



OHIO STATE BOARD OF PHARMACY

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New Rules and Rule Changes Effective October 24, 2014

New Rules

4729-8-01: Provides definitions for a new rule chapter on drug collection boxes and drug collection events.

4729-8-02: Provides the requirements for a law enforcement agency when operating a permanent drug collection box. The rule also allows for non-law enforcement agencies to utilize drug collection boxes upon adoption of rules by the United States Drug Enforcement Agency (DEA).

4729-8-03: Provides the procedures for operating a drug collection event.

4729-8-04: Provides the procedures for the destruction of drugs collected by drug collection boxes and collection events.

4729-16-01: Provides definitions for a new rule chapter on compounding of dangerous drugs.

4729-16-02: Provides the requirements for operation of an outsourcing facility. Outsourcing facilities provide sterile non-patient specific compounded drugs.

Rule Changes

4729-7-02: Provides another continuing education unit (C.E.U.) reporting year extension for pharmacists to assist with the recent amendment to this rule that moved the reporting date from March 1st to September 15th.

4729-11-02: Updates a recently adopted rule to provide additional clarity to chemists in determining whether a synthetic cannabinoid (commonly referred to as synthetic marijuana) is a Schedule I controlled substance.

4729-16-02**STERILE COMPOUNDED DRUGS PROVIDED BY AN
OUTSOURCING FACILITY.**

(A) An entity may provide, without a patient specific prescription, a non-patient specific sterile compounded drug preparation for human use only, if the following conditions apply:

(1) The entity is registered with the United States Food and Drug Administration as an outsourcing facility pursuant to section 503B of the Federal Food, Drug, and Cosmetic Act (11/27/2013); and

(2) The entity is licensed as a wholesale distributor of dangerous drugs with an outsourcing facility classification pursuant to section 4729.52 of the Revised Code. The entity must include a licensed pharmacist as the responsible person on the license.

(B) This rule does not apply to pharmacies that compound drugs for direct administration by a prescriber pursuant to rule 4729-9-25 of the Administrative Code.

(C) The outsourcing facility shall comply with all labeling and recordkeeping requirements pursuant to section 503B of the Federal Food, Drug, and Cosmetic Act (11/27/2013).

(D) If an entity licensed as a wholesale distributor of dangerous drugs with an outsourcing facility classification pursuant to division (A) of this rule dispenses patient specific drugs, it must also register as a terminal distributor of dangerous drugs. All laws and rules applicable to the terminal distributor license shall apply to dispensing of patient specific drugs.

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Rule Amplifies: 4729.01, 4729.51, 4729.52, 4729.54, 4729.55, 4729.56

4729-16-01**DEFINITIONS.**

(A) As used in this section of the Administrative Code:

- (1) "Outsourcing facility" means a facility at one geographic location or address that is engaged in anticipatory compounding of sterile drugs and complies with the United States Food and Drug Administration section 503B of the Federal Food, Drug, and Cosmetic Act (11/27/2013).
- (2) "Sterile" means a dosage form free of living microorganisms (aseptic).

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4729-11-02

Scheduling of compounds.

(A) The state board of pharmacy hereby schedules the following synthetic cannabinoid compounds:

(1) PB-22 (chemical name: quinolin-8-yl 1-pentyl-1H-indole-3-carboxylate) shall be a schedule I controlled substance;

(2) 5-Fluoro-PB-22 (chemical name: quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate) shall be a schedule I controlled substance.

(B) Except as otherwise provided in section 3719.41 of the Revised Code, any synthetic cannabinoid compound that meets at least three of the following pharmacophore requirements to bind at the CB1 and CB2 receptors, as identified by a report from an established forensic laboratory, is a schedule I controlled substance:

(1) ~~Aminoalkylindole compounds;~~ A chemical scaffold consisting of substituted or non-substituted ring structures that facilitate binding of required elements (such as: indole compounds, indazoles, benzimidazoles or other ring types);

(2) ~~Alkyl or aryl side chain of four to six carbons off the indole nitrogen~~ chemical scaffold providing hydrophobic interaction with the CB1 and CB2 receptors;

(3) Carbonyl or ester or equivalent for hydrogen bonding;

(4) ~~Cyclohexane, or naphthalene ring~~ naphthalene ring, substituted butanamide or equivalent for steric requirements for CB1 and CB2 receptor binding.

(C) Except as otherwise provided in section 3719.41 of the Revised Code, any synthetic cathinone that contains the structural requirements of the cathinone pharmacophore, as identified by a report from an established forensic laboratory, is a schedule I controlled substance.

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4729-8-04

PROCEDURE FOR DISPOSAL OF COLLECTED DRUGS.

