



# COLORADO

## Solid & Hazardous Waste Commission

Department of Public Health & Environment

### NOTICE OF PROPOSED RULEMAKING HEARING BEFORE THE COLORADO SOLID AND HAZARDOUS WASTE COMMISSION

#### SUBJECT:

For consideration of the amendments to 6 CCR 1010-23, along with the accompanying Statement of Basis and Purpose, the following will be considered:

#### **Amendment of 6 CCR 1010-23 - Rules and Regulations Governing the Household Medication Take-Back Program**

These modifications are made pursuant to the authority granted to the Solid and Hazardous Waste Commission in Section 25-15-328(7), C.R.S.

The purpose of these amendments are to implement Senate Bill 19-227, through the establishment of qualifications, operational procedures, and recordkeeping requirements for program collectors, transporters, treatment facilities and disposal locations of household sharps (needles, syringes, and other devices used to inject medications). The Colorado General Assembly passed Senate Bill 19-227 in the 2019 legislative session. Additional amendments add clarity to the existing regulation.

Any information that is incorporated by reference in these proposed rules is available for review at the Colorado Department of Public Health and Environment, Division of Environmental Health and Sustainability.

Pursuant to C.R.S. §24-4-103(3), a notice of proposed rulemaking was submitted to the Secretary of State on January 9, 2020. Copies of the proposed rulemaking will be mailed to all persons on the Solid and Hazardous Waste Commission's mailing list on or before the date of publication of the notice of proposed rulemaking in the Colorado Register on January 25, 2020.

The proposed rulemaking materials may also be accessed at <https://www.colorado.gov/pacific/cdphe/shwc-rulemaking-hearings> or the Solid and Hazardous Waste Commission Office, Colorado Department of Public Health and Environment, 4300 Cherry Creek Drive South, 5<sup>th</sup> Floor, Building A, Denver, CO 80246-1530.

#### WRITTEN TESTIMONY

Any alternative proposals for rules or written comments relating to the proposed amendment of the regulation will be considered. The Solid and Hazardous Waste Commission will accept




written testimony and materials regarding the proposed alternatives. **The commission strongly encourages interested parties to submit written testimony or materials to the Solid and Hazardous Waste Commission Office, via email to [cdphe.hwcrequests@state.co.us](mailto:cdphe.hwcrequests@state.co.us) by Wednesday, February 5, 2020, at 11:59 p.m. Written materials submitted in advance will be distributed to the commission members prior to the day of the hearing.** Submittal of written testimony and materials on the day of the hearing will be accepted, but is strongly discouraged.

**HEARING SCHEDULE:**

DATE: Tuesday, February 18, 2020  
TIME: 9:00 a.m.  
PLACE: Colorado Department of Public Health and Environment  
4300 Cherry Creek Drive South  
Building A, Sabin Conference Room  
Denver, CO 80246

Oral testimony at the hearing regarding the proposed amendments may be limited.

  
\_\_\_\_\_  
Brandy Valdez Murphy, Administrator



1 DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

2 Division of Environmental Health and Sustainability

3 RULES AND REGULATIONS GOVERNING THE COLORADO HOUSEHOLD MEDICATION AND  
4 HOUSEHOLD SHARPS TAKE-BACK PROGRAM

5 6 CCR 1010-23

6 [Editor's Notes follow the text of the rules at the end of this CCR Document.]

7

8 23.1 Authority

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

13 23.2 Scope and Purpose

14 A. This regulation governs the Colorado Household Medication and Household Sharps Take-Back  
15 Program (program) established in Section 25-15-328, C.R.S. This ~~Regulation-regulation~~  
16 establishes:

17 1. Rules pertaining to department-approved program participants voluntarily engaging in the  
18 collection of household medications or household sharps;

19 2. Rules for department-approved collectors of ~~unused~~ household medications;

20 3. Rules for the acquisition and transportation of ~~unused~~ household medications from  
21 department-approved collectors to department-approved disposal locations~~by approved~~  
22 ~~transporters; and;~~

23 4. Rules for the destruction of ~~unused~~ household medications at approved disposal  
24 locations;

25 5. Rules for department-approved collectors of household sharps;

26 6. Rules for the acquisition of household sharps from department-approved collectors and  
27 individuals by department-approved transporters; and

28 7. Rules for the treatment and disposal of household sharps.

29 B. This regulation does not apply to:

30 1. The authority to collect and reuse medications pursuant to Section 12-42.5-133, C.R.S.;

32 2. Wastes generated by non-household waste generators subject to Section 13 of the  
33 *Regulations Pertaining to Solid Waste Sites and Facilities*, 6 CCR 1007-2;

34 3. Wastes generated by non-household waste generators subject to the *Hazardous Waste*  
35 *Regulations*, 6 CCR 1007-3;

- 36 4. The operation of other household medication and household sharps take-back and  
37 disposal programs regulated by the department;
- 38 5. ~~Generators~~ ~~Individuals disposing of unused~~ household medications and household  
39 sharps; or
- 40 6. Schedule I controlled substances as defined in U.S. Department of Justice, Drug  
41 Enforcement Administration, Title 21 Code of Federal Regulations (CFR) Part § 1308.11,  
42 Schedule of Controlled Substances, Schedule I; revised as of April 1, 2019, and hereby  
43 incorporated by reference as amended.
- 44 C. Persons who comply with this regulation may participate in the ~~Program~~program. Department-  
45 contracted ~~transporters~~ ~~participants~~ who incur costs associated with the collection, transportation,  
46 treatment, disposal, or destruction of household medications and household sharps pursuant to  
47 the ~~Program~~program may apply to the department for ~~money from the cash fund establish by the~~  
48 ~~General Assembly in Section 25-15-328(5) C.R.S. The department will adopt policies for the~~  
49 ~~distribution of this money reimbursement.~~

### 50 23.3 Applicability

- 51 A. The provisions of this section shall be applicable to the Colorado Household Medication and  
52 Household Sharps Take-Back Program as created by Section 25-15-328, C.R.S.
- 53 B. Participation in the Colorado Household Medication and Household Sharps Take-Back Program  
54 is voluntary.
- 55 C. Participants in the Colorado Household Medication and Household Sharps Take-Back Program  
56 include: ~~department~~-approved collectors, ~~approved~~ transporters, ~~approved~~ treatment facilities,  
57 and ~~approved~~ disposal locations.
- 58 D. These regulations shall not limit the powers and duties of local governments to issue such orders  
59 and adopt regulations as stringent or more stringent than the provisions contained herein.

### 60 23.4 Definitions

- 61 A. For the purpose of these rules and regulations:
- 62 1. Collection means to receive household medications from individuals for the purpose of  
63 destruction. If a household medication is a controlled substance, collection means to  
64 receive a controlled substance for the purpose of destruction from an ultimate user or an  
65 individual lawfully entitled to dispose of an ultimate user decedent's property; and means  
66 to receive household sharps from individuals for the purpose of treatment and disposal.
- 67 2. Collector means a DEA-registrant or law enforcement agency approved by the  
68 department for the collection of ~~unused~~ household medications; and an entity approved  
69 by the department for the collection of household sharps.
- 70 3. Colorado Household Medication and Household Sharps Take-Back Program or Program  
71 program means the program established in Section 25-15-328, C.R.S to facilitate the  
72 safe and effective collection, transportation, ~~and~~ destruction, and disposal of household  
73 medications; and to facilitate the safe and effective collection, transportation, treatment  
74 and disposal of household sharps.
- 75 4. Commission means the Solid and Hazardous Waste Commission created pursuant to  
76 Section 25-15-302, C.R.S.

