

COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Division of Environmental Health and Sustainability

6 CCR 1010-23

**RULES AND REGULATIONS GOVERNING
THE COLORADO HOUSEHOLD MEDICATION TAKE-BACK PROGRAM**

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9
10 **23.1 Authority**

11
12 This regulation is adopted pursuant to the authority in Section 25-15-328(7), C.R.S., and is
13 intended to be consistent with the requirements of the State Administrative Procedures Act,
14 Section 24-4-101, et seq., C.R.S. Where there is a conflict between the requirements of the
15 State Administrative Procedures Act and Section 25-15-328, C.R.S., the provisions of Section
16 25-15-328, C.R.S. shall prevail.

17
18 **23.2 Scope and Purpose**

19
20 A. This regulation governs the Colorado Household Medication Take-Back Program
21 established in Section 25-15-328, C.R.S. This Regulation establishes:

- 22
23 1. Rules for department approved collectors of unused household medications;
24
25 2. Rules for the acquisition and transportation of unused household medications
26 from approved collectors to approved disposal locations by approved
27 transporters; and
28
29 3. Rules for the destruction of unused household medications at approved disposal
30 locations.

31
32 B. This regulation does not apply to:

- 33
34 1. The authority to collect and reuse medications pursuant to Section 12-42.5-
35 133, C.R.S.;
36
37 2. Wastes generated by non-household waste generators subject to Section 13 of
38 the *Regulations Pertaining to Solid Waste Sites and Facilities*, 6 CCR 1007-2.;
39
40 3. Wastes generated by non-household waste generators subject to the *Hazardous*
41 *Waste Regulations*, 6 CCR 1007-3;
42
43 4. The operation of other medication take-back and disposal programs regulated
44 by the department;
45
46 5. Individuals disposing of unused household medications; or
47
48 6. Schedule I controlled substances as defined in Title 21 CFR Part 1308.11, as
49 amended.

- 50
51 C. Persons who comply with this regulation may participate in the Program. Department-
52 contracted transporters who incur costs associated with the collection, transportation,
53 or destruction of household medications pursuant to the Program may apply to the
54 department for money from the cash fund established by the General Assembly in
55 Section 25-15-328(5), C.R.S. The department will adopt policies for the distribution of
56 this money.
57

58 23.3 Applicability

59

- 60 A. The provisions of this section shall be applicable to the Colorado Household Medication
61 Take-Back Program as created by Section 25-15-328, C.R.S.
62
63 B. Participation in the Colorado Household Medication Take-Back Program is voluntary.
64
65 C. Participants in the Colorado Household Medication Take-Back Program include:
66 approved collectors, approved transporters, and approved disposal locations.
67
68 D. These regulations shall not limit the powers and duties of local governments to issue
69 such orders and adopt regulations as stringent or more stringent than the provisions
70 contained herein.
71

72 23.4 Definitions

73

- 74 A. For the purpose of these rules and regulations:
75
76 1. Collection means to receive household medications from individuals for the
77 purpose of destruction. If a household medication is a controlled substance,
78 collection means to receive a controlled substance for the purpose of
79 destruction from an ultimate user or an individual lawfully entitled to dispose
80 of an ultimate user decedent's property.
81
82 2. Collector means a DEA-registrant or law enforcement agency approved by the
83 department for the collection of unused household medications.
84
85 3. Colorado Household Medication Take-Back Program or Program means the
86 program established in Section 25-15-328, C.R.S to facilitate the safe and
87 effective collection, transportation, and destruction of household medications.
88
89 4. Commission means the Solid and Hazardous Waste Commission created
90 pursuant to Section 25-15-302, C.R.S.
91
92 5. Common Carrier means a for-hire carrier that holds itself out to serve the
93 general public at reasonable rates and without discrimination.
94
95 6. Contract Carrier means a for-hire interstate operator which offers
96 transportation services to certain shippers under contracts.

