Rules for Stakeholder Feedback – Responsible Person and Pick-Up Station

Date Issued: 10/24/2024

In accordance with Chapter 119. of the Revised Code, the Ohio Board Pharmacy proposes adoption of or amendments to the following rules:

- **4729:5-2-01 – Responsible person - terminal distributor. (AMEND)**
- **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  (NOTE: This is intended to replace the current pick up station rule OAC 4729:5-5-14, which would be rescinded)
- **4729:6-2-01 – Responsible person - drug distributor. (AMEND)**

Comments on the proposed rules will be accepted until close of business on **Friday, November 13, 2024**.

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Rule 4729:5-2-01 | Responsible person - terminal distributor.

(A) ~~**Except as provided in paragraph (B) of this rule, for 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 whose name appears on the terminal distributor of dangerous drugs license**.** ~~**a pharmacy as defined in division (A) of section 4729.01 of the Revised Code. A pharmacist shall be the responsible person for no more than one such pharmacy or campus unless granted permission in accordance with paragraph (G) of this rule.**~~

(2) 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.

(3) The person to whom the terminal distributor of dangerous drugs license has been issued 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.

(4) The pharmacist serving as the responsible person shall work a minimum of eight hours per week at the pharmacy or pharmacies where the pharmacist serves as the responsible person, except when absent due to authorized leave (e.g., vacation, illness, federal or state holiday, or temporary leave of absence lasting no more than thirty 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 ~~**licensed under section 4729. of the Revised Code**~~ may be the responsible person whose name appears on the terminal distributor of dangerous drugs license**.** ~~**for an institutional pharmacy. A pharmacist shall be the responsible person for no more than one such pharmacy or campus unless granted permission in accordance with paragraph (G) of this rule.**~~

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

(a) The practice of the profession of pharmacy performed within the institutional 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.

(3) The person to whom the terminal distributor of dangerous drugs license has been issued 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.

(4) Except as provided in paragraph (B)(5) of this rule, the pharmacist serving as the responsible person shall work a minimum of eight hours per week at the institutional pharmacy or pharmacies where the pharmacist serves as the responsible person, except when absent due to authorized leave (e.g., vacation, illness, federal or state holiday, or temporary leave of absence lasting no more than thirty calendar days).

(5) The requirements of paragraph (B)(4) of this rule do not apply to terminal distributor 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) **For a non-resident** pharmacy licensed as a terminal distributor of dangerous drugs **in accordance with chapter 4729:5-8 of the Administrative Code, the non-resident terminal distributor shall comply with either:**

(1) The responsible person shall meet the supervision requirements of the state in which the non-resident terminal distributor of dangerous drug is located; or

(2) If no such requirements exist, the responsible person shall meet the requirements of paragraph (A) of this rule.

(~~C~~**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 whose name appears on the category III terminal distributor of dangerous drugs with a pain management classification license as defined in section 4729.552 of the Revised Code. ~~**A physician shall be the responsible person for no more than one such location unless granted permission in accordance with paragraph (G) of this rule. 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.**~~

(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 the pain management clinic where the physician serves as the responsible person, except when absent due to authorized leave (e.g., vacation, illness, federal or state holiday, or temporary leave of absence lasting no more than thirty calendar days).

(~~**2**~~ **3**) The responsible person shall submit to a criminal records check in accordance with section 4776.02 of the Revised Code.

(~~**3**~~ **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 must 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) 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.

(**4** **5**) The person to whom the category III terminal distributor of dangerous drugs license with a pain management clinic classification has been issued, the responsible person, 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 the 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 who is a physician licensed under Chapter 4731 of the Revised Code.

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

(a) Work a minimum of eight 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 (e.g., vacation, illness, federal or state holiday, or temporary leave of absence lasting no more than thirty calendar days); or

(b) Conduct an on-site, in-person visit of the terminal distributor where they serve as the responsible person on, at a minimum, a quarterly basis to ensure compliance with the requirements of Chapter 4729 of the Revised Code and all applicable rules adopted thereunder.