- 77 5. Common Carrier means a for-hire carrier that holds itself out to serve the general public  
78 at reasonable rates and without discrimination.
- 79 6. Contract Carrier means a for-hire interstate operator which offers transportation services  
80 to certain shippers under contracts.
- 81 7. Controlled Substance means a drug or other substance, or immediate precursor,  
82 included in schedule II - V and listed in U.S. Department of Justice, Drug Enforcement  
83 Administration, 21 CFR ~~Parts-§§~~ 1308.12 through 1308.15, Schedules of Controlled  
84 Substances; revised as of April 1, 2019, and hereby incorporated by reference  
85 amended.
- 86 8. DEA means the Drug Enforcement Administration and its authorized agents and  
87 employees.
- 88 9. DEA Registrant or Registrant means any person who is registered pursuant to U.S.  
89 Department of Justice, Drug Enforcement Administration, 21 CFR ~~Part- §~~ 1301.11(a),  
90 Persons required to register; revised as of April 1, 2019, and hereby incorporated by  
91 referenceas amended.
- 92 10. Department means the Colorado Department of Public Health and Environment and its  
93 authorized agents and employees.
- 94 11. Disposal Location means a site approved by the department where ~~unused~~ household  
95 medications are destroyed in compliance with applicable laws and rendered non-  
96 retrievable and cannot be diverted for illicit purposes; and means a site approved by the  
97 department where treated household sharps are disposed in compliance with applicable  
98 laws.
- 99 12. Distribute means to deliver (other than by administering or dispensing) a controlled  
100 substance or to deliver (other than by administering or dispensing) a listed chemical  
101 designated in U.S. Department of Justice, Drug Enforcement Administration, 21 CFR ~~Part~~  
102 § 1310.02, Substances covered; revised as of April 1, 2019, and hereby incorporated by  
103 referenceas amended.
- 104 13. Distributor means a person who delivers (other than by administering or dispensing) a  
105 controlled substance or delivers (other than by administering or dispensing) a listed  
106 chemical designated in U.S. Department of Justice, Drug Enforcement Administration,  
107 Title-21 CFR ~~Part- §~~ 1310.02, Substances covered, revised as of April 1, 2019, and  
108 hereby incorporated by referenceas amended.
- 109 14. Employee means an individual directly paid by a program participant; subject to direct  
110 oversight by a program participant; required, as a condition of employment, to follow a  
111 program participant's procedures and guidelines pertaining to the handling of household  
112 medications, including controlled substances, or pertaining to the handling of household  
113 sharps; subject to receive a performance rating or performance evaluation on a  
114 regular/routine basis from a program participant; subject to disciplinary action by a  
115 program- participant; and required to render services at the site of a Programprogram  
116 participant's covered activities. At a law enforcement agency collector an employee may,  
117 at the agency's discretion, be a paid or unpaid reserve officer as defined pursuant to 16-  
118 2.5-110, C.R.S.
- 119 15. Household Medications means controlled substances approved for collection by federal  
120 law, prescription drugs, and over-the-counter medications in the possession of an  
121 individual, not generated by a commercial or industrial entity.

- 122        16.     Household Medication Take-Back Event means a scheduled, organized occasion of  
123        limited duration, managed by a law enforcement agency for the collection of household  
124        medications, including controlled substances collected from ultimate users and  
125        individuals lawfully entitled to dispose of an ultimate user decedent's property.
- 126        17.     Household Sharps means blood-sampling lancets, needles, and needle-containing  
127        devices used to inject medications including syringes, auto injectors, and injection  
128        cartridges in the possession of an individual, not generated by a commercial or industrial  
129        entity.
- 130        18.     Law Enforcement Agency means, but is not limited to, a municipal, tribal, university, or  
131        college police department; a county sheriff's office; a district attorney's office; a county  
132        coroner's office; a town marshal's office; the Colorado Department of Public Safety; and  
133        the Colorado Department of Corrections.
- 134        19.     Law Enforcement Officer means an individual who:
- 135                a.        Is an employee of either a law enforcement agency or law enforcement  
136                component of a federal agency;
- 137                b.        Is under the direction and control of a federal, state, tribal, or local government;
- 138                c.        Acts in the course of the law enforcement officer's official duty; and
- 139                d.        Is duly sworn and given the authority by a federal, state, tribal, or local  
140                government to carry firearms, execute and serve warrants, make arrests without  
141                warrant, and make seizures of property.
- 142        20.     Non-retrievable means, for the purpose of destruction, the condition or state to which  
143        household medications shall be rendered following a process that permanently alters the  
144        household medications' physical or chemical condition or state through irreversible  
145        means and thereby renders the household medications unavailable and unusable for all  
146        practical purposes, thus preventing their diversion to illicit purposes. The process to  
147        achieve a non-retrievable condition or state may be unique to a household medication's  
148        chemical or physical properties. A controlled substance is considered non-retrievable  
149        when permanently altered in such manner and it cannot be transformed to a physical or  
150        chemical condition or state as a controlled substance or controlled substance analogue.
- 151        21.     On-site means located on or at the physical premises of the registrant's registered  
152        location. A controlled substance is destroyed on-site when destruction occurs on the  
153        physical premises of the destroying registrant's registered location. A hospital/clinic has  
154        an on-site pharmacy when it has a pharmacy located on the physical premises of the  
155        registrant's registered location.
- 156        22.     Reverse Distribute means to acquire controlled substances from another registrant or law  
157        enforcement for the purpose of:
- 158                a.        Return to the registered manufacturer or another registrant authorized by  
159                manufacturer to accept returns on the manufacturer's behalf; or
- 160                b.        Destruction.
- 161        ~~22.~~     ~~Take-Back Event means a scheduled, organized occasion of limited duration, managed~~  
162        ~~by a law enforcement agency for the collection of household medications, including~~

163 ~~controlled substances collected from ultimate users and individuals lawfully entitled to~~  
164 ~~dispose of an ultimate user decedent's property.~~

165 23. Reverse Distributor means a person registered with the Drug Enforcement Administration  
166 to reverse distribute controlled substances.

167 24. Transporter means any entity approved by the department to acquire ~~unused~~ household  
168 medications from approved collectors ~~and for transport them to approved disposal~~  
169 ~~locations; and means any entity approved by the department to acquire household~~  
170 ~~sharps from approved collectors or individuals for treatment and disposal.~~

171 25. Treatment Facility means a department-approved location where household sharps are  
172 rendered non-infectious.

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

177 **23.5 Standards for Department-Approved Program Participants**

178 A. All Programprogram participants shall comply with requirements of federal, state, tribal, and local  
179 laws and regulations.

180 **Part I Household Medications**

181 **23.6 Specific Standards for Household Medication Department-Approved Collectors,**  
182 **Transporters, and Disposal Locations**

183 **23.6.1 Household Medication Collectors**

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

186 1. Be a law enforcement agency; or a DEA-registered location of a retail pharmacy or a  
187 hospital/clinic with an on-site pharmacy, whose registrations have been modified  
188 consistent with DEA requirements described in U.S. Department of Justice, Drug  
189 Enforcement Administration, Title 21 CFR Part § 1301.51, *Modification in registration;*  
190 revised as of April 1, 2019, and hereby incorporated by reference as amended, to  
191 authorize collection of controlled substances.

192 2. Have an application form approved by the department.

193 3. Designate an individual responsible for oversight of household medication collection  
194 activities.

195 4. Develop, implement, and maintain on site in an easily retrievable format a Medical Waste  
196 Management Plan containing, at a minimum, the following elements:

197 a. Procedures for household medication identification, collection, packaging,  
198 storage, transport and disposal;

199 b. A contingency plan for spills and releases;

200 c. Employee and volunteer training procedures;

201 d. Designation of an individual or individuals responsible for implementing the plan;  
202 and

203 e. Recordkeeping methods.

