October 2025 – Rules and Resolutions

Resolutions

To Rescind (Effective 11/3/2025):

To ensure streamlined vaccine administration, the State of Ohio Board of Pharmacy temporarily authorizes records of COVID-19 vaccine administration by pharmacy personnel (pharmacists, interns, technicians) to comprise the following:

Records of COVID-19 vaccine administration by pharmacy personnel shall contain the name, strength, dosage form, and quantity of the vaccine administered, the name and date of birth of the person to whom or for whose use the vaccine was administered, the date of administration, and the identification of the pharmacy personnel administering the drug. This resolution does not supersede any record keeping requirements from the Ohio Department of Health or any federal agency.

This resolution is being issued in accordance with a Board resolution adopted on May 5, 2020. This resolution shall remain in effect until rescinded by the Board.

To maximize the safe administration of COVID-19 vaccines, the State of Ohio Board of Pharmacy temporarily expands the pharmacy intern supervision requirements in OAC 4729:2-1-01 (O)(4) as follows:

Pursuant to OAC 4729:2-1-01, the Board authorizes a pharmacist to supervise up to six pharmacy interns providing immunizations. The Board hereby expands the number of pharmacy interns providing COVID-19 vaccines a pharmacist can supervise as follows:

- *A pharmacist may supervise between 7-12 pharmacy interns at once if a nurse licensed or registered under Chapter 4723. of the Revised Code or an Ohio EMS certificate holder*

practicing in accordance with the vaccine administration guidance from the Ohio EMS Board is present and assisting with the administration of COVID-19 vaccines.

- *A pharmacist may supervise between 13-18 pharmacy interns at once if two or more nurses licensed or registered under Chapter 4723. of the Revised Code or two or more Ohio EMS certificate holders practicing in accordance with the vaccine administration guidance from the Ohio EMS Board are present and assisting with the administration of COVID-19 vaccines.*

  This resolution is being issued in accordance with a Board resolution adopted on May 5, 2020. This resolution shall remain in effect until rescinded by the Board.

In order to ensure uniform vaccination requirements, the State of Ohio Board of Pharmacy has adopted the following resolution regarding the informed consent requirements set forth in OAC 4729:1-3-02 and 4729:5-5-04 of the Administrative Code. This resolution is being issued in accordance with a Board resolution adopted on May 5, 2020.

In lieu of the informed consent requirement, pharmacy personnel may adhere to the "Information for Recipients" guidance issued by the FDA for drug approved via Emergency Use Authorization (EUA) (see page 24 of the following document: https://www.fda.gov/media/97321/download). Please note that this resolution does not replace or supersede any patient education requirements set forth by any other federal or state agency.

Resolution (Adopted 11.2.2020) – Updated 3.16.2021 To promote improved access to vaccinations during the COVID-19 pandemic, the Ohio Board of Pharmacy hereby authorizes a long-term care facility or other institutional facility, as defined under agency 4729 of the Ohio Administrative Code, to possess and administer COVID-19 or other vaccines to patients and staff under the terminal distributor of dangerous drugs license issued to the facility's servicing pharmacy (e.g., contingency stock license). This resolution shall also permit the use of the servicing pharmacy's contingency stock license to maintain dangerous drugs used to treat adverse reactions to vaccines stored at the facility.

Rules

For filing with JCARR:

4729:5-3-24 - Dispensing Dangerous Drugs to an Alternate Location. (NEW)

(D) A terminal distributor of dangerous drugs that serves as an alternate location shall comply with the following:

…

(4) The location acknowledges that any patient specific dangerous drug dispensed by a pharmacy is the property of that patient, except that a dangerous drug that is not distributed or administered to that patient within six months **of dispensation** shall be deemed abandoned. A terminal distributor of dangerous drugs may do any of the following with an abandoned drug:

…

4729:1-3-03 - Administration of dangerous drugs by injection. (AMEND)

(C) Each time a pharmacist administers a drug pursuant to this rule, the pharmacist shall comply with all the following:

(4) Permission obtained in accordance with this paragraph shall also include notification of the patient's right to request a private area **or chaperone** in accordance with paragraph (J) of this rule.

4729:5-18-01 - Definitions - remote dispensing pharmacies. (NEW)

(B) "Telepharmacy system" means a system that monitors the dispensing of drugs and provides for related drug utilization review and patient counseling services by an electronic method~~,~~ that complies with the requirements of ~~**Chapter**~~ **rule** 4729:5-18-06 **of the Administrative Code**. The telepharmacy system shall include the following technologies:

…

(C) "Surveillance system" means a system providing continuous video footage of the remote dispensing pharmacy that is recorded and stored for at least sixty days, and **~~that~~** complies with the requirements of **~~Chapter~~ rule** 4729:5-18-07 **of the Administrative Code**.

(F) "Responsible person" means the same as in **~~Chapter~~ rule** 4729:5-2-01 of the Administrative Code.

4729:5-18-02 - Licensure of remote dispensing pharmacies. (NEW)

…

(C) Remote dispensing pharmacies shall have a pharmacist designated as the responsible person in accordance with **~~Chapter~~ rule** 4729:5-2-01 of the Administrative Code.

(D) The responsible person designated for a remote dispensing pharmacy shall be the same responsible person **~~as is~~** designated for the supervising pharmacy. The responsible person may, but is not required to, act as a supervising pharmacist.

4729:5-18-03 - Demonstration of need. (NEW)

(E) During the sixty-day period that begins on the date that the board sends the electronic notice, a pharmacy currently operating in the state may submit a request to the board for approval ~~as a location for operation of~~ to operate a remote dispensing pharmacy.

(F) At the board's next regularly scheduled meeting that occurs on or after the date that is ninety days after the electronic notices are sent, the board shall review all the requests received and make its determination of whether any should be approved. As part of the board's determination, ~~the board~~ it shall consider the following:

…

(2) The geographic proximity of ~~a~~ the supervising pharmacy to ~~a~~ the proposed remote dispensing pharmacy;

(3) The supervising pharmacy has not been disciplined for a violation of rule 4729:5- 5-02 and all subsequent rules thereunder within the preceding twelve months;

(4) The supervising pharmacy has not been disciplined for any ~~significant~~ theft or significant loss of dangerous drugs within the preceding twelve months; and

4729:5-18-04 - Operation of a remote dispensing pharmacy. (NEW)

(A) ~~The~~ **A** remote dispensing pharmacy ~~must~~ **shall** be located within this state in a building that is zoned for commercial or industrial use**. A remote dispensing pharmacy shall not operate** ~~and not~~ out of a personal residence.

(B) Remote dispensing pharmacies shall display a sign at the point of sale indicating that the facility is a remote dispensing pharmacy~~, that the facility is~~ under continuous video surveillance~~,~~ and that the video is recorded and retained.

(C) ~~The~~ **A** supervising pharmacy shall be exclusively responsible for the operation of ~~the~~ **a** remote dispensing pharmacy and its employees.

(D) There shall be one supervising pharmacist at all times when the remote dispensing pharmacy is operational**.** ~~who~~ **The supervising pharmacist** shall be located in this state when serving as a supervising pharmacist.

(E) ~~The~~ **A** supervising pharmacist shall not be located more than fifty miles from a remote dispensing pharmacy under ~~that~~ **the** pharmacist's supervision.

(F) (F) To avoid disruption in pharmacy services, the supervising pharmacy shall have a process in place to ensure there is a pharmacist who meets the training requirements of this chapter if the regularly scheduled supervising pharmacist is unable to provide supervision ~~in accordance with this chapter~~.

(G) The remote dispensing pharmacy shall be **physically** staffed by at least two certified pharmacy technicians and/or pharmacy interns ~~physically present in the remote dispensing pharmacy~~ for the pharmacy to be open to the public.

(H) **Unless a pharmacist is located on-site,** there shall be no more than a total of three certified pharmacy technicians and/or pharmacy interns working within a remote dispensing pharmacy ~~location unless a pharmacist is physically located on-site~~.

(I) Unless approved by the board, a supervising pharmacist shall not simultaneously oversee the activities of more than one remote dispensing pharmacy. The board may consider

expanding this limit ~~**to up**~~ to two remote dispensing pharmacies per one supervising pharmacist. For the board to consider a waiver of this limitation, the supervising pharmacy shall submit documentation, in a manner determined by the ~~**Board**~~ board, that sufficiently demonstrates the following:

…

(J) Certified pharmacy technicians, pharmacy interns, and pharmacists shall complete a training program to ensure that the telepharmacy system can be operated in a safe and effective manner. Training documentation shall be maintained at, or accessible by, the remote dispensing pharmacy and be produced for review immediately upon request of agent, officer, or inspector of the board. Remote dispensing pharmacies ~~**must**~~ **shall** conduct additional training for their employees if any of the following occurs:

…

(K) Unless approved by the board, a remote dispensing pharmacy shall not dispense ~~**drugs pursuant to Chapter 4729:5-5 of the Administrative Code**~~ more than an average of one hundred fifty prescriptions per day during a ninety-day period. For the board to consider a waiver of this limitation, a remote dispensing pharmacy shall submit documentation, in a manner determined by the board, that sufficiently demonstrates the following:

…

(2) It is not economically feasible for the remote dispensing pharmacy to convert to an outpatient pharmacy as defined by Chapter 4729:5-5-~~**01**~~ of the Administrative Code.

(M) In the event that the telepharmacy system is not in operation, the supervising pharmacist ~~**must**~~ **shall** be physically located on-site to dispense prescriptions.

4729:5-18-05 - Personnel requirements. (NEW)

…

(C) ~~**In serving as a supervising pharmacist, the**~~ **The** supervising pharmacist shall do all of the following:

(1) Supervise no more than three certified pharmacy technicians and**/or** pharmacy interns per remote dispensing pharmacy.

(2) Be in full and actual charge of the remote dispensing pharmacy by using the pharmacy's telepharmacy ~~**system**~~ and ~~**by using a**~~ surveillance system ~~**that meets standards established in this Chapter of the Administrative Code**~~.

(3) Through the telepharmacy system and surveillance system, oversee the pharmacy interns and**/or** certified pharmacy technicians who are staffing the remote dispensing pharmacy.

(4) Verify each prescription and drug dispensed pursuant to the prescription ~~**before the drug leaves the remote dispensing pharmacy**~~ and provide ~~**the**~~ verification through visual review**,** ~~**and the use of**~~ barcoding**,** and any other technology as specified in rule 4729:5-18-06 of the Administrative Code.

(a) All barcodes shall be scanned, and not manually typed, into the system.

(b) Documentation of verification shall capture the positive identification of the supervising pharmacist.

…

(D) Before a certified pharmacy technician may work in a remote dispensing pharmacy, the certified pharmacy technician shall:

(2) Hold a national certification as a pharmacy technician from an organization ~~**approved**~~ **recognized** by the board~~**,**~~ ~~**in accordance with**~~ **as defined in** rule 4729:3-1-01 of the Administrative Code.

…

(E) The supervising pharmacy ~~must~~ **shall** attest that all certified pharmacy technicians meet the requirements of paragraph (D) of this rule~~., and a~~ **A** record of such attestation ~~must~~ **shall** ~~be immediately retrievable at the remote dispensing pharmacy.~~ **be maintained at, or accessible by, the remote dispensing pharmacy and be produced for review immediately upon request of agent, officer, or inspector of the board.**

…

(F) Before a pharmacy intern may work in a remote dispensing pharmacy, the pharmacy intern shall:

(3) Only five hundred hours of experience earned as part of the intern's introductory pharmacy practice experience or advanced pharmacy practice experience may count towards the ~~one thousand hour~~ **hourly** requirement**s** ~~as~~ described in paragraph (F)(2) of this rule.

(G) The supervising pharmacy ~~must~~ **shall** attest that all working pharmacy interns meet the requirements of paragraph (F) of this rule~~., and a~~ **A** record of such attestation ~~must~~ **shall** ~~be immediately retrievable at the remote dispensing pharmacy.~~ **be maintained at, or accessible by, the remote dispensing pharmacy and be produced for review immediately upon request of agent, officer, or inspector of the board.**

4729:5-18-06 - Technology requirements for a telepharmacy system. (NEW)

(A) There shall be a fully functioning telepharmacy system in the remote dispensing pharmacy**.** ~~**that is**~~ **The system shall always be** operational ~~**at all times**~~ **when** ~~**that**~~ pharmacy personnel are working in the pharmacy.

…

~~**(2) All pharmacy personnel must complete a training program on proper use of the telepharmacy system and documentation of this completion must be maintained and immediately retrievable at the remote dispensing pharmacy.**~~

(NOTE: This is already required under 4729:5-18-04)

(~~**3**~~ **2**) In the event that the telepharmacy system is not functional for more than one-business day, the supervising pharmacist or another pharmacist employed by the supervising pharmacy shall be required to be physically on-site to allow for prescriptions to be dispensed during **the** normal business hours of the remote dispensing pharmacy

(**4 5**) In the event of a temporary telepharmacy system outage of less than the duration of one business day, the supervising pharmacist may direct the certified pharmacy technicians and/or pharmacy interns at the remote dispensing pharmacy to complete activities not requiring pharmacist verification or use of the telepharmacy system. Staff at the remote dispensing pharmacy may continue to sell prescriptions that have already been **verified and** dispensed by the pharmacist. In this case, patients shall be provided with a phone number where they can obtain patient counseling in accordance with rule 4729:5-5-09 of the Administrative Code.

(**5 6**) The telepharmacy system shall comply with all the following:

(a) Chapter 3798. of the Revised Code;

(b) 42 U.S.C. 1320d et. seq. **(9/5/2025)**; and

(c) 45 C.F.R. parts 160, 162, and 164 **(9/5/2025)** for individually identifiable health information (HIPAA).

(B) The telepharmacy system shall, at a minimum, have high-definition image resolution with variable viewing options to accurately and safely dispense a dangerous drug or drug device and~~,~~ sufficient data retention capabilities to investigate any quality related events.

(1) The telepharmacy system must produce images that are high definition ~~in that the~~ **with** image resolution ~~is~~ **of** at least 300 pixels per inch.

(4) Images associated with the verification **and dispensing** of ~~the~~ **a** prescription **or device** ~~will~~ **shall** be retained and become part of the patient's profile and maintained for one year.

(C) There shall be a working computer link, video link**,** and audio link to the supervising pharmacist ~~at a supervising pharmacy~~ whenever the remote dispensing pharmacy is open to the public. The required technology must allow the supervising pharmacist to provide the personal assistance, direction, and approval needed to verify and ensure remote tasks are safely and properly performed.

(D) Written prescriptions presented to the remote dispensing pharmacy shall be scanned into the telepharmacy system**.** ~~to ensure initial dispensing and each refill and the~~ **The** original prescription ~~may~~ **must be able to be** viewed at both the remote dispensing pharmacy and the supervising pharmacy.

…

(E) Certified pharmacy technicians and/or pharmacy interns shall use barcoding technology when filling prescriptions at ~~the~~ **a** remote dispensing pharmacy to ensure the accuracy of prescriptions dispensed in accordance with this chapter. Barcodes shall be scanned, and not manually typed, into the system.

(F) All records of prescriptions dispensed including the records of the actions performed through the telepharmacy system shall be maintained at the remote dispensing pharmacy**, in a readily retrievable manner,** ~~and shall be maintained~~ for three years after the ~~filling~~ **dispensation** of the prescription.