~~(D) For locations licensed as a category III terminal distributor of dangerous drugs with an office-based opioid treatment classification under section 4729.553 of the Revised Code:~~

~~(1) Only a physician or certified nurse practitioner who meets the following may be the responsible person whose name appears on the category III terminal distributor of dangerous drugs with an office-based opioid treatment classification license as defined in section 4729.553 of the Revised Code:~~

~~(a) The physician is authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery or the certified nurse practitioner is designated as a certified nurse practitioner in accordance with section 4723.42 of the Revised Code and rules adopted by the board of nursing; and~~

~~(b) The physician or certified nurse practitioner possesses a waiver to prescribe or personally furnish buprenorphine under the Drug Addiction Treatment Act of 2000 (DATA 2000) (2/20/2017).~~

~~(2) The responsible person shall submit to a criminal records check in accordance with section 4776.02 of the Revised Code.~~

~~(3) A physician or certified nurse practitioner shall not be designated the responsible person for a location licensed as a category III terminal distributor of dangerous drugs with an office-based opioid treatment classification unless the physician or certified nurse practitioner will be physically present at the location for at least fifteen hours per week. If the facility is not open more than fifteen hours per week, the minimum amount of on-site supervision shall be at least fifty per cent of the total hours the facility is open, as reported to the board by the licensee on the application. Any changes to the licensee's hours of operation shall be reported to the board, in a manner determined by the board, within three business days.~~

~~(a) The hour requirements of this paragraph do not apply if either:~~

~~(i) The responsible person is unable to meet the requirements due to a documented illness or emergency and there is another physician or certified nurse practitioner on-site who meets the requirements of paragraph (C)(1) of this rule who can provide on-site supervision in accordance with the requirements described in this paragraph. The physician or certified nurse practitioner shall assume all responsibilities for compliance with this rule in the absence of the responsible person.~~

~~(ii) The location is closed for a state or federal holiday or other documented reason.~~

~~**(4) The person to whom the category III terminal distributor of dangerous drugs license with an office-based opioid treatment classification has been issued, the responsible person and all licensed health professionals practicing at that location are responsible for compliance with all state and federal laws, regulations, and rules regulating the operation of an office-based opioid treatment facility and prescribing of controlled substances.**~~

(F) Except as otherwise provided in paragraphs (A), (B), (C), (D), and (E) of this rule, the 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 (e.g., vacation, illness, temporary leave of absence lasting no more than thirty calendar days); or

(2) Conduct an on-site, in-person visit of the terminal distributor where they serve as the responsible person on, at minimum, a quarterly basis to ensure compliance with the requirements of Chapter 4729 of the Revised Code and all applicable rules adopted thereunder.

(~~**E**~~ **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. 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. This paragraph does not apply to a pharmacy licensed a terminal distributor of dangerous drug that is located outside of the state unless the pharmacy engages in the following:

(a) Drug compounding pursuant to rule 4729:5-8-03 of the Administrative Code; or

(b) Preparation, compounding, dispensing, and repackaging of radiopharmaceuticals pursuant to rule 4729:5-8-04 of the Administrative Code.

~~**(5) 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.**~~

(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 credentials specified 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).

(F) 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 disciplined by the state board of pharmacy pursuant to Chapter 4729. of the Revised Code, except for a disciplinary action related to the failure to timely obtain continuing education required pursuant to agency 4729 of the Administrative Code.

(~~8~~ **9**) Has been excluded from participation in medicare or a state health care program.

(~~9~~ **10**) Has been denied a license or registration by the drug enforcement administration or appropriate issuing body of any state or jurisdiction.

(~~10~~ **11**) 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.

