### LEGISLATIVE ANALYSIS AND PUBLIC POLICY ASSOCIATION

### DRUG TAKE-BACK AND DISPOSAL PROGRAMS: SUMMARY OF STATE LAWS





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# DRUG TAKE-BACK AND DISPOSAL PROGRAMS: SUMMARY OF STATE LAWS

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#### **SUMMARY**

In this document, the Legislative Analysis and Public Policy Association (LAPPA) examines state-level legislative and administrative responses to the public health risk posed by expired, unwanted, and unused prescription medications (also known as "household pharmaceutical waste"). In the last several years, states across the country have enacted legislation or adopted administrative regulations to authorize drug take-back programs where household pharmaceutical waste can be collected from the public by authorized persons or entities and disposed of in a safe and environmentally friendly manner.

Household pharmaceutical waste poses a significant public health risk, particularly for medications classified as controlled substances. Keeping expired, unused, or unwanted prescription medications in the home can lead to accidental poisoning, misuse, or overdose. According to the 2021 National Survey on Drug Use and Health, 71.7 million individuals aged 12 and older used a prescription pain reliever in the past year, with 8.7 million of those individuals reporting misuse of those drugs. For the year prior to the survey, a further 3.7 million individuals aged 12 or older reported misuse of prescription stimulants; 4.8 million reported misuse of prescription tranquilizers or sedatives; and 3.9 million reported misuse of prescription benzodiazepines. The most common source for those prescription medications was a friend or relative, with 45 percent of respondents reporting misuse of prescription pain relievers, 73 percent for stimulants, 61 percent for prescription tranquilizers, and 55 percent of respondents for prescription sedatives reporting that the prescription medications were either given by, purchased from, or stolen from a friend or relative.

Misuse of prescription medications can lead to dependence and overdose. The ongoing drug epidemic is at catastrophic levels across the nation, and its impact is devastating, with nearly 110,000 overdose deaths in the United States during the 12-month period ending February 2023.<sup>4</sup> In an effort to combat the very real public health danger that household pharmaceutical waste can pose, in September 2010, the U.S. Drug Enforcement Administration (DEA), in coordination with local law enforcement agencies, began conducting a free semi-annual National Prescription Take Back Day (Take Back Day).<sup>5</sup> These Take Back Days serve to encourage the proper disposal of controlled substance prescription medications; decrease prescription medication diversion, abuse, and accidental overdoses; and decrease environmental hazards resulting from improper disposal of prescription medications by, for example, flushing medications in the toilet or disposing of them in the trash.<sup>6</sup> As of the most recent Take Back Day

<sup>&</sup>lt;sup>1</sup> Results from the 2021 National Survey on Drug Use and Health: Detailed Tables, U.S. DEP'T OF HEALTH & HUM. SERVS., SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., Tables 1.44A and 1.45A (2022), <u>2021 NSDUH</u> Detailed Tables | CBHSQ Data (samhsa.gov).

<sup>&</sup>lt;sup>2</sup> *Id.* at Tables 1.48A, 1.51A, and 1.60A.

<sup>&</sup>lt;sup>3</sup> *Id.* at Tables 8.9B, 8.11B, 8.13B, and 8.15B.

<sup>&</sup>lt;sup>4</sup> Provisional Drug Overdose Death Counts, CTRS. FOR DISEASE CONTROL & PREVENTION, NAT'L CTR. FOR HEALTH STATISTICS (Feb. 15, 2023), https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm.

<sup>&</sup>lt;sup>5</sup> DEA Heads First-ever Nationwide Prescription Drug Take-back Day, DEP'T. OF JUST., OFF. OF PUB. AFFS. (Aug. 19, 2010), https://www.justice.gov/opa/pr/dea-heads-first-ever-nationwide-prescription-drug-take-back-day.

<sup>&</sup>lt;sup>6</sup> Jeffrey Gray, Nicholas Hagemeir, *Prescription Drug Abuse and DEA-Sanctioned Drug Take-Back Events: Characteristics and Outcomes in Rural Appalachia*. ARCH INTERN MED. (2012) 1186–1187, 1186, doi:10.1001/archinternmed.2012.2374.

in April 2023, 17,300,434 pounds of prescription medications have been collected during these events.<sup>7</sup>

Within a month of the first Take Back Day, Congress passed the Secure and Responsible Drug Disposal Act of 2010 (Disposal Act), an amendment to the Controlled Substances Act (CSA).<sup>8</sup> The Disposal Act allows the Attorney General to promulgate regulations that permit consumers to deliver household pharmaceutical waste to authorized entities for disposal.<sup>9</sup> Crucially, the Disposal Act amended the CSA to allow the recipient (*i.e.*, the "ultimate user") of a controlled substance prescription to deliver the expired, unwanted, or unused portion of that prescription medication to an authorized collector for disposal, something that was not allowed under prior federal law or regulation.<sup>10</sup>

Following passage of the Disposal Act, the DEA adopted regulations that explicitly authorize drug manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals and clinics with on-site pharmacies, and retail pharmacies to voluntarily administer mail-back programs and maintain drug take-back collection receptacles on-site for the disposal of prescription medications without the need for state authorization. <sup>11</sup> In addition, retail pharmacies and hospitals or clinics with an on-site pharmacy may also install, manage, and maintain drug take-back collection receptacles at long-term care facilities for the disposal of controlled substances on behalf of a recipient who resides in, or has resided in, the facility. <sup>12</sup>

The Disposal Act only addresses the collection and disposal of Schedule II - V controlled substances. States have the authority, without DEA authorization or regulation, to regulate the collection and disposal of non-controlled prescription and over-the-counter medications through, among other methods, state-authorized drug take-back programs, mail-back packages, and take-back events. Many states authorize the collection and disposal of both controlled and non-controlled substances through these programs and events.  $^{13}$ 

As of August 2023, 40 states have laws or regulations that specifically authorize drug take-back programs or provide mechanisms for the collection and disposal of prescription medications. <sup>14</sup> The states without specific laws or regulations permitting drug take-back programs are: Alaska, Arkansas, Delaware, Florida, Kansas, New Mexico, North Carolina, North Dakota, Oklahoma, and South Dakota, plus the District of Columbia and the U.S. territories of Guam, Puerto Rico, and the U.S. Virgin Islands. However, with the exception of the territories mentioned previously, every U.S. state and the District of Columbia have state websites related to drug take-back events and/or safe disposal of prescription medications that include a list or link to locations where residents of the state can dispose of their expired, unwanted, or unused prescription medications.

<sup>&</sup>lt;sup>7</sup> National Take Back Day Results, DRUG ENF'T ADMIN. (Apr. 2023), Take Back Day (dea.gov).

<sup>&</sup>lt;sup>8</sup> 21 U.S.C.A. §§ 822 and 822a (West 2023).

<sup>&</sup>lt;sup>9</sup> Secure and Responsible Drug Disposal Act of 2010 § 2, 21 U.S.C.A. § 822.

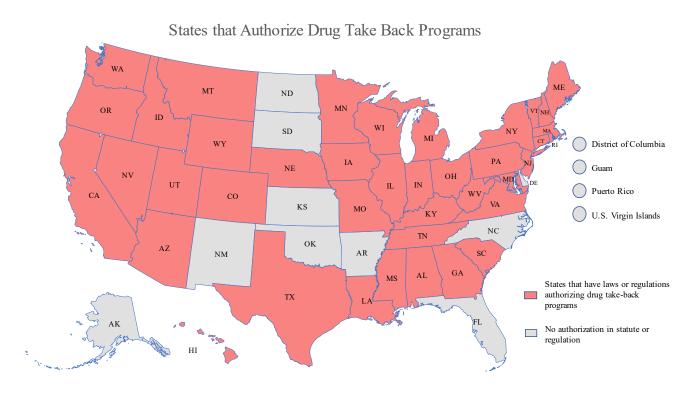
<sup>&</sup>lt;sup>10</sup> *Id.* at §§ 2 and 3.

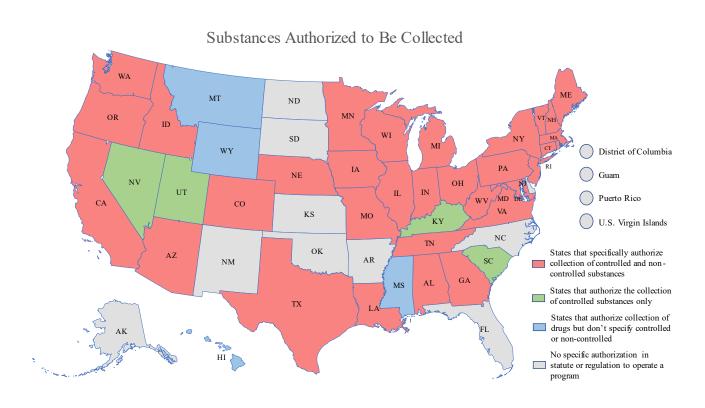
<sup>&</sup>lt;sup>11</sup> 21 C.F.R. §§ 1317.30 and 1317.4 (2023).

<sup>&</sup>lt;sup>12</sup> 21 C.F.R. § 1317.80 (2023).

<sup>&</sup>lt;sup>13</sup> See individual state charts for more information.

<sup>&</sup>lt;sup>14</sup> See individual state charts for more information.





Federal and state laws permit authorized collectors (*i.e.*, drug manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals and clinics with on-site pharmacies, and retail pharmacies) to collect household pharmaceutical waste through a variety of methods, including through permanent on-site collection receptacles, mail-back packages provided free or for a fee to consumers, at-home disposal methods that render substances "non-retrievable," and through drug take-back events. Mail-back programs and local take-back events are particularly useful in rural and other underserved areas within a state. Authorized collectors who choose to operate a take-back event must conduct such events in coordination with law enforcement.<sup>15</sup>

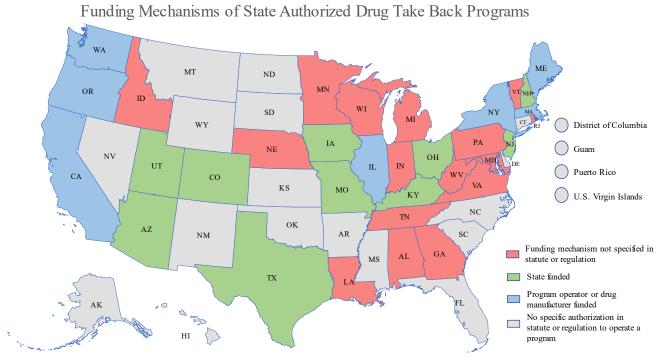
State drug take-back programs are funded through a variety of mechanisms, although most states do not specify a funding source in statute or regulation, with the inference being that the authorized collector will be responsible for all costs associated with operating a drug take-back program. Nine states (Arizona, Colorado, Iowa, Kentucky, Missouri, New Jersey, Ohio, Texas, and Utah) specifically provide that the state will fund the programs. <sup>16</sup> New Hampshire provides that funding may come from the state, grants, donations, and fees charged to individuals participating in the program. <sup>17</sup> California requires program operators to fund the drug take-back program in that state, and a further six states (Illinois, Maine, Massachusetts, New York, Oregon, and Washington) require drug manufacturers to pay the cost of administering and operating programs in those states. <sup>18</sup>

<sup>&</sup>lt;sup>15</sup> See 21 C.F.R. §§ 1317.35 and 1317.40 (2023).

<sup>&</sup>lt;sup>16</sup> See Ariz. Rev. Stat. Ann. § 36-123.01 (2023); Colo. Rev. Stat. Ann. § 25-15-328 (West 2023); Iowa Code Ann. § 155A.43 (West 2023); Ky. Rev. Stat. Ann. § 15.291 (West 2023); Mo. Ann. Stat. § 2220-2.990 (West 2023); N.J. Stat. Ann. § 24:21-55 (West 2023); Ohio Rev. Code Ann. § 109.90 (West 2023); Tex. Health & Safety Code Ann. § 442A.151 (West 2023); and Utah Code Ann. § 67-5-36 (West 2023).

<sup>&</sup>lt;sup>17</sup> N.H. REV. STAT. ANN. § 318-E:1 (2023).

<sup>&</sup>lt;sup>18</sup> See Cal. Pub. Res. Code § 42034 (West 2023); 410 Ill. Comp. Stat. Ann. 720/25 (West 2023); Me. Rev. Stat. Ann. tit. 38, § 1612 (West 2023); Mass. Gen. Laws Ann. ch. 94H, § 3 (West 2023); N.Y. Pub. Health Law § 291 (McKinney 2023); Or. Rev. Stat. Ann. § 459A.233 (West 2023); Wash. Rev. Code Ann. § 69.48.090 (West 2023).



\* New Hampshire law provides that funding may come from the state, grants, donations, and fees charged to individuals partici pating in the program.

Federal law prohibits the Drug Enforcement Administration from adopting any regulation that requires any entity to operate a drug take-back program. <sup>19</sup> However, the same restriction does not apply to states. Those states that require manufacturers and/or program operators to fund the drug take-back program also require certain entities, typically drug manufacturers, to establish drug take-back programs within the state. <sup>20</sup> Kentucky requires practitioners who dispense a controlled substance that "contains any salt, compound, derivative, or preparation of an opioid, benzodiazepine, a barbiturate, codeine, or an amphetamine" to either make available for purchase or distribute with the substance an at-home method of destruction and disposal of any unused, unwanted, or expired substance. <sup>21</sup> Connecticut and New York have bills pending that include similar provisions. <sup>22</sup> If passed, the Connecticut bill would require that every pharmacist who dispenses an opioid drug to a consumer shall also provide the patient with a free "personal opioid drug deactivation and disposal product," which means a product that is designed for personal use and enables a patient to permanently deactivate and destroy an opioid drug. <sup>23</sup> Similarly, the New York bills also require that patients be provided with personal use

<sup>&</sup>lt;sup>19</sup> 21 U.S.C.A. § 822 (2023).

<sup>&</sup>lt;sup>20</sup> See Cal. Pub. Res. Code § 42031.4 (West 2023); 410 Ill. Comp. Stat. Ann. 720/15 (West 2023); Me. Rev. Stat. Ann. tit. 38, § 1612 (West 2023); Mass. Gen. Laws Ann. ch. 94H, § 2 (West 2023); N.Y. Pub. Health Law § 291 (McKinney 2023); Or. Rev. Stat. Ann. § 459A.203 (West 2023); Wash. Rev. Code Ann. § 69.48.030 (West 2023).

<sup>&</sup>lt;sup>21</sup> Ky. REV. STAT. ANN. § 218A.170 (West 2023).

<sup>&</sup>lt;sup>22</sup> H.B. 6696, Jan. Sess. (Conn. 2023) (in committee); A.B. 5086, 246<sup>th</sup> Leg. Sess. (N.Y. 2023) (in committee); and S.B. 5738, 246<sup>th</sup> Leg. Sess. (N.Y. 2023) (in committee).

<sup>&</sup>lt;sup>23</sup> H.B. 6696, Jan. Sess. (Conn. 2023).

deactivation and disposal products.<sup>24</sup> Assembly Bill 5086 limits the requirement to opioid prescriptions, while S.B. 5738 includes all controlled substance prescriptions.<sup>25</sup>

Beginning on the following page, LAPPA examines state and federal statutes and regulations related to drug take-back and disposal programs across the country and provides jurisdiction-by-jurisdiction tables describing aspects of each law or regulation in effect as of August 10, 2023. Following those tables is a section related to pending state and federal legislation and regulations on the subject. The state tables include information regarding the following:

- Statutory or regulatory citations of drug take-back and disposal programs, if any;
- The effective date(s) of such provisions;
- Whether the state authorizes drug take-back and disposal programs by law or rule;
- Specific drug take-back program components;
- Any miscellaneous provisions related to drug disposal;
- Recently introduced legislation or regulations; and
- The jurisdiction's website, if any, related to drug take-back events and/or safe disposal of prescription medications.

NOTE: The terminology and language used in the statutory descriptions set forth in this document in the following pages are those that are used within the statutes and regulations being described. Therefore, substances might variously be called "derivatives," "compounds," and "analogs" or "analogues." Further, where terms such as "addict," "addicted," and "substance abuse" appear, that is the language used in the statute or regulation.

<sup>&</sup>lt;sup>24</sup> A.B. 5086, 246<sup>th</sup> Leg. Sess. (N.Y. 2023) and S.B. 5738, 246<sup>th</sup> Leg. Sess. (N.Y. 2023).

	FEDERAL
Statute(s) and regulation(s)	<ul> <li>21 U.S.C.A. § 822 (West 2023) (persons required to register)</li> <li>21 U.S.C.A. § 822a (West 2023) (prescription drug take back expansion)</li> <li>21 U.S.C.A. § 826 (West 2023) (production quotas for controlled substances)</li> <li>34 U.S.C.A. § 10701 (West 2023) (description)</li> <li>21 C.F.R. § 1300.01 (2023) (definitions relating to controlled substances)</li> <li>21 C.F.R. § 1300.05 (2023) (definitions relating to the disposal of controlled substances)</li> <li>21 C.F.R. § 1304.22 (2023) (records for manufacturers, distributors, dispensers, researchers, importers, exporters</li> <li>21 C.F.R. §§ 1317.05 to 1317.95 (2023) (collectively titled "Disposal")</li> </ul>
Effective date(s) of	• October 12, 2010 (§ 822)
provision(s)	• October 9, 2014 (§§ 1317.05 to 1317.95)
	• July 22, 2016 (§§ 822a, 10701)
Describe et et allem deman	• October 24, 2018 (§ 826)
Does the state allow drug take-back programs by statute/regulation?	Yes.
Program components	§ 822 – (g) an ultimate user who has lawfully obtained a controlled substance in accordance with this section may, without being registered, deliver the controlled substance to another person for the purpose of disposal of the controlled substance if:  (a) the person receiving the controlled substance is authorized under this section to engage in such activity; and (b) the disposal takes place in accordance with regulations issued by the Attorney General to prevent diversion of controlled substances.
	In developing regulations under this section, the Attorney General shall take into consideration the public health and safety, as well as the ease and cost of program implementation and participation by various communities. Such regulations may not require any entity to establish or operate a delivery or disposal program.
	The Attorney General may, by regulation, authorize long-term care facilities to dispose of controlled substances on behalf of ultimate users who reside, or have resided, at such long-term care facilities in a manner that the Attorney General determines will provide effective controls against diversion and be consistent with the public health and safety.

### **Program components** (continued)

If a person dies while lawfully in possession of a controlled substance for personal use, any person lawfully entitled to dispose of the decedent's property may deliver the controlled substance to another person for the purpose of disposal under the same conditions as provided in this section for an ultimate user.

§ 822a – definition of "covered entity," which means a state, local, or tribal law enforcement agency; a manufacturer, distributor, or reverse distributor of prescription medications; a retail pharmacy; a registered narcotic treatment program; a hospital or clinic with an onsite pharmacy; an eligible long-term care facility; or any other entity authorized by the Drug Enforcement Administration (DEA) to dispose of prescription medications.

The Attorney General, in coordination with the Administrator of the DEA, the Secretary of Health and Human Services, and the Director of the Office of National Drug Control Policy, shall coordinate with covered entities in expanding or making available disposal sites for unwanted prescription medications.

§ 1300.01 – definitions include "collection," which means to receive a controlled substance for the purpose of destruction from an ultimate user, a person lawfully entitled to dispose of an ultimate user decedent's property, or a long-term care facility on behalf of an ultimate user who resides or has resided at that facility. The term "collector" means a registered manufacturer, distributor, reverse distributor, narcotic treatment program, hospital or clinic with an on-site pharmacy, or retail pharmacy that is authorized under this chapter to so receive a controlled substance for the purpose of destruction.

#### § 1300.05 – definitions include:

"non-retrievable," which means, for the purpose of destruction, the condition or state to which a controlled substance shall be rendered following a process that permanently alters that controlled substance's physical or chemical condition or state through irreversible means and thereby renders the controlled substance unavailable and unusable for all practical purposes. A controlled substance is considered "non-retrievable" when it cannot be transformed to a physical or chemical condition or state as a controlled

# Program components (continued)

- substance or controlled substance analogue. The purpose of destruction is to render the controlled substance(s) to a non-retrievable state and thus prevent diversion of any such substance to illicit purposes; and
- "on-site," which means located on or at the physical premises of the registrant's registered location. A controlled substance is destroyed on-site when destruction occurs on the physical premises of the destroying registrant's registered location. A hospital or clinic has an on-site pharmacy when it has a pharmacy located on the physical premises of the registrant's registered location.

§ 1304.22 – (e) records for registrants that reverse distribute. Each person registered or authorized to reverse distribute controlled substances shall maintain records with the following information for each controlled substance:

For each sealed inner liner acquired from collectors or law enforcement and each sealed mail-back package acquired from law enforcement pursuant to § 1317.55 of this chapter:

- (1) the number of sealed inner liners acquired from other persons, including the date of acquisition, the number and, for sealed inner liners the size, of all sealed inner liners and mailback packages acquired to inventory, the unique identification number of each sealed inner liner and mail-back package, and the name, address, and, for registrants, the registration number of the person from whom the sealed inner liners and mail-back packages were received; and
- (2) the date, place, and method of destruction; the number of sealed inner liners and mail-back packages destroyed; the name, address, and, for registrants, the registration number of the person from whom the sealed inner liners and mail-back packages were received; the number and, for sealed inner liners the size, of all sealed inner liners and mail-back packages destroyed; the unique identification number of each sealed inner liner and sealed mail-back package destroyed; and the names and signatures of the two employees of the registrant that witnessed the destruction.
- (f) records for collectors. Each person registered or authorized to collect controlled substances from ultimate users shall maintain the following records:

### **Program components** (continued)

Mail-back packages:

- (1) for unused packages that the collector makes available to ultimate users and other authorized non-registrants at the collector's registered address: the date made available, the number of packages, and the unique identification number of each package;
- (2) for unused packages provided to a third party to make available to ultimate users and other authorized non-registrants: the name of the third party and physical address of the location receiving the unused packages, date sent, and the number of unused packages sent with the corresponding unique identification numbers;
- (3) for sealed mail-back packages received by the collector: date of receipt and the unique identification number on the individual package; and
- (4) for sealed mail-back packages destroyed on-site by the collector: number of sealed mail-back packages destroyed, the date and method of destruction, the unique identification number of each mail-back package destroyed, and the names and signatures of the two employees of the registrant who witnessed the destruction.

#### Collection receptacle inner liners:

- (1) date each unused inner liner acquired, unique identification number, and size of each unused inner liner acquired;
- (2) date each inner liner is installed, the address of the location where each inner liner is installed, the unique identification number and size of each inner liner installed, the registration number of the collector, and the names and signatures of the two employees that witnessed each installation;
- (3) date each inner liner is removed and sealed, the address of the location from which each inner liner is removed, the unique identification number and size of each inner liner removed, the registration number of the collector, and the names and signatures of the two employees that witnessed each removal;
- (4) date each sealed inner liner is transferred to storage, the unique identification number and size of each sealed inner liner stored, and the names and signatures of the two

# Program components (continued)

- employees that transferred each sealed inner liner to storage;

  (5) date each sealed inner liner is transferred for destruction, the address and registration number of the reverse distributor or distributor to whom each sealed inner liner was transferred, the unique identification number and the size of each sealed inner liner transferred, and the names and signatures of the two employees that transferred each sealed inner liner to the reverse distributor or distributor; and
- (6) for sealed inner liners destroyed on-site by the collector, the date, place, and method of destruction; the number of sealed inner liners and mail-back packages destroyed; the name, address, and, for registrants, the registration number of the person from whom the sealed inner liners and mail-back packages were received; the number and, for sealed inner liners the size, of all sealed inner liners and mail-back packages destroyed; the unique identification number of each sealed inner liner and sealed mail-back package destroyed; and the names and signatures of the two employees of the registrant that witnessed the destruction.

§ 1317.05 (registrant disposal) – (c) any collector in lawful possession of a controlled substance acquired by collection from an ultimate user or other authorized non-registrant person shall dispose of that substance in the following ways:

- (1) mail-back program. Upon receipt of a sealed mail-back package, the collector shall promptly: (a) destroy the package; or (b) securely store the package and its contents at the collector's registered location in a manner consistent with this chapter, or in a manner consistent with the security requirements for Schedule II controlled substances until prompt on-site destruction can occur;
- (2) collection receptacles. Upon removal from the permanent outer container, the collector shall seal it and promptly: (a) destroy the sealed inner liner and its contents; (b) securely store the sealed inner liner and its contents at the collector's registered location in a manner consistent with this chapter until prompt destruction can occur; or (c) securely store the sealed inner liner and its contents at a long-term care facility;
- (3) practitioner methods of destruction. Collectors that are practitioners (i.e., retail pharmacies and hospitals/clinics) shall dispose of sealed inner liners and their contents by utilizing

### Program components (continued)

- and method in this section, or by delivering sealed inner liners and their contents to a distributor's registered location by common or contract carrier pick-up or by distributor pick-up at the collector's authorized collection location; and
- (4) non-practitioner methods of destruction. Collectors that are non-practitioners (i.e., manufacturers, distributors, narcotic treatment programs, and reverse distributors) shall dispose of sealed inner liners and their contents by utilizing any method in this section, or by delivering sealed inner liners and their contents to a distributor's registered location by common or contract carrier or by distributor pick-up at the collector's authorized collection location for destruction. Freight forwarding facilities may not be utilized to transfer sealed inner liners and their contents.

§ 1317.15 (reverse distributor registration requirements and authorized activities) – any person that reverse distributes a controlled substance shall be registered with the administration as a reverse distributor, unless exempted by law or otherwise authorized pursuant to this chapter.

A reverse distributor shall acquire controlled substances from a registrant in the following manner:

- (1) pick-up controlled substances from a registrant at the registrant's registered location or authorized collection site; or
- (2) receive controlled substances delivered by common or contract carrier or delivered directly by a non-practitioner registrant. Delivery to the reverse distributor by an authorized registrant directly or by common or contract carrier may only be made to the reverse distributor at the distributor's registered location. Once en route, such deliveries may not be re-routed to any other location or person, regardless of registration status. All controlled substance deliveries shall be personally received by an employee of the reverse distributor at the registered location.

Upon acquisition of a controlled substance by delivery or pick-up, a reverse distributor shall:

- (1) immediately store the controlled substance at the reverse distributor's registered location or immediately transfer the

# Program components (continued)

controlled substance to the reverse distributor's registered location for secure storage until timely destruction or prompt return of the controlled substance to the registered manufacturer or other registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf;

- (2) promptly deliver the controlled substance to the manufacturer or another registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf; or
- (3) timely destroy the controlled substance in a manner authorized by law.

A reverse distributor shall destroy or cause the destruction of any controlled substance received for the purpose of destruction no later than 30 calendar days after receipt.

§ 1317.30 (authorization to collect from non-registrants) – the following persons are authorized to collect controlled substances from ultimate users and other non-registrants for destruction in compliance with this chapter: (a) any registrant authorized by the administration to be a collector pursuant to § 1317.40; and (b) federal, state, tribal, or local law enforcement when in the court of official duties and pursuant to § 1317.35.

The following non-registrant persons in lawful possession of a Schedule II - V controlled substance may transfer that substance to the authorized persons listed above, and in a manner authorized by this part, for the purpose of disposal:

- (1) an ultimate user in lawful possession of a controlled substance:
- (2) any person lawfully entitled to dispose of a decedent's property if that decedent was an ultimate user who died while in lawful possession of a controlled substance; and
- (3) a long-term care facility on behalf of an ultimate user who resides or resided at such long-term care facility and is/was in lawful possession of a controlled substance, in accordance with § 1317.80 only.

§ 1317.35 (collection by law enforcement) – federal, state, tribal, or local law enforcement may collect controlled substances from ultimate users and persons lawfully entitled to dispose of an

### **Program components** (continued)

ultimate user decedent's property using the following collection methods: (1) take-back events; (2) mail-back programs; or (3) collection receptacles located inside law enforcement's physical address.

Law enforcement that conducts a take-back event or a mail-back program or maintains a collection receptacle should maintain any records of removal, storage, or destruction of the controlled substances collected in a manner that is consistent with that agency's recordkeeping requirements for illicit controlled substances evidence.

Any controlled substances collected by law enforcement through a take-back event, mail-back program, or collection receptacle should be stored in a manner that prevents the diversion of controlled substances and is consistent with that agency's standard procedures for storing illicit controlled substances.

Any controlled substances collected by law enforcement through a take-back event, mail-back program, or collection receptacle should be transferred to a destruction location in a manner that prevents the diversion of controlled substances and is consistent with that agency's standard procedures for transferring illicit controlled substances.

Law enforcement that transfers controlled substances collected from ultimate users pursuant to this part to a reverse distributor for destruction should maintain a record that contains the following information:

- (1) if a sealed inner liner is used, the unique identification number of the sealed inner liner transferred, and the size of the sealed inner liner transferred;
- (2) if a mail-back package is used, the unique identification number of each package;
- (3) the date of the transfer; and
- (4) the name, address, and registration number of the reverse distributor to whom the controlled substances were transferred.

§ 1317.40 (registrants authorized to collect and authorized collection activities) – manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals and clinics

# Program components (continued)

with an on-site pharmacy, and retail pharmacies that desire to be collectors shall modify their registration to obtain authorization to be a collector. Authorization to be a collector is subject to renewal. If a registrant that is authorized to collect ceases activities as a collector, such registrant shall notify the administration in accordance with regulation.

Collection by registrants shall occur only at the following locations:

- (1) those registered locations of manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals and clinics with an on-site pharmacy, and retail pharmacies that are authorized for collection; and
- (2) long-term care facilities at which registered hospitals and clinics or retail pharmacies are authorized to maintain collection receptacles.

Collectors may conduct the following activities:

- (1) receive and destroy mail-back packages at an authorized registered location that has an on-site method of destruction;
- (2) install, manage, and maintain collection receptacles located at their authorized collection location(s); and
- (3) promptly dispose of sealed inner liners and their contents as provided for in § 1317.05.

§ 1317.55 (reverse distributor and distributor acquisition of controlled substances from collectors or law enforcement) – a reverse distributor is authorized to acquire controlled substances from law enforcement that collected the substances from ultimate users. A reverse distributor is authorized to acquire controlled substances through a collection receptacle in accordance with §§ 1317.75 and 1317.80.

A distributor is authorized to acquire controlled substances through a collection receptacle in accordance with §§ 1317.75 and 1317.80.

A reverse distributor or a distributor that acquires controlled substances in accordance with this section shall:

### Program components (continued)

- (1) acquire the controlled substances in the manner authorized for reverse distributors;
- (2) dispose of the controlled substances in the manner authorized for reverse distributors; and
- (3) securely store the controlled substances in a manner consistent with the security requirements for Schedule II controlled substances until timely destruction can occur.

§ 1317.60 (inner liner requirements) – an inner liner shall meet the following requirements:

- (1) the inner liner shall be waterproof, tamper-evidence, and tear-resistant;
- (2) the inner liner shall be removable and sealable immediately upon removal without emptying or touching the contents;
- (3) the contents of the inner liner shall not be viewable from the outside when sealed:
- (4) the size of the inner liner shall be clearly marked on the outside of the liner; and
- (5) the inner liner shall bear a permanent, unique identification number that enables the inner liner to be tracked.

Access to the inner liner shall be restricted to employees of the collector. The inner liner shall be sealed by two employees immediately upon removal from the permanent outer container and the sealed inner liner shall not be opened, x-rayed, analyzed, or otherwise penetrated.