4729:5-18-07 - Security requirements for a remote dispensing pharmacy. (NEW)

(B) The surveillance system must allow the supervising pharmacist to determine who has accessed the pharmacy. A supervising pharmacist shall complete a training program on proper use of the surveillance system and documentation of this completion must be maintained **at, or accessible by, the remote dispensing pharmacy and be produced for review immediately upon request of agent, officer, or inspector of the board.** ~~**and immediately retrievable at the remote dispensing pharmacy.**~~

(E) Pharmacy technicians and pharmacy interns who meet the qualifications of rule 4729:5-18-05 **of the Administrative Code** and are employed by the remote dispensing pharmacy may only access the pharmacy if the supervising pharmacist is providing ~~**regular**~~ supervision via the pharmacy's surveillance system.

(G) All schedule II controlled substance dangerous drugs shall be stored in a securely locked, substantially constructed cabinet or safe and shall not be dispersed through**out** the stock of dangerous drugs **maintained by the pharmacy**. The cabinet or safe shall remain locked and secured when not in use. Schedule III through V controlled substance dangerous drugs may be stored with Schedule II controlled substance dangerous drugs.

(H) A remote dispensing pharmacy shall be secured by both:

(1) A physical barrier (i.e., barricade) with suitable locks approved by the board. Except for extraordinary circumstances beyond the pharmacy's control, a pharmacy shall notify the board**, in a manner determined by the board,** of any installation or modification to a physical barrier prior to implementation.

(2) An alarm system approved by the board that is monitored by a central station for control and can detect unauthorized access to the pharmacy. The alarm system shall be tested on a biannual basis. The pharmacy or the entity that manages security for the pharmacy shall maintain testing records for three years from the date of testing and shall make such records readily retrievable. The pharmacy shall be responsible for obtaining testing records if such records are maintained by a third-party. Except for extraordinary circumstances beyond the pharmacy's control, a pharmacy shall notify the board**, in a manner determined by the board,** of any installation or modification to an alarm system prior to implementation.

…

(M) New or refill prescription**s** ~~**orders**~~ may be deposited into a secure area within the building where the pharmacy is located when the pharmacy is closed.

4729:7-1-01 Compounding references.

As used in this division and in agency 4729 of the Administrative Code:

(A) "The national institute for occupational safety and health's list of antineoplastic and other hazardous drugs in healthcare settings" means publication number **2025-103** ~~**2016-161 or any official supplement thereto**~~ (~~**March 10, 2020**~~ **December 2024**).

…

(E) The board may grant **an existing licensee** a temporary extension to the requirements to comply with the standards listed in paragraphs (B) and (C) of this rule ~~**to an existing licensee**~~ if ~~**a**~~ **the** licensee can demonstrate all **of** the following:

(1) The licensee was compliant with the standards in effect immediately prior to the effective date of this rule;
(2) Significant hardship in meeting the standards; and
(3) Sufficient progress towards compliance with the standards.

For Filing with CSI and JCARR:

Rule 4729:5-3-19 | Naloxone for emergency use and distribution via automated mechanisms. (RESCIND – DEFER BACK TO REQUIREMENTS IN ORC 3715.50)

(A) As used in this rule, "tamper-evident" means a package, storage container or other physical barrier that is sealed or secured in such a way that access to the drugs stored within is not possible without leaving visible proof that such access has been attempted or made.

(B) In accordance with section 4729.515 of the Revised Code, a terminal distributor of dangerous drugs may acquire and maintain a supply of naloxone for use in emergency situations and for distribution through an automated mechanism. The naloxone may be maintained at a location other than the location licensed as a terminal distributor of dangerous drugs.

(C) In the case of naloxone for use in emergency situations, a terminal distributor of dangerous drugs shall do all of the following:

(1) Provide written materials regarding the emergency administration of naloxone to any individual who accesses the naloxone, to include:

(a) Specific instruction to summon emergency services pursuant to division (D)(2) of section 4729.515 of the Revised Code.

(b) Procedures for administering naloxone contained within the kit, including the possible administration of multiple doses.

(c) Performing rescue breathing and the use of a face shield or other rescue breathing barrier device, which shall be provided with the naloxone.

(d) Proper method for placing an individual into the recovery position.

(2) Specify a process to be used to notify the terminal distributor that the naloxone has been accessed within a reasonable time of its being accessed, which may include any of the following:

(a) Documented checks of the emergency naloxone and its required components, to be conducted at least every thirty days, by an employee of the terminal distributor of dangerous drugs. The terminal distributor shall include a telephone number where persons can report that the emergency naloxone has been used and needs replenishment.

(b) An automated alert that notifies the terminal distributor when the emergency naloxone is accessed.

(c) Any other method approved by the board's executive director or the director's designee.

(3) Except in instances where naloxone is not commercially available, including the absence of a manufacturer for the drug or the lack of a readily available supply of the drug from a manufacturer or wholesaler, a terminal distributor of dangerous drugs shall replace any naloxone and, if missing or used, any required components (instructions, rescue breathing barrier device, etc.) no later than forty-eight hours following notification that naloxone has been accessed in accordance with paragraph (C)(2) of this rule.

(4) Maintain the naloxone in accordance with the manufacturer's or distributor's instructions.

(a) All naloxone maintained for emergency use in accordance with this paragraph shall be sealed in a tamper-evident manner to ensure the integrity of the drug.

(b) Any naloxone that shows sign of tampering or adulteration shall be immediately removed by the terminal distributor of dangerous drugs and replaced within forty-eight hours of discovering the naloxone has been tampered with or is adulterated.

(c) A terminal distributor shall develop and implement a policy to ensure that naloxone that exceeds its manufacturer's expiration date is removed and properly disposed.

(5) A terminal distributor maintaining naloxone in accordance with this paragraph shall:

(a) Maintain a complete list that includes the address and description of the location (e.g. first floor hallway, second floor conference room, etc.) of where the terminal distributor maintains the naloxone for emergency use. The list shall be immediately available for inspection upon request of an employee of the board.

(b) Keep a record of the naloxone maintained for emergency use that includes the name, strength, dosage form, national drug code and expiration date. Records shall be readily retrievable and maintained for a period of three years.

(c) Ensure the naloxone is maintained in a container or device that is securely fastened to a permanent structure and is clearly marked to indicate naloxone is available for emergency use.

(6) The requirements of this paragraph shall not apply to a service entity that maintains naloxone for emergency administration in accordance section 4729.514 of the Revised Code.

(D) In the case of naloxone for distribution through an automated mechanism, a terminal distributor of dangerous drugs shall do all the following:

(1) Ensure the mechanism is securely fastened to a permanent structure or is of an appropriate size and weight to reasonably prevent it from being removed from its intended location.

(2) Develop a process to be used to monitor and replenish the inventory of naloxone maintained in the automated mechanism, which may include any of the following:

(a) Documented checks of the mechanism, to be conducted at least every thirty days, by an employee of the terminal distributor of dangerous drugs.

(b) An electronic system to monitor the inventory of naloxone within the mechanism.

(c) Any other method approved by the Board's executive director or the director's designee.

(3) Provide written educational materials to the person accessing the naloxone appropriate to the dosage form of naloxone distributed, including, but not limited to, all of the following:

(a) Risk factors of opioid overdose.

(b) Strategies to prevent opioid overdose.

(c) Signs of opioid overdose.

(d) Steps in responding to an overdose, including:

(i) The proper method for placing an individual into the recovery position.

(ii) Specific instruction to summon emergency services pursuant to division (D)(2) of section 4729.515 of the Revised Code.

(e) Information on naloxone.

(f) Procedures for administering naloxone.

(g) Proper storage and expiration of naloxone product distributed.

(h) Information on where to obtain a referral for substance abuse treatment.

(i) Information, as required in paragraph (D)(4) of this rule, on where individuals may call for additional questions regarding naloxone administration. The telephone number must include the hours where an appropriately trained representative is available to answer questions.

(4) Provide a telephone number where individuals can call representatives with the requisite training necessary to answer questions regarding naloxone administration.

(5) Maintain the naloxone in accordance with the manufacturer's or distributor's instructions.

(a) Any naloxone that shows sign of tampering or adulteration shall be immediately removed by the terminal distributor of dangerous drugs.

(b) A terminal distributor shall develop and implement a policy to ensure that naloxone that exceeds its manufacturer's expiration date is removed and properly disposed.

(6) A terminal distributor maintaining naloxone in accordance with this paragraph shall:

(a) Maintain a complete list that includes the address and description of the location (e.g. first floor hallway, second floor conference room, etc.) of where the terminal distributor maintains an automated mechanism. The list shall be immediately available for inspection upon request of an employee of the board.

(b) Maintain a record of the naloxone stored within the automated mechanism that includes the name, strength, dosage form, national drug code and expiration date. Records shall be readily retrievable and maintained for a period of three years.

(7) Naloxone removed from an automated mechanism shall not be returned to the mechanism or transferred in accordance with rule 4729:5-3-09 of the Administrative Code, except if it was removed by an employee of the terminal distributor of dangerous drugs.

(E) The state board of pharmacy may grant variances from this rule in cases in which:

(1) The applicable provision is not statutorily mandated.

(2) Granting the variance would not:

(a) Be contrary to public interest; or

(b) Compromise the integrity of the drug.

(3) No party will be injured by the granting of the variance.

(F) An approval for a variance pursuant to paragraph (E) of this rule may be revocable, may be granted for a limited period or may be granted subject to the conditions as the state board of pharmacy may prescribe.

> ***Rationale for Recission of Rule:*** *Effective April 6, 2023, ORC 3715.50 removed most Ohio Board of Pharmacy licensure requirements for locations that store overdose reversal medications (such as naloxone) for use in emergency situations and for distribution through an automated mechanism (such as a vending machine).*
>
> *Additionally, this section of the Ohio Revised Code implemented specific requirements for all persons maintaining overdose reversal medications for use in emergency situations and for distribution through an automated mechanism.*
>
> *With these standards in place, the Board is proposing the rescission of previous requirements specifically for terminal distributors of dangerous drugs (OAC 4729:5-3-19).*

Rule 4729:5-5-15 | Manner of issuance of a prescription – Comments

Name	Organization	Comment	Draft Board Response
Elizabeth Schwartz	N/a	In regards to weight. Unless you are going to require doctors to put a weight of patient on every script this is no pheasible. Not every pharmacy has a scale. Not every patient comes in to get their own medicine or brings child in. You can not rely on parent for child's weight, I get a lot of I don't know from parents. I call provider if dosage doesn't add up. But sometimes that can be a delay in care. If this is a requirement I see a lot of delay in care happening. Not in best interest of patient	Maintain for weight-based drugs. Requiring for all pediatric prescriptions would not be feasible at this time.
Bonnie L. Briggs RPh, MBA, CPHIMSS, PMP	Wolters Kluwer Embedded Content Program and Project Management, Associate Director	I wish to comment on the proposed rule for the Manner of Issue of Prescriptions, specifically the point of including pediatric weights. Hallelujah! This is long over-due. I appreciate that this will be one more step for both the prescriber and the pharmacist; however its importance in ensuring more	Supportive comment. While the Board understands the concerns about weight changing, the rule is attempted to establish a baseline. New weights are received annually when a new prescription is issued.

		accurrate dosing is invaluable. I do have one point for consideration: the proposed text talks about various means of recording the metric weight of the patient at its initiation. While prescriptions are only good for one year, a pediatric patient, especially the youngest ones, can grow and change weight rapidly. I am suggesting that some consideration be made to include instructions to re-check the weight at every refill. As a side note, I am employed by a publishing company whose health division publishes drug and diagnostic information. Our embedded clinical data product line (the most popular drug database used by retail pharmacies in the U.S.) offers clinical screening capabilities. For pediatrics, that functionality is largely based on weight. Not having this information currently available in the majority of pediatric records in commercial pharmacy settings greatly reduces the screening capabilities for	

		appropriate dosing for these patients. Including this as a necessary portion of the prescription is a tremendous improvement in patient care. I applaud this effort to include this critical information.	
Lauren Forsythe, PharmD, MBA, DICVP	Foresight Pharma Solutions, LLC	I am submitting a comment regarding the requirement for a weight on pediatric prescriptions. I agree with the importance of the weight being included to facilitate the pharmacist checking weight-based dosing to ensure it's appropriate. If the board is adding a rule requiring weight on pediatric prescriptions for this reason, veterinary prescriptions should also require a weight for the same reason. Veterinary prescriptions are almost always dosed based on patient weight since there can be substantial size variation within a species. Without the weight on the prescription, the pharmacist is not able to perform their duty of verifying the appropriateness of the dose. Therefore, since this concern mirrors the pediatric	Will consult OVMA and Vet Board to get feedback.

		concern, I recommend that veterinary prescriptions also require a patient weight be included. Please let me know there are any questions or if additional information is needed.	
Justin W. Cole, PharmD, BCPS, FPPA	Cedarville University School of Pharmacy	Good afternoon, and thank you for the opportunity to comment on changes to the proposed changes to Rule 4729:5-5-15 | Manner of issuance of a prescription. I fully endorse the change to require metric weight on prescriptions for patients under the age of 18 years. As a pediatric pharmacist for 20 years, I strongly believe this will enhance the safety of Ohio's children related to dosing errors outside of our pediatric-specific care facilities. I also support the current language that gives the pharmacist flexibility to obtain the weight using other methods when necessary. While there are certainly some drugs that do not require weight-based dosing (e.g., ophthalmic preparations,	Supportive comment. Will provide at least six-month runway for implementation.

		topical agents, some oral drugs in adolescents), this should not be a reason to avoid a weight requirement. If needed, exceptions could be made for some of these special cases while still putting the rule in place. Pragmatically, it may be wise to provide sufficient lead time for implementation of this rule requirement (e.g., 6-12 months) to allow EHR and pharmacy systems to adapt to the new requirements. Again, thank you for the opportunity to comment on this proposed change, and please let me know if you have any questions.	
Elizabeth Ezell	N/a	I hope that you have had a good weekend. My name is Elizabeth Ezell and I am a pharmacy student in my APPE year. I am writing because I have read "The Manner of Issuance of Prescriptions" document and I think that this is a great idea. It will help out a lot of pharmacists in filling medications and provide	Supportive comment.

		better care for the pediatric population.	
Jacob Grasser, Pharm D, RPh	Cedarville University	Thank you for released a draft with the amended rule 4729:5-5-15 | Manner of issuance of a prescription, regarding the inclusion of the patient's weight if the patient is pediatric. Throughout my practice as a pharmacist, I have often found myself limited in my ability to properly verify a pediatric prescription due to the lack of patient's weight included on the prescription. As you are aware, many pediatric medications require weight-based dosing. So by neglecting to add the patient's weight to a prescription, the pharmacist's job becomes much more difficult. The pharmacist is left with an ethical dilemma of putting the prescription on hold until the weight can be verified, or dispensing the weight-based antibiotic without verifying the weight so that it is ready when the eager mother and sick child show up in the drive thru.	Supportive comment.

		In regards to the proposed methods of collecting the weight, I believe contacting the provider is the best option available, however I see that verifying the weight in the pharmacy manually or asking the caregiver the child's weight would also be effective. I do see some potential problems with this though. Pharmacies remain open several hours after the PCP's office has closed. Should there be a weight discrepancy after normal business hours, it is possible the PCP will not be open, and their nursing line may not have a live staff member who answers the phone. Many offices now use an off-site location that transcribes the message and then sends the on-call provider an instant message versus letting the pharmacist speak directly with the provider. This can create delays in getting the patient their medication, and thus harm the patient.	

