

July 2025 – Rules and Resolutions

Resolution: Appointment to the 2025 Rules Review Committee

In accordance with OAC 4729-2-02, the Ohio Board of Pharmacy hereby appoints the following individuals to the 2025 Rules Review Committee:

Name	Job Title	Employer
Krystina Hepler	Outpatient Pharmacy Supervisor	Akron Children's Hospital
Joshua Pearson	Director of Pharmacy Services	Health Partners Free Clinic
Marla Samide	Pharmacy Team Leader/Clinical	Giant Eagle
Kayla McCord	Pharmacist In Charge	Kroger
Hannah Cross	Pharmacist in Charge	Summa Health Rootstown Pharmacy
Louisa Chin	Cleveland Clinic Union Hospital Outpatient Pharmacy Manager	Cleveland Clinic Union Hospital
Ginger Berrie	Director of Retail Pharmacy	Bon Secours Mercy Health
JoMarie Richardson	Ohio Pharmacy Director	Equitas Health
Kelley Sullivan Dragar	Chief Pharmacy Officer	Signature Health
Taylor Hardwick	Lead Certified Pharmacy Technician	Walmart
Erica Harrison	Lead Tech (Certified)	Community First Pharmacy
Colleen Longstreet	Senior Pharmacy Technician (Certified)	Meijer

For Filing with JCARR and/or CSI

4729:5-14-01 Emergency medical services - definitions

(H)

- (1) "Positive identification" means a method of identifying EMS personnel that does not rely solely on the use of a private personal identifier such as a password, but must also include a secure means of identification such as the following:
 - (a) A manual signature on a hard copy record;
 - (b) A magnetic card reader;
 - (c) A bar code reader;
 - (d) A biometric method;
 - (e) A proximity badge reader;
 - (f) A board approved system of randomly generated personal questions;
 - (g) A printout of every transaction that is verified and manually signed within a reasonable period of time by the individual who prescribed, administered, or dispensed the dangerous drug. The printout must be maintained for three years and made available on request to those individuals authorized by law to review such records; or
 - (h) Other effective methods for identifying individuals that have been approved by the board.
- (2) A method relying on a magnetic card reader, a bar code reader, a proximity badge reader, or randomly generated questions for identification must also include a private personal identifier; ~~such as a password, for entry into a secure mechanical or electronic system.~~

4729:5-19-02 Personally furnishing dangerous drugs.

...

(K) Any patient specific dangerous drug dispensed by a pharmacy that is provided to a patient by a prescriber pursuant to rule **4729:5-5-14 4729:5-3-24** of the Administrative Code is the property of that patient and is not considered personally furnishing. No prescriber that provides a patient with a drug pursuant to rule **4729:5-5-14 4729:5-3-24** of the Administrative Code shall charge any additional fees or require any additional monetary compensation for the dangerous drug.

4729:5-20-02 Personally furnishing dangerous drugs.

...

(H) Any patient specific dangerous drug dispensed by a pharmacy that is provided to an owner or caregiver by a veterinarian pursuant to rule **4729:5-5-14 4729:5-3-24** of the Administrative Code is the property of that owner or caregiver and is not considered personally furnishing. No veterinarian that provides an owner or caregiver with a drug pursuant to rule **4729:5-5-14 4729:5-3-24** of the Administrative Code shall charge any additional fees or require any additional monetary compensation for the dangerous drug.

4729:5-21-02 Personally furnishing dangerous drugs from an opioid treatment program.

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(K) Any patient specific dangerous drug dispensed by a pharmacy that is provided to a patient by a prescriber pursuant to rule **4729:5-5-14 4729:5-3-24** of the Administrative Code is the property of that patient and is not considered personally furnishing. No prescriber that provides a patient with a drug pursuant to rule **4729:5-5-14 4729:5-3-24** of the Administrative Code shall charge any additional fees or require any additional monetary compensation for the dangerous drug.

4729:9-1-01 Schedule I controlled substances.

(d) Naphthylmethylenes: any compound containing a ~~naphthylmethylenindene~~ **naphthylmethyldene** structure with or without substitution at the 3-position of the indene ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, (N-methylpiperidin-2-yl)methyl, cyanoalkyl, (N-methylpyrrolidin-2-yl)methyl, (tetrahydropyran-4-yl)methyl, ((N-methyl)-3-morpholinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted on the indene group to any extent or whether or not substituted on the naphthyl group to any extent. Naphthylmethylenes include, but are not limited to, (1-[(3-pentyl)-1H-inden-1-ylidene)methyl]naphthalene (JWH-176).