§ 1317.65 (take-back events) – federal, state, tribal, or local law enforcement may conduct a take-back event and collect controlled substances from ultimate users and persons lawfully entitled to dispose of an ultimate user decedent's property in accordance with this section. Any person may partner with law enforcement to hold a collection take-back event in accordance with this section.

Law enforcement shall appoint a law enforcement officer employed by the agency to oversee the collection. Law enforcement officers employed and authorized by the law enforcement agency or law enforcement component of a federal agency conducting a take-back event shall maintain control and custody of the controlled substances from the time the substances

### **Program components** (continued)

are collected from the ultimate user or person authorized to dispose of the ultimate user decedent's property until secure transfer, storage, or destruction of the controlled substances has occurred.

Each take-back event should have at least one receptacle for the collection of controlled substances. The receptacle should be a securely locked, substantially constructed container with an outer container and a removable inner liner as specified in § 1317.60 of this chapter. The outer container should include a small opening that allows contents to be added to the inner liner, but that does not allow removal of the inner liner's contents.

Only those controlled substances listed in Schedules II - V that are lawfully possessed by an ultimate user or a person entitled to dispose of an ultimate user decedent's property may be collected. Controlled and non-controlled substances may be collected together be comingled, although comingling is not required.

Only ultimate users and persons entitled to dispose of an ultimate user decedent's property in lawful possession of a Schedule II - V controlled substance may transfer such substances to law enforcement during the take-back event. No other person may handle the controlled substances at any time.

§ 1317.70 (mail-back programs) – a mail-back program may be conducted by federal, state, tribal, or local law enforcement or any collector. A collector conducting a mail-back program shall have and utilize at their registered location a method of destruction consistent with § 1317.90 of this chapter.

Only those controlled substances listed in Schedules II - V that are lawfully possessed by an ultimate user or person lawfully entitled to dispose of an ultimate user decedent's property may be collected. Controlled and non-controlled substances may be collected together and comingled, although comingling is not required.

Collectors or law enforcement that conduct a mail-back program shall make packages available, for sale or for free, as specified in this paragraph to ultimate users and persons lawfully entitled to dispose of an ultimate user decedent's property, for the collection

### Program components (continued)

of controlled substances by common or contract carrier. Any person may partner with a collector or law enforcement to make such packages available in accordance with this section. The packages made available shall meet the following specifications:

- (1) the package shall be nondescript and shall not include any markings or other information that might indicate that the package contains controlled substances;
- (2) the package shall be water- and spill-proof, tamperevident, tear-resistant, and sealable;
- (3) the package shall be pre-addressed with and delivered to the collector's registered address or the participating law enforcement's physical address;
- (4) the cost of shipping the package shall be postage paid;
- (5) the package shall have a unique identification number that enables the package to be tracked; and
- (6) the package shall include instructions for the user that indicate the process for mailing back the package, the substances that can be sent, notice that packages may only be mailed from within the customs territory of the United States, and notice that only packages provided by the collector will be accepted for destruction.

Ultimate users and persons lawfully entitled to dispose of an ultimate user decedent's property shall not be required to provide any personally identifiable information when mailing back controlled substances to a collector. The collector or law enforcement may implement a system that allows ultimate users or persons lawfully entitled to dispose of an ultimate user decedent's property to notify the collector or law enforcement that they are sending one of the designated packages by giving the unique identification number on the package.

A collector that conducts a mail-back package program shall:

- (1) accept only those controlled substances contained within packages that the collector made available for the collection of controlled substances by mail and packages that are lawfully forwarded to the collector;
- (2) within three business days of receipt, notify the Field Division Office of the administration in their area of the receipt of a package that likely contains controlled substances

### Program components (continued)

that the collector did not make available or did not agree to receive;

- (3) when discontinuing activities as a collector or ceasing an authorized mail-back program: (a) make a reasonable effort to notify the public prior to discontinuing such activities or ceasing the authorized mail-back program; and (b) obtain the written agreement of another collector that has and utilizes at its registered location a method of destruction consistent with § 1317.90 of this chapter to receive all remaining mail-back packages that were disseminated but not returned and arrange for the forwarding of only such packages to that location.

Only law enforcement officers employed by the law enforcement agency or law enforcement component of a federal agency and employees of the collector shall handle packages received through an authorized mail-back program. Upon receipt of a mail-back package by a collector conducting a mail-back program, the package shall not be opened, x-rayed, analyzed, or otherwise penetrated.

§ 1317.75 (collection receptacles) – collectors or federal, state, tribal, or local law enforcement may manage and maintain collection receptacles for disposal. Only those Schedule II – V controlled substances that are lawfully possessed by an ultimate user or other authorized non-registrant person may be collected. Controlled and non-controlled substances may be collected together and be comingled, although comingling is not required.

Collectors shall only allow ultimate users and other authorized non-registrant persons in lawful possession of a Schedule II - V controlled substance to deposit such substances in a collection receptacle at a registered location. Collectors shall not permit an ultimate user to transfer such substance to any person for any reason. Once a substance has been deposited into a collection receptacle, the substance shall not be counted, sorted, inventoried, or otherwise individually handled.

Collection receptacles shall be securely placed and maintained:

- (1) inside a collector's registered location, inside law enforcement's physical location, or at an authorized long-term care facility;

### Program components (continued)

- (2) at a registered location, be located in the immediate proximity of a designated area where controlled substances are stored at which an employee is present. Except as follows:

(a) at a hospital/clinic – a collection receptacle shall be located in an area regularly monitored by employees, and shall not be located in the proximity of any area where emergency or urgent care is provided; (b) at a narcotic treatment program – a collection receptacle shall be located in a room that does not contain any other controlled substances and is securely locked with controlled access; and (c) at a long-term care facility – a collection receptacle shall be located in a secured area regularly monitored by long-term care facility employees.

A controlled substance collection receptacle shall meet the following design specifications:

- (1) be securely fastened to a permanent structure so that it cannot be removed:
- (2) be a securely locked, substantially constructed container with a permanent outer container and a removable inner liner;
- (3) the outer container shall include a small opening that allows contents to be added to the inner liner, but does not allow removal of the inner liner's contents; and
- (4) the outer container shall prominently display a sign indicating that only Schedule II V controlled and non-controlled substances, if a collector chooses to comingle substances, are acceptable substances.

Except at a narcotic treatment program, the small opening in the outer container of the collection receptacle shall be locked or made otherwise inaccessible to the public when an employee is not present, or when the collection receptacle is not being regularly monitored by long-term care facility employees.

The installation and removal of the inner liner of the collection receptacle shall be performed by or under the supervision of at least two employees of the authorized collector.

§ 1317.80 (collection receptacles at long-term care facilities) – a long-term care facility may dispose of Schedule II – V controlled substances on behalf of an ultimate user who resides, or has resided, at such facility by transferring those controlled substances into an authorized collection receptacle located at that

# Program components (continued)

facility. When disposing of such controlled substances by transferring those substances into a collection receptacle, such disposal shall occur immediately, but no longer than three business days after the discontinuation of use by the ultimate user. Discontinuation of use includes a permanent discontinuation of use as directed by a prescriber, as a result of the resident's transfer from the long-term care facility, or as a result of death.

Only authorized retail pharmacies and hospitals/clinics with an on-site pharmacy may install, manage, and maintain collection receptacles at long-term care facilities and remove, seal, transfer, and store, or supervise the removal, sealing, transfer, and storage of sealed inner liners at long-term care facilities. Collectors authorized to install, manage, and maintain collection receptacles at long-term care facilities shall comply with all requirements of this chapter.

The installation, removal, transfer, and storage of inner liners shall be performed either by or under the supervision of one employee of the authorized collector and one supervisor-level employee of the long-term care facility designated by the authorized collector; or by, or under the supervision of, two employees of the authorized collector.

Upon removal, sealed inner liners may only be stored at the long-term care facility for up to three business days in a securely locked, substantially constructed cabinet, or a securely locked room with controlled access until transfer in accordance with § 1317.05.

Neither a hospital/clinic with an on-site pharmacy nor a retail pharmacy shall operate a collection receptacle at a long-term care facility until its registration has been modified in accordance with this chapter.

§ 1317.90 (methods of destruction) – all controlled substances to be destroyed by a registrant, or caused to be destroyed by a registrant, shall be destroyed in compliance with applicable federal, state, tribal, and local laws and regulations and shall be rendered non-retrievable.

Where multiple controlled substances are comingled, the method of destruction shall be sufficient to render all such controlled

### **Program components** (continued)

substances non-retrievable. When the actual substances collected for destruction are unknown but may reasonably include controlled substances, the method of destruction shall be sufficient to render non-retrievable any controlled substance likely to be present. The method of destruction shall be consistent with the purpose of rendering all controlled substances to a non-retrievable state in order to prevent diversion of any such substance to illicit purposes and to protect the public health and safety.

§ 1317.95 (destruction procedures) – the destruction of any controlled substance shall be in accordance with the following requirements:

- (1) transfer to a person registered or authorized to accept controlled substances for the purpose of destruction. If the controlled substances are transferred to a person registered or authorized to accept the controlled substances for the purpose of destruction, two employees of the transferring registrant shall load and unload or observe the loading and unloading of any controlled substances until transfer is complete;
- (2) transport to a registered location. If the controlled substances are transported by a registrant to a registered location for subsequent destruction, the following procedures shall be followed: (a) transportation shall be directly to the registered location; (b) two employees of the transporting registrant shall accompany the controlled substances to the registered location; and (c) two employees of the transporting registrant shall load and unload or observe the loading and unloading of the controlled substances until transfer is complete;
- (3) transport to a non-registered location. If the controlled substances are transported by a registrant to a destruction location that is not a registered location, the following procedures shall be followed: (a) transportation shall be directly to the destruction location; (b) two employees of the transporting registrant shall accompany the controlled substances to the destruction location; (c) two employees of the transporting registrant shall load and unload or observe the loading and unloading of the controlled substances; (d) two employees of the transporting registrant shall handle or observe the handling of any controlled substance until the substance is rendered non-retrievable; and (e) two employees

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Program components (continued)	of the transporting registrant shall personally witness the destruction of the controlled substance until it is rendered non-retrievable;  - (4) on-site destruction. If the controlled substances are destroyed at a registrant's registered location utilizing an on-site method of destruction, the following procedures shall be followed: (a) two employees of the registrant shall handle or observe the handling of any controlled substance until the substance is rendered non-retrievable; and (b) two employees of the registrant shall personally witness the destruction of the controlled substance until it is rendered non-retrievable.
Miscellaneous provisions	§ 826 – (i)(3) not later than one year after October 24, 2018, the Attorney General shall submit to Congress a report on how the Attorney General, when fixing and adjusting production and manufacturing quotas under this section for covered controlled substances will work with the Secretary of Health and Human Services on methods to appropriately and anonymously estimate the type and amount of covered controlled substances that are submitted for collection from approved drug collection receptacles, mail-back programs, and take-back events.
	subchapter, the Attorney General may make grants to states, units of local government, and Indian tribes, for use by the state, unit of local government, or Indian tribe to provide services primarily relating to opioid abuse, including for any one or more of the listed items, including for developing, implementing, or expanding a prescription drug take-back program.
Recently proposed legislation	None.
Program website	Take Back Day (dea.gov)

	<u>ALABAMA</u>
Statute(s) and regulation(s)	ALA. ADMIN. CODE r. 680-X-242 (West 2023) (requirements for the disposal of prescription drugs by pharmacies collected from ultimate user(s) or person(s) entitled to dispose of drugs)
Effective date(s) of provision(s)	November 25, 2013
Does the state allow drug take-back programs by statute/regulation?	Yes.
Program components	680-X-242 – this rule only applies to the collection and disposal of prescription drugs by pharmacies returned or received from an ultimate user or a person entitled to dispose of prescription drugs.  For purposes of this rule, an ultimate user is a person who has lawfully obtained and who possesses the controlled substance for his own use or for the use of a member of his household, including an animal. A person entitled to dispose of prescription drugs is one lawfully entitled to dispose of a decedent's property if that decedent was an ultimate user who died while in possession of prescription drugs.  Any pharmacy that intends to receive, collect, and dispose of controlled substances shall submit to the board the necessary authorization to be a collector issued by the U.S. Drug Enforcement Administration within 10 days of the receipt thereof. In the event a pharmacy ceases to be a collector, the board shall be notified in the same manner as required by the applicable federal rule or regulation.  Any pharmacy that also intends to receive, collect, and dispose of non-controlled prescription drugs shall notify the board at the same time of the submission of the authorization referenced above, and shall also notify the board if the pharmacy ceases such
Miscallaneous provisions	activities. None.
Miscellaneous provisions Recently proposed	None.
legislation	TVOIIC.
Program website	Medication Disposal Resources

	<u>ALASKA</u>
Statute(s) and regulation(s)	None.
Effective date(s) of provision(s)	N/A
Does the state allow drug take-back programs by statute/regulation?	No.
Program components	N/A
Miscellaneous provisions	None.
Recently proposed legislation	None.
Program website	Prescription and Veterinary Medicine Disposal

	ADIZONA
	<u>ARIZONA</u>
Statute(s) and regulation(s)	<ul> <li>ARIZ. REV. STAT. ANN. § 9-500.45 (2023) (drug disposal programs; business assessments prohibited; restrictions; state preemption; definition)</li> <li>ARIZ. REV. STAT. ANN. § 11-269.26 (2023) (drug disposal programs; business assessments prohibited; restrictions; state preemption; definition)</li> <li>ARIZ. REV. STAT. ANN. § 36-123.01 (2023) (drug disposal education and awareness; controlled substances; public-private partnership; fund)</li> </ul>
Effective date(s) of provision(s)	August 3, 2018 (§§ 9-500.45, 11-269.26, and 36-123.01)
Does the state allow drug take-back programs by statute/regulation?	Yes.
Program components	§ 9-500.45 – (A) a city or town may not: (1) impose a tax, fee, assessment, or charge on any consumer or owner or operator of a business to pay for or support a drug disposal program in the city's or town's jurisdiction; or (2) require an owner or operator of a business to establish, pay for, or operate a drug disposal program in the city's or town's jurisdiction.  (B) Subsection (A) does not prohibit a city or town from using other general fund monies for the purpose of operating a drug disposal program.
	(C) The establishment or regulation of a drug disposal program by an owner or operator of a business that complies with state and federal law and rules adopted pursuant to those laws is a matter of statewide concern and is not subject to further regulation by a city or town.
	(D) For purposes of this section, "drug disposal program" means a program to collect, transport, or dispose of prescription drugs, including controlled substances, nonprescription drugs, needles, or sharps that are no longer wanted by the owner or that have been abandoned or discarded or are intended to be abandoned or discarded by the owner.
	§ 11-269.26 – (A) a county may not: (1) impose a tax, fee, assessment, or charge on any consumer or owner or operator of a business to pay for or support a drug disposal program in the county's jurisdiction; or (2) require an owner or operator of a

#### **ARIZONA**

### Program components (continued)

business to establish, pay for, or operate a drug disposal program in the county's jurisdiction.

- (B) The establishment or regulation of a drug disposal program by an owner or operator of a business that complies with state and federal law and rules adopted pursuant to those laws is a matter of statewide concern and is not subject to further regulation by a county.
- (C) This section does not prohibit the board of supervisors of a county from complying with the requirements of § 11-269.20 relating to establishing at least one location in the county for the drop off of any legal or illegal drug or substance and drug paraphernalia.
- (D) For purposes of this section, "drug disposal program" means a program to collect, transport, or dispose of prescription drugs, including controlled substances, nonprescription drugs, needles, or sharps that are no longer wanted by the owner or that have been abandoned or discarded or are intended to be abandoned or discarded by the owner.
- § 36-123.01 on or before January 1, 2019, the department shall enter into a public-private partnership to develop an education and awareness program regarding the disposal of prescription drugs, including controlled substances, nonprescription drugs, needles, and sharps. The education and awareness program may include:
- (1) A web-based resource that: (a) describes available drug disposal options, including drug disposal take-back sites, drug disposal take-back events, in-home drug disposal options that render products safe from misuse, and any other method that complies with state and federal laws and the rules adopted pursuant to those laws; (b) may reduce the availability of unused controlled substances and may minimize the potential environmental impact of drug disposal options; (c) provides a list of drug disposal take-back sites that may be sorted and searched by name or location; (d) provides a list of drug disposal take-back events in this state, including the date, time and location information for each event; and (e) describes appropriate disposal methods for needles and sharps and location sites providing for disposal of needles and sharps.

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	<u>ARIZONA</u>
Program components (continued)	- (2) Educational activities designed to ensure consumer awareness of the safe storage and effective disposal of prescription drugs, including controlled substances, and nonprescription drugs.
	Establishes the drug disposal education and awareness fund which consists of monies donated or contributed to the fund by private persons or organizations. The department shall administer the fund. Monies in the fund shall be used to pay for the costs of administering the education and awareness program established pursuant to this section.
Miscellaneous provisions	None.
Recently proposed legislation	None.
Program website	Prescription Drug Disposal   ADEQ Arizona Department of Environmental Quality

<u>ARKANSAS</u>	
Statute(s) and regulation(s)	016.26.4 ARK. CODE R. § 6 (2023) (reporting requirements)
Effective date(s) of provision(s)	January 1, 2021
Does the state allow drug take-back programs by statute/regulation?	No.
Program components	N/A
Miscellaneous provisions	§ 6 – requires drug task forces to provide monthly or quarterly statistical data and submit such reports to the Drug Director's Office and the DFA—IGS. The reports shall include, among other things, the number of prescription drugs – prescription take-back collected in pounds.
Recently proposed legislation	None.
Program website	Drug Take-Back Guide Arkansas Takeback

	L. CIV. CODE § 1714.24 (West 2023) (collector maintaining
	L. CIV. CODE § 1714.24 (West 2023) (collector maintaining
• CA	decure drug take-back bin; civil or criminal liability; requirements for immunity)  L. HEALTH & SAFETY CODE § 443.20 (West 2023) (disposal of unused aid-in-dying drugs)  L. PUB. RES. CODE §§ 42030 to 42036.4 (West 2023) (collectively titled "Pharmaceutical and Sharps Waste Stewardship")  L. CODE REGS. tit. 14, §§ 18972.1 to 18975.2 (2023) (collectively titled "Pharmaceutical and Sharps Waste Stewardship Program")  L. CODE REGS. tit. 16, §§ 1776 to 1776.6 (2023) (collectively itled "Prescription Drug Take-back Services")
Effective date(s) of provision(s)  • Jun • Jun • Jun • Jun	ne 9, 2016 (§ 443.20) nuary 1, 2017 (§ 1714.24) ne 6, 2017 (16, §§ 1776 to 1776.6) nuary 1, 2019 (§§ 42030 to 42036.4) nuary 7, 2021 (14, §§ 18972.1 to 18975.2)
Does the state allow drug take-back programs by statute/regulation?	
(b) A not b pros main the coof the	14.24 – (a) includes definitions for certain terms including: collector," which means only those entities authorized by and registered with the federal Drug Enforcement Administration to receive a controlled substance for the purpose of destruction, if the entity is in good standing with any applicable licensing authority; shome-generated pharmaceutical waste," which means a charmaceutical that is no longer wanted or needed by the consumer and includes any delivery system, such as pills, iquids, and inhalers; and secure drug take-back bin," which means a receptacle as described in 21 C.F.R. § 1317.75.  Any collector that maintains a secure drug take-back bin shall be liable in a civil action, or be subject to criminal ecution, for any injury or harm that results from the collector stain a secure drug take-back bin on its premises provided that collector, not for compensation, acts in good faith to take all the following steps to ensure the health and safety of sumers and employees and the proper disposal in the waste

#### **CALIFORNIA**

# Program components (continued)

the collector's gross negligence or willful and wanton misconduct:

- (1) complies with all applicable state and federal laws and regulations relating to the collection and disposal of homegenerated pharmaceutical waste;
- (2) notifies local law enforcement and any local environmental health department as to the existence and location of any secure drug take-back bin on the collector's premises and the status of the collector's registration as a collector with the federal Drug Enforcement Administration;
- (3) ensures that the secure drug take-back bin is placed in a location that is regularly monitored by employees of the collector;
- (4) ensures that conspicuous signage is posted on the secure drug take-back bin that clearly notifies customers as to what controlled and noncontrolled substances are and are not acceptable for deposit into the bin, as well as the hours during which collection is allowed;
- (5) ensures that public access to the secure drug take-back bin is limited to hours in which employees of the registered collector are present and able to monitor the operation of the secure drug take-back bin;
- (6) regularly inspects the area surrounding the bin for potential tampering or diversion and such inspections shall be logged in writing;
- (7) notifies local law enforcement authorities of any suspected or known tampering, theft, or significant loss of controlled substances, within one business day of discovery; and
- (8) notify local law enforcement as to any decision to discontinue its voluntary collection of controlled substances.
- (c) Nothing in this section requires an entity that may qualify as a collector to acquire, maintain, or make available to the public a secure drug take-back bin on its premises.

§ 42030 (definitions) – includes definitions for terms including:

- "authorized collection site," which means a location where an authorized collector operates a secure collection receptacle for collecting covered products;
- "authorized collector" means a person or entity that has entered into an agreement with a program operator to collect covered drugs including, but not limited to, any of the following: (1) a person or entity registered with the U.S. Drug

#### **CALIFORNIA**

# Program components (continued)

- Enforcement Administration and that qualifies under federal law to modify that registration to collect controlled substances for the purpose of destruction; (2) a law enforcement agency; or (3) a retail pharmacy that offers drug take-back services in compliance with California regulations;
- "covered drug," which means a drug sold, offered for sale, or dispensed in California in any form, including, but not limited to prescription and nonprescription drugs, a drug marketed pursuant to an over-the-counter drug monograph, and a drug in a medical device. It does not include vitamins or supplements; herbal-based remedies and homeopathic drugs, products or remedies; cosmetics, soap, laundry detergent, and other personal care products; a drug for which a pharmaceutical product stewardship program or drug take-back program is provided in the state as part of a managed risk evaluation and mitigation strategy; biological drug products; a medical device if it does not contain a covered drug; drugs that are used for animal medicines, including, but not limited to, parasiticide products for animals; and drugs required to perform kidney dialysis;
- "covered entity," which means: (1) the manufacturer of covered products that are sold in or into the state; or (2) if no entity meets that definition, the distributor of covered products that are sold into or into the state; or (3) if no entity meets that definition, then it means a repackager of covered products sold in or into the state; or (4) if no entity meets that definition, the owner or licensee of a trademark or brand under which covered products are sold in or into the state, regardless of whether the trademark is registered; or (5) if no entity meets that definition, it means the importer of the covered products that are sold in or into the state;
- "covered product," which means a covered drug or homegenerated sharps waste;
- "mail-back program," which means a method of collecting covered products from ultimate users by using prepaid, preaddressed mailing envelopes;
- "program operator," which means a covered entity, or stewardship organization on behalf of a group of covered entities, that is responsible for operating a stewardship program;
- "stewardship organization," which means an organization exempt from taxation that is established by a group of covered entities in accordance with this chapter to develop, implement, and administer a stewardship program;

- "stewardship plan" means the plan for collecting and properly managing covered products that is developed by a covered entity or stewardship organization pursuant to this chapter;
- "stewardship program" means a stewardship program for the collection, transportation, and disposal of covered products; and
- "ultimate user," which means a state resident or other nonbusiness entity and includes a person who has lawfully obtained, and who possesses, a covered product, including a controlled substance, for the person's own use or for the use of a member of the person's household. It does not include a needle exchange program or a medical waste generator.
- § 42031 (list of covered products; notification to state board; verification; letters of inquiry; proprietary information; notification of violation) (a) requires that, no later than 90 days after the effective date of this section, a covered entity shall provide a list of covered products, and a list and description of any drugs or sharps that are not covered products, that it sells or offers for sale in the state to the state board. Such list shall be updated on or before January 15 of each year or upon request of the department.
- (b) No later than 90 days after the effective date of this section, a retail pharmacy that sells a covered product under its own label shall provide written notification to the state board identifying the covered entity from which the retail pharmacy obtains a covered product that the retail pharmacy sells under its store label.
- (d) The state board may issue a letter of inquiry to any entity listed in § 42030, definition of "covered entity," requesting a list of all drugs and sharps it distributes in California, regardless of whether the drugs or sharps are covered under this chapter, the name of the manufacturer of such products, and any additional information necessary to carry out this chapter. An entity that is issued a letter of inquiry pursuant to this subdivision shall respond in writing no later than 60 days after receipt of the letter. Responses to those inquiries may be shared with the department, but are otherwise deemed proprietary and exempt from disclosure. If the entity does not believe it is a covered entity for purposes of this chapter, it shall submit all of the following to the state board in response to the letter of the inquiry: (1) the basis for the claim that it is not a covered entity; (2) a list of any drugs and sharps it sells, distributes, repackages, or otherwise offers for sale

## **Program components** (continued)

within the state; and (3) if applicable, the name and contact information of the person or entity from which it obtains a drug or sharp identified pursuant to (2).

- (e) The state board shall obtain and verify and, within 30 days of receipt or upon request by the department, submit to the department a list of drugs and sharps sold or offered for sale in the state excluded from the definition of "covered drugs."
- (g) The state board shall notify the department if any covered entity or stewardship organization is in violation of this section for enforcement purposes.
- § 42031.2 (adoption of regulations for implementation and administration of chapter).
- § 42031.4 (compliance with this chapter) except as otherwise provided by law, a covered entity is not in compliance with this chapter and is subject to penalties if, commencing one year from the adoption of regulations, a covered product sold or offered for sale by the covered entity is not subject to an approved stewardship plan, which is submitted by the covered entity or by a stewardship organization that includes the covered entity, that has been approved by the department. A covered entity may establish and implement a stewardship program independently, or as part of a group of covered entities through membership in a stewardship organization.
- § 42031.6 (education and outreach program requirements) a program operator shall conduct a comprehensive education and outreach program intended to promote participation in the stewardship program. At a minimum, the education and outreach program shall do all of the following:
- (1) promote its stewardship program to ultimate users by providing signage for hospitals, pharmacies, and other locations, as necessary;
- (2) provide educational and outreach materials for persons authorized to prescribe drugs, pharmacies, pharmacists, ultimate users, and others, as necessary;
- (3) establish an internet website that publicizes the location of authorized collectors and provides other information intended to promote the use of the stewardship program;

- (4) prepare and provide additional outreach materials not specified in this section, as needed to promote the collection and proper management of covered drugs; and
- (5) encourage ultimate users to separate products that are not covered products from covered products, when appropriate, before submitting the covered products to an authorized collection site or mail-back program.
- $\S$  42032 (stewardship plan; submittal to department; review; approval; implementation; availability to public) (a) requires that, within six months of the adoption of regulations by the department, a program operator shall submit a stewardship plan that meets statutory requirements to the department for approval. The department shall approve the plan if the program operator submits a completed plan that meets the requirements of this section.
- (b) Before submitting a plan to the department, the program operator shall submit its proposed plan to the state board for review. An agency that receives a plan shall review it for compliance with state and federal laws and regulations. The agency shall determine compliance with such laws and regulations, and provide to the program operator that determination and an explanation for any finding of noncompliance, within 90 days of receipt of the plan. If, 90 days after submitting a plan to an applicable agency, a program operator has not received a response from the agency, the program operator may submit a certification to the department that the plan is consistent with all other applicable laws and regulations.
- (c) The department shall determine if a plan is complete, including the determinations required to subsection (b), and notify the program operator within 30 days of receipt. If the department finds that the plan is complete, the department's 90-day review period for consideration shall commence upon the original date of receipt. If the plan is incomplete, the department shall identify the required additional information, and the program operator shall resubmit the plan within 30 days. If the resubmitted plan is complete, the department's 90-day review period for consideration of approval of the plan shall commence upon the date of receipt of the resubmitted plan.

- (d) The department shall review a complete submitted plan and shall approve, disapprove, or conditionally approve the plan within 90 days of receipt of the complete plan. The department may consult with, or submit a plan for review to, the state board or another state agency it determines is necessary to determine the completeness of the plan or for making a determination on the approval of the stewardship plan or an amendment to the plan.
- (e) A program operator shall submit any significant changes to a plan in writing for approval by the department, and shall not implement the changes prior to that approval.
- (f) If a plan is not approved, the department shall explain, in writing within 30 days, how the plan does not comply with this chapter, and the program operator shall resubmit a revised plan to the department. If the revised plan is not approved, the program operator is not in compliance with this chapter until it submits a plan that the department approves.
- (g) A program operator shall fully implement operation of an approved stewardship program no later than 270 days after approval of the plan.
- (h) If a plan is revoked or terminated by a program operator, a covered entity no longer subject to the plan may, without penalty, sell or offer for sale covered products in the state for a period of up to one year after the plan terminated or was revoked if the covered entity continues to operate under the most recent approved plan to which the entity was subject.
- (i) The department shall make all stewardship plans submitted pursuant to this section available to the public.
- § 42032.2 (stewardship plan requirements; authorized collectors; supplemental services; home-generated sharps waste; provision for expansion; educational and outreach provisions) (a) to be complete, a stewardship plan for covered drugs shall do all of the following:
- (A) identify and provide contact information for the stewardship organization, if applicable, and each participating covered entity, and identify each covered drug sold or offered for sale by each participating covered entity;

- (B) identify and provide contact information for the authorized collectors for the program, as well as the reasons for excluding any potential authorized collectors from participation in the program;
- (C) include any determinations provided by a state agency;
- (D) demonstrate adequate funding for all administrative and operational costs of the program, to be borne by the participating covered entities;
- (E) provide for a handling, transport, and disposal system that complies with applicable state and federal laws and regulations;
- (F) provide for a collection system that complies with the requirements of this chapter and meets all of the following requirements for authorized collection sites in each county in which the plan will be implemented: (a) provides for a minimum of five authorized collection sites or one authorized collection site per 50,000 people, whichever is greater; (b) provides for a reasonable geographic spread of authorized collection sites and an explanation for the geographic spread; and (c) provides for a mail-back program covering any counties where there is not an authorized retail pharmacy operating as an authorized collection site;
- (G) require a program operator to do all of the following: (a) permit an ultimate user who is homeless, homebound, or disabled individual to request prepaid, pre-addressed mailing envelopes, or an alternative form of a collection and disposal system that would render the covered drug inert; (b) provide alternative methods of collection from ultimate users for any covered drugs, other than controlled substances, that cannot be accepted or commingled with other covered drugs in secure collection receptacles or through a mail-back program, to the extent technically feasible and permissible by law or regulation; (c) provide a service schedule that meets the needs of each authorized collection site to ensure that each secure collection receptacle is serviced as often as necessary to avoid reaching capacity and that collected covered drugs are transported to final disposal in a timely manner;
- (H) provide the policies and procedures for the safe and secure collection, transporting, and disposing of the covered drug, describe how and where records will be maintained and how, at a minimum, instances of security problems that occur will be addressed, and explain the processes that will be taken to change the policies, procedures, and tracking mechanisms to alleviate the problems and to improve safety and security.