204 **23.6.2 Household Medication Transporters**

205 A. In order to acquire household medications from collectors as a department-approved participant  
206 in the program and transport them to disposal locations for destruction, or transfer them to  
207 another registrant for subsequent destruction~~as an approved participant in the Program~~, a  
208 transporter shall be:

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

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

215 **23.6.3 Household Medication Disposal Locations**

216 A. In order to ~~be approved to~~ destroy collected household medications ~~collected as a department-~~  
217 ~~approved participant~~ in the ~~Program~~program, a disposal location shall:

218 1. Utilize a method of destruction that renders household medications non-retrievable; and

219 2. Comply with applicable federal, state, tribal, and local laws and regulations.

220 **23.7 Allowable Household Medication Collection Methods**

221 **23.7.1 DEA-Registered Household Medication Collectors**

222 A. DEA-registered collectors participating in the ~~Program~~program may collect household  
223 medications, including controlled substances collected from ultimate users, utilizing the following  
224 collection method:

225 1. Collection receptacles and inner liners in accordance with Sections 23.8 and 23.9.

226 **23.7.2 Law Enforcement Agency Household Medication Collectors**

227 A. Law enforcement agency collectors participating in the ~~Program~~program may collect household  
228 medications in the course of official duties, including controlled substances collected from  
229 ultimate users, utilizing the following collection methods:

230 1. Collection receptacles and inner liners in accordance with Sections 23.8 and 23.9; and/or

231 2. Take-back events in accordance with Section 23.10.

232 **23.8 Household Medication Collection Receptacle Requirements**

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

235 B. For collection receptacles located inside a DEA-registered collector's location:



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

270 **23.9 Household Medication Collection Receptacle Inner Liner Requirements**

- 271 A. The inner liner used in a collection receptacle shall meet the following requirements:
- 272 1. The inner liner shall be opaque, waterproof, tamper-evident, and tear-resistant;
- 273 2. The inner liner shall be removable and sealable immediately upon removal without  
274 emptying or touching the contents;

- 275 3. The contents of the inner liner shall not be viewable from the outside when sealed;
- 276 4. The size of the inner liner shall be clearly marked on the outside of the liner (e.g., 5-  
277 gallon, 10-gallon, etc.); and
- 278 5. The inner liner shall bear a permanent, unique identification number that enables the  
279 inner liner to be tracked in accordance with Section 23.16.2(A) and (B).
- 280 B. Access to the inner liner shall be restricted to employees of a DEA-registered collector or  
281 employees of a law enforcement agency collector.
- 282 C. Installation and removal of the inner liner shall be performed by:
- 283 1. Two employees of a DEA-registered collector; or
- 284 2. Unless otherwise approved by the department, two employees of a law enforcement  
285 agency collector.
- 286 D. The inner liner shall be sealed immediately upon removal from the permanent outer container of  
287 the collection receptacle and the sealed inner liner shall not be opened, x-rayed, analyzed, or  
288 otherwise penetrated. The inner liner shall be sealed by:
- 289 1. Two employees of a DEA-registered collector; or
- 290 2. Unless otherwise approved by the department, two employees of a law enforcement  
291 agency collector.
- 292 **23.10 Household Medication Take-Back Events**
- 293 A. A law enforcement agency may conduct a take-back event and collect household medications,  
294 including controlled substances collected from ultimate users and individuals lawfully entitled to  
295 dispose of an ultimate user decedent's property. A law enforcement agency may partner with  
296 other persons or entities to hold a collection take-back event in accordance with this Section.
- 297 B. A law enforcement agency shall appoint at a minimum one law enforcement officer employed by  
298 the agency to oversee the collection. Law enforcement officers employed by the law enforcement  
299 agency conducting a take-back event shall maintain control and custody of the household  
300 medications from the time they are collected until secure transfer, storage, or destruction has  
301 occurred.
- 302 C. A law enforcement agency may conduct a take-back event at its physical location or at another  
303 location, provided the law enforcement officer(s) overseeing the collection are able to maintain  
304 custody and control of the household medications in accordance with this Section.
- 305 D. A collection receptacle, as described in Section 23.8 and Section 23.9, may be used at a take-  
306 back event for the collection of household medications.
- 307 E. If a collection receptacle is not used at a take-back event, collected household medications shall  
308 be placed in an opaque, waterproof, tamper-evident, and tear-resistant bag bearing the markings  
309 required for inner liners as described in Sections 23.9(A)(4) and (5).
- 310 F. Only those controlled substances listed in Schedule II, III, IV, or V that are lawfully possessed by  
311 an ultimate user or individual entitled to dispose of an ultimate user decedent's property may be  
312 collected. Controlled and non-controlled substances may be collected together and be comingled.

- 313 G. Only ultimate users and individuals entitled to dispose of an ultimate user decedent's property in  
314 lawful possession of a controlled substance in Schedule II, III, IV, or V may transfer such  
315 substances to the law enforcement officer described in Section 23.10(B) during the take-back  
316 event. No other individual may handle the controlled substances at any time.

317 **23.11 Disposal of Collected Household Medications**

318 **23.11.1 DEA-Registered Household Medication Collectors**

- 319 A. DEA-registered collectors shall dispose of collected household medications in the following  
320 manner:

- 321 1. Upon inner liner removal from the permanent outer container of a collection receptacle,  
322 the sealed inner liner and its contents shall be:
- 323 a. Sent by two employees to a ~~reverse distributor's or distributor's~~transporter's  
324 registered location by common carrier or contract carrier delivery; or
- 325 b. Transferred by two employees to a ~~reverse distributor or distributor~~transporter by  
326 on-site pick-up at the DEA-registered collector's location for transport to the  
327 ~~reverse distributor's or distributor's~~transporter's registered location or transport to  
328 a disposal location.
- 329 2. A sealed inner liner and its contents shall be placed into secure storage by two  
330 employees at the DEA-registered collector's location, in accordance with Section  
331 23.15.2., until prompt delivery or transfer to a ~~reverse distributor or distributor~~transporter  
332 can occur. In no case shall a sealed inner liner be stored at the DEA-registered  
333 collector's location for more than 90-days.

334 **23.11.2 Law Enforcement Agency Household Medication Collectors**

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

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

- 355 B. Law enforcement agency collectors shall dispose of household medications collected at take-  
356 back events held at sites other than the agencies' physical locations in the following manner:
- 357 1. Sealed inner liners and their contents removed from collection receptacles and opaque,  
358 waterproof, tamper-evident, and tear-resistant bags containing household medications  
359 collected at take-back events through means other than a collection receptacle shall be:
- 360 a. Transferred by the law enforcement officer described in Section 23.10(B) to a  
361 ~~reverse distributor~~ transporter by pick-up at the take-back event site for transport  
362 to the ~~reverse distributor's~~ transporter's registered location or transport to a  
363 disposal location; or
- 364 b. Transported by the law enforcement officer described in Section 23.10(B) to the  
365 law enforcement agency's physical location for disposal in accordance with  
366 Section 23.11.2(A).

367 **23.12 Transporter Acquisition of Household Medications from Collectors**

368 **23.12.1 Authorized Household Medication Acquisition by Reverse Distributors**

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

373 **23.12.2 Authorized Household Medication Acquisition by Distributors**

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

377 **23.12.3 Household Medication Acquisition Methods**

- 378 A. ~~Reverse distributors or distributors~~ Transporters that acquire household medications in  
379 accordance with Sections 23.12.1(A) and 23.12.2(A) are authorized to utilize only the following  
380 methods:
- 381 1. On-site pick-up.
- 382 a. Household medications acquired by on-site pick-up shall be transported to the  
383 ~~reverse distributor's or distributor's~~ transporter's registered location, ~~or~~ to a  
384 disposal location, or to another registrant for subsequent destruction.  
385 Transportation shall be directly to the ~~reverse distributor's or~~  
386 ~~distributor's~~ transporter's registered location, ~~or~~ to a disposal location, or to  
387 another registrant for subsequent destruction (the substances shall be constantly  
388 moving towards their destination and unnecessary or unrelated stops and stops  
389 of an extended duration shall not occur).
- 390 b. Upon transfer of household medications acquired by on-site pick-up to the  
391 ~~reverse distributor's or distributor's~~ transporter's registered location, household  
392 medications shall be immediately stored in a manner consistent with the security  
393 requirements for Schedule II controlled substances and in accordance with the  
394 security controls in Section 23.15.4(A) until timely destruction occurs.
- 395 2. Delivery by common carrier or contract carrier.

