Rules – September 2022

4729:10 – Drug Disposal (For Filing with CSI & JCARR)

Comments Received during Initial Stakeholder Comment:

Comment	Draft Board Response
1) "Ultimate user" - There's no obvious reason to restrict who can dispose of drugs. Any person who encounters drugs needing disposal should be able to deposit them in a box for destruction. Even a pedestrian who finds a bottle of pills on the sidewalk should be able to so so, and in fact should be encouraged. Under current law, when a person dies in hospice, there's not a legal way for the family to transport unused Schedule II drugs to a disposal facility.	This is a DEA definition and cannot be modified.
2) Why can't Schedule I drugs be similarly disposed of. If a person decides to discontinue use of heroin, or if a person discovers heroin in a child's possessions, should s/he not be able to dispose of it legally?	This is a DEA prohibition and cannot be modified. DEA only authorizes the collection of Schedule II – V controlled substances.

Rule 4729:10-1-01 | Definitions - prescription drug collection. (NO CHANGE)

As used in division 4729:10 of the Administrative Code:

(A) "Authorized collector" means a registered manufacturer, distributor, reverse distributor, narcotic treatment program, hospital/clinic with an on-site pharmacy, or retail pharmacy that is authorized by the United States drug enforcement administration to receive controlled substances for the purpose of destruction.

(B) "Controlled substance" has the same meaning as in section 3719.01 of the Revised Code.

(C) "Dangerous drugs" has the same meaning as in section 4729.01 of the Revised Code.

(D) "Drug collection receptacle" means a secured, lined receptacle into which prescription medications, including controlled substances, dangerous drugs, and over-the-counter medications can be deposited by ultimate users for the purposes of collecting unused or expired drugs. Except for a law enforcement agency, a drug collection receptacle shall meet the requirements specified in 21 CFR 1317.75 (4/1/2018).

(E) "Drug" has the same meaning as in section 4729.01 of the Revised Code.

(F) "Law enforcement agency" means a government entity that employs peace officers to perform law enforcement duties or a federal law enforcement agency.

(G) "Law enforcement officer" has the same meaning as 21 CFR 1300.05 (4/1/2018).

(H) "Mail-back program" means a program operated by an authorized collector or law enforcement agency that accepts prescription medications, including controlled substances, dangerous drugs, and over-the-counter medications from ultimate users through the mail for purposes of collecting unused or expired drugs. Except for a law enforcement agency, a mail-back program shall meet the requirements specified in 21 CFR 1317.70 (4/1/2018).

(I) "Non-retrievable" means the condition or state to which a drug shall be rendered following a process that permanently alters that drug's physical or chemical condition or state through irreversible means and thereby renders the drug unavailable and unusable for all practical purposes.

(J) "Take-back event" means a one-day program operated by a law enforcement agency through which ultimate users may safely dispose of unused or expired prescription medications, including controlled substances, dangerous drugs, and over-the-counter medications. A take-back event shall meet the requirements specified in 21 CFR 1317.65 (4/1/2018).

(K) "Ultimate user" means a person who has lawfully obtained, and who possesses, a dangerous drug for their own use or for the use of a member of their household or for an animal owned by an individual or a member of their household. It also includes any person lawfully entitled to dispose of a decedent's property.

Rule 4729:10-1-02 | Authorized collectors. (AMEND)

(A) An authorized collector may operate a drug collection receptacle if they meet the requirements specified in 21 CFR Part 1300, 21 CFR Part 1301, 21 CFR Part 1304, 21 CFR Part 1305, 21 CFR Part 1307 and 21 CFR Part 1317 (4/1/2018).

(B) If an authorized collector operates a drug collection receptacle for the collection of non-controlled substances only, the collector shall meet all of the requirements specified in paragraph (A) of this rule.

(C) A long-term care facility may dispose of prescription medications, including controlled substances, dangerous drugs, and over-the-counter medications on behalf of an ultimate user who resides, or has resided, at that long-term care facility pursuant to 21 CFR 1317.80 (4/1/2018).

(D) An authorized collector may operate a mail-back program if they meet the requirements specified in 21 CFR Part 1300, 21 CFR Part 1301, 21 CFR Part 1304, 21 CFR Part 1305, 21 CFR Part 1307 and 21 CFR Part 1317 (4/1/2018).

(E) If an authorized collector operates a mail-back program for the collection of non-controlled substances only, the collector shall meet all of the requirements specified in paragraph (D) of this rule.

(F) An authorized collector shall indicate on a ~~**mail-back package or**~~ drug collection receptacle **or with written materials accompanying a mail-back package** that the collection of any of the following is prohibited:

(1) Medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers); and

(2) Schedule I controlled substances.

(G) An authorized collector shall not dispose of the collector's inventory or stock of controlled substances, dangerous drugs or over-the-counter medications in a drug collection receptacle or through a mail-back program.

(H) An authorized collector shall maintain the confidentiality of the ultimate user pursuant to all applicable state and federal laws, rules, and regulations.

(I) An authorized collector shall not operate a take-back event as defined in rule 4729:10-1-01 of the Administrative Code.

Rule 4729:10-1-03 | Law enforcement agencies. (NO CHANGE)

(A) Law enforcement agencies may operate a drug collection receptacle if all the following apply:

(1) The receptacle is located inside the premises of the law enforcement agency.

(2) The receptacle is placed in a location that is accessible to the public during posted hours.

(3) The receptacle is placed within reasonable view of law enforcement personnel or under continuous video surveillance.