		This amendment is a step in the right direction towards improving patient health, however if we are trying to help the patient as much as possible, we must advocate for requiring our PCP colleagues to include the weight on their orders. This will be met with pushback, however since it is such a critical part of prescribing, it must be included. Thank you for your time and consideration. I am very thankful for what you are doing to advance the profession of pharmacy in the state of Ohio and in the United States as a whole.	
Kembral Carper, Pharm D, MS, BCSCP, CMQOE	Nationwide Children's Hospital	On behalf of Nationwide Children's Hospital (NCH), we appreciate the opportunity to comment on the State of Ohio Board of Pharmacy's reissued changes on the Manner of issuance of a prescription rule. We appreciate the revisions made to the original proposal in (B)(8). There are pertinent factors we want the Board to consider.	

		1. Pediatric patients' weight frequently changes between birth and 18 years of age- which may not be captured and updated in the outpatient pharmacy system in real-time when assessing medication dosing (including medication refills and over-the-counter meds).[1,3,5,6] We'd like to raise a point for consideration regarding patient weight documentation and compliance expectations. Specifically, there may be compliance and mis-dosing risks when patient weights are not reconciled within a certain timeframe. It may be helpful for the Board to provide guidance or clarification on what constitutes an "acceptable" weight for clinical or dispensing purposes (ie a weight obtained within the last 12 months is sufficient). In practice, we occasionally encounter patients who have not had a weight check in an extended period. We have also noticed that weights on prescriptions are not always the correct weight for dosing. It may be the last recorded	Added actual body weight.

		weight versus actual patient's dosing weight. Therefore, clearer guidance could help ensure consistent compliance and safety measures are in place across pharmacies. 2. Additionally, not all pharmacy software systems for processing prescriptions have the current capability to display the patient's weight and/or height to the pharmacist. As written, pharmacists would not be able to verify that the weight is included or use the information due to system limitations.[2] This is something to consider when determining the enforcement of this role to allow organizations to enhance their systems. 3. Weight-based medications are at high-risk for dosing errors for patients weighing 50 kg or less and pediatric patients with obesity.[2,4] Several medications require dosing based on weight, body surface area, ideal body weight, and adjusted body weight.[5] We recommend the Board to	The Board is proposing a six-month implementation window. This should be conducted as part of the DUR.

		acknowledge within the rule that the patient's height and other metrics (in addition to their weight) may be needed to provide safe, appropriate, and effective dosing. Thank you for your attention to this matter. **References:** 1. Cicero M., et al. Pediatric Committee of NAEMSP adopted by NAEMSP Board of Directors (2021) Medication Dosing Safety for Pediatric Patients: Recognizing Gaps, Safety Threats, and Best Practices in the Emergency Medical Services Setting. A Position Statement and Resource Document from NAEMSP, Prehospital Emergency Care, 25:2, 294-306, DOI: 10.1080/10903127.2020.1794085 2. ISMP. Prescribing and dispensing errors with oral solutions. *Community/Ambulatory Care ISMP Medication Safety Alert!*. 2016 May; 15(5): 1-3. 3. Medication Errors: Significance of Accurate	

		Patient Weights. Pa Patient Saf Advis 2009 Mar;6(1):10-5. 4. Palsgraf H., et al. Impact of guided weight-based medication dosing in pediatric patients with obesity. *Journal of the American Pharmacist Association.* 2023. 63(3):p873-877. 5. The Joint Commission (TJC). Sentinel Event. Sentinel Event Alert 39: Preventing pediatric medication errors. 2021. Available at: http://www.jointcommission.org/sentinel_event.aspx. 6. Wu A. Minimizing medication errors in pediatric patients. *US Pharm. 2018;44(4):20-23.*	
Janice Moreland	N/a	I am in favor of the addition of weight of patient for prescriptions for pediatric patients. As a pediatric nurse practitioner, this measure adds an additional safety step to ensure safe dosing.	Supportive comment.
Peter Hopwood, PharmD	MetroHealth Medical Center	In response to the request for comment on the proposed pediatric dosing rule change: In my opinion, providing a pediatric patient's weight on a prescription is a valuable	Supportive comment.

		verification checkpoint for a vulnerable patient population. The addition of a pediatric patient's weight to a weight-based prescription can serve two purposes. These purposes can be beneficial for both provider and patient. First, this can help ensure a smoother transition from diagnosis to effective treatment. Weight-based dosing can be susceptible to subtherapeutic or supratherapeutic therapy, so enabling pharmacists to further assist in the decision making/verification process for medications like this can help ensure that treatment needs are being adequately met. Secondly, optimizing dosing regimens by enabling a pharmacist to double-check a weight-based medication helps protect the provider, pharmacist, and patient from avoidable errors. The cost-benefit analysis seems to favor this amendment. The benefit being an additional check for patient and provider safety, and the cost being a small addition to a workflow	

		that should already be focused on patient safety.	
I-Cheng Sung, Pharm D	MetroHealth Glick Center	Respond to Board of Pharmacy in pediatric dosing based on ISMP: I agree to add body weight for every patients in their prescriptions, especially for pediatric patients. Here are my reasons: 1. Provide the accurate information for pharmacists to check pediatric dosing for the indications, especially in outpatient and ambulatory setting. 2. Set up the interdisciplinary communication between healthcare teams. For example, pharmacist could verify the dosing based on the body weight that provider used. 3. Reduce the potential errors. For example, pharmacists might be able to ask the caregiver for further clarification, but the caregiver might not know the current body	Supportive comment.

		weight. That might lead to confusion and incorrectly interpretation of the prescription dosing. In addition, caregiver might only know the pounds instead of kilograms. That might potentially result in any misinterpretation for numbers. 4. Facilitate the workflow in outpatient setting. For outpatient setting, if the patients' body weight didn't show up in their profile or prescription, pharmacists might need to take more time to gain the body weight in order to verify the prescription or do compounding if needed. That may cause delay for patients or increase workload for pharmacy to take care other patients in a busy working flow. Reference:	

		Lubsch L, Kimler K, Passerrello N, Parman M, Dunn A, Meyers R. Patient Weight Should Be Included on All Medication Prescriptions. J Pediatr Pharmacol Ther. 2023;28(4):380-381. doi:10.5863/1551-6776-28.4.380	
Julie Magraw, PharmD	MetroHealth Main Campus	I am a currently a pharmacy resident and I agree with ISMP best practices for including weight-based dosing on prescriptions for pediatric patients. My reasoning for this is included below: 1. To reduce dosing errors. Dosing a medication correctly is critical especially in pediatric patients as they are more vulnerable to potential toxicities if given too much of a medication. By adding the weights on the prescription, it can reduce potential errors of using an incorrect weight or misinterpretation of the prescription. 2. Pharmacist can verify whether the weight-based dose the	Supportive comment.

		prescriber used is. Some medications may be dosed completely differently based on the weight of the patient and by including the weight on the prescription the pharmacist does not have to guess what weight the prescriber used to determine the dose. Therefore, pharmacists are able verify more readily the correct weight-based dose for this patient. 3. It would help with workflow. By including the weight on the patient's prescription for weight-based doses, the pharmacist doesn't have to go searching for the weight in the patients' chart. Furthermore, including the weight on the prescription reduces the time it would take to have to call the prescriber for clarification. I hope you consider these reasons for support of the	

		ISMP best practices guidance for weight based dosing.	
Yu-Hsin Huang, Pharm D	MetroHealth Main Campus	I am a current PGY1 pharmacy resident at MetroHealth, and I speak for myself in support of requiring a patient's weight on the prescription when the medication prescribed is dosed by weight. It will allow for more safety checks to be conducted, ultimately benefiting the patients. I just have some considerations for this clause. - Should a date be associated with the weight? For example, "30 kg (03/05/2020)". If so, how often does the weight have to be updated? Or, until when is a weight invalid? The answer may have to be variable. Some medications have wide therapeutic windows while others do not, and children's weights may change drastically depending on their age group. - Outside of the pharmacist's knowledge and	If prescription based, it will only be for one year. Adding a date may make it difficult to update their system. The pharmacy can document the weight in the notes. This should be reviewed as part of the DUR.

		resources available in the pharmacy, will there be any other indications that the medication is weight-dosed? For example, “ibuprofen 45 mg (5-10 mg/kg/dose) every 6-8 hour” vs “ibuprofen 45 mg every 6-8 hour.” This stems from the concern that the pharmacist may not be aware of when to reach out to the physician’s office/caregivers. Please let me know if I was unclear with the above comments, and thank you for the consideration,	
Lindsey B. Amerine, Pharm. D., MS, BCPS, CPEL, FASHP, FHOPA	Cleveland Clinic	In section (8) the Pharmacy Board proposes to add patient weight to the prescription if the dosing of the drug prescribed is based on the patient’s weight. We urge the Board to add subsection (d), which would state that “a pharmacist may utilize the medical record as a reasonable method to obtain the patient's weight, provided the weight has been obtained from the patient within one	Comment incorporated into the rule.

		month of the prescription being ordered." This addition would recognize the reliability of recent medical record documentation and facilitate safe and efficient pharmacy practice. Thank you for conducting a thoughtful process that allows us to provide input on such important issues and for your consideration of our feedback. Should you need any further information, please contact me.	
Curtis Rude	N/a	Pharmacists have an intrinsic opportunity to service the public in a patient care setting and often pediatric patients and families seeking care in retail and community establishments are underserved. This has been a long standing problem in the community for generations. Pharmacists are often overwhelmed in retail practice with dispensing, consulting, and billing duties and are unable to accommodate pediatric patients in an effective manner. While other health care professions (i.e. nursing) have filled the patient	N/A

		care gap in some areas, there continues to be a dearth of services for pediatric patients. Pharmacy technicians in the community setting, although capable, cannot be consistently depended upon for accurate and in-depth clinical judgements on pediatric patients. It is also unethical and medically inappropriate to place pharmacy technicians in clinical decision-making positions. A solution to these issues may lie in the development of **pharmacy-based AI** (Artificial Intelligence) platforms that assist both pharmacists and technicians in data collections and medical decision making for the care of pediatric patients.	
Mark Johnston RPh, PharmD	CVS Health	I am writing to you in my capacity as Executive Director of Board of Pharmacy Advocacy and Regulatory Affairs for CVS Health and its family of pharmacies. CVS Health, the largest pharmacy health care provider in the United States, is uniquely positioned to provide diverse access points of care to	

		patients in the state of Ohio through our integrated offerings across the spectrum of pharmacy care. We appreciate the opportunity to provide comments in regard to proposed rule 4729:5-5-15 – Manner of Issuance of Prescription, and respectfully submit the following: 1. The rule as currently constructed creates a mandate for the pharmacist to ensure that the patient's weight is included on prescriptions issued for pediatric patients, but there is no corresponding mandate placed on the prescriber to include this information on the prescription at the point of issuance. Absent a corresponding requirement on the part of the prescriber, pharmacists are put in the position of having to monitor for and enforce an element of	Will reach out to the Medical Board and Nursing Board.

		a prescription that a prescriber themselves are not required to include. We urge the concurrent promulgation and enactment of regulations that create a corresponding requirement upon prescribers to include the patient's current weight when issuing a prescription for pediatric patients. 2. Implementation of the rule will require enhancements to our pharmacy systems. We believe that other stakeholders, pharmacies and prescribers alike, may be similarly situated. Upon enactment, we propose that the Board provide a 12-month grace period to allow for implementation of necessary system enhancements required to comply with the rule.	The Board is proposing a six-month implementation window.

		3. We suggest the addition of a clause that allows a pharmacist to utilize their professional judgment to not withhold treatment if the patient's weight is not reported by the prescriber and cannot be readily obtained through the options outlined in the rule, if the pharmacist determines that a delay in therapy presents a greater risk to the patient.	If patient weight is essential to dosing, this information should be required.
		4. We recommend that the regulation provide flexibility for the patient's weight to be reported in either the metric units or in pounds and ounces (United States Customary Units). Conversions between the two units of measure can be made within our pharmacy systems, eliminating the potential for	If the prescriber provides weight using non-metric units, the pharmacist may convert to meet the requirement of the rule.

		human error in calculating the conversion.	
		5. If the prescriber does not include the patient's weight on a prescription for a pediatric patient, the rule should allow a pharmacy technician to obtain the patient's weight through the other mechanism outlined in the rule. In all cases, pharmacy technicians should be allowed to data enter the patient's weight into the pharmacy system as they would any other required element of a prescription.	Added "pharmacy personnel" to be able to obtain patient's weight.
		6. To the extent that the pharmacy has access to the patient's electronic medical record through a health information exchange network, allow the pharmacy to obtain the patient's weight through this	This has been addressed in the updated rule draft.

		mechanism if it is not reported by the prescriber on the prescription. 7. In the event that a pediatric patient is old enough to present to the pharmacy without a parent or caregiver, allow the patient to self-report their weight to the pharmacy if it has not been provided on the on prescription by the prescriber. Please see the following red lined edits for the Board's consideration: (8) For patients under the age of eighteen, indicate the patient's weight ~~in metric units~~ if the dosing of the drug being prescribed is based upon a patient's weight, however nothing in this rule prohibits a pharmacist from utilizing professional judgment to dispense if this weight is missing to avoid a delay in therapy that may result in patient harm. If not	This provision was added to the rule. If patient weight is essential to dosing, this information should be required.

		indicated on the prescription, this information may be added to the prescription by a pharmacy~~ist~~ using any of the following methods: (a) Contacting the issuing prescriber; (b) If the pharmacy has the necessary equipment on-site, obtaining the weight of the patient; ~~or~~ (c) Contacting the patient, patient's parent or caregiver; or (d) From the patient's electronic medical record)EMR)	

Rule 4729:5-5-15 | Manner of issuance of a prescription. (AMEND)

(A) A prescription, to be valid, must be issued for a legitimate medical purpose by an individual prescriber acting in the usual course of the prescriber's professional practice. The responsibility for the proper prescribing is upon the prescriber, but a corresponding responsibility rests with the pharmacist who dispenses the prescription. An order purporting to be a prescription issued not in the usual course of bona fide treatment of a patient is not a prescription and the person knowingly dispensing such a purported prescription, as well as the person issuing it, shall be subject to the penalties of law.

(B) All outpatient prescriptions issued by a prescriber shall:

(1) Be dated as of and on the day when issued.

(2) Contain the manually printed, typewritten, or preprinted full name, professional title, and address of the prescriber. The prescriber's address shall include the physical address of the prescriber's practice location.

(3) Indicate a telephone number where the prescriber can be contacted during normal business hours.

(4) Indicate the full name and residential address of the patient; or, if the patient is an animal, the last name of the owner, name of animal (if applicable), and species of the animal or animals. The patient or owner's residential address shall include a physical street address.

(5) Indicate the drug name and strength.

(6) Indicate the quantity to dispense.

(7) Indicate the appropriate and explicit directions for use.