# Program components (continued)

- (b) At least 120 days before submitting a stewardship plan to the department, the operator of a program shall notify potential authorized collectors in the county or counties in which it operates of the opportunity to serve as an authorized collector for the proposed program. If a potential authorized collector expresses interest in participating in the program, the program operator shall commence good faith negotiations with the potential authorized collector within 30 days. Requires retail pharmacies to make a reasonable effort to serve as an authorized collector as part of a program in the county in which it is located. A program operator shall include as an authorized collector under its stewardship program any entity listed in § 42030(b) that offers to participate in the program, in writing and without compensation, even if the minimum convenience standards have been achieved.
- (c) After a plan for covered drugs has been approved, the program operator may supplement service, if approved by the department, for a county in which it operates that does not have the minimum number of authorized collection sites due to circumstances beyond the operator's control, by establishing a mail-back program or an alternative form of collection and disposal that complies with state and federal laws and regulations.
- § 42033 (initial stewardship program budget; requirements) requires program operators to submit a program budget with the submission of a stewardship plan
- § 42033.2 (written report and program budget; submittal to department; annual report and program budget; review and approval) on or before March 31, 2022, and each year thereafter, a program operator shall prepare and submit to the department both of the following: (1) a written report describing the program activities during the previous reporting period of one year; and (2) a written program budget for program implementation for the upcoming calendar year.

An annual report shall include, at a minimum, all of the following for the prior year:

- (1) a list of covered entities participating in the stewardship entities;

## Program components (continued)

- (2) the updated and reverified list of covered products that each covered entity subject to the stewardship plan sells or offers for sale;
- (3) the amount, by weight, of covered products collected from ultimate users at each authorized collection site that is part of the stewardship program;
- (4) for a stewardship plan for covered drugs, the name and location of authorized collection sites at which covered drugs were collected;
- (5) for a stewardship plan for home-generated sharps waste, information on the mail-back program;
- (6) whether policies and procedures for collecting, transporting, and disposing of covered products, as establishing in the plan, were followed during the reporting period and a description of each instance of noncompliance, if any;
- (7) whether any safety or security problems occurred during collection, transportation, or disposal of collected covered products during the reporting period and, if so, what changes have been or will be made to policies, procedures, or tracking mechanisms to alleviate the problem and to improve safety and security;
- (8) how the program operator complied with all elements in its stewardship plan; and
- (9) any other information the department reasonably requires.

An annual program budget shall include an independent financial audit and anticipated costs and recommended funding level necessary to implement the program.

§ 42033.4 (minutes, books, and records; audit) – requires the program operator to keep minutes, books, and records which shall be audited at least once each calendar year.

§ 42034 (administrative and operational costs associated with establishing and implementing stewardship program; payment by covered entity) – each covered entity, either individually or through a stewardship organization, shall pay all administrative and operational costs associated with establishing and implementing the stewardship program in which it participates, including the cost of collecting, transporting, and disposing of covered products.

- § 42034.2 (administrative fees; establishment of Pharmaceutical and Sharps Stewardship Fund) requires program operators to pay an administrative fee to the department on March 1 and September 1 of each year which is adequate to cover the department's and other state agency's projected full costs of administering and enforcing this chapter.
- § 42034.4 (audit of covered entities or authorized collectors; requirements) a stewardship organization may conduct an audit of covered entities that are required to remit a charge or administrative fee to the stewardship organization to verify that the administrative fees and charges paid are proper and accurate.
- § 42035 (list of stewardship organizations; posting to department web site; certification letter; compliance with chapter) on or before June 30, 2022, and at least annually thereafter, the department shall post on its website a list of stewardship organizations, including entities with an approved stewardship plan, and covered entities, authorized collection sites, retail pharmacies, and retail pharmacy chains in the stewardship plans that are in compliance with this chapter.
- § 42035.2 (administrative penalty for violation of chapter; exemptions; deposit of funds) provides that the department may impose an administrative penalty on any covered entity, program operator, stewardship organization, or authorized collector that sells, offers for sale, or provides a covered product in violation of this chapter. The amount of the administrative penalty imposed shall not exceed \$10,000 per day unless the violation is intentional, knowing, or reckless, in which case the administrative penalty shall not exceed \$50,000 per day. The department shall not impose a penalty on a program operator pursuant to this section for failure to comply with this chapter if the program operator demonstrates it received false or misleading information that contributed to its failure to comply, including, for a stewardship organization, from a participating covered entity.
- § 42035.4 (actions to ensure compliance with requirements of chapter) upon a finding that a covered entity, program operator, stewardship organization, or authorized collector has not met a material requirement of this chapter, in addition to any other penalties authorized under this chapter, the department may take one or both of the following actions to ensure compliance after affording the entity a reasonable opportunity to respond to, or

# Program components (continued)

rebut the finding: (1) revoke the program operator's stewardship plan approval or require the program operator to resubmit the plan; and (2) require additional reporting relating to compliance with the material requirement of this chapter that was not met.

§ 42035.6 (reasonable and timely access to facilities and operations; records retention; disciplinary action) – a covered entity, stewardship organization, program operator, retail pharmacy, or retail pharmacy chain shall do both of the following: (1) upon request, provide the department with reasonable and timely access to its facilities and operations, as necessary to determine compliance; and (2) upon request, provide the department with relevant records necessary to determine compliance.

All reports and records provided to the department pursuant to this chapter shall be provided under penalty of perjury. The department may take disciplinary action against a covered entity, stewardship organization, program operator, pharmacy, retail pharmacy, or retail pharmacy chain that fails to provide the department with the access to information required pursuant to this section, including one or both of the following: (1) imposing an administrative penalty; and (2) posting a notice on the department's website that the covered entity, stewardship organization, program operator, pharmacy, retail pharmacy, or retail pharmacy chain is no longer in compliance with this chapter.

The department shall not prohibit as a disciplinary action a covered entity, stewardship organization, program operator, pharmacy, retail pharmacy, or retail pharmacy chain from selling a covered product.

§ 42036 (application of Cartwright Act, Unfair Practices Act, or Unfair Competition Law to actions taken by a stewardship organization or covered entity) – (a) except as otherwise provide by law, an action specified in subdivision (b) that is taken by a stewardship organization or a covered entity pursuant to this chapter is not a violation of the Cartwright Act, the Unfair Practices Act, or the Unfair Competition Law.

(b) Subdivision (a) shall apply to all of the following actions taken by a stewardship organization or covered entity:

## **Program components** (continued)

- (1) the creation, implementation, or management of a stewardship plan approved by the department and the determination of the types or quantities of covered products collected or otherwise managed pursuant to a stewardship plan;
- (2) the determination of the cost and structure of an approved stewardship plan; and
- (3) the establishment, administration, collection, or disbursement of the charge or administrative fee imposed pursuant to this chapter.
- (c) Subdivision (a) shall not apply to an agreement that does any of the following:
- (1) fixes a price of or for covered products, except for an agreement related to costs, charges, or administrative fees associated with participation in a stewardship plan approved by the department and otherwise in accordance with this chapter;
- (2) fixes the output of production of covered products; and
- (3) restricts the geographic area in which, or customers to whom, covered products are sold.

§ 42036.2 (application of chapter to local stewardship programs in effect prior to April 18, 2018; preemption of local stewardship programs enacted on or after April 18, 2018) – this chapter does not apply to a drug or sharp within a jurisdiction that is subject to a local stewardship program pursuant to an ordinance that took effect before April 18, 2018. This chapter shall preempt a local stewardship program for drugs enacted by an ordinance or ordinances with an effective date on or after April 18, 2018.

§ 42036.4 (protection of proprietary information as confidential) – proprietary information submitted to the department under this chapter shall be protected by all parties as confidential and shall be exempt from public disclosure.

14, § 18972.1 (definitions)

14, § 18972.2 (criteria for determining a covered entity) – the department shall identify the covered entity for any covered products consistent with § 42030.

## **Program components** (continued)

14, § 18973 (document submittals: stewardship plan, initial program budget, annual report, and annual budget) — a stewardship plan, initial program budget, annual report, annual budget, or any document associated with the foregoing that is submitted to the department shall meet all the requirements of this section:

- (1) the document is required to be in compliance with state law to allow for posting on the department's website;
- (2) the document shall be submitted electronically;
- (3) any submittals to the department that the program operator believes are confidential in nature shall include a cover letter explaining the justification of confidentiality;
- (4) the document shall be complete and correct; and
- (5) the document shall be provided to the department under penalty of perjury.

14, § 18973.1 (document approvals: stewardship plan, initial program budget, annual report, and annual budget) – a program operator that submits a stewardship plan, initial program budget, annual report, or annual budget to the department shall meet the requirements of this section.

14, § 18973.2 (stewardship plan for covered drugs) – within six months of the adoption date of the regulations in this article by the department, a program operator shall submit a stewardship plan to the department. Lists the specific information to be included in the plan, including:

- (1) contact information for the corporate officer, or designee, responsible for submitting and overseeing the plan;
- (2) contact information for each covered entity participating in the plan;
- (3) list of each covered drug sold or offered for sale by each participating covered entity covered by the plan;
- (4) contact information for each participating authorized collector operating a collection site where covered drugs are collected;
- (5) initial program budget and program funding;
- (6) descriptions of the processes and policies that will be used to safely and securely collect, track, and properly manage covered drugs from collection through final disposal; tracking mechanisms; service provider information; mail-back services.

- 14, § 18973.4 (annual report for covered drugs) annual report requirements for program operators.
- 14, § 18973.6 (program budgets) requires program operators to submit an initial stewardship program budget and sets forth the minimum information required.
- 14, § 18974 (record keeping requirements) sets forth the record keeping requirements for each party required to comply with § 42030, et seq.
- 14, § 18974.1 (administrative and operational costs) each covered entity, either individually or through a stewardship organization, shall pay all administrative and operational costs associated with establishing and implementing the stewardship program in which it participates, including the cost of collecting, transporting, and disposing of covered products.
- 14, § 18974.2 (stewardship organization audits of covered entities or authorized collectors) if a stewardship organization conducts an audit of covered entities or authorized collectors, the organization shall provide a copy of the audit to the department within 30 days of its completion.
- 14, § 18975 (criteria to impose an administrative civil penalty) the department shall impose an administrative civil penalty if it determines that any covered entity, program operator, stewardship organization, or an authorized collector that sells, offers for sale, or provides a covered product in California has violated this article or statutes related to this article. Sets forth the disciplinary actions that may be taken and the circumstances to be considered when assessing or reviewing the amount of a penalty to be imposed.
- 14, § 18975.1 (procedure for imposing administrative civil penalties) requires the department to issue a written notice of violation before commencing an action to impose administrative civil penalties which shall list and describe the nature of the violation(s).
- 14, § 18975.2 (procedure for stewardship plan revocation, resubmittal, or additional compliance reporting) if the department finds that a covered entity, program operator, stewardship organization, or authorized collector has failed to

## Program components (continued)

meet a material requirement of this article or statutes, the department shall, in addition to imposing any authorized civil penalties, take one or all of the following actions:

- (1) revoke a previously approved stewardship plan;
- (2) require resubmittal of the stewardship plan; and/or
- (3) require additional reporting relating to compliance with the material requirement(s) that was/were not met.

16, § 1776 (prescription drug take-back services: authorization) — pharmacies, hospitals/clinics with onsite pharmacies, distributors and reverse distributors licensed by the board may offer, under the requirements in this article, specified prescription drug take-back services through collection receptacles and/or mail back envelopes or packages to provide options for the public to discard unwanted, unused, or outdated prescription drugs. Each entity must comply with regulations of the federal Drug Enforcement Administration and this article. Only applies to California-licensed entities.

16, § 1776.1 (pharmacies) – pharmacies may provide take-back services to the public. Retail pharmacies and hospitals/clinics with onsite pharmacies may maintain collection receptacles in their facilities. Pharmacies may offer drug take-back services in skilled nursing facilities. Once drugs are deposited into a collection receptacle or mail back envelopes or packages by a consumer, they are not to be removed, counted, sorted, or otherwise individually handled. The collection receptacle shall contain signage that includes: (1) the name and phone number of the responsible pharmacy; (2) medical sharps and needles shall not be deposited; and (3) consumers may deposit prescription drugs including Schedule II-V controlled substances.

Prescription drugs that are eligible for collection are only those prescription drugs that have been dispensed by any pharmacy or practitioner to a consumer. As part of its drug take-back services, a pharmacy shall not: (1) review, accept, count, sort, or otherwise individually handle any prescription drugs from consumers; (2) accept or possess prescription drugs from skilled nursing facilities, residential care homes, healthcare practitioners, or any other entity; and (3) dispose of quarantined, recalled, or outdated prescription drugs from pharmacy stock.

## **Program components** (continued)

Any pharmacy that maintains a drug take-back collection receptacle shall notify the board in writing within 30 days of establishing the program. Any pharmacy that ceases to maintain a collection receptacle shall notify the board in writing within 30 days. Any tampering with a collection receptacle or theft of deposited drugs shall be reported to the board in writing within 14 days. Any tampering, damage, or theft of a removed liner shall be reported to the board in writing within 14 days. If the pharmacy ceases to maintain a registered collection receptacle, the pharmacy must notify the DEA within 30 days.

16, § 1776.2 (pharmacies offering mail back envelope or package services) – pharmacies that provide drug take-back services may do so by providing preaddressed mailing envelopes or packages to allow a consumer to return prescription drugs to an authorized DEA destruction location. The preaddressed envelopes and packages must be water and spill proof, tamper evident, tear resistant, and sealable. The exterior shall be nondescript and not include markings that indicate the envelope or package contains prescription drugs. Postage shall be prepaid on each envelope or package.

16, § 1776.3 (collection receptacles in pharmacies) – a pharmacy may maintain a collection receptacle for the public to deposit their unwanted prescription drugs for destruction. The pharmacy is responsible for the management and maintenance of the receptacle. The receptacle shall be substantially constructed, with a permanent outer container and a removable inner liner. The collection receptacle shall be locked at all times to prevent access to the inner liner. The receptacle must be securely fastened to a permanent structure so it cannot be removed and installed in an inside location. Except as otherwise provided, the receptacle is visible to pharmacy or DEA registrant employees, but not located in or near emergency areas, nor behind the pharmacy's counter.

In hospitals/clinics with a pharmacy on the premises, the receptacle must be located in an area that is regularly monitored by pharmacy or DEA registrant employees and not in the proximity of any emergency or urgent care areas. When no pharmacy or DEA registrant employees are present, the collection receptacle shall be locked so that drugs may not be deposited.

The receptacle shall include a small opening that allows deposit of drugs directly into the inner liner but does not allow for an

## **Program components** (continued)

individual to reach into the receptacle's contents. During hours when the pharmacy is closed, the collection receptacle shall not be accessible to the public for deposit of drugs. The pharmacy shall lock the deposit opening on the collection receptacle. The liner shall be waterproof, tamper evident, and tear resistant. The liner shall be opaque to prevent viewing or removal of any contents once the liner has been removed from a collection receptacle. The liner shall be clearly marked to display the maximum contents and shall bear a permanent, unique identification number established by the pharmacy or pre-entered onto the liner by the liner's manufacturer or distributor. The liner shall be removable. If the liner is not already itself rigid or already inside of a rigid container when removed from the collection receptacle, the liner must be immediately, without interruption, placed in a rigid container for storage, handling, and transport. A rigid container may be disposable, reusable, or recyclable. Rigid containers shall be leak resistant, have sealable tight-fitting covers, and be kept clean and in good repair.

The liner may be removed from a locked collection receptacle only by or under the supervision of two employees of the pharmacy. Upon removal, the liner shall be immediately, without interruption, sealed and the pharmacy employees shall record, in a log, their participation in the removal of each liner from a receptacle. Liners and their rigid containers shall not be opened, x-rayed, analyzed, or penetrated at any time by the pharmacy or pharmacy personnel. Liners and their rigid containers that have been filled and removed from a collection receptacle must be stored in a secured, locked location in the pharmacy no longer than 14 days.

A pharmacy shall not accept, count, sort, or otherwise handle prescription drugs from consumers. The pharmacy shall ensure the sealed inner liners and their contents are shipped to a reverse distributor's registered location by common or contract carrier or by a licensed reverse distributor pick-up at the pharmacy's premises.

16, § 1776.4 (drug take-back services in skilled nursing facilities) – a pharmacy may offer drug take-back services in skilled nursing facilities licensed pursuant to law.

16, § 1776.5 (reverse distributors) – a licensed reverse distributor registered with the DEA may accept the sealed inner liners of

<u>CALIFORNIA</u>		
Program components (continued)	collection receptacles at the reverse distributor's registered location by common or contract carrier pick-up, or by reverse distributor pick-up at the collector's authorized collection location. Once received, the reverse distributor shall establish records required by this section.	
	A licensed reverse distributor may not open, survey, or otherwise analyze the contents of inner liners. All liners shall be destroyed by an appropriately licensed and registered DEA reverse distributor in a manner that makes the drugs irretrievable.	
	For each sealed liner or mail back envelopes or packages received, the reverse distributor shall maintain records of the number of sealed inner liners or mail back envelopes or packages, including the: (1) date of acquisition; (2) number and size; (3) unique identification number of each liner or envelope/package; (4) the method of delivery to the reverse distributor, the signature of the individuals delivering the liners to the reverse distributor, and the reverse distributor's employees who received the sealed liner; (5) the date, place, and method of destruction; (6) number of packages and inner liners received; (7) number of packages and inner liners destroyed; and (8) the name and signature of the two employees of the registrant that witnessed the destruction.	
	16, § 1776.6 (record keeping requirements for board licensees providing drug take-back services) – each entity authorized by this article to collect unwanted prescription drugs from consumers shall maintain the records required by this article for three years. Includes a list of the records required to be maintained.	
Miscellaneous provisions	§ 443.20 – a person who has custody or control of any unused aid-in-drying drugs prescribed pursuant to this part after the death of the patient shall personally deliver the unused aid-in-dying drugs for disposal by delivering it to the nearest qualified facility that properly disposes of controlled substances or, if none is available, shall dispose of it by lawful means in accordance with guidelines promulgated by the Board of Pharmacy or a federal Drug Enforcement Administration approved drug take-back program.	
Recently proposed legislation	None.	
Program website	California Drug Take-back Program	

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<u>COLORADO</u>	
Statute(s) and regulation(s)	<ul> <li>COLO. REV. STAT. ANN. § 25-15-328 (West 2023) (household medication take-back program—creation—collection and disposal of medication injection devices—liability—definitions—cash fund—rules)</li> <li>COLO. REV. STAT. ANN. § 25-48-120 (West 2023) (safe disposal of unused medical aid-in-dying medications)</li> <li>6 COLO. CODE REGS. 1010-23:1 to 23:18 (2023) (collectively titled "Rules and Regulations Governing the Colorado Household Medication Take-back Program")</li> </ul>
Effective date(s) of	• August 6, 2014 (§ 25-15-328)
provision(s)	• July 1, 2016 (6 CCR 1010-23:1 to 23:18)
	• December 16, 2016 (§ 25-48-120)
Does the state allow drug take-back programs by statute/regulation?	Yes.
Program components	§ 25-15-328 – establishes a household medication take-back program to facilitate the safe and effective collection and proper disposal of unused medications.
	Includes definitions, including:
	<ul> <li>"approved collection site," which means a site approved by the department for the collection of unused household medications;</li> <li>"disposal location," which means a site approved by the department where unused household medications are destroyed in compliance with applicable laws so that the household medications are in a nonretrievable state and cannot be diverted for illicit purposes; and</li> <li>"household medications," which means controlled substances approved for collection by federal law, prescription drugs, and over-the-counter medications in the possession of an individual.</li> </ul>
	Starting in the 2020-21 fiscal year, the department shall use the money appropriated to the department to implement a process for the safe collection and disposal of needles, syringes, and other devices used to inject medication.
	A collection site, carrier, or disposal location is not subject to liability for incidents arising from the collection, transport, or disposal of household medications if the collection site, carrier, or disposal location complies with the household medication takeback program in good faith and does not violate any applicable laws.

## **Program components** (continued)

Creates the household medication take-back cash fund in the state treasury for the direct and indirect costs associated with the implementation of this section. The fund consists of money appropriated or transferred to the fund by the general assembly and any gifts, grants, and donations from any public or private entity. The department shall transmit gifts, grants, and donations collected by the department to the state treasurer, who shall credit the money to the fund.

6 CCR 1010-23:2 (scope and purpose) – this regulation governs the Colorado Household Medication and Household Sharps Take-back Program; This regulation does not apply to the authority to collect and reuse medications, wastes generated by non-household waste generators, the operation of other household medication and household sharps take-back and disposal programs regulated by the department; generators of household medications and household sharps, or Schedule I controlled substances.

6 CCR 1010-23:4 (definitions) – definitions include:

- "collection," which means to receive household medications from individuals for the purpose of destruction. If a household medication is a controlled substance, collection means to receive a controlled substance for the purpose of destruction from an ultimate user or an individual lawfully entitled to dispose of an ultimate user decedent's property;
- "collector" means a DEA-registrant or law enforcement agency approved by the department for the collection of household medications;
- "disposal location" means a site approved by the department where household medications are destroyed in compliance with applicable laws and rendered non-retrievable and cannot be diverted for illicit purposes;
- "household medications" means controlled substances approved for collection by federal law, prescription drugs, and over-thecounter medications in the possession of an individual, not generated by a commercial or industrial entity;
- "household medication take-back event" means a scheduled, organized occasion of limited duration, managed by a law enforcement agency for the collection of household medications, including controlled substances collected from ultimate users and individuals lawfully entitled to dispose of an ultimate user decedent's property;

## Program components (continued)

- "non-retrievable" means, for the purpose of destruction, the condition or state to which household medications shall be rendered following a process that permanently alters the household medications' physical or chemical condition or state through irreversible means and thereby renders the household medications unavailable and unusable for all practical purposes, thus preventing their diversion to illicit purposes; and
- "reverse distribute" means to acquire controlled substances from another registrant or law enforcement for the purpose of return to the registered manufacturer or another registrant authorized by the manufacturer to accept returns on its behalf or destruction.

6 CCR 1010-23:6 (specific standards for household medication department-approved collectors, transporters, and disposal locations) – in order to collect household medications as a department-approved participant in the program, a collector shall:

- (1) be a law enforcement agency; or a DEA-registered location of a retail pharmacy or a hospital/clinic with an on-site pharmacy, whose registrations have been modified consistent with DEA requirements to authorize collection of controlled substances;
- (2) have an application form approved by the department;
- (3) designate an individual responsible for oversight of household medication collection activities;
- (4) develop, implement, and maintain on site in an easily retrievable format a Medical Waste Management Plan containing, at a minimum, the following elements: (a) procedures for household medication identification, collection, packaging, storage, transport, and disposal; (b) a contingency plan for spills and releases; (c) employee and volunteer training procedures; (d) designation of an individual or individuals responsible for implementing the plan; and (e) recordkeeping methods.

In order to acquire household medications from collectors as a department-approved participant in the program and transport them to disposal locations for destruction, or transfer them to another registrant for subsequent destruction, a transporter shall be:

- (1) a reverse distributor or distributor under contract or other written, signed service agreement with the department if acquiring household medications from a DEA-registered

## **Program components** (continued)

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

In order to destroy collected household medications as a department-approved participant in the program, a disposal location shall utilize a method of destruction that renders household medications non-retrievable and comply with all applicable laws and regulations.

6 CCR 1010-23:7 (allowable household medication collection methods) – DEA-registered collectors participating in the program may collect household medications, including controlled substances collected from ultimate users, utilizing collection receptacles and inner liners in accordance with Sections 23.8 and 23.9.

Law enforcement agency collectors participating in the program may collect household medications in the course of official duties, including controlled substances collected from ultimate users, utilizing collection receptacles and inner liners in accordance with Sections 23.8 and 23.9 and/or take-back events in accordance with Section 23.10.

6 CCR 1010-23:8 (household medication collection receptacle requirements) – requires collection receptacles to be securely placed and maintained either inside a DEA-registered collector's location or inside a law enforcement agency collector's physical location.

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

- (1) at a retail pharmacy, receptacles shall be located in an area accessible to the public and in the immediate proximity of a designated area where controlled substances are stored, and at which an employee is present; and
- (2) at a hospital/clinic, receptacles shall be located in an area accessible to the public and regularly monitored by employees, and shall not be located in the proximity of any area where emergency or urgent care is provided.

## Program components (continued)

For collection receptacles located inside a law enforcement agency collector's location, receptacles shall be located in an area monitored by employees or law enforcement officers.

Sets forth the design specifications for collection receptacles.

- (1) at a DEA-registered collector's location, be securely fastened to a permanent structure;
- (2) be securely locked;
- (3) include a small opening that allows contents to be added but does not allow removal of the inner liner's contents;
- (4) prominently display a sign on the outer container indicating that only Schedule II-V controlled and non-controlled substances are acceptable; Schedule I controlled substances, controlled substances not lawfully possessed by the ultimate user, and other illicit or dangerous substances are not permitted; and
- (5) except at a law enforcement agency location, the opening shall be locked or made otherwise inaccessible to the public when an employee is not present.

Except at a law enforcement location, once household medications have been deposited into a collection receptable, the household medications shall not be counted, sorted, inventoried, or otherwise individually handled.

Law enforcement agency collectors may allow ultimate users and other authorized non-registrant individuals in lawful possession of a Schedule II-V controlled substance to transfer such substances and other household medications to a law enforcement officer or law enforcement agency employee for immediate deposit in a collection receptable, if the receptacle is located in an area not accessible to the public.

6 CCR 1010-23:9 (household medication collection receptacle inner liner requirements) – sets forth the requirements for inner liners in collection receptacles. Provides that access to the inner liner is restricted to employees of a DEA-registered collector or employees of a law enforcement agency collector.

6 CCR 1010-23:10 (household medication take-back events) – a law enforcement agency may conduct a take-back event and collect household medications, including controlled substances from ultimate users and individuals lawfully entitled to dispose of an

## Program components (continued)

ultimate user decedent's property. A law enforcement agency may partner with other persons or entities to hold a collection take-back event in accordance with this section.

A law enforcement agency shall appoint at a minimum one law enforcement officer employed by the agency to oversee the collection. Officers conducting a take-back event shall maintain control and custody of the household medications from the time they are collected until secure transfer, storage, or destruction has occurred.

A law enforcement agency may conduct a take-back event at its physical location or at another location, provided the officer(s) overseeing the collection are able to maintain custody and control of the household medications in accordance with this section.

6 CCR 1010-23:11 (disposal of collected household medications) – DEA-registered collectors shall dispose of collected household medications in the following manner:

- (1) upon inner liner removal from the permanent outer container of a collection receptacle, the sealed inner liner and its contents shall be sent by two employees to a transporter's registered location by common carrier or contract carrier delivery or transferred by two employees to a transporter by on-site pick-up at the DEA-registered collector's location for transport to the transporter's registered location or transport to a disposal location; and
- (2) a sealed inner liner and its contents shall be placed into secure storage by two employees at the DEA-registered collector's location until prompt delivery or transfer can occur. In no case shall a sealed inner liner be stored at the DEAregistered collector's location for more than 90 days.

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

- (1) sealed inner liners and their contents removed from collection receptacles and opaque, waterproof, tamper-evident, and tear-resistant bags containing household medications collected at take-back events through means other than collection receptacles shall be sent by two law enforcement agency employees to a transporter's registered location by

## Program components (continued)

common carrier or contract carrier delivery or transferred by two law enforcement agency employees to a transporter by onsite pick-up at the law enforcement agency collector's location for transport to the transporter's registered location or transport to a disposal location;

- (2) sealed inner liners and their contents and opaque, waterproof, tamper-evident, and tear-resistant bags and their contents shall be placed into secure storage at the law enforcement agency by two law enforcement agency employees until prompt delivery or transfer to a transporter can occur. In no case shall sealed inner liners or opaque, waterproof, tamper-evidence, and tear-resistant bags be stored at the law enforcement agency collector's location for more than 90 days.

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

- (1) sealed inner liners and their contents removed from collection receptacles and opaque, waterproof, tamper-evidence, and tear-resistant bags containing household medications collected at take-back events through means other than a collection receptacle shall be: (a) transferred by the law enforcement officer to a transporter by pick-up at the take-back event site for transport to the transporter's registered location or transport to a disposal location; or (b) transported by the law enforcement officer to the law enforcement agency's physical location for disposal.

6 CCR 1010-23:12 (transporter acquisition of household medications from collectors) – 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.

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

Transporter that acquire household medications are authorized to utilize only the following methods:

### Program components (continued)

- (1) on-site pick-up; or
- (2) delivery by common carrier or contract carrier.

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

6 CCR 1010-23:13 (transporter procedures for destruction of acquired household medications) – sets forth the destruction requirements for transporters.

6 CCR 1010-23:14 (methods of household medication destruction) – household medications shall be destroyed in compliance with all applicable federal, state, tribal, and local laws and regulations. The method of destruction shall be sufficient to render household medications, including all controlled substances that may be present, non-retrievable in order to prevent diversion to illicit purposes and to protect the public health and safety.

6 CCR 1010-23:15 (security requirements) – sets for the requirements for employees, physical security controls for DEA-registered household medication collectors, physical security controls for law enforcement agency household medication collectors, and physical security controls for transporters.

6 CCR 1010-23:16 (registrant household medication records and inventories) – every registrant required to keep records pursuant to 21 C.F.R § 1304 shall maintain, on a current basis, a complete and accurate record of each inner liner and sealed inner liner, except that no registrant shall be required to maintain a perpetual inventory. Registrants shall maintain separate records fore ach independent activity and collection activity for which they are registered or authorized.

Registrants shall maintain a record of destruction for all sealed inner liners and sealed bags containing household medications destroyed. The records shall be complete and accurate, and include the name and signature of the two employees who witnessed the destruction.

Transporters participating in the program and required to keep inventories of controlled substances pursuant to 21 C.F.R. § 1304 shall include, for household medications, including controlled substances collected from ultimate users, acquired from DEA-

## Program components (continued)

registered collectors and law enforcement agency collectors: the number and size of sealed liners on hand.

DEA-registered collectors participating in the program and required to keep inventories of controlled substances shall include the following information in their inventories:

- (1) the date of the inventory;
- (2) the number and size of sealed inner liners in storage; and
- (3) the unique identification number of each inner liner.

6 CCR 1010-23:17 (law enforcement agency collector household medication records) – law enforcement agency collectors shall maintain the records required in this section in an easily retrievable format, on-site, for three years from the date the waste was acquired by the transporter.

Law enforcement agency collectors shall maintain the following records:

- (1) collection receptacle inner liners: (a) date each unused inner liner is obtained and its unique identification number and size;
   (b) date each inner liner is installed and the address of the location where installed; (c) date each inner liner is removed and sealed and the address of the location from which each inner liner is removed; (d) date each sealed inner liner is transferred to storage; (e) date each sealed inner liner is transferred for destruction.
- (2) opaque, waterproof, tamper-evidence, and tear-resistant bags with household medications collected at take-back events through means other than a collection receptacle: (a) date each bag is sealed and the address of the location at which each bag is sealed; (b) date each sealed bag is transferred to storage and the name and signature of the officer that transferred each bag to storage; (c) date each sealed bag is transferred for destruction; and
- (3) if approved by the department, a law enforcement agency may utilize a method of inner liner documentation other than those described herein. The alternative method must be consistent with the agency's recordkeeping requirements for illicit controlled substances evidence.

