~(H)~~ "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.

~~(I)~~ "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.

~~(J)~~ "Dangerous drug" has the same meaning as in section 4729.01 of the Revised Code.

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~~(K)~~ "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.

~~(L)~~ "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

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

~~(ML)~~ "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.

~~(NM)~~ "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.

~~(ON)~~ "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.

~~(PO)~~

(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.

~~(Q)~~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.

~~(R)~~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.

~~(S)~~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.

~~(T)~~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.

~~(U)~~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.

~~(V)~~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.

~~(W)~~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.

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~~(XW)~~ "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.

~~(YX)~~ "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.

~~(ZY)~~ "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.

~~(AAZ)~~ "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.

~~(BBAA)~~ "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.

~~(CCBB)~~ "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 4729:6-2-01 | Responsible Person - Drug Distributor. (AMEND)

(A) A location licensed as a distributor of dangerous drugs, in accordance with section 4729.52 of the Revised Code, shall have a responsible person at all times.

(B) When there is a change of responsible person, the state board of pharmacy shall be notified by the new responsible person within ten days of the effective date of the appointment of the new responsible person in a manner determined by the board. The new responsible person shall submit to a criminal records check in accordance with rule 4729:6-2-03 of the Administrative Code.

(C) For all category III drug distributor licenses, a complete inventory, pursuant to rule 4729:6-3-06 of the Administrative Code shall be taken of the controlled substances on site by the new responsible person no later than thirty days from the separation date of the responsible person. The new responsible person shall be responsible for completing and maintaining this inventory record at the location licensed as a drug distributor.

(D) The responsible person for a location licensed as a distributor of dangerous drugs shall be responsible for compliance with all applicable state and federal laws, regulations, and rules governing the manufacture, sale and distribution of dangerous drugs.

(E) The responsible person shall be physically present at the location for a sufficient amount of time to provide supervision and control of dangerous drugs on-site.

(F) The board of pharmacy shall issue a resolution providing the credential types or qualifications required for the responsible person of each license/classification/business type of a distributor of dangerous drugs licensed in accordance with section 4729.52 of the Revised Code. Only individuals that meet the credentials specified may be the responsible person for that license/classification/business type. The resolution shall be updated as necessary and made available on the board's web site, www.pharmacy.ohio.gov.

(G) Unless otherwise approved by the board, a drug distributor shall not have a responsible person who:

(1) 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.

(2) 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.

(3) Has committed an act that constitutes a ~~misdemeanor~~ disqualifying offense, regardless of the jurisdiction in which the act was committed.

~~(4) Has committed an act that constitutes a misdemeanor drug offense, except for a minor misdemeanor drug offense, regardless of the jurisdiction in which the act was committed.~~

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~~(5) Has committed an act that constitutes a felony, regardless of the jurisdiction in which the act was committed.~~

(64) 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.

~~(75)~~ Has been granted entry into a diversion program, deferred prosecution program, or the equivalent thereof.

~~(86)~~ Cannot practice according to acceptable and prevailing standards of care by reason of mental illness or physical illness, including, but not limited to, physical deterioration that adversely affects cognitive, motor, or perceptive skills.

~~(97)~~ Is addicted to or abusing alcohol or drugs.

~~(108)~~ 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.

~~(119)~~ Has been excluded from participation in medicare or a state health care program.

~~(1210)~~ Has been denied a license or registration by the drug enforcement administration or appropriate issuing body of any state or jurisdiction.

~~(1311)~~ Has been the subject of any of the following by the drug enforcement administration or licensing agency of any state:

(a) A disciplinary action that resulted in the suspension, probation, surrender 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, securing, personally furnishing, compounding, supplying or selling a controlled substance or other dangerous drug.

(14) Has committed an act that constitutes a misdemeanor that is related to, or committed in, the employees professional practice.

~~(15) Has committed an act of moral turpitude that constitutes a felony or misdemeanor in this state, regardless of the jurisdiction in which the act was committed.~~

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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 a 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 ~~felony in this state~~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).
- (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.