(8) For patients under the age of eighteen, indicate the patient's actual body weight in metric units if the dosing of the drug being prescribed is based upon a patient's weight. If not indicated on the prescription, this information may be added to the prescription by pharmacy personnel using any of the following methods:

(a) Contacting the issuing prescriber;

(b) If the pharmacy has the necessary equipment on-site, obtaining the weight of the patient;

(c) Accessing the patient's medical record, provided the patient's weight has been obtained from the patient within one month of the prescription being issued; or

(d) Contacting the patient, patient's parent, or caregiver.

(**9** ~~**8**~~) Specify the number of times or the period of time for which the prescription may be refilled. If no such authorization is given, the prescription may not be refilled except in accordance with section 4729.281 of the Revised Code.

(a) Prescriptions for non-controlled substance dangerous drugs bearing "PRN," "Ad lib," or other similar prescription refill designation permitting the pharmacist to refill the prescription as needed by the patient, shall be refilled only in keeping with the number of doses ordered and according to the directions for use, and, in no instance, shall such prescription be refilled beyond one year from the date of issue. The prescription shall not be refilled out of context with the dosage schedule indicated in the directions for use unless specifically authorized by the prescriber.

(b) Prescriptions for controlled substance dangerous drugs bearing "PRN," "Ad lib," or other similar prescription refill designation are not considered a valid refill authorization.

(**10** ~~**9**~~) Not authorize any refills for schedule II controlled substances.

(**11** ~~**10**~~) Authorize refills for schedules III and IV controlled substances only as permitted by section 3719.05 of the Revised Code.

(**12** ~~**11**~~) Not authorize a refill beyond one year from the date of issuance for schedule V controlled substances and for dangerous drugs that are not controlled substances.

(**13** ~~**12**~~) Identify the trade name or generic name of the drug(s) in a compounded prescription.

(**14** ~~**13**~~) Not be coded in such a manner that it cannot be dispensed by any pharmacy of the patient's choice.

(**15** ~~**14**~~) For a controlled substance:

(a) Indicate the drug enforcement administration registration number of the prescriber pursuant to 21 CFR 1306.05 (3/31/2010).

(b) Except for veterinarians licensed pursuant to Chapter 4741. of the Revised Code, indicate either:

(i) The ICD-10-CM medical diagnosis code of the primary disease or condition that the controlled substance is being used to treat. The code shall, at a minimum, include the first four alphanumeric characters of the ICD-10-CM medical diagnosis code, sometimes referred to as the category and the etiology (ex. M 16.5).

(ii) For dentists licensed pursuant to Chapter 4715. of the Revised Code, the Code on Dental Procedures and Nomenclature (CDT Code), as published by the American dental association, of the dental treatment requiring the controlled substance prescription.

(**16** ~~**15**~~) Except for veterinarians licensed under Chapter 4741. of the Revised Code, for all controlled substances and products containing gabapentin: indicate the prescriber's intended days' supply of the prescription.

(**17** ~~**16**~~) For a managing pharmacist acting as an agent of a physician pursuant to section 4729.39 of the Revised Code and Chapter 4729:1-6 of the Administrative Code, the prescription shall include the full name of the managing pharmacist.

(**18** ~~**17**~~) Be issued in compliance with all applicable federal and Ohio laws, rules, and regulations.

(C) Failure of a prescription to contain the requirements set forth in paragraphs (B)(~~**14**~~ **15**)(b) and (B)(~~**15**~~ **16**) of this rule or of the pharmacist to obtain the information set forth in paragraphs (B)(~~**14**~~ **15**)(b) and (B)(~~**15**~~**16**) of this rule shall not render the prescription, if dispensed in good faith, to be invalid.

(D) All prescriptions issued on paper to a patient by a prescriber shall be:

(1) Manually signed on the day issued by the prescriber in the same manner as the prescriber would sign a check or legal document.

(2) Issued in compliance with rule 4729:5-5-05 of the Administrative Code.

(E) When forms are used that create multiple copies of a prescription issued to a patient by a prescriber, the original prescription that includes the actual signature of the prescriber must be issued to the patient for dispensing by a pharmacist.

(F) Pursuant to section 4729.38 of the Revised Code, a pharmacist shall not select a generically equivalent drug or interchangeable biological product if either of the following applies:

(1) In the case of a written or electronic prescription, including a computer-generated prescription, the prescriber handwrites or actively causes to display on the prescription "dispense as written," "D.A.W.," "do not substitute," "brand medically necessary," or any other statement or numerical code that indicates the prescriber's intent to prevent substitution. Such a designation shall not be preprinted or stamped on the prescription, but a reminder to the prescriber of the designation procedure may be preprinted or displayed on the prescription form or electronic system the prescriber uses to issue the prescription.

(2) In the case of an oral prescription, the prescriber or the prescriber's agent specifies that the drug as prescribed is medically necessary or otherwise indicates the prescriber's intent to prevent substitution.

(G) **~~Pursuant to section 4729.40 of the Revised Code, a~~ A** pharmacist shall **comply with the requirements of section 4729.40 of the Revised Code when converting prescriptions authorizing refills. ~~not dispense a quantity or amount of drug that varies from the quantity or amount of the drug that otherwise would be dispensed unless all the conditions are met in accordance with that section and either of the following applies:~~**

~~(1) The prescriber includes "dispense as written" or another phrase having a similar meaning on the prescription. Such a designation shall not be preprinted or stamped on the prescription, but a reminder to the prescriber of the designation procedure may be preprinted or displayed on the prescription form or electronic system the prescriber uses to issue the prescription.~~

~~(2) When issuing a prescription electronically or orally, the prescriber specifies that the quantity or amount of the drug to be dispensed may not vary from the quantity or amount specified in the prescription.~~

(H) Pursuant to section 4729.382 of the Revised Code, a pharmacist shall not make the substitution of an epinephrine autoinjector if either of the following applies to the prescription:

(1) In the case of a written or electronic prescription, including a computer-generated prescription, the prescriber handwrites or actively causes to display on the prescription "dispense as written," "D.A.W.," "do not substitute," "medically necessary as prescribed," or any other statement or numerical code that indicates the prescriber's intent to prevent substitution. Such a designation shall not be preprinted or stamped on the prescription, but a reminder to the prescriber of the designation procedure may be preprinted or displayed on the prescription form or electronic system the prescriber uses to issue the prescription.

(2) In the case of an oral prescription, the prescriber specifies that the epinephrine autoinjector as prescribed is medically necessary or otherwise indicates the prescriber's intent to prevent substitution.

(I) A patient or patient's caregiver shall have the exclusive right to freedom of choice for any pharmacy to dispense prescriptions.

(J) A pharmacist may dispense a prescription from a prescriber practicing outside of Ohio, if all the following apply:

(1) The prescriber who issued the prescription would ordinarily be entitled to issue prescriptions under Ohio law and the state where the prescription was issued;

(2) The prescription meets all the requirements of this rule, including whether the prescription is for a legitimate medical purpose in accordance with paragraph (A) of this rule.

(3) The prescription is transmitted in accordance with rule 4729:5-3-11 of the Administrative Code; and

(4) For a controlled substance prescription, the prescriber holds a valid drug enforcement administration registration number in the state of origin of the prescription.

4729:5-2-01 - Responsible Person – CSI Comments

Name	Organization	Comment	Draft Board Response
Kembral Nelson, PharmD, MS, BCSCP, CMQOE	Nationwide Children's Hospital	On behalf of Nationwide Children's Hospital (NCH), we appreciate the opportunity to comment on the State of Ohio Board of Pharmacy's proposed rule changes on the Responsible Person – terminal distributor rule. While we fully support the Board's intent to ensure patient safety and maintain strong oversight, we respectfully submit that the proposed requirements should be revised to reduce unintended operational, compliance, and patient access challenges. We urge the Board to reconsider these proposals and recommend alternative approaches to better balance safety, compliance, and access to care. **1. On-Site Hour Requirements for Pharmacies.** **a. Purpose and Intent:** In response to national safety and oversight concerns, the Board established minimum standards (4729:5-5-02), the Continuous Quality improvement Programs in Pharmacy Service (4729:5-3-22), and Duty to Report (4729:5-4-02) rules. Based on these rules and the current escalation of safety and	The Board contends that such a minimum standard is required to prevent situations where licensees have a responsible person "in name only."

		operational concerns to leadership programs established by organizations (ie administrator on-call, etc), pharmacies have processes to ensure concerns are addressed in a timely manner regardless of where the RP is working (ie within the health-system, physically in the pharmacy, remote, etc). Introducing additional on-site requirements may create redundancy and administrative burdens without clear benefits. **b. Onsite Expectation:** The Ohio Board has previously approved flexibility for remote order verification (OAC 4729:5-9-02.14 and 4759:5-5-20) and the 135th Ohio General Assembly authorized the Ohio Board of Pharmacy to license and regulate remote dispensing pharmacies. Such rules and laws show a regulatory precedent for remote pharmacy oversight where appropriate. Imposing rigid on-site hour requirements may reduce the flexibility that pharmacies	While CQI and duty to report regulations are intended to improve the quality and safety of pharmacy services, the Board believes that these are supplemental and should not be in place of having a responsible person be on site to provide supervision. This is vital given the statistics around drug diversion in the healthcare space. Researchers estimate that as many of 10-15 percent of all healthcare workers divert drugs at least once in their careers. Diversion, especially from a hospital system, can lead to significant quantities of controlled substances ending up on the street. For example, due to lack of proper oversight, a hospital pharmacy in the Cleveland area was found to be diverting

		have in maintaining compliance, especially when effective systems are already in place to monitor and manage operations remotely. Several RP may not physically work within the pharmacy (ie their office may be at a different location within the health-system or campus) or work from home. Additionally, Workforce demographics show pharmacists increasingly require flexible work schedules.[6] Based on the proposed rule, it's unclear how the Board defined "on-site" or "at the pharmacy". Enforcement could be inconsistent without a clear, standardized definition.	thousands of doses of controlled substances. The Board initially authorized remote order verification during COVID-19. Remote order verification is the first step in the dispensing process. It still requires a pharmacist on-site to perform the final verification. These rules do not absolve or eliminate any requirements for a pharmacist to be on-site. Additionally, the pending regulations for remote dispensing pharmacies require continuous oversight by a supervising pharmacist and for a pharmacist to be physically present in the pharmacy at least quarterly. Therefore, equating the Board's passage of these regulations to less stringent oversight is not a correct assertion.

			Lastly, the Board appreciates the need for flexible scheduling. However, that does not override the responsibility of the RP or the licensee to provide effective controls to deter and detect the diversion of dangerous drugs.
		c. Increase requirements with limited workforce[10-12]: High turnover among pharmacy personnel (including pharmacists and managers) is correlated with greater regulatory and medication safety risks. Increasing requirements for the RP could lead to a reduction in services pharmacies are able to provide and chances of inexperienced, new grads serving as the RP. See sections 3 and 5. **Recommendation:** The proposed 20-hour per week on-site requirement for pharmacies may not increase patient safety or improve patient care. The Board should consider alternative compliance models like quarterly on-site visits, documented oversight activities, and remote monitoring. If the Board desires to have an onsite requirement, we recommend providing clear definition of "onsite"	The Board understands the concerns related to pharmacist turnover. However, the Board contends that this is an employer issue and not the result of any regulations promulgated by the Board. 4-8 hours is not sufficient to properly establish oversight. This is particularly true for large hospital pharmacies with large quantities of drugs on-site.

		that allows for flexibility and to require 4-8 hours per week (or 10-20% of pharmacy hours of operations per week) – with the organization having an established escalation of safety or operational concerns program. We also recommend modifying B(2) to align with Outpatient pharmacy TDDD RP requirements and remove the campus requirement. **2. On-Site Hour Requirements for Non-Pharmacies.** **a. Onsite Expectation:** The proposed 20-hour per week on-site requirement for EMS organizations and 8-hour monthly presence for clinics raise significant concerns. For **EMS operations** present a similar challenge: EMS units are mobile (ambulances, helicopters, mobile stations) — tying oversight to a fixed dispatch location is impractical. These locations are generally secured and used only for replenishment between patient care travels. For clinics, there are some clinics that are not opened 40 hours per week and a shared spaces or services amongst different specialties. Additionally, some clinics rarely handle medications (or dangerous drugs). The proposed language increases risk to organizations and could cease facilities (such as close to home clinics) and	Aligning with the outpatient rules would reduce flexibility for institutional pharmacies to serve as the RP on more than one site. This flexibility is provided as long as the pharmacies are on the same hospital campus. The commenter is incorrect regarding the EMS requirements. EMS is required to work 20 hours per week on-site **or** conduct an on-site quarterly visit. For clinics, the requirement is also a quarterly check. The commenter discusses that clinics share spaces among different specialties. This further reinforces the fact that someone should be responsible and checking on these activities.

		access to care, especially in underserved and rural areas. See section 3. **Recommendation:** For **non-pharmacy sites (clinics, EMS, etc.)**, we recommend removing the onsite requirement and to require the RP complete an assessment (on a quarterly basis) as suggested by the Board. In these settings, we believe the on-site, in person visit on a quarterly basis would be sufficient. We recommend only permitting one option to ensure consistency amongst these areas. If the Board desires to keep an onsite requirement, we recommend delineating requirements based on a minimum number of medications used or hours of operation. **3. Access to Care Concerns** **a. Pharmacy and Health Care Deserts**[2-4]: According to the Ohio Pharmacy Trend Dashboard and the 2022 National Community Pharmacists Association Report, Pharmacy deserts currently exist in Ohio, and rural closures are increasing. There are also increasing reports of health care deserts in Ohio, especially for primary care and behavioral health. The proposed rule on-site requirements for	The rules already allow for quarterly visits instead of on-site hourly requirements for both clinics and EMS. The Board believes that there should be some flexibility and does not plan to eliminate the option to have on-site hourly requirements. Such hourly requirements exist in a number of rural states, including TN, WV, OK, AK, MS, KY, & WY. There is no evidence to suggest that requiring RP presence is what is contributing to pharmacy deserts.