(4) The receptacle is securely fastened to a permanent structure so that it cannot be removed and must be locked to prevent the unauthorized retrieval of its contents.

(5) The receptacle is clearly marked indicating the following information:

(a) No needles, syringes, or lancets shall be placed in the receptacle.

(b) No iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers) shall be placed in the receptacle.

(6) If a law enforcement agency chooses to limit the types of drugs that are acceptable for return, such limitations shall be clearly stated on or near the drug collection receptacle.

(7) The law enforcement agency shall check the drug collection receptacle regularly and remove deposits to prevent the receptacle from reaching capacity.

(8) The law enforcement agency shall maintain the confidentiality of the ultimate user disposing of the drugs pursuant to all applicable state and federal laws, rules, and regulations.

(9) The drugs collected shall be stored in a manner that prevents the diversion of controlled substances and is consistent with the agency's standard procedures for storing illicit controlled substances collected as evidence.

(10) The law enforcement agency shall maintain custody and control of the contents deposited in the drug collection receptacle until the drugs are destroyed pursuant to rule 4729:10-1-04 of the Administrative Code.

(11) The law enforcement agency shall maintain any records of removal, storage, and destruction of the drugs collected in a manner that is consistent with the agency's record keeping requirements for illicit controlled substances collected as evidence.

(B) Law enforcement agencies may conduct a mail-back program if all the following apply:

(1) Packages are made available (for sale or for free) for the collection of pharmaceutical drugs by common or contract carrier.

(2) The packages made available meet the following specifications:

(a) The package must be nondescript and shall not include any markings or other information that might indicate that the package contains pharmaceutical drugs.

(b) The package must be water- and spill-proof, tamper-evident, tear-resistant, and sealable.

(c) The package must be preaddressed with and delivered to the participating law enforcement's physical address.

(d) The cost of shipping the package shall be postage paid.

(e) The package must include instructions for the user that indicate the process for mailing back the package, the substances that can be sent, notice that packages may only be mailed from within the customs territory of the United States (the fifty states, the District of Columbia, and Puerto Rico), and notice that only packages provided by the collector will be accepted for destruction.

(f) The instructions for the package shall indicate the following information:

No medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers) shall be placed in the package.

(g) If a law enforcement agency chooses to limit the types of drugs that are acceptable for return, such limitations shall be clearly stated on the package instructions.

(3) The law enforcement agency shall maintain custody and control of the sealed packages until the packages are destroyed pursuant to rule 4729:10-1-04 of the Administrative Code.

(4) The law enforcement agency shall maintain the confidentiality of the ultimate user disposing of the drugs pursuant to all applicable state and federal laws, rules, and regulations.

(5) The sealed mail-back packages shall be stored in a manner that prevents the diversion of controlled substances and is consistent with the agency's standard procedures for storing illicit controlled substances collected as evidence.

(6) The law enforcement agency shall maintain any records of removal, storage, and destruction of the drugs collected in a manner that is consistent with the agency's record keeping requirements for illicit controlled substances collected as evidence.

(C) Law enforcement agencies may operate a take-back event if all the following apply:

(1) A law enforcement agency shall appoint a law enforcement officer employed by the agency to oversee the collection. Law enforcement officers employed and authorized by the law enforcement agency or law enforcement component of a federal agency conducting a take-back event shall maintain control and custody of the collected drugs from the time the drugs are collected from the ultimate user until secure transfer, storage, or destruction of the drugs has occurred.

(2) Each take-back event shall have at least one receptacle for the collection of drugs. The collection receptacle should be a securely locked, substantially constructed container with an outer container and a removable inner liner.

(3) Ultimate users disposing of unused or expired drugs shall place them directly into the drug collection receptacle or hand them directly to a law enforcement officer.

(4) No needles, syringes or lancets shall be collected unless a bulk sharps disposal container is provided at each take-back event for the disposal of sharps.

(5) No iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (e.g., cancer chemotherapy drugs, cytotoxic drugs), compressed cylinders or aerosols (e.g., asthma inhalers) shall be collected.

(6) At the conclusion of the collection event, the drugs shall be removed from the event location and either:

(a) Stored in a manner that prevents the diversion of the collected drugs and is consistent with the agency's standard procedures for storing illicit controlled substances collected as evidence; or

(b) Destroyed pursuant to rule 4729:10-1-04 of the Administrative Code.

(7) The law enforcement agency shall maintain any records of removal, storage, and destruction of the drugs collected in a manner that is consistent with the agency's record keeping requirements for illicit controlled substances collected as evidence.

(D) The law enforcement agency shall ensure that the confidentiality of the ultimate user is maintained pursuant to applicable state and federal laws, rules, and regulations.

Rule 4729:10-1-04 | Procedure for destruction of collected drugs.

(A) All drugs collected pursuant to this rule shall be destroyed in compliance with applicable federal, state, tribal, and local laws and regulations and shall be rendered non-retrievable.

(B) The method of destruction shall ensure that the confidentiality of the ultimate user is maintained pursuant to applicable state and federal laws, rules, and regulations.

For Filing with CSI & JCARR

Rule 4729:1-3-02 | Immunization administration. (AMEND)

(A) A course in the administration of immunizations developed pursuant to division (B)(1) of section 4729.41 of the Revised Code shall meet the following requirements:

(1) The instructor shall be a licensed health care professional and have the appropriate education and experience to teach a course in the administration of immunizations.

(2) The content must meet the standards established for such courses by the centers for disease control and prevention in the public health service of the United States department of health and human services.

(3) The course shall be conducted by an accreditation council for pharmacy education (ACPE) accredited provider.