6 CCR 1010-23:18 (household medication collectors ceasing collection activities) – DEA-registered collectors ceasing

<u>COLORADO</u>	
Program components (continued)	participation in the program and ceasing collection of household medications shall:
	<ul> <li>(1) notify the department;</li> <li>(2) dispose of household medications on hand in accordance with 23.11; and</li> <li>(3) notify the DEA of the intent to cease collection.</li> </ul>
	Law enforcement agency collectors ceasing participation in the program and ceasing collection of household medications, including controlled substances collected from ultimate users, shall notify the department and dispose of household medications on hand in accordance with 23.11.
Miscellaneous provisions	§ 25-48-120 – a person who has custody or control of medical aid-in-dying medication dispensed under this article that the terminally ill individual decides not to use or that remains unused after the terminally ill individual's death shall dispose of the unused medication either by:
	<ul> <li>(1) returning the unused medication to the attending physician who prescribed the medication, who shall dispose of the unused medication in the manner required by law; or</li> <li>(2) lawful means in accordance with § 25-15-328 or any other state or federally approved medication take-back program.</li> </ul>
Recently proposed legislation	None.
Program website	Colorado Household Medication and Sharps Takeback program Department of Public Health & Environment

	CONNECTICUT	
Statute(s) and regulation(s)	<ul> <li>CONN. GEN. STAT. ANN. § 20-576a (West 2023) (acceptance and disposal of unused prescription drugs at pharmacies; regulations)</li> <li>CONN. GEN. STAT. ANN. § 20-636 (West 2023) (sign re storage and disposal of prescription drugs)</li> <li>CONN. GEN. STAT. ANN. § 21a-262 (West 2023) (commissioner's authority and duties re controlled substances; when seizing authority may destroy; disposal by long-term care facilities, outpatient surgical facilities and home health care agencies)</li> <li>CONN. AGENCIES REGS. §§ 20-576a-1 to -7 (2023) (collectively titled "Return of Prescription Drugs to Pharmacies")</li> </ul>	
Effective date(s) of provision(s)  Does the state allow drug	• 1976 (§ 21a-262) • July 6, 2017 (§ 20-576a) • July 8, 2019 (§§ 20-576a-1 to -7) • July 1, 2022 (§ 20-636) Yes.	
take-back programs by statute/regulation?		
Program components	§ 20-576a – not later than July 1, 2018, the Commissioner of Consumer Protection, with the advice and assistance of the commission of pharmacy, shall adopt regulations to allow not more than fifty retail locations during the first year and not more than an additional fifty retail locations in each year thereafter, at pharmacies licensed pursuant to law, to accept and dispose of unused prescription drugs.	
	Such regulations shall: (1) comply with federal law regarding the acceptance and disposal of unused prescription drugs at pharmacies; (2) establish a tracking and monitoring system and security requirements for such drugs; and (3) specify locations within pharmacies where such drugs may be accepted and stored. The commissioner, after consulting with the Commissioner of Energy and Environmental Protection, shall establish a process in such regulations to ensure the secure removal and destruction of such unused prescription drugs including, but not limited to, allowing for optional prescription drug disposal agreements with law enforcement authorities.	
	§ 21a-262 – authorizes the Commissioner of Consumer Protection to receive, take into custody, or destroy excess or undesired controlled substances. The commissioner shall keep a full and complete record of all substances received and of all substances disposed of, showing the exact kinds, quantities, and forms of such	

#### **CONNECTICUT**

## **Program components** (continued)

substances, the persons from whom received and to whom delivered, by whose authority received, delivered, and destroyed, and the dates of receipt, disposal, or destruction.

§ 20-576a-1 (definitions) – definitions include:

- "authorized collector," which means a retail pharmacy authorized to handle controlled substances, currently licensed pursuant to Connecticut law, with an active registration to be a collector of drugs for disposal issued by the U.S. Drug Enforcement Administration and the department;
- "collection receptacle," which means a secured receptacle into which unused or expired drugs, including controlled substances and legend and non-legend drugs, can be deposited by ultimate users; and
- "reverse distributor," which means a wholesaler or distributor, whether within or without the state, who receives and destroys prescription medications, including controlled substances and legend and non-legend drugs, from an authorized collector.

§ 20-576a-2 (authorized collector) – a pharmacy may operate a collection receptacle if the pharmacy: (1) meets federal requirements; (2) meets the requirements set forth in these regulations; and (3) registers with the department as an authorized collector.

Requires an authorized collector to submit an application and all other required documentation on forms prescribed by the commissioner. Registrations shall be renewed annually on or before January 31. Prior to the issuance of a certificate of registration, the commissioner shall perform an initial inspection of the applicant's premises, collection receptacle, and written operating procedures prior to the commencement of collection activities from ultimate users.

An authorized collector shall not:

- (1) participate in a take back event within the interior of the same building in which the authorized collector's receptacle is located;
- (2) participate in a mail back program, whereby the authorized collector receives drugs returned to it via mail; or
- (3) dispose of its inventory or stock of drugs in the collection receptacle.

#### **CONNECTICUT**

## Program components (continued)

No employees, including authorized employees, of an authorized collector shall handle, count, sort, or inventory any drugs brought by ultimate users for deposit in the collection receptacle.

Any authorized collector that intends to discontinue its use of a collection receptacle shall notify the director of the Drug Control Division in writing 30 days prior to discontinuing collection activities.

§ 20-576a-3 (collection receptacles) – collection receptacles shall be lockable, sturdy, and securely fixed within the authorized collector's registered location, and shall have a one-way access point to allow ultimate users to deposit drugs.

The collection receptacle shall:

- (1) be located in the immediate proximity of a designated area where controlled substances are stored and at which an authorized employee is present and the collection receptacle is visible to such authorized employee;
- (2) accept drugs only when the authorized collector is open for business and an authorized employee is present;
- (3) be secured pursuant to these regulations when the pharmacy is closed; and
- (4) prominently display a sign indicating: (a) the types of drugs permitted for disposal; (b) the prohibited items; and (c) that no drugs intended for return are to be left in the vicinity of the collection receptacle at any time.

Any loss, theft, serious damage, or destruction of a collection receptacle or its contents shall be reported by an authorized collector within 72 hours of any such occurrence to the director of the Drug Control Division.

§ 20-576a-4 (inner liners and rigid containers) – all inner liners shall:

- (1) have a permanent unique identification number, which shall be tracked and maintained in a record log;
- (2) contain an absorbent material sufficient to prevent leakage of any drugs deposited into the collection receptacle; and
- (3) be placed in or a part of a rigid container prior to use and placement inside a collection receptacle. The inner liner shall remain inside the rigid container from the point of placement in

#### CONNECTICUT

### Program components (continued)

the collection receptacle to the time of destruction. Rigid containers shall be leak resistant and have sealable openings.

§ 20-576a-5 (disposal) – to dispose of inner liners and rigid containers:

- (1) the reverse distributor shall be present and ready to receive the inner liner;
- (2) two authorized employees shall be present and performing the removal and replacement of the rigid container and inner liner, and one such employee shall be a Connecticut licensed pharmacist;
- (3) the rigid container, including the inner liner, shall be removed from the collection receptacle together and the inner liner shall be immediately sealed and replaced with a new rigid container and inner liner;
- (4) the rigid container shall then be sealed at all openings with tamper evidence tape;
- (5) the rigid container shall not have any outer markings that would indicate the nature of its contents;
- (6) the authorized employees present during the disposal shall record all required information and perform all actions necessary to record log entries;
- (7) the authorized employees shall provide the sealed rigid container than contains the sealed inner liner to a registered reverse distributor for destruction; and
- (8) the entire process shall be monitored and recorded by video camera.

No on-site destruction of any rigid container, inner liner, or its contents shall be permitted by the authorized collector or at such collector's premises.

Law enforcement authorities may, pursuant to an agreement with an authorized collector, accept delivery of the sealed rigid container that contains the sealed inner liner in the same manner as a reverse distributor, provided law enforcement authorities shall not be required to register with the department as a reverse distributor. Law enforcement authorities may destroy the sealed inner liner and rigid container pursuant to their department procedures and policies. Law enforcement authorities shall not be required by this section to participant in the collection and disposal of returned drugs to pharmacies.

CONNECTICUT	
CONNECTICUT	
Program components (continued)	§ 20-576a-6 (reverse distributors) – no reverse distributor shall operate as such until it has registered with the department, which registration shall be renewed annually on or before January 31.
	Upon annual review, the reverse distributor shall provide information related to the amount of drugs destroyed and any additional information required by the department.
	Any loss, theft, serious damage, or destruction of an inner liner or rigid container shall be reported by a reverse distributor, within 72 hours of any such occurrence, to the director of the Drug Control Division.
	§ 20-576a-7 (grounds for discipline) – sets forth the grounds upon which the commissioner may suspend, revoke, or refuse to renew a registration of an authorized collector or reverse distributor, place conditions on such registration, issue a letter of reprimand, or take other actions permitted by law.
Miscellaneous provisions	§ 20-636 – each pharmacy shall post a sign in a conspicuous place on the premises of such pharmacy notifying consumers that they may visit the website of the Department of Consumer Protection for information concerning the safe storage and disposal of unused and expired prescription drugs.
	§ 21a-262 – a registered nurse licensed by the Department of Public Health and employed by a home healthcare agency may, with the permission of a designated representative of the patient, oversee the destruction and disposal of the patient's controlled substances, using the recommendations for the proper disposal of prescription drugs on the website of the Department of Consumer Protection. Such registered nurse shall maintain written or electronic documentation for a period of three years of any such destruction and disposal and such documentation shall be maintained with the patient's medical record. Nothing in this subsection shall prevent the registered nurse and patient's designated representative from depositing the patient's controlled substances in a statutorily authorized prescription drug drop box.
Recently proposed	Yes. See Pending Federal and State Legislation.
legislation	
Program website	Prescription Drug Drop Box Program

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<u>DELAWARE</u>	
Statute(s) and regulation(s)	24 Del. Admin. Code § 5.0 (2023)
Effective date(s) of provision(s)	March 1, 2015
Does the state allow drug take-back programs by statute/regulation?	No.
Program components	N/A
Miscellaneous provisions	§ 2500-5.0 – dispensed medications returned by the public shall be properly disposed of in accordance with Delaware Controlled Substance laws and regulations and the federal Controlled Substance Act, 21 CFR 1300 to the end. Proposed disposal methods must be authorized by the Delaware Office of Controlled Substances and federal authority.
Recently proposed legislation	None.
Program website	Delaware Prescription Drug Take Back Events - Delaware Health and Social Services - State of Delaware

DISTRICT OF COLUMBIA	
Statute(s) and regulation(s)	D.C. CODE ANN. § 48-851.02 (West 2023) (safe disposal of unused pharmaceuticals)
Effective date(s) of provision(s)	March 5, 2010
Does the state allow drug take-back programs by statute/regulation?	No.
Program components	N/A
Program components Miscellaneous provisions	<ul> <li>N/A</li> <li>§ 48-851.02 – (a) the board of pharmacy shall design a public education campaign to educate individuals on:</li> <li>(1) the importance of promptly disposing of unused pharmaceuticals to avoid accidental overdoses, medication errors, and household drug theft;</li> <li>(2) how disposing of pharmaceuticals by flushing them into the public sewer system or throwing them in the trash can be harmful to the environment and can contaminate the drinking water supply; and</li> <li>(3) how to dispose of unused pharmaceuticals in a safe and environmentally sound manner.</li> <li>Each retail pharmacy licensed in D.C. shall implement the public education campaign as required by the board of pharmacy.</li> <li>(b)(1) By July 1, 2010, the board of pharmacy shall make recommendations to the Mayor regarding the establishment of a program to enable consumers to dispose of unused pharmaceuticals, including controlled substances, in a safe and environmentally sound manner.</li> <li>(2) In developing recommendations, the board of pharmacy shall give consideration to a mail-in program that:</li> <li>(a) utilizes prepaid mailing envelopes that allow an individual to mail unused pharmaceuticals to a single collection location approved for all pharmaceuticals including controlled substances;</li> </ul>
	<ul> <li>(b) distributes the prepaid mailing envelopes to the public at various locations, including to all retail pharmacies;</li> <li>(c) provides for the collected pharmaceuticals to be disposed of in a manner that is safe, secure, environmentally sound, and in compliance with District and federal environmental requirements; and</li> </ul>

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DISTRICT OF COLUMBIA	
Program components (continued)	- (d) randomly assesses the toxicity of pharmaceuticals received; provided, that the assessment results do not identify the patient, person who mailed the material, prescriber, or pharmacy.
Recently proposed legislation	None.
Program website	Safe Disposal of Medications   doh

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<u>FLORIDA</u>	
Statute(s) and regulation(s)	None.
Effective date(s) of provision(s)	N/A
Does the state allow drug take-back programs by statute/regulation?	No.
Program components	N/A
Miscellaneous provisions	None.
Recently proposed legislation	None.
Program website	Pharmaceutical Waste Management for Businesses and Homeowners   Florida Department of Environmental Protection

	CEOPCIA
<u>GEORGIA</u>	
Statute(s) and regulation(s)	<ul> <li>GA. COMP. R. &amp; REGS. 480-705 (2023) (reverse distributors)</li> <li>GA. COMP. R. &amp; REGS. 480-5001 to07 (2023) (collectively titled "Drug Disposal and Authorized Collectors")</li> </ul>
Effective date(s) of provision(s)	• August 26, 2001 (480-705) • February 9, 2016 (480-5001 to07)
Does the state allow drug take-back programs by statute/regulation?	Yes.
Program components	480-705 – every firm, whether located inside or outside the state, which receives drugs for destruction, return credit, or otherwise disposes of drugs received from a registrant located in the state which holds a permit or license to dispense or possess drugs, shall be known as a reverse distributor or a reverse drug distributor.
	480-5001 (definitions) – definitions include:
	<ul> <li>"authorized collectors" or "collectors," which means retail pharmacies, hospitals/clinics with an on-site pharmacy, narcotic treatment programs, manufacturers, distributors, and reverse distributors which have registered with the DEA to become authorized collectors of drugs for disposal, are authorized to handle controlled substances, and are currently licensed by the board of pharmacy;</li> <li>"collection receptacle," which means a lockable and sturdy container with a permanent outer container and a removable numbered inner liner with a small opening that allows contents to be added but not removed and which container is securely fastened to a permanent structure in a secure area;</li> <li>"drugs" which means controlled substances and dangerous drugs (non-controlled substances) as defined by law;</li> <li>"mail-back packages," which means pre-paid postage packages provided by authorized collectors at a price or at no cost to the patient or patient's family;</li> <li>"mail-back programs," which means programs that utilize mail-back packages provided by authorized collectors in which the packages are mailed directly to a reverse distributor and can never be mailed back to the authorized collector; and</li> <li>"numbered inner liner," which means a removable, tamperevidence, and tear-resistant liner that bears a unique identification number that is used inside a collection receptacle and which can be securely sealed for transfer to a reverse distributor for transportation to a drug destruction site.</li> </ul>

#### **GEORGIA**

## **Program components** (continued)

480-50-.02 (collection receptacles located at authorized collectors) – authorized collectors may place, utilize, and maintain collection receptacles at their DEA-registered location. Receptacles can only be available to receive drugs when the collector is open for business and only when an authorized employee is present.

Collection receptacles must be lockable, sturdy, and securely fixed within the collector's location. If the authorized collector is in a pharmacy, the collection receptacle must be in the immediate vicinity of and can be observed from the prescription department areas where controlled substances are stored by registrants and where an authorized employee is present. Receptacles must display a sign stating that non-controlled and Schedule II – V controlled drugs can be accepted and placed in the receptacle.

If the receptacle is in a hospital/clinic, it must be in an area monitored by employees, but shall not be in an area where emergency or urgent care is provided.

If the receptacle is in an opioid treatment facility, it must be located in a room that does not contain other controlled substances and is securely locked with controlled access.

Each receptacle must also be capable of holding a removable, tamper-evidence, and tear-resistant inner liner bearing a unique identification number to receive the drugs. To dispose of the contents of a receptacle, the sealed liners may be promptly delivered or transferred to a representative for a licensed reverse distributor for destruction. No on-site disposal of any drug is permitted.

Authorized collectors may store inner liners that have been sealed upon removal from a collection receptacle in a securely locked, substantially constructed cabinet or securely locked room with controlled access for up to three business days until the liners can be transferred for destruction, and then transferred to a representative for a licensed reverse distributor for destruction.

480-50-.03 (collection receptacles located at long term care facilities (LTCF)) – collection receptacles in long-term care facilities must be located in a secured area monitored by LTCF employees and can only be used in facilities where a consultant pharmacist's services are required.

#### **GEORGIA**

### **Program components** (continued)

An LTCF may dispose of drugs on behalf of an ultimate user who resides, or has resided, at such LTCF by transferring those drugs into an authorized collection receptacle located at such LTCF. The drugs must be transferred into the receptacle within three business days after discontinuation of use by the ultimate user.

The drugs placed in the authorized receptacle and stored in secure inner liner and those secured inner liners stored by the LTCF can only be removed from the LTCF for disposal for destruction by transfer to a representative for a reverse distributor.

Authorized collectors may not transfer sealed inner liners from LTCFs to their primary registered location.

480-50-.04 (numbered inner liner requirements) – a numbered inner liner shall meet the following requirements:

- (1) be waterproof, tamper-evident, and tear-resistant;
- (2) be removable and sealable immediately upon removal without emptying or touching the contents;
- (3) the contents shall not be viewable from the outside when sealed;
- (4) the size of the inner liner shall be clearly marked on the outside of the liner; and
- (5) shall bear a permanent, unique identification number that enables the inner liner to be tracked.

480-50-.05 (mail-back programs) – pre-paid mail-back packages may be provided by authorized collectors to patients and their families for a price or at no cost to the patient. Mail-back packages cannot be returned or mailed back to the authorized collector, unless the collector is a licensed reverse distributor. Collectors that are pharmacies cannot receive or dispose of mail-back packages. All such packages must be shipped directly to a licensed reverse distributor for disposal.

480-50-.06 (reverse distributors) – a reverse distributor shall acquire controlled substances and non-controlled drugs from a collector in the following manner:

- (1) pick-up of sealed inner liner from a collector at the collector's licensed location or authorized receptacle collection site such as an LTCF; or

<u>GEORGIA</u>	
Program components (continued)	- (2) receive a sealed inner liner delivered by common or contract carrier or delivered directly by a registrant or an LTCF to the reverse distributor.
	Upon acquisition of a drug by delivery or pick-up, a reverse distributor shall immediately store the substance at the reverse distributor's registered location or immediately transfer the drugs to the reverse distributor's registered location for secure storage until timely destruction. A reverse distributor shall destroy or cause the destruction of any drug received for the purpose of destruction no later than 30 calendar days after receipt.
	480-5007 (inspections) – provides that the Georgia Drugs and Narcotics Agency shall have the authority to conduct inspections of any place, premises, or receptacle utilized by any authorized collector in relation to collection, retention, and disposal of drugs.
Miscellaneous provisions	None.
Recently proposed legislation	None.
Program website	Disposal of Prescription Drugs   Georgia Attorney General's Consumer Protection Division

	<u>HAWAII</u>
Statute(s) and regulation(s)	<ul> <li>HAW. REV. STAT. ANN. § 327L-15 (West 2023) (disposal of unused medication)</li> <li>HAW. REV. STAT. ANN. § 461-10.2 (West 2023) (return for disposal of unused, remaining, or expired drugs; pharmacy options)</li> </ul>
Effective date(s) of	• January 1, 2019 (§ 327L-15)
provision(s)	• July 1, 2019 (§ 461-10.2)
Does the state allow drug take-back programs by statute/regulation?	Yes.
Program components	§ 461-10.2 - no pharmacy shall accept the return of any prescription drug unless the pharmacy is collecting the prescription drug for disposal only and the pharmacy is registered with the U.S. Drug Enforcement Administration as an authorized collector pursuant to 21 C.F.R. § 1317.40.  Any pharmacy accepting prescription drugs for disposal shall use the following methods:  - (1) secured collection receptacles in compliance with 21 C.F.R. § 1317.75; or
	- (2) mail-back programs.  In any pharmacy accepting prescription drugs for disposal under this section, the pharmacist-in-charge shall ensure that only DEA-approved reverse distributors acquire prescription drugs collected through collection receptacles and mail-back programs.
Miscellaneous provisions	§ 327L-15 – a person who has custody or control of any unused medication dispensed under this chapter after the death of a qualified patient shall personally deliver the unused medication for disposal to the nearest qualified facility that properly disposes of controlled substances or, if none is available, shall dispose of it by lawful means.
Recently proposed legislation	None.
Program website	Hawaii Medication Take Back Program

<u>IDAHO</u>	
Statute(s) and regulation(s)	IDAHO ADMIN. CODE r. 24.36.01.408 (2023) (destruction or return of drugs or devices: restrictions)
Effective date(s) of provision(s)	March 31, 2022
Does the state allow drug take-back programs by statute/regulation?	Yes.
Program components	24.36.01.408 – a drug outlet registered with the DEA as a collector may collect controlled and non-controlled drugs for destruction in accordance with applicable federal law. Otherwise, a dispensed drug or prescription device may only be accepted for return when, among other things, the pharmacist determines that harm could result if the drug is not returned.
Miscellaneous provisions	None.
Recently proposed legislation	None.
Program website	Year-Round Prescription Drug Disposal Locations   Office of Drug Policy

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<u>ILLINOIS</u>	
Statute(s) and regulation(s)	<ul> <li>20 ILL. COMP. STAT. ANN. 3930/9.3 (West 2023) (the prescription pill and drug disposal fund)</li> <li>210 ILL. COMP. STAT. ANN. 150/17 (West 2023) (pharmaceutical disposal)</li> <li>410 ILL. COMP. STAT. ANN. 720/1 to 720/999 (West 2023) (collectively titled "Drug Take-back Act")</li> <li>ILL. ADMIN. CODE tit. 35, §§ 889.100 to 889.220 (2023) (collectively titled "Medication Takeback Program")</li> </ul>
Effective date(s) of	• January 1, 2012 (3930/9.3 and 150/17)
provision(s)	• May 1, 2018 (§§ 889.100 to 889.220) • June 10, 2022 (720/1 to 720/999)
Does the state allow drug take-back programs by statute/regulation?	Yes.
Program components	3930/9.3 – creates the prescription pill and drug disposal fund in the state treasury. Provides that moneys in the fund shall be used for grants by the Illinois Criminal Justice Information Authority to local law enforcement agencies for the purpose of facilitating the collection, transportation, and incineration of pharmaceuticals from residential sources that are collected and transported by law enforcement agencies under Section 17.9A of the Environmental Protection Act; to municipalities or organizations that establish containers designed for the collection and disposal of unused controlled substances and conduct collection of unused controlled substances through mail-back programs; and for the publication or advertising of collection events or mail-back programs conducted by municipalities or organizations.  720/10 (definitions) – definitions include:  - "authorized collector," which means any of the following who collect covered drugs through participation in a drug take-back program: (a) a person who is registered with the U.S. Drug Enforcement Administration to collect controlled substances for the purpose of destruction; (b) a law enforcement agency; (c) a unit of local government working in conjunction with a law enforcement agency; or (d) a household waste drop-off point or one-day household waste collection event, as those terms are defined in the Environmental Protection Act;  - "collection site," which means the location where an authorized collector collects covered drugs as part of a drug take-back program;

# Program components (continued)

- "covered drug," which means a drug, legend drug, nonlegend drug, brand name drug, or generic drug. "Covered drug" does not include a dietary supplement, Schedule I controlled substances, personal care products, drugs for which manufacturers provide a pharmaceutical stewardship or drug take-back program, biological products, drugs administered in a clinical setting, emptied injector products or medical devices, needles or sharps, pet pesticide products, dialysate drugs or other saline solutions required to perform kidney dialysis, or homeopathic drugs;
- "manufacturer program operator," which means a covered manufacturer, a group of covered manufacturers, or an entity acting on behalf of a covered manufacturer or group of covered manufacturers, that implements a drug take-back program; and
- "potential authorized collector," which means a person who is eligible to be an authorized collector by participating in a drug take-back program.

720/15 (participation in a drug take-back program) — each covered manufacturer must, beginning January 1, 2024, or six months after becoming a covered manufacturer, whichever is later, individually or collectively implement an approved drug take-back program that complies with the requirements of this act. A covered manufacturer must establish, fund, and implement a drug take-back program independently or as part of a group of covered manufacturers.

720/20 (identification of covered manufacturers) – no later than April 1, 2023, each pharmacy, private label distributor, and repackager that sells or offers for sale in Illinois, under its own label, a covered drug must provide writing notification to the agency identifying the covered manufacturer from which the covered drug is obtained.

All covered manufacturers of covered drugs sold or offered for sale in Illinois must register with the agency and pay to the agency the annual registration fee as set forth under Section 60.

720/25 (drug take-back program requirements) – at least 120 days prior to submitting a proposal under Section 35, a manufacturer program operator must notify potential authorized collectors of the opportunity to serve as an authorized collector for the proposed drug take-back program. No later than 30 days after a

## **Program components** (continued)

potential authorized collector expresses interest in participating in a proposed program, the manufacturer program operator must commence good faith negotiations with the potential authorized collector regarding the collector's participation in the program.

A person may serve as an authorized collector for a drug takeback program voluntarily or in exchange for compensation. Nothing in this act requires any person to serve as an authorized collector for a program. A pharmacy shall not be required to participate in a drug take-back program.

A drug take-back program must include as a collector any person who: (1) is a potential authorized collector; and (2) offers to participate in the program. The manufacturer program operator must include the person in the program as an authorized collector no later than 90 days after receiving a written offer to participate.

A drug take-back program must pay for all administrative and operational costs of the program.

An authorized collector operating a program collection site must accept all covered drugs from consumers during the hours that the location used as a collection site is normally open for business to the public.

A drug take-back program collection site must collect covered drugs and store them in compliance with state and federal law. The manufacturer program operator must provide for transportation and disposal of collected covered drugs in a manner that ensures each collection site is serviced as often as necessary to avoid reaching capacity and that collected covered drugs are transported to final disposal in a manner compliant with law, including a process for additional prompt collection service upon notification from the collection site.

Covered drugs shall be disposed of at a permitted hazardous waste facility; a permitted municipal waste incinerator; or a permitted hospital, medical, and infectious waste incinerator.

A drug take-back program must provide for the collection, transportation, and disposal of covered drugs on an ongoing, year-round basis and must provide access for residents across the state. a program shall provide, in every county with a potential authorized collector, one authorized collection site and a

### **Program components** (continued)

minimum of at least one additional collection site for every 50,000 county residents, provided that there are enough potential authorized collectors offering to participate in the program.

A program may include mail-back distribution locations or periodic collection events for each county in the state. The manufacturer program operator shall consult with each county authority identified in the written notice prior to preparing the program plan to determine the role that mail-back distribution locations or periodic collection events will have in the program.

The requirement to hold periodic collection events shall be deemed satisfied if a manufacturer program operator makes reasonable efforts to arrange periodic collection events but they cannot be scheduled due to lack of law enforcement availability.

A drug take-back program must permit a consumer who is a homeless, homebound, or disabled individual to request prepaid, pre-addressed mailing envelopes. A manufacturer program operator shall accept the request through a website and toll-free telephone number that it must maintain to comply with the requests.

720/30 (manufacturer program operator requirements) – a manufacturer program operator shall:

- (1) adopt policies and procedures to be followed by persons handling covered drugs collected under the program;
- (2) ensure the security of patient information on drug packaging during collection, transportation, recycling, and disposal;
- (3) promote the program by providing consumers, pharmacies, and other entities with educational and informational materials as required; and
- (4) consider: (a) the use of existing providers of pharmaceutical waste transportation and disposal services; (b) separation of covered drugs from packaging to reduce transportation and disposal costs; and (c) recycling of drug packaging.

720/35 (drug take-back program approval) – by July 1, 2023, each covered manufacturer must individually or collectively submit to the agency for review and approval a proposal for the establishment and implementation of a drug take-back program.

### **Program components** (continued)

The proposal must demonstrate that the program will fulfill the requirements of Section 25. If the agency receives more than one proposal for a program, the agency shall review all proposals in conjunction with one another to ensure the proposals are coordinated to achieve the authorized collection site coverage set forth in Section 25.

Sets forth the requirements for approval, rejection, or approval with modification of proposals, and the time periods within which the agency must take action to approve, reject, or approve with modification.

720/40 (changes or modifications to the approved manufacturer drug take-back program) – a manufacturer program operator shall maintain records for five years of any changes to an approved drug take-back program. These include, but are not limited to, changes in: (a) participating covered manufacturers; (b) collection methods; (c) collection site locations; or (d) contact information for the program operator or authorized collectors.

720/45 (drug take-back program promotion) — each program must include a system of promotion, education, and public outreach about the proper collection and management of covered drugs. If there is more than one drug take-back program operated by more than one manufacturer program operator, the requirements of this section shall be implemented by all programs collectively using a single toll-free number and website, and similar education, outreach, and promotional materials. This may include, but is not limited to, signage, written materials to be provided at the time of purchase or delivery of covered drugs, and advertising or other promotional materials. At a minimum, promotion, education, and public outreach must include the following:

- (1) promoting the proper management of drugs by residents and the collection of covered drugs through a drug take-back program;
- (2) discouraging residents from disposing of drugs in household waste, sewers, or septic systems;
- (3) promoting the use of the program so that where and how to return covered drugs is readily understandable to residents;
- (4) maintaining a toll-free telephone number and website publicizing collection options and collection sites, and discouraging improper disposal practices for covered drugs,

# **Program components** (continued)

such as disposal in household waste, sewers, or septic systems;

- (5) preparing and distributing to program collection sites, for dissemination to consumers, the educational and outreach materials, which materials must use plain language and explanatory images; and
- (6) promotional materials prepared and distributed in conjunction with an approved drug take-back program under this section may not be used to promote in-home disposal products of any kind, including, but not limited to, in-home disposal products of authorized collectors participating in a program.

720/50 (annual program report) – by April 1, 2025, and each April 1 thereafter, a manufacturer program operator must submit to the agency a report describing implementation of the drug takeback program during the previous calendar year. The report must include:

- (1) a list of the covered manufacturers participating in the drug take-back program during the program year;
- (2) the total amount, by weight, of covered drugs collected and the amount, by weight, from each collection method used during the program year, reported by county;
- (3) the total amount, by weight, of covered drugs collected from each collection site during the prior year;
- (4) the following details regarding the program's collection system: (a) a list of collection sites, with addresses; (b) collection sites where mailers to program collection sites, for dissemination to consumers, and education and outreach materials were made available to the public; (c) dates and locations of collection events held; and (d) the transporters and disposal facility or facilities used to dispose of the covered drugs collected;
- (5) a description of the promotion, education, and public outreach activities implemented;
- (6) a description of how collected packaging was recycled to the extent feasible; and
- (7) an evaluation of the program's effectiveness in collecting covered drugs during the program year and of any program changes that have been implemented.

720/55 (manufacturer drug take-back program funding) – a covered manufacturer or group of covered manufacturers must

### **Program components** (continued)

pay all administrative and operational costs associated with establishing and implementing the drug take-back program in which it participates. Such costs include, but are not limited to, collection and transportation supplies for each collection site, purchase of collection receptables, ongoing maintenance or replacement of collection receptacles, costs related to mail-back program, compensation of authorized collectors, operation of periodic collection events, and proper disposal of all collected covered drugs.

A manufacturer program operator, covered manufacturer, authorized collector, or other person may not charge:

- (1) a specific point-of-sale fee to consumers to recoup the costs of a drug take-back program;
- (2) a specific point-of-collection fee at the time covered drugs are collected from a person; or
- (3) an increase in the cost of covered drugs to recoup the costs of a drug take-back program.

