Common Sense Initiative

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Business Impact Analysis

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

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

Executive Director or Director's Designee

Rule Number(s): 4729:5-1-01, 4729:6-1-01, 4729:1-5-03, 4729:2-2-05

Date of Submission for CSI Review: 2/8/2024

Public Comment Period End Date: 2/20/2024

Rule Type/Number of Rules:

New/___ rules
No Change/____ rules (FYR? ___)
Amended/_4__ rules (FYR? _N_)
Rescinded/____ rules (FYR?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 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.**
   4729:2-2-05 – Requires prior approval from the Board to obtain practical experience at a site other than a pharmacy licensed by the Board.

   b. ☒ **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**
   4729:5-1-01/4729:6-1-01 – An application that is deemed abandoned will result in a forfeiture of the licensure fee (fees are for a two-year license).

   c. ☒ **Requires specific expenditures or the report of information as a condition of compliance.**
   4729:1-5-03 – Requires submission of documentation to obtain a military continuing education extension or military continuing education credits.

   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.

Amend:

- 4729:5-1-01 - Definition section for the division of the OAC pertaining to terminal distributors of dangerous drugs. Replaces references to the director of licensing with the executive director or the director's designee.
- 4729:6-1-01 - Provides the definitions for the drug distributor division of the Administrative Code. Replaces references to the director of licensing with the executive Director or the director's designee.
- 4729:1-5-03: Provides extensions for pharmacist continuing education requirements for military members and their spouses. Replaces references to the director of licensing with the executive director or the director's designee.

- 4729:2-2-05: Provides the internship credit hours necessary for a pharmacy intern to sit for the pharmacist licensure examinations. Replaces references to the director of licensing with the executive director or the director's designee.

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

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

4. **Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?**
   If yes, please briefly explain the source and substance of the federal requirement.

   These rules do not implement a federal requirement.

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

   N/a

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

Section 4729.26 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules governing the practice of pharmacy. Without these regulations the Board would not be able to:

- Ensure clear standards for licensure and education requirements for pharmacists and pharmacy interns; and
- Provide definitions for the licensure and regulation of drug distributors and terminal distributors.

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.

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

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

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

    No input was provided by the stakeholders, as these rules just have minor updates to change all references from "director of licensing" to "executive director or the director's designee."

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?**
    Alternative regulations may include performance-based regulations, which define the required outcome, but do not dictate the process the regulated stakeholders must use to comply.

    As the modifications to the regulations are just to update "director of licensing" to "executive director or the director's designee", the State of Ohio Board of Pharmacy did not consider any regulatory alternatives.

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

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

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

The rules will be posted on the Board of Pharmacy's web site, information concerning the rules will be included in materials e-mailed to licensees, and notices will be sent to associations, individuals, and groups. Board of Pharmacy staff are also available via phone or email to answer

questions regarding implementation of the rules. In addition, the Board's compliance agents are trained to educate licensees on current and/or new regulations during on-site inspections.

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

Adverse Impact to Business

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

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

- Terminal distributors of dangerous drugs
- Distributors of dangerous drugs (wholesalers, manufacturers, 3PLs, outsourcing facilities, and repackagers)
- Pharmacists
- Pharmacy Interns

b. Quantify and identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance, etc.).
The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a representative business. Please include the source for your information/estimated impact.

- *4729:2-2-05 – Requires prior approval from the Board to obtain practical experience at a site other than a pharmacy licensed by the Board. To comply with the requirements of this rule, an applicant must obtain an advanced degree from an approved school of pharmacy or complete the required training hours. Additionally, an applicant who seeks to obtain practical experience at a site other than a pharmacy will have to submit a request to the Board. This request can take anywhere from 30-60 minutes to complete but does not have a fee associated with it.*
- *4729:5-1-01 – An application that is deemed abandoned will result in a forfeiture of the licensure fee (fees are for a two-year license). The fee for terminal distributors is $320 or $440 (depending on the drugs sold).*
- *4729:6-1-01 – An application that is deemed abandoned will result in a forfeiture of the licensure fee (fees are for a two-year license). The fee for drug distributors is $1,900 or $2,000 (depending on the drugs sold).*
- *4729:1-5-03 – Requires submission of documentation to obtain a military continuing education extension or military continuing education credits. The estimated time to submit these materials is estimated is approximately 5 minutes, as such documentation can be provided electronically.*

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

No, as the only changes to the rules are just to update "director of licensing" to "executive director or the director's designee".