(4) The course must be a minimum of five hours in length and include the following:

(a) A review of immunology that includes a discussion of the body's immune system reaction to immunizations.

(b) A review of each immunization ~~authorized~~ **recommended by the committee on immunization practices of the centers for disease control and prevention in the United States department of health and human services (8/5/2022)** that includes the following:

(i) Disease states associated with the immunization;

(ii) Type or nature of activity of the immunization;

(iii) Administration schedules;

(iv) Routes of administration;

(v) Injection sites;

(vi) Dosages;

(vii) Monitoring and treatment of the patient for adverse reactions, including the use of diphenhydramine and epinephrine;

(viii) Patient populations;

(ix) Precautions and contraindications; and

(x) Proper storage requirements for the immunization.

(c) A review of sterile technique in injectable dosage preparation and administration.

(d) A minimum of one hour of instruction and physical participation in administration techniques.

(e) A review of the proper disposal procedures for contaminated needles and immunizations.

(f) A review of the proper procedures for accidental needle sticks.

(5) The course must provide a method to evaluate the successful comprehension of the content.

(6) The course must provide a method to demonstrate the participant has successfully completed the course.

(B) Courses on immunization administration may be reviewed by the state board of pharmacy. A training course that fails to comply with the requirements set forth in this rule shall be considered in violation of this rule.

(C)

~~(1) Pharmacists seeking to administer any immunization listed in paragraph (G) of this rule that was added after the completion of an initial immunization course shall, at a minimum, conduct a review of appropriate clinical resources to familiarize themselves with all the following prior to the administration of the immunization:~~

~~(a) Disease states associated with the immunization;~~

~~(b) Type or nature of activity of the immunization;~~

~~(c) Administration schedules;~~

~~(d) Routes of administration;~~

~~(e) Injection sites;~~

~~(f) Dosages;~~

~~(g) Monitoring and treatment of the patient for adverse reactions;~~

~~(h) Patient populations;~~

~~(i) Precautions and contraindications; and~~

~~(j) Proper storage requirements for the immunization.~~

~~(2)~~ Failure to adhere to the standard of care for administration of an immunization shall be considered a violation of this rule and may subject a pharmacist to discipline in accordance with rule 4729:1-4-01 of the Administrative Code.

(D) Pursuant to section 4729.41 of the Revised Code, a physician-established protocol for the administration of immunizations shall include the following:

(1) For each **immunization authorized:** ~~dangerous drug listed in paragraph (G) of this rule:~~

(a) Name and strength;

(b) Precautions and contraindications;

(c) Intended audience or patient population;

(d) Dosage;

(e) Administration schedules;

(f) Routes of administration; and

(g) Injection sites.

(2) The length of time the pharmacist or pharmacy intern under the direct supervision of a pharmacist must observe an individual for adverse effects, which shall be based on appropriate standards of care established by the physician. The location of the observation shall be in the general vicinity of the administering pharmacist or pharmacy intern to allow for on-going evaluation.

(3) A method to address emergency situations including, but not limited to, adverse reactions, anaphylactic reactions, and accidental needle sticks.

(4) A method to notify an individual's physician or the applicable board of health within thirty days after administering an immunization, except for influenza immunizations administered to individuals eighteen years of age and older.

(5) The locations that a pharmacist or pharmacy intern under the direct supervision of a pharmacist may engage in the administration of immunizations.

(E) All physician-established protocols must be signed and dated by the physician prior to implementation and maintained by the terminal distributor of dangerous drugs. The protocols shall be renewed by a physician on a biennial basis.

(1) A physician may sign one protocol for multiple locations licensed as terminal distributors of dangerous drugs.

(2) Each location licensed as a terminal distributor of dangerous drugs shall maintain a copy of the protocol on-site for inspection by an agent, inspector or employee of the state board of pharmacy.

(F) Upon the request of the state board of pharmacy, a pharmacist or terminal distributor of dangerous drugs shall immediately provide the protocols for immunizations. The state board of pharmacy, after review, may approve the protocol or return it to the pharmacist or terminal distributor for revision without approval. If a protocol has been returned for revision without approval, it may not be implemented until the board has granted approval.

(G) A pharmacist may administer the following immunizations in accordance with section 4729.41 of the Revised Code and this rule:

(1) In the case of an individual who is seven years of age or older but not more than thirteen years of age, administer to the individual an immunization for any of the following:

(a) Influenza;

(b) COVID-19;

(c) Any other disease, but only pursuant to a prescription.

(2) In the case of an individual who is thirteen years of age or older, administer to the individual an immunization for any disease, including an immunization for influenza or COVID-19.

~~(1) Any immunization or vaccine that is included in either of the following schedules and is administered according to those schedules:~~

~~(a) The immunization schedule for persons aged zero through eighteen years recommended by the advisory committee on immunization practices of the centers for disease control and prevention in the United States department of health and human services (1/15/2020).~~

~~(b) Except as listed in paragraph (G)(2) of this rule, the adult immunization schedule recommended by the advisory committee on immunization practices of the centers for disease control and prevention in the United States department of health and human services (1/15/2020).~~

~~(2) The herpes zoster vaccine according to the age criteria specified in the United States food and drug administration's approved labeling.~~

~~(3) Except as provided in paragraphs (G)(4) and (G)(5) of this rule, any other immunization or vaccine recommended by the advisory committee on immunization~~

~~practices of the centers for disease control and prevention in the United States department of health and human services if administered in accordance with the recommendations adopted by the committee.~~