720/60 (registration fee) – by January 1, 2023, and by January 1 of each year thereafter, each covered manufacturer and manufacturer program operator shall register with the agency and submit a \$2,500 registration fee.

720/65 (rules; enforcement; penalties) – gives the agency the authority to adopt any rules it deems necessary to implement and administer this act.

Provides that, except as otherwise provided, any person who violates any provision of this act is liable for a civil penalty of \$7,000 per violation per day, provided that the penalty for failure to register or pay a fee under this act shall be double the applicable registration fee.

Provides that any person who knowingly makes a false, fictitious, or fraudulent material statement, orally or in writing, to the agency, related to or required by this act or any rule adopted under this act commits a Class 4 felony, and each such statement or writing shall be considered a separate Class 4 felony. A second or subsequent violation is a Class 3 felony.

720/70 (antitrust immunity) – the activities authorized by this act require collaboration among covered manufacturers and among

## **Program components** (continued)

authorized collectors. These activities will enable safe and secure collection and disposal of covered drugs and are, therefore, in the best interest of the public. The benefits of collaboration, together with active state supervision, outweigh potential adverse impacts. Therefore, the General Assembly intend to exempt from state antitrust laws, and provide immunity through the state action doctrine from federal antitrust laws, activities that are undertaken pursuant to this act that might otherwise be constrained by such laws.

720/90 (home rule) — on and after the date of this act, no local government shall mandate that a new drug take-back or disposal program be created and no expansion or change of an existing program or program requirement by a unit of local government shall occur that is inconsistent with this act. A home rule municipality may not regulate drug take-back programs in a manner inconsistent with the regulation by the state of programs under this act.

§ 889.105 (definitions) – definitions include:

- "household waste," which means waste generated from a single residence or multiple residences;
- "household waste drop-off point," which means the portion of a site or facility used solely for the receipt and temporary storage of household waste;
- "medication takeback location," which means a household waste drop-off point that accepts pharmaceutical products for which the agency has agreed to make disposal arrangements; and
- "operator," which means a person responsible for the operation and maintenance of a household waste drop-off point at which pharmaceutical products are accepted.

§ 889.200 (application) – any person seeking to have the agency arrange for the disposal of pharmaceutical products accepted at a medication takeback location must submit to the agency an application requesting that the agency arrange for the disposal. Sets forth the requirements for applications, including required information.

§ 889.205 (agency action) – subject to appropriation, the agency may provide for the disposal of pharmaceutical products accepted

### 84 **ILLINOIS** at one or more medication takeback locations selected pursuant to **Program components** (continued) this section. Subject to appropriation, the agency will review applications submitted in accordance with this section and select applicants for whom the agency will provide for the disposal of accepted pharmaceutical products. In making its selection, the agency will consider site-specific factors, such as the geographic location of the medication takeback location, the geographic area served by the location, the population of the area served by the location, the names and locations of other known entities that collect pharmaceutical products within a 25 mile radius of the location, and the estimated cost to the agency of accepting and disposing of the products collected at the medication takeback location. § 889.210 (operating requirements) – medication takeback locations must be located at a site or facility where pharmaceutical products are lawfully sold, distributed, or dispensed. This does not apply to household waste drop-off points operated by a government or by an association or other organization of government. The location of acceptance of pharmaceutical products at the medication takeback location must be clearly identified. Pharmaceutical products that are accepted at medication takeback locations may only be accepted in accordance with this act, this part, and other applicable law. Products must be accepted only from private individuals. Pharmaceutical products accepted at the medication takeback location must be managed separately from all other household waste accepted at the medication takeback location prior to its packaging for off-site transfer. § 889.220 (termination) – any operator of a medication takeback location that ceases to accept pharmaceutical products for agency arranged disposal must submit a written notification to the agency within 30 days after the date the collection terminates. The agency may terminate disposal arrangements made pursuant to this part for any reason, including but not limited to the operation of a medication takeback location in violation of the act. 150/17 – notwithstanding any other law, any county or Miscellaneous provisions

municipality may authorize the use of its city hall, police

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Miscellaneous provisions (continued)	department, or any other facility under the county's or municipality's control to display a container suitable for use as a receptacle for used, expired, or unwanted pharmaceuticals. These may include unused medication and prescription drugs, as well as controlled substances if collected in accordance with federal law. This receptacle shall only permit the deposit of items, and the contents shall be locked and secured. The container shall be accessible to the public and shall have posted clearly legible signage indicating that expired or unwanted prescription drugs may be disposed of in the receptacle. The county or municipality shall provide continuous or regular notice to the public regarding the availability of the receptacle. To the extent allowed under federal law, pharmaceuticals collected under this section may be disposed of in a drug destruction device.
Recently proposed legislation	None.
Program website	Medication Disposal

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	<u>INDIANA</u>
Statute(s) and regulation(s)	<ul> <li>IND. CODE ANN. §§ 25-26-23-1 to -9 (West 2023) (collectively titled "Returning Unused Medication")</li> <li>856 IND. ADMIN. CODE 7-1-1 to 7-9-1 (West 2023) (collectively titled "Prescription Drug Take Back Programs")</li> </ul>
Effective date(s) of provision(s)	• July 1, 2011 (§§ 25-26-23-1 to -8) • September 18, 2012 (7-1-1 to 7-9-1) • May 5, 2019 (§ 25-26-23-9)
Does the state allow drug take-back programs by statute/regulation?	Yes.
Program components	§ 25-26-23-3 (determination of entities participating in program) – the board of pharmacy shall determine the entities that may participate in a program under this chapter, but must include health facilities licensed under Indiana Code 16-28 and pharmacies.
	§ 25-26-23-4 (guidelines for acceptance of unused medication) – the rules adopted under this chapter must set forth the guidelines for an entity to accept unused medication. The rules must set forth:
	<ul> <li>(1) the responsibilities of the entities who are accepted the unused medication;</li> <li>(2) details concerning recordkeeping of the medication collected;</li> <li>(3) the proper methods to destroy unused medication;</li> <li>(4) privacy protocols;</li> <li>(5) security standards; and</li> <li>(6) proper transportation procedures.</li> </ul>
	§ 25-26-23-5 (return of unused medication) – the board may adopt rules allowing an entity determined under section 3 of this chapter to return unused medication to the pharmacy that dispensed the medication.
	§ 25-26-23-6 (consultation with other agencies and task force) – the board shall consult with the following agencies and task force in promulgating rules under this chapter: the department of environmental management, the Indiana department of health, the state police department, and the Indiana hazardous waste task force.
	§ 25-26-23-7 (limitations) – the rules under this chapter may not:

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### Program components (continued)

- (1) mandate any public or private entity to establish, operate, or fund a disposal program under this chapter;
- (2) mandate that law enforcement participate in a program under this chapter;
- (3) require any new licensing or fees for a program under this chapter;
- (4) create liability for an entity not participating in or a patient not using a program under this chapter; and
- (5) have a fiscal impact to the state or any state agencies.

§ 25-26-23-8 (civil liability) – an entity or employee of an entity who is operating a program under this chapter is immune from civil liability for an act or omission related to the operation of the program. The civil immunity described in this section does not apply to an act or omission that constitutes gross negligence or willful, wanton, or intentional misconduct and the enforcement of rules adopted under this chapter by a government entity.

§ 25-26-23-9 (program to accept unused medication by business or other entity; restrictions on unit) – as used in this section, "unit" means a city, town, or county. A program to accept unused medication by a business or other entity that complies with applicable state and federal law is not subject to regulation by a unit. A unit may not do any of the following:

- (1) impose a tax, fee, assessment, or charge on a consumer, business, or other entity to pay for or support a program to accept unused medication in the unit's jurisdiction;
- (2) require a business or other entity to establish, pay for, or operate a program to accept unused medication in the unit's jurisdiction.

Nothing in this section prohibits a unit from using money in the unit's general fund to operate a program to accept unused medication.

7-2-4 ("return of unused medication" defined) – "return of unused medication" refers to medications that are collected under the auspices of an eligible take back program. This does not include medication that is returned for credit, resale, and redistribution. This also does not include drugs listed in Schedule I.

7-2-5 ("entities" defined) – "entities" means those licensed facilities that are eligible to run a legal take back program under

### **Program components** (continued)

Indiana law. Licensed facilities included in this definition are all pharmacies licensed under Indiana Code 25-26 listed as active and in good standing and healthcare facilities licensed under Indiana Code 16-28 listed as active and in good standing.

- 7-2-7 ("unused or unwanted medication" defined) "unused or unwanted medication" could mean all drugs that fall under the definition of drug as defined in Ind. Code Ann. § 16-42-19. Entities that run take back programs may further define or limit what drugs they are capable or willing to accept for destruction purposes. They are not required or mandated to take all drugs in order to maintain eligibility as a take back program.
- 7-2-8 ("drug storage device" defined) "drug storage device" means the device in which the returned prescription drugs are stored after return by the consumer and before disposal.
- 7-2-9 ("drug return receptacle" defined) "drug return receptacle" means the receptacle into which the consumer places the returned prescription drugs, whether or not it is the drug storage device.
- 7-3-1 (personnel) entities that run a take back program must have licensed personnel that directly manage and have oversight for implementation and the day-to-day activities of the program and services. The individual responsible for managing the program or services must have an active and in good standing license issued by the Indiana professional licensing agency under Indiana Code 25.
- 7-3-2 (documented policies and procedures) entities that run a take back program must have documented policies and procedures that address all the requirements of this act.
- 7-3-3 (management of vendor relationships) entities that run a take back program must maintain a documented contract that provides for the roles and responsibilities of each party performing services related to transportation, destruction, and security, and that is available for review by the board. This section does not require board approval and does not require a contract where the entity is eligible to perform this service independent of a third party vendor.

# Program components (continued)

- 7-3-4 (prohibition on reuse and resale) unused or unwanted medications collected by an entity running a take back program shall not be returned to saleable inventory nor made available for subsequent relabeling and redispensing unless otherwise permitted by law.
- 7-4-1 (requirement to keep records) entities that engage in a take back program shall be required to keep a record of policies and procedures, personnel involved with or who have access to returned medications, dates when medications were collected by the party responsible for destruction, and personnel responsible for destruction, transportation, and security.
- 7-5-1 (requirement for destruction) drugs collected by a take back program being implemented under this article are required to be destroyed and may not be resold, reused, redistributed, or otherwise interfered with in any way that might present an opportunity for harm, misuse, or diversion.
- 7-5-2 (required time period for destruction) the frequency of drug destruction can be determined by the entity that runs the take back programs as determined by need and volume, but destruction must occur at least on a quarterly basis to ensure drugs are not stored indefinitely and do not pose a threat to public health and safety.
- 7-5-3 (acceptable methods of destruction) entities that run take back programs must use a means of destruction that results in incineration of the drugs ensuring that those destroyed drugs do not pose a risk to public health and safety and ensure that the drugs or drug remains do not pose an unacceptable level of risk or harm to water systems or landfills. Entities that run programs that utilize their own means to destroy collected drugs must be able to evidence that their incinerator or destruction method is capable of safely destroying drugs and rendering them harmless to the public.

Entities that do not destroy the collected drugs on site or within their own company must have a contract in place with a vendor that will manage the destruction. Such contract must include documented policies and procedures that address destruction. Those policies and procedures must at least include a discussion of the transportation, security, and destruction means which would otherwise comply with this rule. A system of receipt

### **Program components** (continued)

and/or logs that evidence each destruction, the total weight of the drugs destroyed, and the date it occurred must be included as part of this contract.

Entities that wish to utilize a different method of destruction not otherwise listed or discussed above may petition the board to approve another documented and proven destruction process. Such process must include documented policies and procedures that at least address the following issues: public health and safety; diversion; and environmental hazards.

7-6-1 (privacy generally) – entities and vendors must ensure that patient privacy rights are protected.

7-6-2 (privacy protocols and policy) – an entity that runs a take back program shall be responsible for providing documented policies and procedures that outline how they protect patient privacy consistent with state and federal laws. An entity shall provide privacy training to all staff involved with a program and have documentation of said training available for board inspection.

7-6-3 (notice to patients or customers) – an entity that runs a take back program is required to provide a notice to consumers and/or patients a copy of their privacy policy and how they protect consumers' private health information from being disclosed. The notice and policy should include a statement to how the drugs are collected, the security safeguards, and the method of destruction. This notice may be posted or provided in any one of the following ways:

- (1) pamphlets or leaflets that describe the policy available to the public upon request;
- (2) a notice posted on the box or device where the drugs are collected; or
- (3) a notice posted in the area where take back occurs and is reasonably accessible to view by patients and other consumers.

7-7-1 (storage device or drug return receptacle) – an acceptable storage device or drug return receptacle will meet the following criteria:

### Program components (continued)

- (1) does not allow for the removal of contents except by authorized personnel;
- (2) is secured in a manner that will only allow authorized personnel to remove the contents of the container; and
- (3) utilizes a design that is tamper resistant and will not represent a risk to patient or customer safety.

7-7-2 (location of storage device or drug return receptacle) – if the storage device is movable, the device and/or receptacle must be located in the pharmacy department and must be capable of being monitored by whatever security features or personnel that pharmacy department utilizes. If the storage device is stationary and secure, then the device and/or receptacle may be located anywhere in the interior of the building housing the pharmacy, but only personnel included within this article and as provided for in the policies and procedures of the entity running the take back program may have access to that storage device or receptacle.

7-7-3 (access to contents and secure method of drug drop off) – it is not required that licensed personnel physically facilitate the placement of the drugs by the patient or customer into the storage device or receptacle. If done by the patient into a secure device, then no other involvement or documentation need occur. If pharmacy staff is involved in assisting with the drop off and collection of drugs, the personnel involved will witness and document that the drop off and placement of the drugs into the storage device or receptacle occurred.

Only personnel designated in the policies and procedures governing the take back program for each individual entity and program shall have access to remove the storage device(s) from the receptacle where the drugs are collected or to transfer the device to the party performing the destruction services.

7-7-5 (maintenance, monitoring, and emptying) – the drug receptacle into which drugs are placed or returned must be maintained in such a way as to prevent unintended access, diversion, or harm to the personnel or patients/customers that might use or be in the vicinity of the receptacle.

The storage device and drug receptacle should be monitored in accordance with the security provisions discussed in this article. In the event the device being used to accept returned medications is full or exceeds capacity, personnel involved in managing the

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Program components (continued)	program may remove the contents to the extent necessary to secure the returned medications until such time as personnel can arrange for destruction. Whatever contents are removed must be secured in an area separate from merchandise or prescriptions available for sale to customers or patients.
	7-7-6 (requirement for notice or signage of acceptable returns) – if an entity engaged in a drug take back program chooses to limit those drugs which are acceptable for return under that program, such limitations shall be clearly and conspicuously placed on or near the drug receptacle in plain view of the patient/customer returning prescription drugs.
	7-8-2 (minimum standards) – the following minimum standards shall apply to the transportation solutions utilized by entities that run take back programs or the contracted provider they use:
	<ul> <li>(1) an appropriate level of security that protects against diversion;</li> <li>(2) insurance and liability coverage similar to that maintained by common carriers or reverse distributors;</li> <li>(3) does not utilize a vehicle or mode of transportation that is primarily used for personal nonbusiness uses; and</li> <li>(4) the minimum level of driver licensure required by the state to operate a commercial vehicle for business purposes.</li> </ul>
	7-9-1 (liability and immunity defined) – any person or entity which exercises reasonable care in collecting dispensed drugs or devices for disposal pursuant to this section shall be immune from civil or criminal liability or professional disciplinary action of any kind for any injury, death, or loss to person or property relating to such activities.
Miscellaneous provisions	None.
Recently proposed legislation	None.
Program website	Bitterpill: Medicine Disposal

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<u>IOWA</u>	
Statute(s) and regulation(s)	<ul> <li>IOWA CODE ANN. § 155A.43 (West 2023) (pharmaceutical collection and disposal program—annual allocation)</li> <li>IOWA ADMIN. CODE r. 657-6.7 (2023) (security)</li> <li>IOWA ADMIN. CODE r. 657-10.2 (2023) (definitions)</li> <li>IOWA ADMIN. CODE r. 657-10.13 (2023) (security requirements)</li> <li>IOWA ADMIN. CODE r. 657-10.19 (2023) (physical count and record of inventory)</li> <li>IOWA ADMIN. CODE r. 657-10.23 (2023) (disposal of previously dispensed controlled substances)</li> <li>IOWA ADMIN. CODE r. 657-23.2 (2023) (definitions)</li> <li>IOWA ADMIN. CODE r. 657-23.21 (2023) (disposal of previously dispensed controlled substances)</li> </ul>
Effective date(s) of	July 1, 2011 (§ 155A.43)
provision(s)  Does the state allow drug take-back programs by statute/regulation?	Yes.
Program components	§ 155A.43 – of the fees collected by the board pursuant to §§ 124.301 (related to the registration and control of the manufacture, distribution, and dispensing of controlled substances) and 147.80 (board administrative costs) and this chapter, and retained by the board, the board may annually allocate a sum deemed by the board to be adequate for administering the pharmaceutical collection and disposal program. The program shall provide for the management and disposal of unused, excess, and expired pharmaceuticals, including the management and disposal of controlled substances pursuant to state and federal regulations. The board may contract with one or more vendors for the provision of supplies and services to manage and maintain the program and to safely and appropriately dispose of pharmaceuticals collected through the program.  657-10.2 and 657-23.2 – definitions include "authorized collection program," which means a program administered by a registrant that has modified its registration with the DEA to collect controlled substances for the purpose of disposal. Modification of the registrant's Iowa controlled substances act registration shall not be required.
	657-10.13 – controlled substances collected via an authorized collection program for the purpose of disposal shall be stored pursuant to federal regulations.

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Program components (continued)	657-10.19 – controlled substances obtained through an authorized collection program for the purpose of disposal shall not be examined, inspected, counted, sorted, inventoried, or otherwise handled.
	657-10.23 – a registrant may not dispose of previously dispensed controlled substances unless the registrant has modified its registration with the DEA to administer an authorized collection program.
	657-23.21 – pharmacies registered with the DEA as authorized collectors may install and manage a collection receptacle in a care facility for the purpose of disposal of unwanted medications, including prescription drugs and controlled substances, pursuant to federal regulations.
Miscellaneous provisions	657-6.7 – while on duty, each pharmacist shall be responsible for the security of the prescription department and of the provisions for effective control against theft of, diversion of, or unauthorized access to prescription drugs, including those collected through an authorized collection program and records for such drugs and authorized collection program activities.
Recently proposed legislation	None.
Program website	Iowa Pharmacy Association - Medication Disposal

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<u>KANSAS</u>	
Statute(s) and regulation(s)	None.
Effective date(s) of provision(s)	N/A
Does the state allow drug take-back programs by statute/regulation?	No.
Program components	N/A
Miscellaneous provisions	None.
Recently proposed legislation	None.
Program website	Kansas Medication Drug Disposal Program Guide

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<u>KENTUCKY</u>	
Statute(s) and regulation(s)	<ul> <li>KY. REV. STAT. ANN. § 15.291 (West 2023) (Kentucky Opioid Abatement Advisory Commission; membership; meetings; criteria for award of moneys from opioid abatement trust fund)</li> <li>KY. REV. STAT. ANN. § 218A.170 (West 2023) (sale, distribution, administration, or prescription of controlled substances by licensed manufacturers, distributors, wholesalers, pharmacists, or practitioners; nontoxic compositions for safe disposal of controlled substances; duties of pharmacists and practitioners; penalties)</li> <li>902 KY. ADMIN. REGS. 55:120 (2023) (disposal of prescription controlled substances)</li> </ul>
Effective date(s) of	• July 14, 2018 (§ 218A.170)
provision(s)	• November 1, 2019 (902 KAR 55:120)
	• March 24, 2021 (§ 15.291)
Does the state allow drug take-back programs by statute/regulation?	Yes.
Program components	<ul> <li>§ 218A.170 – (4) upon dispensing of any prescription that contains any sale, compound, derivative, or preparation of an opioid, benzodiazepine, a barbiturate, codeine, or an amphetamine, a pharmacist or pharmacist's designee may:</li> <li>(a) make available for purchase, or at no charge distribute, a nontoxic composition for the sequestration, deactivation, destruction, and disposal of any unused, unwanted, or expired prescription; or</li> <li>(b) provide an on-site, safe, and secure medicine disposal receptacle or kiosk for the safe disposal of any unused, unwanted, or expired prescription.</li> <li>(5) A manufacturer or distributor of nontoxic compositions for the sequestration, deactivation, or destruction and disposal of controlled substances is strongly encouraged to enter into a consignment-reimbursement contract with a pharmacy in order for a pharmacy to expand its inventory of the nontoxic compositions.</li> <li>(7) A practitioner who dispenses a controlled substance that</li> </ul>
	(7) A practitioner who dispenses a controlled substance that contains any sale, compound, derivative, or preparation of an opioid, benzodiazepine, a barbiturate, codeine, or an amphetamine shall make available for purchase, or at no cost distribute, a nontoxic composition for the sequestration,

	<b>KENTUCKY</b>
Program components (continued)	deactivation, or destruction and disposal of unused, unwanted, or expired controlled substances.
Miscellaneous provisions	§ 15.291 - creates the Opioid Abatement Advisory Commission, which will award moneys from the opioid abatement trust fund to reimburse prior expenses or fund projects related to opioid use disorder including programs that provide drug take-back disposal or destruction programs.
	902 KAR 55:120 – a long-term care facility or other cabinet-licensed facility with custodial control of patient-owned controlled substance medications shall:
	<ul> <li>(1) dispose of all expired, abandoned, or otherwise unwanted controlled substances in accordance with 21 C.F.R. Part 1317; and</li> <li>(2) develop and implement written policies and procedures for the disposal of controlled substances. Disposal methods shall include: (a) on-site destruction that renders the controlled substance unrecoverable and beyond reclamation so that the medication cannot be diverted; or (b) transfer of the controlled substance to an authorized collection receptacle maintained by a law enforcement agency or pharmacy.</li> </ul>
	Controlled substances shall not be destroyed by flushing into a sewage treatment system unless disposal by flushing is permitted by instructions on the label, the patient information leaflet with the medication, or the U.S. Food and Drug Administration's flush list posted on the FDA website.
Recently proposed legislation	None.
Program website	Prescription Drug Disposal Locations - Office of Drug Control Policy

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<u>LOUISIANA</u>		
Statute(s) and regulation(s)	<ul> <li>LA. STAT. ANN. § 40:2191 (2023) (disposal of deceased patient's unused controlled substances)</li> <li>LA. ADMIN. CODE tit. 46, § 1519 (2023) (drug returns; drug disposal)</li> <li>LA. ADMIN. CODE tit. 46, § 2503 (2023) (drug returns; drug disposal)</li> <li>LA. ADMIN. CODE tit. 46, § 2517 (2023) (prescription dispensing; equivalent drug product interchange; drug returns; drug disposal)</li> <li>LA. ADMIN CODE. tit. 46, § 2749 (2023) (disposal of controlled substances)</li> </ul>	
Effective date(s) of provision(s)	• August 1, 2018 (§ 2191) • June 20, 2020 (§§ 1519, 2503, and 2517)	
Does the state allow drug take-back programs by statute/regulation?	Yes.	
Program components	<ul> <li>§§ 1519, 2503, 2517, and 2749 – when a patient or his designee wishes to return previously dispensed prescription drugs to a pharmacy for disposal, the pharmacy shall inform the patient or his designee of the disposal mechanisms available to him. In the event the pharmacy elects to accept such previously dispensed products for disposal, the pharmacy shall comply with the following requirements:</li> <li>(1) from the time of receipt of such products until the time of disposal, the pharmacy shall quarantine such products to keep them separate from its active dispensing stock and shall take appropriate security measures to prevent the theft or diversion of such products;</li> <li>(2) the pharmacy shall comply with 21 C.F.R. § 1317 or its successor for the pharmacy's disposal of controlled substances and other non-hazardous waste pharmaceuticals; and</li> <li>(3) the pharmacy shall comply with the provisions of 40 C.F.R. § 261 or its successor for the pharmacy's disposal of hazardous waste pharmaceuticals.</li> </ul>	
Miscellaneous provisions	§ 2191 – upon death of a patient receiving hospice services, ownership of the patient's unused Schedule II – V controlled substances may transfer to the hospice for immediate disposal pursuant to the following provisions:	

<u>LOUISIANA</u>	
Miscellaneous provisions (continued)	<ul> <li>(1) each hospice shall establish a written procedure to ensure safe disposal of unused controlled substances by a hospice nurse at the time of a patient's death;</li> <li>(2) upon the death of the patient, in the presence of a witness, the hospice nurse shall record in the medical record the name and quantity of each unused controlled substance; and</li> <li>(3) the hospice nurse shall conduct immediate disposal of the controlled substance at the site of care by complying with the Environmental Protection Agency and Drug Enforcement Administration guidelines for safe disposal or immediate mail-back to a registered authorized collector. If conducting immediate disposal at the site of care, the hospice nurse shall perform the disposal in the presence of a witness, who shall sign a document indicating their witnessing the disposal. If participating in immediate mail-back to a registered authorized collector, the hospice nurse shall deposit the unused controlled substance into the mail-back envelope and seal the envelope at the site of care. This shall be done in the presence of a witness, who shall sign a document indicating their witnessing the sealing of the substance in the envelope. The hospice nurse shall immediately initiate its delivery to the registered authorized collector; and</li> <li>(4) the hospice nurse shall record the method of disposal in the medical record.</li> </ul>
Recently proposed legislation	None.
Program website	Safely Dispose of Unused Medications During National Prescription Drug Take Back Day

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<u>MAINE</u>	
Statute(s) and regulation(s)	<ul> <li>ME. REV. STAT. ANN. tit. 22, § 2140 (West 2023) (patient-directed care at the end of life)</li> <li>ME. REV. STAT. ANN. tit. 22, § 2700 (West 2023) (unused pharmaceutical disposal program)</li> <li>ME. REV. STAT. ANN. tit. 22, § 8624 (West 2023) (medication disposal)</li> <li>ME. REV. STAT. ANN. tit. 38, § 1612 (West 2023) (drug take-back stewardship program)</li> </ul>
Effective date(s) of	• July 1, 2005 (§ 2700)
provision(s)	• September 19, 2019 (§ 2140)
	• October 18, 2021 (§§ 1612 and 8624)
Does the state allow drug take-back programs by statute/regulation?	Yes.
Program components	§ 1612 – (1) Definitions include:
	<ul> <li>"authorized collector," which means: (a) a person, company, corporation, or other entity registered with the U.S. Department of Justice, Drug Enforcement Administration, to collect controlled substances and noncontrolled substances for the purposes of safe disposal and destruction; (b) a law enforcement agency; or (c) a person, company, corporation, or other entity authorized by the department to provide alternative collection methods for covered drugs that are household pharmaceutical waste and that are noncontrolled substances. "Authorized collector" includes a mandatory pharmacy collector;</li> <li>"collection receptacle," which means a secure box, kiosk, or other container: (a) into which a person may deposit for disposal covered drugs that are household pharmaceutical waste and that is prominently labeled in a manner indicating that only such types of covered drugs may be deposited for disposal; (b) that meets applicable federal standards for the use described in paragraph (a); and (c) that is located on the premises of an authorized collector participating in a stewardship program under this section;</li> <li>"covered drug," which means any substance recognized as a drug under 21 U.S.C. § 321(g)(1) and any regulations adopted pursuant to that provision, that is sold, offered for sale or dispensed in the state, whether directly or through a wholesaler, in any form, including, but not limited to, prescription and non-prescription drugs, drugs in medical devices and combination products, brand and general drugs,</li> </ul>

### **Program components** (continued)

and drugs for veterinary use. "Covered drug" does not include vitamins or supplements, herbal-based remedies and homeopathic drugs, personal care products, pet pesticide products, biological products, drugs for which a manufacturer provides a program to take back those drugs, emptied syringes or medical devices, drugs that are administered in a clinical setting, or dialysate drugs required to perform kidney dialysis;

- "drug take-back stewardship organization" or "stewardship organization," which means a corporation, nonprofit organization, or other legal entity created by one or more manufacturers to implement a stewardship program under this section;
  - "drug take-back stewardship program" or "stewardship program," which means a system implemented under this section for the collection, transportation, and disposal of covered drugs that are household pharmaceutical waste;
- "household pharmaceutical waste," which means useless, unwanted, expired, or discarded drugs generated by a household. For purposes of this definition, "household" includes, but is not limited to, a single residential unit, a multifamily residential unit, an apartment, and an independent living community. "Household" does not include a hospital, health clinic, hospice facility, skilled nursing facility, or other long-term care facility, physician's office, pharmacy, or veterinary office or clinic;
- "mail-back envelope," which means a prepaid, preaddressed mailing envelope that is provided by or through a company or organization licensed or otherwise authorized to dispose of covered drugs that are household pharmaceutical waste received in such mailing envelopes and that is made available through a stewardship program to persons seeking to dispose of covered drugs that are household pharmaceutical waste;
- "mandatory pharmacy collector," which means a pharmacy licensed by the Maine Board of Pharmacy. "Pharmacy" does not include a pharmacy that purchases drugs for and dispenses drugs to a limited, institutional patient population; and
- "operator," which means a manufacturer or a stewardship organization that implements and operates a stewardship program.

#### (2) A manufacturer shall:

- (a) individually or jointly with one or more manufacturers, implement, administer, and operate a stewardship program

# Program components (continued)

pursuant to a plan that has been approved by the department; or

- (b) enter into an agreement with a stewardship organization to implement, administer, and operate a stewardship program pursuant to a plan that has been approved by the department.
- (3) A manufacturer, individually or jointly with one or more manufacturers, or a stewardship organization contracted by one or more manufacturers, shall submit to the department for approval a proposed plan. The plan must include, at a minimum:
- (a) a certification that the stewardship program will accept all covered drugs that are household pharmaceutical waste regardless of who manufactured the covered drugs; (b) contact information for the person submitting the plan, a list of participating manufacturers and their brands, contact information for each participating manufacturer, and a list of the covered drugs manufactured by any participating manufacturer that are branded or labeled for sale in the state by a retailer under the retailer's own brand or store label;
- (c) a description of how the stewardship plan will make available free, convenient, and ongoing collection opportunities for covered drugs that are household pharmaceutical waste to all persons seeking to dispose of such covered drugs and how the collection opportunities will be geographically distributed in a way to ensure access in rural and underserved areas, as determined based on geographic information systems modeling. The plan must include a list of authorized collectors and collection locations;
- (d) a description of the collection methods to be used to ensure that only covered drugs that are household pharmaceutical waste will be collected by authorized collectors under the stewardship program and a description of how separation of those covered drugs from packaging by consumers will be encouraged to reduce transportation and disposal costs. The plan must ensure that collection methods include mail-back envelopes and collection receptacles and do not include home disposal methods involving packets, bottles, or other containers that a person may use to render non-retrievable or destroy a covered drug that is household pharmaceutical waste by means of a chemical process;
- (e) a certification that, upon implementation of the plan, the operator, jointly with the operators of other approved plans, if any, will develop and administer a publicly accessible website

## Program components (continued)

that includes: (I) a list of authorized collectors, collection locations, and the collection methods available at each collection location, updated as necessary; (II) general information regarding the purpose and scope of the stewardship program or programs; and (III) a statement that the stewardship program or programs are designed for the collection of covered drugs that are household pharmaceutical waste only;

- (f) information on how covered drugs will be safely and securely tracked, handled, and transported from collection through final disposition, and policies to ensure security and compliance with all applicable federal and state laws and rules; (g) a description of how the collection system will be designed and monitored to prevent tampering;
- (h) a description of how the stewardship program will measure the amount of collected and disposed of covered drugs;
- (i) a description of the education and outreach materials that will be used by the stewardship program to encourage consumer awareness and participation;
- (j) a description of the performance goals to be established under the stewardship program to measure the success of the program;
- (k) a description of how the manufacturer or stewardship organization will fund a representative survey of state residents by an independent third party prior to implementation of the stewardship program to assess baseline public awareness regarding proper disposal methods for unwanted drugs; and
- (l) information on how the stewardship program will be financed.
- (4) Sets forth the time periods within which the department must review a plan and approve, approve with conditions, or reject the plan. Permits the department to hold a public hearing prior to making a decision.
- (5) A manufacturer, individually or jointly with one or more manufacturers, shall pay all costs associated with the implementation, administration, and operation of the manufacturer's stewardship program including, but not limited to:
- (a) costs of installing, managing, and servicing collection receptacles at and collecting covered drugs from participating

# **Program components** (continued)

- authorized collectors, transporting such covered drugs for disposal, disposing of such covered drugs, and providing mail-back envelopes;
- (b) costs related to the development of, with input from authorized collectors and the department, a readily recognizable, consistent design for collection receptacles, as well as clear, standardized instructions for consumers regarding the use of collection receptacles;
- (c) costs incurred by the department in accordance with the review of submitted plans and plan amendments, the review of annual reports, and the administration and enforcement of this section; and
- (d) costs associated with the stewardship program assessments required under this section.