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~~(10) Commission of an act of moral turpitude that constitutes a felony or misdemeanor, regardless of the jurisdiction in which the act was committed.~~

(~~11~~10) Commission of a crime of moral turpitude as defined in section 4776.10 of the Revised Code.

(~~12~~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.

(~~13~~12) Exclusion from participation in Medicare or a state health care program.

(1413) Being denied a license or registration by the drug enforcement administration or appropriate issuing body of any state or jurisdiction.

(1514) 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.

~~(16) Commission of an act that constitutes a misdemeanor theft offense, regardless of the jurisdiction in which the act was committed.~~

~~(17) Commission of an act that constitutes a misdemeanor drug offense, except for a minor misdemeanor drug offense, regardless of the jurisdiction in which the act was committed.~~

(~~18~~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.

(~~19~~16) Has been granted entry into a diversion program, deferred prosecution program, or the equivalent thereof.

(~~20~~17) Is addicted to or abusing alcohol or drugs.

(~~21~~18) Commission of an act that constitutes a misdemeanor that is related to, or committed in, the person's professional practice.

(~~22~~19) Employs a responsible person that does not meet the requirements set forth in rule 4729:6-2-01 of the Administrative Code.

(~~23~~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.

(~~24~~21) The method used by the drug distributor to store, possess or distribute dangerous drugs poses serious harm to others.

(~~25~~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.

(~~26~~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 the former owner or who allows the former owner to be present within the physical confines of the location to be licensed.

(~~27~~24) Unless otherwise approved by the board, a distributor knowingly employs a person 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 ~~misdemeanor-theft~~disqualifying offense, regardless of the jurisdiction in which the act was committed.

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(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 committed an act that constitutes a felony, regardless of the jurisdiction in which the act was committed.~~

(f) 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.

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

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

(i) 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.

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

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

(l) 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.

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

Rule 4729:11-1-01 | Definitions - home medical equipment. (AMEND)

As used in this division:

(A) "24/7 coverage" means that facilities that provide HME services must have a telephone number that is operational twenty-four hours a day, seven days a week that clients can call to seek assistance. The telephone line may be an answering service that is monitored on a regular basis by the HME provider and should also alert clients to contact 911 in an emergency.

(B) "Abandoned application" means an application submitted for licensure or registration where an applicant fails to complete all application requirements within thirty days after being notified of the incomplete application by the board. 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 an application is abandoned, the applicant shall be required to reapply for licensure or registration, submit the required fee and comply with the licensure or registration requirements in effect at the time of reapplication.

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

(1) An administrative proceeding; or

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

(C) "Accrediting body" means an agency recognized by the board under rule 4729:11-2-04 of the Administrative Code.

~~(D) "Act of moral turpitude" means an act or behavior that gravely violates moral sentiment or accepted moral standards of the community and is a morally culpable quality held to be present in some criminal offenses as distinguished from others.~~

~~(ED)~~ "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.

~~(FE)~~ "Board" means the state board of pharmacy.

~~(GF)~~ "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.

~~(HG)~~ "Certificate of registration" or "registration" means a person holding a valid certificate of registration issued under Chapter 4752. of the Revised Code.

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(~~H~~) "CMS" means the centers for medicare and medicaid services.

(~~I~~) "Contact hour" means a period of sixty minutes with a minimum of fifty minutes of instruction. For credit hours earned on an academic quarter system, one credit hour is equivalent to ten contact hours. For credit hours earned on an academic trimester system, one credit hour is equivalent to twelve contact hours.

For credit hours earned on an academic semester system, one credit hour is equivalent to fifteen contact hours.

(~~K~~) "Disciplinary action" means any of the following by a federal agency 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 monetary 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 of a license or other relinquishment, 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 in the future.

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(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.

~~(LK)~~ "Expired certificate of registration" means the holder of a certificate of a registration under Chapter 4752. of the Revised Code has failed to fulfill all requirements of certificate renewal and has failed to request that the board place the certificate into inactive status.

