3/5/19

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 rules.

New

- 4729:2-1-01: Provides the definitions for the pharmacy intern division of the Administrative Code.
- 4729:1-1-01: Provides the definitions for the pharmacist division of the Administrative Code.

Amend:

- 4729:6-1-01: Provides the definitions for the drug distributor division of the Administrative Code.
- 4729:3-1-01: Provides the definitions for the pharmacy technician division of the Administrative Code.

Rescind:

- 4729:2-1-01: Provides the definitions for the pharmacy intern division of the Administrative Code. (Being replaced with new rule)

Comments on the proposed rules will be accepted until close of business on **March 21, 2019**. Please send all comments to the following email address: **Ali.Simon@pharmacy.ohio.gov**

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

CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: State of Ohio Board of Pharmacy

Regulation/Package Title: Definitions

Rule Number(s):

New:

- 4729:2-1-01; 4729:1-1-01

Amend:

- 4729:3-1-01; 4729:6-1-01

Rescinds:

- 4729:2-1-01

Date: 3/5/2019

Rule Type:

New	5-Year Review
Amended	Rescinded

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent

1. **Please briefly describe the draft regulation in plain language.**

New

- 4729:2-1-01: Provides the definitions for the pharmacy intern division of the Administrative Code.
- 4729:1-1-01: Provides the definitions for the pharmacist division of the Administrative Code.

Amend:

- 4729:6-1-01: Provides the definitions for the drug distributor division of the Administrative Code.
- 4729:3-1-01: Provides the definitions for the pharmacy technician division of the Administrative Code.

Rescind:

- 4729:2-1-01: Provides the definitions for the pharmacy intern division of the Administrative Code. (Being replaced with new rule)

2. Please list the Ohio statute authorizing the Agency to adopt this regulation.

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

3. 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?

The rules do not implement a federal requirement.

4. 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.

5. 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)?

The purpose of these rules is to provide standardized definitions for all entities licensed under Chapter 4729. of the Revised Code.

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

The success of these 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 rule.

Development of the Regulation

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

This rule package posted to the Board's website for public comment and disseminated to the Board's external stakeholder list. Prior to filing with CSI, the rule was reviewed and approved by the Board of Pharmacy.

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

The Board received feedback from the National Association of Chain Drug Stores and CVS Health to correct the definition of positive identification to permit the use of end of day reports. This omission has been corrected.

9. **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.

10. **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 regulations are essential to protecting the public's safety by ensuring uniform definitions, the State of Ohio Board of Pharmacy did not consider any regulatory alternatives.

11. **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. It is the Board's responsibility to ensure uniform procedures for licensure and the practice of pharmacy.

12. 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.

13. 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 and feedback from the Board's legal department for every citation submitted.

Adverse Impact to Business

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

a. Identify the scope of the impacted business community;

The rule package impacts the following:

- Ohio licensed drug distributors; terminal distributors; pharmacy interns; pharmacy technicians; and pharmacists.

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

Each rule includes a provision regarding abandoned applications. An abandoned application is 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.

c. Quantify the expected adverse impact from the regulation.

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)

15. 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 without the regulations the Board would not be able to provide uniform definitions for persons regulated under Chapter 4729. of the Revised Code.

Regulatory Flexibility

16. 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.

17. 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. However, any failure to not meet and maintain accreditation standards is not considered a paperwork error but a quality assurance issue by the licensee that is necessary for the protection of the public.

18. 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 and host regional meetings to discuss changes to Ohio laws and rules. Additionally, staff are trained to educate licensees on compliance with all Board of Pharmacy rules and regulations.

4729:6-1-01 – Definitions – Drug Distributors (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 ~~requirements~~ 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 or registration, 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:

(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.

(~~E~~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.~~A compounded dangerous drug if it exceeds the beyond use date as indicated in United States pharmacopeia chapters 795 and 797, USP 41 - NF 36, or any official supplement thereto (5/1/2018).~~

(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~~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 a wholesale distributor pursuant to section 4729.52 of the Revised Code with a broker classification.

(~~G~~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.

(~~H~~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.

(~~H~~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 360eee (11/27/2013); and

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

(~~J~~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.

(~~K~~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 as 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.

~~(L) "Place on probation," as used in Chapter 4729. of the Revised Code, means to take action against a license or registration suspending some or all of the sanctions imposed by the board against that license or registration. The terms of the probation shall state the period of time covered by the probation and may include other conditions as determined by the state board of pharmacy.~~

(~~M~~O)

(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 also include a secure means of identification such as 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.

~~"Positive identification" means a method of identifying an individual who disposes of or destroys a dangerous drug in accordance with this division.~~

~~(1) A method of positive identification may not rely solely on the use of a private personal identifier such as a password, but must also include a secure means of identification such as 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; or~~

~~(g) 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.~~

(~~N~~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.

