



Ohio Administrative Code

Rule 4729:5-3-01 Disposal of controlled substances.

Effective: July 1, 2024

(A) As used in this rule:

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

(2) "Controlled substance proof-of-use sheet" means a record that captures, at a minimum, the following information:

(a) Date;

(b) Patient name;

(c) Drug name;

(d) Drug strength;

(e) Quantity; and

(f) The positive identification of the individuals authorized by this rule who are responsible for removing the dangerous drugs from the medication cart, or other storage area, and transferring the drugs to the secure storage area.

(3) "Non-retrievable" means the condition or state to which a controlled substance shall be rendered following a process that permanently alters that controlled substance's physical or chemical condition or state through irreversible means and thereby renders the dangerous drugs which are controlled substances unavailable and unusable for all practical purposes. The process to achieve a non-retrievable condition or state may be unique to a substance's chemical or physical properties. A dangerous drug which is a controlled substance is considered non-retrievable when it cannot be transformed to a physical or chemical condition or state as a controlled substance or controlled



substance analogue. The purpose of destruction is to render the controlled substance(s) to a non-retrievable state and thus prevent diversion of any such substance to illicit purposes.

(4)

(a) "Positive identification" means a method of identifying a person that does not rely on the use of a private personal identifier such as a password, but must use a secure means of identification that includes any of the following:

(i) A manual signature on a hard copy record;

(ii) A magnetic card reader;

(iii) A bar code reader;

(iv) A biometric method;

(v) A proximity badge reader;

(vi) A board approved system of randomly generated personal questions;

(vii) A printout of every transaction that is verified and manually signed within a reasonable period of time by the individual who performed the action requiring positive identification. The printout must be maintained for three years and made readily retrievable; or

(viii) Other effective methods for identifying individuals that have been approved by the board.

(b) A method relying on a magnetic card reader, a bar code reader, a proximity badge reader, or randomly generated questions for identification must also include a private personal identifier, such as a password, for entry into a secure mechanical or electronic system.

(5) "State or local correctional facility" means any of the following:



(a) A "state correctional institution," as defined in section 2967.01 of the Revised Code;

(b) A "local correctional facility," as defined in section 2903.13 of the Revised Code.

(B) A terminal distributor of dangerous drugs shall dispose of controlled substance dangerous drugs in accordance with 21 C.F.R. 1317 (9/25/2023). The method of destruction must render the controlled substances to a state of non-retrievable. Records of controlled substance destruction that are required pursuant to 21 C.F.R. 1304 (9/25/2023) shall be maintained for a minimum of three years and made readily retrievable.

(1) If a long term care facility uses a method of destruction pursuant to 21 C.F.R. 1317 (9/25/2023), the controlled substances transferred to a collection receptacle or mail-back envelope must be completed by the director of nursing and witnessed by a nurse licensed in accordance with Chapter 4723. of the Revised Code. The amount of controlled substances transferred to the receptacle or mail-back envelope and the method of disposal used must be documented with the positive identification of both individuals on the corresponding controlled substance proof-of-use sheet.

(C) If a pharmacy is servicing a long term care facility or a consultant pharmacist is employed by a long term care facility and is having a pharmacist engage in the on-site destruction of ultimate user (i.e., patient-owned) controlled substances in the custodial care of nursing staff, the pharmacy or consultant pharmacist shall have policies and procedures in place to ensure compliance with and shall comply with all the following:

(1) Upon discontinuation of a patient's use of a controlled substance medication, a nurse and director of nursing, or other pharmacy or pharmacist-approved supervisory nurse, must document the removal of the patient's medication from the medication cart or storage area and record the transfer of the drugs to a secure storage area for disposal.

(2) The record of the controlled substances removed from the medication cart, or other area of storage, for disposal shall be made on a controlled substance proof-of-use sheet. The proof-of-use sheet shall be maintained on-site at the location licensed as a terminal distributor of dangerous drugs for a minimum of three years from the date of removal and made readily retrievable.



(3) An Ohio licensed pharmacist or the director of nursing and another pharmacy or pharmacist-approved supervisory level nurse may destroy an ultimate user's controlled substances using an on-site method at the location licensed as a terminal distributor of dangerous drugs. Both individuals shall personally witness and document the destruction of the controlled substance medication pursuant to paragraph (C)(4) of this rule. The on-site method does not have to meet the definition of non-retrievable but must render the drug unavailable and unusable.

(4) A record of controlled substances destroyed shall be made containing the date of destruction, patient name, drug name, drug strength, quantity, method of destruction and the positive identification of the two individuals listed in paragraph (C)(3) of this rule responsible for the destruction.

(5) The record of controlled substance destruction pursuant to paragraph (C)(4) of this rule shall be maintained on-site at the location licensed as a terminal distributor of dangerous drugs for a minimum of three years from the date of destruction and made readily retrievable.

(6) Controlled substances shall be destroyed pursuant to this paragraph no later than ten days from the date the patient's controlled substance medication is removed from the medication cart or storage area in accordance with paragraph (C)(1) of this rule.

(D) A state or local correctional facility may engage in the on-site destruction of ultimate user (i.e., patient-owned) controlled substances in the custodial care of nursing staff, as follows:

(1) The correctional facility shall be licensed as a category III terminal distributor of dangerous drugs.

(2) The responsible person shall have policies and procedures in place to ensure compliance with and shall comply with all the following:

(a) Upon discontinuation of a patient's use of a controlled substance medication, the responsible person, director of nursing or a licensed pharmacist and another responsible person-approved nurse or corrections officer must document the removal of the patient's medication from the medication cart or storage area and record the transfer of the drugs to a secure storage area for disposal.



(b) The record of the controlled substances removed from the medication cart, or other area of storage, for disposal shall be made on a controlled substance proof-of-use sheet. The proof-of-use sheet shall be maintained on-site at the location licensed as a terminal distributor of dangerous drugs for a minimum of three years from the date of removal and made readily retrievable.

(c) The responsible person, director of nursing, or a licensed pharmacist and another responsible person-approved nurse or corrections officer may destroy ultimate user controlled substances using an on-site method at the location licensed as a terminal distributor of dangerous drugs. Both individuals shall personally witness and document the destruction of the controlled substance medication pursuant to paragraph (D)(2)(d) of this rule. The on-site method does not have to meet the definition of non-retrievable but must render the drug unavailable and unusable.

(d) A record of controlled substances destroyed shall be made containing the date of destruction, patient name, drug name, drug strength, quantity, method of destruction and the positive identification of the two individuals listed in the paragraph (D)(2)(c) of this rule responsible for the destruction. The record of controlled substance destruction shall be maintained on-site at the location licensed as a terminal distributor of dangerous drugs for a minimum of three years from the date of destruction and made readily retrievable.

(e) Controlled substances shall be destroyed no later than ten days from the date the patient's controlled substance medication is removed from the medication cart or storage area in accordance with paragraph (D)(2)(a) this rule.

(E) The unused portion of a controlled substance resulting from administration to a patient from a licensee's stock or emergency supply may be destroyed using an on-site method by any person legally authorized under Chapters 3719. and 4729. of the Revised Code and this division of the Administrative Code to possess controlled substance dangerous drugs. The on-site method does not have to meet the definition of non-retrievable but must render the drug unavailable and unusable. A record of such destruction shall be made in accordance with 21 C.F.R. 1304 (9/25/2023) and shall be maintained for a minimum of three years from the date of destruction and made readily retrievable to the board of pharmacy upon request.