- 97 7. Controlled Substance means a drug or other substance, or immediate
98 precursor, included in schedule II - V and listed in 21 CFR Parts 1308.12 through
99 1308.15, as amended.
100
- 101 8. DEA means the Drug Enforcement Administration and its authorized agents and
102 employees.
103
- 104 9. DEA Registrant or Registrant means any person who is registered pursuant to
105 Title 21 CFR Part 1301.11, as amended.
106
- 107 10. Department means the Colorado Department of Public Health and Environment
108 and its authorized agents and employees.
109
- 110 11. Disposal Location means a site approved by the department where unused
111 household medications are destroyed in compliance with applicable laws and
112 rendered non-retrievable and cannot be diverted for illicit purposes.
113
- 114 12. Distribute means to deliver (other than by administering or dispensing) a
115 controlled substance or to deliver (other than by administering or dispensing) a
116 listed chemical designated in Title 21 CFR Part 1310.02, as amended.
117
- 118 13. Distributor means a person who delivers (other than by administering or
119 dispensing) a controlled substance or delivers (other than by administering or
120 dispensing) a listed chemical designated in Title 21 CFR Part 1310.02, as
121 amended.
122
- 123 14. Employee means an individual directly paid by a program participant; subject
124 to direct oversight by a program participant; required, as a condition of
125 employment, to follow a program participant's procedures and guidelines
126 pertaining to the handling of household medications, including controlled
127 substances; subject to receive a performance rating or performance evaluation
128 on a regular/routine basis from a program participant; subject to disciplinary
129 action by a program participant; and required to render services at the site of
130 a program participant's covered activities. At a law enforcement agency
131 collector an employee may, at the agency's discretion, be a paid or unpaid
132 reserve officer as defined pursuant to 16-2.5-110, C.R.S.
133
- 134 15. Household Medications means controlled substances approved for collection by
135 federal law, prescription drugs, and over-the-counter medications in the
136 possession of an individual.
137
- 138 16. Law Enforcement Agency means, but is not limited to, a municipal, tribal,
139 university, or college police department; a county sheriff's office; a district
140 attorney's office; a county coroner's office; a town marshal's office; the
141 Colorado Department of Public Safety; and the Colorado Department of
142 Corrections.
143
- 144 17. Law Enforcement Officer means an individual who:
145

- a. Is an employee of either a law enforcement agency or law enforcement component of a federal agency;
- b. Is under the direction and control of a federal, state, tribal, or local government;
- c. Acts in the course of the law enforcement officer's official duty; and
- d. Is duly sworn and given the authority by a federal, state, tribal, or local government to carry firearms, execute and serve warrants, make arrests without warrant, and make seizures of property.
18. Non-retrievable means, for the purpose of destruction, the condition or state to which household medications shall be rendered following a process that permanently alters the household medications' physical or chemical condition or state through irreversible means and thereby renders the household medications unavailable and unusable for all practical purposes, thus preventing their diversion to illicit purposes. The process to achieve a non-retrievable condition or state may be unique to a household medication's chemical or physical properties. A controlled substance is considered non-retrievable when permanently altered in such manner and it cannot be transformed to a physical or chemical condition or state as a controlled substance or controlled substance analogue.
19. On-site means located on or at the physical premises of the registrant's registered location. A controlled substance is destroyed on-site when destruction occurs on the physical premises of the destroying registrant's registered location. A hospital/clinic has an on-site pharmacy when it has a pharmacy located on the physical premises of the registrant's registered location.
20. Reverse Distribute means to acquire controlled substances from another registrant or law enforcement for the purpose of:
- a. Return to the registered manufacturer or another registrant authorized by manufacturer to accept returns on the manufacturer's behalf; or
- b. Destruction.
21. Reverse Distributor means a person registered with the Drug Enforcement Administration to reverse distribute controlled substances.
22. Take-Back Event means a scheduled, organized occasion of limited duration, managed by a law enforcement agency for the collection of household medications, including controlled substances collected from ultimate users and individuals lawfully entitled to dispose of an ultimate user decedent's property.

23. Transporter means any entity approved by the department to acquire unused household medications from approved collectors and transport them to approved disposal locations.

24. Ultimate User means an individual who has lawfully obtained, and who possesses, a controlled substance for the individual's own use or for the use of a member of the individual's household or for an animal owned by the individual or by a member of the individual's household.

23.5 Standards for Approved Program Participants

- A. All Program participants shall comply with requirements of federal, state, tribal, and local laws and regulations.

