

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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8 THE COLORADO HOUSEHOLD MEDICATION TAKE-BACK PROGRAM

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 25-15-238(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.

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7. Controlled Substance means a drug or other substance, or immediate precursor, included in schedule II - V and listed in 21 CFR Parts 1308.12 through 1308.15, as amended.
 8. DEA means the Drug Enforcement Administration and its authorized agents and employees.
 9. DEA Registrant or Registrant means any person who is registered pursuant to Title 21 CFR Part 1301.11, as amended.
 10. Department means the Colorado Department of Public Health and Environment and its authorized agents and employees.
 11. Disposal Location means a site approved by the department where unused household medications are destroyed in compliance with applicable laws and rendered non-retrievable and cannot be diverted for illicit purposes.
 12. Distribute means to deliver (other than by administering or dispensing) a controlled substance or to deliver (other than by administering or dispensing) a listed chemical designated in Title 21 CFR Part 1310.02, as amended.
 13. Distributor means a person who delivers (other than by administering or dispensing) a controlled substance or delivers (other than by administering or dispensing) a listed chemical designated in Title 21 CFR Part 1310.02, as amended.
 14. Employee means an individual directly paid by a program participant; subject to direct oversight by a program participant; required, as a condition of employment, to follow a program participant's procedures and guidelines pertaining to the handling of household medications, including controlled substances; subject to receive a performance rating or performance evaluation on a regular/routine basis from a program participant; subject to disciplinary action by a program participant; and required to render services at the site of a program participant's covered activities. At a law enforcement agency collector an employee may, at the agency's discretion, be a paid or unpaid reserve officer as defined pursuant to 16-2.5-110, C.R.S.
 15. Household Medications means controlled substances approved for collection by federal law, prescription drugs, and over-the-counter medications in the possession of an individual.
 16. Law Enforcement Agency means, but is not limited to, a municipal, tribal, university, or college police department; a county sheriff's office; a district attorney's office; a county coroner's office; a town marshal's office; the Colorado Department of Public Safety; and the Colorado Department of Corrections.
 17. Law Enforcement Officer means an individual who:

- 146 a. Is an employee of either a law enforcement agency or law enforcement
147 component of a federal agency;
148
149 b. Is under the direction and control of a federal, state, tribal, or local
150 government;
151
152 c. Acts in the course of the law enforcement officer's official duty; and
153
154 d. Is duly sworn and given the authority by a federal, state, tribal, or local
155 government to carry firearms, execute and serve warrants, make arrests
156 without warrant, and make seizures of property.
157
- 158 18. Non-retrievable means, for the purpose of destruction, the condition or state
159 to which household medications shall be rendered following a process that
160 permanently alters the household medications' physical or chemical condition
161 or state through irreversible means and thereby renders the household
162 medications unavailable and unusable for all practical purposes, thus
163 preventing their diversion to illicit purposes. The process to achieve a non-
164 retrievable condition or state may be unique to a household medication's
165 chemical or physical properties. A controlled substance is considered non-
166 retrievable when permanently altered in such manner and it cannot be
167 transformed to a physical or chemical condition or state as a controlled
168 substance or controlled substance analogue.
169
- 170 19. On-site means located on or at the physical premises of the registrant's
171 registered location. A controlled substance is destroyed on-site when
172 destruction occurs on the physical premises of the destroying registrant's
173 registered location. A hospital/clinic has an on-site pharmacy when it has a
174 pharmacy located on the physical premises of the registrant's registered
175 location.
176
- 177 20. Reverse Distribute means to acquire controlled substances from another
178 registrant or law enforcement for the purpose of:
179
- 180 a. Return to the registered manufacturer or another registrant authorized
181 by manufacturer to accept returns on the manufacturer's behalf; or
182
183 b. Destruction.
184
- 185 21. Reverse Distributor means a person registered with the Drug Enforcement
186 Administration to reverse distribute controlled substances.
187
- 188 22. Take-Back Event means a scheduled, organized occasion of limited duration,
189 managed by a law enforcement agency for the collection of household
190 medications, including controlled substances collected from ultimate users and
191 individuals lawfully entitled to dispose of an ultimate user decedent's
192 property.
193

- 194 23. Transporter means any entity approved by the department to acquire unused
195 household medications from approved collectors and transport them to
196 approved disposal locations.
197
- 198 24. Ultimate User means an individual who has lawfully obtained, and who
199 possesses, a controlled substance for the individual's own use or for the use of
200 a member of the individual's household or for an animal owned by the
201 individual or by a member of the individual's household.
202

203 **23.5 Standards for Approved Program Participants**
204

- 205 A. All Program participants shall comply with requirements of federal, state, tribal, and
206 local laws and regulations.
207

208 **23.6 Specific Standards for Approved Collectors, Transporters, and Disposal Locations**
209

210 **23.6.1 Collectors**
211

- 212 A. In order to collect household medications as an approved participant in the Program, a
213 collector shall:
214

- 215 1. Be a law enforcement agency; or a DEA-registered location of a retail pharmacy
216 or a hospital/clinic with an on-site pharmacy, whose registrations have been
217 modified consistent with DEA requirements described in Title 21 CFR Part
218 1301.51, as amended, to authorize collection of controlled substances.
219
- 220 2. Have an application form approved by the department.
221
- 222 3. Develop, implement, and maintain on site in an easily retrievable format a
223 Medical Waste Management Plan containing, at a minimum, the following
224 elements:
225
 - 226 a. Procedures for household medication identification, collection,
227 packaging, storage, transport and disposal;
 - 228
 - 229 b. A contingency plan for spills and releases;
 - 230
 - 231 c. Employee and volunteer training procedures;
 - 232
 - 233 d. Designation of an individual or individuals responsible for implementing
234 the plan; and
 - 235
 - 236 e. Recordkeeping methods.
237