~~(4) The rabies vaccine for post exposure, if all the following are met:~~

~~(a) A pharmacist does not provide the initial dose of the rabies post exposure vaccine;~~

~~(b) Follow-up doses are administered pursuant to a prescription issued by a prescriber; and~~

~~(c) The follow-up doses are administered in accordance with recommendations adopted by the advisory committee on immunization practices of the centers for disease control and prevention in the United States department of health and human services (1/15/2020).~~

~~(5) The requirements listed in paragraph (G)(4) of this rule do not apply to the rabies vaccine for preexposure if administered in accordance with recommendations adopted by the advisory committee on immunization practices of the centers for disease control and prevention in the United States department of health and human services (1/15/2020).~~

~~(6) Any immunization to an individual eighteen years of age or older pursuant to a prescription if all the following apply:~~

~~(a) The pharmacist is authorized to administer the immunization pursuant to a physician-approved protocol established in paragraph (D) of this rule; and~~

~~(b) The pharmacist has the required training in accordance with this rule to administer the immunization.~~

~~(7) Any immunization approved by the United States food and drug administration for the prevention of COVID-19 in accordance with the limitations set forth in section 4729.41 of the Revised Code.~~

(H) A pharmacist shall obtain informed consent pursuant to rule 4729:5-5-04 of the Administrative Code to administer an immunization.

(I) Immunization records shall be maintained in accordance with rule 4729:5-5-04 of the Administrative Code.

(J) A pharmacist shall comply with the vaccine information statement requirements of the National Vaccine Childhood Injury Act, 42 USC Section 300aa-26 (12/14/1993).

(K) An immunization or vaccine specified in this rule shall not be administered to any individual who is less than thirteen years of age, except in the following situations:

(1) The immunization for influenza is administered to individuals who are seven years of age or older; or

(2) Pursuant to a prescription from a licensed prescriber, an immunization or vaccine is administered to individuals who are seven years of age or older but not more than thirteen years of age.

(L) For each immunization administered to an individual by a pharmacist, other than an immunization for influenza administered to an individual eighteen years of age or older, the pharmacist shall notify the individual's ~~family physician~~ **primary care provider** or, if the individual has no ~~family physician~~ **primary care provider,** the board of health of the health district in which the individual resides or the authority having the duties of a board of health for that district under section 3709.05 of the Revised Code. The notice shall be given not later than thirty days after the immunization is administered. Notification shall be conducted using one of the following methods that is capable of confirming delivery of the required notification:

(1) Electronic mail;

(2) Interoperable electronic medical records system;

(3) Facsimile;

(4) Electronic prescribing system;

(5) Electronic pharmacy record system;

(6) Documented verbal communication; ~~or~~

(7) Any other method of notification that might reasonably be expected to allow for the confirmed transmission of the required notification~~.~~**; or**

(8) Reporting to the state's immunization registry.

(M) A pharmacist administering immunizations in accordance with this rule shall receive and maintain certification to perform basic life-support procedures by successfully completing a basic life-support training course certified by the American red cross, American heart association or other training course approved by the board. Certification shall be obtained and maintained through courses that are conducted in-person or, at a minimum, offer an in-person training component.

(N) A pharmacist who completed a course in the administration of immunizations that complied with the training requirements in effect immediately prior to the adoption of this rule shall be deemed in compliance with division (B)(1) of section 4729.41 of the Revised Code.

(O) A pharmacist shall maintain the following records on file at the location(s) where the pharmacist administers immunizations in accordance with this rule:

(1) Proof of successful completion of a training course specified in paragraph (A) of this rule; and

(2) Proof of maintenance of certification to perform basic life-support procedures in accordance with paragraph (M) of this rule.

(P) As part of engaging in the administration of immunizations or supervising a pharmacy intern's administration of immunizations, a pharmacist may administer epinephrine or diphenhydramine, or both, to individuals in emergency situations resulting from adverse reactions to the immunizations administered by the pharmacist or pharmacy interns.

For Filing with CSI & JCARR

Rule 4729:2-3-03 | Immunization administration by pharmacy interns. (AMEND)

(A) Pharmacy interns working under the direct supervision of a pharmacist may administer immunizations listed in paragraph (C) of this rule if an intern complies with the following:

(1) Successfully completes a course in the administration of immunizations that meets the requirements set forth in rule 4729:1-3-02 of the Administrative Code.

(2) Practices in accordance with a definitive set of treatment guidelines specified in a protocol established by a physician that complies with the requirements of rule 4729:1-3-02 of the Administrative Code.

(3) Receives and maintains certification to perform basic life-support procedures by successfully completing a basic life-support training course certified by the American red cross, American heart association or other training course approved by the board. Certification shall be obtained and maintained through courses that are conducted in-person or, at a minimum, offer an in-person training component.

(4) The supervising pharmacist has completed all of the training necessary to administer immunizations in accordance with rule 4729:1-3-02 of the Administrative Code.

(B)

~~(1) Pharmacy interns working under the direct supervision of a pharmacist seeking to administer any immunization listed in paragraph (C) of this rule that was added after the completion of an initial immunization course approved pursuant to rule 4729:1-3-02 of the Administrative Code shall, at a minimum, conduct a review of appropriate clinical resources to familiarize themselves with all the following prior to the administration of the immunization:~~

~~(a) Disease states associated with the immunization;~~

~~(b) Type or nature of activity of the immunization;~~

~~(c) Administration schedules;~~

~~(d) Routes of administration;~~

~~(e) Injection sites;~~

~~(f) Dosages;~~

~~(g) Monitoring and treatment of the patient for adverse reactions;~~

~~(h) Patient populations;~~

~~(i) Precautions and contraindications; and~~

~~(j) Proper storage requirements for the immunization.~~

~~(2)~~ Failure to adhere to the standard of care for administration of an immunization shall be considered a violation of this rule and may subject a pharmacy intern to discipline in accordance with rule 4729:2-4-01 of the Administrative Code.