23.6 Specific Standards for Approved Collectors, Transporters, and Disposal Locations

23.6.1 Collectors

- A. In order to collect household medications as an approved participant in the Program, a collector shall:

1. Be a law enforcement agency; or a DEA-registered location of a retail pharmacy or a hospital/clinic with an on-site pharmacy, whose registrations have been modified consistent with DEA requirements described in Title 21 CFR Part 1301.51, as amended, to authorize collection of controlled substances.
2. Have an application form approved by the department.
3. Develop, implement, and maintain on site in an easily retrievable format a Medical Waste Management Plan containing, at a minimum, the following elements:
 - a. Procedures for household medication identification, collection, packaging, storage, transport and disposal;
 - b. A contingency plan for spills and releases;
 - c. Employee and volunteer training procedures;
 - d. Designation of an individual or individuals responsible for implementing the plan; and
 - e. Recordkeeping methods.

23.6.2 Transporters

- A. In order to acquire household medications from collectors and transport them to disposal locations for destruction as an approved participant in the Program, a transporter shall be:

1. A reverse distributor or distributor under contract or other written, signed service agreement with the department if acquiring household medications from a DEA-registered collector by on-site pick-up or by common carrier or contract carrier delivery; or
2. A reverse distributor under contract or other written, signed service agreement with the department if acquiring household medications from a law enforcement agency collector by on-site pick-up or by common carrier or contract carrier delivery.

23.6.3 Disposal Locations

- A. In order to be approved to destroy household medications collected in the Program, a disposal location shall:
 1. Utilize a method of destruction that renders household medications non-retrievable; and
 2. Comply with applicable federal, state, tribal, and local laws and regulations.

23.7 Allowable Collection Methods

23.7.1 DEA-Registered Collectors

- A. DEA-registered collectors participating in the Program may collect household medications, including controlled substances collected from ultimate users, utilizing the following collection method:
 1. Collection receptacles and inner liners in accordance with Sections 23.8 and 23.9.

23.7.2 Law Enforcement Agency Collectors

- A. Law enforcement agency collectors participating in the Program may collect household medications in the course of official duties, including controlled substances collected from ultimate users, utilizing the following collection methods:
 1. Collection receptacles and inner liners in accordance with Sections 23.8 and 23.9; and/or
 2. Take-back events in accordance with Section 23.10.

23.8 Collection Receptacle Requirements

- A. Collection receptacles shall be securely placed and maintained either (1) inside a DEA-registered collector's location, or (2) inside a law enforcement agency collector's physical location.
- B. For collection receptacles located inside a DEA-registered collector's location:

1. At a retail pharmacy, receptacles shall be located in an area accessible to the public and in the immediate proximity of a designated area where controlled substances are stored, and at which an employee is present (e.g., can be seen from the pharmacy counter); and
 2. At a hospital/clinic, receptacles shall be located in an area accessible to the public and regularly monitored by employees, and shall not be located in the proximity of any area where emergency or urgent care is provided.
- C. For collection receptacles located inside a law enforcement agency collector's location, receptacles shall be located in an area monitored by employees or law enforcement officers.
- D. A collection receptacle shall meet the following design specifications:
1. At a DEA-registered collector's location, be securely fastened to a permanent structure so that it cannot be removed;
 2. Be a securely locked, substantially constructed container with a permanent outer container and a removable inner liner as specified in Section 23.9;
 3. Include a small opening in the outer container that allows contents to be added to the inner liner, but does not allow removal of the inner liner's contents;
 4. Prominently display a sign on the outer container indicating that only Schedule II-V controlled and non-controlled substances are acceptable substances. Schedule I controlled substances, controlled substances that are not lawfully possessed by the ultimate user, and other illicit or dangerous substances are not permitted; and
 5. Except at a law enforcement agency location, the small opening in the outer container of the collection receptacle shall be locked or made otherwise inaccessible to the public when an employee is not present (e.g., when a pharmacy is closed).
- E. Except at a law enforcement agency location specifically authorized by the department, once household medications have been deposited into a collection receptacle, the household medications shall not be counted, sorted, inventoried, or otherwise individually handled.
- F. Only those controlled substances listed in Schedule II, III, IV, or V that are lawfully possessed by an ultimate user or other authorized non-registrant individual may be collected along with other household medications that are non-controlled substances. Controlled and non-controlled substances may be collected together and be comingled.
- G. Law enforcement agency collectors may allow ultimate users and other authorized non-registrant individuals in lawful possession of a controlled substance in Schedule II, III, IV, or V to transfer such substances and other household medications to a law enforcement officer or law enforcement agency employee for immediate deposit in a

collection receptacle, if the collection receptacle is located in an area not accessible to the public.