238 **23.6.2 Transporters**
239

- 240 A. In order to acquire household medications from collectors and transport them to
241 disposal locations for destruction as an approved participant in the Program, a
242 transporter shall be:
243

- 244 1. A reverse distributor or distributor under contract or other written, signed
245 service agreement with the department if acquiring household medications
246 from a DEA-registered collector by on-site pick-up or by common carrier or
247 contract carrier delivery; or
- 248 2. A reverse distributor under contract or other written, signed service agreement
249 with the department if acquiring household medications from a law
250 enforcement agency collector by on-site pick-up or by common carrier or
251 contract carrier delivery.
252

253 **23.6.3 Disposal Locations**

- 254
- 255 A. In order to be approved to destroy household medications collected in the Program, a
256 disposal location shall:
257
- 258 1. Utilize a method of destruction that renders household medications non-
259 retrievable; and
260
- 261 2. Comply with applicable federal, state, tribal, and local laws and regulations.
262

263 **23.7 Allowable Collection Methods**

264 **23.7.1 DEA-Registered Collectors**

- 265
- 266
- 267 A. DEA-registered collectors participating in the Program may collect household
268 medications, including controlled substances collected from ultimate users, utilizing
269 the following collection method:
270
- 271 1. Collection receptacles and inner liners in accordance with Sections 23.8 and
272 23.9.
273

274 **23.7.2 Law Enforcement Agency Collectors**

- 275
- 276 A. Law enforcement agency collectors participating in the Program may collect household
277 medications in the course of official duties, including controlled substances collected
278 from ultimate users, utilizing the following collection methods:
279
- 280 1. Collection receptacles and inner liners in accordance with Sections 23.8 and
281 23.9; and/or
282
- 283 2. Take-back events in accordance with Section 23.10.
284

285 **23.8 Collection Receptacle Requirements**

- 286
- 287 A. Collection receptacles shall be securely placed and maintained either (1) inside a DEA-
288 registered collector's location, or (2) inside a law enforcement agency collector's
289 physical location.
290
- 291 B. For collection receptacles located inside a DEA-registered collector's location:
292

- 293 1. At a retail pharmacy, receptacles shall be located in an area accessible to the
 294 public and in the immediate proximity of a designated area where controlled
 295 substances are stored, and at which an employee is present (e.g., can be seen
 296 from the pharmacy counter); and
 297
- 298 2. At a hospital/clinic, receptacles shall be located in an area accessible to the
 299 public and regularly monitored by employees, and shall not be located in the
 300 proximity of any area where emergency or urgent care is provided.
 301
- 302 C. For collection receptacles located inside a law enforcement agency collector's
 303 location, receptacles shall be located in an area monitored by employees or law
 304 enforcement officers.
 305
- 306 D. A collection receptacle shall meet the following design specifications:
 307
- 308 1. At a DEA-registered collector's location, be securely fastened to a permanent
 309 structure so that it cannot be removed;
 310
- 311 2. Be a securely locked, substantially constructed container with a permanent
 312 outer container and a removable inner liner as specified in Section 23.9;
 313
- 314 3. Include a small opening in the outer container that allows contents to be added
 315 to the inner liner, but does not allow removal of the inner liner's contents;
 316
- 317 4. Prominently display a sign on the outer container indicating that only Schedule
 318 II-V controlled and non-controlled substances are acceptable substances.
 319 Schedule I controlled substances, controlled substances that are not lawfully
 320 possessed by the ultimate user, and other illicit or dangerous substances are
 321 not permitted; and
 322
- 323 5. Except at a law enforcement agency location, the small opening in the outer
 324 container of the collection receptacle shall be locked or made otherwise
 325 inaccessible to the public when an employee is not present (e.g., when a
 326 pharmacy is closed).
 327
- 328 E. Except at a law enforcement agency location specifically authorized by the
 329 department, once household medications have been deposited into a collection
 330 receptacle, the household medications shall not be counted, sorted, inventoried, or
 331 otherwise individually handled.
 332
- 333 F. Only those controlled substances listed in Schedule II, III, IV, or V that are lawfully
 334 possessed by an ultimate user or other authorized non-registrant individual may be
 335 collected along with other household medications that are non-controlled substances.
 336 Controlled and non-controlled substances may be collected together and be
 337 comingled.
 338
- 339 G. Law enforcement agency collectors may allow ultimate users and other authorized
 340 non-registrant individuals in lawful possession of a controlled substance in Schedule II,
 341 III, IV, or V to transfer such substances and other household medications to a law
 342 enforcement officer or law enforcement agency employee for immediate deposit in a

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

345 **23.9 Collection Receptacle Inner Liner Requirements**

347
348 A. The inner liner used in a collection receptacle shall meet the following requirements:

- 349
350 1. The inner liner shall be opaque, waterproof, tamper-evident, and tear-
351 resistant;
- 352
353 2. The inner liner shall be removable and sealable immediately upon removal
354 without emptying or touching the contents;
- 355
356 3. The contents of the inner liner shall not be viewable from the outside when
357 sealed;
- 358
359 4. The size of the inner liner shall be clearly marked on the outside of the liner
360 (e.g., 5-gallon, 10-gallon, etc.); and
- 361
362 5. The inner liner shall bear a permanent, unique identification number that
363 enables the inner liner to be tracked in accordance with Section 23.16.2(A) and
364 (B).

