Rules – February 2026

Classification of Mitragynine-Related Compounds as Schedule I Controlled Substances – Emergency Rule

Replace the following citation (Page 13):

xiv Ellis CR, Racz R, Kruhlak NL, Kim MT, Zakharov AV, Southall N, et al. (2020) Evaluating kratom alkaloids using PHASE. PLoS ONE 15(3):e0229646. https://doi.org/10.1371/journal.pone.0229646

With the following:

xiv American Pharmaceutical Review. Statement from FDA Commissioner on Agency's Scientific Evidence on the Presence of Opioid Compounds in Kratom. https://www.americanpharmaceuticalreview.com/1315-News/346939-Statement-from-FDA-Commissioner-on-Agency-s-Scientific-Evidence-on-the-Presence-of-Opioid-Compounds-in-Kratom/. (Accessed Jan. 14, 2025).

For Filing with JCARR:

4729:4-1-01 - Definitions - impaired licensees, registrants, and probation. (AMEND)

As used in division 4729:4 of the Administrative Code:

(A) "Aftercare" is a counselor-facilitated group meeting which directly responds to problems relating to the ongoing treatment and monitoring of the licensee or registrant's sobriety and should extend for a minimum of twelve months.

(B) "Approved monitoring program" means a board approved and designated monitor pursuant to section 4729.18 of the Revised Code and rule 4729:4-1-06 of the Administrative Code.

(C) "Approved treatment provider" means a designated treatment program pursuant to section 4729.18 of the Revised Code and rule 4729:4-1-03 of the Administrative Code.

(D) "Business day" means any day other than Saturday, Sunday or a holiday recognized by the state of Ohio on which the offices of the board of pharmacy are not open for business.

(E) "Designated person" for an approved treatment provider or approved monitoring program is an individual who shall be in full and actual charge of the treatment or monitoring program including, but not limited to, the following:

(1) Ensuring the provider has the necessary facilities and personnel to provide services;

(2) Maintaining records; and

(3) Notification of the board when required.

(F) "Hemp ~~**products**~~" has the same meaning as ~~**defined**~~ in section ~~924.212~~ **928.01** of the Revised Code.

(G) "Impaired licensee or registrant" means a licensee or registrant who, because of the person's mental illness, habitual or excessive use or abuse of drugs or alcohol, use of psychoactive substances, or use of other substances that impair the ability to practice, is rendered unable to practice pharmacy or conduct authorized activities within a pharmacy with requisite judgment, skill, competence, or safety to the public.

(H) "Individualized treatment plan" is a document which shall provide for inpatient treatment, outpatient treatment, family therapy, psychotherapy, professional support groups, twelve-step programs, aftercare including support and self-help groups, monitoring programs consisting of random~~, chain of evidence~~ drug screens, and work site review. Such services and other services may be determined by an approved treatment provider or an approved monitoring program.

(I) "Inpatient treatment" shall consist of placing the licensee or registrant in an approved treatment provider facility that will provide lodging and food, as well as care and treatment for detoxification and rehabilitation as indicated by the treatment contract.

(J) "Intervenor" means a person who is employed by or affiliated with an approved treatment provider or an approved monitoring program and participates in a process whereby a licensee or registrant alleged to be impaired is confronted to evaluate the presence of impairment and, if indicated, who refers the licensee or registrant for assessment and treatment of the impairment.

(K) "Outpatient treatment" shall consist of the licensee or registrant not residing in an inpatient treatment facility but who is participating in aftercare, twelve-step programs, professional support group (if available), and monitoring programs consisting of random~~,~~ ~~chain of evidence~~ drug screens and work site review, to establish compliance.

(L) "Professional support group" is a group of peers meeting to discuss the problems specific to recovery and re-entry to practice of the licensee or registrant.

(M) "Referral for assessment" means a process whereby an intervenor or designated person who has reason to believe that a licensee or registrant is impaired directs that individual to be examined for diagnosis and treatment.

(N) "Relapse" means any use of, or obtaining for the purpose of using, drugs, alcohol, psychoactive substances, or any use of other substances that impair the ability to practice; it also includes a positive drug screen or a return to a pattern of impairment activities which affects the licensee or registrant's ability to practice. Relapse also refers to a mental health or mental illness episode that impacts or impairs the ability to practice pharmacy or conduct

authorized activities within a pharmacy with the requisite judgment, skill or competence to ensure the safety of the public.