23.9 Collection Receptacle Inner Liner Requirements

A. The inner liner used in a collection receptacle shall meet the following requirements:

1. The inner liner shall be opaque, waterproof, tamper-evident, and tear-resistant;
2. The inner liner shall be removable and sealable immediately upon removal without emptying or touching the contents;
3. The contents of the inner liner shall not be viewable from the outside when sealed;
4. The size of the inner liner shall be clearly marked on the outside of the liner (e.g., 5-gallon, 10-gallon, etc.); and
5. The inner liner shall bear a permanent, unique identification number that enables the inner liner to be tracked in accordance with Section 23.16.2(A) and (B).

B. Access to the inner liner shall be restricted to employees of a DEA-registered collector or employees of a law enforcement agency collector.

C. Installation and removal of the inner liner shall be performed by:

1. Two employees of a DEA-registered collector; or
2. Unless otherwise approved by the department, two employees of a law enforcement agency collector.

D. The inner liner shall be sealed immediately upon removal from the permanent outer container of the collection receptacle and the sealed inner liner shall not be opened, x-rayed, analyzed, or otherwise penetrated. The inner liner shall be sealed by:

1. Two employees of a DEA-registered collector; or
2. Unless otherwise approved by the department, two employees of a law enforcement agency collector.

23.10 Take-Back Events

A. A law enforcement agency may conduct a take-back event and collect household medications, including controlled substances collected from ultimate users and individuals lawfully entitled to dispose of an ultimate user decedent's property. A law enforcement agency may partner with other persons or entities to hold a collection take-back event in accordance with this Section.

- B. A law enforcement agency shall appoint at a minimum one law enforcement officer employed by the agency to oversee the collection. Law enforcement officers employed by the law enforcement agency conducting a take-back event shall maintain control and custody of the household medications from the time they are collected until secure transfer, storage, or destruction has occurred.
- C. A law enforcement agency may conduct a take-back event at its physical location or at another location, provided the law enforcement officer(s) overseeing the collection are able to maintain custody and control of the household medications in accordance with this Section.
- D. A collection receptacle, as described in Section 23.8 and Section 23.9, may be used at a take-back event for the collection of household medications.
- E. If a collection receptacle is not used at a take-back event, collected household medications shall be placed in an opaque, waterproof, tamper-evident, and tear-resistant bag bearing the markings required for inner liners as described in Sections 23.9(A)(4) and (5).
- F. Only those controlled substances listed in Schedule II, III, IV, or V that are lawfully possessed by an ultimate user or individual entitled to dispose of an ultimate user decedent's property may be collected. Controlled and non-controlled substances may be collected together and be comingled.
- G. Only ultimate users and individuals entitled to dispose of an ultimate user decedent's property in lawful possession of a controlled substance in Schedule II, III, IV, or V may transfer such substances to the law enforcement officer described in Section 23.10(B) during the take-back event. No other individual may handle the controlled substances at any time.

23.11 Disposal of Collected Household Medications

23.11.1 DEA-Registered Collectors

- A. DEA-registered collectors shall dispose of collected household medications in the following manner:
1. Upon inner liner removal from the permanent outer container of a collection receptacle, the sealed inner liner and its contents shall be:
 - a. Sent by two employees to a reverse distributor's or distributor's registered location by common carrier or contract carrier delivery; or
 - b. Transferred by two employees to a reverse distributor or distributor by on-site pick-up at the DEA-registered collector's location for transport to the reverse distributor's or distributor's registered location or transport to a disposal location.
 2. A sealed inner liner and its contents shall be placed into secure storage by two employees at the DEA-registered collector's location, in accordance with

Section 23.15.2., until prompt delivery or transfer to a reverse distributor or distributor can occur. In no case shall a sealed inner liner be stored at the DEA-registered collector's location for more than 90-days.