365
366 B. Access to the inner liner shall be restricted to employees of a DEA-registered collector
367 or employees of a law enforcement agency collector.

368
369 C. Installation and removal of the inner liner shall be performed by:

- 370
371 1. Two employees of a DEA-registered collector; or
- 372
373 2. Unless otherwise approved by the department, two employees of a law
374 enforcement agency collector.

375
376 D. The inner liner shall be sealed immediately upon removal from the permanent outer
377 container of the collection receptacle and the sealed inner liner shall not be opened,
378 x-rayed, analyzed, or otherwise penetrated. The inner liner shall be sealed by:

- 379
380 1. Two employees of a DEA-registered collector; or
- 381
382 2. Unless otherwise approved by the department, two employees of a law
383 enforcement agency collector.

384 **23.10 Take-Back Events**

385
386
387 A. A law enforcement agency may conduct a take-back event and collect household
388 medications, including controlled substances collected from ultimate users and
389 individuals lawfully entitled to dispose of an ultimate user decedent's property. A law
390 enforcement agency may partner with other persons or entities to hold a collection
391 take-back event in accordance with this Section.
392

- 393 B. A law enforcement agency shall appoint at a minimum one law enforcement officer
394 employed by the agency to oversee the collection. Law enforcement officers employed
395 by the law enforcement agency conducting a take-back event shall maintain control
396 and custody of the household medications from the time they are collected until
397 secure transfer, storage, or destruction has occurred.
398
- 399 C. A law enforcement agency may conduct a take-back event at its physical location or at
400 another location, provided the law enforcement officer(s) overseeing the collection
401 are able to maintain custody and control of the household medications in accordance
402 with this Section.
403
- 404 D. A collection receptacle, as described in Section 23.8 and Section 23.9, may be used at
405 a take-back event for the collection of household medications.
406
- 407 E. If a collection receptacle is not used at a take-back event, collected household
408 medications shall be placed in an opaque, waterproof, tamper-evident, and tear-
409 resistant bag bearing the markings required for inner liners as described in Sections
410 23.9(A)(4) and (5).
411
- 412 F. Only those controlled substances listed in Schedule II, III, IV, or V that are lawfully
413 possessed by an ultimate user or individual entitled to dispose of an ultimate user
414 decedent's property may be collected. Controlled and non-controlled substances may
415 be collected together and be comingled.
416
- 417 G. Only ultimate users and individuals entitled to dispose of an ultimate user decedent's
418 property in lawful possession of a controlled substance in Schedule II, III, IV, or V may
419 transfer such substances to the law enforcement officer described in Section 23.10(B)
420 during the take-back event. No other individual may handle the controlled substances
421 at any time.
422

423 23.11 Disposal of Collected Household Medications

424 23.11.1 DEA-Registered Collectors

- 425
- 426
- 427 A. DEA-registered collectors shall dispose of collected household medications in the
428 following manner:
429
- 430 1. Upon inner liner removal from the permanent outer container of a collection
431 receptacle, the sealed inner liner and its contents shall be:
432
 - 433 a. Sent by two employees to a reverse distributor's or distributor's
434 registered location by common carrier or contract carrier delivery; or
435
 - 436 b. Transferred by two employees to a reverse distributor or distributor by
437 on-site pick-up at the DEA-registered collector's location for transport
438 to the reverse distributor's or distributor's registered location or
439 transport to a disposal location.
440
 - 441 2. A sealed inner liner and its contents shall be placed into secure storage by two
442 employees at the DEA-registered collector's location, in accordance with

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

447 23.11.2 Law Enforcement Agency Collectors

448
449 A. Law enforcement agency collectors shall dispose of household medications collected
450 at their physical locations in the following manner:

451
452 1. Sealed inner liners and their contents removed from collection receptacles and
453 opaque, waterproof, tamper-evident, and tear-resistant bags containing
454 household medications collected at take-back events through means other than
455 a collection receptacle shall be:

456
457 a. Sent by two, unless otherwise approved by the department, law
458 enforcement agency employees, to a reverse distributor's registered
459 location by common carrier or contract carrier delivery; or

460
461 b. Transferred by two, unless otherwise approved by the department, law
462 enforcement agency employees to a reverse distributor or distributor by
463 on-site pick-up at the law enforcement agency collector's location for
464 transport to the reverse distributor's or distributor's registered location
465 or transport to a disposal location.

466
467 2. Sealed inner liners and their contents and opaque, waterproof, tamper evident
468 and tear resistant bags and their contents shall be placed into secure storage at
469 the law enforcement agency by two, unless otherwise approved by the
470 department, law enforcement agency employees, in accordance with Section
471 23.15.3, until prompt delivery or transfer to a reverse distributor or distributor
472 can occur. In no case shall sealed inner liners or opaque, waterproof, tamper-
473 evident, and tear-resistant bags be stored at the law enforcement agency
474 collector's location for more than 90-days.