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

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

Regulatory Flexibility

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

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

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

The 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.

Rule 4729:1-5-03 | Veteran and military family provisions related to continuing education. (AMEND)

(A) Extension of continuing education requirements.

(1) In accordance with section 5903.12 of the Revised Code, the state board of pharmacy shall grant extension periods and waivers for the completion of continuing education requirements for active duty veteran members and the spouses of active duty veterans. If a current pharmacist or their spouse is called to active duty for military service, the time period allowed for completion of any continuing education requirements will be extended by the amount of time that the pharmacist or the pharmacist's spouse was on active duty.

(2) Upon receiving the application and proper documentation, the board's ~~**director of licensing**~~ **executive director or the director's designee** shall extend the continuing education reporting period by an amount of time equal to the total number of months that the licensee or their spouse spent on active duty during the current reporting period. For purposes of this division, any portion of a month served on active duty shall be considered one full month.

(3) The licensee shall submit proper documentation certifying the active duty service and the length of that active duty service. Documentation required to obtain an extension or waiver pursuant to paragraph (A)(1) of this rule will be published on the state board of pharmacy's website: www.pharmacy.ohio.gov.

(B) Determining fulfillment of continuing education.

(1) If a pharmacist is a veteran, the state board of pharmacy shall consider relevant military education, training or service that has been completed by the license holder no more than two years prior to September fifteenth of the year in which a pharmacists license must be renewed when determining the fulfillment of any continuing education requirements.

(2) For the board to consider relevant education, training, or service completed by a pharmacist, the licensee shall submit a request for consideration and evidence or documentation of the education, training, or service to the ~~**director of licensing**~~ **executive director or the director's designee** at least sixty days prior to the required continuing education reporting period pursuant to rule 4729:1-5-02 of the Administrative Code.

Rule 4729:2-2-05 | Internship credit. (AMEND)

(A) The pharmacy internship credit requirement for the licensure examinations shall be deemed satisfactorily completed when the intern has either:

(1) Successfully graduated after December 31, 2006 with a doctor of pharmacy degree ("Pharm.D.") from a school of pharmacy approved by the "Accreditation Council for Pharmacy Education" (A.C.P.E.) and the state board of pharmacy; or

(2) Obtained a total of at least one thousand seven hundred and forty hours of documented supervised practical experience accepted by the state board of pharmacy which may include any hours:

(a) Documented on a practical experience affidavit pursuant to rule 4729:2-2-06 of the Administrative Code; or

(b) Worked in another state where the appropriate licensing agency submits to the board an official verification of the actual practical experience contact hours completed that meets the requirements in paragraph (A)(2) of this rule.

(B) No internship credit shall be granted by the board for practical experience until a foreign pharmacy graduate has established educational equivalency by obtaining a "Foreign Pharmacy Graduate Examination Commission" (FPGEC) certificate, and has established proficiency in spoken English by successfully completing the "Test of English as a Foreign Language, Internet-based test (TOEFL iBT)" pursuant to rule 4729:2-2-07 of the Administrative Code.