4729:5-21-05 Mobile opioid treatment programs.

(B) For any opioid treatment program intending to operate a mobile opioid treatment program, the licensee shall:

(1) ~~notify~~ Notify the following:

(a) The local drug enforcement administration (DEA) office, in writing, its intent to do so, and the opioid treatment program must receive explicit written approval from the local DEA office prior to operating the mobile opioid treatment program. The mobile opioid treatment program may only operate in the same state in which the opioid treatment program is registered with the DEA.

(b) When submitting notification to the DEA in accordance with paragraph (B)(1)(a) of this rule, the opioid treatment program shall also notify the board of pharmacy in a manner determined by the board.

(12) Licensees are not required to obtain a separate terminal distributor of dangerous drugs license for conveyances (mobile components) utilized by the licensee to transport dangerous drugs away from licensed locations for use as part of a mobile opioid treatment program. Vehicles must possess valid county/city and state information (e.g., a vehicle identification number (VIN) or license plate number) on file at the licensed location of the opioid treatment program licensed by the board.

(23) A mobile opioid treatment program is not permitted to reverse distribute, share, or transfer dangerous drugs from one mobile component to another mobile component while deployed outside of the licensed location. These mobile components of opioid treatment programs may not function as hospitals, long-term care facilities, or emergency medical service vehicles, and shall not transport patients.

CSI Comments – Administration of Injectable Drugs and Dispensing Drugs to an Alternate Location

Name	Organization	Comment	DRAFT Response
Kristen Monarch-Mocek, PharmD, BCPS, RPh	ProMedica Health System	For the proposed changes to 4729:1-3-03: --the methotrexate administrations would require quite a bit of additional control for patient safety as unlike the other medications it is a NIOSH category 1 medication. I suggest additional considerations for receiving and maintaining training and competency for hazardous drug handling / storage be added to help prevent accidental harmful pharmacist or non-prescribed patient exposure.	Propose adding a requirement to protocol instructions to include: <u>(i) Any special handling instructions, precautions, or use of personal protective equipment if applicable.</u>
David E. Burke, RPh, MBA	Ohio Pharmacists Association	Proposed Rule 4729:1-3-03 We support the additions and changes to this rule and applaud the Board of Pharmacy. The increased access to allowed administration of medications by pharmacists and the expansion of permitting additional prescribers to exercise this privilege	Supportive comment.

		<p>increases patient access and assists to maintain the quality of care intended by the prescriber in the outpatient setting.</p> <p>Proposed Rule 4729:5-3-24 (rescind 4729:5-5-14) The Board of Pharmacy continues to clarify and adjust the rules related to the movement of medications between entities. We support the rule change and the Board's consistent work in modernizing these provisions.</p>	
Tracy L. Vanneman, CAE	Ohio Association of Physician Assistants	<p>On behalf of the Ohio Association of Physician Assistants (OAPA), I am writing to request that the Ohio Board of Pharmacy restore language in the proposed rule <i>4729:1-3-03 Administration of Drugs by Injection</i> that recognizes physician assistants (PAs) who have entered into supervision agreements with physicians as authorized prescribers.</p> <p>In a prior version of ORC 4729.45, only physicians were explicitly referenced; however, the Board took</p>	<p>New amendments to the statute now specify which mid-level practitioners are able to prescribe injectable medications for administration by pharmacists.</p> <p>If the legislature intended on allowing PAs to have such authority it would be specified in statute with all other mid-level prescribers. Therefore, the commenter should seek a legislative fix to address the absence of PAs from the statute. With the updated legislative language, the Board cannot exercise its</p>

		<p>the appropriate and pragmatic step of recognizing that PAs functioning under valid supervision agreements were also authorized prescribers in the Ohio Administrative Code. This interpretation aligned with the statutory framework governing PA practice in Ohio and supported collaborative, team-based care.</p> <p>Although the revised statute (ORC 4729.45) again does not explicitly name PAs, it also does not preclude their inclusion. The current rule proposal removes this previously granted recognition, which could create confusion and barriers to efficient patient care.</p> <p>We respectfully urge the Board to restore language that acknowledges PAs in supervision agreements as authorized prescribers, consistent with past practice and the intent of team-based care models.</p>	<p>authority beyond what is specifically stated in statute.</p>
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4729:1-3-03 – Administration of Drugs by Injection (AMEND)