When two or more manufacturers participate in a stewardship program, or if multiple stewardship programs exist, the costs of implementing, administering, and operating the program or programs must be fairly and reasonably allocated between each participating manufacturer so that the share of the costs is reasonably related to the revenue-based market share of covered drugs that the manufacturer sells in the state.

- (6) An approved plan shall be implemented no later than 180 days after the date of approval.
- (7) A mandatory pharmacy collector shall participate in a stewardship program and shall provide for the safe collection of covered drugs that are household pharmaceutical waste under that program through the use of mail-back envelopes provided to consumers upon request, collection receptacles, or any other method of collection that complies with DEA regulations and that has been approved by the department as a method of collection. The department may not approve for use in any program a method of home disposal involving packets, bottles, or other containers that a person may use to render non-retrievable or destroy a covered drug by means of a chemical process.

A mandatory pharmacy collector that is a pharmacy not located in Maine that provides covered drugs to residents in the state by mail shall provide for the safe collection of covered drugs through the use of mail-back envelopes and shall ensure that consumers in the state purchasing covered drugs from the pharmacy are provided with information regarding the availability of such

## Program components (continued)

envelopes upon request and instructions regarding how the customer can request an envelope.

An operator shall notify all authorized collectors that are not mandatory pharmacy collectors of the opportunity to serve on a voluntary basis as a collection location under the stewardship program and shall ensure that any such authorized collector that requests to participate in the program is added to the program within 90 days of the operator's receipt of the request.

The operator shall ensure that all collection receptacles located at a collection location under the stewardship program are emptied and serviced as often as necessary to avoid the receptacles reaching storage capacity and to ensure proper operation.

As part of a stewardship program, all collection mechanisms, program information, and other program services must be provided by the operator free of charge to authorized collectors, including, but not limited to, the installation, maintenance, and emptying of collection receptacles; the provision of mail-back envelopes, educational materials, brochures, and signage; and drug-disposal-specific surveillance.

Collection of covered drugs that are household pharmaceutical waste at collection locations under a stewardship program must be made available to consumers free of charge. An operator and an authorized collector may not charge a point-of-sale fee to consumers, a fee that could be passed on to consumers or any other fee relating to the collection and disposal of covered drugs.

- (8) During the second and third years of implementation of a stewardship program, and every two years after that third year, the operator of the program shall fund an independent third party assessment of the effectiveness of the program's education and outreach efforts including, but not limited to, progress achieving the consumer awareness goal described in this section and efforts under the program to discourage the use of improper disposal methods.
- (9) Within 90 days after the first full year of implementation of a stewardship program, and annually thereafter, the operator of the program shall submit to the department a report describing the activities of the program during the prior calendar year, which must include, at a minimum:

# Program components (continued)

- (a) a list of manufacturers participating in the stewardship program, including contact information;
- (b) the amount by weight of material collected under the stewardship program in the prior calendar year, including the amount by weight from each collection method used, both in total and by county;
  - (c) details regarding the stewardship program's collection system, including a list of authorized collectors and associated collection locations with addresses; a list of locations where mail-back envelopes were provided under the program; a list of collection locations where collection receptacles were made available under the program; dates and location events held under the program; and a list of the transporters and disposal facilities used under the program for the transportation and disposal of collected covered drugs;
- (d) information regarding any safety or security issues encountered in the collection, transportation, or disposal of covered drugs under the program during the prior calendar year and, if such issues occurred, a description of completed or anticipated changes to program policies, procedures, or tracking mechanisms to address those issues:
- (e) a description of the public education, outreach, and evaluation activities implemented in accordance with the approved plan and the results of the third-party assessment;
- (f) a description of how packaging collected under the program was recycled, to the extent feasible;
- (g) a description of the methods used under the program to collect, transport, and dispose of covered drugs, including information regarding efforts by the operator to ensure that only covered drugs that are household pharmaceutical waste were collected;
- (h) a summary of the program's achievement of its performance goals as set forth in the approved plan;
- (i) an analysis of the convenience of the collection system for people living in various regions of the state;
- (j) the total cost of implementing, administering, and operating the stewardship program in the prior calendar year;
- (k) any recommendations for changes to the stewardship program to improve the convenience of the collection system, to increase customer awareness and education, or to better evaluate program performance; and
- (l) an analysis of the revenue-based market share of covered drugs sold by participating manufacturers in the state and any

### **MAINE**

## **Program components** (continued)

other information required by the department for determining appropriate cost allocation.

- (10) the department shall charge a reasonable fee to be paid by a manufacturer or stewardship organization for review of a plan or amendments to an approved plan. The department may establish a reasonable annual fee to cover the department's actual costs for annual report review, oversight, administration, and enforcement of a stewardship program, except that the fee may not exceed the greater of \$100,000 per year and 1% of total stewardship program costs.
- (11) A manufacturer or stewardship organization implementing an approved plan under this section that is in compliance with all applicable requirements of this section may bring a civil action against a manufacturer for damages when the plaintiff manufacturer has incurred \$3,000 in actual, direct costs in collecting, handling, and disposing of covered drugs and the defendant manufacturer or manufacturers are not in compliance with this section, and the plaintiff manufacturer or stewardship organization has not received reimbursement for the costs within the provided time limits.
- (12) The department shall annually report to the joint standing committee of the legislature having jurisdiction over environment and natural resources matters on the status of stewardship programs established pursuant to this section and shall recommend amendments to the provisions of this section as necessary.
- (13) To ensure maximum effectiveness through uniform statewide application, the state intends to occupy the whole field of regulation of government-mandated, manufacturer-funded drug take-back, collection or disposal programs. A local government may not adopt an ordinance mandating a manufacturer-funded drug take-back, collection or disposal program, and any ordinance or regulation that violates this subsection is void and has no force or effect.
- § 2700 establishes the Unused Pharmaceutical Disposal Program whose purpose is to ensure the safe, effective, and proper disposal of unused pharmaceuticals. For purposes of compliance with federal law and regulation, the return of pharmaceuticals under this section is deemed to be for law

#### **MAINE**

# Program components (continued)

enforcement purposes. The program is administered by the Maine Drug Enforcement Agency.

The agency may create systems for the safe, effective, and proper disposal of unused pharmaceuticals, which may include the use of prepaid mailing envelopes into which the unused pharmaceuticals are placed and returned to a single collection location. The prepaid mailing envelopes must be made available to the public at various locations including, but not limited to, pharmacies, physicians' offices, and post offices. All unused pharmaceuticals received under the program must be disposed of in a manner that is designed to be effective, secure, and in compliance with local, state, and federal environmental requirements.

Establishes the Unused Pharmaceutical Disposal Program Fund within the agency to be used by the director to fund or assist in funding the safe, effective, and proper disposal of unused pharmaceuticals.

Nothing in this section prohibits a law enforcement agency from participating as an authorized collector in a drug take-back stewardship program.

### Miscellaneous provisions

§ 2140 – a person who has custody of or control over any unused medications prescribed pursuant to this act after the death of the qualified patient shall personally deliver the unused medications to the nearest facility qualified to dispose of controlled substances or, if such delivery is impracticable, personally dispose of the unused medications by any lawful means, in accordance with any guidelines adopted by the department.

§ 8624 – a hospice provider who provides services to a client in the home of the client or the family of the client or another person shall provide a written policy to the client or family as part of developing the care plan. The written policy must include, but is not limited to, the following:

- (1) information on safe and environmentally sound disposal of medications; and
- (2) requirements for return envelopes or disposal kits or any other method of collection or disposal that the pharmacy providing the medication or the hospice provider has provided or recommended to the client and the family that is consistent

<u>MAINE</u>	
Miscellaneous provisions (continued)	with Maine Drug Enforcement Agency recommendations and requirements.
Recently proposed legislation	None.
Program website	Maine Drug Take Back Program   Prescription Disposal   Eyes Open for ME

	MADVI AND
	MARYLAND
Statute(s) and regulation(s)  Effective date(s) of	<ul> <li>MD. Code Regs. 10.34.33.01 (2023) (definitions)</li> <li>MD. Code Regs. 10.34.33.06 (2023) (repositories—general requirements)</li> <li>MD. Code Regs. 10.34.33. (2023) (disposal program—requirements)</li> <li>May 9, 2016 (all)</li> </ul>
provision(s)	(dif)
Does the state allow drug take-back programs by statute/regulation?	Yes.
Program components	<ul> <li>10.34.33.01 – definitions include: "disposal program," which means pharmacies that voluntarily participate as repositories to collect returned drugs and medical supplies for purposes of safe disposal; and "repository," which means a pharmacy that applies to and is designated by the board for the purpose of collecting prescription drugs or medical supplies for disposal as part of the disposal program.</li> <li>10.34.33.06 – in order to become a repository, a pharmacy shall: <ul> <li>(1) submit an application to the board to be designated as a repository;</li> <li>(2) shall indicate on the application if the applicant intends to participate in the donation program, participate in the disposal program by collecting only non-controlled dangerous substances and medical supplies for safe disposal, or participate in the disposal program by collecting controlled dangerous substances, non-controlled dangerous substance, and medical supplies for safe disposal;</li> <li>(3) shall be in good standing with the board;</li> <li>(4) may not have a final disciplinary order issued against it by the board; and</li> <li>(5) may not be owned or operated by a healthcare practitioner who has not fulfilled the requirements of a final disciplinary order that may have been issued against the owner or operator by a health occupations board.</li> </ul> </li> <li>10.34.33.07 – pharmacies that collect returned prescription drugs or medical supplies for proper disposal shall be approved by the board as repositories.</li> <li>Repositories that only collect non-controlled dangerous substances for proper disposal shall:</li> </ul>

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<u>MARYLAND</u>	
Program components (continued)	<ul> <li>(1) dispose of prescription drugs or medical supplies collected for disposal in compliance with applicable state and federal laws and regulations;</li> <li>(2) have policies and procedures regarding the safe and secure handling and disposal of prescription drugs and medical supplies, to include specific guidelines for prescription drugs requiring special disposal or care;</li> <li>(3) dispose of collected prescription drugs and medical supplies through a third party processor or a reverse distributor, as appropriate; and</li> <li>(4) maintain a separate, secure container behind the prescription counter that is clearly marked for the disposal program.</li> </ul>
	Repositories that collect controlled dangerous substances for disposal:
	- (1) shall comply with the requirements of the Secure and Responsible Drug Disposal Act of 2010;
	<ul> <li>(2) may collect non-controlled dangerous substances and medical supplies in the same manner; and</li> <li>(3) may commingle the collection of controlled and non-controlled dangerous substances and medical supplies in accordance with the Secure and Responsible Drug Disposal Act of 2010.</li> </ul>
Miscellaneous provisions	None.
Recently proposed legislation	None.
Program website	Maryland Prescription Medication Disposal   211 Maryland

	<u>MASSACHUSETTS</u>
` '	ASS. GEN. LAWS ANN. ch. 94H §§ 1 to 6 (West 2023) (collectively
	tled "Drug Stewardship Program")
Effective date(s) of provision(s)	anuary 1, 2017
• ``	es.
	1 (definitions) – definitions include:
\$ re pi	"covered drug," which means any grand name or generic opioid drug placed in Schedule II or III; provided, however, that "covered drug" shall also include benzodiazepines; provided, further, that "covered drug" shall not include drugs intended for use solely in veterinary care, substances regulated as cosmetics, drugs compounded under a specialty license, hypodermic needles, or drugs approved and used primarily for medication-assisted substance use disorder treatment; "drug stewardship program," which means a program financed by a pharmaceutical product manufacturer or a group of manufacturers to collect, secure, transport, and safely dispose of unwanted drugs; "stewardship organization," which means an organization designated by a manufacturer or a group of manufacturers to act as an agent on behalf of the manufacturer or the group of manufacturers to implement and operate a drug stewardship program; and "unwanted drug," which means a covered drug: (a) that is no longer wanted or intended to be consumed, or that is abandoned, discarded, expired, or surrendered by the person to whom it was prescribed; or (b) voluntarily deposited at collection points co-located with a law enforcement agency; provided, however, that "unwanted drug" shall not include: (i) waste or unused drug products from a pharmacy, hospital, or health clinic, or other commercial sources that the department may determine by regulation to be a nonresidential source; or (ii) drug products seized by law enforcement officers in the course of their law enforcement duties.  2 (operation or participation in drug stewardship program equired; powers and duties of department) – any pharmaceutical roduct manufacturer selling or distributing a covered drug to onsumers in the commonwealth, whether directly or through a

#### **MASSACHUSETTS**

### Program components (continued)

- (1) operate a drug stewardship program approved by the department individually or jointly with other manufacturers;
- (2) enter into an agreement with a stewardship organization that shall operate a drug stewardship program approved by the department; or
- (3) enter into an agreement with the department to operate an alternative plan under § 6.

Requires the department to establish a process to review applications for approval and renewal of a manufacturer's drug stewardship plan.

Each operator of a stewardship program shall file an annual written report to the department describing the program's activities for the prior year and the volume and type of unwanted drugs collected not later than March 1.

The department shall publish and make publicly available a list and description of each approved drug stewardship program and shall update this list at a frequency determined by the department.

- § 3 (drug stewardship program plan; requirements) a manufacturer or stewardship organization seeking approval for a drug stewardship program shall submit, in a manner and form determined by the department, a plan that meets, but is not limited to, the following requirements:
- (1) a collection system to provide convenient, ongoing collection services to all persons seeking to dispose of unwanted drugs; provided, however, that the system may accept any covered drug and any other prescription drug in a pill formulation regardless of its schedule, brand, or source of manufacture; provided further, that the collection system shall include two methods as recommended by the department, which may include, but not be limited to: (a) a mail-back program that provides prepaid and pre-addressed packaging for a pharmacy to distribute when filling a prescription for a covered drug or upon request by a consumer; (b) collection kiosks; (c) drop-off day events at regional locations; (d) in-home disposal methods that render a product safe from misuse and that comply with applicable controlled substance regulations and environmental safety regulations; or (e) any other method recommended pursuant to U.S. Drug Enforcement Administration guidelines;

#### **MASSACHUSETTS**

## **Program components** (continued)

- (2) adequate provisions for the security of unwanted drugs throughout the collection process and the safety of any person involved in monitoring, staffing, or servicing the stewardship program;
- (3) a plan for public outreach and education about the program;
- (4) a plan for the manufacturer or stewardship organization that provides the operational and administrative costs associated with the program; provided, however, that no point-of-sale, point-of-collection, processing fees, or other drug cost increases may be charged to individual consumers to recoup program costs;
- (5) an attestation that the program shall comply with all applicable state and federal requirements; and
- (6) any other requirements established by the department for the safe and effective administration of a stewardship program.
- § 4 (notice of requirements or of noncompliance; penalty; appeal) the department shall send a notice to a pharmaceutical product manufacturer that sells or distributes a covered drug in the commonwealth that has not submitted an application for approval under § 2, informing the manufacturer of the requirements to comply. Includes requirements for department sending notices of noncompliance and penalties for such noncompliance.
- § 5 (scope of requirements; application to retail or outpatient pharmacies) nothing in this chapter shall require a retail pharmacy or a pharmacist practicing in a retail setting to participate in the collection, securing, transport, or disposal of unwanted drugs. No stewardship program shall require an outpatient pharmacy to participate in the collection, securing, transport, or disposal of unwanted drugs or to provide a space for or to maintain a collection kiosk within an outpatient pharmacy unless the pharmacy certifies, in writing, that this participation is voluntary.
- § 6 (alternative plan to drug stewardship program) the department shall develop an alternative plan to the drug stewardship program. A manufacturer that opts into a plan established under this section is exempt from §§ 2 to 5, inclusive. A plan established under this section may permit contributions by manufacturers to the Substance Abuse Services Fund in a manner determined by the department. a manufacturer participating in a plan established under this section shall not pass the cost of any contribution on to the consumer or a health insurance carrier.

<u>MASSACHUSETTS</u>	
Miscellaneous provisions	None.
Recently proposed legislation	None.
Program website	Safely Dispose of Prescription Drugs

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	<u>MICHIGAN</u>
Statute(s) and regulation(s)	<ul> <li>MICH. COMP. LAWS ANN. § 333.21418 (West 2023) (controlled substance disposal policy; promulgation of rules)</li> <li>MICH. ADMIN. CODE r. 338.3633 (2023) (collection of prescription drugs and other medication for destruction and disposal; requirements; limitations)</li> <li>MICH. ADMIN. CODE r. 338.3635 (2023) (collection device; requirements)</li> <li>MICH. ADMIN. CODE r. 338.3637 (2023) (access; destruction of collected drugs)</li> </ul>
Effective date(s) of	• September 24, 2014 (r. 338.3633, 338.3635, and 338.3637)
provision(s)	• March 19, 2019 (§ 333.21418)
Does the state allow drug take-back programs by statute/regulation?	Yes.
Program components	r. 338.3633 – a participating pharmacy or charitable clinic shall accept from any person a prescription drug or any other medication that is ineligible for distribution under the program for destruction and disposal.
	Unless permitted by federal law, controlled substances shall not be collected by a participating pharmacy or charitable clinic for destruction and disposal. If a participating pharmacy or charitable clinic accepts a chemotherapeutic agent for destruction, it shall not be mixed with other prescription drugs collected for disposal under the program but shall be mixed with the participating pharmacy's or charitable clinic's hazardous waste. The collection shall occur on-site at the participating pharmacy or charitable clinic and according to these rules and all applicable state and federal laws and regulations.
	r. 338.3635 – a participating pharmacy or charitable clinic shall utilize a collection device to collect prescription drugs and other medications that are ineligible for distribution under the program for destruction and disposal that meets all of the following criteria:
	<ul> <li>(1) is designed to allow contents to be added to the device but not removed, except by authorized personnel for the purpose of destruction and disposal;</li> <li>(2) is labeled pursuant to all applicable state and federal laws and regulations;</li> <li>(3) is lined with a removable liner that is waterproof, tamper-evidence, tear resistant, and capable of being sealed. The</li> </ul>

### **MICHIGAN**

# Program components (continued)

- contents of the liner shall not be viewable from the outside, and the size or capacity of the liner shall be clearly marked on the outside of the liner;
- (4) is secured in a manner that will only allow authorized personnel to remove the contents of the container for the purpose of destruction and disposal;
- (5) uses a design that is tamper resistant and is securely locked;
- (6) is securely fastened to permanent structure within the designated pharmacy area so that it cannot be removed;
- (7) is consistently monitored by security features and pharmacy personnel;
- (8) shall have the following statements prominently placed on the collection device and posted as signage near the location of the collection device: "controlled substances cannot be accepted for destruction and disposal, unless permitted under federal law," and "chemotherapeutic agents shall not be placed in this collection device"; and
- (9) the collection device for the yellow jugs old drugs program operated by the Great Lakes clean water organization is deemed to satisfy the requirements of this rule, provided the participating pharmacy or charitable clinic is a compliant participant in the yellow jugs old drugs program.
- r. 338.3637 a collection device utilizing a removable liner shall only be accessed for the following purposes:
- (1) to remove the contents to process for safe, effective, and immediate transportation;
- (2) to immediately transfer the contents to a waste disposal facility; or
- (3) to immediately transfer the contents to a responsible third party for transportation to a waste disposal facility.

A collection device utilizing a removable liner shall only be accessed as follows:

- (1) the access shall be done by two personnel, one of whom shall be a licensed pharmacist; and
- (2) upon being accessed, the liner shall be immediately sealed and the weight of the contents immediately recorded in the destruction and disposal log. A copy of the destruction log shall be transferred with the sealed contents.

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Program components (continued)	collection device for the yellow jug old drugs program operated by the Great Lakes clean water organization shall be weighed at the time the collection device leaves the pharmacy and the weight shall be recorded in the destruction and disposal log.
	Within one year of collection, the contents of the collection device shall be transferred to a waste disposal facility for destruction. The contents shall be destroyed pursuant to all applicable state and federal laws and regulations.
Miscellaneous provisions	§ 333.21418 – beginning 90 days after the department
viscentificous provisions	promulgates rules to implement this section, a hospice or hospice residence that provides services in a patient's private home shall establish and implement a written controlled substance disposal policy establishing procedures to be followed to mitigate the diversion of controlled substances that are prescribed to the patient. The policy must include all of the following:
	<ul> <li>(1) a procedure for offering to assist with the disposal of a controlled substance that is prescribed to a patient as part of the patient's hospice plan of care;</li> <li>(2) a requirement that an employee provide the patient or the patient's family education on safe disposal locations for a controlled substance and techniques for the safe disposal of a controlled substance when the controlled substance is no longer needed by the patient or at the time of death;</li> <li>(3) procedures for offering assistance with the disposal of a controlled substance to a patient who revokes hospice care and services;</li> <li>(4) a requirement that an employee document whether the patient or the patient's family accepted or refused an offer to assist with the disposal of the controlled substance when the controlled substance is no longer needed by the patient or at the time of death;</li> <li>(5) a requirement that if an employee assists with the disposal of a controlled substance, the disposal is performed by the employee and witnessed by another competent adult; or (b) performed by the patient or the patient's family and witnessed by another competent adult;</li> <li>(6) a requirement that if an employee assists with the disposal of a controlled substance, the disposal must be performed in the patient's private home.</li> </ul>

<u>MICHIGAN</u>	
Recently proposed legislation	None.
Program website	Drug Disposal

<u>MINNESOTA</u>	
Statute(s) and regulation(s)	MINN. STAT. ANN. § 152.105 (West 2023) (disposal)
Effective date(s) of provision(s)	May 20, 2016
Does the state allow drug take-back programs by statute/regulation?	Yes.
Program components	§ 152.105 – controlled substances listed in subdivisions (3) – (6) of § 152.02 may be collected and disposed of only pursuant to the provisions of the Code of Federal Regulations that are applicable to the disposal of controlled substances. Disposal of controlled substances and legend and non-legend drugs must also comply with the requirements of § 116.07 governing the disposal of hazardous waste, and the rules promulgated thereunder.  The sheriff of each county shall maintain or contract for the maintenance of at least one collection receptacle for the disposal of noncontrolled substances, pharmaceutical controlled substances, and other legend drugs, as permitted by federal law. The collection receptacle must comply with federal law. In maintaining and operating the collection receptacle, the sheriff shall follow all applicable provisions of the Code of Federal Regulations.  A sheriff may meet the requirements of this section by providing
	public educational information and making an alternative method available to the public, at no charge, for safely destroying unwanted legend drugs, including an at-home prescription drug deactivation and disposal product, so long as the alternative method meets the requirements of the Minnesota Pollution Control Agency, the United States Drug Enforcement Administration, and the Board of Pharmacy.
Miscellaneous provisions	None.
Recently proposed legislation	None.
Program website	Drug Take Back   Dose of Reality MN

<u>MISSISSIPPI</u>	
Statute(s) and regulation(s)	MISS. CODE ANN. § 41-29-191 (West 2023) (collection of prescription pills and drugs brought from residential sources)
Effective date(s) of provision(s)	July 1, 2012
Does the state allow drug take-back programs by statute/regulation?	Yes.
Program components	§ 41-29-191 – on the first Monday of each month, each drug task force may collect prescription pills and drugs that are brought to the main office of the task force from residential sources and shall transport the collected pills and drugs to the incinerator maintained by the Mississippi Bureau of Narcotics for disposal. For the purposes of this section, the term "drug task force" means a drug or narcotics task force or enforcement team created through an interlocal cooperation agreement under § 17-13-1, et seq.
Miscellaneous provisions	None.
Recently proposed legislation	None.
Program website	Drug Disposal - Mississippi State Department of Health

MISSOURI	
Statute(s) and regulation(s)	<ul> <li>Mo. Ann. Stat. § 195.265 (West 2023) (disposal of unused controlled substances, permitted methods—awareness program)</li> <li>Mo. Ann. Stat. § 338.142 (West 2023) (drug take-back program, board authorized to expend, allocate, or award funds)</li> <li>Mo. Code Regs. Ann. tit. 19, § 30-1.078 (2023) (disposing of unwanted controlled substances)</li> <li>Mo. Code Regs. Ann. tit. 20, § 2220-2.095 (2023) (collection of medication for destruction)</li> <li>Mo. Code Regs. Ann. tit. 20, § 2220-2.990 (2023) (Rx Cares for Missouri Program)</li> </ul>
Effective date(s) of	• March 30, 2017 (§ 2220-2.095)
provision(s)	<ul> <li>August 28, 2017 (§ 338.142)</li> <li>September 27, 2018 (§ 30-1.078)</li> <li>July 6, 2018 (§ 195.265)</li> <li>July 28, 2019 (§ 2220-2.990)</li> </ul>
Does the state allow drug take-back programs by statute/regulation?	Yes.
Program components	§ 195.265 - unused controlled substances may be accepted from ultimate users, from hospice or home healthcare providers on behalf of ultimate users to the extent federal law allows, or from any person lawfully entitled to dispose of a decedent's property if the decedent was an ultimate user who died while in lawful possession of a controlled substance, through:
	<ul> <li>(1) collection receptacles, drug disposal boxes, mail-back packages, and other means by a Drug Enforcement Agency-authorized collector in accordance with federal regulations, even if the authorized collector did not originally dispense the drug; or</li> <li>(2) drug take-back programs conducted by federal, state, tribal, or local law enforcement agencies in partnership with any person or entity.</li> </ul>
	This subsection shall supersede and preempt any local ordinances or regulations, including any ordinances or regulations enacted by any political subdivision of the state, regarding the disposal of unused controlled substances.
	For purposes of this section, the term "ultimate user" shall mean a person who has lawfully obtained and possesses a controlled

# Program components (continued)

substance for his or her own use or for the use of a member of his or her household or for an animal owned by him or her or a member of his or her household.

Requires the department of health and senior services to develop an education and awareness program regarding drug disposal, including controlled substances. The education and awareness program may include, but not be limited to:

- (1) a web-based resource that: (a) describes available drug disposal options, including take-back events, mail-back packages, in-home disposal options that render a product safe from misuse, or any other methods that comply with state and federal laws and regulations, may reduce the availability of unused controlled substances, and may minimize the potential environmental impact of drug disposal; (b) provides a list of drug disposal take-back sites, which may be sorted and searched by name or location and is updated every six months by the department; (c) provides a list of take-back events in the state, including the date, time, and location information for each event and is updated every six months by the department; and (d) provides information for authorized collectors regarding state and federal requirements to comply with the provisions of this section; and
- (2) promotional activities designed to ensure consumer awareness of proper storage and disposal of prescription drugs, including controlled substances.

 $\S$  30-1.078 – collection receptacle boxes and mail-back programs for patients' unwanted controlled substance prescriptions.

Manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies are authorized to install collection receptacle boxes or participate in a DEA approved mail-back method to collect unwanted controlled substance medications from patients. Registrants must comply with federal regulations regarding security and record keeping. Collection receptacles shall only be used for patients' unwanted medications and not for the expired or unwanted stock of a practitioner or facility.

All facilities and locations with collection receptacle boxes and mail-back systems shall comply with federal regulations. Patients' medications from long-term care facilities and narcotic

## **Program components** (continued)

treatment programs shall be placed in a receptacle within three days of the expiration date on the medication; or upon a discontinuation of use authorized by a prescriber; or upon the death of a patient.

Record keeping for collection receptacle boxes. Registrants or their employees shall not inventory the contents of the collection receptacle box. The box is to be opened by two people, one of whom shall be a pharmacy employee and the other may be an employee of the facility receiving pharmaceutical services. All registrants with collection receptacle boxes shall maintain a perpetual log that documents entry into the collection receptacle box, changing of liners, and transfers of drugs from the registrant to a reverse distributor. These logs shall be maintained on file at the registered location for inspection and shall document the date of entries into the collection receptacle box, the names of the employees entering the collection box, the reason for entering the box, the serial number of a liner being removed, and the serial number of the new liner being installed. This log shall also be used to document the transfer of a liner from the registrant to a reverse distributor by documenting the date of transfer, serial number of the liner, names of the persons involved in the transfer, and the DEA number of the reverse distributor. The log shall also document when the pharmacy changes out the interior liner bags and document the serial number of the bag being removed and of the new bag being installed.

- § 2220-2.095 Missouri licensed pharmacies may collect medication from the public for destruction in compliance with this rule. Pharmacies collecting controlled substances shall comply with all applicable state and federal controlled substance laws. Pharmacies collected non-controlled substances shall comply with sections (2) to (9) of this rule. Participation in a medication return or destruction program is voluntary. This rule shall not be construed to require that a licensee or permit holder participate in or establish a return/destruction program.
- (2) Definitions include: "mail," which includes mailing via the U.S. postal service or shipping via a common carrier; and "nonretrievable," which means, for the purposes of destruction, a condition or state to which medication is rendered after undergoing a process that permanently alters the medication's physical condition or state through irreversible means and thereby

# Program components (continued)

renders the medication unavailable or unusable for all practical purposes.

(3) Pharmacies may maintain a collection receptacle or establish an authorized mail-back program to collect non-controlled medication from the general public for destruction. Collection receptacles may not be used to dispose of unused/unwanted medication in the pharmacy's inventory. Collected medication shall not be resold or reused.

Pharmacies collecting medication under this rule shall develop and implement written policies and procedures governing medication collection which must include, but not be limited to, authorized destruction procedures and methods. This rule does not preempt or modify return/reuse of medication as authorized by the rule governing the Prescription Drug Repository Program, or any provision of state or federal law governing controlled substances or the destruction, handling, or transporting of medical or pharmaceutical waste.