23.11.2 Law Enforcement Agency Collectors

A. Law enforcement agency collectors shall dispose of household medications collected at their physical locations in the following manner:

1. Sealed inner liners and their contents removed from collection receptacles and opaque, waterproof, tamper-evident, and tear-resistant bags containing household medications collected at take-back events through means other than a collection receptacle shall be:
 - a. Sent by two, unless otherwise approved by the department, law enforcement agency employees, to a reverse distributor's registered location by common carrier or contract carrier delivery; or
 - b. Transferred by two, unless otherwise approved by the department, law enforcement agency employees to a reverse distributor by on-site pick-up at the law enforcement agency collector's location for transport to the reverse distributor's registered location or transport to a disposal location.
2. Sealed inner liners and their contents and opaque, waterproof, tamper evident and tear resistant bags and their contents shall be placed into secure storage at the law enforcement agency by two, unless otherwise approved by the department, law enforcement agency employees, in accordance with Section 23.15.3, until prompt delivery or transfer to a reverse distributor can occur. In no case shall sealed inner liners or opaque, waterproof, tamper-evident, and tear-resistant bags be stored at the law enforcement agency collector's location for more than 90-days.

B. Law enforcement agency collectors shall dispose of household medications collected at take-back events held at sites other than the agencies' physical locations in the following manner:

1. Sealed inner liners and their contents removed from collection receptacles and opaque, waterproof, tamper-evident, and tear-resistant bags containing household medications collected at take-back events through means other than a collection receptacle shall be:
 - a. Transferred by the law enforcement officer described in Section 23.10(B) to a reverse distributor by pick-up at the take-back event site for transport to the reverse distributor's registered location or transport to a disposal location; or
 - b. Transported by the law enforcement officer described in Section 23.10(B) to the law enforcement agency's physical location for disposal in accordance with Section 23.11.2(A).

23.12 Transporter Acquisition of Household Medications from Collectors

23.12.1 Authorized Acquisition by Reverse Distributors

- A. Reverse distributors participating in the Program as transporters are authorized to acquire household medications, including controlled substances collected from ultimate users, from DEA-registered collectors, law enforcement collectors, and law enforcement take-back event locations.

23.12.2 Authorized Acquisition by Distributors

- A. Distributors participating in the Program as transporters are authorized to acquire household medications, including controlled substances collected from ultimate users, from DEA-registered collectors.

23.12.3 Acquisition Methods

- A. Reverse distributors or distributors that acquire household medications in accordance with Sections 23.12.1(A) and 23.12.2(A) are authorized to utilize only the following methods:
1. On-site pick-up.
 - a. Household medications acquired by on-site pick-up shall be transported to the reverse distributor's or distributor's registered location or to a disposal location. Transportation shall be directly to the reverse distributor's or distributor's registered location or to a disposal location (the substances shall be constantly moving towards their destination and unnecessary or unrelated stops and stops of an extended duration shall not occur).
 - b. Upon transfer of household medications acquired by on-site pick-up to the reverse distributor's or distributor's registered location, household medications shall be immediately stored in a manner consistent with the security requirements for Schedule II controlled substances and in accordance with the security controls in Section 23.15.4(A) until timely destruction occurs.
 2. Delivery by common carrier or contract carrier.
 - a. Delivery to the reverse distributor or distributor by common carrier or contract carrier may only be made to the reverse distributor or distributor at the reverse distributor's or distributor's registered location. Once in route, such deliveries may not be re-routed to any other location or person, regardless of registration status.
 - b. All common carrier or contract carrier deliveries of household medications to a reverse distributor or distributor shall be personally

received by an employee of the reverse distributor or distributor at the registered location.

- c. Upon acquisition of household medications by common carrier or contract carrier delivery, the reverse distributor or distributor shall immediately store the household medications in a manner consistent with the security requirements for Schedule II controlled substances, in accordance with the physical security controls in Section 23.15.4(A) until timely destruction occurs.

23.12.4. Timely Destruction of Acquired Household Medications

- A. A reverse distributor or distributor shall destroy or cause the destruction of acquired household medications no later than 30 calendar days after acquisition.

23.13 Transporter Procedures for Destruction of Acquired Household Medications

23.13.1 Destruction at Transporter's Registered Location Acquiring Household Medications

- A. If a reverse distributor's or distributor's registered location acquiring household medications by on-site pick-up or delivery by common or contract carrier is a disposal location, the following procedures shall be used if household medications are destroyed on-site:
 - 1. Two employees of the reverse distributor or distributor shall handle or observe the handling of the household medications until destruction has occurred; and
 - 2. Two employees of the reverse distributor or distributor shall personally witness the destruction of the household medications until all are rendered non-retrievable.