(A) A pharmacist licensed under Chapter 4729. of the Revised Code may administer by injection any of the following drugs as long as the drug that is to be administered has been prescribed by a physician, certified nurse-midwife, clinical nurse specialist, or certified nurse practitioner and the individual to whom the drug was prescribed has an ongoing physician-patient or nurse-patient relationship with the physician or nurse:

~~(A) A pharmacist licensed under Chapter 4729. of the Revised Code may administer, by injection, any of the following dangerous drugs if the dangerous drug that is to be administered has been prescribed by a physician and the individual to whom the dangerous drug was prescribed has an ongoing relationship with the physician, an advanced practice registered nurse who has entered into a standard care arrangement with the physician, or a physician assistant who has entered into a supervision agreement with the physician:~~

(1) An addiction treatment drug administered in a long-acting or extended-release form, which may include any medication indicated for relapse prevention; An opioid antagonist used for treatment of drug addiction and administered in a long-acting or extended-release form. An opioid antagonist may also be administered for the treatment of alcohol dependence in accordance with approved labeling by the United States food and drug administration.

(2) An antipsychotic drug administered in a long-acting or extended-release form;

(3) A human immunodeficiency virus treatment or prevention drug administered in a long-acting or extended-release form;

(3) Hydroxyprogesterone caproate for pregnant women;

(4) Medroxyprogesterone acetate for non-pregnant women;

(5) Cobalamin, to include: cyanocobalamin, hydroxocobalamin or any other vitamin B12 injection approved by the United States food and drug administration;

(6) Antibiotics;

(7) Denosumab or romosozumab;

(8) Methotrexate;

(9) Heparin, low molecular weight heparin, and factor Xa inhibitors; and

(6) (10) Any other dangerous drugs authorized for pharmacist administration pursuant to section 4729.45 of the Revised Code.

(B) To be authorized to administer drugs pursuant to this rule, a pharmacist shall comply with all the following:

(1) Successfully complete a course in the administration of drugs that satisfies the requirements pursuant to paragraph (L) of this rule.

(2) Receive and maintain certification to perform basic life-support procedures by successfully completing a basic life-support training course certified by the American red cross, American heart association, **American safety and health institute**, or other training course approved by the board. Certification shall be obtained and maintained through courses that are conducted in-person or, at a minimum, offer an in-person training component.

(3) Practice in accordance with a protocol that meets the requirements of paragraphs (F) and (G) of this rule.

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

(1) For each drug administered by a pharmacist to an individual who is eighteen years of age or older, the pharmacist shall obtain written permission from the individual.

(2) For each drug administered by a pharmacist to an individual who is under eighteen years of age, the pharmacist shall obtain written permission from the individual's parent or other person having care or charge of the individual.

(3) For each drug administered by a pharmacist to an individual who lacks the capacity to make informed health care decisions, the pharmacist shall obtain written permission from the person authorized to make such decisions on the individual's behalf.

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

(5) In the case of an **addiction treatment drug described in paragraph (A)(1) of this rule** **opioid antagonist**, obtain, in accordance with paragraph (D) of this rule, test results indicating that it is appropriate to administer the drug to the individual if either of the following is to be administered:

(a) The initial dose of the drug;

(b) Any subsequent dose, if the administration occurs more than thirty days after the previous dose of the drug was administered.

(6) Observe the individual to whom the drug is administered to determine whether the individual has an adverse reaction to the drug.

(7) Notify the physician, **certified nurse-midwife, clinical nurse specialist, or certified nurse practitioner** who prescribed the drug within seven days that the drug has been administered to the individual. Notification ~~of the physician~~ shall be conducted using one of the following methods that is capable of confirming delivery of the required notification:

(a) Electronic mail;

(b) Interoperable electronic medical records system;

(c) Facsimile;

(d) Electronic prescribing system;

(e) Electronic pharmacy record system;

(f) Documented verbal communication; or

(g) Any other method of notification that might reasonably be expected to allow for the confirmed transmission of the required notification.

(D) A pharmacist may obtain the test results described in paragraph (C)(5) of this rule:

(1) From the prescribing physician, **certified nurse-midwife, clinical nurse specialist, certified nurse practitioner; or the physician's agent; or**

(2) From an agent of the prescribing physician, certified nurse-midwife, clinical nurse specialist, certified nurse practitioner; or

(3) By ordering blood and urine tests for the individual to whom the opioid antagonist is to be administered.

(E) If a pharmacist orders blood and urine tests pursuant to paragraph (D) of this rule, the pharmacist shall evaluate the results of the tests to determine whether they indicate that it is appropriate to administer the **addiction treatment drug opioid antagonist**. A pharmacist's authority to evaluate test results pursuant to this rule does not authorize the pharmacist to make a diagnosis.