- (4) Pharmacies that maintain a collection receptacle to collect non-controlled medication for destruction must comply with the following:
- (a) collection receptacles must be securely placed and maintained inside the physical building of the pharmacy in a manner that prevents theft, diversion, or unauthorized removal, must be securely fastened to a permanent structure and must be visible to pharmacy staff at all times and shall not be located in or near exit doors;
- (b) the receptacle must be a securely locked, substantially constructed container with a permanent outer container, and must contain an inner liner that complies with this rule; the receptacle must have an opening that allows medication to be added to the inner liner but does not allow the contents of the inner liner to be removed. The opening must be locked or otherwise made inaccessible to the public so that drugs cannot be deposited into the collection receptacle when the pharmacy is closed for business;
- (c) a sign must be prominently displayed on the outer container of the receptacle indicating that only non-controlled substances may be deposited into the receptacle. If the receptacle is also used to collect controlled substances, the

# Program components (continued)

required sign must comply with state and federal controlled substance laws;

- (d) inner liners must be removable, waterproof, tamperevident, and tear-resistant and must bear a prominent, unique identification number and identifier that enables the inner liner to be tracked. The contents of the inner liner shall not be viewable from the outside;
- (e) inner liners must be installed or removed from a collection receptacle by or under the supervision of at least two board licensees or registrants. Inner liners must be immediately sealed once removed from the receptacle; the sealed inner liner shall not be opened, x-rayed, analyzed, or otherwise penetrated by the pharmacy or pharmacy staff. After removal, sealed inner liners pending destruction may be stored at the pharmacy in a securely locked, substantially constructed cabinet or in a securely locked room or area with controlled access for no more than 30 business days; and
- (f) pharmacies must report any theft or diversion of or from a collection receptacle to the board in writing within 14 days in a manner designated by the board.
- (5) Pharmacies may provide mail-back packages to the public for the purpose of mailing medication to a collector that is authorized by the DEA or federal law to receive prescription medication for destruction (an "authorized collector"). Packages may be provided directly by the pharmacy or the pharmacy's authorized designee, provided the pharmacy is responsible for ensuring compliance with this section.

Mail-back packages must be pre-addressed with the address of the authorized collector. The cost of shipping shall be postage or otherwise prepaid. Packages must be mailed directly to the authorized collector by the consumer or his/her agent.

Mail-back packages must be nondescript and shall not include any markings or other information that might indicate that the package contains medication. Packages must be waterproof, spill-proof, tamper-evidence, tear-resistant, and sealable. Packages must be provided with instructions for mailing, notice that packages may only be mailed from within the United States or territories and notice that only packages provided by or on behalf of the pharmacy may be used to mail medication. Senders shall not be required to provide any personally identifiable information when mailing back medication.

# Program components (continued)

Mail-back packages must include a unique identification number or other unique identifier that enables the package to be tracked.

(6) Pharmacies may provide and maintain a collection receptacle at a long-term care facility to collect medication from the public or facility residents for destruction. This section does not apply to medication collected for return and reuse as authorized by rule. Sets forth the requirements for collection receptacles in such facilities, including that the receptacles must be securely placed and maintained in the building in a manner that prevents theft, diversion, or unauthorized removal.

Provides that inner liners may only be installed, removed, and transferred either: (a) by or under the supervision of two board licensees or registrants acting on behalf of the pharmacy; or (b) by or under the supervision of a board licensee/registrant and an employee/staff member of the facility designated by the pharmacy. After removal, sealed inner liners may be stored at the facility in a securely locked, substantially constructed cabinet or in a securely locked room or area with controlled access for no more than three business days.

- (7) Medication collected for destruction shall be rendered non-retrievable and destroyed in compliance with all applicable federal and state laws. Medication shall be destroyed in one of the following ways:
- (a) medication may be destroyed on the physical premises of the pharmacy, provided two board licensees or registrants must personally witness the destruction of the medication and handle or observe the handling of the medication until the substance is rendered non-retrievable; or
- (b) collected medication may be mailed, shipped, or transferred to an entity authorized to destroy the medication off-site, provided two board licensees or registrants must witness or observe the mailing, shipping, or transfer. If medication is transported by the pharmacy to the off-site location, the medication must be constantly moving towards its final location.
- (8) Except as otherwise provided herein, pharmacies shall maintain a complete and accurate record of the following:

## **Program components** (continued)

- (a) pharmacies shall conduct an inventory every 12 months of inner liners that are present at the pharmacy or at a long-term care facility that are unused or awaiting destruction;
- (b) the unique identification number and size of each unused inner liner; the date each liner is installed; and the date each liner is removed and sealed;
- (c) for medication destroyed on-site, the date and method of destruction; and for medication destroyed off-site, the date each liner was transferred for destruction.
- (9) Licensees/permit-holders shall be exempt from compliance with this rule when participating in medication collection programs conducted by local, state, or federal law enforcement agencies provided:
- (a) collected medication is placed into a collection container or area that is under the supervision of law enforcement personnel at all times;
- (b) law enforcement personnel are present whenever drugs are collected or on-site; and
- (c) the licensee/permit-holder does not take possession of the collection medications. Medications must remain under the control of, and must be removed by, law enforcement.

§ 2220-2.990 – establishes a medication destruction and disposal program for purposes of collecting unused or unwanted medication from the public for disposal in accordance with state and federal law. Operation of the program may be delegated to a board approved vendor or third party.

To be eligible for participation, applicants must be physically located in Missouri and currently registered to collect unwanted controlled substances with the U.S. Drug Enforcement Administration and the Missouri Bureau of Narcotics and Dangerous Drugs unless exempt from registration by state or federal law. Additionally, the applicant must be: (a) a licensed pharmacy or drug distributor; (b) a licensed healthcare provider authorized to prescribe controlled substances; (c) a hospital, office, clinic, or other medical institution that provides healthcare services; (d) a federal, state, local, or municipal public health, law enforcement, or other government agency; or (e) a higher education institution located in Missouri that is accredited by a national or regional accrediting body recognized by the U.S. Secretary of Education.

# Program components (continued)

Approved participants must establish and operate a public medication collection program in compliance with program requirements, including, but not limited to, all applicable board or vendor requirements for collecting, submitting, or forwarding medication for destruction and disposal. Participants must promptly enroll in the program after notification of approval is received from the board.

Subject to appropriation, approved program participants will be provided a collection receptacle and inner liners to be used for collecting medication pursuant to the program. Participants may alternatively use an existing collection receptacle if approved by the board or program vendor. Participants are responsible for installing of the receptacle in accordance with vendor requirements.

Collection receptacles must be physically located in Missouri at an address approved by the board. A board approved sign must be located on or near the receptacle indicating that the collection program has been funded by the board of pharmacy as part of the Rx Cares for Missouri Program. Collection receptacles may not be used to dispose of medication from the pharmacy's inventory.

Medication must be collected and handled in compliance with all state and federal controlled substance laws. Participants may submit collected medication to the vendor or the vendor's authorized designee for disposal at no cost to the participant up to 12 times per participation year. Program participants may arrange for additional medication disposal at the participant's cost.

Participants shall notify the board in writing within 10 days after ceasing or terminating program participation. Unless otherwise agreed by the board for good cause, participants shall reimburse the board for the cost of the collection receptacle if the participant fails to actively maintain and operate a collection program during the participation year.

Applications must be submitted to the board on an approved form and include the following:

- (1) applicant's name, address, telephone number, and email;
- (2) the Missouri address where the receptacle will be located;
- (3) a copy of the applicant's DEA and Bureau controlled substance collector registrations;

will be operated, including operational times and how the program will be advertised to the public;  (5) a designation of whether the applicant will be using a board approved collection receptacle or supplying their own; and  (6) a description of the need for a medication collection program in the proposed collection site area along with any supporting data or evidence.  At the discretion of the board, applicants will be approved for program participation subject to funding availability. Participation approval shall be valid for one calendar year. Sets forth the criteria to be considered when reviewing applications, including, but not limited to:  (1) the need for a medication collection program in the proposed collection site area;  (2) relevant evidence or data regarding drug use, abuse, fatalities, or trends;  (3) the nature and structure of the proposed collection program including operational times and any public restrictions; and  (4) the applicant's financial need and available resources.  As a condition of participation, applicants must agree that program information collected or maintained by the vendor or the vendor's designee may be disclosed to the board or the board's authorized designee on request and the governor and general assembly.  Sass.142 – the board of pharmacy, in consultation with the department of health and senior services, shall be authorized to		130
will be operated, including operational times and how the program will be advertised to the public;  - (5) a designation of whether the applicant will be using a board approved collection receptacle or supplying their own; and  - (6) a description of the need for a medication collection program in the proposed collection site area along with any supporting data or evidence.  At the discretion of the board, applicants will be approved for program participation subject to funding availability.  Participation approval shall be valid for one calendar year. Sets forth the criteria to be considered when reviewing applications, including, but not limited to:  - (1) the need for a medication collection program in the proposed collection site area;  - (2) relevant evidence or data regarding drug use, abuse, fatalities, or trends;  - (3) the nature and structure of the proposed collection program including operational times and any public restrictions; and  - (4) the applicant's financial need and available resources.  As a condition of participation, applicants must agree that program information collected or maintained by the vendor or the vendor's designee may be disclosed to the board or the board's authorized designee on request and the governor and general assembly.  Sabs. 142 - the board of pharmacy, in consultation with the department of health and senior services, shall be authorized to		<u>MISSOURI</u>
Miscellaneous provisions § 338.142 – the board of pharmacy, in consultation with the department of health and senior services, shall be authorized to	Program components (continued)	will be operated, including operational times and how the program will be advertised to the public;  (5) a designation of whether the applicant will be using a board approved collection receptacle or supplying their own; and  (6) a description of the need for a medication collection program in the proposed collection site area along with any supporting data or evidence.  At the discretion of the board, applicants will be approved for program participation subject to funding availability.  Participation approval shall be valid for one calendar year. Sets forth the criteria to be considered when reviewing applications, including, but not limited to:  (1) the need for a medication collection program in the proposed collection site area;  (2) relevant evidence or data regarding drug use, abuse, fatalities, or trends;  (3) the nature and structure of the proposed collection program including operational times and any public restrictions; and  (4) the applicant's financial need and available resources.  As a condition of participation, applicants must agree that program information collected or maintained by the vendor or the vendor's designee may be disclosed to the board or the board's authorized designee on request and the governor and general
expend, allocate, or award funds appropriated to the board to private or public entities to develop a drug take-back program.  Such program shall collect and dispose of Schedule II and III controlled substances.	Miscellaneous provisions	§ 338.142 – the board of pharmacy, in consultation with the department of health and senior services, shall be authorized to expend, allocate, or award funds appropriated to the board to private or public entities to develop a drug take-back program. Such program shall collect and dispose of Schedule II and III
	Recently proposed legislation	None.
Program website P2D2   Missouri Prescription Pill and Drug Disposal	Program website	P2D2   Missouri Prescription Pill and Drug Disposal

<u>MONTANA</u>	
Statute(s) and regulation(s)	MONT. CODE ANN. § 1-1-232 (West 2023) (Montana prescription drug take-back day)
Effective date(s) of provision(s)	October 1, 2019
Does the state allow drug take-back programs by statute/regulation?	Yes.
Program components	§ 1-1-232 – the day in October designated as national prescription drug take-back day is designated as Montana prescription drug take-back day in order to provide an annual day for citizens to properly dispose of unused and unneeded prescription drugs, to raise awareness about the consequences of failure to properly dispose of prescription drugs, and to educate citizens on proper methods of prescription drug disposal.
Miscellaneous provisions	None.
Recently proposed legislation	None.
Program website	Prescription Drugs/Medication: Proper Use, Storage and Disposal

<u>NEBRASKA</u>	
Statute(s) and regulation(s)  Effective date(s) of provision(s)	NEB. REV. STAT. ANN. § 38-28,107 (West 2023) (collection or return of dispensed drugs and devices; conditions; fee; liability; professional disciplinary action)  March 17, 1999
Does the state allow drug take-back programs by statute/regulation?	Yes.
Program components	<ul> <li>§ 38-28,107 – to protect the public safety, dispensed drugs or devices:</li> <li>(1) may be collected in a pharmacy for disposal;</li> <li>(2) shall not be returned to saleable inventory nor made available for subsequent relabeling and redispensing; or</li> <li>(3) may be accepted from a long-term care facility by the pharmacy from which they were dispensed for credit or for relabeling and redispensing, except that no controlled substance may be returned, no prescription drug or medical device that has restricted distribution by the FDA may be returned, and the dispensed drug or device shall be in the original and unopened labeled container with a tamper-evidence seal intact.</li> <li>Pharmacies may charge a fee for collecting dispensed drugs or devices for disposal.</li> </ul>
Miscellaneous provisions	None.
Recently proposed legislation	None.
Program website	Every Day Is Take Back Day   Nebraska MEDS Coalition

<u>NEVADA</u>	
Statute(s) and regulation(s)	NEV. ADMIN. CODE § 639.050 (2023) (storage and destruction of certain controlled substances)
Effective date(s) of provision(s)	December 21, 2015
Does the state allow drug take-back programs by statute/regulation?	Yes.
Program components	<ul> <li>639.050 – any entity that is authorized pursuant to federal law to collect controlled substances and conducts a mail-back program to collect controlled substances or maintains collection receptacles for controlled substances shall provide to the board:</li> <li>(1) written notification that the entity has registered with the Drug Enforcement Administration to obtain authorization to be a collector; and</li> <li>(2) a copy of each Form DEA-41 submitted to the Drug Enforcement Administration.</li> </ul>
Miscellaneous provisions	None.
Recently proposed legislation	Yes. See <u>Pending Federal and State Legislation</u> .
Program website	Storage and Disposal of Medication - Nevada State Opioid Response

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<u>NEW HAMPSHIRE</u>	
Statute(s) and regulation(s)	<ul> <li>N.H. REV. STAT. ANN. § 318-B:2 (2023) (acts prohibited)</li> <li>N.H. REV. STAT. ANN. § 318-E:1 (2023) (pharmaceutical drug take-back programs authorized)</li> <li>N.H. CODE ADMIN. R. ANN. Jus. 1601.01 to 1608.01 (2023) (collectively titled "Procedures for Pharmaceutical Drug Collection and Disposal Programs")</li> </ul>
Effective date(s) of provision(s)	• July 1, 2011 (§§ 318-B:2 and 318-E:1) • August 23, 2012 (1601.1 to 1608.01)
Does the state allow drug take-back programs by statute/regulation?	Yes.
Program components	§ 318-E:1 – a local, county, regional, state, or other governmental entity or private entity in conjunction with the chief law enforcement officer of a law enforcement agency may establish a controlled and non-controlled pharmaceutical drug take-back program. For the purposes of this chapter, "pharmaceutical drug" means a prescription or over-the-counter drug, including, but not limited to, controlled drugs.
	A registered pharmacy may establish a controlled and non-controlled pharmaceutical drug take-back program provided it complies with the U.S. Drug Enforcement Administration regulations, 21 C.F.R. part 1300, et seq.
	A pharmaceutical drug take-back program shall enable individuals with dispensed drugs to voluntarily return the unused drugs for collection, storage, and disposal in accordance with applicable state and federal statutes and regulations.
	Provides that the disposal requirements for controlled drugs stipulated in RSA 318-B:17 shall not apply to controlled and non-controlled drugs collected in accordance with this section.
	Nothing in the implementation of a pharmaceutical drug take- back program shall require, at the place of collection, any individual who is returning drugs to disclose his or her personal identification in order to return unused drugs.
	Pharmaceutical drug take-back programs established under this chapter may accept public and private grants and donations of money for the purpose of covering the costs of such programs, including, but not limited to public funds appropriated for this

### **NEW HAMPSHIRE**

# Program components (continued)

purpose and a fee from participating individuals returning unused pharmaceuticals.

An authorized collector may establish and maintain a pharmaceutical drug take-back program at the site of a long-term care facility, nursing home, or assisted living facility, provided that all parties comply with DEA regulations and any applicable state and federal laws and regulations. A long-term care facility, nursing home, or assisted living facility may utilize a collection receptacle under such a drug take-back program on behalf of the ultimate user residing at, or who has resided at, the long-term care facility, nursing home, or assisted living facility.

1602.01 ("collection box") – definition of "collection box," which means a secured, lined receptacle into which pharmaceutical drugs can be deposited and which remains in possession of designated law enforcement officers for the purposes of a collection event.

1602.02 ("collection event") – definition of "collection event," which means a one-day program through which the public may safely dispose of unused or expired home-generated pharmaceutical drugs that are no longer wanted or needed by the consumer, at a secure collection site.

1602.05 ("drop box") – definition of "drop box," which means a double-locked, lined receptacle into which pharmaceutical drugs are deposited, situated in a police station and constructed in a manner that prevents tampering or access by non-authorized persons.

1603.01 (police station permanent drop boxes) – the chief law enforcement officer of an agency seeking to place a permanent drop box in a police station shall first request and obtain written authorization from the Drug Enforcement Administration, Office of Diversion Control.

A permanent drop box shall only be located in a police station and shall remain in the custody of law enforcement at all times. The drop box shall be placed in a location that is accessible to the public and under constant video recording surveillance. The drop box shall be securely mounted to a wall or floor to prohibit removal of the box or retrieval of the contents from within the box without a key.

### **NEW HAMPSHIRE**

## **Program components** (continued)

The drop box shall be clearly marked with the following information: "Pharmaceutical drugs, to include controlled, noncontrolled, and over-the-counter drugs from households and residences only. Pharmaceutical drugs may be disposed of in the original containers or in a sealed plastic bag. Liquid pharmaceuticals shall remain in the original container. No needles, syringes, or lancets shall be placed in the drop box."

Individuals shall place unused pharmaceutical drugs directly into the collection box. Individuals utilizing the drop box shall not be questioned or required to disclose personal identification.

The chief law enforcement officer of an agency maintaining a permanent drop box shall designate two law enforcement officers who shall be the sole possessors of keys to the drop box. Each shall have a separate and distinct key, with both keys required in order to access the drop box. The designated law enforcement officers shall both be present when removing the contents of the drop box.

The contents of the drop box shall remain in a secured area of the law enforcement agency until they are disposed of in accordance with the procedures outlined in these rules.

The chief law enforcement officer of an agency maintaining a permanent drop box shall provide written notification to the attorney general that the agency has established a program in accordance with these rules.

1603.02 (pharmaceutical drugs collected in permanent drop box) – collected pharmaceutical drugs shall remain secured until ready for disposal. An inventory of collected pharmaceutical drugs shall not be required. Collected pharmaceutical drugs shall not be resold or reused.

1604.01 (participation) – a pharmaceutical drug take-back event established by any government or private entity shall be voluntary. If an event is established, it shall be done in accordance with these rules and in conjunction with a participating chief law enforcement officer of a law enforcement agency.

The chief law enforcement officer of the law enforcement agency seeking to establish a collection event in conjunction with a

### **NEW HAMPSHIRE**

## **Program components** (continued)

government entity or private entity, shall first request and obtain written authorization from the Drug Enforcement Administration, Office of Diversion Control. The chief law enforcement officer shall provide written notification to the attorney general that the agency has established an event in accordance with these rules.

1604.02 (standards and procedures for the collection event) – at least two law enforcement officers designated by the chief law enforcement officer of an agency participating in a collection event shall, at all times, be present and responsible for supervising the collection event. The law enforcement officers shall, at all times, have sole control over, and sold possession of, all pharmaceuticals collected, and the collection box(es) in which the collected pharmaceuticals are stored.

Individuals disposing of unused pharmaceutical drugs shall place them directly into the collection box. Law enforcement officers shall not directly handle the surrendered pharmaceuticals at any time. Individuals utilizing the collection event shall not be questioned or required to disclose personal identification.

Only controlled and non-controlled pharmaceutical drugs and over-the-counter drugs from the individual's household or residence shall be collected. No needles, syringes, or lancets shall be placed in the collection box.

1604.03 (removal of collection boxes) – at the conclusion of the collection event, law enforcement officers shall be responsible for removing the collection box(es) the same day from the event location for disposal. Collected pharmaceutical drugs shall remain secured until ready for disposal. An inventory of collected drugs is not required. Collected pharmaceutical drugs shall not be resold or reused.

1605.01 (procedure for disposal of pharmaceutical drugs) – pharmaceutical drugs collected pursuant to these rules shall be destroyed via incineration at a solid waste disposal facility that is authorized to accept the waste under the destination state's laws and rules. Pharmaceutical drugs collected shall remain in a secured area of the designated law enforcement area until the destruction of the material is witnessed by a designated law enforcement officer.

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Program components (continued)	1605.02 (documentation of disposal of pharmaceutical drugs) – a designated law enforcement officer shall document the following:
	- (1) the date and location of the collection event or location of the permanent drop box;
	<ul> <li>(2) the weight of the collected pharmaceuticals;</li> <li>(3) the date and location where the collected pharmaceutical drugs were destroyed; and</li> <li>(4) the name(s) of the designated participating law</li> </ul>
Miscellaneous provisions	enforcement officers.  § 318-B:2 – persons who have lawfully obtained a controlled substance or a person acting as an authorized agent for a person holding a lawful prescription for a controlled substance may deliver any unwanted or unused controlled substances to law enforcement officers acting within the scope of their employment and official duties for the purpose of collection, storage, and disposal of such controlled drugs in conjunction with a pharmaceutical drug take-back program.
Recently proposed legislation	None.
Program website	New Hampshire's Prescription Drug Drop Box Initiative

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Statute(s) and regulation(s)	<ul> <li>N.J. STAT. ANN. § 24:21-55 (West 2023) (Project Medicine Drop program)</li> <li>N.J. STAT. ANN. § 26:2H-81.1 (West 2023) (acceptance of unused prescription medications for disposal by hospice care program; surrender of unused prescription medications; liability)</li> <li>N.J. STAT. ANN. § 26:16-12 (West 2023) (disposal of unused medication; designation of responsible party)</li> <li>N.J. STAT. ANN. § 45:14-67.6 (West 2023) (advising patients on the proper disposal of unused prescription drugs and controlled dangerous substances; dispensing prescription drugs)</li> </ul>
Effective date(s) of	• April 29, 2015 (§ 24:21-55)
provision(s)	• February 1, 2018 (§ 26:2H-81.1)
	• August 1, 2019 (§ 26:16-12)
	• April 20, 2020 (§ 45:14-67.6)
Does the state allow drug take-back programs by statute/regulation?	Yes.
Program components	§ 24:21-55 – establishes the Project Medicine Drop program to be administered by the director of the Division of Consumer Affairs, the purpose of which shall be to provide for the secure collection and safe disposal of unused and expired prescription drugs and other common household medications that are surrendered by members of the public in accordance with the program.
	The director shall continue to maintain at each participating law enforcement agency that meets program participation requirements a secure prescription medicine drop-off receptacle wherein unused or expired prescription drugs and other common household medications may be anonymously surrendered by members of the public seven days a week, 365 days a year.
	Within the limits of funds made available for purposes of the program, the director shall supply and install at each participating law enforcement agency that agrees to participate in the program and meets program requirements a secure prescription medication drop-off receptacle wherein unused or expired prescription drugs and other common household medications may be anonymously surrendered by members of the public seven days a week, 365 days a year.

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## **Program components** (continued)

Within the limits of funds made available for purposes of the program, the director shall deploy or cause to be deployed mobile secure prescription medication drop-off receptacles wherein unused or expired prescription drugs and other common household medications may be anonymously surrendered by members of the public. The director shall arrange for the periodic deployment of the mobile receptacles by participating law enforcement agencies that are selected by the director at the times and in the places as shall be determined to be necessary and appropriate to provide maximum access to members of the public in all geographic regions of the state.

A law enforcement agency that does not maintain or otherwise have a secure prescription medicine drop-off receptacle on its premises shall display, in a conspicuous location, notice informing members of the public where the closest secure prescription medicine drop-off receptacles are located.

The Division of Consumer Affairs shall post a list of all secure prescription medicine drop-off locations in the state on its website, which shall include receptacles maintained by the division, as well as any receptacle located in the state that is approved by the federal Drug Enforcement Administration, and the hours of operation. The website shall also contain information about mobile receptacles and collection events.

Includes immunity provisions.

§ 45:14-67.6 – a pharmacy practice site that dispenses prescription drugs, other than a long-term care pharmacy, shall, when dispensing to an individual located in this state a prescription drug or medication which is a controlled dangerous substance, and when dispensing any other prescription drug or medication as may be designated by the commissioner of health by regulation make available on-site, for purchase or at no cost to the patient, at least one consumer method for individuals to dispose of unwanted or expired prescription drugs, including, but not limited to, over-the-counter at-home or site-of-use solutions or secured medication collection kiosks or boxes, subject to the following requirements:

- (1) all at-home or site-of-use drug disposal products shall alter the characteristics of the prescription drug through chemical,

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Program components (continued)	<ul> <li>biological, or physical means so as to have a beneficial effect on the environment;</li> <li>(2) secured medication collection kiosks or boxes shall be marked and identified by prominent signage;</li> <li>(3) any manufacturer of a non-toxic at-home or site-of-use composition for consumer drug disposal shall provide a method that renders the active ingredients in the prescription medication unusable so that the active ingredients cannot be transformed to a physical or chemical condition or transformed to the state of a controlled substance or controlled substance analog; and</li> <li>(4) the manufacturer of an at-home or site-of-use composition or a secured medicine collection kiosk or box made available by a pharmacy pursuant to this paragraph shall represent to the pharmacy that none of the components or methods of disposal individually or as a blend or as a solution or as treatment and destruction facility are toxic, and that the composition or medicine collection kiosk or box follows waste regulations outlined by the federal Environmental Protection Agency for municipal household waste disposal.</li> </ul>
Miscellaneous provisions	<ul> <li>§ 26:2H-81.1 – a licensed hospice care program may choose, but shall not be required, to accept for disposal, at such time as a hospice care patient ceases to use the drug or medication or cases to receive hospice care services through the program, the hospice care patient's unused prescription drugs and medications. A hospice care program that chooses to accept unused prescription drugs and medications for disposal pursuant to this section shall, among other things:</li> <li>(1) establish a written policy setting forth procedures for accepting and disposing of unused prescription drugs and medications;</li> <li>(2) furnish a copy of the policy to each patient and patient's healthcare representative at the time of enrollment in the program;</li> <li>(3) accept drugs and medications prescribed and dispensed to the patient;</li> <li>(4) obtain any certifications, authorizations, or waivers as may be required under state or federal law in order to accept and dispose of unused prescription drugs and medications pursuant to this section; and</li> <li>(5) at the time the patient is enrolled in the hospice care program, at such time as any change is made to the patient's</li> </ul>

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Miscellaneous provisions (continued)	course of treatment that results in a change in the drugs or medications prescribed for the patient, or in the patient discontinuing the use of a prescription drug or medication, and at such time as the patient ceases to receive hospice care services through the program, the program shall make available on-site, for purchase or at no cost to the patient, at least one consumer method for individuals to dispose of unwanted or expired prescription drugs, including, but not limited to, over-the-counter at-home or site-of-use solutions or secured medication collection kiosks or boxes.
	At the time a hospice care patient ceases to receive hospice care services, a program representative shall provide a written request for surrender of unused drugs and medications to the patient or the patient's healthcare representative, which shall, among other things, offer to accept and dispose of any other prescription drug or medication which the patient will not use.
	A nurse accepted the surrender of unused prescription drugs or medications shall dispose of the drugs or medications at the site where hospice care was provided; in no case shall the nurse transport the unused prescription medications off-site for disposal or for any other purpose. The nurse may dispose of the unused drugs or medications using an over-the-counter at-home or site-of-use solution that meets the requirements of state law.
	§ 26:16-12 – any medication dispensed pursuant to the medical aid-in-dying laws that a qualified terminally ill patient chooses not to self-administer shall be disposed of by lawful means including, but not limited to, surrendering the medication to a prescription medication drop-off receptacle.
Recently proposed legislation	None.
Program website	Project Medicine Drop - NJ Division of Consumer Affairs

<u>NEW MEXICO</u>	
Statute(s) and regulation(s)	None.
Effective date(s) of provision(s)	N/A
Does the state allow drug take-back programs by statute/regulation?	No.
Program components	N/A
Miscellaneous provisions	None.
Recently proposed legislation	None.
Program website	Drug Take-back Day Provides Safe Way to Dispose of Prescriptions - NM Dept. of Health

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NEW YORK	
Statute(s) and regulation(s)	<ul> <li>N.Y. Pub. Health Law §§ 290 to 294 (McKinney 2023) (collectively titled "Drug Take Back")</li> <li>N.Y. Pub. Health Law § 3343-b (McKinney 2023) (safe disposal of unused controlled substances)</li> <li>N.Y. Comp. Codes R. &amp; Regs. tit. 10, §§ 60-4.1 to 60-4.7 (2023) (collectively titled "Drug Take Back")</li> </ul>
Effective date(s) of	• August 27, 2012 (§ 3343-b)
provision(s)	• January 6, 2019 (§§ 290 to 294) • March 10, 2021 (§§ 60-4.1 to 60-4.7)
Does the state allow drug take-back programs by statute/regulation?	Yes.
Program components	§ 290 (definitions) and § 60-4.1 – definitions include:
	<ul> <li>"authorized collector," which means: (a) a person, company, corporation, or other entity that is registered with the U.S. Drug Enforcement Administration to collect controlled substances for the purposes of safe disposal and destruction; (b) a law enforcement agency; or (c) a person, company, corporation, or other entity authorized by the department to provide alternative collection methods for covered drugs that are not controlled substances;</li> <li>"covered drug," which means any substance recognized as a drug under 21 U.S.C. § 321(g)(1), as amended, and any regulations promulgated thereunder, that is sold, offered for sale, or dispensed in the state, whether directly or through a wholesaler, in any form including prescription and nonprescription drugs, drugs in medical devices and combination products, brand and generic drugs and drugs for veterinary use; provided, however, "covered drug" shall not include vitamins or supplements, herbal-based remedies and homeopathic drugs, personal care products, pet pesticide products, biological products, drugs for which a manufacturer provides a take back program, emptied injector products or medical devices, and drugs used solely in a clinical setting; and</li> <li>"drug take back organization," which means an organization designated by a manufacturer or a group of manufacturers to act as an agent on behalf of the manufacturer or group of manufacturers to operate and implement a drug take back program as authorized by this article.</li> </ul>

## **Program components** (continued)

§ 291 (drug take back) – any manufacturer of a covered drug shall: (a) operate a drug take back program approved by the department individually or jointly with other manufacturers; (b) enter into an agreement with a drug take back organization which shall operate a drug take back program approved by the department; or (c) enter into an agreement with the department to operate a drug take back program on its behalf.

Any manufacturer of a covered drug, individually or jointly, or a drug take back organization contracted by a manufacturer of a covered drug, shall, within 180 days from the effective date of this section, submit to the department, in a manner and form determined by the department, a proposed drug take back program that meets, at a minimum, the following requirements:

- (1) certifies the drug take back program will accept all covered drugs regardless of who produced them;
- (2) provides contact information for the person submitting the planned drug take back program with whom the department shall direct all inquiries;
- (3) details a collection system to provide convenient, ongoing collection services to all persons seeking to dispose of covered drugs that is geographically distributed in a way to ensure access in rural and underserved areas;
- (4) describes other collection methods by which covered drugs will be collected by authorized collectors;
- (5) explains how covered drugs will be safely and securely tracked and handled from collection through final disposal and destruction, policies to ensure security and compliance with all applicable laws and regulations including disposal and destruction at a permitted waste disposal facility meeting federal requirements;
- (6) describes the public education and outreach activities that will be undertaken which shall include advertising of collection locations on a website and through use of signage and other written materials, and how effectiveness will be evaluated;
- (7) details how the costs of pharmacy collection and other authorized collectors will be reimbursed which shall include costs retroactive to the effective date of this article, and where more than one manufacturer will be involved in the planned drug take back program, a plan for the fair and reasonable manner of allocated costs among the participants in such program such that the costs paid by each manufacturer is

## **Program components** (continued)

- reasonably related to the volume or value of covered drugs sold in the state; and
- (8) provides any further information deemed appropriate by the department.