(O) "Substance abuse/chemical dependency" means a substance use disorder as defined by the "Diagnostic and Statistical Manual of Mental Disorders" (DSM-5) or any official supplement thereto (~~**03/1/2018**~~ **March 18, 2022**).

(P) "Treatment assessor" means any of the following:

(1) An individual who is licensed under Chapter 4731. of the Revised Code as a doctor of medicine or a doctor of osteopathic medicine and surgery and who is a certified addiction specialist; or

(2) An individual who is licensed by the Ohio chemical dependency professionals board as a licensed independent chemical dependency counselor, licensed chemical dependency counselor 3 or 2 pursuant to Chapter 4758. of the Administrative Code and, who by training and experience, can make an assessment of a licensee or registrant's impairment.

(3) An individual who holds a license or certification approved by the board or the board's probation committee and, who by training and experience, can make an assessment of a licensee or registrant's impairment.

(Q) "Treatment contract" means a document which outlines the individualized treatment plan, the requirement to cease practice, the requirement for compliance by the impaired licensee or registrant, and the requirement for notification of the board for non-compliance or relapse pursuant to section 4729.18 of the Revised Code.

(R) "Twelve-step program" means a self-help program such as alcoholics anonymous or narcotics anonymous or a related organization that addresses substance use disorders and promotes sobriety and recovery through peer group support, self-help, and anonymity, and which is based on an abstinence model of recovery. An impaired licensee or registrant shall be required to personally attend face-to-face twelve-step programs not less than three documented meetings each week, on separate days. Meetings that occur online, telephonically, or via other electronic means shall not be counted towards the minimum requirement.

Amendment Summary:

- *Paragraph F: Updates definition of hemp products to refer to the definition of hemp in ORC 928.01. The current cross reference has been repealed in statute.*
- *Paragraph O: Updated to reflect latest version of the DSM-5 criteria with a new incorporation by reference date.*

4729:8-3-02 **Information required for submission.**

(A) Pharmacies pursuant to paragraphs (A) and (B) of rule 4729:8-3-01 of the Administrative Code that dispense drugs listed in Chapter 4729:8-2 of the Administrative Code to outpatients shall report the following dispensing information to the board of pharmacy in accordance with rule 4729:8-3-03 of the Administrative Code:

(1) Pharmacy drug enforcement administration registration number. If not applicable, another mutually acceptable identifier;

(2) Pharmacy name;

(3) Pharmacy address;

(4) Pharmacy telephone number;

(5) Pharmacy dispensing software vendor or proprietary software;

(6) Pharmacy license number, if both the drug enforcement administration registration and national provider identifier are not provided;

(7) Type of pharmacy or dispenser;

(8) Indication if entity is a mail order pharmacy;

~~(5)~~(9) Patient full name;

~~(6)~~(10) Patient residential address;

~~(7)~~(11) Patient telephone number;

~~(8)~~(12) Patient date of birth;

~~(9)~~(13) Patient gender;

(14) Species code;

(15) Owner's name for veterinary patients;

~~(16) Owner's date of birth for veterinary patients;~~

~~(17) Owner's gender for veterinary patients;~~

(18) Name of animal;

Amendment Summary:

- *Removes two required ASAP reporting fields. After a review by the OARRS team, it was determined that these fields cannot be accurately captured and reported by pharmacies under the current outpatient record keeping rule.*

For Filing with CSI & JCARR:

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 paragraphs (A)(6) or (A)(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 Board's executive director, or the director's designee, may grant approval to allow for a pharmacist to temporarily serve as the responsible person for two outpatient pharmacies without meeting the supervision requirements in paragraphs (A)(5) or (A)(6) of this rule if the following are met:

(a) The pharmacy can document that a death, incapacity, emergency medical leave (does not include planned medical leave), unexpected resignation, or discharge of the responsible person has occurred.

(b) The pharmacy can document that current staffing is not sufficient to meet the supervision requirements of this rule.

(c) The temporary approval is valid for thirty-one days from the date it is approved by the board's executive director or the director's designee and cannot be renewed.

(d) On or before the end of the temporary approval issued by the board, the pharmacy shall designate a responsible person that meets the requirements set forth in this rule. Upon designation of a new responsible person, the temporary approval issued by the board is no longer valid.

(e) The responsible person shall either:

(i) For a pharmacy operational at least forty hours per week: work a minimum of ten hours per week at each pharmacy; or

(ii) For a pharmacy that is not operational for forty hours per week: work a minimum of twenty-five percent of the total hours the pharmacy is open per week.