(F) A ~~physician-established~~ protocol for the administration of dangerous drugs in accordance with section 4729.45 of the Revised Code shall include the following:

(1) For the dangerous drugs listed in paragraph (A) of this rule:

(a) Name and strength;

(b) Precautions and contraindications;

(c) Intended audience or patient population;

(d) Dosage;

(e) Administration schedules;

(f) Routes of administration;

(g) Injection sites; **and**

(h) The type of tests that may be ordered in accordance with paragraph (E) of this rule; **and** .

(i) Any special handling instructions or precautions if applicable.

(2) The length of time the pharmacist must observe an individual for adverse effects, which shall be based on standards of care established by the **authorizing physician, certified nurse-midwife, clinical nurse specialist, or certified nurse practitioner**. The location of the observation shall be in the general vicinity of the administering pharmacist to allow for on-going evaluation.

(3) A method to address emergency situations including, but not limited to, adverse reactions, anaphylactic reactions, and accidental needle sticks.

(4) The locations that a pharmacist shall engage in the administration of dangerous drugs in accordance with paragraph (J) of this rule.

(5) Specify procedures to be followed by a pharmacist when administering epinephrine, diphenhydramine, or both, to an individual who has an adverse reaction to a drug administered by the pharmacist.

(G) All ~~physician-established~~ protocols pursuant to this rule and section 4729.45 of the Revised Code shall comply with the following:

(1) The protocol shall be signed and dated by the **authorizing physician, certified nurse-midwife, clinical nurse specialist, or certified nurse practitioner** prior to implementation and shall be readily available to the administering pharmacist. The protocol shall be renewed by ~~the physician~~ on a biennial basis.

(2) A physician, **certified nurse-midwife, clinical nurse specialist, or certified nurse practitioner** may sign one protocol for multiple locations licensed as terminal distributors of dangerous drugs.

(3) Each location licensed as a terminal distributor of dangerous drugs shall maintain a copy of the protocol on-site for **immediate** inspection by an agent, inspector, or employee of the state board of pharmacy.

(4) The protocol must be established by a physician, **certified nurse-midwife, clinical nurse specialist, or certified nurse practitioner** who has a scope of practice that includes

treatment of the condition for which the individual has been prescribed the drug to be administered.

(H) Upon the request of the state board of pharmacy, a pharmacist or terminal distributor of dangerous drugs shall immediately provide the protocols for administration of drugs in accordance with this rule. The state board of pharmacy, after review, may approve the protocol or return it to the pharmacist or terminal distributor for revision without approval. If a protocol has been returned for revision without approval, it may not be implemented until the board has granted approval.

(I) A pharmacist may administer epinephrine or diphenhydramine, or both, to an individual in an emergency situation resulting from an adverse reaction to a drug administered by the pharmacist.

(J) Dangerous drugs administered in accordance with this rule shall be administered in a location that ensures the privacy and dignity of the patient and is consistent with state and federal privacy laws and regulations. When necessary to protect patient privacy, or if requested by the patient, this shall include a private area located outside of the pharmacy.

(K) Administration records shall be maintained in accordance with rule 4729:5-5-04 of the Administrative Code.

(L) A course in the administration of dangerous drugs developed pursuant to section 4729.45 of the Revised Code shall meet the following requirements:

(1) The course shall be conducted by an accreditation council for pharmacy education (ACPE) accredited provider.

(2) The course must include the following components:

(a) A minimum of an hour and a half (0.15 C.E.U.s) of live or home study coursework for each category of dangerous drug listed in paragraph (A) of this rule that is covered by the course and shall include:

(i) A review of the conditions treated or prevented;

(ii) Mechanisms of action;

- (iii) Routes of administration;
 - (iv) Injection sites and ensuring patient privacy;
 - (v) Dosages and administration schedules;
 - (vi) Monitoring and treatment of the patient for adverse reactions, including the use of diphenhydramine and epinephrine;
 - (vii) Patient populations;
 - (viii) Precautions and contraindications; and
 - (ix) Proper storage requirements.
- (b) A minimum of thirty minutes (0.05 C.E.U.s) of live or home study coursework that includes:
- (i) A review of sterile technique in injectable dosage preparation and administration;
 - (ii) A review of the proper disposal procedures for contaminated needles and dangerous drugs; and
 - (iii) A review of the proper procedures for accidental needle sticks.
- (c) A minimum of one hour (0.1 C.E.U.s) of live and supervised physical participation in administration techniques for the categories of drugs covered by the course.
- (d) If the course includes instruction on administration of an opioid antagonist, a minimum of one hour (0.1 C.E.U.s) of live or home study coursework that includes a review of the tests necessary to comply with paragraph (C)(5) of this rule and the evaluation of such tests.
- (3) A pharmacist is not required to meet the training requirements of paragraph (L)(2)(b) of this rule if the pharmacist has met the training requirements in paragraphs (A)(4)(c), (A)(4)(e) and (A)(4)(f) of rule 4729:1-3-02 of the Administrative Code;