475
476 B. Law enforcement agency collectors shall dispose of household medications collected
477 at take-back events held at sites other than the agencies' physical locations in the
478 following manner:

479
480 1. Sealed inner liners and their contents removed from collection receptacles and
481 opaque, waterproof, tamper-evident, and tear-resistant bags containing
482 household medications collected at take-back events through means other than
483 a collection receptacle shall be:

484
485 a. Transferred by the law enforcement officer described in Section
486 23.10(B) to a reverse distributor by pick-up at the take-back event site
487 for transport to the reverse distributor's registered location or transport
488 to a disposal location; or

489
490 b. Transported by the law enforcement officer described in Section
491 23.10(B) to the law enforcement agency's physical location for disposal
492 in accordance with Section 23.11.2(A).

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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

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

544
545 c. Upon acquisition of household medications by common carrier or
546 contract carrier delivery, the reverse distributor or distributor shall
547 immediately store the household medications in a manner consistent
548 with the security requirements for Schedule II controlled substances, in
549 accordance with the physical security controls in Section 23.15.4(A)
550 until timely destruction occurs.

551
552 **23.12.4. Timely Destruction of Acquired Household Medications**

553
554 A. A reverse distributor or distributor shall destroy or cause the destruction of acquired
555 household medications no later than 30 calendar days after acquisition.

556
557 **23.13 Transporter Procedures for Destruction of Acquired Household Medications**

558
559 **23.13.1 Destruction at Transporter's Registered Location Acquiring Household**
560 **Medications**

561
562 A. If a reverse distributor's or distributor's registered location acquiring household
563 medications by on-site pick-up or delivery by common or contract carrier is a disposal
564 location, the following procedures shall be used if household medications are
565 destroyed on-site:

- 566
- 567 1. Two employees of the reverse distributor or distributor shall handle or observe
568 the handling of the household medications until destruction has occurred; and
 - 569 2. Two employees of the reverse distributor or distributor shall personally witness
570 the destruction of the household medications until all are rendered non-
571 retrievable.

572
573
574 **23.13.2 Transport to a Registered Disposal Location for Destruction**

575
576 A. If a reverse distributor or distributor does not destroy acquired medications at their
577 registered location as described in Section 23.13.1(A), another registered location with
578 destruction capabilities may serve as the disposal location. Household medications
579 shall be transported to the registered disposal location either from a transporter's
580 registered location that acquired medications by on-site pick-up or delivery by
581 common or contract carrier, or directly from a collector if acquired by on-site pick-up,
582 using the following procedures:

- 583
- 584 1. Transportation shall be directly to the registered disposal location (the
585 household medications shall be constantly moving towards their final location
586 and unnecessary or unrelated stops and stops of an extended duration shall not
587 occur);
 - 588 2. Two employees of the transporting reverse distributor or distributor shall
589 accompany the household medications to the registered disposal location; and

590
591

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 23.15.1 Employee Status

637
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

642 case of DEA-registered participants, any individual who, at any time, had an
643 application for registration with DEA denied, had a DEA registration revoked or
644 suspended, or has surrendered a DEA registration for cause. For purposes of this
645 subsection, "for cause" means in lieu of, or as a consequence of, any federal or State
646 administrative, civil, or criminal action resulting from an investigation of the
647 individual's handling of controlled substances.
648

649 **23.15.2 Physical Security Controls for DEA-Registered Collectors**

- 650
- 651 A. DEA-registered collectors shall store sealed inner liners containing household
652 medications in a securely locked, substantially constructed cabinet or a securely
653 locked room with controlled access.
654

655 **23.15.3 Physical Security Controls for Law Enforcement Agency Collectors**

- 656
- 657 A. Law enforcement agency collectors shall store sealed inner liners and opaque,
658 waterproof, tamper-evident, and tear-resistant bags containing household medications
659 at the law enforcement agency in a securely locked storage area in a manner
660 consistent with that agency's standard procedures for storing illicit controlled
661 substances.
662

663 **23.15.4 Physical Security Controls for Reverse Distributors and Distributors**

- 664
- 665 A. Sealed inner liners acquired by reverse distributors and distributors and opaque,
666 waterproof, tamper-evident, and tear-resistant bags containing household medications
667 acquired by reverse distributors shall be securely stored in accordance with Title 21
668 CFR Part 1301.72(a), as amended.
669

670 **23.16 Registrant Records and Inventories**

671 **23.16.1 General Recordkeeping Requirements for Registrants**

- 672
- 673
 - 674 A. Every registrant required to keep records pursuant to Title 21 CFR Part 1304, as
675 amended, shall maintain, on a current basis, a complete and accurate record of each
676 inner liner and sealed inner liner, except that no registrant shall be required to
677 maintain a perpetual inventory.
678
 - 679 B. Registrants shall maintain separate records for each independent activity and
680 collection activity for which they are registered or authorized.
681
 - 682 C. In recording dates of receipt, transfer, or destruction, the date on which the
683 household medications are actually received, transferred, or destroyed shall be used
684 as the date of receipt, transfer, or destruction (e.g., invoices, packing slips, manifests
685 or DEA Form 41).
686
 - 687 D. In addition to any other recordkeeping requirements, any DEA-registrant that destroys
688 a sealed inner liner or sealed bag containing household medications, or causes the
689 destruction of sealed inner liner or sealed bag containing household medications, shall
690 maintain a record of destruction on a DEA Form 41. The records shall be complete and
691 accurate, and include the name and signature of the two employees who witnessed

692 the destruction.