- 396 a. Delivery to the ~~reverse distributor or distributor~~transporter by common carrier or  
397 contract carrier may only be made to the ~~reverse distributor or~~  
398 ~~distributor~~transporter at the ~~reverse distributor's or distributor's~~transporter's  
399 registered location. Once in route, such deliveries may not be re-routed to any  
400 other location or person, regardless of registration status.
- 401 b. All common carrier or contract carrier deliveries of household medications to a  
402 ~~reverse distributor or distributor~~transporter shall be personally received by an  
403 employee of the ~~reverse distributor or distributor~~transporter at the registered  
404 location.
- 405 c. Upon acquisition of household medications by common carrier or contract carrier  
406 delivery, the ~~reverse distributor or distributor~~transporter shall immediately store  
407 the household medications in a manner consistent with the security requirements  
408 for Schedule II controlled substances, in accordance with the physical security  
409 controls in Section 23.15.4(A) until timely destruction occurs.

410 **23.12.4 Timely Destruction of Acquired Household Medications**

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

413 **23.13 Transporter Procedures for Destruction of Acquired Household Medications**

414 **23.13.1 Destruction at Transporter's Registered Location Acquiring Household Medications**

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

422 **23.13.2 Household Medication Transport to a Registered Disposal Location for Destruction**

- 423 A. If a ~~reverse distributor or distributor~~transporter does not destroy acquired medications at their  
424 registered location as described in Section 23.13.1(A), another registered location with  
425 destruction capabilities may serve as the disposal location. Household medications shall be  
426 transported to the registered disposal location either from a transporter's registered location that  
427 acquired medications by on-site pick-up or delivery by common or contract carrier, or directly from  
428 a collector if acquired by on-site pick-up, using the following procedures:
- 429 1. Transportation shall be directly to the registered disposal location (the household  
430 medications shall be constantly moving towards their final location and unnecessary or  
431 unrelated stops and stops of an extended duration shall not occur);
  - 432 2. Two employees of the ~~transporting reverse distributor or distributor~~transporter shall  
433 accompany the household medications to the registered disposal location; and
  - 434 3. Two employees of the ~~transporting reverse distributor or distributor~~transporter shall load  
435 and unload or observe the loading and unloading of the household medications until  
436 transfer is complete.

437 **23.13.3 Household Medication Transport to a Non-Registered Disposal Location for Destruction**

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

- 444 1. Transportation shall be directly to the non-registered disposal location (the household  
445 medications shall be constantly moving towards their final disposal location and  
446 unnecessary or unrelated stops and stops of an extended duration shall not occur);
- 447 2. Two employees of the ~~transporting reverse distributor or distributor transporter~~ shall  
448 accompany the household medications to the non-registered disposal location;
- 449 3. Two employees of the ~~transporting reverse distributor or distributor transporter~~ shall load  
450 and unload or observe the loading and unloading of the household medications;
- 451 4. Two employees of the ~~transporting reverse distributor or distributor transporter~~ shall  
452 handle or observe the handling of any household medications until all are rendered non-  
453 retrievable; and
- 454 5. Two employees of the ~~transporting reverse distributor or distributor transporter~~ shall  
455 personally witness the destruction of the household medications until all are rendered  
456 non-retrievable.

457 **23.13.4 Household Medication Transport to Another Registered Location for Subsequent**  
458 **Destruction**

459 A. If a transporter does not destroy acquired medications at their registered location as described in  
460 Section 23.13.1(A), the medications may be transferred to another registered location that is not a  
461 disposal location, for subsequent destruction at a registered or non-registered disposal location.  
462 Household medications shall be transported to the registered location either from a transporter's  
463 registered location that acquired medications by on-site pick-up or delivery by common or  
464 contract carrier, or directly from a collector if acquired by on-site pick-up, using the following  
465 procedures:

- 466 1. Transportation shall be directly to the registered location (the household medications  
467 shall be constantly moving towards their final location and unnecessary or unrelated  
468 stops and stops of an extended duration shall not occur);
- 469 2. Two employees of the transporter shall accompany the household medications to the  
470 registered location; and
- 471 3. Two employees of the transporter shall load and unload or observe the loading and  
472 unloading of the household medications until transfer is complete.

473 **23.14 Methods of Household Medication Destruction**

474 A. All household medications to be destroyed pursuant to Section 23.13 shall be destroyed in  
475 compliance with applicable federal, state, tribal, and local laws and regulations.

- 476 B. The method of destruction shall be sufficient to render household medications, including all  
477 controlled substances that may be present, non-retrievable in order to prevent diversion to illicit  
478 purposes and to protect the public health and safety.

479 **23.15 Security Requirements**

480 **23.15.1 Employee Status**

- 481 A. Participants in the ~~Program-program~~ shall not employ, as an agent or employee who has access  
482 to or influence over household medications acquired by collection, any individual who has been  
483 convicted of any felony offense relating to controlled substances; and in the case of DEA-  
484 registered participants, any individual who, at any time, had an application for registration with  
485 DEA denied, had a DEA registration revoked or suspended, or has surrendered a DEA  
486 registration for cause. For purposes of this subsection, "for cause" means in lieu of, or as a  
487 consequence of, any federal or State administrative, civil, or criminal action resulting from an  
488 investigation of the individual's handling of controlled substances.

489 **23.15.2 Physical Security Controls for DEA-Registered Household Medication Collectors**

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

493 **23.15.3 Physical Security Controls for Law Enforcement Agency Household Medication Collectors**

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

498 **23.15.4 Physical Security Controls for ~~Reverse Distributors and Distributors-Transporters.~~**

- 499 A. Sealed inner liners ~~acquired by reverse distributors and distributors~~ and opaque, waterproof,  
500 tamper-evident, and tear-resistant bags containing household medications acquired by ~~reverse~~  
501 ~~distributor~~~~transporters~~ shall be securely stored in accordance with U.S. Department of Justice,  
502 Drug Enforcement Administration, Title 21 CFR-Part § 1301.72(a), *Physical security controls for*  
503 *non-practitioners; (a) Schedules I and II, revised as of April 1, 2019, and hereby incorporated by*  
504 *referenceas amended.*

505 **23.16 Registrant Household Medication Records and Inventories**

506 **23.16.1 ~~General~~ Household Medication Recordkeeping Requirements for Registrants**

- 507 A. Every registrant required to keep records pursuant to U.S. Department of Justice, Drug  
508 Enforcement Administration, Title 21 CFR-Part § 1304, *Records and Reports of Registrants,*  
509 *revised as of April 1, 2019, and hereby incorporated by referenceas amended,* shall maintain, on  
510 a current basis, a complete and accurate record of each inner liner and sealed inner liner, except  
511 that no registrant shall be required to maintain a perpetual inventory.
- 512 B. Registrants shall maintain separate records for each independent activity and collection activity  
513 for which they are registered or authorized.
- 514 C. In recording dates of receipt, transfer, or destruction, the date on which the household  
515 medications are actually received, transferred, or destroyed shall be used as the date of receipt,  
516 transfer, or destruction (e.g., invoices, packing slips, manifests or DEA Form 41).

517 D. In addition to any other recordkeeping requirements, any DEA-registrant that destroys a sealed  
518 inner liner or sealed bag containing household medications, or causes the destruction of sealed  
519 inner liner or sealed bag containing household medications, shall maintain a record of destruction  
520 on a DEA Form 41. The records shall be complete and accurate, and include the name and  
521 signature of the two employees who witnessed the destruction.