(4) A pharmacist is not required to meet the training requirements of paragraph (L)(2)(c) of this rule if all of the following apply:

(a) The pharmacist has met the training requirements in paragraph (A)(4)(d) of rule 4729:1-3-02 of the Administrative Code; and

(b) The instruction on administration techniques provided in accordance with rule 4729:1-3-02 of the Administrative Code includes the same techniques necessary to administer each category of dangerous drug covered by the training.

(5) The course must provide a method to evaluate the successful comprehension of the content.

(6) The course must provide a method to demonstrate the pharmacist has successfully completed the course.

(7) All live coursework shall be taught by an instructor that is a licensed health care professional who has the appropriate education and experience to teach a course in the administration of the dangerous drugs included in the categories listed in paragraph (A) of this rule.

(M) Courses may be reviewed by the state board of pharmacy. A training course that fails to comply with the requirements set forth in this rule shall be considered in violation of this rule.

(N) A pharmacist who has not successfully completed a course in drug administration that meets the requirements set forth in this rule must complete a course that meets the requirements specified in this rule prior to the administration of a dangerous drug listed in paragraph (A) of this rule.

(O) A pharmacist shall maintain the following records on file at the location(s) where the pharmacist administers dangerous drugs in accordance with this rule:

(1) Proof of successful completion of a training course specified in paragraph (L) of this rule; and

(2) Proof of maintenance of certification to perform basic life-support procedures in accordance with paragraph (B)(2) of this rule.

(P) A pharmacist shall not intravenously administer any drug listed in paragraph (A) of this rule.

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

NOTE: This is intended to replace the current pick up station rule OAC [4729:5-5-14](#), which would be rescinded.

(A) As used in this rule, “alternate location” means a location other than a patient or caregiver’s address on file with the pharmacy that complies with the requirements set forth in this rule.

(B) This rule does not apply to a central fill pharmacy as defined in rules 4729:5-5-19 and 4729:5-9-02.13 of the Administrative Code.

(C) A pharmacy licensed as a terminal distributor of dangerous drugs may dispense dangerous drugs to an alternate location in accordance with this rule. An alternate location may include either:

(1) A pharmacy as defined in section [4729.01](#) of the Revised Code; or

(2) A location licensed as a terminal distributor of dangerous drugs or who is exempted from licensure in accordance with section 4729.541 of the Revised Code and all the following apply:

(a) The dispensing pharmacy maintains a record keeping system that provides accountability for the delivery, return, and, if returned, the disposal of all dangerous drugs dispensed in accordance with this division of the administrative code.

(b) There is clear and convincing evidence that delivery of a dangerous drug directly to the patient would result in:

(i) Danger or harm to public health or safety; or

(ii) Danger or harm to the patient without increased involvement by a health care professional in the patient's drug therapy.

(c) The receipt, storage, control, and distribution of the dispensed dangerous drugs are in the full and actual charge of a health care professional licensed pursuant to Chapter 4715., 4723., 4729., 4730., 4731., or 4741. of the Revised Code and in accordance with the professional’s scope of practice.

(d) There is a documented method in place to ensure compliance with rule [4729:5-5-09](#) of the Administrative Code.

(e) The dispensing complies with federal law, rules, and regulations.

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

(1) Maintain a record keeping system that will provide accountability for the receipt, disposal, and return of all dangerous drugs dispensed by the pharmacy in accordance with this division of the administrative code.

(2) Unless donated to a drug repository program pursuant to section [3715.87](#) of the Revised Code, a dangerous drug that is not distributed or administered to a patient shall either:

(a) Be returned to the dispensing pharmacy for disposal or, if applicable, returned to stock;

(b) Be disposed of in accordance the applicable rules set forth in this division of the Administrative Code.

(3) Only receive drugs from the dispensing pharmacy if there is clear and convincing evidence that the delivery of a dangerous drug directly to the patient would result in:

(a) Danger or harm to public health or safety; or

(b) Danger or harm to the patient without increased involvement by a health care professional in the patient's drug therapy.