~~(ML)~~ "Expired license" means the holder of a license under Chapter 4752. of the Revised Code has failed to fulfill all requirements of licensure renewal, and who has failed to request that the board place the certificate on inactive status.

~~(NM)~~ "Home medical equipment" or "HME" has the same meaning as defined in section 4752.01 of the Revised Code. Pursuant to division (B)(3) of that section, HME shall also include the following equipment:

- (1) Hospital grade pulse oximeters pursuant to a prescription issued by a prescriber;
- (2) Home photo therapy (bili lights or blankets);
- (3) Individually sized or customized accessories that are an integral part of equipment defined in this paragraph and paragraphs (T) and (DD) of this rule;
- (4) Transcutaneous electronic nerve stimulators (TENS), excluding devices labeled by the federal food and drug administration for over-the-counter use and are identified with the federal food and drug administration product code "NUH.OTC TENS";
- (5) Drop foot stimulators;
- (6) Bone growth stimulators;
- (7) Vision restoration therapy devices;
- (8) In-home patient lifts;
- (9) Life-sustaining equipment as defined in paragraph (T) of this rule; and
- (10) Technologically sophisticated medical equipment as defined in paragraph (DD) of this rule.

~~(ON)~~ "Home medical equipment services" or "HME services" has the same meaning as defined in section 4752.01 of the Revised Code.

~~(PO)~~ "Home medical equipment services provider" or "HME services provider" has the same meaning as defined in section 4752.01 of the Revised Code.

~~(QP)~~ "Inactive status" means the status of a license or registration issued under Chapter 4752. of the Revised Code of a facility that has made a request, in a manner determined by the board, that

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the board place the license or registration into inactive status. A facility with an inactive license does not hold a current, valid license or certificate of registration under Chapter 4752. of the Revised Code.

~~(RQ)~~ "In-service education" means that a continuing education program is offered by a HME service provider organization and not an approved peer review organization.

~~(SR)~~ "Joint commission on accreditation of healthcare organizations," as used in section 4752.12 of the Revised Code, means "the joint commission" or its predecessor organization.

~~(TS)~~ "Life sustaining equipment" has the same meaning as defined in section 4752.01 of the Revised Code and includes the following:

- (1) Ventilators;
- (2) Oxygen concentrators;
- (3) Oxygen liquid systems;
- (4) Oxygen compressed gas systems;
- (5) Non-invasive ventilator system (e.g. bi-level, iron lungs, rocking beds, diaphragmatic pacers, etc.);
- (6) Any other life sustaining equipment as determined by the board.

~~(UT)~~ "Person" includes any individual, partnership, association, limited liability company, or corporation, the state, any political subdivision of the state, and any district, department, or agency of the state or its political subdivisions. It also includes any individual member, regardless of the percentage of ownership, of any partnership, association, limited liability company, or corporation.

~~(VU)~~ "Place on probation" means to take action against a license or registration 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 or registrant may engage.

~~(WV)~~ "Readily retrievable" means that records maintained in accordance with this chapter 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.

~~(XW)~~ "Refuse to grant or renew" means to deny original or continued licensure or registration 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 or registered by the board or a person seeking to attain such status by licensure or registration, and whose license or registration 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 or registration,

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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.

~~(YX)~~ "Registered" and "licensed" mean that a person has met the initial qualifications for a certificate of registration (registered) or license (licensed) with the state board of pharmacy under Chapter 4752. of the Revised Code and rules adopted thereunder and have complied with renewal procedures, including payment of applicable fees.

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

~~(AAZ)~~ "Staff" means employees or their representatives of a licensee or registrant.

~~(BBA)~~ "Suspend" means to take action against a license or certificate of registration rendering such license or registration without force and effect for a period of time as determined by the state board of pharmacy.

~~(ECBB)~~ "Summary suspension" means to take immediate action against a license or registration without a prior hearing rendering such license or registration without force and effect for a period of time as indicated in section 4752.09 of the Revised Code. The board may suspend a license or registration issued pursuant to Chapter 4752. of the Revised Code by utilizing a telephone conference call to review the allegations and take a vote.

