Common Sense Initiative

Mike DeWine, *Governor*
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Business Impact Analysis

Date Issued: 7/10/2025

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

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

Responsible Person Requirements

Rule Number(s): 4729:5-2-01

Date of Submission for CSI Review: 7/10/2025

Public Comment Period End Date: 8/11/2025

Rule Type/Number of Rules:

New/_1__ rules **No Change/____ rules (FYR? ___)**

Amended/____ rules (FYR? ___) **Rescinded/__1__ rules (FYR? ___)**

Comments on the proposed rules will be accepted until close of business on August 8, 2025. Please send all comments to the following email address: RuleComments@pharmacy.ohio.gov

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

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Reason for Submission

1. **R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

   Which adverse impact(s) to businesses has the agency determined the rule(s) create?

   The rule(s):

   a. ☐ **Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**

   b. ☒ **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**

   c. ☒ **Requires specific expenditures or the report of information as a condition of compliance.**

   d. ☒ **Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**

Regulatory Intent

2. **Please briefly describe the draft regulation in plain language.**
   Please include the key provisions of the regulation as well as any proposed amendments.

Rescind:

- 4729:5-2-01 – Provides the current requirements for being the responsible person on a terminal distributor of dangerous drugs license.

New:

- 4729:5-2-01 – Replaces the current responsible person rule. Provides requirements for responsible persons on a terminal distributor of dangerous drugs license. The rule adds specific hourly or quarterly inspection requirements for licensees to ensure compliance with Ohio laws and rules (an Appendix II is attached to this BIA that outlines the requirements).

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

   The proposed rule is authorized by sections 4729.26 and 4729.55 of the Ohio Revised Code.

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

   This rule does not implement a federal requirement.

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

   The rule exceeds federal requirements because the regulation of pharmacies and other healthcare facilities has traditionally been done at the state level by legislatively created state boards of pharmacy.

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

   Section 4729.26 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules governing the practice of pharmacy.

Section 4729.55 of the Ohio Revised code requires a pharmacist, licensed health professional authorized to prescribe drugs, other person authorized by the board, animal shelter or county dog warden licensed under section 4729.531 of the Revised Code, or laboratory will maintain supervision and control over the possession and custody of dangerous drugs and controlled substances that may be acquired by or on behalf of a terminal distributor of dangerous drugs.

The Board contends that setting a minimum threshold for supervision is essential to ensuring licensees maintain compliance with ORC 4729.55 and to prevent drug diversion, including controlled substances.

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

   The success of the regulation will be measured by having the rule written in plain language, licensee compliance with the rule, and minimal questions from licensees regarding the provisions of the rule.

8. **Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**
   If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.

   No.

Development of the Regulation

9. **Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**
   If applicable, please include the date and medium by which the stakeholders were initially contacted.

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

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

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

    The comments received by the Board are included in Appendix I of this document along with responses. The comments provided did not result in any significant changes to the draft regulation.

11. **What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?**

    Scientific data was not used to develop this rule. However, a recent case examples of individuals being the "responsible person in name only" and hourly requirements in at least 21 other states were used to develop the rule.

12. **What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?** ***Alternative regulations may include performance-based regulations, which define the required outcome, but do not dictate the process the regulated stakeholders must use to comply.***

    As the regulations are essential to protecting the public's safety by ensuring oversight and compliance with Ohio law for terminal distributors of dangerous drugs, the Board did not consider any regulatory alternatives.

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

    The Board of Pharmacy's Director of Policy and Communications reviewed the proposed rule to ensure that it does not duplicate another Ohio Board of Pharmacy regulation.

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

    The rule will be posted on the Ohio Board of Pharmacy's web site, information concerning

the rule will be included in materials e-mailed to licensees (including inspection guides), and notices will be sent to associations, individuals and groups.

Ohio Board of Pharmacy staff are also available via phone or email to answer questions regarding the implementation of the rule. In addition, the Board's compliance staff are trained to educate licensees on current and/or new regulations during on-site inspections.

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

Adverse Impact to Business

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

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

Terminal distributors of dangerous drugs.

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

The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a representative business. Please include the source for your information/estimated impact.

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

The proposed rule requires submission of a new responsible person application if there is a change in the person responsible. This change takes approximately 5-20 minutes using Ohio's eLicense system and will cost $15 dollars (on/after September 28th – per HB 96 – 136th GA).

Additionally, the rule will require staff to work a certain number of hours at a facility or conduct quarterly site visits for certain facilities that may result in increased staff time.