~~O~~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 ~~any~~ all requirements established by the board in rule and as may be set forth in the person's board order.

(~~P~~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.

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

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

(2) Destruction or disposal.

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

(~~S~~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 ~~wasting~~ 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.

(~~T~~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.

(~~U~~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.

(X~~V~~) "Summary suspension" means to take immediate action against a license or registration 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.

(~~W~~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.

(~~X~~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.

(~~Y~~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.

(~~Z~~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.

4729:1-1-01 – Definitions – Pharmacists (NEW)

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.

(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) "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.

(E) "Compounding" has the same meaning as defined in division (C) of section 4729.01 of the Revised Code.

(F) "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.

(G) "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.

(H) "Good moral character" pursuant to sections 4729.08 and 4729.09 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.

(I) "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.

(J) "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.

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

(L) "Place on probation," means to take action against a license, for a period of time as 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.

(M)

(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 also include a secure means of identification such as 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.

(N) "Practice of pharmacy" has the same meaning as in division (B) of section 4729.01 of the Revised Code.

(O) "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.

(P) "Responsible person" has the same meaning as defined in agency 4729. of the Administrative Code.

(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) "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.

(S) "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.

(T) "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.

(U) "Summary suspension" means to take immediate action against a license or registration 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.

(V) "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.

4729:2-1-01 – Definitions – Pharmacy Interns (NEW) (RESCIND 4729:2-1-01)

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.

(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) "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.

(E) "Compounding" has the same meaning as defined in division (C) of section 4729.01 of the Revised Code.

(F) "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.

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

(H) "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.

(I) "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;

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

(J) "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.

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

(L) "Pharmacy internship" means the supervised practical experience required for licensure as a pharmacist. The purpose of the pharmacy internship program is to provide those individuals, who intend to become licensed pharmacists, with the knowledge and practical experience necessary for functioning competently and effectively upon licensure.

(L) "Place on probation," means to take action against a license, for a period of time as 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.

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

(N)

(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 also include a secure means of identification such as 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; or

(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.

(O) "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.

(P) "Practice of pharmacy" has the same meaning as in division (B) of section 4729.01 of the Revised Code.

(Q) "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) "Responsible person" has the same meaning as defined pursuant to agency 4729. of the Administrative Code.

(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.

(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) "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.

(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) "Statement of preceptor" is a form provided by the state board of pharmacy that identifies the preceptor and internship site for a pharmacy intern.

(X) "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.

(Y) "Summary suspension" means to take immediate action against a license or registration 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.

(Z) "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.

4729:3-1-01 – Definitions – Pharmacy Technicians. (AMEND)

As used in this division ~~4729:3 of the Administrative Code~~:

(A) "Abandoned application" means an application for a registration 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 registration, submit the required fee and comply with the registration 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) "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.

(~~B~~E) "Certified pharmacy technician" means a person who:

(1) Has completed an approved training program pursuant to rule 4729:3-3-02 of the Administrative Code; ~~or complies with the education and training requirements in division (E)(2) of section 4729.90 of the Revised Code;~~

(2) Is registered with the state board of pharmacy;

(3) Practices in this state in accordance with rule 4729:3-3-04 of the Administrative Code; and

(4) Maintains a current pharmacy technician certification from an organization that has been recognized by the board.

(~~C~~F) "Compounding" has the same meaning as defined in division (C) of section 4729.01 of the Revised Code.

(~~D~~G) "Current pharmacy technician certification from an organization that has been recognized by the board" pursuant to division (B)(2)(d) of section 4729.90 of the Revised Code means either:

(1) The ExCPT certification provided by the national healthcareer association; or

(2) The pharmacy technician certification board (PTCB) certification.

(~~E~~H) ~~"supervision" means that a licensed pharmacist is:~~ "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 a pharmacy technician trainee, registered pharmacy technician or certified pharmacy technician shall:

(1) Be readily available to answer questions of the technician or trainee;

(2) Make appropriate in-process and end-process verifications of the activities of the technician or trainee; and

(3) Be fully responsible for the practice of the technician or trainee.

~~(1) Physically present in a facility licensed as a terminal distributor of dangerous drugs, licensed outsourcing facility, or in the area where the practice of pharmacy is occurring, and providing personal review and approval of all professional activities;~~

~~(2) Readily available to answer questions of the pharmacy technician trainee, registered pharmacy technician or certified pharmacy technician;~~

~~(3) Making appropriate in-process and end-process verifications of the activities of the pharmacy technician trainee, registered pharmacy technician or certified pharmacy technician; and~~

~~(4) Fully responsible for the practice of the pharmacy technician trainee, registered pharmacy technician or certified pharmacy technician.~~

(I) "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.