(C) Practical experience obtained pursuant to paragraph (A)(2)(a) of this rule may include up to five hundred hours of internship credit at a site other than a pharmacy licensed as a terminal distributor of dangerous drugs (e.g., manufacturing, research, consulting, drug information, and drug utilization review). To receive credit for such experience, a formal request must be submitted to the **~~director of licensing~~** **executive director or the director's designee** for approval prior to beginning the experience in these areas. The request shall include a detailed description of the internship with respect to time, place, duties, responsibilities, professional supervision, and the person supervising the experience. The request must be signed by both the intern and the person supervising the experience and returned with a completed statement of preceptor form. If approved by the board, the hours must be documented using a practical experience affidavit pursuant to rule 4729:2-2-06 of the Administrative Code.

(D) Internship credit may be denied for the practical experience accumulated when an intern is found in violation of section 4729.16 of the Revised Code or agency 4729 of the Administrative Code.

Rule 4729:5-1-01 | Definitions – terminal distributors of dangerous drugs. (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~~** **executive director or the director's designee** 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~~** **executive director or the director's designee** for a one-time, ninety-day extension.

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

(a) An administrative proceeding; or

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

(C) "Access to drug stock" includes not only physical access, but also any influence over the handling of dangerous drugs such as purchases, inventories, issuance of medical orders, etc. It does not include employees or contractors such as maintenance, janitorial, 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) "Addicted to or abusing alcohol or drugs" means the chronic and habitual use of alcohol or the use of a drug of abuse as defined in section 3719.011 of the Revised Code by an individual to the extent that the individual no longer can control the individual's use of alcohol or drugs, the individual is physically or psychologically dependent on alcohol or drugs, or the individual's use or abuse of alcohol or drugs endangers the health, safety, or welfare of the individual or others.

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

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

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

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

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

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

(G) "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.

(I) "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).

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

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

(L) "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.

(M) "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.

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

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

(P) "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.

(Q) "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.

(R) "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.

(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.

(T) "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.

(U) "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) "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.

(W) "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.

(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. The board may require that an individual whose license or registration has been suspended may not be employed by or work in a facility licensed by the state board of pharmacy to possess or distribute dangerous drugs during such period of suspension.

(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 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.

(AA) "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 4729:6-1-01 | Definitions – Distributors of dangerous drugs. (AMEND)

As used in this division:

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

(1) Wholesale distributors of dangerous drugs, including:

(a) Brokers; and

(b) Virtual wholesalers.

(2) Manufacturers of dangerous drugs.

(3) Outsourcing facilities.

(4) Third-party logistics providers.

(5) Repackagers of dangerous drugs.

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

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

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

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

(c) An applicant that fails to demonstrate compliance with appropriate security and control rules pursuant to this division of the Administrative Code. The applicant may submit a request to the

~~**director of licensing**~~ **executive director or the director's designee** for a one-time, ninety-day extension.

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

(a) An administrative proceeding; or

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

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

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

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

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

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

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

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

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

(G) "Broker" means any person engaged in the marketing, offering, or contracting for wholesale distribution and sale of dangerous drugs in or into Ohio who does not take physical possession of

the dangerous drugs. A broker shall be licensed as a wholesale distributor pursuant to section 4729.52 of the Revised Code with a broker classification.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(O)

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

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

(b) A magnetic card reader;

(c) A bar code reader;

(d) A biometric method;

(e) A proximity badge reader;

(f) A board approved system of randomly generated personal questions;

(g) A printout of every transaction that is verified and manually signed within a reasonable period of time by the individual who performed the action requiring positive identification. The printout must be maintained for three years and made readily retrievable; or

(h) Other effective methods for identifying individuals that have been approved by the board.

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

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

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

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

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

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

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

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

(2) Destruction or disposal.

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

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

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

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

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

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

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

(Z) "Virtual wholesaler" or "virtual wholesaler distributor" means any person engaged in wholesale distribution of dangerous drugs in or into Ohio who has title but does not take physical possession of the dangerous drugs. A virtual wholesale distributor shall be licensed as a

wholesale distributor pursuant to section 4729.52 of the Revised Code with a virtual wholesale distributor classification.

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

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