(f) The requirements of paragraphs (A)(2)(b) through (A)(2)(e) can be met.

(g) All requests made pursuant to this paragraph shall be submitted, in a manner determined by the board, no later than ten business days after the death, incapacity, commencement of emergency medical leave, unexpected resignation, or discharge of a pharmacist serving as the responsible person.

(B) For an institutional pharmacy, including an institutional outpatient 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 comply with one of the following:

(a) For a pharmacy that is operational for forty or more hours per week, 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.

(b) For a pharmacy that is not operational for forty hours per week, 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.

(c) Conduct an on-site, in-person visit of the pharmacy where they serve as the responsible person on a quarterly basis pursuant to the requirements of paragraph (G) of this rule. The pharmacy shall be owned and operated by the institutional facility and shall be located on the campus or directly adjacent to the campus of the institutional facility, as defined in paragraph (J) of this rule.

(6) The Board's executive director, or the director's designee, may grant approval to allow for a pharmacist to temporarily serve as the responsible person for two pharmacies, either outpatient or institutional, without meeting the supervision requirements in paragraphs (B)(5)(a) or (B)(5)(b) of this rule if the following are met:

(a) The pharmacy can document that a death, incapacity, emergency medical leave (does not include planned medical leave), unexpected resignation, or discharge of the responsible person has occurred.

(b) The pharmacy can document that current staffing is not sufficient to meet the supervision requirements of this rule.

(c) The temporary approval is valid for thirty-one days from the date it is approved by the board's executive director or the director's designee and cannot be renewed.

(d) On or before the end of the temporary approval issued by the board, the pharmacy shall designate a responsible person that meets the requirements set forth in this rule. Upon designation of a new responsible person, the temporary approval issued by the board is no longer valid.

(e) During the period that the temporary approval is valid, the responsible person shall either:

(i) For a pharmacy operational at least forty hours per week: work a minimum of ten hours per week at each pharmacy; or

(ii) For a pharmacy that is not operational for forty hours per week: work a minimum of twenty-five percent of the total hours that each pharmacy is open per week.

(f) The requirements of paragraph (B)(2) can be met.

(g) All requests made pursuant to this paragraph shall be submitted, in a manner determined by the board, no later than ten business days after the death, incapacity, commencement of emergency medical leave, unexpected resignation, or discharge of a pharmacist serving as the responsible person.

(7) The requirements of paragraphs (B)(2) and (B)(5) 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) Unless the licensee can demonstrate that such compliance would cause the nonresident terminal distributor of dangerous drugs to violate either the statutory or regulatory requirements of the state in which it is located or federal statutory or regulatory requirements, 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) Unless the licensee can demonstrate that such compliance would cause the nonresident terminal distributor of dangerous drugs to violate either the statutory or regulatory requirements of the state in which it is located or federal statutory or regulatory requirements, 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 pursuant to the requirements of paragraph (G) of this rule.

(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 comply with any of the following:

(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 pursuant to the requirements of paragraph (G) of this rule.

(3) For terminal distributors owned and operated by an institutional facility, conduct an on-site, in-person visit of the terminal distributor by a pharmacist employed by the institutional facility on a quarterly basis pursuant to the requirements of paragraph (G) of this rule.

(G) An on-site, quarterly in-person visit as described in this rule shall consist of the following:

(1) A process to review and document compliance with the following requirements, if applicable:

(a) Drug security, including possible diversion of dangerous drugs;

(b) Drug purchases and sales;

(c) Compounding in accordance with division 4729:7 of the Administrative Code;

(d) Record keeping;

(e) Temperature monitoring;

(f) Storage and disposal of adulterated or expired drugs; and

(g) Any other requirements of Chapters 4729., 3719., and 3715. of the Revised Code and all applicable rules adopted thereunder based upon the operation of the terminal distributor of dangerous drugs.

(2) Except as provided in paragraph (G)(3) of this rule, all on-site, in-person visits shall be documented by the responsible person.

(3) For on-site, in-person visits conducted in accordance with paragraph (F)(3) of this rule, the pharmacist shall document the visit and such documentation shall be provided to the responsible person no later than three business days from the visit.

(4) All documentation required by this paragraph shall be maintained for three years from the date of visit at the terminal distributor of dangerous drugs where the visit is conducted for immediate on-site inspection by an agent, officer, or inspector of the board.