(C) A pharmacy intern working under the direct supervision of a pharmacist may administer the same immunizations authorized for pharmacist administration **as authorized by section 4729.41 of the Revised Code and rule 4729:1-3-02 of the Administrative Code.** ~~listed in paragraph (G) of rule 4729:1-3-02 of the Administrative Code.~~

(D) A pharmacy intern shall obtain informed consent pursuant to rule 4729:5-5-04 of the Administrative Code to administer an immunization.

~~(E) A pharmacy intern shall comply with the vaccine information statement requirements of the National Vaccine Childhood Injury Act, 42 USC Section 300aa-26 (12/14/1993).~~

~~(F) An immunization specified in this rule shall not be administered to any individual who is less than thirteen years of age, except in the following situations:~~

~~(1) The immunization for influenza is administered to individuals who are seven years of age or older; or~~

~~(2) Pursuant to a prescription from a licensed prescriber, an immunization or vaccine is administered to individuals who are seven years of age or older but not more than thirteen years of age.~~

(~~G~~ **E**) For each immunization administered to an individual by a pharmacy intern, other than an immunization for influenza administered to an individual eighteen years of age or older, the pharmacy intern shall notify the individual's ~~family physician~~**primary care provider** or, if the individual has no ~~family physician~~**primary care provider**, the board of health of the health district in which the individual resides or the authority having the duties of a board of health for that district under section 3709.05 of the Revised Code. The notice shall be given not later than thirty days after the immunization is administered. Notification shall be conducted using one of the following methods that is capable of confirming delivery of the required notification:

(1) Electronic mail;

(2) Interoperable electronic medical records system;

(3) Facsimile;

(4) Electronic prescribing system;

(5) Electronic pharmacy record system;

(6) Documented verbal communication; ~~or~~

(7) Any other method of notification that might reasonably be expected to allow for the confirmed transmission of the required notification~~.~~**; or**

(8) Reporting to the state's immunization registry.

(~~H~~ **F**) A pharmacy intern shall maintain the following records on file at the location(s) where the pharmacy intern administers immunizations in accordance with this rule:

(1) Proof of successful completion of a training course specified in paragraph (A)(1) of this rule; and

(2) Proof of maintenance of certification to perform basic life-support procedures in accordance with paragraph (A)(3) of this rule.

For Filing with CSI & JCARR

Rule 4729:5-3-09 | Occasional sale and drug transfers. (AMEND)

(A) The term "occasional sale" as used in section 4729.51 of the Revised Code means a wholesale sale of a commercially manufactured dangerous drug to a person licensed in accordance with section 4729.52 of the Revised Code, terminal distributor of dangerous drugs or any entity or person exempted from licensure as a terminal distributor of dangerous drugs **by any of the following:** ~~**either**~~**:**

(1) A pharmacy licensed as a terminal distributor of dangerous drugs; ~~**or**~~

(2) A licensed terminal distributor of dangerous drugs that is not a pharmacy, but only as authorized in section 4729.51 of the Revised Code~~.~~**; or**

(3) A local health department, as defined in paragraph (H) of this rule, licensed as a terminal distributor of dangerous drugs for the purpose of improving or promoting public health within the department's jurisdiction, but only for the sale of non-controlled dangerous drugs.

(B) The dosage units of all dangerous drugs distributed by the pharmacy pursuant to this rule shall not exceed five per cent of the total dosage units dispensed by the pharmacy during the same calendar year.

(C) The limits set forth in this rule do not apply to the following:

(1) A licensed terminal distributor of dangerous drugs as described in paragraph (A)(2) **and (A)(3)** of this rule; and

(2) Pharmacies that are also licensed to conduct sales of dangerous drugs in accordance with section 4729.52 of the Revised Code.

(D) The requirements of this rule do not apply to the transfer of dangerous drugs pursuant to paragraph (E) of this rule.

(E) A licensed terminal distributor of dangerous drugs having more than one licensed location may transfer or deliver dangerous drugs from one licensed location to another licensed location owned by that terminal distributor if the license issued for each location is in effect at the time of the transfer or delivery. Such transfer or delivery includes either of the following:

(1) Intracompany sales, which includes any transaction or transfer between any division, subsidiary, parent or affiliated or related company under the common ownership and control.

(2) The sale, purchase, or transfer of a drug or an offer to sell, purchase, or transfer of a drug among hospitals or other health care entities that are under common control. Common control means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract, or otherwise.

(F) Occasional sales by a licensed terminal distributor shall comply with the reporting requirements set forth in division 4729:8 of the Administrative Code.

(G) "Drug shortage," with respect to an occasional sale, means a drug on the United States food and drug administration's drug shortage list that is not commercially available regardless of the reason that the drug is not available, including the absence of a manufacturer for the drug or the lack of a readily available supply of the drug from a manufacturer or wholesaler.

(H) "Local health department" means a department operated by a board of health of a city or general health district or the authority having the duties of a board of health as described in section 3709.05 of the Revised Code.

For Filing with JCARR

Rule 3796:7-2-01 | Procedure for patient registration. (NO CHANGE)

(A) Before medical marijuana may be dispensed to or for, possessed by or for, or administered by or for a prospective patient, the prospective patient must be placed on the registry established by the state board of pharmacy in accordance with section 3796.08 of the Revised Code.