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

(a) Return the drug to the dispensing pharmacy for disposal or, if applicable, returned to stock;

(b) Be disposed of in accordance the applicable rules set forth in this division of the Administrative Code;

(c) Donate to a drug repository program in accordance with Chapter 4729:5-10 of the Administrative Code. For the purposes of meeting the requirements under division (H) of section 3715.873 of the Revised Code and rule 4729:5-10-06 of the Administrative Code, a

terminal distributor of dangerous drugs that possesses an abandoned drug shall be deemed as the owner of the drug for the sole purpose of providing consent for the drug's donation to a drug repository program; or

(d) If dispensed by a pharmacy under common ownership and control as the receiving terminal distributor of dangerous drugs, the drug may be returned to stock in accordance with 4729:5-5-22 of the Administrative Code.

(5) Nothing shall authorize a terminal distributor of dangerous drugs to return to inventory or otherwise repurpose an abandoned drug for use on another patient, unless the terminal distributor:

(a) Operates a drug repository program in accordance with Chapter 4729:5-10 of the Administrative Code; or

(b) Returns the drug in accordance with paragraph (D)(4)(d) of this rule.

(E) The state board of pharmacy may restrict a site from acting as an alternate location if it has clear and convincing evidence that the activities of that location present the following:

(1) Danger or harm to public health or safety; or

(2) Danger or harm to the patient.

(F) No prescriber or pharmacy that provides a patient with a drug pursuant this rule shall charge any additional fees or require any additional monetary compensation for the dangerous drug.

(G) Paragraph (F) of this rule does not prohibit a prescriber or pharmacy from charging a patient for any of the following:

(1) The cost of an office visit or any expense related to the administration of a dangerous drug; or

(2) The cost of a dangerous drug dispensed by a pharmacy to a patient if paid for by the prescriber or pharmacy.

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

Name & Org	Comment	DRAFT Comment Response
Paul Miller, PharmD, BCPS - OhioHealth	<p>I would like to see some specific verbiage surrounding Institutional facilities, and for me specifically, I manage pharmacy operations for several Free Standing Emergency Departments in central Ohio that are part of the OhioHealth organization.</p> <p>In current state, and since 2017, each of these FSEDs have been licensed as a "clinic" TDDD. 2021 is when the BOP classified FSEDs as Institutional facilities. An Associate Medical Director currently serves as the RP at each of these sites, however, One of OhioHealths Institutional pharmacies services all of the FSEDs. We already have policies and procedures in place, where the Institutional pharmacy (myself as the RP) oversees all pharmacy/medication related activities, performs controlled substance inventories, monitors for and diversion, etc.</p> <p>The associate medical directors who are listed as the RPs are Emergency medicine physicians, and for all intents and purposes, do not really fulfill the functions of an RP, those RP functions and responsibilities, from an organizational standpoint, are fulfilled by the Institutional pharmacy/RP that services them.</p> <p>Our institutional facility FSEDs have one automated dispensing cabinet at each location as the only means for any</p>	<p>Currently, free standing emergency departments are classified as institutional facilities and hold a clinic license. This would require freestanding EDs to have an RP work at least 8 hours per month or have the RP conduct quarterly checks.</p>

	<p>medication dispensing. We do not dispense controlled substances home, all compounding is performed by nursing for immediate use (with virtual/remote pharmacy oversight), No prescriber compounding is occurring.</p> <p>I believe the opportunity, for a setup and operation such as ours, is for the FSED or institutional facility, to be managed via a pharmacy supplied contingency stock license and the responsibilities of pharmacy rules and operations fall under the Institutional pharmacy/RP that services them.</p>	
Arthur “Rich” Davis – Heritage Complete Home Care	<p>Proposed rule does not adequately address durable medical equipment providers who have a TDDD and responsible party solely for the purpose of distributing medical oxygen.</p>	<p>This is addressed in paragraph (F) of the rule. It would require the RP to work at the facility for 8 hours per month or conduct a quarterly check-in.</p>
William Kupka, PharmD, BCPS, 340B ACE – UH Hospitals	<p>My comments are on behalf of myself, as a Registered Pharmacist in the State of Ohio, and not my Employer.</p> <p><u>I am submitting a comment in regard to disagreeing with the Proposed Requirement for supervision as the Responsible Person and ask the Rule Committee to consider keeping the Current Requirement.</u></p> <p>I believe it is a mistake to require a specific number of physical hours for a pharmacist to serve as the Responsible Person.</p>	<p>The Board believes that setting a minimum threshold is essential to ensuring licensees maintain compliance with Ohio laws and rules.</p>

