



Rules for Stakeholder Feedback – Responsible Person Requirements

Date Issued: 4/9/2025

Comments Due: 5/13/2025

The Ohio Board of Pharmacy is requesting public comment on the repeal and replacement of OAC 4729:5-2-01, which governs the responsible person requirements for terminal distributors of dangerous drugs.

Comments on the proposed rules will be accepted until the close of business on **Tuesday, May 13, 2025**. Please send all comments to the following email address:
rulecomments@pharmacy.ohio.gov

The complete rule text can be found starting on the next page of this document. To assist commenters, the Board has developed a summary chart that is included as Appendix I to this document.

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 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 1

| Requirement Type | Current Requirement | Proposed Requirement |
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| <p>Outpatient Pharmacies (In-State)</p> | <p><u>Supervision</u> 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><u>Multiple RPs</u> 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.</p> <p>No limitation on the total number of pharmacies that a pharmacist may serve as multiple RP.</p> | <p><u>Supervision</u> If open 40+ hours, 20 hours per week.</p> <p>If open less than 40 hours per week, 50% of the total hours the pharmacy is open.</p> <p>Exceptions for authorized leave: scheduled vacation, illness, federal or state holiday, or temporary leave of absence lasting no more than 31 calendar days.</p> <p><u>Multiple RPs</u> Limits to two outpatient pharmacies if the following conditions are met:</p> <ol style="list-style-type: none"> 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. |
| <p>Institutional Pharmacies (In-State)</p> | <p><u>Supervision</u> 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.</p> | <p><u>Supervision</u> If open 40+ hours, 20 hours per week.</p> <p>If open less than 40 hours per week, 50% of the total hours the pharmacy is open.</p> |

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| | <p><u>Multiple RPs</u></p> <p>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.</p> <p>No limitation on the total number of pharmacies that a pharmacist may serve as multiple RP.</p> <p>No limitation on the total number of pharmacies that a pharmacist may serve as multiple RP.</p> | <p>Exceptions for authorized leave: scheduled vacation, illness, federal or state holiday, or temporary leave of absence lasting no more than 31 calendar days.</p> <p>NOTE: Specific hour requirements and multiple RP restrictions 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.</p> <p><u>Multiple RPs</u></p> <p>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.</p> |
| <p>Non-Resident Pharmacy (Out-of-State)</p> | <p><u>Supervision</u></p> <p>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.</p> <p><u>Multiple RPs</u></p> | <p><u>Supervision</u></p> <p>Defers to home state requirements. However, requires the designation of a new RP if the RP is absent in excess of 31days.</p> <p><u>Multiple RPs</u></p> |

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| | <p>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.</p> <p>No limitation on the total number of pharmacies that a pharmacist may serve as multiple RP.</p> | <p>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</p> |
| <p>Non-Resident TDDDs (Out-of-state - non-pharmacy)</p> | <p><u>Supervision</u></p> <p>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.</p> <p><u>Multiple RPs</u></p> <p>No limitation on RPs for multiple licenses.</p> | <p><u>Supervision</u></p> <p>Defers to home state requirements. However, requires the designation of a new RP if the RP is absent in excess of 31-days.</p> <p><u>Multiple RPs</u></p> <p>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.</p> |
| <p>Pain Management Clinics</p> | <p><u>Supervision</u></p> <p>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.</p> <p><u>Multiple RPs</u></p> | <p><u>Supervision</u></p> <p>Eight hours per week.</p> <p>Exceptions for authorized leave: scheduled vacation, illness, federal or state holiday, or temporary leave of absence lasting no more than 31 calendar days.</p> <p><u>Multiple RPs</u></p> |

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| | <p>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.</p> <p>No limitation in rule on the total number of PMCs that a MD/DO may serve as multiple RP.</p> | <p>No limitation proposed as long as the responsible person can meet the hourly requirements (8 hours per week) at each location.</p> |
| EMS | <p><u>Supervision</u></p> <p>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.</p> <p>Usually the medical director, however, the rules allow delegation to EMS staff.</p> <p><u>Multiple RPs</u></p> <p>No limitation.</p> | <p><u>Supervision</u></p> <p>Permits physician, pharmacist, paramedic or advanced EMT to serve as the RP.</p> <p>Work a minimum of twenty hours per week at the location licensed, except when absent due to authorized leave.</p> <p>-OR-</p> <p>Conduct an on-site, documented in-person visit of the terminal distributor where they serve as the responsible person on a quarterly basis.</p> <p><u>Multiple RPs</u></p> <p>No limitation if they can meet supervision requirements above.</p> |
| Prescriber Clinics | <p><u>Supervision</u></p> <p>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.</p> | <p><u>Supervision</u></p> <p>Work a minimum of 8 per month at the licensed location, except when absent due to authorized leave.</p> <p>-OR-</p> |

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| | <p><u>Multiple RPs</u></p> <p>No limitation.</p> | <p>Conduct an on-site, documented in-person visit of the terminal distributor where they serve as the responsible person on a quarterly basis.</p> <p><u>Multiple RPs</u></p> <p>No limitation if they can meet supervision requirements above.</p> |
| <p>Responsible Person Licensure Requirements</p> | <p>Current rules require Ohio licensure of responsible person if in-state and the following non-resident entities:</p> <ol style="list-style-type: none"> 1. Nuclear pharmacies; 2. Compounding pharmacies; 3. Outsourcing facilities. | <p>Requires the responsible person for a TDDD license to hold an Ohio professional license.</p> |