



## **Controlled Substance Inventory Disposal**

**Updated 1/16/2017**

Effective February 1, 2017, rule 4729-9-06 will no longer require approval from the Board prior to the disposal of a licensee's controlled substance inventory. Instead, the rule will require adherence to all Drug Enforcement Administration (DEA) disposal requirements set forth in [21 C.F.R. 1317](#) and all recordkeeping requirements set forth in [21 C.F.R. 1304](#). A complete copy of the new rule is included with this document.

For questions regarding disposal of controlled substance inventory, please review the following guidance document and rule. If you need additional information, the most expedient way to have your questions answered will be to e-mail the Board office by visiting: <http://www.pharmacy.ohio.gov/contact.aspx>.

*NOTE: This rule only applies to a licensee's controlled substance inventory and does not apply to the disposal of drugs collected from the public via drug takeback receptacles or mail back programs. More information on this can be accessed by visiting: [www.pharmacy.ohio.gov/disposal](http://www.pharmacy.ohio.gov/disposal)*

### **Q1) Will I need to submit any information to the Board to dispose of my organization's controlled substance inventory?**

No. The new rule no longer requires the submission of any information to the Board prior to the disposal of a licensee's controlled substance inventory. However, a licensee is required to keep all records of disposal in accordance with federal regulations and [rule 4729-9-14](#).

### **Q2) How long am I required to keep records documenting the disposal of controlled substance inventory?**

While some federal agencies have shorter record retention requirements, the State of Ohio Board of Pharmacy requires all records, including those documenting the disposal of controlled substance inventory, be maintained and readily retrievable for a minimum of three years.



### **Q3) How do I know that my method of disposal meets the definition of non-retrievable?**

In the [2014 issuance of its final regulations](#) regarding the disposal of controlled substance inventory, the DEA states the following (emphasis added):

*...the DEA indicated **that incineration and chemical digestion are some examples of current technology that may be utilized to achieve the non-retrievable standard.** The preamble of the NPRM states **that sewerage (disposal by flushing down a toilet or sink) and landfill disposal (mixing controlled substances with undesirable items such as kitty litter or coffee grounds and depositing in a garbage collection) are examples of current methods of disposal that do not meet the non-retrievable standard.** The term non-retrievable is defined in the rule and is results-oriented because the DEA's concern is that the substance be permanently rendered to an unusable state. The performance standard is that the method renders the substance so that it cannot be transformed to a physical or chemical condition or state as a controlled substance or controlled substance analogue...The DEA will not be routinely engaged in evaluating new technologies intended to render controlled substances "non-retrievable." Much like the DEA does not evaluate, review, or approve the specific processes or methods utilized to produce, synthesize or propagate a controlled substance, the DEA will not evaluate, review, or approve the processes or methods utilized to render a controlled substance non-retrievable, as long as the desired result is achieved.*

The Board, much like the DEA, will not evaluate technologies to determine if they meet the non-retrievable definition set forth in rule. For disposal methods other than incineration or use of a DEA registered reverse distributor, the Board recommends having proper documentation from the manufacturer demonstrating how such a method meets the definition of non-retrievable.

### **Q4) Does the rule address the disposal of controlled substance waste?**

Yes. Paragraph (D) of the rule defines waste as "the unused portion of a controlled substance resulting from administration to a patient from a registrant's stock or emergency supply." It does not require the disposal of such waste to meet the non-retrievable standard for inventory but requires the licensee to use a method to render the drug unavailable and unusable. Furthermore, a licensee is required to maintain a record of such disposal in accordance with [221 C.F.R. 1304](#) and [rule 4729-9-14](#).

### **Q5) Does the rule address the disposal of controlled substances for residents of long-term care facilities (LTCFs)?**

Yes. Paragraph (C) of the rule outlines the process by which LTCFs may dispose of patient-owned controlled substances. Positive identification of the Ohio-licensed pharmacist and the director of nursing or other pharmacy or pharmacist-approved supervisory level nurse responsible for the disposal is required. Methods for achieving positive identification are listed in paragraph (N) of [rule 4729-5-01](#) and may include wet-ink signatures of the individuals responsible for the disposal on the required records.

4729-9-06

**Disposal of dangerous drugs which are controlled substances.**

- (A) As used in this rule, "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.
- (B) Any person legally authorized under Chapters 3719. and 4729. of the Revised Code to possess dangerous drugs which are controlled substances shall dispose of such drugs in accordance with 21 C.F.R. 1317 (1/1/2016). The method of destruction must render the dangerous drugs which are controlled substances to a state of non-retrievable. Records of controlled substance destruction that are required pursuant to 21 C.F.R. 1304 (1/1/2016) shall be maintained for a minimum of three years and made available to the board of pharmacy upon request.
- (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 witness the destruction of ultimate user (patient-owned) controlled substances in the custodial care of nursing staff in an inpatient setting, then the pharmacy or consultant pharmacist shall have policies and procedures in place to ensure compliance with and shall comply with all of the following:
- (1) Upon discontinuation of a patient's controlled substance medication, a nurse and director of nursing, or other pharmacy-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 medications 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 the required controlled substance proof-of-use sheet pursuant to rule 4729-17-05. Records shall contain the date, patient name, drug name, drug strength, quantity, and the positive identification of the two nurses responsible for removing the medications from the medication cart, or other storage area, and transferring the medications into the secure storage area.
  - (3) An Ohio licensed pharmacist and the director of nursing, or other pharmacy or pharmacist approved supervisory level nurse, may destroy ultimate user (patient owned) controlled substances using an on-site method. 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 Ohio licensed pharmacist and the director of nursing, or other pharmacy or pharmacist approved supervisory level nurse, responsible for the destruction.

(5) The record of controlled substance destruction pursuant to paragraph (C)(4) of this rule shall be maintained on-site for a minimum of three years and made available to the board of pharmacy upon request.

(D) The unused portion of a controlled substance resulting from administration to a patient from a registrant'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 to possess dangerous drugs which are controlled substances. 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 (1/1/2016) and shall be maintained for a minimum of three years and made available to the board of pharmacy upon request.