(B) To qualify for placement on the registry, a prospective patient must:

(1) Establish and maintain a bona fide physician-patient relationship with a recommending physician who shall submit a complete patient registration submission;

(2) Receive a diagnosis or confirmation of a qualifying condition from the recommending physician;

(3) Consent to treatment with medical marijuana. If the patient is a minor or individual with a court-appointed legal guardian, the prospective patients parent or legal representative shall consent to treatment with medical marijuana;

(4) Remit to the state board of pharmacy the required fee; and

(5) Unless otherwise provided pursuant to a reciprocal agreement under division (A) of section 3796.16 of the Revised Code, be an Ohio resident.

(C) A physician with whom a prospective patient has a bona fide physician-patient relationship, or, subject to the limitations under section 3796.08 of the Revised Code, the physicians delegate, shall submit the patient registration. For a registration submission, related to a patient who is eighteen years of age or older, to be considered complete, a completed recommendation from a physician, applicable patient registration fee, and the following items must be submitted to the state board of pharmacy in a manner suitable to the board:

(1) Patient's full name, residential address, telephone number, date of birth, electronic mail address, and qualifying condition(s);

(2) Patients government-issued identification number (such as drivers license number). Patients and caregivers must present a recommending physician with an unexpired drivers license, other identification issued by the Ohio bureau of motor vehicles (BMV) or other identification proving Ohio residency as approved by the board of pharmacy;

(3) Recommending physicians full name (first name and last name);

(4) Drug enforcement administration physician identification number and medical license number issued by the state medical board;

(5) Date recommendation was issued by the recommending physician;

(6) Recommending physicians business address, telephone number, and email address;

(7) Indication whether the recommendation is new or a renewal;

(8) The following patient attestations:

(a) The physician has explained to the individual the possible risks and benefits associated with the use of medical marijuana;

(b) The individual consents to treatment with medical marijuana; and

(c) The individual agrees to comply with Chapters 2925. and 3796. of the Revised Code and this division.

(9) An attestation from the recommending physician in accordance with division (A)(2) of section 3796.08 of the Revised Code; and

(10) Such other information as the state board of pharmacy may reasonably require.

(D) If a prospective patient is younger than eighteen years of age or has a court-appointed legal guardian, a patient registration submission must be accompanied by a caregiver registration submission in accordance with rule 3796:7-2-03 of the Administrative Code, before it will be considered complete. Patients who become eighteen years of age during the time period in which their registration is valid may apply for a new registration either immediately or in accordance with the renewal process under paragraph (K) of this rule. A submission from a patient that includes all information found in paragraph (C) of this rule, shall be considered complete.

(E) A complete patient registration submission must be received by the state board of pharmacy within ninety calendar days of the date on which the recommendation was created by the prospective patients recommending physician. Failure to comply with this requirement will void the recommendation and the persons registration shall be deemed abandoned.

(F) To qualify for registration as a patient diagnosed with a terminal illness, the prospective patients registration submission shall include with the registration submission, an attestation specifying that the patient has a terminal illness, submitted by the patients recommending physician.

(G) If a registration submission is determined to be inaccurate or incomplete, the state board of pharmacy shall send the prospective patient notice of the deficiency. If the deficiency is not corrected within ninety calendar days from the date that the registration was submitted by a physician, the submission shall be considered abandoned.

(H) Prospective patients must provide proof of Ohio residency to their recommending physician or the physicians delegate during the physicians initiation of the registration submission process. Proof of Ohio residency shall include one of the following:

(1) The prospective patients unexpired Ohio drivers license;

(2) The prospective patients unexpired Ohio identification card issued by the Ohio bureau of motor vehicles (BMV); or

(3) Any other identification proving residency as approved by the board of pharmacy.

(I) A patient registration shall be valid from the date of issuance and expire one year later, on the last day of the month it was issued.

(J) The state board of pharmacy shall send a notification to each patient forty-five calendar days before the expiration date on the patients registry identification card.

(K) To maintain a valid patient registration, a patient must annually renew, before the expiration date stated on the patients registry identification, a patient registration, in accordance with this rule. Renewal submissions, fees, and required documentation may be submitted up to thirty calendar days before the registration will expire. Failure to renew a patient registration will result in an automatic expiration of the registration card.

For Filing with JCARR

Rule 3796:7-2-04 | Purchase of medical marijuana. (NO CHANGE)

(A) A patient or caregiver may only purchase medical marijuana pursuant to a valid and active recommendation issued by a physician pursuant to rule 4731-32-03 of the Administrative Code.

(B) No patient under eighteen years of age shall purchase medical marijuana.

(C) Patients and caregivers must provide their registry identification card and identification before entering the dispensary department. Acceptable identification includes:

(1) An unexpired Ohio drivers license;

(2) An unexpired Ohio identification card issued by the Ohio bureau of motor vehicles (BMV); or

(3) Any other identification proving residency as approved by the board.

(D) The identification number on the identification provided to a dispensary employee must be identical to the identification number included in the patient or caregivers registration record.

(E) Before purchasing medical marijuana, patients and caregivers must provide the dispensing employee their registry identification card and identification described in paragraph (C) of this rule.

(F) A patients ninety-day recommendation shall be divided into two forty-five-day fill periods, except that the first fill period of a patients new recommendation shall be forty-six days. A patient may purchase up to a forty-five-day supply or, if applicable a forty-six-day supply for the first fill period of a new recommendation, at any time during a fill period.