- (A) All drugs collected pursuant to this chapter 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 be sufficient to render all drugs collected non-retrievable.
- (C) The method of destruction shall be consistent with the purpose of rendering all drugs collected to a non-retrievable state in order to prevent diversion of any such substance to illicit purposes and to protect the public health and safety.
- (D) The method of destruction shall ensure that the confidentiality of the individuals disposing of drugs is maintained pursuant to applicable state and federal laws, rules, and regulations.

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4729-8-03

PRESCRIPTION DRUG COLLECTION EVENTS.

- (A) At least one law enforcement officer of an agency participating in a collection event shall, at all times, be present for the collection event. The law enforcement officer is responsible for control, monitoring, and custody of the drugs during the collection event until the drugs are secured by the agency or destroyed pursuant to 4729-8-04 of the Ohio Administrative Code.
- (B) The law enforcement agency seeking to establish a collection event in conjunction with a government entity or private entity, shall first request and obtain written permission from a federal drug enforcement agency office located in Ohio. The request letter must include the following:
- (1) names and addresses of all agencies involved;
 - (2) description, date and time of the event(s); and
 - (3) description of law enforcement official to be present.
- (C) The law enforcement officer(s) referred to in division (A) of this section shall, at all times, have sole control over, and sole possession of, all drugs collected, and the receptacle(s) in which the collected drugs are stored.
- (D) Individuals disposing of unused drugs shall place them directly into the drug collection box or hand them directly to a law enforcement officer.
- (E) Only prescription medications and over-the-counter drugs from the individual's household or residence shall be collected.
- (F) No needles, syringes or lancets shall be placed in the drug collection box. A bulk sharps disposal container may be provided at each collection event for the disposal of sharps.
- (G) No radiopharmaceuticals shall be collected.
- (H) At the conclusion of the collection event, the law enforcement officer(s) shall be responsible for removing the collection box(es) the same day from the event location for disposal pursuant to 4729-8-04 of the Administrative Code.
- (I) The law enforcement agency shall keep records of the collection and destruction of the drugs, which shall include, but is not limited to, the following:
- (1) the amount of drugs acquired by the agency (i.e. pounds collected);
 - (2) the manner, location and date in which the drugs were disposed; and
 - (3) the name(s) of the law enforcement officer(s) to oversee the collection, security and destruction of the drugs.

(J) The law enforcement agency shall ensure that the confidentiality of the individual disposing a drug is maintained pursuant to applicable state and federal laws, rules, and regulations.

(K) Law enforcement agencies that participate in prescription drug collection events pursuant to this rule are not subject to 4729-9-06 of the Administrative Code.

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4729-8-02

PERMANENT DRUG COLLECTION BOXES.

- (A) Except pursuant to paragraph (K) of this rule, a drug collection box shall only be located in a law enforcement agency and shall remain in the custody of law enforcement at all times.
- (B) The drug collection box shall be placed in a location that is accessible to the public during posted hours.
- (C) The drug collection box shall be placed within reasonable view of law enforcement personnel or under continuous video surveillance.
- (D) The drug collection box shall be securely mounted to a wall or floor to prohibit removal of the box and must be securely locked to prevent the unauthorized retrieval of the contents from within the box.
- (E) The drug collection box shall be clearly marked indicating the following information:
- (1) Only prescription medications and over-the-counter drugs from the individual's household or residence can be deposited.
 - (2) No needles, syringes, or lancets shall be placed in the drug collection box.
 - (3) No radiopharmaceuticals shall be placed in the drug collection box.
- (F) If a law enforcement agency chooses to limit the types of drugs which are acceptable for return, such limitations shall be clearly stated on or near the drug collection box.
- (G) The law enforcement agency shall check the drug collection box regularly and remove deposits to prevent the box from reaching capacity. When removing a deposit, a law enforcement officer shall remove the inner liner of the drug collection box and process the drugs accordingly. The drugs must be removed in such a manner as to maintain the confidentiality of the individual disposing of the drugs pursuant to all applicable state and federal laws, rules, and regulations.
- (H) The agency shall maintain custody and control of the contents deposited in the drug collection box until the drugs are disposed pursuant to 4729-8-04 of the Administrative Code.
- (I) The law enforcement agency shall keep records of the collection and destruction of the drugs, which shall include, but is not limited to, the following:
- (1) the amount of drugs acquired by the agency (i.e. pounds collected);
 - (2) the manner, location and date in which the drugs were disposed; and
 - (3) the name(s) of the law enforcement officer(s) to oversee the destruction of the drugs.

(J) Law enforcement agencies that operate a drug collection box pursuant to this rule are not subject to 4729-9-06 of the Administrative Code.