693

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

697

698 **23.16.2 Required Registrant Records**

699

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

701

702 1. For sealed inner liners acquired from collectors by reverse distributors and
703 distributors pursuant to Section 23.12.3:

704

705 a. The number of sealed inner liners acquired to inventory, including the
706 dates of acquisition; the size (e.g., five 10-gallon liners, etc.) of all
707 sealed inner liners acquired; the weight of each sealed inner liner
708 acquired; the unique identification number of each sealed inner liner
709 acquired; and the name, address, and, for DEA-registrant collectors, the
710 registration number of the collector from whom the sealed inner liners
711 were acquired; and

712

713 b. The number of sealed inner liners destroyed; the date, place, and
714 method of destruction; the size (e.g., five 10-gallon liners, etc.) of all
715 sealed inner liners destroyed; the unique identification number of each
716 sealed inner liner destroyed; the name, address, and, for DEA-registrant
717 collectors, the registration number of the collector from whom the
718 sealed inner liners were acquired; and the name and signatures of the
719 two employees of the reverse distributor or distributor that witnessed
720 the destruction.

721

722 2. For opaque, waterproof, tamper-evident, and tear-resistant bags containing
723 household medications acquired from law enforcement agency collectors by
724 reverse distributors pursuant to Section 23.12.3:

725

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

731

732 b. The number of bags destroyed; the date, place, and method of
733 destruction; the size (e.g., five 10-gallon liners, etc.) of all bags
734 destroyed; the unique identification number of each bag destroyed; the
735 name and address of the law enforcement agency collector from whom
736 the bags were acquired; and the name and signatures of the two
737 employees of the reverse distributor that witnessed the destruction.

738

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

741

- 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

- 792 1. The date of the inventory;
793
794 2. The number and size of sealed inner liners in storage (e.g., five 10-gallon
795 liners, etc.); and
796
797 3. The unique identification number of each inner liner.
798

799 **23.17 Law Enforcement Agency Collector Records**

800 **23.17.1 General Recordkeeping Requirements for Law Enforcement Agency Collectors**

- 803 A. Law enforcement agency collectors shall maintain the records required in Section
804 23.17.2 in an easily retrievable format, on-site for three (3) years from the date the
805 waste was acquired by a transporter.
806

807 **23.17.2 Required Law Enforcement Agency Collector Records**

- 808
809 A. Law enforcement agency collectors shall maintain the following records:
810

811 1. Collection receptacle inner liners:
812

813 a. Date each unused inner liner is obtained and its unique identification
814 number and size (e.g., 5-gallon, 10-gallon, etc.);
815

816 b. Date each inner liner is installed, the address of the location where
817 each inner liner is installed, the unique identification number and size
818 (e.g., 5-gallon, 10-gallon, etc.) of each installed inner liner, and the
819 names and signatures of the employees described in Section 23.9(C)(2)
820 or the law enforcement officer described in Section 23.10(B) that
821 performed each installation;
822

823 c. Date each inner liner is removed and sealed, the address of the location
824 from which each inner liner is removed, the unique identification
825 number and size (e.g., 5-gallon, 10-gallon, etc.) of each inner liner
826 removed, and the names and signatures of the employees described in
827 Section 23.9(C)(2) or the law enforcement officer described in Section
828 23.10(B) that performed each removal;
829

830 d. Date each sealed inner liner is transferred to storage, the unique
831 identification number and size (e.g., 5-gallon, 10-gallon, etc.) of each
832 sealed inner liner stored, and the names and signatures of the
833 employees that transferred each sealed inner liner to storage as
834 described in Section 23.11.2(A)(2); and
835

836 e. Date each sealed inner liner is transferred for destruction, the address
837 and registration number of the reverse distributor to whom each sealed
838 inner liner was transferred, the unique identification number and the
839 size (e.g., 5-gallon, 10-gallon, etc.) of each sealed inner liner
840 transferred, and the names and signatures of the employees that
841 transferred each sealed inner liner to the reverse distributor as

842 described in Section 23.11.2(A)(1) or Section 23.11.2(B)(1).
843

- 844 2. Opaque, waterproof, tamper-evident, and tear-resistant bags with household
845 medications collected at take-back events through means other than a
846 collection receptacle:
- 847
- 848 a. Date each bag is sealed, the address of the location at which each bag
849 is sealed, the unique identification number and size (e.g., 5-gallon, 10-
850 gallon, etc.) of each bag sealed, and the name and signature of the law
851 enforcement officer described in Section 23.10(B) that sealed each bag;
852
- 853 b. Date each sealed bag is transferred to storage, the unique identification
854 number and size (e.g., 5-gallon, 10-gallon, etc.) of each sealed bag
855 stored, and the name and signature of the law enforcement officer
856 described in Section 23.10(B) that transferred each bag to storage; and
857
- 858 c. Date each sealed bag is transferred for destruction, the address and
859 registration number of the reverse distributor to whom each sealed bag
860 was transferred, the unique identification number and the size (e.g., 5-
861 gallon, 10-gallon, etc.) of each sealed bag transferred, and the names
862 and signatures of the employees or law enforcement officer that
863 transferred each sealed bag to the reverse distributor as described in
864 Section 23.11.2(A)(1) or Section 23.11.2(B)(1)(a).
865

866 **23.18 Collectors Ceasing Collection Activities** 867

- 868 A. DEA-registered collectors ceasing participation in the Program and ceasing collection
869 of household medications shall:
- 870
- 871 1. Notify the department;
- 872
- 873 2. Dispose of household medications on hand in accordance with Section 23.11.1;
874 and
- 875
- 876 3. Notify the DEA of their intent to cease collection of controlled substances from
877 ultimate users in accordance with Title 21 CFR Part 1301.52(f), as amended.
878
- 879 B. Law enforcement agency collectors ceasing participation in the Program and ceasing
880 collection of household medications, including controlled substances collected from
881 ultimate users shall:
- 882
- 883 1. Notify the department; and
- 884
- 885 2. Dispose of household medication on hand in accordance with Section 23.11.2.