(G) Except as provided in paragraph (G)(1) of this rule, a caregiver may obtain no more than a forty-five day supply of medical marijuana in any forty-five day fill period on behalf of a single patient.

(1) A caregiver may purchase up to a forty-six-day supply in a forty-six-day period on behalf of a single patient during the patients first fill period of a new recommendation.

(2) A caregiver shall purchase no more than the aggregate amount of medical marijuana authorized for each of the caregivers patients.

For Filing with JCARR

4729:5-3-20 | Pharmacy Pilot or Research Projects. (NO CHANGE)

(A) The purpose of this rule is to specify the process and procedures to be followed when a licensee petitions for approval of a pilot or research project for innovative system applications in the practice of pharmacy that are not currently permitted under agency 4729 of the Administrative Code. In reviewing projects, the board shall consider only projects that expand pharmaceutical care services that contribute to positive patient outcomes.

(B) A project shall not expand the definition of the practice of pharmacy as set forth in Chapter 4729. of the Revised Code and shall not apply to licensees regulated under Chapter 3796. of the Revised Code.

(C) Approval of a project by the board may include the grant of a limited exception to or a waiver of rules adopted under Chapter 4729. of the Revised Code. Project approval, including limited exception to or waiver of board rules, shall initially be for a specified period of time not exceeding twenty-four months from commencement of the project.

(D) Following the completion of the project period, the board may do any of the following based upon a review of the final project report submitted in accordance with paragraph (I) of this rule and any other factors or information the board deems necessary:

(1) Refuse to extend or renew the project;

(2) Approve the extension or renewal of a project following consideration of a petition that clearly identifies the need for extension and must include a report similar to the final project report, which should describe and explain any proposed changes to the originally approved and implemented project, and that justifies the need for extending or renewing the term of the project; or

(3) Approve the project in perpetuity following a consideration of a petition that clearly identifies and justifies the need to continue the project indefinitely.

(E) A licensee who wishes the board to consider approval of a project shall submit to the board a petition for approval that contains at least the following information:

(1) Responsible pharmacist. Name, address, telephone number, and pharmacist license number of each pharmacist responsible for overseeing the project.

(2) Location of project. Name, address, and telephone number of each specific location and, if a location is a pharmacy, the pharmacy's terminal distributor of dangerous drugs license number where the proposed project will be conducted.

(3) Project summary. A detailed summary of the proposed project that includes at least the following information:

(a) The goals, hypothesis, and objectives of the proposed project.

(b) A full explanation of the project and how it will be conducted.

(c) The time frame for the project including the proposed start date and length of the project. The time frame may not exceed eighteen months from the proposed start date of the project.

(d) Background information or literature review to support the proposed project.

(e) The rule or rules to be waived in order to implement the project, an explanation of why such a waiver would not be a detriment to the public, to include procedures to be used during the project to ensure that the public health and safety are not compromised as a result of the waiver, and a request to waive the rule or rules.

(F) Projects submitted shall be reviewed as follows:

(1) Staff review. Upon receipt of a petition for approval of a project, board staff shall initially review the petition. If the petition is incomplete or fails to meet the board's outlined purpose, staff shall return the petition to the requestor with a letter explaining the reason the petition is being returned. A petition that has been returned pursuant to this paragraph may be amended or supplemented as necessary and submitted for reconsideration. A petition that is deemed appropriate and complete shall move on the board member review process.

(2) Board member review. After initial staff review, two members of the board, appointed by the board president, shall be provided the petition and any additional materials. Board members shall conduct a review, in consultation with appropriate staff, and make a recommendation to the full board. Board members conducting a review may request additional documentation and information from the petitioner as part of this review process.

(3) Board review. Following the board member review, the board shall consider the project request at a regularly scheduled meeting of the board. Upon review, the board shall either approve or deny the petition. The board shall not approve any such project if such proposal might jeopardize public health or welfare. If the board approves the petition, the approval:

(a) Shall be specific for the project requested, with any modifications the Board deems necessary for patient safety;

(b) Shall approve the project for a specific time period; and

(c) May include conditions or qualifications applicable to the project, including limited waivers of applicable/related rules.

(G) The project site and project documentation shall be available for inspection and review by the board or its representative(s) at any time during the approval or denial processes and, if a project is approved, throughout the approved term of the project.

(H) Project documentation shall be maintained in a readily retrievable manner and available for inspection, review, and copying by the board or its representative for at least three years following completion or termination of the project.

(I) The pharmacist responsible for overseeing a project shall be responsible for submitting to the board any reports required as a condition of a project, including the final project report.

(1) The final project report shall include a written summary of the results of the project and the conclusions drawn from those results. The final project report shall be submitted to the board within ninety days after completion or termination of the project.

(2) The board shall review any required report regarding the progress of a project and the final project report at a regularly scheduled meeting of the board.

(J) The board may rescind approval and terminate projects, including those it has approved in perpetuity, pursuant to the following:

(1) If the board deems the project does not the comply with the requirements of this rule or the conditions of its approval, the board shall provide notice to the pharmacist responsible for the project indicating the projects approval has been rescinded. The notice shall provide sixty days for the pharmacist to address any deficiencies prior to the termination of the project. If the deficiencies cited in the notice are addressed, the board may reinstate the project prior to its proposed termination date.

(2) If the board has reasonable cause to believe the project poses a threat of immediate or serious harm to the public, the board shall provide notice to the pharmacist responsible for the project indicating the projects approval has been rescinded. The termination of the project shall take effect immediately.