		TDDDs could significantly limit patient access to pharmacy and healthcare services. Rigid RP presence requirements could deter pharmacy investment in rural or underserved areas. **Recommendation:** The more rigid on-site proposal for a fixed number of hours may strain operational capacities, potentially leading to reduced hours of operation or even closures. While the goal of ensuring robust oversight and compliance is commendable, the proposed on-site hour requirements for Responsible Person may introduce challenges without clear evidence of benefit. We recommend the Board reassess the impact of increased RP requirements to the safety of patients, patient care, and patient outcomes. **4. Authorized Leave for Responsible Persons** **a. Federal Law Misalignment[1]:** The proposed amendments concerning RP leave raise practical and legal concerns. Requiring a new RP designation during authorized leave (e.g., FMLA leave) could conflict with federal protections intended to prevent discrimination based on health or family leave. The proposed	Rather, studies indicate that declining drug reimbursement rates and a challenging retail environment are the primary driver of closures. While the Board understands that aligning with federal law may make things more convenient on the licensee, it cannot foresee a scenario where a licensee has no

		verbiage in the rule states exceptions to the onsite requirements include for authorized leave lasting no more than 31 calendar days. We recommend aligning the authorized leave language to Federal Law. The U.S. Department of Labor outlines leave benefits, including the Family and Medical Leave Act (FMLA).[1] FMLA provides certain employees with up to 12 weeks of unpaid, job-protected leave per year. The proposed verbiage in the rule poses risk for organizations to violate their approved federal leave benefits and job protection. **Recommendation:** We recommend the Board aligns the authorized leaves language with the U.S. Department of Labor and the federal standards on leave benefits. We also suggest the Board allows temporary coverage models without requiring RP reassignment for protected leave.	responsible person for 12 weeks (nearly 3 months). Nothing prevents a hospital from designating a temporary RP to serve in the place of the pharmacist requiring FMLA. Hospitals and other healthcare facilities should have contingency planning for FMLA and non-FMLA events. Additionally, a process allowing temporary coverage was added to the rule. As stated previously, 3 months is too long for a licensee to go without a responsible person. There are minimum competency standards for a responsible person. For one, it requires valid licensure as a pharmacist and/or a prescriber. Any additional requirements are based upon the needs of the

		Standards for Who Can Be a Responsible Person[7-9] **a. Competency and experience:** Currently, there are no minimum competency or experience standards to serve as an RP. Merely working 20 hours at a site does not ensure sufficient competency to manage complex compliance and patient safety obligations. No required participation in a quality improvement or management training program before assuming RP duties. **b. New grad or inexperience RP risk:** Research shows that pharmacist burnout and experience increase error risk. Although this concern, and references, are focused on pharmacy – this concern also applies to clinicians and any role that can serve as RP by the Ohio Board. **Recommendation:** We recommend the Board to establish minimum experience requirements (e.g., 1–2 years post-licensure practice in a management or supervisory role) and require baseline RP-specific education (e.g., pharmacy law, quality systems management) prior to assuming the RP role.	licensee. Therefore, it should be up to the licensee to establish any training requirements for those serving as the responsible person, as the operation of each TDDD is different. While the Board does not mandate training for RPs, it does offer free training courses throughout the year. In 2025, the Board is hosting 8 trainings for RPs (2 per quarter). This is in addition to law reviews that are also conducted once per quarter for licensees who are interested in updates to Ohio law.

		In conclusion, we fully support efforts to ensure RPs are actively engaged in maintaining the highest standards of patient safety and compliance. However, rigid on-site hour requirements risk harming access to care, straining pharmacy operations, and creating new legal risks without providing measurable safety improvements to patients or employees. There is limited empirical evidence to suggest that a mandated number of on-site hours for RPs directly correlates with improved compliance or patient safety outcomes. Effective oversight is more closely tied to the quality of management practices and adherence to protocols rather than the physical presence of a specific individual for a set number of hours. We encourage the Board to adopt a more flexible, evidence-based framework. Thank you for your careful consideration. **References:** 1. U.S. Department of Labor. Leave Benefits. https://www.dol.gov/general/topic/benefits-leave 2. Ohio Pharmacy Access: Ohio Pharmacy Access | DataOhio	

		3. National Community Pharmacists Association (NCPA). *NCPA Diges*t. 2022. 2022-Digest.pdf 4. Schladen M. Ohio suffers badly from health 'dead zones,' new report finds. https://ohiocapitaljournal.com/. 5. Hendrickson S. There are no doctors here: Rural Ohians face deadly shortage of health care options. (2025). https://www.usatoday.com/. 6. Prescott, William A., et al. Remote Work in Pharmacy Academia and implications for the New Normal. (2022) *American Journal of Pharmaceutical Education*, 86 (10) Article 8950. 7. American Association of Colleges of Pharmacy (AACP). 2022 National Pharmacist Workforce Study. Website: 2022-npws-final-report.pdf 8. American Pharmacists Association (APhA). 2021 APhA/NASPA National State-Based Pharmacy Workplace Survey. Website: National State-Based Pharmacy Workplace	

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Mark Johnston RPh, PharmD (Honorary)	CVS Health	I am writing to you in my capacity as Executive Director of Advocacy and Pharmacy Regulatory Affairs for CVS Health and its family of pharmacies. CVS Health, the largest pharmacy health care provider in the United States, is uniquely positioned to provide diverse access points of care to patients in the state of Ohio through our integrated offerings across the spectrum of pharmacy care. We appreciate the opportunity to propose revisions to proposed rule 4729:5-2-01– Responsible Person Requirements, specifically 4729:5-2-01(C), regulating non-resident pharmacies licensed as terminal distributors of dangerous drugs. It is our understanding that the Board's intent in proposing Rule 4729:5-2-01(C) is to require an Ohio-licensed pharmacist to serve as the "responsible person" for a non-resident pharmacy licensed as a terminal distributor of dangerous drugs (though, as currently drafted the rule does not clearly reflect such intent). We strongly encourage the Board to reconsider this proposed rule that would require pharmacist licensure in a state other than the state in which the pharmacist is physically located while practicing. The corresponding burden for a	Currently, as it stands, the Board can only license non-resident businesses. Should a non-resident pharmacy engage in behavior that violates Ohio law, the Board can only take action against the non-resident pharmacy. Recent case examples demonstrate that nothing stops the person running that pharmacy from forming a new

		responsible person if such a requirement were adopted across the country would be sizeable: obtaining - and maintaining - up to 51 different licenses in the United States. Moreover, there would be little benefit associated with such a requirement, given that the non-resident pharmacies hold licenses as terminal distributors of dangerous drugs. Therefore, the Ohio Board of Pharmacy is currently able to hold non-resident pharmacies accountable for the actions of its agents and employees without the need for this proposed promulgation. Should the Board decide to move forward in promulgating 4729:5-2-01(C), we urge the Board to consider amendments to the proposed rule consistent with existing rule 4729:5-8-03. In Rule 4729:5-8-03, the Ohio Board of Pharmacy set forth a well-considered and comprehensive list of Ohio rules to which licensed non-resident pharmacies must adhere and recognized that it is not always possible to follow both Ohio and home state law by including the following exception to the requirement to comply with the enumerated Ohio laws: "unless the licensee can demonstrate that such compliance would cause the nonresident terminal	company and reapplying for Ohio licensure. Therefore, having an Ohio licensed healthcare professional on the hook allows the Board to take action against both the business and the professional to safeguard the public. It also ensures that someone who has knowledge of Ohio laws (via licensure) is responsible for the operation of the business. The Board already has requirements that some non-resident pharmacies have Ohio licensed persons as the RP. For example, those shipping in radiopharmaceuticals need an RP who is an Ohio licensed pharmacist. As to the question of the clarity of this requirement, the rule specifically says that for all TDDDs: A responsible

		distributor of dangerous drugs to violate either the statutory or regulatory requirements of the state in which it is located or federal statutory or regulatory requirements." The rationale underlying this provision of Rule 4729:5-8-03 applies equally here, but the proposed rule does not contain such an exception. For these reasons, we request the following revisions: 4729:5-2-01(C)(1)(d): The terminal distributor of dangerous drugs and all pharmacists on duty are responsible for compliance with all the state and federal laws, regulations, and rules governing the distribution of drugs and the practice of pharmacy detailed in 4729:5-8-03, unless the licensee can demonstrate that such compliance would cause the nonresident terminal distributor of dangerous drugs to violate either the statutory or regulatory requirements of the state in which it is located or federal statutory or regulatory requirements. Again, we thank the Board for the opportunity to provide these comments. Should you have any	person shall hold a valid license, registration, or certification to from an occupational licensing board as defined in section 4798.01 of the Revised Code. Given that the rule is pointing directly to the definition of occupational licensing board, which is specific to Ohio, the requirement is clear. However, to avoid any confusion the word "Ohio" was added to that paragraph. This language was incorporated into the rule in the non-resident section of the rule.

		questions, please do not hesitate to contact me.	
Jennifer A Wick PharmD, MPH, BCACP and Justin Gamble, PharmD	The Christ Hospital Health Network	We are writing on behalf of the Christ Hospital Health Network, a health system which includes a network of physician offices and surgery centers operating across a diverse geographic area in Ohio. We appreciate the Board's commitment to enhancing patient safety and operational standards within the pharmacy sector. However, we have significant concerns regarding the proposed rules on responsible person requirements, as outlined in the document titled "For Stakeholder Comment – Responsible Person Requirements" (comments due August , 2025). Our organization operates numerous facilities where providers rotate to optimize space utilization and deliver a diverse range of patient care services. This model is essential for meeting the varied healthcare needs of our communities. The proposed regulations, particularly those mandating a specific on-site hour requirement or quarterly inspection for responsible persons, pose several challenges to our operational efficiency and patient care objectives. These have been detailed in our prior comment letter sent to the Board.	The rotating nature of the supervision expressed by the commenter is the reason why there needs to be someone responsible for the operations of a licensee. While the Board supports operational flexibility, it cannot come at the expense of oversight.

		The primary area where there will be undue burden is our physician practices. The pharmacy department has collaborated closely with practicing physicians and physician leadership to develop and implement comprehensive policies and procedures that align with Board of Pharmacy regulations. This multidisciplinary approach ensured that all stakeholders contributed to a compliant and practical framework, addressing key areas such as medication storage, prescribing practices, and documentation standards. By proactively engaging physician leaders in the policy-making process, the pharmacy department was able to tailor procedures that support clinical workflow while meeting regulatory requirements. As a result of this collaborative and preventative strategy, ongoing compliance was maintained without the need for quarterly inspections, as the implemented controls and oversight mechanisms proved sufficient to ensure sustained adherence to Board standards. This was evidenced by our recent Board inspections by both Sharon Shields and Elizabeth Bond, where no issues were found in our physician practices. At our Harper's Point inspection, TCH was verbally asked if our practice	

		would be willing to serve as a model for other clinic sites – a very high mark of praise from the Board. Adding a quarterly inspection requirement would unnecessarily increase the administrative burden to our network, without additional benefit. We would ask that the Board consider an annual or biannual inspection schedule (once every 6-12 months) rather than quarterly to help address the additional administrative and time burden these new regulations may generate.	While the Board appreciates that this hospital system has developed safeguards necessary to avoid any inspection issues, they did not provide any specifics that could be incorporated into the rule as a potential solution. Rather, they have asked for inspections to be conducted once every 6-12 months. While the Board appreciates their efforts to maintain compliance, it has to consider rules that will apply to all licensed locations. Therefore, it believes that to ensure compliance across all license types it is essential to have at least quarterly

			compliance checks. This aligns with pending regulations supported by the pharmacy community for remote dispensing pharmacies that require quarterly site visits by the supervising pharmacist. It should also be noted that Christ Hospital's prescriber clinics have been subject to two disciplinary actions within the past 5 years. For example, one dermatology clinic was found to have drugs on-site without a proper license.
Katie Posendek, PharmD, BCACP, 340B ACE	Neighborhood Family Practice Community Health Centers	I am emailing to share comments on the Responsible Person rule update. In theory, this rule makes sense, however for smaller independents and health clinics with less staff this could pose challenges at times. 1. Rule states that pharmacist that is responsible must work at least 20 hours a week at a location. This does not allow for transitions. For example, say a	To address this concern, the Board added a temporary process in the rule that allows for a pharmacist to oversee

		pharmacist leaves to seek employment elsewhere and there is just enough staff to cover the pharmacies, another individual will need to be placed on the license temporarily while a replacement is hired. Sometimes working 20 hours per week is not possible in these situations if they are also covering another pharmacy. I think there needs to be exceptions listed in the event that employee statuses change or remove the requirement of 20 hours. 2. In point 5 and 6 it lists that authorized leave cannot last more than 31 days for a responsible pharmacist. I would recommend extending this and adding maternity and paternity leave. These are often longer than 31 days and is very common. Once again, I think 31 days makes sense in theory but does not account for different life situations and feels overly strict.	more than one pharmacy in the event of death, incapacity, commencement of emergency medical leave, unexpected resignation, or discharge of the responsible person. As stated previously, 3 months is too long for a licensee to go without a responsible person. A process allowing temporary coverage was added to the rule.
Brian Stroh, MD	Netcare Corporation	Hi - as a community mental health center, some of the draft rules would prove tough for us:	

		1. **Minimum On-Site Requirements The draft rule requires an RP to be physically present at the licensed location for at least 8 hours per month or one quarterly visit.** This may impose logistical and financial challenges for: - Low-volume outpatient or specialty clinics - Facilities with RPs serving at multiple affiliated sites - Clinics with highly integrated remote oversight systems and compliance protocols Possible Board Recommendation: Consider allowing flexibility by permitting remote oversight and virtual inspections under clearly defined criteria (e.g., low drug volume, absence of prior violations, annual audit compliance). 2. **Credentialing Restrictions Restricting RP roles to prescribers or pharmacists** This may unintentionally limit qualified personnel in compliant operations, especially in rural or underserved areas.	A review of licensing data shows that Netcare Corporation operates one clinic in the state of Ohio. The Board questions the logistical or financial challenges of requiring the RP to either work at the facility for 8 hours per month or visit once per quarter. These requirements are established under Ohio law (ORC 4729.55(B)) and cannot be expanded to

		Possible Board Recommendation: Allow flexibility for licensed administrators, compliance officers, or nurses with specialized training to serve as RPs under delegated prescriber supervision—with appropriate safeguards and Board approval. 3. **Implementation Timeline The current implementation timeline** This may be difficult for clinics needing to restructure leadership or staffing to meet the proposed standards. Possible Board Recommendation: Please allow a grace period of at least 6–12 months for compliance to avoid disruption of services and unnecessary license actions	non-licensed healthcare professionals for clinics. The Board has committed to a six-month implementation window to ensure that all licensees can get into compliance.
Eric Eby	Norwich Township Fire Department	Thank you for evaluating the effectiveness and efficiency of the responsible person role. As an administrator at our EMS agency, this change is highly beneficial. While our medical director does an excellent job, like many EMS agencies, he's not directly involved in the daily operational and compliance oversight. He relies on departmental leaders like me to ensure we meet Ohio Board of Pharmacy (OBP) requirements.	Supportive comment.

		Allowing a paramedic to serve as the responsible person shifts the responsibility to those directly involved in purchasing and securing medications. It also speeds up operations by eliminating the need for signatures from the medical director for standard events. This change assigns responsibility to those engaged in daily medication management, improving both efficiency and compliance. I do understand the concern for small, volunteer departments; however, I believe the quarterly inspection documentation is not unreasonable.	
Dr. Andrea Reed, PharmD	N/A	In this paragraph copied below, regarding the person responsible, please consider changing the temporary leave of absence length to no more than 12 weeks. This would make more sense for any pharmacy manager to take a maternity leave, as that is the typical leave of absence, in that case. Plus, if someone has a surgery, usually recovery time is less than that. "(5) Except as provided in paragraph (A)(6) of this rule, the pharmacist serving as the responsible person shall work a minimum of twenty hours per week at the pharmacy or pharmacies	While the Board understands that aligning with federal law may make things more convenient on the licensee, it cannot foresee a scenario where a licensee has no responsible person for 12 weeks (nearly 3 months). Nothing prevents a pharmacy from designating a temporary RP to serve in the place of the pharmacist requiring FMLA.

		where the pharmacist serves as the responsible person, except when absent due to authorized leave. Authorized leave includes a scheduled vacation, illness, federal or state holiday, or temporary leave of absence lasting no more than **31 calendar days"**	Pharmacist should have contingency planning for FMLA and non-FMLA events. Additionally, a process allowing temporary coverage was added to the rule. As stated previously, 3 months is too long for a licensee to go without a responsible person. Temporary coverage is already contemplated in that a change of RP can be easily processed within a few days (it's a change request in eLicense). Furthermore, this rule protects the RP. An RP on maternity leave cannot be expected to be in full and actual charge of the pharmacy. By requiring a change, it protects the RP's pharmacist license from any sanctions related to the operation of that pharmacy while they are on leave.