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

525 **23.16.2 Required Registrant Household Medication Records**

526 A. ~~Reverse distributors and distributors acquiring household medications~~Transporters shall maintain  
527 the following records:

528 1. For sealed inner liners acquired from collectors by ~~reverse distributors and~~  
529 ~~distributor~~transporters pursuant to Section 23.12.3:

530 a. The number of sealed inner liners acquired to inventory, including the dates of  
531 acquisition; the size (e.g., five 10-gallon liners, etc.) of all sealed inner liners  
532 acquired; the weight of each sealed inner liner acquired; the unique identification  
533 number of each sealed inner liner acquired; and the name, address, and, for  
534 DEA-registrant collectors, the registration number of the collector from whom the  
535 sealed inner liners were acquired; and

536 b. The number of sealed inner liners destroyed; the date, place, and method of  
537 destruction; the size (e.g., five 10-gallon liners, etc.) of all sealed inner liners  
538 destroyed; the unique identification number of each sealed inner liner destroyed;  
539 the name, address, and, for DEA-registrant collectors, the registration number of  
540 the collector from whom the sealed inner liners were acquired; and the name  
541 and signatures of the two employees of the ~~reverse distributor or~~  
542 ~~distributor~~transporter that witnessed the destruction.

543 2. For opaque, waterproof, tamper-evident, and tear-resistant bags containing household  
544 medications acquired from law enforcement agency collectors by ~~reverse~~  
545 ~~distributor~~transporters pursuant to Section 23.12.3:

546 a. The number of bags acquired to inventory, including the dates of acquisition; the  
547 size (e.g., five 10-gallon liners, etc.) of all bags acquired; the weight of each bag  
548 acquired; the unique identification number of each bag acquired; and the name  
549 and address of the law enforcement agency collector from whom the bags were  
550 acquired; and

551 b. The number of bags destroyed; the date, place, and method of destruction; the  
552 size (e.g., five 10-gallon liners, etc.) of all bags destroyed; the unique  
553 identification number of each bag destroyed; the name and address of the law  
554 enforcement agency collector from whom the bags were acquired; and the name  
555 and signatures of the two employees of the ~~reverse distributor~~transporter that  
556 witnessed the destruction.

557 3. For all records, the record of acquisition shall be maintained together with the  
558 corresponding record of destruction on a DEA Form 41.

559 B. DEA-registered household medication collectors shall maintain the following records:



- 560 1. Collection receptacle inner liners:
- 561 a. Date each unused inner liner is acquired and its unique identification number and  
562 size (e.g., 5-gallon, 10-gallon, etc.);
- 563 b. Date each inner liner is installed, the address of the location where each inner  
564 liner is installed, the unique identification number and size (e.g., 5-gallon, 10-  
565 gallon, etc.) of each installed inner liner, the registration number of the collector,  
566 and the names and signatures of the two employees that performed each  
567 installation as described in Section 23.9(C)(1);
- 568 c. Date each inner liner is removed and sealed, the address of the location from  
569 which each inner liner is removed, the unique identification number and size  
570 (e.g., 5-gallon, 10-gallon, etc.) of each inner liner removed, the registration  
571 number of the collector, and the names and signatures of the two employees that  
572 performed each removal as described in Section 23.9(C)(1);
- 573 d. Date each sealed inner liner is transferred to storage, the unique identification  
574 number and size (e.g., 5-gallon, 10-gallon, etc.) of each sealed inner liner stored,  
575 and the names and signatures of the two employees that transferred each sealed  
576 inner liner to storage as described in Section 23.11.1(A)(2); and
- 577 e. Date each sealed inner liner is transferred for destruction, the address and  
578 registration number of the ~~reverse distributor or distributor~~transporter to whom  
579 each sealed inner liner was transferred, the unique identification number and the  
580 size (e.g., 5-gallon, 10-gallon, etc.) of each sealed inner liner transferred, and the  
581 names and signatures of the two employees that transferred each sealed inner  
582 liner to the ~~reverse distributor or distributor~~transporter as described in Section  
583 23.11.1(A)(1).

584 **23.16.3 Required Registrant Controlled Substance Inventories**

- 585 A. ~~Reverse distributors and distributors~~Transporters participating in the ~~Program program~~ and  
586 required to keep inventories of controlled substances pursuant to U.S. Department of Justice,  
587 Drug Enforcement Administration, Title 21 CFR-Part § 1304, *Records and Reports of Registrants;*  
588 revised as of April 1, 2019, and hereby incorporated by reference as amended, shall include the  
589 following information in their inventories:
- 590 1. For household medications, including controlled substances collected from ultimate  
591 users, acquired from DEA-registered collectors and law enforcement agency collectors:  
592 The number and size (e.g., five 10-gallon liners, etc.) of sealed inner liners on hand.
- 593 B. DEA-registered collectors participating in the ~~Program program~~ and required to keep inventories  
594 of controlled substances pursuant to U.S. Department of Justice, Drug Enforcement  
595 Administration, -21 CFR-Part § 1304, *Records and Reports of Registrants; revised as of April 1,*  
596 2019, and hereby incorporated by reference as amended, shall include the following information in  
597 their inventories:
- 598 1. The date of the inventory;
- 599 2. The number and size of sealed inner liners in storage (e.g., five 10-gallon liners, etc.);  
600 and
- 601 3. The unique identification number of each inner liner.

602 **23.17 Law Enforcement Agency Collector Household Medication Records**

603 **23.17.1 General Household Medication Recordkeeping Requirements for Law Enforcement**  
604 **Agency Collectors**

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

608 **23.17.2 Required Law Enforcement Agency Collector Household Medication Records**

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

610 1. Collection receptacle inner liners:

611 a. Date each unused inner liner is obtained and its unique identification number and  
612 size (e.g., 5-gallon, 10-gallon, etc.);

613 b. Date each inner liner is installed, the address of the location where each inner  
614 liner is installed, the unique identification number and size (e.g., 5-gallon, 10-  
615 gallon, etc.) of each installed inner liner, and the names and signatures of the  
616 employees described in Section 23.9(C)(2) or the law enforcement officer  
617 described in Section 23.10(B) that performed each installation;

618 c. Date each inner liner is removed and sealed, the address of the location from  
619 which each inner liner is removed, the unique identification number and size  
620 (e.g., 5-gallon, 10-gallon, etc.) of each inner liner removed, and the names and  
621 signatures of the employees described in Section 23.9(C)(2) or the law  
622 enforcement officer described in Section 23.10(B) that performed each removal;

623 d. Date each sealed inner liner is transferred to storage, the unique identification  
624 number and size (e.g., 5-gallon, 10-gallon, etc.) of each sealed inner liner stored,  
625 and the names and signatures of the employees that transferred each sealed  
626 inner liner to storage as described in Section 23.11.2(A)(2); and

627 e. Date each sealed inner liner is transferred for destruction, the address and  
628 registration number of the ~~reverse distributor~~ transporter to whom each sealed  
629 inner liner was transferred, the unique identification number and the size (e.g., 5-  
630 gallon, 10-gallon, etc.) of each sealed inner liner transferred, and the names and  
631 signatures of the employees that transferred each sealed inner liner to the  
632 ~~reverse distributor~~ transporter as described in Section 23.11.2(A)(1) or Section  
633 23.11.2(B)(1).