(5) A terminal distributor of dangerous drugs shall develop and implement a policy that requires the correction of any violations identified as part of an on-site, in-person visit.

(H) 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 Ohio 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).

(I) 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.

(J) As used in this rule:

(1) “Campus” has the same meaning as in rule 4729:5-1-01 of the Administrative Code.

(2) "Directly adjacent" means any adjacent property that is within one mile (5,280 feet) from all or a part of the campus of an institutional facility.

Amendment Summary:

- *At the request of the Common Sense Initiative, the Board engaged with the institutional facilities that raised operational concerns related to the rule. After discussion with several of these facilities, it is recommended to add some additional flexibility as it pertains to satellite pharmacies on a hospital campus and remote hospital owned clinics.*

- *Additionally, commenters requested clarity on the requirements for the quarterly, in-person visits. Therefore, paragraph (G) was added to the rule.*

Rule 4729:5-3-25 | Electronic product verification. (NEW)

(A) As used in this rule:

(1) "Electronic product verification" or “electronic verification” means the non-physical dispensation (“final check”) of a drug by a pharmacist using an electronic verification system to verify the accuracy of the final contents **or components in accordance with paragraph (F) of this rule** of the prepared drug or device and affixed label prior to dispensing. Electronic final verification does not include the following:

(a) Operation of a remote dispensing pharmacy pursuant to Chapter 4729:5-18 of the Administrative Code;

(b) The practice of remote outpatient prescription processing pursuant to rule 4729:5-5-20 of the Administrative Code;

(c) The practice of remote medication order processing pursuant to rule 4729:5-9-02.14 of the Administrative Code;

(d) The practice of personally furnishing by a prescriber pursuant to division 4729:5 of the Administrative Code; or

(e) The dispensation of a drug or device from an automated pharmacy system pursuant to rule 4729:5-3-17 of the Administrative Code.

(2) “Electronic verification system” means a system that complies with the requirements set forth in this rule.

(B) For a pharmacist to engage in remote prescription dispensing, the pharmacist shall:

(1) Be licensed as a pharmacist in this state;

(2) Physically practice in a pharmacy licensed as a terminal distributor of dangerous drugs that is located in this state **where the electronic product verification is being conducted**;

(3) Complete the required training and competency evaluations in paragraph (G) of this rule; and

(4) Is a current **or contracted** employee of the pharmacy operating the electronic verification system.

(C) An electronic verification system shall allow the pharmacist to see an exact, clear, and unobstructed visual images of the ~~filled prescription or medication order~~ **drugs or devices dispensed** ~~contents~~ and the label affixed to the container. The system shall, at a minimum, have high-definition image resolution with variable viewing options to accurately and safely dispense a dangerous drug or drug device and sufficient data retention capabilities to investigate any quality-related events.

(1) The system shall use barcoding technology to ensure the accuracy of prescriptions or orders verified in accordance with this rule. Barcodes shall be scanned, and not manually typed, into the system. The board may waive or modify the barcode technology requirements listed in this paragraph if the electronic verification system can provide an alternative method to ensure the accuracy of prescriptions or orders dispensed in accordance with this rule.

(2) The system shall produce images that are high definition with image resolution of at least 300 pixels per inch **and in full color**.

(3) If multiple units are being dispensed, the pharmacist must be able to see and verify an image or images of each unit and each individual affixed label.

(4) The images shall contain the following to ensure the pharmacist is able to appropriately verify the prescription prior to dispensing.

(a) A clear image of the prescription label affixed to the medication or device;

(b) The full quantity of the filled prescription;

(c) Except as provided in paragraph (C)(**5**) of this rule, the medication stock bottle or container and label of a drug that has been returned to stock in accordance with rule 4729:5-5-22 of the Administrative Code used to fill the prescription, if applicable; and

(d) Clear markings present on the **drug (tablets, capsules, etc.)** ~~**pill or capsule**~~, if applicable.

(e) A clear image of the drug's national drug code (NDC) number or global trade item number (GTIN), serial number, lot number, and expiration date, if not otherwise captured or maintained in the pharmacy system.

(5) The board may waive or modify the requirements listed in paragraph (C)(4)(c) of this rule if the electronic verification system can provide an alternative method that accurately captures information from the medication stock bottle and/or container and label of a drug that has been returned to stock in accordance with rule 4729:5-5-22 of the Administrative Code.

(6) The system shall use stock images of the correct drug being dispensed, including markings, if applicable.

