Ohio Administrative Code

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

Effective: April 25, 2022

(A) Except as provided in paragraph (B) of this rule, for a pharmacy licensed as a terminal distributor of dangerous drugs:

(1) Only a pharmacist may be the responsible person whose name appears on the terminal distributor of dangerous drugs license for 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.

(B) For an institutional pharmacy licensed as a terminal distributor of dangerous drugs:

(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.

(C) 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 responsible person shall submit to a criminal records check in accordance with section

4776.02 of the Revised Code.

(3) 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) 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.

(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.

(E) 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 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 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.

(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.