23.13.2 Transport to a Registered Disposal Location for Destruction

- A. If a reverse distributor or distributor does not destroy acquired medications at their registered location as described in Section 23.13.1(A), another registered location with destruction capabilities may serve as the disposal location. Household medications shall be transported to the registered disposal location either from a transporter's registered location that acquired medications by on-site pick-up or delivery by common or contract carrier, or directly from a collector if acquired by on-site pick-up, using the following procedures:
 - 1. Transportation shall be directly to the registered disposal location (the household medications shall be constantly moving towards their final location and unnecessary or unrelated stops and stops of an extended duration shall not occur);
 - 2. Two employees of the transporting reverse distributor or distributor shall accompany the household medications to the registered disposal location; and

- 592 3. Two employees of the transporting reverse distributor or distributor shall load
593 and unload or observe the loading and unloading of the household medications
594 until transfer is complete.
595

596 23.13.3 Transport to a Non-Registered Disposal Location for Destruction 597

- 598 A. If a reverse distributor or distributor does not destroy acquired medications at their
599 registered location as described in Section 23.13.1(A), a non-registered disposal
600 location may be used for destruction. Household medications shall be transported to
601 the non-registered disposal location either from a transporter's registered location
602 that acquired medications through on-site pick-up or delivery by common or contract
603 carrier, or directly from a collector if acquired by on-site pick-up, using the following
604 procedures:
605

- 606 1. Transportation shall be directly to the non-registered disposal location (the
607 household medications shall be constantly moving towards their final disposal
608 location and unnecessary or unrelated stops and stops of an extended duration
609 shall not occur);
610
611 2. Two employees of the transporting reverse distributor or distributor shall
612 accompany the household medications to the non-registered disposal location;
613
614 3. Two employees of the transporting reverse distributor or distributor shall load
615 and unload or observe the loading and unloading of the household medications;
616
617 4. Two employees of the transporting reverse distributor or distributor shall
618 handle or observe the handling of any household medications until all are
619 rendered non-retrievable; and
620
621 5. Two employees of the transporting reverse distributor or distributor shall
622 personally witness the destruction of the household medications until all are
623 rendered non-retrievable.
624

625 23.14 Methods of Destruction 626

- 627 A. All household medications to be destroyed pursuant to Section 23.13 shall be
628 destroyed in compliance with applicable federal, state, tribal, and local laws and
629 regulations.
630
631 B. The method of destruction shall be sufficient to render household medications,
632 including all controlled substances that may be present, non-retrievable in order to
633 prevent diversion to illicit purposes and to protect the public health and safety.
634

635 23.15 Security Requirements 636

637 23.15.1 Employee Status 638

- 639 A. Participants in the Program shall not employ, as an agent or employee who has access
640 to or influence over household medications acquired by collection, any individual who
641 has been convicted of any felony offense relating to controlled substances; and in the

case of DEA-registered participants, any individual who, at any time, had an application for registration with DEA denied, had a DEA registration revoked or suspended, or has surrendered a DEA registration for cause. For purposes of this subsection, "for cause" means in lieu of, or as a consequence of, any federal or State administrative, civil, or criminal action resulting from an investigation of the individual's handling of controlled substances.

23.15.2 Physical Security Controls for DEA-Registered Collectors

- A. DEA-registered collectors shall store sealed inner liners containing household medications in a securely locked, substantially constructed cabinet or a securely locked room with controlled access.

23.15.3 Physical Security Controls for Law Enforcement Agency Collectors

- A. Law enforcement agency collectors shall store sealed inner liners and opaque, waterproof, tamper-evident, and tear-resistant bags containing household medications at the law enforcement agency in a securely locked storage area in a manner consistent with that agency's standard procedures for storing illicit controlled substances.

23.15.4 Physical Security Controls for Reverse Distributors and Distributors

- A. Sealed inner liners acquired by reverse distributors and distributors and opaque, waterproof, tamper-evident, and tear-resistant bags containing household medications acquired by reverse distributors shall be securely stored in accordance with Title 21 CFR Part 1301.72(a), as amended.