(K) A drug collection box may be housed in a location other than a law enforcement agency pursuant to rules and regulations adopted by the United States Drug Enforcement Agency. The entity shall comply with the following requirements:

(1) Comply with all applicable state and federal laws, rules, and regulations regarding the collection and destruction of drugs collected.

(2) Ensure that the confidentiality of the individual disposing a drug is maintained pursuant to applicable state and federal laws, rules, and regulations.

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4729-8-01

DEFINITIONS.

As used in Chapter 4729-8 of the Administrative Code:

- (A) "Drug collection box" means a secured, lined receptacle into which prescription medications, including controlled substances and dangerous drugs, and over-the-counter medications can be deposited for the purposes of collecting unused or expired drugs.
- (B) "Collection event" means a one-day program through which the public may safely dispose of unused or expired prescription medications, including controlled substances and dangerous drugs, and over-the-counter medications generated from a household residence that are no longer wanted or needed by the consumer, at a secure collection site.
- (C) "Controlled substances" has the same meaning as defined in division (C) of section 3719.01 of the Revised Code.
- (D) "Dangerous drugs" has the same meaning as defined in division (F) of section 4729.01 of the Revised Code.
- (E) "Drugs" has the same meaning as defined in division (E) of section 3719.01 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" means "peace officer" as defined in section 2921.51 of the Revised Code, a board of pharmacy compliance agent or an officer of a federal law enforcement agency.

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4729-7-02

Requirements for renewal of a pharmacist identification card.

- (A) Except as provided in rule 4729-7-08 of the Administrative Code, evidence of six C.E.U.s of approved continuing education shall be submitted to the board no later than September fifteenth of the year in which evidence of the continuing pharmacy education is required for identification card renewal. At least 0.3 C.E.U.s of the total required C.E.U.s must be obtained from Ohio state board of pharmacy approved programs in jurisprudence.
- (B) The C.E.U.s must be obtained within a period of time that is no more than three years prior to September fifteenth of the year in which evidence of the continuing pharmacy education is required for identification card renewal. A pharmacist shall be subject to further action of the board if the continuing pharmacy education is not submitted to the board by September fifteenth of the year in which evidence of the continuing pharmacy education is required for identification card renewal. If reporting continuing education is required after a pharmacist's license has lapsed or where the license is being renewed after board action, continuing education must be obtained during the three year period immediately preceding the date the renewal application is filed with the board office.
- (C) C.E.U.s obtained in excess of the required C.E.U.s at the time the continuing education is required for identification card renewal, may not be transferred and applied to future requirements.
- (D) For the first ~~three~~ four C.E.U. reporting years following the adoption of this rule (2014, 2015, 2016 and 2017), the board may accept C.E.U.s within a period of time from March first, three years prior to September fifteenth of the year in which evidence of the continuing pharmacy education is required for identification card renewal.
- (E) A pharmacist whose identification card has lapsed or has been suspended may renew his/her identification card, if he/she qualifies for renewal pursuant to section 4729.12 or section 4729.13 of the Revised Code, by paying the required fee, completing the application for renewal, and, if he/she would have been required to report continuing pharmacy education during the period of lapse or suspension, by providing evidence of having obtained the number of C.E.U.s required at the time of renewal by submitting the certificates of participation obtained during the three-year period immediately preceding the date of applying for renewal.
- (F) Ohio-registered pharmacists who hold a current license in states where continuing education is mandatory, have met the continuing pharmacy education requirements of that state, and who do not practice pharmacy in Ohio, may renew their identification card by paying the required fee, completing the application for renewal, and submitting the following signed statement on their continuing pharmacy education report form:

"I declare under penalties of falsification that I hold a current and valid pharmacist license, number (insert license number), in the state of (insert name of state), that I have met the continuing pharmacy education requirements of this state and I do not presently practice pharmacy in the state of Ohio. I hereby agree to immediately notify the Ohio state board of pharmacy if I return and commence the practice of pharmacy in the state of Ohio."

- (G) The state board of pharmacy may grant extension periods and waivers for the completion of license renewal and continuing education requirements for active military service members and their spouses. If a current pharmacist or their spouse is called to active duty for military service, the time period allowed for completion of any continuing education requirements will be extended by the amount of time that the pharmacist or the pharmacist's spouse was on active duty. A pharmacist seeking an extension period or waiver must provide documentation to the board demonstrating active-duty service.

- (H) If a pharmacist is a member of the armed forces, reserves, the Ohio national guard, the Ohio military reserve, or the Ohio naval militia, the state board of pharmacy shall consider relevant military education, training or service that has been completed by the license holder when determining the fulfillment of any continuing education requirements.

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