634 2. Opaque, waterproof, tamper-evident, and tear-resistant bags with household medications  
635 collected at take-back events through means other than a collection receptacle:

636 a. Date each bag is sealed, the address of the location at which each bag is sealed,  
637 the unique identification number and size (e.g., 5-gallon, 10-gallon, etc.) of each  
638 bag sealed, and the name and signature of the law enforcement officer described  
639 in Section 23.10(B) that sealed each bag;

640 b. Date each sealed bag is transferred to storage, the unique identification number  
641 and size (e.g., 5-gallon, 10-gallon, etc.) of each sealed bag stored, and the name  
642 and signature of the law enforcement officer described in Section 23.10(B) that  
643 transferred each bag to storage; and

644 c. Date each sealed bag is transferred for destruction, the address and registration  
645 number of the ~~reverse distributor~~transporter to whom each sealed bag was  
646 transferred, the unique identification number and the size (e.g., 5-gallon, 10-  
647 gallon, etc.) of each sealed bag transferred, and the names and signatures of the  
648 employees or law enforcement officer that transferred each sealed bag to the  
649 ~~reverse distributor~~transporter as described in Section 23.11.2(A)(1) or Section  
650 23.11.2(B)(1)(a).

651 3. If approved by the department, a law enforcement agency may utilize a method of inner  
652 liner documentation other than those described in Section 23.17.2(A)(1) and Section  
653 23.17.2(A)(2). The alternative method must be consistent with the agency's  
654 recordkeeping requirements for illicit controlled substances evidence.

## 655 **23.18 Household Medication Collectors Ceasing Collection Activities**

656 A. DEA-registered collectors ceasing participation in the ~~Program-program~~ and ceasing collection of  
657 household medications shall:

- 658 1. Notify the department;
- 659 2. Dispose of household medications on hand in accordance with Section 23.11.1; and
- 660 3. Notify the DEA of their intent to cease collection of controlled substances from ultimate  
661 users in accordance with U.S. Department of Justice, Drug Enforcement Administration,  
662 Title-21 CFR ~~Part- §~~ 1301.52(f), *Termination of registration; revised as of April 1, 2019,*  
663 and hereby incorporated by reference as amended.

664 B. Law enforcement agency collectors ceasing participation in the ~~Program-program~~ and ceasing  
665 collection of household medications, including controlled substances collected from ultimate  
666 users shall:

- 667 1. Notify the department; and
- 668 2. Dispose of household medication on hand in accordance with Section 23.11.2.

## 669 Part II. Household Sharps

### 670 23.19 Specific Standards for Department-Approved Household Sharps Collectors, Transporters, 671 and Disposal Locations

#### 672 23.19.1 Household Sharps Collectors

673 A. Application to Become a Department-Approved Collector: In order to collect household sharps as  
674 a department-approved participant in the program, a collector shall:

- 675 1. Submit a department-approved application form.
- 676 2. Designate an individual responsible for oversight of household sharps collection  
677 activities.
- 678 3. Install a department-provided collection receptacle at the collector's physical location in  
679 an area regularly monitored by employees.
- 680 4. Provide training to employees in accordance with U.S. Department of Labor,  
681 Occupational Safety and Health Administration's (OSHA) *Bloodborne Pathogens*

682 standard, 29 CFR § 1910.1030(g)(2), effective June 4, 1992, hereby incorporated by  
683 reference.

684 5. Develop, implement, and maintain on site, in an easily retrievable format, a Medical  
685 Waste Management Plan containing, at a minimum, the following elements:

686 a. Procedures for household sharps identification, collection, packaging, storage,  
687 transport and disposal designed to prevent adverse events to the public and  
688 collector, transporter, treatment facility and disposal location employees;

689 b. A contingency plan for spills and releases;

690 c. Employee training procedures;

691 d. Designation of an individual or individuals responsible for implementing the plan;  
692 and

693 e. Recordkeeping methods.

694 B. Collector Recordkeeping Responsibilities

695 1. Household sharps collectors shall maintain a record of employee training provided in  
696 accordance with Section 23.19.1(A)(4) in an easily retrievable format, on-site, for three  
697 years from the date of training.

698 2. Household sharps collectors shall maintain copies of transporter-provided waste  
699 manifests, tracking documents, or chain of custody forms in an easily retrievable format,  
700 on-site for three years from the date of receipt.

701 C. Household Sharps Collectors Ceasing Collection Activities

702 1. Household sharps collectors ceasing participation in the program and ceasing collection  
703 of household sharps shall:

704 a. Notify the department; and

705 b. Transfer household sharps on hand to a department-approved transporter in  
706 accordance with Section 23.19.2(B)(1).

707 **23.19.2 Household Sharps Transporters**

708 A. Application to Become a Department-Approved Transporter: In order to acquire household  
709 sharps from collectors or from individuals as a department-approved participant in the program, a  
710 transporter shall:

711 1. Execute a contract or other written, signed service agreement with the department;

712 2. Provide training to its employees in accordance with *Regulations Pertaining to Solid*  
713 *Waste Sites and Facilities*, 6 CCR 1007-2, Part 1, Part B, Section 13.7.2(C)(9), that  
714 includes, but is not limited to: medical waste identification, bloodborne pathogens, waste  
715 containment and labeling; storage requirements; equipment operations including  
716 equipment startup, shutdown, maintenance, and associated procedures to assure safe  
717 operation; and roles and responsibilities when implementing a facility contingency plan;

- 718 3. Utilize a department-approved treatment facility that renders acquired household sharps  
719 non-infectious in accordance with Section 23.19.2(C); and
- 720 4. Dispose of treated household sharps in accordance with Section 23.19.2(D).
- 721 B. Transporter Procedures for the Acquisition of Household Sharps
- 722 1. Transporters that acquire household sharps from department-approved collectors are  
723 authorized to utilize only the following methods: on-site pick-up or delivery by common  
724 carrier or contract carrier.
- 725 2. Transporters that acquire household sharps from individuals are authorized to utilize only  
726 delivery by common carrier or contract carrier.
- 727 C. Transporter Procedures for the Treatment of Household Sharps
- 728 1. All household sharps shall be treated at a department-approved treatment facility in  
729 compliance with applicable federal, state, tribal, and local laws and regulations.
- 730 2. The method of treatment shall render sharps non-infectious in accordance with  
731 Regulations Pertaining to Solid Waste Sites and Facilities, 6 CCR 1007-2, Part 1, Part B,  
732 Section 13.6.1(A), or as otherwise approved by the department.
- 733 D. Transporter Procedures for the Disposal of Household Sharps
- 734 1. All household sharps shall be disposed in compliance with applicable federal, state, tribal,  
735 and local laws and regulations.
- 736 2. All household sharps shall have undergone treatment in accordance with Section  
737 23.19.2(C)(2) prior to disposal.
- 738 E. Transporter Recordkeeping Responsibilities
- 739 1. Household sharps transporters shall maintain the following records in an easily  
740 retrievable format, on-site, for three years:
- 741 a. Weight of sharps acquired from household sharps collectors and individuals.
- 742 b. The location and treatment method utilized.
- 743 c. The location and method of disposal.
- 744 d. Copies of transportation waste manifests, tracking document, or chain-of-custody  
745 forms.
- 746 **23.19.3 Household Sharps Disposal Locations**
- 747 A. Application to Become a Department-Approved Disposal Location: In order to dispose collected  
748 household sharps as a department-approved participant in the program, a disposal location shall:
- 749 1. Dispose of household sharps that have been treated in accordance with Section  
750 23.19.2(C)(2); and
- 751 2. Comply with applicable federal, state, tribal, and local laws and regulations.

752 **23.20 Incorporation by Reference**

753  
754 A. Throughout this regulation, standards and requirements of federal agencies have been adopted  
755 and incorporated by reference. The material incorporated by reference cited herein includes only  
756 those versions that were in effect as of the most recent effective date of this rule, and not later  
757 amendments to the incorporated materials. This rule incorporates by reference the following:

- 758  
759 1. United States Department of Labor, Occupational Safety and Health Administration's  
760 (OSHA) *Bloodborne Pathogen Standard*, 29 CFR § 1910.1030(g)(2), effective June 4,  
761 1992 [1910.1030(i)(1)].  
762  
763 2. United States Department of Justice, Drug Enforcement Administration, 21 CFR §§  
764 1301.11, 1301.51, 1301.52(f), 1301.72(a), 1304, 1308.11, 1308.12 through 1308.15, and  
765 1310.02, revised as of April 1, 2019.