(~~F~~J) "Entering information into and retrieving information from a database or patient profile" as used in section 4729.91 of the Revised Code means to enter new or refill prescription information into a database or patient profile.

(~~G~~K) "Good moral character" pursuant to ~~division (B)(1)(c) of~~ section 4729.90 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.

~~(H) "Hazardous drug" means any dangerous drug identified by at least one of the following criteria:~~

~~(1) Carcinogenicity, teratogenicity, or developmental toxicity;~~

~~(2) Reproductive toxicity in humans;~~

~~(3) Organ toxicity at low dose in humans or animals; or~~

~~(4) Genotoxicity or new drugs that mimic existing hazardous drugs in structure or toxicity.~~

(~~H~~L) "In good standing" means a pharmacist to which all the following apply:

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

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

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

(~~J~~M) "Pharmacy technician trainee" means a person who:

(1) Intends to enroll or is enrolled in an approved training program pursuant to rule 4729:3-3-02 of the Administrative Code to obtain a registration as a registered or certified pharmacy technician;

(2) Is registered as a pharmacy technician trainee with the state board of pharmacy; and

(3) Practices in this state in accordance with rule 4729:3-3-01 of the Administrative Code.

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

(O) "Place on probation," means to take action against a license, for a period of time as 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.

(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 also include a secure means of identification such as 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; or

(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.

(~~K~~Q) "Refill authorization" means authorization from a prescriber or prescriber's agent for a new non-controlled prescription renewal, provided that the prescription remains unchanged.

~~(1) As used in this paragraph:~~

~~(a) "Prescription refill" means the dispensing of dangerous drugs pursuant to a prescriber's authorization provided on the original prescription; and~~

~~(b) "Prescription renewal" means the dispensing of dangerous drugs pursuant to a prescriber's authorization to fill an existing prescription that has no refills remaining.~~

(R) "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.

(~~L~~S) "Registered pharmacy technician" means a person who:

(1) Has completed an approved training program pursuant to rule 4729:3-3-02 of the Administrative Code; ~~or complies with the education and training requirements in division (E)(1) of section 4729.90 of the Revised Code;~~

(2) Is registered with the state board of pharmacy; and

(3) Practices in this state in accordance with rule 4729:3-3-03 of the Administrative Code.

(~~M~~T) "Responsible person" has the same meaning as defined in agency 4729 of the Administrative Code. ~~and who is 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.~~

(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.

(~~N~~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.

(~~O~~W)

(1) "Support personnel" means the following:

(a) An individual employed or performing contracted services at a location licensed as a terminal distributor of dangerous drugs, trained to perform clerical duties associated with the practice of pharmacy, including pricing, cashiering, drug purchasing, delivering, scheduling deliveries, answering non-professional telephone inquiries, transportation of dispensed medications within a hospital, documenting and processing third-party billing information for reimbursement or any other activity as determined by the board.

(b) An individual contracted by a terminal distributor of dangerous drugs to perform drug inventories.

(2) Except for those responsible for the delivery of dangerous drugs, support personnel shall not have unsupervised access to dangerous drugs.

(3) Except as provided in paragraphs (~~O~~W)(4) and (~~O~~W)(5) of this rule or unless otherwise authorized by the board in agency 4729, support personnel shall not perform the tasks of a pharmacist, pharmacy intern, certified pharmacy technician, registered pharmacy technician, or pharmacy technician trainee.

(4) Support personnel may have access to or retrieve information from patient records, including a database or patient profile to perform clerical duties associated with the practice of pharmacy. Support personnel shall not enter prescription information into a patient profile.

(5) Support personnel may perform the following:

(a) Transporting dangerous drugs from a loading dock, warehouse or other area that receives shipments from a licensed wholesaler; and

(b) Stocking and retrieving from inventory non-controlled dangerous drugs that are not dispensed by the pharmacy.

(6) The terminal distributor of dangerous drugs shall be responsible for ensuring all support personnel comply with state and federal requirements to ensure the confidentiality of patient health records.

(7) Support personnel shall not serve as a pharmacist's delegate pursuant to section 4729.80 of the Revised Code.

(8) Support personnel are not required to obtain licensure or registration under Chapter 4729. of the Revised Code.

~~(P) "United States Pharmacopeia Chapter <795>" or "USP <795>" means United States Pharmacopeia Chapter <795>, USP 40-NF 35, or any official supplement thereto (10/2/2017).~~

~~(Q) "United States Pharmacopeia Chapter <797>" or "USP <797>" means United States Pharmacopeia Chapter <797>, USP 40-NF 35, or any official supplement thereto (10/2/2017).~~

(X) "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.

(Y) "Summary suspension" means to take immediate action against a license or registration 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.

(~~R~~Z) "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.