	<p>The responsibilities for the Responsible Person are:</p> <p><i>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.</i></p> <p>Pharmacy automation and information technology has changed the practice of pharmacy. A pharmacist can be responsible for the requirements of Responsible Person without physically being on-site a specific, required number of hours. I ask the Rule Committee to consider who is ultimately “in-charge” of a pharmacy. A leader who writes the policies, drives the business changes, pushes through new technology, audits the ordering, directs the operations, or would the Rule Committee prefer it be a pharmacist who is physically on-site the required hours but it not the true Responsible Person. The original requirements were correct. It gives the Board of Pharmacy the flexibility to determine who truly is “Responsible”.</p> <p>I believe you will receive additional comments such as “Why 20 hours?”, you will receive arguments for 16 hours (two business days) or why not 24 hours (three business days).</p>	
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	<p>Instead of trying to “thread the needle” for a perfect number of hours, keep the original definition. I believe that the Board wants the Responsible Person to be “the” Responsible Person for the Pharmacy. The current requirements get it right.</p> <div><p>Appendix 1</p><table><tr><th>Requirement Type</th><th colspan="2">Current Requirement</th></tr><tr><td>Outpatient Pharmacies (In-State)</td><td><p>Supervision</p><p>A responsible person (RP) must be physically present at the location for a sufficient amount of time to provide supervision and control of dangerous drugs on-site.</p></td><td><p>Supervision</p><p>If open 40+ hours per week</p><p>If open less than 40 hours per week, the pharmacy is exempt from the requirement.</p><p>Exceptions for federal or state agencies more than 31 days.</p></td></tr></table></div> <p>Thank you for your consideration.</p>	Requirement Type	Current Requirement		Outpatient Pharmacies (In-State)	<p>Supervision</p> <p>A responsible person (RP) must be physically present at the location for a sufficient amount of time to provide supervision and control of dangerous drugs on-site.</p>	<p>Supervision</p> <p>If open 40+ hours per week</p> <p>If open less than 40 hours per week, the pharmacy is exempt from the requirement.</p> <p>Exceptions for federal or state agencies more than 31 days.</p>	
Requirement Type	Current Requirement							
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<p>Danni Schneider</p>	<p>Thank you for sending out information regarding comments on responsible person changes. I wanted to provide perspective from an EMS standpoint.</p> <p>Currently I serve as a medical director for various different agencies in multiple different counties. For full-time departments, I do not feel that there would be much issue with the new proposed changes. I do worry about the volunteer department perspective. For many townships in rural communities, it will likely make for a quite challenging ask to have 20+ hours a week requirement for a responsible person.</p> <p>Also, for quarterly checks, this would be fairly demanding on medical direction. I fear this would put quite a burden on volunteer EMS departments to maintain requirements and could threaten their</p>	<p>This individual is the RP on 24 licenses. The new rule permits paramedics and advanced EMTs to serve as the RP on a license. This should alleviate the burden on medical directors who serve as the RP on multiple EMS licenses.</p>						

	<p>coverage for rural communities. Any consideration for requirements related to these communities would be much appreciated.</p> <p>I would hope that the quarterly requirement could be reconsidered in addition to the 20+ hour requirement for EMS agency.</p>	
Anna Keller, PharmD – Cardinal Health	<p><i>(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 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.</i></p> <p>As a PIC Director of Pharmacy for a mailorder pharmacy that does not contain/distribute dangerous drugs or controlled substances I do not feel that the requirement on site is relevant. However it is not a difficult number of hours to meet and happy to do so if the ruling is passed. I would like to suggest that should a pharmacy exist outside the typical outpatient/institutional settings to request an exception based on their business model and needs.</p>	<p>The commenter is from a DME pharmacy. She indicates that the supervision requirements are not difficult to meet. Parsing out DME vs. non-DME pharmacies may be difficult from an enforcement perspective. Therefore, the Board did not include any exceptions for DME pharmacies.</p>
Nick Newman, PharmD –	<p>Thank you for defining what the rules and requirements are for a Responsible Person of an Ohio Pharmacy.</p>	<p>The Board understands the concerns raised. There is already a process to review all RPs to determine if it is</p>