766  
767 B. Copies of the incorporated material can be obtained at reasonable cost and the incorporated  
768 material is available for public inspection during regular business hours at:

769  
770 Division of Environmental Health and Sustainability  
771 Colorado Department of Public Health and Environment  
772 4300 Cherry Creek Drive South  
773 Denver, Colorado 80246-1530

774  
775 C. The incorporated materials are available at:

776  
777 U.S. Department of Labor  
778 Occupational Safety and Health Administration  
779 200 Constitution Avenue, N.W.  
780 Washington, D.C. 20210

781  
782 U.S. Drug Enforcement Administration  
783 800 K Street, N.W., Suite 500  
784 Washington, DC 20001

785 **Editor's Notes**

786  
787 **History**

788 Entire rule eff.

1 DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

2  
3  
4 Solid and Hazardous Waste Commission

5  
6 Division of Environmental Health and Sustainability

7  
8 6 CCR 1010-23

9  
10 STATEMENT OF BASIS AND PURPOSE  
11 AND SPECIFIC STATUTORY AUTHORITY FOR

12  
13 Amendments to rules and regulations governing the Colorado Household Medication Take-Back Program (6  
14 CCR 1010-23).

15  
16 **Basis and Purpose**

17  
18 I. Statutory Authority

19  
20 This regulation is adopted pursuant to the authority granted to the Solid and Hazardous Waste  
21 Commission in Section 25-15-328(7), C.R.S. The regulation was initially adopted in May 2016, as a  
22 result of General Assembly passage of House Bill 14-1207. Amendments adopted in February 2020  
23 are the result of General Assembly passage of Senate Bill 19-227 in 2019.

24  
25 II. House Bill 14-1207

26  
27 In House Bill 14-1207, the General Assembly declared (1) that prescription drug abuse is a rampant  
28 problem in Colorado, in part due to the accidental and intentional abuse of leftover household  
29 medications, and (2) that citizen access to a disposal location to return unused household medications  
30 will reduce the availability of household medications for unintended or abusive purposes and will further  
31 protect the environment through proper disposal. House Bill 14-1207 directed the Colorado Department  
32 of Public Health and Environment's (department) executive director to establish a household medication  
33 take-back program, subject to available funds, to facilitate the safe and effective collection and proper  
34 disposal of unused household medications.

35  
36 III. Senate Bill 19-227

37  
38 In Senate Bill 19-227, the General Assembly directed the department's executive director to expand the  
39 Colorado Household Medication Take-Back Program (program) through implementation of processes  
40 and establishment of locations for the safe collection and disposal of needles, syringes, and other  
41 devices used to inject medications (sharps).

42  
43 IV. Purpose of Regulation Amendments:

44  
45 The primary purpose of the regulation amendments is implementation of Senate Bill 19-227, through  
46 establishment of qualifications, operational procedures, and recordkeeping requirements for program  
47 collectors, transporters, treatment facilities, and disposal locations of household sharps. Additional  
48 amendments add clarity and experience-based changes to sections of the regulation dealing with  
49 household medication collection, transport and disposal.

50  
51 **Discussion of Regulatory Proposal**

52  
53 I. Background

54  
55 The department implemented House Bill 14-1207 in 2016, by establishing the Colorado Household  
56 Medication Take-Back Program, capable of accepting prescribed controlled substances along with other  
57 prescription and over-the-counter medications for disposal. A \$300,000 legislative annual appropriation

58 allowed the department to embark on a statewide program expansion with a goal of establishing at least  
59 one permanent collection location in every Colorado county and in a majority of cities with populations  
60 of 1,000 or more.

61  
62 As of October 31, 2019, the program had enrolled more than 160 collection sites in 62 of Colorado's 64  
63 counties and collected more than 90,000 pounds of unused household medications, removing them  
64 from homes where they may be misused or abused and directing them to proper disposal.

65  
66 While successful, the program lacked the ability to collect sharps used by the public to administer a  
67 significant volume of medications. If handled or disposed improperly, these devices pose a risk for injury  
68 and transmission of bloodborne pathogens. Options for safe disposal are offered by some drug  
69 manufacturers, local agencies, or others, but such services are limited in scope and geographic  
70 coverage. The implementation of SB 19-227 through amendments to 6 CCR 1010-23, (1) expands the  
71 existing, state-funded program for the collection and disposal of household medication waste to include  
72 sharps, (2) potentially decreases trash disposal of used sharps by offering a broadly available, no-fee  
73 system for collection and disposal, and (3) potentially reduces confusion regarding available options for  
74 safe sharps disposal. The legislature appropriated funds, for fiscal year 2020 and beyond, for  
75 development and implementation of the sharps element of the program.

## 76 77 II. Scope, Purpose, and Applicability

78  
79 The amendments to Section 23.2(A) of the proposed regulations emphasize that a program participant  
80 may volunteer to collect household medications or household sharps, or both, and establishes that the  
81 regulations apply to program participants involved in the collection, transport, treatment and disposal of  
82 household sharps. The amendments to section 23.2(B) add an exclusion for household sharps  
83 collection activities taking place through other programs and clarifies that those generating the  
84 household medications and household sharps are not covered by the regulation. Section 23.2(B)(6) was  
85 amended to incorporate by reference the definition of schedule I controlled substances as defined in  
86 U.S. Department of Justice, Drug Enforcement Administration, 21 CFR § 1308 revised April 1, 2019.  
87 The amendments to Section 23.2(C) clarify that department-contracted program participants incurring  
88 costs related to medications or sharps may apply for reimbursement. Amended Section 23.3 establishes  
89 the regulation's applicability to the collection, transport, treatment and disposal of sharps.

## 90 91 III. Definitions

92  
93 The amendments added two new definitions to Section 23.4(A). A definition of household sharps was  
94 added as Section 23.4(A)(17) and a definition of treatment facility was added as Section 23.4(A)(25).  
95 Although the definition was not amended, the term "take-back event" was changed to "household  
96 medication take-back event" and is now included as 23.4(A)(16). Several definitions were amended to  
97 include the collection, transport, treatment and disposal of sharps. These definitions do not apply to any  
98 other regulations promulgated by the Solid and Hazardous Waste Commission or the Board of Health.  
99 Definitions for the terms "controlled substance", "DEA registrant or registrant", "distribute", and  
100 "distributor" were amended to incorporate by reference various sections of U.S. Department of Justice,  
101 Drug Enforcement Administration regulations at 21 CFR §§ 1301, 1308, and 1310, revised April 1,  
102 2019.

## 103 104 IV. Standards for Program Participants – Household Medication

105  
106 Part I - Sections 23.6 through 23.18 establish standards, qualifications, operational procedures,  
107 recordkeeping procedures, and security requirements for household medication collectors, transporters,  
108 and disposal locations participating in the Program. Amendments added two new sections, based on  
109 the department's experiences with the program, including Section 23.13.4 which allows a transporter to  
110 transfer medications to another DEA-registrant for subsequent destruction, and Section 23.17.2(A)(3)  
111 which allows for department-approved, alternative inner-liner documentation methods by law  
112 enforcement agencies. Several sections were amended for clarity, including the replacing the terms  
113 "reverse distributor" and "distributor" with the term "transporter." Requirements for collector registration  
114 [23.6.1 (A)(1)], transporter physical security controls [23.15.4(A)], recordkeeping [23.16.1(A)],  
115 transporter records and reports [23.16.3(A)], collector records and reports [23.16.3(B)], and collector



116 termination of registration [23.18(A)(3)] were amended to incorporate by reference various sections of  
117 the U.S. Department of Justice, Drug Enforcement Administration regulations at 21 CFR §§ 1301 and  
118 1304, revised April 1, 2019.