23.16 Registrant Records and Inventories

23.16.1 General Recordkeeping Requirements for Registrants

- A. Every registrant required to keep records pursuant to Title 21 CFR Part 1304, as amended, shall maintain, on a current basis, a complete and accurate record of each inner liner and sealed inner liner, except that no registrant shall be required to maintain a perpetual inventory.
- B. Registrants shall maintain separate records for each independent activity and collection activity for which they are registered or authorized.
- C. In recording dates of receipt, transfer, or destruction, the date on which the household medications are actually received, transferred, or destroyed shall be used as the date of receipt, transfer, or destruction (e.g., invoices, packing slips, manifests or DEA Form 41).
- D. In addition to any other recordkeeping requirements, any DEA-registrant that destroys a sealed inner liner or sealed bag containing household medications, or causes the destruction of sealed inner liner or sealed bag containing household medications, shall maintain a record of destruction on a DEA Form 41. The records shall be complete and accurate, and include the name and signature of the two employees who witnessed

the destruction.

- E. Registrants shall maintain the records required in Section 23.16.2 and inventories required in Section 23.16.3 in an easily retrievable format, on-site for three (3) years from the date the waste was acquired by a transporter.

23.16.2 Required Registrant Records

- A. Reverse distributors and distributors shall maintain the following records:

1. For sealed inner liners acquired from collectors by reverse distributors and distributors pursuant to Section 23.12.3:
 - a. The number of sealed inner liners acquired to inventory, including the dates of acquisition; the size (e.g., five 10-gallon liners, etc.) of all sealed inner liners acquired; the weight of each sealed inner liner acquired; the unique identification number of each sealed inner liner acquired; and the name, address, and, for DEA-registrant collectors, the registration number of the collector from whom the sealed inner liners were acquired; and
 - b. The number of sealed inner liners destroyed; the date, place, and method of destruction; the size (e.g., five 10-gallon liners, etc.) of all sealed inner liners destroyed; the unique identification number of each sealed inner liner destroyed; the name, address, and, for DEA-registrant collectors, the registration number of the collector from whom the sealed inner liners were acquired; and the name and signatures of the two employees of the reverse distributor or distributor that witnessed the destruction.
2. For opaque, waterproof, tamper-evident, and tear-resistant bags containing household medications acquired from law enforcement agency collectors by reverse distributors pursuant to Section 23.12.3:
 - a. The number of bags acquired to inventory, including the dates of acquisition; the size (e.g., five 10-gallon liners, etc.) of all bags acquired; the weight of each bag acquired; the unique identification number of each bag acquired; and the name and address of the law enforcement agency collector from whom the bags were acquired; and
 - b. The number of bags destroyed; the date, place, and method of destruction; the size (e.g., five 10-gallon liners, etc.) of all bags destroyed; the unique identification number of each bag destroyed; the name and address of the law enforcement agency collector from whom the bags were acquired; and the name and signatures of the two employees of the reverse distributor that witnessed the destruction.
3. For all records, the record of acquisition shall be maintained together with the corresponding record of destruction on a DEA Form 41.

742 B. DEA-registered collectors shall maintain the following records:

743
744 1. Collection receptacle inner liners:

- 745
746 a. Date each unused inner liner is acquired and its unique identification
747 number and size (e.g., 5-gallon, 10-gallon, etc.);
748
749 b. Date each inner liner is installed, the address of the location where
750 each inner liner is installed, the unique identification number and size
751 (e.g., 5-gallon, 10-gallon, etc.) of each installed inner liner, the
752 registration number of the collector, and the names and signatures of
753 the two employees that performed each installation as described in
754 Section 23.9(C)(1);
755
756 c. Date each inner liner is removed and sealed, the address of the location
757 from which each inner liner is removed, the unique identification
758 number and size (e.g., 5-gallon, 10-gallon, etc.) of each inner liner
759 removed, the registration number of the collector, and the names and
760 signatures of the two employees that performed each removal as
761 described in Section 23.9(C)(1);
762
763 d. Date each sealed inner liner is transferred to storage, the unique
764 identification number and size (e.g., 5-gallon, 10-gallon, etc.) of each
765 sealed inner liner stored, and the names and signatures of the two
766 employees that transferred each sealed inner liner to storage as
767 described in Section 23.11.1(A)(2); and
768
769 e. Date each sealed inner liner is transferred for destruction, the address
770 and registration number of the reverse distributor or distributor to
771 whom each sealed inner liner was transferred, the unique identification
772 number and the size (e.g., 5-gallon, 10-gallon, etc.) of each sealed
773 inner liner transferred, and the names and signatures of the two
774 employees that transferred each sealed inner liner to the reverse
775 distributor or distributor as described in Section 23.11.1(A)(1).
776