Essentra Pharmacy	<p>Upon reading through the rules, I did find one area of concern that would negatively affect our pharmacy and potentially many other pharmacies across the state. In section H.10.b., it reads that unless otherwise approved by the board, a terminal distributor shall not have a responsible person who has be subject to "disciplinary action that was based, in whole or in part, on the person's inappropriate prescribing, dispensing, diverting, administering, storing, securing, personally furnishing, compounding, supplying or selling a controlled substance or other dangerous drug."</p> <p>I have been the Responsible Pharmacist since our pharmacy opened in 2016. In 2020, a newly hired pharmacy technician was involved in a theft of CII substances. Because our video security system was not positioned in a way that we could prove the technician was responsible for this theft, the responsibility of the "storing and securing" fell on me, the Responsible Pharmacist (although all the evidence was pointing to the technician). Therefore, I was disciplined with a fine and had to complete extra continuing education. Although we have put in extra safeguards since that occurrence, that event still haunts me to this day. I hope and pray nothing like this ever happens under my watch again. I have had no other discipline from the Board before this event nor since the event.</p>	<p>appropriate to issue a license. The Board will issue additional guidance around this process to address this concern.</p>
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	<p>I worry with how this new rule is proposed, it would no longer allow me to be the Responsible Pharmacist for the pharmacy I helped open in 2016 and serve the patients I love so dearly. I also worry about other pharmacists across the state who are also Responsible Pharmacists who might be in similar situations. Pharmacists who have had things happen out of their control, or made a honest mistake, or made a drug error that they corrected, etc. who will be removed from their position and potentially fired to make room to hire a new pharmacist as the Responsible Pharmacist. Also, in a time where pharmacies are closing at the highest rate in years and pharmacy schools in Ohio with low admissions, what more might this rule do to our profession if we start removing all of these pharmacists from their positions with honest mistakes in the past or ones they may make in the future.</p> <p>I would like to make the following recommendation to the rule: Can we modify the rule to include language of "reckless behavior" somehow vs just any disciplinary action? The Board has used this wording recently with the new Continuous Quality Improvement rules on when it is required to report medication errors to the Board. This shows the Board understands that errors and mistakes happen in the pharmacy world, but there's a difference between honest mistakes and reckless behavior. A pharmacist who has reckless behavior should not be a Responsible</p>	
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	<p>Pharmacist of any pharmacy. But I believe any pharmacist that makes an honest error and has worked to prevent that error from occurring again (like in my case with storing and securing a CII) should be allowed to be a Responsible Pharmacist.</p> <p>Thank you for taking the time to read my concern and recommendation. I would be happy to provide any additional information or answer any questions you may have. Thank you.</p>	
Kevin Beireis, R.Ph.	<p>I feel that a free-standing emergency department should have some amount of on-site supervision by the Responsible Pharmacist required. There should not be months or even years going by with the Responsible Person of record having no idea what is actually happening in that emergency department from a pharmacy standpoint.</p> <p>I might suggest 8 hours per month. Or some similar requirement.</p>	The proposed rule would apply to free-standing EDs and require the RP to be there 8 hours per month or visit once per quarter.
Jennifer Wick PharmD, MPH, BCACP – Christ Hospital Network	<p>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</p>	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.

	<p>Person Requirements" (comments due May 13, 2025).</p> <p>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.</p> <ol style="list-style-type: none"> 1. Administrative Burden: The requirement for a quarterly inspection at each site would impose substantial administrative responsibilities. Our current operational structure does currently impose biannual inspection, but does not align with this stipulation. Implementing such a change would necessitate significant adjustments to our staffing and scheduling systems, diverting resources from direct patient care activities. 2. Impact on Clinical Services: The time commitment required from a responsible person to comply with the proposed regulations could detract from their clinical duties. This shift may lead to reduced availability of providers for patient care, adversely affecting service delivery and patient outcomes. Furthermore, the rule as written does not allow delegation of 	
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	<p>quarterly inspection to supporting staff. At present, we have many members of the team share the inspection duties (rotating pharmacists for example). The proposed rule places that burden singularly on one individual, creating limitation. Clarification of this section, outlining delegation, would be helpful if that is not the intention.</p> <p>3. Operational Flexibility: Our model allows for the efficient use of space and resources, accommodating a broad spectrum of medical specialties. The proposed rules could limit this flexibility, potentially leading to underutilized facilities and decreased access to specialized care for patients.</p> <p>Given these considerations, we respectfully request that the Board reassess the proposed responsible person requirements. We advocate for a more flexible approach that considers the operational realities of diverse healthcare providers and limits the administrative burden, particularly those serving multiple locations with rotating staff.</p>	
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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 (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 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.

(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 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) 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) 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 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.