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 Rules and regulations pertaining to the Colorado Household Medication Take-Back Program (6 CCR
14 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
21 Waste Commission in Section 25-15-328(7), C.R.S. This Regulation is a direct result of, and
22 implementation of, House Bill (HB) 14-1207, passed by the legislature in 2014.

23
24 II. House Bill 14-1207

25
26 In HB 14-1207, the General Assembly declared (1) that prescription drug abuse is a rampant
27 problem in Colorado, in part due to the accidental and intentional abuse of leftover
28 household medications, and (2) that citizen access to a disposal location to return unused
29 household medications will reduce the availability of household medications for unintended
30 or abusive purposes and will further protect the environment through proper disposal. HB
31 14-1207 directed the department's executive director to establish a household medication
32 take-back program, subject to available funds, to facilitate the safe and effective collection
33 and proper disposal of unused household medications.

34
35 HB 14-1207 codified the department's earlier-established Colorado Household Medication
36 Take-Back Program (Program); provided liability protection to participants complying with
37 the Program in good faith and complying with applicable laws; created a cash-fund in the
38 state treasury for the direct and indirect costs associated with program implementation
39 consisting of moneys appropriated or transferred to the fund by the General Assembly and
40 any gifts, grants and donations from any public or private entity; authorized the collection
41 of controlled substances approved for collection by federal law, prescription drugs, and
42 over-the-counter medications in the possession of an individual; and granted authority to
43 the Commission to promulgate rules for the Program. HB 14-1207 does not affect the
44 authority to collect and reuse medications pursuant to Section 12-42.5-133, C.R.S., nor does
45 it prohibit the operation of existing medication take-back and disposal programs regulated
46 by the department.

47
48 III. Purpose of Regulation:

49
50 The purpose of this Regulation is to establish qualifications, operational and recordkeeping
51 procedures, and security requirements for collectors, transporters, and disposal locations
52 participating in the Colorado Household Medication Take-Back Program. This Regulation

53 also provides access to the Program's cash fund for department-approved Program
54 participants incurring costs associated with collection, transportation and destruction of
55 household medications, pursuant to the Program and subject to availability. This Regulation
56 does not affect the collection, transport, or disposal of household medications outside the
57 Program.
58

59 Discussion of Regulatory Proposal

60 61 I. Background

62
63 The department implemented the Colorado Household Medication Take-Back Program in
64 December 2009. As of April 1, 2016, the Program had collected more than 60,000 pounds of
65 unused household medications, removing them from homes where they may be misused or
66 abused and directing them to proper disposal. While successful, the Program's effectiveness
67 has been limited due to its small geographic coverage - just 11 collection locations in the
68 Denver metropolitan area and Summit County - and due to its inability to collect prescribed
69 controlled substances which have a high potential for abuse.
70

71 A \$300,000 legislative appropriation to the Program's cash fund for FY2015-2016 allowed the
72 department to begin expanding the Program with a goal of establishing at least one
73 permanent collection location in every county. The Drug Enforcement Administration's (DEA)
74 Final Rule for Disposal of Controlled Substances, effective October 9, 2014, has been used as
75 a basis for this Regulation. By incorporating this DEA rule, this Regulation aligns with
76 federal law and allows the collection of controlled substances along with other household
77 medications. Program expansion and the addition of controlled substance collection will
78 increase the Program's scope and complexity. This Regulation creates controls to limit
79 opportunities for diversion of collected medications to illicit purposes and meets the intent
80 of HB 14-1207 to facilitate the safe and effective collection and proper disposal of unused
81 household medications.
82

83 This Regulation aligns with DEA's two-category approach to household medication
84 collection. First, this Regulation allows law enforcement agencies not required to register
85 with DEA to apply for participation in the Program as collectors. Many law enforcement
86 agencies have been collecting household medications, including controlled substances, since
87 September 2010 through permanent collection receptacles and/or during DEA-funded,
88 biannual National Take-Back Initiative (NTBI) events. Medications collected through either
89 means have been disposed by DEA during NTBI events. The future of the NTBI and DEA-
90 funded disposal is uncertain beyond April 2016. Law enforcement agencies approved by the
91 department to participate in the Program will have access to Program funds, subject to
92 availability. Second, DEA-registrants, including retail pharmacies and hospitals/clinics with
93 on-site pharmacies, can apply to the Program as collectors if they have amended their DEA
94 registrations to allow collection of controlled substances. DEA-registrant collectors
95 approved by the department to participate in the Program will also have access to Program
96 funds, subject to availability. The department will develop and adopt guidance that will
97 establish conditions for access to Program funds.
98

99 II. Scope and Purpose, and Applicability

100
101 Sections 23.2 and 23.3 discuss to whom this Regulation applies and to whom it does not
102 apply. Specifically, this Regulation applies to persons participating in the Program as
103 collectors, transporters, or disposal locations. This Regulation does not apply to persons
104 collecting, transporting, or disposing of household medications outside the Program.