119  
120 V. Standards for Program Participants – Household Sharps

121  
122 The amendments added Part II - Section 23.19, establishing standards, qualifications, operational  
123 procedures, and recordkeeping procedures for household sharps collectors, transporters, treatment  
124 facilities, and disposal locations.

125  
126 VI. Federal Regulations Incorporated by Reference

127  
128 The amendments added Section 23.20, incorporating by reference applicable sections of the United  
129 States Department of Justice, Drug Enforcement Administration (DEA) regulations and United States  
130 Department of Labor, Occupational Safety and Health Administration (OSHA) regulations.

131  
132 **Description of Local Government Involvement in the Stakeholder Process**

133  
134 Executive Order D 2011-005 (EO5), “Establishing a Policy to Enhance the Relationship between State and  
135 Local Government” requires state rulemaking agencies to consult with and engage local governments prior to  
136 the promulgation of any rules containing mandates. Although this Regulation contains no mandate, but instead  
137 contains requirements for voluntary participation in the sharps-expanded medication take-back program, the  
138 department completed an EO5 – Internal Communication Form – Draft Phase which was transmitted to local  
139 governments on July 1, 2019. Four respondents to this EO5 outreach requested to be included as stakeholders  
140 and provided an opportunity to participate in the stakeholder process.

141  
142 **Stakeholder Engagement**

143  
144 The department held a Rules Committee meeting on July 31, 2019 to gain input from potential stakeholders  
145 before it began drafting the amended regulation. After developing a first draft, the department held three  
146 stakeholder meetings on October 11, November 8 and November 20, 2019. These meetings were part of a  
147 comprehensive and robust review process, during which the department collaborated with a stakeholder group  
148 including local law enforcement agencies, local public health agencies, pharmacists, educators, health care  
149 professionals, drug manufacturers, water and wastewater utilities, waste disposal companies, department  
150 representatives and others. The stakeholders and department successfully reached consensus on the content  
151 of the amended regulation. Based on discussions during the stakeholder process, the following issues were  
152 identified as the most consequential to stakeholders and the department with regard to the expansion of the  
153 Program to include the safe collection and disposal of sharps:

154  
155 I. Medication collectors should not be required to also collect sharps

156  
157 Stakeholders expressed concern that program expansion would result in a requirement for medication  
158 collectors to also collect sharps. Program participants successfully incorporating medication collection  
159 into their business practices may not be able to handle the additional burden of sharps collection. The  
160 initial regulation established the voluntary nature of the program. The amendments establish that  
161 collection of household medications or household sharps are both done voluntarily.

162  
163 II. The regulation amendments must be protective of public safety and the safety of program participants

164  
165 Sharps collection receptacle construction - Several stakeholders expressed the need for sharps  
166 collection receptacles to be constructed in such a manner as to reduce the risks of injury and  
167 transmission of bloodborne pathogens. The amended regulation does not mandate a particular  
168 receptacle design, but states they must have department approval. The department intends to use the  
169 Request for Proposals (RFP) process to require transporter submission of safe collection receptacle  
170 designs and will consider the appropriateness of those designs when selecting a program transporter.

171  
172 Sharps collection receptacle placement - The amended regulation requires that sharps collection  
173 receptacles be placed at a collector’s physical location in an area regularly monitored by employees.

174 This requirement is intended to reduce opportunities for improper use of a kiosk, i.e. placement of loose  
175 sharps in receptacles not intended for such deposits, contamination of receptacles with bodily fluids,  
176 and deposit of trash or other items that might interfere with safe receptacle operation. The amended  
177 regulation does not prohibit the installation of collection receptacles outdoors. The department will  
178 consider approval of outdoor placements, if they can be accomplished in a safe manner.  
179

180 Sharps collection site housekeeping - Stakeholders expressed the need for good housekeeping at  
181 sharps collection sites to reduce the risks of injury, including transmission of bloodborne pathogens.  
182 This issue was deemed appropriate for inclusion in Medical Waste Management Plans.  
183

184 Safety training - The amended regulation incorporates by reference and requires sharps collectors to  
185 provide training to employees in accordance with U.S. Department of Labor, Occupational Safety and  
186 Health Administration's (OSHA) *Bloodborne Pathogens* standard, 29 CFR § 1910.1030(g)(2), effective  
187 June 4, 1992. Also, department-approved collectors must describe the training in their Medical Waste  
188 Management Plans and must maintain documentation of training for three years from the date on which  
189 the training occurred. The amended regulation also includes a requirement for transporter employee  
190 training in accordance with *Regulations Pertaining to Solid Waste Sites and Facilities*, 6 CCR 1007-2,  
191 Part 1, Part B, Section 13.7.2(C)(9).  
192

193 Sharps shipping - Stakeholders stated that the shipping of sharps by transporters via common or  
194 contract carrier should utilize containers that comply with Department of Transportation regulations or  
195 carrier standards. The department intends to use the RFP process to require use of compliant shipping  
196 containers and methods and will consider their appropriateness when selecting a program transporter.  
197

198 Sharps treatment - The amended regulation requires transporter treatment of acquired sharps to a non-  
199 infectious state prior to disposal. The possibility exists that treatment may occur outside the state of  
200 Colorado. The amended regulation allows for department approval of treatment methods that may be  
201 permissible in other states, but not specifically listed in the *Regulations Pertaining to Solid Waste Sites  
202 and Facilities*, 6 CCR 1007-2, Part 1, Part B, 732 Section 13.6.1(A).  
203

204 III. A mail-back option for sharps containers should be allowed  
205

206 Several stakeholders expressed the need for a mail-back option, whereby a transporter provides sharps  
207 containers directly to individuals. This option would allow an individual to obtain sharps containers  
208 directly from a transporter and then have them delivered back to the transporter when full. Stakeholders  
209 felt this option might prove more economical and may better serve rural areas of the state, where  
210 collection sites might be located too far from residents who need them. The mail-back option was  
211 included in the amended regulation by allowing transporters to receive sharps directly from individuals  
212 by common or contract carrier delivery.  
213

214 IV. The homeless and those injecting illicit drugs should not be excluded from the program  
215

216 Several stakeholders stated that the homeless and those injecting illicit drugs should not be excluded  
217 from using sharps collection receptacles. The amended regulation does not exclude these groups.  
218 Sharps that are in the possession of an individual will be accepted, provided they were not generated by  
219 a commercial or industrial entity. Generators of the deposited sharps are not covered by the amended  
220 regulation, so no questions will be asked regarding the use of the injection devices. The amended  
221 regulation allows for department-approved outdoor kiosk placements. Such approval may be granted in  
222 areas that could benefit from outdoor access.  
223

224 V. Household sharps collection events or mobile collection should be offered  
225

226 Stakeholders expressed an interest in allowing sharps take-back events or offering mobile sharps  
227 collection options. While these options are not addressed specifically in the amended regulation, the  
228 department may choose to pilot such efforts with collection sites if specific needs are identified and  
229 sufficient funding is available.  
230  
231

232 VI. Collectors should maintain manifests documenting transporter acquisition of sharps from their locations  
233  
234 Stakeholders stated that collectors should maintain manifests or other documentation demonstrating  
235 that collected sharps were transferred to a transporter for treatment and disposal. Since it will not be  
236 known what paperwork might be generated until a transporter is chosen and procedures implemented,  
237 the amended regulation states that collectors shall maintain transporter-provided waste manifests,  
238 tracking documents, or chain-of-custody forms for three years.  
239

240 **Regulatory Alternatives**

241  
242 No other regulatory alternatives were evaluated.  
243

244 **Cost/Benefit Analysis**

245  
246 A cost benefit analysis will be performed if requested by the Colorado Department of Regulatory  
247 Agencies.