Sean T. McCullough	OSMA	On behalf of the Ohio Dermatological Association (ODA), we respectfully resubmit the comments originally provided to the Board on May 13, 2025, regarding the proposed amendments to OAC 4729:5-2-01, concerning the responsibilities of Responsible Persons (RPs) for Terminal Distributors of Dangerous Drugs (TDDDs). We understand that the Board has included with its BIA submission a matrix of comments received pursuant to early stakeholder outreach, but we have not received, nor does the matrix contain, a response to our comments. As previously noted, we have specific concerns about Subsection (F) of the proposed rule, particularly as it relates to the 31-day leave limit for Responsible Persons utilizing the "8 hours on-site per month" compliance option. Specifically, we remain concerned that the proposed rule does not adequately address scenarios involving extended or unplanned RP absences (e.g., hospitalization, maternity leave, or other medical emergencies), **especially in solo-practitioner or rural practice settings.** We again respectfully recommend that the Board consider including a	By law (ORC 4729.54 (K)), a TDDD is required to have an RP at all times. If a solo practice provider is out of the office for an extended period, the clinic cannot operate unless there is another provider present.

		provision that allows for Board discretion to extend the leave period in cases of documented medical or personal emergencies. In addition, we continue to request that the Board provide greater clarity regarding the procedure for documenting and reporting such absences, including required inventories, temporary designees, or notifications, to ensure that licensees can maintain compliance during unforeseen events. We appreciate your work and welcome the opportunity for future dialogue. Please do not hesitate to let us know how we may better serve this discussion and address our concerns. Previous comment: On behalf of the Ohio Dermatological Association, please accept these comments regarding the proposed amendments to OAC 4729:5-2-01, which address the requirements for responsible persons (RPs) as terminal distributors of dangerous drugs (TDDD). We appreciate the Board's ongoing efforts to improve compliance confidence for TDDD licensees. We respectfully request the opportunity for further dialogue with the Board to better understand the rationale behind these changes and to discuss their	Nothing in the rule prohibits another provider from serving as the RP on a temporary basis due to unforeseen circumstances. Also, solo practice doctors are generally exempted from TDDD licensure from the Board unless they possess higher-risk drugs on site that require oversight such as controlled substances and compounded drugs. Therefore, oversight is important. As always, the Board will issue additional guidance on reporting such absences and compliance information.

		practical implications for licensees. Subsection (F) of the proposed rule introduces the option for an RP to fulfill supervisory obligations either a minimum of 8 hours on site per month, or to complete quarterly on-site compliance documentation. The proposed rule also limits authorized leave for an RP to 31 consecutive days when electing to comply using the 8 hour per month on-site option. While we understand the intent to ensure continuous oversight, we request clarification concerning extended, unplanned absences, such as medical emergencies or maternity leave. For example, if an RP is unexpectedly hospitalized or placed on extended medical leave, it may be challenging for that RP to designate a new RP within the 31-day window, particularly in rural or solo-practitioner settings. We respectfully request that the Board consider adding a provision allowing for additional time for leave at the discretion of the Board along with additional clarification of the process for documenting and reporting such extended absences, including any required inventories or notifications, to ensure licensees can maintain compliance without undue administrative burden.	

		We believe that the Board's intent is to improve confidence in and ease of compliance standards for RPs. To that end, we are ready and willing meet to discuss these issues in detail, and to work collaboratively on developing clear guidance or supplemental materials (such as FAQs or sample documentation) that will assist licensees in understanding and meeting their obligations under the proposed rule changes. Thank you for your consideration of these comments. We look forward to further engagement with the Board and to supporting the development of rules that promote both regulatory compliance and practical feasibility for Ohio's healthcare providers. We look forward to hearing from you.	

Rule 4729:5-2-01 | Responsible person - terminal distributor. (NEW – Replaces Current Rule)

(A) For an outpatient pharmacy licensed as a terminal distributor of dangerous drugs in accordance with chapter 4729:5-5 of the Administrative Code:

(1) Only a pharmacist may be the responsible person for an outpatient pharmacy licensed as a terminal distributor of dangerous drugs.

(2) Except as provided for in this paragraph, a pharmacist shall not serve as the responsible person for more than one outpatient pharmacy. A pharmacist may serve as the responsible person for up to two outpatient pharmacies if the following requirements are met:

(a) The pharmacist can meet the supervision requirements in paragraph (A)(5) or (A)(6) of this rule;

(b) The outpatient pharmacies have not been disciplined for any significant theft or loss of dangerous drugs within the preceding twelve months;

(c) The outpatient pharmacies have not been disciplined for violation of rule 4729:5-5-02 and all subsequent rules thereunder within the preceding twelve months;

(d) Neither of the outpatient pharmacies are open more than 20 hours per day;

(e) The pharmacist seeking to be the responsible person has been licensed to practice pharmacy in this state for at least one year;

(f) The pharmacist is not currently on probation or is otherwise restricted from serving as the responsible person on multiple licenses pursuant to a settlement agreement or order of the board.

(3) The responsible person shall be responsible for the practice of the profession of pharmacy, including, but not limited to, the supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, adequate safeguards as required in division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs and maintaining all drug records otherwise required.

(4) The terminal distributor of dangerous drugs and all pharmacists on duty are responsible for compliance with all state and federal laws, regulations, and rules governing the distribution of drugs and the practice of pharmacy.

(5) Except as provided in paragraph**s** (A)(6) **or (A)(7)** of this rule, the pharmacist serving as the responsible person shall work a minimum of twenty hours per week at the pharmacy or pharmacies where the pharmacist serves as the responsible person, except when absent due to authorized leave. Authorized leave includes a scheduled vacation, illness, federal or state holiday, or temporary leave of absence lasting no more than 31 calendar days.

(6) The pharmacist serving as a responsible person of a pharmacy that is not operational for forty hours per week shall work a minimum of fifty percent of the total hours the pharmacy is open per week, except when absent due to authorized leave. Authorized leave includes a scheduled vacation, illness, federal or state holiday, or temporary leave of absence lasting no more than 31 calendar days.

(7) The Board's executive director, or the director's designee, may grant approval to allow for a pharmacist to temporarily serve as the responsible person for two outpatient pharmacies without meeting the supervision requirements in paragraphs (A)(5) or (A)(6) of this rule if the following are met:

(a) The pharmacy can document that a death, incapacity, emergency medical leave (does not include planned medical leave), unexpected resignation, or discharge of the responsible person has occurred.

(b) The pharmacy can document that current staffing is not sufficient to meet the supervision requirements of this rule.

(c) The temporary approval is valid for thirty-one days from the date it is approved by the board's executive director or the director's designee and cannot be renewed.

(d) On or before the end of the temporary approval issued by the board, the pharmacy shall designate a responsible person that meets the requirements set forth in this rule. Upon designation of a new responsible person, the temporary approval issued by the board is no longer valid.

(e) The responsible person shall either:

(i) For a pharmacy operational at least forty hours per week: work a minimum of ten hours per week at each pharmacy; or

(ii) For a pharmacy that is not operational for forty hours per week: work a minimum of twenty-five percent of the total hours the pharmacy is open per week.

(f) The requirements of paragraphs (A)(2)(b) through (A)(2)(f) can be met.

(g) All requests made pursuant to this paragraph shall be submitted, in a manner determined by the board, no later than ten business days after the death, incapacity, commencement of emergency medical leave, unexpected resignation, or discharge of a pharmacist serving as the responsible person.

(B) For an institutional pharmacy licensed as a terminal distributor of dangerous drugs in accordance with chapter 4729:5-9 of the Administrative Code:

(1) Only a pharmacist may be the responsible person for an institutional pharmacy licensed as a terminal distributor of dangerous drugs.

(2) Except as provided in paragraphs (B)(7) of this rule, a pharmacist may serve as the responsible person on no more two pharmacies, either outpatient or institutional, licensed as terminal distributors of dangerous drugs if both locations are located on a campus as defined in section 4729:5-1-01 of the Administrative Code and the pharmacist is not currently on probation or is otherwise restricted from serving as the responsible person on multiple licenses pursuant to a settlement agreement or order of the board.

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

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

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

(c) In conjunction with the appropriate interdisciplinary committees, the development of written policies and procedures which are consistent with this division of the Administrative Code and other applicable federal and state laws, regulations and rules governing the legal distribution of drugs, adherence to these policies and procedures in order to provide for the safe distribution of drugs in all areas of the institutional facility, and making readily retrievable a current copy of these written policies and procedures.

(4) The terminal distributor of dangerous drugs and all pharmacists on duty are responsible for compliance with all state and federal laws, regulations, and rules governing the distribution of drugs and the practice of pharmacy.

(5) Except as provided in paragraphs (B)(6) and (B)(7) of this rule, the pharmacist serving as the responsible person shall work a minimum of twenty hours per week at the pharmacy or pharmacies where the pharmacist serves as the responsible person, except when absent due to authorized leave. Authorized leave includes a scheduled vacation, illness, federal or state holiday, or temporary leave of absence lasting no more than 31 calendar days.

(6) The pharmacist serving as a responsible person of a pharmacy that is not operational for forty hours per week shall work a minimum of fifty percent of the total hours the pharmacy is open per week, except when absent due to authorized leave. Authorized leave includes a scheduled vacation, illness, federal or state holiday, or temporary leave of absence lasting no more than 31 calendar days.

(7) The Board's executive director, or the director's designee, may grant approval to allow for a pharmacist to temporarily serve as the responsible person for two pharmacies, either outpatient or institutional, without meeting the supervision requirements in paragraphs (B)(5) or (B)(6) of this rule if the following are met:

(a) The pharmacy can document that a death, incapacity, emergency medical leave (does not include planned medical leave), unexpected resignation, or discharge of the responsible person has occurred.

(b) The pharmacy can document that current staffing is not sufficient to meet the supervision requirements of this rule.

(c) The temporary approval is valid for thirty-one days from the date it is approved by the board's executive director or the director's designee and cannot be renewed.

(d) On or before the end of the temporary approval issued by the board, the pharmacy shall designate a responsible person that meets the requirements set forth in this rule. Upon designation of a new responsible person, the temporary approval issued by the board is no longer valid.

(e) During the period that the temporary approval is valid, the responsible person shall either:

(i) For a pharmacy operational at least forty hours per week: work a minimum of ten hours per week at each pharmacy; or

(ii) For a pharmacy that is not operational for forty hours per week: work a minimum of twenty-five percent of the total hours that each pharmacy is open per week.

(f) The requirements of paragraph (B)(2) can be met.

(g) All requests made pursuant to this paragraph shall be submitted, in a manner determined by the board, no later than ten business days after the death, incapacity, commencement of emergency medical leave, unexpected resignation, or discharge of a pharmacist serving as the responsible person.

(8) The requirements of paragraphs (B)(2), (B)(5), and (B)(6) of this rule do not apply to terminal distributors of dangerous drugs with a pharmacy supplied contingency stock classification. An institutional pharmacy shall develop and implement policies and procedures on the management of pharmacy supplied contingency stock to ensure compliance with the requirements of Chapter 4729 of the Revised Code and all applicable rules adopted thereunder.

(C)

(1) For a non-resident pharmacy licensed as a terminal distributor of dangerous drugs in accordance with chapter 4729:5-8 of the Administrative Code:

(a) Only a pharmacist may be the responsible person for a non-resident pharmacy licensed as a terminal distributor of dangerous drugs.

(b) A pharmacist shall not serve as the responsible person for more than one non-resident pharmacy licensed as a terminal distributor of dangerous drugs, unless the non-resident pharmacies are located on a campus as defined in section 4729:5-1-01 of the Administrative Code.

(c) The responsible person shall be responsible for the practice of the profession of pharmacy, including, but not limited to, the supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, adequate safeguards as required in division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs, and maintaining all drug records otherwise required.

(d) **Unless the licensee can demonstrate that such compliance would cause the nonresident terminal distributor of dangerous drugs to violate either the statutory or regulatory requirements of the state in which it is located or federal statutory or regulatory requirements,** the terminal distributor of dangerous drugs and all pharmacists on duty are responsible for compliance with all state and federal laws, regulations, and rules governing the distribution of drugs and the practice of pharmacy.

(e) The non-resident pharmacy shall comply with the supervision requirements for the responsible person, pharmacist/person-in-charge, or any other similar licensure requirement of the state in which the pharmacy is operating. Any absence of the responsible person from the non-resident pharmacy that exceeds 31 days requires the designation of a new responsible person.

(2) For a non-resident terminal distributor of dangerous drugs that is not a pharmacy, the non-resident terminal distributor of dangerous drugs:

(a) Only a pharmacist or prescriber may be the responsible person for a non-resident terminal distributor of dangerous drugs.

(b) A pharmacist or prescriber shall not serve as the responsible person for more than one non-resident terminal distributor of dangerous drugs, unless the non-resident terminal distributor is on a campus as defined in section 4729:5-1-01 of the Administrative Code.

(c) The responsible person shall be responsible for 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, and security and control of dangerous drugs, and maintaining all drug records otherwise required.

(d) **Unless the licensee can demonstrate that such compliance would cause the nonresident terminal distributor of dangerous drugs to violate either the statutory or regulatory requirements of the state in which it is located or federal statutory or regulatory requirements,** the terminal distributor of dangerous drugs and all pharmacists and prescribers on duty are responsible for compliance with all state and federal laws, regulations, and rules governing the distribution of drugs.

(e) The non-resident terminal distributor shall comply with the supervision requirements for the responsible person, pharmacist/person-in-charge, or any other similar licensure requirement of the state in which the terminal distributor is operating. Any absence of the responsible person from the terminal distributor that exceeds 31 days requires the designation of a new responsible person.

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

(1) Only a physician authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery may be the responsible person for a category III terminal distributor of dangerous drugs with a pain management classification license as defined in section 4729.552 of the Revised Code.

(2) The physician serving as the responsible person for a location licensed as a category III terminal distributor of dangerous drugs with a pain management clinic classification shall work a minimum of eight hours per week at pain management clinic where the physician serves as the responsible person, except when absent due to authorized leave. Authorized

leave includes a scheduled vacation, illness, federal or state holiday, or temporary leave of absence lasting no more than 31 calendar days.

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

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

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

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

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

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

(e) Meet both of the following:

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

(ii) Demonstrate conformance with the minimal standards of care in accordance with rule 4731-29-01 of the Administrative Code.

(5) The pain management clinic with a category III terminal distributor of dangerous drugs license and all licensed health professionals practicing at that location are responsible for

compliance with all state and federal laws, regulations, and rules governing the operation of a pain management clinic and prescribing of controlled substances.

(E) For an emergency medical service (EMS) organization licensed as a terminal distributor of dangerous drugs in accordance with chapter 4729:5-14 of the Administrative Code:

(1) Only the following may be the responsible person whose name appears on the terminal distributor of dangerous drugs license for an EMS organization:

(a) Physician licensed in accordance with Chapter 4731 of the Revised Code;

(b) Pharmacist licensed in accordance with Chapter 4729 of the Revised Code; or

(c) Advanced emergency medical technician or paramedic issued a certificate to practice in accordance with Chapter 4765 of the Revised Code.