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III. Definitions

Section 23.4 creates twenty-four (24) definitions which apply to this Section 23. These definitions do not apply to any other regulations promulgated by the Solid and Hazardous Waste Commission or the Board of Health.

IV. Standards for Program Participants

Sections 23.5 through 23.18 establish standards, qualifications, operational procedures, recordkeeping procedures, and security requirements for collectors, transporters, and disposal locations participating in the Program.

Description of Local Government Involvement in the Stakeholder Process

Executive Order D 2011-005 (EO5), "Establishing a Policy to Enhance the Relationship between State and Local Government" requires state rulemaking agencies to consult with and engage local governments prior to the promulgation of any rules containing mandates. Although this Regulation contains no mandate, but instead contains requirements for voluntary participation in the Program, the department completed an EO5 - Internal Communication Form - Internal Conception Phase which was transmitted to local governments on July 7, 2014. The lone respondent to this outreach requested to be included as a stakeholder and participated in the stakeholder process.

Issues Encountered During Stakeholder Process

Because the department based much of this Regulation on the DEA rule, it did not have wide latitude when drafting this Regulation. The department held an informal rules development committee meeting on June 10, 2015 to gain input from potential stakeholders before it began drafting this Regulation. After developing a first draft, the department held five (5) stakeholder meetings between December 2, 2015 and March 24, 2016. These meetings were part of a comprehensive and robust review process, during which the department collaborated with a stakeholder group including local law enforcement agencies, local public health agencies, pharmacists, educators, health care professionals, drug manufacturers, water and wastewater utilities, waste disposal companies, other Colorado Department of Public Health and Environment division representatives, and the Drug Enforcement Administration. The stakeholders and department successfully reached consensus on the content of this Regulation. Based on discussions during the stakeholder process, the following issues were identified as the most consequential to stakeholders and the department:

I. Long-term care facilities and narcotic treatment programs are not included as approved collectors

Long-term care facilities (LTCF) and narcotic treatment programs (NTP) are not included as approved collectors in this Regulation. The DEA rule allows pharmacies or hospitals/clinics with on-site pharmacies to manage and maintain collection receptacles in secure locations at LTCF's for collection of controlled substances on behalf of present or past residents. NTP's are allowed by the DEA rule to collect controlled substances on behalf of their patients, but must locate collection receptacles in locked rooms and accompany patients to the receptacles. Neither of these scenarios offers broad public access to medication disposal. Further, LTCF medication wastes are considered to belong to the facilities and are regulated in the Colorado Hazardous Waste Regulations, 6 CCR 1007-3. Stakeholders

156 indicated no objection to excluding LTCF's and NTP's from this Regulation's list of approved
157 collectors.
158

159 II. DEA-registered manufacturers, DEA-registered reverse distributors, and DEA-registered
160 distributors are not included as approved collectors
161

162 DEA-registered manufacturers, DEA-registered reverse distributors, and DEA-registered
163 distributors are not included as approved collectors in this Regulation. The DEA rule allows
164 these entities to collect controlled substances from ultimate users through collection
165 receptacles or mail-back programs. As with LTCF's and NTP's, the stakeholders indicated no
166 objections to this Regulation's exclusion of these entities as they would not contribute
167 significantly to broad public access to household medication disposal.
168

169 III. Medication mail-back is not included as an approved medication collection method
170

171 This Regulation does not include medication mail-back as an approved medication collection
172 method. The DEA rule allows the use of mail-back envelopes by DEA-registrant collectors
173 and law enforcement collectors as a method for collecting controlled substances from
174 ultimate users. This method involves the production and distribution of nondescript
175 envelopes, bearing unique identification numbers for tracking purposes. The stakeholders
176 indicated no objections to the exclusion of this collection method as it would require an
177 investment in the production of envelopes that may or may not be ultimately used by
178 consumers. Further, this collection method would require more rigorous management given
179 the large number of envelopes that would need to be tracked from production through
180 destruction.
181

182 IV. Limit need for "regulation hopping"
183

184 Several stakeholders expressed concern that creation of a new regulation would burden
185 them with the need to cross reference these new requirements with requirements existing
186 in other regulations. To address this concern, the department, where possible, used the
187 actual language from other regulations, rather than merely citing to other regulations.
188 Where this approach was not deemed feasible or practical, the department limited citation
189 to federal regulations to one section of the federal code - 21 CFR Part 1300, Chapter II. The
190 stakeholders agreed with this approach.
191

192 V. Continued operation of extra-Program collection
193

194 Some stakeholders expressed concern that this Regulation would deter pharmacies from
195 continuing to operate programs that exclude controlled substances from collection. The
196 General Assembly made clear in section 25-15-238(1) and 25-15-238(2)(d) their intention to
197 establish a program to collect household medications, including controlled substances.
198 However, section 23.2(B)(4) addresses this stakeholder concern because it makes clear that
199 this Regulation does not apply to the operation of other medication take-back and disposal
200 programs.
201

202 VI. Alignment with federal rules
203

204 Stakeholders desired that this Regulation align with federal rules intended to expand the
205 options available to collect controlled substances from ultimate users for the purpose of
206 disposal. To address this, the department based this Regulation extensively on DEA's
207 October 9, 2014 rule. This Regulation aligns with DEA's two-category approach to household

208 medication collection and substantially adopts DEA's qualification requirements, operational
209 procedures, recordkeeping procedures, and security requirements for collectors,
210 transporters, and disposal locations. A DEA representative attended stakeholder meetings
211 and DEA comments were incorporated into this Regulation.
212