777 23.16.3 Required Registrant Inventories

778
779 A. Reverse distributors and distributors participating in the Program and required to keep
780 inventories of controlled substances pursuant to Title 21 CFR Part 1304, as amended,
781 shall include the following information in their inventories:

- 782
783 1. For household medications, including controlled substances collected from
784 ultimate users, acquired from DEA-registered collectors and law enforcement
785 agency collectors: The number and size (e.g., five 10-gallon liners, etc.) of
786 sealed inner liners on hand.
787

788 B. DEA-registered collectors participating in the Program and required to keep
789 inventories of controlled substances pursuant to Title 21 CFR Part 1304, as amended,
790 shall include the following information in their inventories:
791

1. The date of the inventory;
2. The number and size of sealed inner liners in storage (e.g., five 10-gallon liners, etc.); and
3. The unique identification number of each inner liner.

23.17 Law Enforcement Agency Collector Records

23.17.1 General Recordkeeping Requirements for Law Enforcement Agency Collectors

- A. Law enforcement agency collectors shall maintain the records required in Section 23.17.2 in an easily retrievable format, on-site for three (3) years from the date the waste was acquired by a transporter.

23.17.2 Required Law Enforcement Agency Collector Records

- A. Law enforcement agency collectors shall maintain the following records:

1. Collection receptacle inner liners:
 - a. Date each unused inner liner is obtained and its unique identification number and size (e.g., 5-gallon, 10-gallon, etc.);
 - b. Date each inner liner is installed, the address of the location where each inner liner is installed, the unique identification number and size (e.g., 5-gallon, 10-gallon, etc.) of each installed inner liner, and the names and signatures of the employees described in Section 23.9(C)(2) or the law enforcement officer described in Section 23.10(B) that performed each installation;
 - c. Date each inner liner is removed and sealed, the address of the location from which each inner liner is removed, the unique identification number and size (e.g., 5-gallon, 10-gallon, etc.) of each inner liner removed, and the names and signatures of the employees described in Section 23.9(C)(2) or the law enforcement officer described in Section 23.10(B) that performed each removal;
 - d. Date each sealed inner liner is transferred to storage, the unique identification number and size (e.g., 5-gallon, 10-gallon, etc.) of each sealed inner liner stored, and the names and signatures of the employees that transferred each sealed inner liner to storage as described in Section 23.11.2(A)(2); and
 - e. Date each sealed inner liner is transferred for destruction, the address and registration number of the reverse distributor to whom each sealed inner liner was transferred, the unique identification number and the size (e.g., 5-gallon, 10-gallon, etc.) of each sealed inner liner transferred, and the names and signatures of the employees that transferred each sealed inner liner to the reverse distributor as

described in Section 23.11.2(A)(1) or Section 23.11.2(B)(1).

2. Opaque, waterproof, tamper-evident, and tear-resistant bags with household medications collected at take-back events through means other than a collection receptacle:
 - a. Date each bag is sealed, the address of the location at which each bag is sealed, the unique identification number and size (e.g., 5-gallon, 10-gallon, etc.) of each bag sealed, and the name and signature of the law enforcement officer described in Section 23.10(B) that sealed each bag;
 - b. Date each sealed bag is transferred to storage, the unique identification number and size (e.g., 5-gallon, 10-gallon, etc.) of each sealed bag stored, and the name and signature of the law enforcement officer described in Section 23.10(B) that transferred each bag to storage; and
 - c. Date each sealed bag is transferred for destruction, the address and registration number of the reverse distributor to whom each sealed bag was transferred, the unique identification number and the size (e.g., 5-gallon, 10-gallon, etc.) of each sealed bag transferred, and the names and signatures of the employees or law enforcement officer that transferred each sealed bag to the reverse distributor as described in Section 23.11.2(A)(1) or Section 23.11.2(B)(1)(a).

23.18 Collectors Ceasing Collection Activities

- A. DEA-registered collectors ceasing participation in the Program and ceasing collection of household medications shall:
 1. Notify the department;
 2. Dispose of household medications on hand in accordance with Section 23.11.1; and
 3. Notify the DEA of their intent to cease collection of controlled substances from ultimate users in accordance with Title 21 CFR Part 1301.52(f), as amended.
- B. Law enforcement agency collectors ceasing participation in the Program and ceasing collection of household medications, including controlled substances collected from ultimate users shall:
 1. Notify the department; and
 2. Dispose of household medication on hand in accordance with Section 23.11.2.