~~(DDCC)~~ "Technologically sophisticated medical equipment" has the same meaning as defined in section 4752.01 of the Revised Code and includes the following:

- (1) Oxygen conservation devices;
- (2) CPAP (continuous positive airway pressure) devices;
- (3) High frequency chest wall oscillators (vests);
- (4) Intrapulmonary percussive ventilation (IPV) devices;
- (5) Intermittent positive pressure breathing (IPPB) devices;
- (6) Cough-assist mechanical in-exsufflator;
- (7) Apnea monitors;
- (8) Percussors for chest physiotherapy;
- (9) Suction machines;

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- (10) Feeding pumps;
- (11) Infusion pumps;
- (12) Continuous passive motion (CPM) devices;
- (13) Custom seating or positioning systems;
- (14) Custom rehab equipment (e.g. standers & gait trainers);
- (15) Vacuum assisted wound closure devices;
- (16) Electric wheelchairs and custom scooters;
- (17) Auto-titrating airway devices; and
- (18) Any other technologically sophisticated medical equipment as determined by the board.

Rule 4729:11-2-02 | Designated representative. (AMEND)

(A) A location licensed or registered as a HME provider shall have a designated representative at all times.

(B) When there is a change of designated representative, the state board of pharmacy shall be notified by the new designated representative within ten days of the effective date of the appointment of the new designated representative in a manner determined by the board.

(C) The designated representative shall be responsible for compliance with all applicable state and federal laws, regulations, and rules governing the provision of HME services.

(D) The designated representative shall be physically present at the licensed or registered location for a sufficient amount of time to provide supervision of the activities conducted by a HME services provider.

(E) Unless otherwise approved by the board, a HME services provider shall not have a designated representative who:

(1) 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.

(2) 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.

(3) Has committed an act that constitutes a ~~misdemeanor-theft~~ **disqualifying** offense, regardless of the jurisdiction in which the act was committed.

~~(4) Has committed an act that constitutes a felony, regardless of the jurisdiction in which the act was committed.~~

~~(54)~~ Is addicted to or abusing alcohol or drugs.

~~(6) Has committed an act that constitutes a misdemeanor involving dishonesty, fraud, or directly related to the provision of HME services, regardless of the jurisdiction in which the act was committed.~~

~~(75)~~ 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.

~~(86)~~ Has been excluded from participation in medicare or a state health care program.

(9) Has been the subject of any of the following by an accrediting agency or a licensing or certification agency of any state or jurisdiction:

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

(b) A disciplinary action that was based, in whole or in part, on the person's provision of home medical equipment services.

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

~~(11) Has committed an act of moral turpitude that constitutes a felony or misdemeanor in this state, regardless of the jurisdiction in which the act was committed.~~

Rule 4729:11-4-01 | Disciplinary Actions. (AMEND)

(A) The state board of pharmacy may, in accordance with Chapter 119. of the Revised Code, impose any one or more of the following sanctions on an applicant for a license or certificate of registration issued under Chapter 4752. of the Revised Code or a license or certificate of registration holder 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 or certificate of registration;

(2) Reprimand or place the license or certificate holder on probation;

(3) Impose a monetary penalty or forfeiture not to exceed in severity any fine designated under the Revised Code for a similar offense or not more than five thousand dollars if the acts committed are not classified as an offense by the Revised Code.

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

(1) Violation of any provision of this chapter or an order or rule of the board, as those provisions, orders, or rules are applicable to persons licensed or registered under this chapter.

(2) ~~Has a conviction for, judicial finding of guilt of, or plea of guilty to a disqualifying offenseA plea of guilty to or a judicial finding of guilt of a felony or a misdemeanor that involves dishonesty or is directly related to the provision of home medical equipment services.~~

(3) Making a material misstatement in furnishing information to the board.

(4) Professional incompetence.

(5) Being guilty of negligence or gross misconduct in providing home medical equipment services.