(2) If the responsible person is a physician licensed in accordance with Chapter 4731 of the Revised Code, that individual may also serve as EMS organization's medical director pursuant to Chapter 4729:5-14 of the Administrative Code. If the responsible person is not a physician, the EMS organization shall designate a medical director that meets the requirements of Chapter 4729:5-14 of the Administrative Code.

(3) A responsible person for an EMS organization shall either:

(a) Work a minimum of twenty hours per week at the location licensed as a terminal distributor of dangerous drugs where they serve as the responsible person, except when absent due to authorized leave. Authorized leave includes a scheduled vacation, illness, federal or state holiday, or temporary leave of absence lasting no more than 31 calendar days.

(b) Conduct an on-site, in-person visit of the terminal distributor where they serve as the responsible person on a quarterly basis to ensure compliance with the requirements of Chapter 4729 of the Revised Code and all applicable rules adopted thereunder. The on-site visit shall be documented by the responsible person and such documentation shall be maintained in an immediately retrievable format at the location licensed as a terminal distributor of dangerous drugs for three years from the date of the visit by the responsible person.

(F) Except as otherwise provided in paragraphs (A), (B), (C), (D), and (E) of this rule, a responsible person of a terminal distributor of dangerous drugs shall either:

(1) Work a minimum of eight hours per month at the location licensed as a terminal distributor of dangerous drugs where they serve as the responsible person, except when absent due to authorized leave. Authorized leave includes a scheduled vacation, illness, federal or state holiday, or temporary leave of absence lasting no more than 31 calendar days.

(2) Conduct an on-site, in-person visit of the terminal distributor where they serve as the responsible person on a quarterly basis to ensure compliance with the requirements of Chapter 4729 of the Revised Code and all applicable rules adopted thereunder. The on-site visit shall be documented by the responsible person and such documentation shall be maintained in an immediately retrievable format at the location licensed as a terminal distributor of dangerous drugs for three years from the date of the visit by the responsible person.

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

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

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

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

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

(5) A responsible person shall hold a valid **Ohio** license, registration, or certification ~~to~~ from an occupational licensing board as defined in section 4798.01 of the Revised Code.

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

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

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

(1) Has been denied the right to work in any facility or serve as the responsible person by the state board of pharmacy as part of an official order of the board.

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

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

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

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

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

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

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

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

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

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

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

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

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

Organization	Comment	Draft Board Response
Health Partners Free Clinic	Reading the proposal rule change to rule 4729:3-2-01 (A)3b ii "is at least seventeen years of age" for requirements for registered technicians, how is this compatible with the parameters of SB 203 of the 127th General Assembly (aka, "Emily's Law") which required age of pharmacy technicians to be at least eighteen years of age or older?	The change to the rule reflects recent statutory changes permitting a trainee to register if they are 17 under the following circumstances: • They are part of a high school technician training program. • They graduated from high school.
Inmar Intelligence	We appreciate the opportunity to offer stakeholder input during your five-year rule review process for administrative rules related to drug distribution licensure. We respectfully request that the Board consider revising its rules to clearly distinguish reverse distribution operations from those of wholesale drug distributors, as the nature and purpose of these business models are fundamentally different. Reverse distributors are entities that receive pharmaceutical products, including controlled substances, solely for the purpose of assessing manufacturer credit eligibility, and/or coordinating the lawful destruction of these drugs. These drugs are not redistributed	This comment doesn't apply to any specific rule. The Board will take this comment under advisement when making updates to its drug distributor rules (OAC 4729:6).

	for sale, resale, dispensing, or clinical use. They are typically shipped from DEA-registered healthcare providers and pharmacies and drug manufacturers or distributors. Shipments to reverse distribution facilities occur often exclusively via common or contract carriers and do not involve transfers of title or distribution into the commercial marketplace. Once received, the drugs are evaluated for return credit, where applicable, and/or routed for destruction in compliance with federal DEA regulations. In short, reverse distributors do not introduce any drug into Ohio—or any state—for the purpose of wholesale trade or distribution. Currently, reverse distributors may be misclassified under the same licensure structures used for wholesalers, whose function is to acquire, store, and redistribute prescription drugs—including controlled substances—for commercial sale. However, reverse distribution involves no sales transactions, no supply to patients or healthcare providers, and no role in the distribution chain for dispensing or administering drugs.	

	The current Ohio licensing system classifies distributors of dangerous drugs into categories that assume commercial redistribution activity, including: • Category 2: Distribution of prescription drugs not including controlled substances; • Category 3: Distribution of all prescription drugs, including controlled substances Reverse distributors do not perform either of these functions. However, the absence of a specific carve-out for reverse distribution may inadvertently require these businesses to seek inappropriate licenses, imposing: • Administrative burdens that serve no public health or compliance purpose; • Regulatory confusion among licensees and enforcement bodies; • Licensing delays that impede the safe and legal removal of expired or unwanted drugs from healthcare environments.	

	Reverse distributors do not meet the criteria for wholesale distribution activity as described under Ohio's rules for Drug Distributors, which include "the sale of prescription drugs" and authorization to "sell controlled substances". This misalignment also risks interfering with DEA's federal regulatory structure, which already mandates registration and oversight for reverse distributors under 21 CFR §1301 and §1317. We respectfully urge the Board to adopt an amendment or policy clarification stating that entities engaged solely in reverse distribution — defined as the receipt of dangerous drugs exclusively for credit return evaluation or destruction — are not subject to licensure as wholesale distributors or terminal distributors under Ohio law. Thank you for your time and thoughtful consideration.	
Individual Pharmacist	I have no issue with the rule changes.	N/A

Rule 4729:3-2-01 | Registration procedures. (AMEND)

(A) An applicant for registration as a pharmacy technician trainee shall:

(1) Comply with all requirements set forth in section 4729.92 of the Revised Code.

(2) Comply with the criminal records check requirements pursuant to rule 4729:3-2-02 of the Administrative Code.

(3) Submit a complete application for registration, in a manner determined by the board, that includes:

(a) The required application fee **established in section 4729.921 of the Revised Code ~~of twenty-five dollars~~**, including any transaction fee as required by section 125.18 of the Revised Code.

(b) **Except as provided in paragraph (A)(3)(c), d**ocumentation, as specified by the board, that the applicant meets **both of** the following requirements:

(i) Has a high school diploma, a certificate of high school equivalence, a foreign school diploma that is equivalent to a U.S. high school diploma or has been employed continuously since prior to April 8, 2009, as a pharmacy technician without a high school diploma or certificate of high school equivalence; **and**

(ii) Is at least ~~**eighteen**~~ **seventeen** years of age.

(c) Notwithstanding the requirements of paragraph (A)(3)(b) of this rule, the board may register as a pharmacy technician trainee an applicant who is seventeen or eighteen years of age and does not possess a high school diploma or certificate of high school equivalence if the applicant is enrolled in a career-technical school program that is approved by the board and conducted by a city, exempted village, local, or joint vocational school district.

(d) Any additional information or documentation as determined by the board.

(4) A pharmacy technician trainee licensed or registered in another state may apply for registration by reciprocity by complying with the requirements listed in paragraphs (A)(1) to (A)(3) of this rule.

(B) An applicant for registration as a registered pharmacy technician shall:

(1) Comply with all requirements set forth in section 4729.90 of the Revised Code.

(2) Comply with either of the following:

(a) Have completed an approved training program pursuant to rule 4729:3-3-02 of the Administrative Code; or

(b) Hold a pharmacy technician registration or license issued by another state and have actively worked as a pharmacy technician for at least one year within the previous five years of application.

(3) Comply with the criminal records check requirements pursuant to rule 4729:3-2-02 of the Administrative Code.

(4) Submit a complete application for registration, in a manner determined by the board, that includes:

(a) The required application fee **established in section 4729.901 of the Revised Code** ~~**of fifty dollars**~~, including any transaction fee as required by section 125.18 of the Revised Code;

(b) Except for applicants currently registered as pharmacy technician trainees, documentation, as specified by the board, that the applicant meets the following requirements:

(i) Has a high school diploma, a certificate of high school equivalence, a foreign school diploma that is equivalent to a U.S. high school diploma or has been employed continuously since prior to April 8, 2009, as a pharmacy technician without a high school diploma or certificate of high school equivalence;

(ii) Is at least eighteen years of age; and

(iii) If the applicant has a foreign school diploma that is equivalent to a U.S. high school diploma, the applicant shall submit evidence of successful completion of the "Test of English as a Foreign Language, Internet-based test" (TOEFL iBT) pursuant to rule 4729:3-2-05 of the Administrative Code.

(c) Paragraph (B)(4)(b)(iii) of this rule shall not apply if the applicant complies with any of the following:

(i) Submits a diploma or transcript demonstrating completion of an associate degree or higher from an accredited college, junior college, community college, or university in the United States.

(ii) Submits verification of active professional license or registration issued under the following chapters of the Revised Code: 4715., 4723., 4725., 4729., 4730., 4731., 4732., 4734., 4741., 4744., 4753., 4755., 4757., 4759., 4760., 4761., 4762., 4774., 4778., 4779., 4783.

(iii) Submits verification of an active professional license or registration from another state that permits the applicant to engage in the same profession, occupation, or occupational activity as any license or registration issued by an agency listed in paragraph (B)(4)(c)(ii) of this rule.

(iv) Submits an attestation signed by the responsible person, or the equivalent in the state where the technician is registered, of the pharmacy where the technician is actively employed or was employed in the five years prior to the date of submission of an application. The responsible person must complete the required attestation form provided by the board and attest to their personal observation that the technician applicant demonstrates the required proficiency (reading, listening, speaking, and writing) in the english language to practice safely and effectively as a registered pharmacy technician.

(v) Submits documentation of any other board approved method for demonstrating english language proficiency.

(d) Any of the following documentation:

(i) An attestation, certificate of completion, or other board approved documentation that the applicant has successfully completed an approved training program in accordance with rule 4729:3-3-02 of the Administrative Code.

(ii) Documentation, as determined by the board, demonstrating compliance with the reciprocity requirements of paragraph (B)(2)(b) of this rule.

(e) Any additional information or documentation as determined by the board.

(C) An applicant for registration as a certified pharmacy technician shall:

(1) Comply with all requirements set forth in section 4729.90 of the Revised Code.

(2) Comply with either of the following:

(a) Have completed an approved training program pursuant to rule 4729:3-3-02 of the Administrative Code;

(b) Hold a pharmacy technician registration or license issued by another state and have actively worked as a pharmacy technician for at least one year within the previous five years of application; or

(c) Holds a current pharmacy technician certification from an organization that has been recognized by the board for at least two years immediately preceding the date the application is submitted and has been actively practicing as a pharmacy technician in a state that does not issue a pharmacy technician license or registration for at least two of the five years immediately preceding the date the application is submitted.

(3) Comply with the criminal records check requirements pursuant to rule 4729:3-2-02 of the Administrative Code.

(4) Submit a complete application for registration, in a manner determined by the board, that includes:

(a) The required application fee **established in section 4729.901 of the Revised Code** ~~**of fifty dollars**~~, including any transaction fee as required by section 125.18 of the Revised Code, except as provided in rule 4729:3-2-03 of the Administrative Code;

(b) Documentation, as specified by the board, that the applicant has a current pharmacy technician certification from an organization that has been recognized by the board.

(c) Except for applicants currently registered as pharmacy technician trainees, documentation, as specified by the board, that the applicant meets the following requirements:

(i) Has a high school diploma, a certificate of high school equivalence or a foreign school diploma that is equivalent to a U.S. high school diploma;

(ii) Is at least eighteen years of age; and

(iii) If the applicant has a foreign school diploma that is equivalent to a U.S. high school diploma, the applicant shall submit evidence of successful completion of the "Test of English as a Foreign Language, Internet-based test" (TOEFL iBT) pursuant to rule 4729:3-2-05 of the Administrative Code.

(d) Paragraph (C)(4)(c)(iii) of this rule shall not apply if the applicant complies with either of the following:

(i) Submits a diploma or transcript demonstrating completion of an associate degree or higher from an accredited college, junior college, community college or university in the United States.

(ii) Submits verification of active professional license or registration issued under the following chapters of the Revised Code: 4715., 4723., 4725., 4729., 4730., 4731., 4732., 4734., 4741., 4744., 4753., 4755., 4757., 4759., 4760., 4761., 4762., 4774., 4778., 4779., 4783.

(iii) Submits verification of an active professional license or registration from another state that permits the applicant to engage in the same profession, occupation, or occupational activity as any license or registration issued by an agency listed in paragraph (C)(4)(d)(ii) of this rule.

(iv) Submits an attestation signed by the responsible person, or the equivalent in the state where the technician is registered, of the pharmacy where the technician is actively employed or was employed in the five years prior to the date of submission of an application. The responsible person must complete the required attestation form provided by the board and attest to their personal observation that the technician applicant demonstrates the required proficiency (reading, listening, speaking, and writing) in the english language to practice safely and effectively as a certified pharmacy technician.

(v) Submits documentation of any other board approved method for demonstrating english language proficiency.

(e) Any of the following documentation:

(i) An attestation, certificate of completion, or other board approved documentation that the applicant has successfully completed an approved training program in accordance rule 4729:3-3-02 of the Administrative Code.

(ii) Documentation, as determined by the board, demonstrating compliance with the reciprocity requirements of paragraphs (C)(2)(b) and (C)(2)(c) of this rule.

(f) Any additional information or documentation as determined by the board.

(D) Pursuant to section 4729.921 of the Revised Code, a registration for a pharmacy technician trainee is valid for eighteen months from the date of issuance.

(E) A pharmacy technician trainee that fails to meet the education and training requirements during the trainee's initial registration period~~,~~ may apply for reinstatement of their registration by submitting an application and ~~**required**~~ fee as required by paragraph (A) of this rule. **Only one reinstatement shall be granted, but an individual may reapply for registration if the individual's previous registration has lapsed for more than five years or the board grants its approval.**

(F) Pursuant to section 4729.96 of the Revised Code, a limited or restricted registration may be issued to an applicant upon the determination of the board.

(G) An initial registration for a registered pharmacy technician and certified pharmacy technician is valid until the renewal date set forth in rule 4729:3-2-03 of the Administrative Code.

(H) Failure to complete all application requirements within thirty days after being notified by the board may result in the application being deemed abandoned as defined in rule 4729:3-1-01 of the Administrative Code.

(I) Registration fees for veterans shall be waived upon submission of the appropriate documentation. Documentation required to obtain a fee waiver will be published on the state board of pharmacy's web site: www.pharmacy.ohio.gov.

Rule 4729:1-2-09 | Expedited pharmacist licensure for members of the military and spouses who are licensed in another jurisdiction. (AMEND)

(A) As used in this rule:

(1) "Military duty" has the same meaning as in section 4743.041 of the Revised Code.

(2) "In good standing" means an applicant to which both the following apply:

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

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

(B) To meet the requirements set forth in section 4743.041 of the Revised Code, the state board of pharmacy shall issue an expedited license to a pharmacist applicant if the individual or the individual's spouse is on military duty in this state and the applicant complies with all the following:

(1) The individual holds a valid license or other authorization to practice as a pharmacist issued by any other state or jurisdiction. Certification of these credentials shall be filed on forms provided by the national association of boards of pharmacy (NABP) or similar forms recognized and approved by the board.