213 VII. Concerns of rural, smaller and western slope communities
214

215 Some stakeholders expressed concern about manpower and physical constraints that would
216 limit the ability of law enforcement agencies in rural, smaller and western slope
217 communities to comply with the requirements of this Regulation and to participate in the
218 Program. Specifically, an early draft of this Regulation required two law enforcement
219 agency employees to operate a collection receptacle. To address this concern, this
220 Regulation allows the department, on a case-by-case basis, to approve the use of one law
221 enforcement agency employee. Similarly, an early draft of this Regulation required that
222 two law enforcement officers be assigned to a take-back event and maintain control and
223 custody of the collected medications. To address this concern, this Regulation requires that
224 a minimum of one law enforcement officer be assigned to a take-back event.
225

226 Some stakeholders expressed concern that smaller law enforcement agencies might not have
227 sufficient physical space to locate a collection receptacle in an area accessible to the
228 public. This Regulation allows a law enforcement officer or law enforcement agency
229 employee to take-custody of household medications for immediate transfer to a collection
230 receptacle if it is located in an area not accessible to the public.
231

232 VIII. Use of reserve officers for medication collection by law enforcement
233

234 Some stakeholders felt this Regulation should allow law enforcement agencies to use reserve
235 officers to operate collection receptacles or maintain control and custody of medications
236 collected at take-back events. This Regulation includes a definition of "employee" that
237 allows inclusion of "reserve officers" at the discretion of a law enforcement agency. The
238 definition of "law enforcement officer" in this Regulation encompasses reserve officers,
239 thereby allowing them to maintain control and custody of medications collected at take-
240 back events, if assigned to the task by a law enforcement agency.
241

242 IX. Local community involvement in take-back events
243

244 Several stakeholders expressed a desire to allow local community groups and agencies to
245 voluntarily participate in medication take-back events held by law enforcement agencies.
246 Stakeholders expressed concern that their participation would be limited if volunteers were
247 not allowed to handle medications turned in for disposal. This Regulation allows for
248 volunteer participation in take-back events, but in compliance with the DEA rule, does not
249 allow anyone other than law enforcement officers assigned to the event to directly handle
250 controlled substances turned in for disposal. Since controlled substances may be comingled
251 with non-controlled medications and may not be easily identified as controlled substances,
252 this restriction effectively limits the handling of all medications to law enforcement officers
253 assigned to a take-back event. However, volunteers can still provide meaningful and
254 necessary support at take-back events such as producing and distributing promotional
255 materials, directing the flow of vehicles and persons, answering questions, and stocking
256 supplies.
257

258
259

260 X. Recycling of packaging turned in along with medications at take-back events
261
262 Several stakeholders expressed concern that packaging materials would unnecessarily be
263 disposed of, and increase disposal costs, if they could not be sorted out from medications
264 turned in for disposal at take-back events. Stakeholders expressed the view that sorting
265 would be impossible if only a law enforcement officers assigned to a take-back event could
266 handle medications. The Stakeholders agreed that this Regulation does not preclude the
267 development of safe and secure procedures intended to reduce the unnecessary disposal of
268 recyclable packaging materials. Such procedures could include establishing an area at an
269 event where individuals could sort out and recycle packaging material themselves or the
270 development of event promotional materials encouraging individuals to remove packaging
271 materials at home prior to the event.

272
273 XI. Collector removal of materials deposited into a collection receptacle
274
275 Some stakeholders expressed a concern that an early draft of this Regulation prohibited the
276 retrieval of inappropriate materials (e.g. syringes or Schedule I controlled substances), once
277 they are deposited into a collection receptacle and prohibited the inventorying of deposited
278 medications. The stakeholders agreed that handling of deposited items could present safety
279 issues, but this Regulation allows law enforcement agency collectors, if specifically
280 authorized by the department, to access materials deposited into a collection receptacle,
281 prior to the inner liner being sealed. The DEA rule does not disallow this activity by law
282 enforcement agency collectors, but specifically prohibits it by DEA-registrant collectors.

283
284 XII. Enforcement of this Regulation
285
286 Stakeholders questioned how this Regulation would be enforced, since no enforcement
287 authority was granted in HB 14-1207. Since collectors, transporters, and disposal locations
288 must be approved by the department to participate in the Program as described in Sections
289 23.5 and 23.6, enforcement can be enacted through revocation of their approved status.
290 Furthermore, it is understood by stakeholders and the department that education and
291 guidance will be the initial and preferred approach to promote compliance with this
292 Regulation. After promulgation of this Regulation, the department will work with
293 stakeholders to draft guidance to assist in the understanding and application of this
294 Regulation; including guidance clarifying how noncompliance with this Regulation may
295 disqualify a participant from the Program.

296
297 XIII. Waste management plan development may be burdensome and costly for law enforcement
298 agency collectors

299
300 A stakeholder expressed concern that this Regulation appears burdensome to law
301 enforcement agency collectors, particularly in regard to the required development of waste
302 management plans. The department intends to create guidance to assist Program
303 participants with implementation of this Regulation. Guidance materials will include a
304 Waste Management Plan template that can be tailored for use by all approved collectors.
305 Stakeholders will be invited to assist the department with guidance development.

306 307 Regulatory Alternatives

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309 No other regulatory alternatives were evaluated.

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311

312 Cost/Benefit Analysis

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314 A cost benefit analysis will be performed if requested by the Colorado Department of
315 Regulatory Agencies.