(6) Aiding, assisting, or willfully permitting another person to violate any provision of this chapter or an order or rule of the board, as those provisions, orders, or rules are applicable to persons licensed or registered under this chapter.

(7) Failing to provide information in response to a written request by the board.

(8) Engaging in conduct likely to deceive, defraud, or harm the public.

(9) Denial, revocation, suspension, or restriction of a license or certificate of registration to provide home medical equipment services, for any reason other than failure to renew, in another state or jurisdiction.

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(10) Directly or indirectly giving to or receiving from any person a fee, commission, rebate, or other form of compensation for services not rendered.

(11) Knowingly making or filing false records, reports, or billings in the course of providing home medical equipment services, including false records, reports, or billings prepared for or submitted to state and federal agencies or departments.

(12) Failing to comply with federal rules issued pursuant to the medicare program established under Title XVIII of the "Social Security Act," 49 Stat. 620(1935), 42 U.S.C. 1395, as amended, relating to operations, financial transactions, and general business practices of home medical services providers if applicable.

(13) Failing to satisfy the qualifications for licensure or registration under Chapter 4752. of the Revised Code or the rules of the board or ceasing to satisfy the qualifications after the license or registration is granted or renewed.

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

~~(15) Commission of an act of moral turpitude that constitutes a felony or misdemeanor, regardless of the jurisdiction in which the act was committed.~~

~~(16)~~ Commission of a crime of moral turpitude as defined in section **4776.10** of the Revised Code.

~~(17)~~ Violation of any restrictions placed by the state board of pharmacy on a license or registration or violating any terms of a board order issued against the licensee or registrant.

~~(18)~~ Exclusion from participation in medicare or a state health care program.

~~(19) Commission of an act that constitutes a misdemeanor theft offense, regardless of the jurisdiction in which the act was committed.~~

~~(20) Commission of an act that constitutes a misdemeanor involving dishonesty, fraud, or directly related to the provision of HME services, regardless of the jurisdiction in which the act was committed.~~

~~(21)~~ Employs a designated representative that does not meet the requirements set forth in rule **4729:11-2-02** of the Administrative Code.

~~(22)~~ Retaliating against or disciplining an employee for filing a complaint with a state 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 employees employer has authority to correct. As used in this paragraph, retaliation or discipline of an employee includes, but is not limited to, the following:

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- (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.

~~(2320)~~ The ownership of such entity has been transferred from a person whose license or registration issued in accordance with Chapter 4752. 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 the spouse or other family member.

~~(2421)~~ The ownership of such facility has been transferred from a licensee or registrant whose license or registration 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 the former owner or who allows the former owner to be present within the physical confines of the location to be licensed or registered.

~~(2522)~~ If applicable, failing to comply with the accreditation standards of a national accrediting body recognized pursuant to rule [4729:11-2-04](#) of the Administrative Code upon which a registration by the board has been granted.

~~(2623)~~ Unless otherwise approved by the board, a HME services provider knowingly employs a person who provides HME services to the public 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 ~~misdemeanor-theft~~disqualifying offense, regardless of the jurisdiction in which the act was committed.
- ~~(d) Has committed an act that constitutes a felony, regardless of the jurisdiction in which the act was committed.~~
- ~~(e)~~ Is addicted to or abusing alcohol or drugs.

~~(f) Has committed an act that constitutes a misdemeanor involving dishonesty, fraud, or directly related to the provision of HME services, regardless of the jurisdiction in which the act was committed~~

(ge) 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.

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

(ig) Has been the subject of any of the following by an accrediting agency or a licensing or certification agency of any state or jurisdiction:

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

(ii) A disciplinary action that was based, in whole or in part, on the person's provision of home medical equipment services.

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

~~(k) Has committed an act of moral turpitude that constitutes a felony or misdemeanor in this state, regardless of the jurisdiction in which the act was committed.~~

(C) On receiving notification, the board shall suspend or revoke any registration found to have the accreditation upon which the certificate of registration was issued revoked, suspended, or otherwise no longer valid.