(2) The individual shall be in good standing in the state or jurisdiction of licensure.

(3) The individual presents adequate proof to the board, in accordance with paragraph (G) of this rule, that the individual or the individual's spouse is on military duty in this state.

(4) The individual complies with sections 4776.01 to 4776.04 of the Revised Code. An applicant shall submit fingerprint impressions for a criminal records check in accordance with rule 4729:1-2-05 of the Administrative Code.

(C) The board shall, within twenty-four hours after receiving the report under division (A) of section 4776.04 of the Revised Code, notify an individual applying for an expedited license in accordance with this rule that the board has received the results of a criminal records check.

(D) The board shall issue an expedited pharmacist license under this rule, provided that the applicant meets the requirements of this rule, within fourteen days of having received the results of a criminal records check. The board shall not be required to issue an expedited license if any of the following apply:

(1) The applicant fails to meet the application requirements set forth in this rule or section 4743.041 of the Revised Code.

(2) The applicant is under investigation by the licensing agency of any other state or jurisdiction.

(3) The applicant is in violation of any provision section 4729.16 of the Revised Code or rules adopted thereunder.

(E) Notwithstanding any other provision of the Revised Code or Administrative Code, the board shall waive or refund all fees associated with the issuance of an initial expedited license issued under this rule. Additional fee waivers or refunds shall be granted in accordance with other provisions of the Revised Code, Administrative Code, and board resolution.

(F) All licenses issued pursuant to this rule shall comply with the licensure renewal requirements set forth in Chapter 4729:1-2 of the Administrative Code.

(G) Pursuant to section 5903.04 of the Revised Code:

(1) A pharmacist shall submit proper documentation necessary to determine if the applicant is a service member or veteran, or the spouse or surviving spouse of a service member or veteran. Documentation requirements shall be published on the state board of pharmacy's website: www.pharmacy.ohio.gov.

(2) The board's executive director or the director's designee shall design a process to record, track, and monitor applications that have been received from a service member, veteran, or the spouse or surviving spouse of a service member or veteran.

(3) The board's executive director or the director's designee shall design a process to prioritize and expedite certification or licensing for each applicant who is a service member, veteran, or the spouse or a surviving spouse of a service member or veteran.

Rule 4729:1-2-10 | Emeritus pharmacists. (AMEND)

(A) As used in this rule:

(1) "Emeritus pharmacist" means an individual who meets all the following:

(a) Is currently or has been licensed to practice pharmacy in this state for at least ten years;

(b) Is retired from the practice of pharmacy;

(c) Is in good standing;

(d) Is at least sixty years old **or have held a license to practice pharmacy in Ohio for at least thirty years**; and

(e) Has applied for an emeritus designation in accordance with this rule.

(2) "In good standing" means a pharmacist to which all the following apply at the time of application:

(a) Does not have a board order restricting the privilege of supervising interns;

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

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

(B) Any person that meets the requirements in paragraph (A)(1) of this rule may apply to the board for emeritus designation.

(C) To apply for emeritus designation, a pharmacist shall submit a form containing information as required by the board and in a manner determined by the board.

(D) There shall be no fee associated with applying for or maintaining an emeritus designation.

(E) The emeritus designation is not a license to engage in the practice of pharmacy.

(1) Emeritus pharmacists shall not engage in the practice of pharmacy.

(2) Upon issuance of an emeritus designation, a license authorizing the person to practice pharmacy shall be considered void and may only be renewed or reinstated in accordance with the provisions of Chapter 4729. of the Revised Code and this chapter of the Administrative Code.

(F) The continuing education requirements of Chapter 4729:1-5 of the Administrative Code are not applicable to an emeritus pharmacist.

(G) An emeritus pharmacist shall not be subject to the licensure renewal requirements or renewal fees pursuant to this chapter.

(H) The board may refuse to issue or may revoke an emeritus designation for acts or conduct that are in violation of any provision of Chapters 4729., 3719., 3796., 3715., and 2925. of the Revised Code or Chapter 4729:1-4 of the Administrative Code. The decision to refuse to issue or revoke an emeritus designation is not subject to hearing rights or appeal under Chapter 119. of the Revised Code.

Rule 4729:2-2-11 | Expedited pharmacy intern licensure for members of the military and spouses who are licensed in another jurisdiction. (AMEND)

(A) As used in this rule:

(1) "Military duty" has the same meaning as in section 4743.041 of the Revised Code.

(2) "In good standing" means an applicant to which both the following apply:

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

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

(B) To meet the requirements set forth in section 4743.041 of the Revised Code, the state board of pharmacy shall issue an expedited license to a pharmacy intern applicant if the individual or the individual's spouse is on military duty in this state and the applicant complies with all the following:

(1) The individual holds a valid license or other authorization to practice as a pharmacy intern issued by any other state or jurisdiction.

(2) The individual shall be in good standing in the state or jurisdiction of licensure.

(3) The individual complies with application requirements set forth in rule 4729:2-2-01 of the Administrative Code.

(4) The individual presents adequate proof to the board, in accordance with paragraph (G) of this rule, that the individual or the individual's spouse is on military duty in this state.

(5) The individual complies with sections 4776.01 to 4776.04 of the Revised Code. An applicant shall submit fingerprint impressions for a criminal records check in accordance with rule 4729:2-2-03 of the Administrative Code.

(C) The board shall, within twenty-four hours after receiving the report under division (A) of section 4776.04 of the Revised Code, notify an individual applying for an expedited license in accordance with this rule that the board has received the results of a criminal records check.

(D) The board shall issue an expedited pharmacy intern license under this rule, provided that the applicant meets the requirements of this rule, within fourteen days of having received the results of a criminal records check. The board shall not be required to issue an expedited license if any of the following apply:

(1) The applicant fails to meet the application requirements set forth in this rule or section 4743.041 of the Revised Code.

(2) The applicant is under investigation by the licensing agency of any other state or jurisdiction.

(3) The applicant is in violation of any provision section 4729.16 of the Revised Code or rules adopted thereunder.

(E) Notwithstanding any other provision of the Revised Code or Administrative Code, the board shall waive or refund all fees associated with the issuance of an initial expedited license issued under this rule. Additional fee waivers or refunds shall be granted in accordance with other provisions of the Revised Code, Administrative Code, and board resolution.

(F) All licenses issued pursuant to this rule shall comply with the licensure renewal requirements set forth in Chapter 4729:2-2 of the Administrative Code.

(G) Pursuant to section 5903.04 of the Revised Code:

(1) A pharmacy intern shall submit proper documentation necessary to determine if the applicant is a service member or veteran, or the spouse or surviving spouse of a service member or veteran. Documentation requirements shall be published on the state board of pharmacy's website: www.pharmacy.ohio.gov.

(2) The board's executive director or the director's designee shall design a process to record, track, and monitor applications that have been received from a service member, veteran, or the spouse or surviving spouse of a service member or veteran.

(3) The board's executive director or the director's designee shall design a process to prioritize and expedite certification or licensing for each applicant who is a service member, veteran, or the spouse or a surviving spouse of a service member or veteran.

Rule 4729:3-2-04 | Change of name, contact information, and place of employment. (AMEND)

(A) An individual registered pursuant to this division who has a legal change of name, shall notify the board of pharmacy within thirty days from the effective date of such change. Such notification of a name change shall be accompanied by one of the following:

(1) A notarized affidavit;

(2) A certified copy of a court record; ~~**or**~~

(3) A certified copy of a marriage certificate~~.~~**;**

(4) A government-issued identification card which reflects the registrant's name change; or

(5) Any other documentation as approved by the board.

(B) An individual registered pursuant to this division who changes their mailing or email address shall notify the board of pharmacy**, in a manner determined by the board,** of the new address within thirty days after the effective date of such change.

(C) An individual registered pursuant to this division who changes their place of employment shall notify the board of pharmacy**, in a manner determined by the board,** of the address of the principal place where they practice as a pharmacy technician trainee, registered pharmacy technician**,** or certified pharmacy technician within thirty days after they have commenced employment.

Rule 4729:3-2-05 | Successful completion of the "Test of English as a Foreign Language Internet-based Test". (NO CHANGE)

Successful completion of the "Test of English as a Foreign Language, Internet-based test" (TOEFL iBT) shall be the following minimum scores or higher:

(A) Writing: fourteen;

(B) Speaking: twenty;

(C) Listening: seventeen; and

(D) Reading: eighteen.

Rule 4729:3-2-06 | Expedited pharmacy technician registration for members of the military and spouses who are licensed or registered in another jurisdiction. (NO CHANGE)

(A) As used in this rule:

(1) "Military duty" has the same meaning as in section 4743.041 of the Revised Code.

(2) "In good standing" means an applicant to which both the following apply:

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

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

(3) "Pharmacy technician" means any of the following registration types issued under Chapter 4729. of the Revised Code:

(a) Certified pharmacy technician;

(b) Registered pharmacy technician; or

(c) Pharmacy technician trainee.

(B) To meet the requirements set forth in section 4743.041 of the Revised Code, the state board of pharmacy shall issue an expedited registration to pharmacy technician applicant if the individual or the individual's spouse is on military duty in this state and the applicant complies with all the following:

(1) The individual holds a valid registration or other authorization to practice as a pharmacy technician issued by any other state or jurisdiction.

(2) The individual shall be in good standing in the state or jurisdiction of licensure or registration.

(3) The individual complies with the application requirements set forth in rule 4729:3-2-01 of the Administrative Code.

(4) The individual presents adequate proof to the board, in accordance with paragraph (G) of this rule, that the individual or the individual's spouse is on military duty in this state.

(5) The individual complies with sections 4776.01 to 4776.04 of the Revised Code. An applicant shall submit fingerprint impressions for a criminal records check in accordance with rule 4729:3-2-02 of the Administrative Code.

(C) The board shall, within twenty-four hours after receiving the report under division (A) of section 4776.04 of the Revised Code, notify an individual applying for an expedited registration in accordance with this rule that the board has received the results of a criminal records check.

(D) The board shall issue an expedited pharmacy technician registration pursuant to this rule, provided that the applicant meets the requirements of this rule, within fourteen days of having received the results of a criminal records check. The board shall not be required to issue an expedited registration if any of the following apply:

(1) The applicant fails to meet the application requirements set forth in this rule or section 4743.041 of the Revised Code.

(2) The applicant is under investigation by the licensing agency of any other state or jurisdiction.

(3) The applicant is in violation of any provision section 4729.96 of the Revised Code or rules adopted thereunder.

(E) Notwithstanding any other provision of the Revised Code or Administrative Code, the board shall waive or refund all fees associated with the issuance of an initial expedited registration issued under this rule. Additional fee waivers or refunds shall be granted in accordance with other provisions of the Revised Code, Administrative Code, and board resolution.

(F) All registrations issued pursuant to this rule shall comply with the registration renewal requirements set forth in Chapter 4729:3-2 of the Administrative Code.

(G) Pursuant to section 5903.04 of the Revised Code:

(1) A pharmacy technician shall submit proper documentation necessary to determine if the applicant is a service member or veteran, or the spouse or surviving spouse of a service member or veteran. Documentation requirements shall be published on the state board of pharmacy's website: www.pharmacy.ohio.gov.

(2) The board's executive director or the director's designee shall design a process to record, track, and monitor applications that have been received from a service member, veteran, or the spouse or surviving spouse of a service member or veteran.

(3) The board's executive director or the director's designee shall design a process to prioritize and expedite certification or licensing for each applicant who is a service member, veteran, or the spouse or a surviving spouse of a service member or veteran.

Rule 4729:3-5-01 | Continuing Education - Definitions. (AMEND)

As used in Chapter 4729:3-5 of the Administrative Code.

(A) "A.C.P.E." means the accreditation council for pharmacy education.

(B) "Continuing education unit" or "C.E.U." means ten contact hours of participation in an organized continuing pharmacy education experience presented by an approved provider.

(C) "Continuing pharmacy education" or "continuing education", as required in section 4729.12 of the Revised Code, means post-registration pharmacy education undertaken to maintain professional competency to practice as a pharmacy technician, improve professional skills, and preserve uniform qualifications for continuing the practice of the profession for the purpose of protecting public health and welfare. Continuing pharmacy education may be obtained from any of the following providers:

(1) A pharmacy jurisprudence program pursuant to paragraph (D) of this rule;

(2) An approved in-state provider of volunteer healthcare services in accordance with section 4745.04 of the Revised Code and agency 4729 of the Administrative Code;

(3) An A.C.P.E. accredited continuing education provider.

(D) "One-third of a licensee's continuing education requirement" as used in division (C) of section 4745.04 of the Revised Code and paragraph (C) of rule 4729:3-5-02 of the Administrative Code, means the total number of required C.E.U.s for licensure renewal divided by three and rounded down to the nearest whole number.

(E) "Pharmacy jurisprudence" means continuing education the includes any of the following:

(1) An A.C.P.E. law program as identified by A.C.P.E numbering convention "03";

(2) A board of pharmacy approved continuing education program provided by an in-state approved jurisprudence provider pursuant to ~~**agency 4729**~~ **Chapter 4729-6** of the Administrative Code that pertains to current or recent changes to laws, rules, and regulations relating to the practice of pharmacy; or

(3) A program presented by the state board of pharmacy that pertains to current or recent changes to laws, rules, and regulations relating to the practice of pharmacy.

(F) "Patient or medication safety" means an A.C.P.E. continuing education program identified by the A.C.P.E. numbering convention "05" that deals with the prevention of healthcare errors and the elimination or mitigation of patient injury caused by healthcare errors.

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

Rule 4729:3-5-02 | Continuing Education Requirements for Registered and Certified Technicians. (AMEND)

(A) As a condition for the renewal of a registration as a registered pharmacy technician, the registrant shall complete a total of ten contact hours (1.0 C.E.Us) of continuing pharmacy education during the twenty-four months preceding the expiration date of the technician's registration. The continuing pharmacy education shall be in pharmacy technician-specific subject matter and shall include, at a minimum, the following:

(1) Two contact hours (0.2 C.E.Us) of continuing pharmacy education shall be in the subject of pharmacy jurisprudence (law).

(2) Two contact hours (0.2 C.E.Us) of continuing pharmacy education shall be in the subject of patient or medication safety.

(B) Paragraph (A) of this rule does not apply to registered pharmacy technicians that obtain an initial registration within six months of the expiration date of the registration.

(C) A registered pharmacy technician may satisfy up to one-third of the technician's continuing education requirements by providing health care services as a volunteer in accordance with section 4745.04 of the Revised Code. The location where health care services are provided shall be an approved in-state provider of volunteer healthcare services in accordance with ~~**agency 4729**~~ **Chapter 4729-6** of the Administrative Code.

(D) Registered pharmacy technicians shall keep all certificates and other documented evidence of participation which have been issued by a non-A.C.P.E. accredited provider for which the pharmacy technician has claimed continuing education units towards renewal of the technician's registration for a period of one year following the year in which evidence was required for renewal.

(1) Documentation, as determined by the state board of pharmacy, shall be submitted only when requested by the board.

(2) The board shall monitor compliance by conducting an audit of registrants.

(3) The board shall require the reporting of continuing education units to a national and/or state register.

(E) As a condition for the renewal of a registration as a certified pharmacy technician, the registrant shall complete all continuing education requirements necessary to maintain the registrant's pharmacy technician certification from an organization that has been recognized by the board.