(K) The petitioner and/or projects responsible person may terminate the project earlier than requested but shall provide notice within three business days of termination and a final project report to the board to include an explanation of why the project was terminated early. Upon either recission of approval or early project termination, any waivers granted will be immediately revoked and the licensee will be required to adhere to those rules that had been excepted or waived.

(L) All documents pertaining to the application, project, and reports are considered a public record under section 149.43 of the Revised Code and will be provided upon request, without notice to the projects petitioners and/or responsible person. Petitioners asserting that some or all of an application contains information exempt from disclosure under Ohio law shall comply with the following:

(1) Submit a memorandum identifying the content not subject to disclosure under section 149.43 of the Revised Code, including supporting legal authority for each assertion.

(2) Submit a redacted version of the materials that the applicant agrees may be released without prior notice to the applicant.

(M) By submitting the application, the petitioner understands, acknowledges, and agrees to all of the following:

(1) The board may independently assess the merits of any public records exception claims made by the petitioner.

(2) The board may reject a claim that information in an application is trade secret or a security or infrastructure record if it determines that the petitioner has not established that the content in question meets a delineated exception to public disclosure under Ohio law, including the use of generic language encompassing substantial portions of the application submission or simple assertions of a document containing information exempt from public disclosure, without substantive explanation of the basis.

(3) The state of Ohio does not assume liability for the use or disclosure of any unredacted material.

(4) The board is required to comply with section 149.43 of the Revised Code, which is construed liberally in favor of broad access, and any doubt shall be resolved in favor of disclosure of public records.

(N) The board will make reasonable efforts to determine the initial approval or denial of a project submission within ninety days of the submission of a completed project petition in accordance with paragraph (E) of this rule.

The board shall be required to make the initial approval or denial of a project submission within one hundred and eighty days of the submission of a completed project petition in accordance with paragraph (E) of this rule. This timeframe may be extended by the board for good cause.

(O) Unless otherwise approved by the board, a petition shall be deemed abandoned if the petitioner fails to submit any requested documentation or information within thirty days after being notified by the board. The board shall not be required to act on any abandoned

petition and the petition may be destroyed by board staff. If the petition is abandoned, the petitioner shall be required to resubmit a new petition for consideration pursuant to the requirements of this rule.

For Re-Filing with CSI & JCARR

3796:6-3-02 **Dispensary premises generally.**

(A) The premises of a dispensary shall be located within Ohio.

(B) Pursuant to section 3796.30 of the Revised Code, no boundary of a parcel of real estate having situated on it a proposed dispensary shall be located within five hundred feet of the boundaries of a parcel of real estate having situated on it a school, church, public library, public playground, ~~or~~ public park, or an opioid treatment program as defined in rule 3796:6-1-01 of the Administrative Code..

~~(C) In addition to the limitations on a dispensary location pursuant to paragraph (B) of this rule, a dispensary shall not be located within five hundred feet of a community addiction services provider as defined under section 5119.01 of the Revised Code.~~

~~(D)~~(C) The dispensary shall be equipped as to land, buildings, and equipment to properly carry on the business of a medical marijuana dispensary.

~~(E)~~(D) The dispensary certificate of operation shall be prominently displayed at the location where the licensee is authorized to operate.

~~(F)~~(E) The premises and operations of a licensee shall conform to all relevant fire codes, local zoning and planning requirements.

~~(G)~~(F) It is the responsibility of a dispensary's associated key employees to promptly notify the state board of pharmacy of any change of the principal place of business.

~~(H)~~(G) No major renovation or modification shall be undertaken without notification to and inspection and approval from the state board of pharmacy and submittal of the required fee. Such renovations include, but are not limited to:

(1) New facilities to be constructed or used for medical marijuana; and

(2) Work or storage areas to be constructed or used for medical marijuana.

~~(I)~~(H) All lighting outside and inside of a dispensary location must be maintained in good working order and wattage sufficient for clear security and surveillance.

~~(J)~~(I) A dispensary shall ensure that any building or equipment used by a dispensary for the storage or sale of medical marijuana is maintained in a clean and sanitary condition.

~~(K)~~(J) Each dispensary that sells edible medical marijuana products shall display a placard that states the following: "Edible medical marijuana products were produced in a

kitchen, not subject to public health inspections, that may also process common food allergens."

(1) The placard shall be no smaller than twenty-four inches tall by thirty-six inches wide, with typed letters no smaller than two inches.

(2) The placard shall be clearly visible and readable by customers and shall be written in English.

(3) The signage shall be placed in the area where edible medical marijuana products are sold, and may be translated into additional languages as needed.

(K) A dispensary shall display a placard, meeting the specifications of the placard described in paragraph (J) of this rule, providing a warning specified by the state board of pharmacy if the board determines that the warning is necessary to avoid imminent harm to public health.

(L) A dispensary shall have an enclosed delivery bay or equally secured delivery area where medical marijuana deliveries will be made pursuant to a standard operating procedure to be approved by the board.

(M) A dispensary shall have a day-storage area for medical marijuana product with pass-through window(s).

(N) A dispensary shall have an approved vault in conformance with C.F.R. 1301.72(a)(3) (6/30/2021) that is in a location not visible to the public.

(O) A dispensary shall have a "mantrap" at any ingress/egress from the dispensary department.

(P) A dispensary shall establish, maintain and comply with written policies and procedures for the safe handling, security, inventory and distribution of medical marijuana. Such policies and procedures shall include methods for identifying, recording and reporting diversion, theft or loss, for correcting errors and inaccuracies in inventories and any other required policy set forth in Chapter 3796. of the Revised Code and this division.