All responsible persons will have to be Ohio licensed which may require current responsible persons for licensees out-of-state to obtain Ohio licensure. The cost to obtain an Ohio pharmacist license via reciprocity is $337.50.

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

    The Board expanded who could serve as a responsible person for EMS agencies to paramedics and advanced EMTs. This may alleviate requirements for EMS medical directors who currently serve on multiple EMS licenses.

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

    The Board determined that the regulatory intent justifies the impact on business this regulation is intended to ensure that healthcare providers provide proper oversight of locations that store dangerous drugs. The Board continues to discover instances where the designated responsible person does not really provide the oversight required by Ohio law. This puts the licensee at-risk for causing patient harm as well as potential diversion of drugs, including controlled substances.

Regulatory Flexibility

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

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

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

    The Ohio Board of Pharmacy does not fine licensees or impose penalties for first-time paperwork violations. However, any failure to meet supervision standards is not considered a paperwork error but a quality assurance issue by the licensee that is necessary for the protection of the public.

20. **What resources are available to assist small businesses with compliance of the regulation?**

    Board of Pharmacy staff is available by telephone and e-mail to answer questions. Board staff members also provide presentations to groups and associations who seek updates on current regulations and host regional meetings to discuss changes to Ohio laws and rules. Additionally, staff are trained to educate licensees on compliance with all Board of Pharmacy rules and regulations.

    The Board has also developed inspection guides that licensees can use to conduct self-inspections. These guides align with internal guidance used by Board inspectors and allow licensees to conduct self-inspections to maintain compliance. The guides also include links to the rules, important definitions, and reminders of when a licensee is required to submit notification or additional information to the Board.

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.

Appendix I – Initial Stakeholder Comments Received

Name & Org	Comment	Comment Response
OhioHealth	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. 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. 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. Our institutional facility FSEDs have one automated dispensing cabinet at each location as the only means for any	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.

	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. 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 responsibilies of pharmacy rules and operations fall under the Institutional pharmacy/RP that services them.	
Heritage Complete Home Care	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.	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.
Pharmacist	My comments are on behalf of myself, as a Registered Pharmacist in the State of Ohio, and not my Employer. 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. I believe it is a mistake to require a specific number of physical hours for a pharmacist to serve as the Responsible Person.	The Board believes that setting a minimum threshold is essential to ensuring licensees maintain compliance with Ohio laws and rules.

	The responsibilities for the Responsible Person are: *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.* 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". 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). 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. **Appendix 1** **Requirement Type** / **Current Requirement** **Outpatient Pharmacies (In-State)** **Supervision** 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. **Supervision** If open 40+ hou If open less tha pharmacy is op Exceptions for a federal or state more than 31 c Thank you for your consideration.	
EMS Medical Director	Thank you for sending out information regarding comments on responsible person changes. I wanted to provide perspective from an EMS standpoint. 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.	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.

	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 coverage for rural communities. Any consideration for requirements related to these communities would be much appreciated. I would hope that the quarterly requirement could be reconsidered in addition to the 20+ hour requirement for EMS agency.	
Cardinal Health	*(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.* 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.	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.

Pharmacist	Thank you for defining what the rules and requirements are for a Responsible Person of an Ohio Pharmacy. 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." 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 Pharmacist of any pharmacy. But I believe any pharmacist that makes an honest error and has worked	The Board understands the concerns raised. There is already a process to review all RPs to determine if it is appropriate to issue a license. The Board will issue additional guidance around this process to address this concern. If you currently serve as an RP, then you have been vetted by the existing process and there is no concern you will be denied in the future, as these restrictions already exist in the current rule.

	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. 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.	
Pharmacist	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. I might suggest 8 hours per month. Or some similar requirement.	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.
Christ Hospital 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 May 13, 2025).	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.

	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. **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. **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 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. **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. 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.	

