



## Rules for Stakeholder Feedback – Drug Take Back

As part of its required 5-year rule review process, the Board proposes the following rules be filed as “no change” rules:

- 4729:10-1-01 Definitions – prescription drug collection.
- 4729:10-1-03 Law enforcement agencies.
- 4729:10-1-04 Procedure for destruction of collected drugs.

The Board also proposes the following rule be filed as “amended”:

- 4729:10-1-02 Authorized collectors. This rule is being amended to ensure that mail back packages comply with regulations set by the DEA, which require all mail back packages to be nondescript and not include any markings or other information that might indicate that the package contains controlled substances.

Comments on the proposed rules will be accepted until close of business on **August 12, 2022**. Please send all comments to the following email address:

[RuleComments@pharmacy.ohio.gov](mailto:RuleComments@pharmacy.ohio.gov).



## **Rule 4729:10-1-01 | Definitions - prescription drug collection.**

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.**

(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.**

(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.