(7) Images associated with the verification and dispensing of a prescription or order shall be retained **in a secure** and **readily retrievable format** ~~**become part of the patient's profile**~~ and maintained for one year from the date of verification.

(8) Use of an electronic verification system shall be terminated if the system is not properly functioning. Prior to resuming the use of the system, the pharmacy shall identify the root cause or causes of the malfunction and shall validate that the system is properly functioning. **The pharmacy shall maintain documentation of the root cause or causes of the malfunction for a period of three years in a readily retrievable format.**

(9) The electronic verification system shall be capable of clearly communicating that the pharmacist has verified the drug or device prior to distribution.

(10) Prior to dispensing, a pharmacist shall review and authorize overrides performed by a pharmacy technician or pharmacy intern of any technologically generated errors, warnings, alerts, or exceptions related to system functionality or verification/accuracy. Documentation of the pharmacist's review and authorization must be captured using electronic positive identification and maintained for three years from the date of review in a readily retrievable format.

(11) A pharmacist shall not be required to conduct electronic product verification if, in the pharmacist's professional judgement, the system, personnel, or processes employed by the pharmacy present a danger to the health and safety of patients.

(D) All electronic product verifications shall be documented using an electronic form of positive identification in accordance with rule 4729:5-5-04 or rule 4729:5-9-02.3 of the Administrative Code.

(E) No further manipulation of the prescription or order shall occur after the pharmacist's electronic verification is complete other than applying the required container lid or seal. Manipulation does not include preparing a finished prescription/medication order for mailing, delivery, or storage.

(F) Except as provided for in this paragraph, a pharmacist shall not conduct electronic product verification of compounded drug preparations.

(1) All electronic product verification of compounded drug preparation shall comply with the requirements of this rule.

(2) Only components used for compounded drug preparations may be verified by a pharmacist using an electronic verification system.

(3) Reconstituted drugs may be used or manipulated for compounding after the pharmacist completes electronic verification.

(**4**) At the completion of the compounding process and prior to release or dispensation, the compounded drug preparation shall be visually inspected by a pharmacist in person to determine whether the physical appearance of the drug is as expected (e.g., free of inappropriate visible particulates or other foreign matter, discoloration, or other defects) and that the container closure integrity is in compliance with all applicable United States Pharmacopeia chapters referenced in rule 4729:7-1-01 of the Administrative Code. A pharmacist shall document this verification using positive identification.

(G) ~~**All pharmacists, pharmacy interns, and pharmacy technicians assisting the pharmacist with electronic final verification**~~ **All pharmacy personnel utilizing electronic product verification** must be trained and competent to perform the duties assigned and have a documented initial and annual assessment of competency using the pharmacy's electronic verification system.

(H) An electronic verification system shall be implemented and validated by an Ohio-licensed pharmacist prior to initial use to ensure proper functioning. The system shall be revalidated by an Ohio-licensed pharmacist in accordance with the pharmacy's policies and procedures at least once every six months.

(1) Proof of compliance with validation/revalidation requirements shall be documented by an Ohio-licensed pharmacist and maintained in a readily retrievable format for three years from the date of validation or revalidation.

(2) The records shall document the positive identification of the pharmacist performing the required validation, date(s) performed, and the results of the validation.

(I) Pharmacies using an electronic verification system as authorized by this rule shall maintain an ongoing and documented quality assurance system that monitors the performance of the electronic verification system to ensure proper and accurate functioning in accordance with rule 4729:5-3-22 of the Administrative Code. The quality assurance system shall also include procedures for reporting system malfunctions.

(J) Pharmacies utilizing an electronic verification system pursuant to this rule shall maintain and implement written policies and procedures governing all aspects of electronic verification activities. Such policies and procedures shall be maintained in a readily retrievable format and shall include, but are not limited to, the following:

(1) Staff training and competency assessments;

(2) Operation of the quality assurance system, including reporting, investigating and addressing errors, system malfunctions, and other quality assurance issues;

(3) Validation and revalidation of electronic verification technology to ensure proper functioning; and

(4) System maintenance, including any routine or preventive maintenance.

(K) Pharmacies using an electronic verification system shall comply with all applicable record keeping requirements pursuant to rule 4729:5-5-04 or rule 4729:5-9-02.3 of the Administrative Code.

~~(L) Only employees of the pharmacy, including a pharmacy chain, shall be permitted to conduct or assist with electronic final verification in accordance with this rule.~~