~~**(G) Written requests for being a responsible person at more than one location pursuant to this rule must be submitted to the state board of pharmacy in a manner determined by the board. The executive director or the director's designee shall have the authority to temporarily approve or deny a request for being a responsible person at more than one location for a period not to exceed sixty days. The full board will review requests the executive director or the director's designee has temporarily approved at the next scheduled board meeting. A terminal distributor of dangerous drugs whose request has been denied either by the executive director, the director's designee or the board will be provided with a written explanation of denial and allowed one opportunity to resubmit its request to address the identified concerns. The board may impose conditions on all**~~

~~**approved requests, including requirements that requests be submitted for reapproval at intervals determined by the board.**~~

Rule 4729:6-2-01 | Responsible person - drug distributor. (AMEND)

(A) A location licensed as a distributor of dangerous drugs, in accordance with section 4729.52 of the Revised Code, shall have a responsible person at all times.

(B) When there is a change of responsible person, the state board of pharmacy shall be notified by the new responsible person within ten days of the effective date of the appointment of the new responsible person in a manner determined by the board. The new responsible person shall submit to a criminal records check in accordance with rule 4729:6-2-03 of the Administrative Code.

(C) For all category III drug distributor licenses, a complete inventory, pursuant to rule 4729:6-3-06 of the Administrative Code shall be taken of the controlled substances on site by the new responsible person no later than thirty days from the separation date of the responsible person. The new responsible person shall be responsible for completing and maintaining this inventory record at the location licensed as a drug distributor.

(D) The responsible person for a location licensed as a distributor of dangerous drugs shall be responsible for compliance with all applicable state and federal laws, regulations, and rules governing the manufacture, sale and distribution of dangerous drugs.

(E) ~~**The responsible person shall be physically present at the location for a sufficient amount of time to provide supervision and control of dangerous drugs on-site.**~~

The responsible person shall work a minimum of eight hours per week at the location licensed as a drug distributor where they serve as the responsible person, except when absent due to authorized leave (e.g., vacation, illness, federal or state holiday, or temporary leave of absence lasting no more than thirty calendar days).

(F) The board of pharmacy shall issue a resolution providing the credential types or qualifications required for the responsible person of each license/classification/business type of a distributor of dangerous drugs licensed in accordance with section 4729.52 of the Revised Code. Only individuals that meet the credentials specified may be the responsible person for that license/classification/business type. The resolution shall be updated as necessary and made available on the board's web site, www.pharmacy.ohio.gov.

(G) Unless otherwise approved by the board, a drug 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 disciplined by the state board of pharmacy pursuant to Chapter 4729. of the Revised Code, except for a disciplinary action related to the failure to timely obtain continuing education required pursuant to agency 4729 of the Administrative Code.

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

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

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

(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.

~~**(12) Has committed an act that constitutes a misdemeanor that is related to, or committed in, the employee's professional practice.**~~

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.

(1) An alternate location may be a pharmacy as defined in section 4729.01 of the Revised Code; or

(2) If not a pharmacy, all of the following apply:

(a) The location receiving the dangerous drugs is licensed as a terminal distributor of dangerous drugs or is exempted from licensure in accordance with section 4729.541 of the Revised Code.

(b) 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.

(c) 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.

(d) The receipt, storage, control, and distribution of 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.

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

(f) 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, administration or provision to the patient, disposal, and return of all dangerous drugs dispensed by the pharmacy in accordance with this division of the administrative code.

(2) 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.

(3) The location acknowledges that any patient specific dangerous drug dispensed by a pharmacy is the property of that patient, except that a dangerous drug that is not distributed or administered to a 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 return;

(b) Dispose of the drug in accordance the applicable rules set forth in this division of the Administrative Code; or

(c) Donate the drug 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.

(4) Nothing in paragraph (D)(3) of this rule 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 operates a drug repository program in accordance with Chapter 4729:5-10 of the Administrative Code.

(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;

(2) Danger or harm to the patient;

(3) Failure to comply with the requirements of this rule or any other laws or rules governing the distribution of dangerous drugs.

(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.