Appendix II – Summary of Rule Change

Requirement Type	Current Requirement	Proposed Requirement
RP Supervision – In-State Pharmacy (Outpatient and Institutional)	A responsible person must be physically present at the location for a sufficient amount of time to provide supervision and control of dangerous drugs on-site.	If open 40+ hours, 20 hours per week. If open less than 40 hours per week, 50% of the total hours the pharmacy is open. Exceptions for authorized leave: scheduled vacation, illness, federal or state holiday, or temporary leave of absence lasting no more than 31 calendar days. **NOTE:** Freestanding EDs are not considered pharmacies and would follow the following requirements for clinics: • Work a minimum of 8 per month at the licensed location, except when absent due to authorized leave. **-OR-** • Conduct an on-site, documented in-person visit of the terminal distributor where they serve as the responsible person on a quarterly basis.
Multiple RPs – Outpatient In-State Pharmacy	A pharmacist shall be the responsible person for no more than one such pharmacy or campus unless granted permission by the Board pursuant to a written request. No limitation on the total number of pharmacies that a pharmacist may serve as multiple RP.	Limits to two outpatient pharmacies if the following conditions are met: 1. Meet the hourly requirements. 2. The pharmacies have not been disciplined in the past 12 months for theft or significant loss. 3. There have been no minimum standards violations in the past 12 months.

		4. Neither of the pharmacies are open more than 20 hours per day (e.g., no 24-hour stores). 5. The proposed RP has been licensed to practice in Ohio for at least one year. 6. The proposed RP is not on probation or otherwise restricted from serving as the RP on multiple licenses.
Multiple RPs – Institutional In-State Pharmacy	A pharmacist shall be the responsible person for no more than one such pharmacy or campus unless granted permission by the Board pursuant to a written request. No limitation on the total number of pharmacies that a pharmacist may serve as multiple RP.	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 otherwise restricted from serving as the responsible person on multiple licenses pursuant to a settlement agreement or order of the board.
Supervision – Contingency Stock	A responsible person must be physically present at the location for a sufficient amount of time to provide supervision and control of dangerous drugs on-site.	Specific hour requirements 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.
Non-Resident Pharmacy – Supervision	A responsible person must be physically present at the location for a sufficient amount of time to provide supervision and control of dangerous drugs on-site.	Defers to home state requirements. However, requires the designation of a new RP if the RP is absent in excess of 31days.
Non-Resident Pharmacy – Multiple RP	A pharmacist shall be the responsible person for no more than one such pharmacy or campus unless granted permission by the Board pursuant to a written request.	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-

	No limitation on the total number of pharmacies that a pharmacist may serve as multiple RP.	resident pharmacies are located on a campus as defined in section 4729:5-1-01 of the Administrative Code.
Non-Resident TDDDs (non-pharmacy) – Supervision	A responsible person must be physically present at the location for a sufficient amount of time to provide supervision and control of dangerous drugs on-site.	Defers to home state requirements. However, requires the designation of a new RP if the RP is absent in excess of 31-days.
Non-Resident TDDDs (non-pharmacy) – Multiple RP	No limitation on RPs for multiple licenses.	A pharmacist/prescriber shall not serve as the responsible person for more than one non-resident TDDD, unless the non-resident pharmacies are located on a campus as defined in section 4729:5-1-01 of the Administrative Code.
Pain Management Clinic – Supervision	A physician shall not be designated the responsible person for a location licensed as a category III terminal distributor of dangerous drugs with a pain management classification unless the physician will be physically present at the location for a sufficient amount of time to provide adequate supervision.	Eight hours per week. Exceptions for authorized leave: scheduled vacation, illness, federal or state holiday, or temporary leave of absence lasting no more than 31 calendar days.
Pain Management Clinic – Multiple RP	A physician shall be the responsible person for no more than one such location unless granted permission by the Board pursuant to a written request. No limitation in rule on the total number of PMCs that a MD/DO may serve as multiple RP.	No limitation proposed as long as the responsible person can meet the hourly requirements (8 hours per week) at each location.
EMS – Supervision	A responsible person must be physically present at the location for a sufficient amount of time to provide supervision and control of dangerous drugs on-site. Usually the medical director, however, the rules allow delegation to EMS staff.	Permits physician, pharmacist, paramedic or advanced EMT to serve as the RP. Work a minimum of twenty hours per week at the location licensed, except when absent due to authorized leave.

		-OR- Conduct an on-site, documented in-person visit of the terminal distributor where they serve as the responsible person on a quarterly basis.
Prescriber Clinics - Supervision	A responsible person must be physically present at the location for a sufficient amount of time to provide supervision and control of dangerous drugs on-site.	Work a minimum of 8 per month at the licensed location, except when absent due to authorized leave. -OR- Conduct an on-site, documented in-person visit of the terminal distributor where they serve as the responsible person on a quarterly basis.
Responsible Person Licensure Requirements	Current rules require Ohio licensure of RP if in-state and the following non-resident entities: 1. Nuclear pharmacies; 2. Compounding pharmacies; 3. Outsourcing facilities.	Requires RP to hold professional Ohio license to be an RP.