Within 30 days of the effective date of this section, each wholesaler that sells covered drugs in or into the state shall provide the department with a list of manufacturers that produce covered drugs. The department may request updated lists at its discretion.

A manufacturer, individually or jointly, must pay all administrative and operational fees associated with the drug take back program, including the cost of collecting, transporting, and disposing of covered drugs from pharmacies and other authorized collectors and the recycling or disposal, or both, of packing collected with the covered drug. Manufacturers shall also pay costs incurred by the state in the administration and enforcement of the drug take back program. Exclusive of fines and penalties, the state shall only recover its actual cost of administration and enforcement. In instances where manufacturers jointly conduct a drug take back program, the costs of administration and enforcement shall be fairly and reasonably allocated such that the portion of costs is reasonably related to the volume or value of covered drugs the manufacturers sell in the state. No manufacturer may charge a point-of-sale or other fee to consumers, or a fee that could be passed on to consumers, to recoup the cost of the drug take back program.

Sets forth the time deadlines for review and approval of proposed drug take back programs and for resubmission of a rejected proposal. Provides that the department shall provide, and update annually, a list of all manufacturers participating in a drug take back program on its website.

At least every three years, a manufacturer, jointly or individually, or a drug take back organization shall update its drug take back program and submit an updated proposal to the department. a manufacturer who begins to offer a covered drug in the state after the effective date of this article shall provide evidence of joining an existing approved drug take back program or submit a proposal for a program within 90 days following the initial offer for sale of a covered drug. Any proposed change to a program

## **Program components** (continued)

shall be submitted in writing and approved by the department prior to any change.

Each approved program shall report to the department at a date and manner set by the department, the department shall submit an annual report to the governor, speaker of the assembly, and president of the senate by January 1 detailing all program activities, the weight collected by each program, a description of collective activities, the name and location of all collection sites, public education and outreach activities, an evaluation of the efficacy of the program and each collection method, and any manufacturer out of compliance or subject to penalties pursuant to this article.

§ 292 (collection) – all pharmacies shall provide for the safe collection of drugs, which shall include:

- (1) offering drug collection by one or more of the following methods: (a) on-site collection, dropbox, or receptacle meeting federal standards; (b) mail-back collection be prepaid envelopes as authorized by federal law and regulation; or (c) other federal Drug Enforcement Administration approved methods of collection; and
- (2) signage prominently displayed advertising such drug collection to consumers.

All drug take back program operators shall notify other potential authorized collectors of the opportunity to serve as an authorized collector for the program. Participation of authorized collectors besides pharmacies shall be voluntary.

All costs of pharmacies and other authorized collectors shall be paid or reimbursed by the manufacturer, jointly or individually, as part of the drug take back programs required by this article.

For any city with a population of 125,000 or more as of the last decennial census, the commissioner shall establish by regulation a distribution plan that ensures that onsite collection receptacle or dropbox placement shall be reasonably accessible to all residents and that provides for program cost efficiency.

Pharmacies providing for mail-back collection shall provide a voucher for a prepaid envelope upon dispensing a covered drug.

# **Program components** (continued)

Such voucher shall include information on drug take back and safe disposal methods.

- § 293 (violations) violation of this article shall be subject to fines pursuant to section 12 of this chapter. Each day in which the violation continues shall constitute a separate violation.
- § 294 (jurisdiction) jurisdiction of all matters pertaining to drug disposal by this article is vested exclusively in the state. Any provision of local law or ordinance, or any rule or regulation promulgated prior to, or upon the effective date of this section, shall be preempted.
- $\S$  3343-b the department shall oversee a program for the safe disposal of unused controlled substances by consumers in accordance with state and federal law. Individual members of the public shall be authorized to voluntarily surrender controlled substances listed in Schedules II V in a secure manner, without identifying themselves. Safe disposal methods shall be publicized consistent with the prescription pain medication awareness program established by state law.

Provides that the surrender of a controlled substance pursuant to this section and article two-B of this chapter shall not constitute the possession, transfer, or sale of such controlled substance for purposes of this article or the penal law.

Except as otherwise provided by law, disposal sites shall be operated by law enforcement agencies, pharmacies, and other federal Drug Enforcement Administration authorized collectors on a voluntary basis; provided, however, that such disposal sites shall not be precluded from operating as part of a drug take-back program established pursuant to article two-B of this chapter. Nothing in this section shall require any political subdivision of the state to participate in the program established in this section.

§ 60-4.2 (convenience standards for certain cities and counties) – authorized drug take back programs must offer a minimum number of collection receptacles in cities and certain counties with a population of 125,000 or more. Provides that the cities of Buffalo, Rochester, Syracuse, and Yonkers and the counties of New York and Richmond must have at least one on-site collection receptacle per 10,000 population; Queens County must have at least one receptacle per 15,000 population; and Kings

### Program components (continued)

County and Bronx County must have one on-site collection receptacle per 20,000 population.

On-site collection receptacles shall be evenly distributed throughout the above cities and counties with regard to geography and population density. Collection receptacles maintained by law enforcement agencies in each of the listed jurisdictions shall be eligible for inclusion to meet the applicable convenience standard.

If a pharmacy with an on-site collection receptacle permanently closes or relocates, or if a law enforcement agency relocates or discontinues its maintenance of a collection receptacle, such that a convenience standard is no longer met, the operator of the drug take back program responsible for the receptacle shall be required to add an on-site receptacle to another pharmacy or law enforcement agency in a manner consistent with this rule and appropriate to ensure the applicable convenience standard continues to be met. The operator shall have 90 days to add the new collection receptacle and 15 days from the addition to provide written notice to the department of the change.

§ 60-4.3 (drug take back programs) – provides that, before implementing or modifying a drug take back program, an operator must submit a proposal to, and obtain approval of such program from, the department, in consultation with the Department of Environmental Conservation. Sets forth the specific requirements for proposals, including the information required to be submitted.

A program operator must update its proposal and submit it to the department at least every three years, from the date of the previous department approval, performed in accordance with such program, including, but not limited to, the following:

- (1) the name of the manufacturer, name of the manufacturer's parent company and any subsidiaries, mailing address, FDA labeler code and DEA number, as applicable, for each manufacturer of covered drug(s) contracted with the drug take back program and the date enrolled;
- (2) the name, address, phone, email address, DEA number, and Bureau of Narcotic Enforcement license number, for any entity that will reverse distribute covered drugs for the drug take back program;

## **Program components** (continued)

- (3) the name and address of each location in which a collection receptacle is installed and the date of its installation, as well as the dates of its discontinuance, removal, or relocation;
- (4) the name and address of each location providing mail back packages, and the date initiated;
- (5) the total weight of covered drugs collected by each collection method annually; and
- (6) any other details the department may direct.

An annual report shall be made to the department, on or before August 1, detailing for the preceding calendar year all program activities including, but not limited to, the following:

- (1) a list of manufacturers that participated during the reporting period that includes the name of the parent company and/or subsidiaries, address, FDA labeler code and DEA number, as applicable, for each manufacturer of covered drug(s) contracted with the drug take back program and the date enrolled:
- (2) the name, address, phone, email address, DEA number, and Bureau of Narcotic Enforcement license number, for any entity that reverse distributes covered drugs for the program;
- (3) a list of all pharmacies and other authorized collectors that maintained collection receptacles across the state during the reporting period that includes DEA number, education department registration number, if applicable, name, address, total weight collected by collection method, and the number of times each collection receptacle liner was replaced;
- (4) a list of pharmacies and other authorized collectors that provided mail back envelopes and/or packages during the reporting period that includes DEA number, education department registration number, if applicable, name, address, process for patient accessing mail back envelopes or packages, number of vouchers and/or mail back envelopes and/or packages utilized, and total weight collected by mail back envelopes and/or packages;
- (5) a list of drug take back events held during the reporting period that includes date of event, name of authorized collector, address, and total weight collected per event;
- (6) total weight of covered drugs collected by method of collection, and by location address, as well as aggregate weights for each of the 62 counties of New York State and the cities of Buffalo, Rochester, Syracuse, and Yonkers;

# Program components (continued)

- (7) description of collection activities, including policies and procedures for methods of collection;
- (8) description of program's statewide outreach and public education activities, including marketing materials, public service messages, and website information;
- (9) evaluation of the program and of each collection method, including an evaluation of education and outreach, an evaluation of program costs and of costs involved for each method and suggestions for overall program improvement;
- (10) a list of manufacturers and authorized collections that have discontinued participation; and
- (11) additional information as determined by the department.

§ 60-4.4 (pharmacies engaged in drug take back) – for purposes of this section, a pharmacy shall also include any pharmacy located in the state and that, though not required to by law, voluntarily participates in an authorized drug take back program.

Pharmacies participating in drug take back shall:

- (1) be properly registered under the Education Law;
- (2) if maintaining an on-site collection receptacle, modify existing registration to obtain authorization from the DEA to be a collector;
- (3) comply with all federal laws and regulations concerning the disposal of controlled substances;
- (4) notify the department and any contracted drug take back program operator, as applicable, within 30 days of drug take back program discontinuance or change of address of collection activity;
- (5) if maintaining a collection receptacle: (a) utilize a receptacle that meets the requirements of all state and federal laws and regulations; (b) ensure proper operation of the receptacle, which includes, but is not limited to, periodic monitoring to determine when it is full; removing and replacing the inner liner when full; and arranging for delivery of sealed inner liners and their contents to a reverse distributor's registered location by common or contract carrier pickup or by reverse distributor pickup; (c) ensure that receptacle box liners that are removed are safely and securely stored until retrieved by the reverse distributor or by common or contract carrier; (d) ensure that pharmacy employees do not handle drugs for disposal, review the contents of the collection receptacle, remove, count, weigh, consume,

## **Program components** (continued)

repurpose, restock, redispense, resell, or touch items placed in the receptacle; and (e) ensure the sealed inner liners and their contents are shipped to a reverse distributor's registered location by common or contract carrier or by licensed reverse distributor pickup at the licensed pharmacy's or residential healthcare facility's premises; and

- (6) report to the department immediately, and in any event within 24 hours of discovery of tampering with, or damage to, a collection receptacle, or diversion or theft of deposited contents, or any tampering with, damage to, or theft of a removed liner.

§ 60-4.5 (collection receptacles) – sets forth the specific requirements for collection receptacles, including that receptacles comply with all applicable state and federal laws and regulations and: (a) be securely fastened to a permanent structure so that it cannot be removed; (b) be a securely locked, substantially-constructed container with a permanent outer container and are movable inner liner; (c) feature an outer container which shall include a small opening that allows contents to be deposited into the inner liner, but which does not allow removal of the liner's contents; and (d) display signage describing the items eligible and not eligible for deposit in the collection receptacle.

Inner liners shall meet the following requirements:

- (1) be accessible only to employees of the pharmacy and shall not be opened, x-rayed, analyzed, or otherwise penetrated;
- (2) be waterproof, tamper-evident, tear-resistant;
- (3) be removable and sealable immediately upon removal without emptying or touching the contents;
- (4) the contents of the inner liner shall not be viewable from the outside when sealed;
- (5) the size of the inner liner shall be clearly marked on the outside of the liner and shall bear a permanent, unique identification number that enables the inner liner to be tracked:
- (6) immediately upon removal from the permanent outer container, be sealed by two pharmacy employees, except that in a residential healthcare facility it may be sealed by one pharmacy employee and one supervisory level New York State-licensed healthcare professional employed by the residential healthcare facility;

<u>NEW YORK</u>	
Program components (continued)	<ul> <li>(7) if at a pharmacy, be removed from a collection receptacle and retrieved by the reverse distributor or common or contract carrier on the same business day whenever possible. If not possible, be safely secured and stored at the pharmacy until retrieved; and</li> <li>(8) if at a residential healthcare facility, be removed from a collection receptacle and retrieved by the reverse distributor or common or contract carrier on the same business day whenever possible. If not possible, it must be safely secured and stored. Such storage shall not exceed three business days.</li> <li>Pharmacy employees may not handle drugs for disposal, review contents of the collection receptacle, remove, count, weigh, consume, repurpose, restock, redispense, resell, or touch items</li> </ul>
	Installation, removal, transfer, and storage of inner liners must be performed in compliance with all applicable state and federal laws and regulations.  § 60-4.6 (mail back envelopes and packages) – pharmacies that provide a mail back option as part of a drug take back program and all non-resident pharmacies that distribute covered drugs to residents by mal shall provide a prepaid package or envelope or provide a voucher for a prepaid package or envelope, which includes patient education regarding the program and safe disposal methods. Patients shall be directed to mail their unused drugs using the packages or envelopes.
Miscellaneous provisions	None.
Recently proposed	Yes. See Pending Federal and State Legislation.
legislation	
Program website	<u>Drug Take Back</u>

NORTH CAROLINA	
Statute(s) and regulation(s)	None.
Effective date(s) of provision(s)	N/A
Does the state allow drug take-back programs by statute/regulation?	No.
Program components	N/A
Miscellaneous provisions	None.
Recently proposed legislation	None.
Program website	Operation Medicine Drop   OSFM

<u>NORTH DAKOTA</u>	
Statute(s) and regulation(s)	None.
Effective date(s) of provision(s)	N/A
Does the state allow drug take-back programs by statute/regulation?	No.
Program components	N/A
Miscellaneous provisions	None.
Recently proposed legislation	None.
Program website	North Dakota Attorney General   Take Back Program

<u>OHIO</u>	
Statute(s) and regulation(s)	<ul> <li>OHIO REV. CODE ANN. § 109.90 (West 2023) (drug take-back program)</li> <li>OHIO REV. CODE ANN. § 4729.69 (West 2023) (drug take-back program; establishment and administration)</li> <li>OHIO REV. CODE ANN. § 4729.691 (West 2023) (drug take-back program; promotion of awareness)</li> <li>OHIO REV. CODE ANN. § 5119.49 (West 2023) (drug take-back program)</li> </ul>
	• Ohio Admin. Code 4719:10-1-01 to 10-1-04 (2023) (collectively titled "Prescription Drug Collection")
Effective date(s) of provision(s)  Does the state allow drug	<ul> <li>May 20, 2011 (§§ 109.90 and 4729.69)</li> <li>September 29, 2013 (§ 5119.49)</li> <li>March 22, 2019 (§ 4729.691)</li> <li>August 1, 2019 (4719:10-1-01 to 10-1-04)</li> <li>Yes.</li> </ul>
take-back programs by statute/regulation?	I es.
Program components	§ 4729.69 – requires the board of pharmacy, in collaboration with the director of mental health and addiction services and attorney general, to establish and administer a drug take-back program under which drugs are collected from the community by participating entities for the purpose of destruction or disposal of the drugs.  Provides that each of the following may participate in the program: a law enforcement agency, any registrant authorized by the federal Drug Enforcement Administration to be a collector, and any other entity specified by the board by rule.  In consultation with the director of mental health and addiction services and attorney general, the board shall adopt rules governing the program. In adopting the rules, the board shall specify all of the following:  - (1) the entities that may participate; - (2) guidelines and responsibilities for accepting drugs by participating entities and the drugs that may be collected; - (3) record-keeping requirements; - (4) proper methods to destroy unused drugs, privacy protocols, and security standards; - (5) drug transportation procedures, including the schedule, duration, and frequency of the collections of drugs; and - (6) any other standards and procedures the board considers necessary for purposes of governing the program.

## **Program components** (continued)

In accordance with state and federal law, the board may adopt rules to allow an entity participating in the program to return any unused drugs to the pharmacy that originally dispensed the drug. The rules shall include procedures to be followed to maintain the confidentiality of the person for whom the drug was dispensed.

Rules adopted under this section may not: (a) require any entity to establish fund or operate a drug take-back program; (b) establish any new licensing requirement or fee to participate in the program; (c) require any entity to compile data on drugs collected; or (d) limit the authority of an entity to collect controlled substances in accordance with federal law.

The board may compile data on the amount and type of drugs collected under the program or may cooperate with a public or private entity in the compilation of data. If the board compiles data, the board shall submit a report to the governor and the general assembly. To the extent possible, the report shall include the total weight of drugs collected.

No entity is required to participate in a drug take-back program, and no entity shall be subject to civil liability or professional disciplinary action for declining to participate.

The board may accept grants, gifts, or donations for purposes of the program.

An ordinance, resolution, or other law that is adopted by a municipal corporation or other political subdivision on or after the effective date of this amendment and regulates the collection of drugs for destruction or disposal shall comply with this section.

§ 4729.691 – the state board of pharmacy shall make available on its website information regarding the drug take-back program which shall include all of the following:

- (1) a description of the drugs eligible for collection by participating entities;
- (2) a description of available options for collection, including take-back events and collection by receptacle or mail;
- (3) a directory of participating entities, including the address, telephone number, and hours of operation for each entity; and
- (4) a list of take-back events, including the date, time, and location for each event.

# **Program components** (continued)

The board may engage in other activities designed to promote public awareness of the program.

4729:10-1-01 (definitions – prescription drug collection) – definitions include:

- "authorized collector," which means a registered manufacturer, distributor, reverse distributor, narcotic treatment program, hospital/clinic with an on-site pharmacy, or retail pharmacy that is authorized by the U.S. Drug Enforcement Administration to receive controlled substances for the purpose of destruction;
- "drug collection receptacle," which means a secured, lined receptacle into which prescription medications, including controlled substances, dangerous drugs, and over-the-counter medications can be deposited by ultimate users for the purposes of collecting unused or expired drugs. Except for a law enforcement agency, a drug collection receptacle shall meet federal requirements;
- "mail-back program," which means a program operated by an authorized collector or law enforcement agency that accepts prescription medications, including controlled substances, dangerous drugs, and over-the-counter medications from ultimate users through the mail for purposes of collecting unused or expired drugs. Except for a law enforcement agency, a mail-back program shall meet federal requirements;
- "non-retrievable," which means the condition or state to which
  a drug shall be rendered following a process that permanently
  alters that drug's physical or chemical condition or state through
  irreversible means and thereby renders the drug unavailable and
  unusable for all practical purposes; and
- "take-back event," which means a one-day program operated by a law enforcement agency through which ultimate users may safely dispose of unused or expired prescription medications, including controlled substances, dangerous drugs, and over-thecounter medications. A take-back event shall meet federal requirements.

4729:10-1-02 (authorized collectors) – if an authorized collector operates a drug collection receptacle for the collection of non-controlled substances only, the collector shall meet all federal requirements.

A long-term care facility may dispose of prescription medications, including controlled substances, dangerous drugs, and over-the-

## **Program components** (continued)

counter medications on behalf of an ultimate user who resides, or has resided, at that facility pursuant to federal regulations.

An authorized collector may operate a mail-back program if they meet the requirements of federal regulations.

An authorized collector shall indicate on a drug collection receptacle or with written materials accompanying a mail-back package that the collection of medical sharps and needles, iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents, compressed cylinders or aerosols, or Schedule I controlled substances is prohibited.

An authorized collector shall not dispose of the collector's inventory or stock of controlled substances, dangerous drugs, or over-the-counter medications in a drug collection receptacle or through a mail-back program.

An authorized collector shall maintain the confidentiality of the ultimate user pursuant to all applicable state and federal laws, rules, and regulations.

An authorized collector shall not operate a take-back event.

4729:10-1-03 (law enforcement agencies) – law enforcement agencies may operate a drug collection receptacle if all of the following apply:

- (1) the receptacle is located inside the premises of the law enforcement agency, placed in a location that is accessible to the public during posted hours, placed within reasonable view of law enforcement personnel or under continuous video surveillance, is securely fastened to a permanent structure, and clearly marked with the items that are prohibited from disposal;
- (2) if a law enforcement agency chooses to limit the types of drugs that are acceptable for return, such limitations shall be clearly stated on or near the drug collection receptacle;
- (3) the agency shall check the receptacle regularly and remove deposits to prevent the receptacle from reaching capacity;
- (4) the law enforcement agency shall maintain the confidentiality of the ultimate user disposing of the drugs pursuant to all applicable state and federal laws and regulations;
- (5) the drugs collected shall be stored in a manner that prevents the diversion of controlled substances and is consistent with the

## **Program components** (continued)

- agency's standard procedures for storing illicit controlled substances collected as evidence;
- (6) the law enforcement agency shall maintain custody and control of the contents deposited in the receptacle until the drugs are destroyed;
- (7) the law enforcement agency shall maintain records of removal, storage, and destruction of the drugs collected in a manner that is consistent with the agency's record keeping requirements for illicit controlled substances collected as evidence.

Law enforcement agencies may conduct a mail-back program if all of the following apply:

- (1) packages are made available for sale or for free for the collection of pharmaceutical drugs by common or contract carrier:
- (2) the packages are nondescript and do not include any markings or other information that might indicate the contents, and are water- and spill-proof, tamper-evidence, tear-resistant, and sealable;
- (3) the package is pre-addressed with and delivered to the participating law enforcement's physical address and is prepaid;
- (4) the package must include instructions for the user that indicate the process for mailing back the package, the substances that can be sent, notice that packages may only be mailed from within the customs territory of the United States, and notice that only packages provided by the collector will be accepted for destruction;
- (5) the law enforcement agency shall maintain custody and control of the sealed packages until the packages are destroyed and shall maintain the confidentiality of the ultimate user disposing of the drugs;
- (6) the sealed mail-back packages shall be stored in a manner that prevents the diversion of controlled substances and is consistent with the agency's standard procedures for storing illicit controlled substances collected as evidence; and
- (7) the agency shall maintain any records of removal, storage, and destruction of the drugs collected in a manner that is consistent with the agency's record keeping requirements for illicit controlled substances collected as evidence.

Law enforcement agencies may operate a take-back event if all of the following apply:

	<u>OHIO</u>
Program components (continued)	<ul> <li>(1) a law enforcement agency shall appoint a law enforcement officer employed by the agency to oversee the collection. Officers conducting a take-back event shall maintain control and custody of the collected drugs from the time the drugs are collected from the ultimate user until secure transfer, storage, or destruction of the drugs has occurred;</li> <li>(2) each take-back event shall have at least one receptacle for the collection of drugs which shall be a securely locked, substantially constructed container with an outer container and removable inner liner;</li> <li>(3) ultimate users disposing of unused or expired drugs shall place them directly into the drug collection receptacle or hand them directly to a law enforcement officer;</li> <li>(4) at the conclusion of the collection event, the drugs shall be removed from the event location and either stored in a manner that prevents the diversion of the collected drugs or destroyed; and</li> <li>(5) the agency shall maintain any records of removal, storage, and destruction of the drugs collected in a manner that is consistent with the agency's record keeping requirements for illicit controlled substances collected as evidence.</li> <li>4729:10-1-04 (procedure for destruction of collected drugs) – all drugs collected pursuant to this rule shall be destroyed in compliance with applicable state and federal laws and regulations and shall be rendered non-retrievable. The method of destruction shall ensure that the confidentiality of the ultimate user is maintained.</li> </ul>
Miscellaneous provisions	§ 109.90 – the attorney general shall collaborate with the state board of pharmacy and director of mental health and addiction services in the establishment and administration of a drug take-back program. The office of the attorney general is solely responsible for the costs incurred in the establishment and administration of the program. The attorney general may accept grants, gifts, or donations for purposes of the program. All moneys shall be deposited into the drug take-back program fund.  § 5119.49 – the director of mental health and addiction services shall collaborate with the state board of pharmacy and attorney general in the establishment and administration of a drug take-back program. The department may accept grants, gifts, or donations for purposes of the program. Money received under this section shall be deposited into the drug take-back program fund.

<u>OHIO</u>	
Recently proposed legislation	None.
Program website	State of Ohio Board of Pharmacy - Drug Disposal Resources

<u>OKLAHOMA</u>	
Statute(s) and regulation(s)	None.
Effective date(s) of provision(s)	N/A
Does the state allow drug take-back programs by statute/regulation?	No.
Program components	N/A
Miscellaneous provisions	None.
Recently proposed legislation	None.
Program website	Rx Take Back Program   Bureau of Narcotics and Dangerous Drugs, OK

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<u>OREGON</u>		
Statute(s) and regulation(s)	<ul> <li>OR. REV. STAT. ANN. §§ 459A.200 to 459A.266 (West 2023) (collectively titled "Drug Take Back")</li> <li>OR. ADMIN. R. 340-098-0000 to 349-098-0480 (2023) (collectively titled "Solid Waste: Electronics Recycling and Drug Take Back Program")</li> <li>OR. ADMIN. R. 855-041-1046 (2023) (secure and responsible drug disposal)</li> <li>OR. ADMIN. R. 855-139-0460 (2023) (drugs and devices: takeback program)</li> </ul>	
Effective date(s) of	• February 23, 2017 (855-041-1046)	
provision(s)	<ul> <li>September 29, 2019 (§§ 459A.200 to 459A.266)</li> <li>September 21, 2020 (340-098-0000 to -0480)</li> <li>January 1, 2022 (855-139-0460)</li> </ul>	
Does the state allow drug take-back programs by statute/regulation?	Yes.	
Program components	<ul> <li>\$ 459A.200 (definitions) – definitions include:</li> <li>"authorized collector," which means a person that enters into an agreement with a program operator for the purpose of collecting covered drugs under a drug take-back program;</li> <li>"covered drug," which means a drug that a covered entity has discarded or abandoned or that a covered entity intends to discard or abandon and includes prescription drugs, non-prescription drugs, drugs marketed under a brand name or generic name, and combination products. "Covered drug" does not include vitamins or supplements, herbal-based remedies or homeopathic drugs, personal care products, biological products, drugs administered in a clinical setting, drugs used for animal medicines, exposed sharps or other used drug products that are medical waste, emptied injector products, dialysis concentrates, or biologics;</li> <li>"covered entity," which means a resident of this state, a nonbusiness entity located in this state, or an ultimate user. "Covered entity" does not include a law enforcement agency or an entity that generates pharmaceutical waste, such as a hospital, healthcare clinic, office of a healthcare provider, veterinary clinic, or pharmacy;</li> <li>"covered manufacturer," which means a person that manufactures covered drugs that are sold within this state, including a person that manufactures covered drugs for another manufacturer pursuant to an agreement. "Covered manufacturer" does not include a person that packages covered manufacturer" does not include a person that packages covered</li> </ul>	

## Program components (continued)

- drugs that are sold within this state or that labels the containers of covered drugs sold within this state or repackages covered drugs;
- "drug take-back organization," which means an organization designated by a covered manufacturer or a group of covered manufacturers to act as an agent of the covered manufacturer or group of covered manufacturers for the purpose of participating in a drug take-back program;
- "mail-back service," which means a method of collecting covered drugs from a covered entity by using prepaid, preaddressed mailing envelopes;
- "potential authorized collector," which means: (a) a person that is registered with the U.S. Drug Enforcement Administration and qualifies under federal law to collect and dispose of controlled substances, or qualifies under federal law to have the registration modified to authorize the person to collect and dispose of controlled substances; or (b) a law enforcement agency; and
- "program operator," which means a covered manufacturer, group of covered manufacturers, or drug take-back organization that develops and implements, or plans to develop and implement, a drug take-back program.

§ 459A.203 (requirement to participate in drug take-back program; rules; fines) – except as otherwise provided, each covered manufacturer shall participate in a drug take-back program that complies with the requirements of this act. A covered manufacturer may participate in a program independently, as part of a group of covered manufacturers, or by delegating the covered manufacturer's duties to a drug take-back organization. a covered manufacturer is not required to participate in a program if the covered manufacturer provides sufficient proof to the Department of Environmental Quality that the covered manufacturer manufactures covered drugs for fewer than 50 patients in this state.

If a covered manufacturer does not participate in a drug take-back program and does not qualify for exemption, the board of pharmacy may assess a fine against the covered manufacturer in an amount not to exceed \$10,000 for each day that covered drugs manufactured by the covered manufacturer are sold in this state.

§ 459A.209 (plan for drug take-back program; requirements; approval; updated plans) – a program operator must submit a plan to the department for participating in a drug take-back program.

# Program components (continued)

The department shall approve a proposed drug take-back program plan if the program operator submits a completed application, the proposed program meets the requirements of this section, and the program operator pays the fee established by the department.

To be approved by the department, a proposed program plan must:

- (1) identify and provide contact information for the program operator and each covered manufacturer participating in the proposed drug take-back program;
- (2) provide for a collection system and a disposal system that complies with state law;
- (3) includes policies and procedures to ensure the safe and secure handling and disposal of covered drugs and to ensure the security of patient information;
- (4) set forth a plan to cover all costs associated with the proposed program, with the costs apportioned among each covered manufacturer participating in the program;
- (5) set forth goals with respect to the amount of drugs collected under the proposed program and with respect to fostering full public awareness of the proposed program;
- (6) provide public outreach and education;
- (7) describe how the program will provide convenient service in every county in this state, including how under the drug takeback program the program operator will establish at least one drop-off site in each county in this state and, per population center, plus an additional drop-off site for every 50,000 residents of the city or town located within a population center;
- (8) identify the transporters and waste disposal facilities that the program will use;
- (9) provide upon request of a covered entity a mail-back service option that is prepaid by the program; and
- (10) provide mail-back service supplies to be used by a hospice services patient upon request of a person who provides in-home hospice services.

The department may waive the convenient service requirements if the proposed drug take-back program plan describes how the program will provide mail-back service in the county. Drop-off sites must be located throughout a population center to provide reasonably convenient and equitable access to all residents of the population center.

## **Program components** (continued)

Provides time limits for department review and approval of proposed plans. Not later than four years after approval of a plan, a program operator must submit an updated plan to the department for the continued operation of a program.

§ 459A.212 (changes to program; preapproval; notification; rules) – except as otherwise provided in this section, a program operator must request preapproval from the department for any change to a drug take-back program that substantively alters the program. A program operator must make a request under this section not later than 30 days before the change is to occur. For purposes of this section, the following types of changes substantively alter a drug take-back program:

- (1) changes involving methods used to collect or dispose of covered drugs;
- (2) changes to the policies and procedures for handling and disposing of covered drugs or for securing patient information;
- (3) changes involving methods used to foster public awareness of the proposed program;
- (4) changes to drop-off sites that do not meet the requirements of § 459A.209 or in the location of a drop-off site; and
- (5) changes to the location or schedule of a collection event.

Provides time limits for approving or rejecting changes to drug take-back program plans. Also provides time limits for proposed changes when the program operator is not able to make the request 30 days prior to the proposed change.

§ 459A.215 (authorized collectors; rules) – before submitting a plan to the department, a program operator must solicit potential authorized collectors for the purpose of collecting covered drugs under the program and enter into agreements with all willing authorized collectors

§ 459A.218 (drop-off sites; rules) – the system by which a program operator collects covered drugs under a drug take-back program must be safe and secure to use on an ongoing basis.

For purposes of a drug take-back program:

- (1) a drop-off site must be available for use during normal business hours of the authorized collector and must use a secure

# **Program components** (continued)

repository in compliance with all state and federal laws and rules;

- (2) the program operator must ensure that each secure repository is serviced as often as necessary to avoid reaching capacity, ensure that collected covered drugs are transported in a timely manner, and provide a method for the authorized collector to notify the program operator of the need for additional collections at the site;
- (3) a sign must be affixed to the secure repository used at a drop-off site that prominently displays a toll-free telephone number and a website address that a covered entity may use to provide feedback to the program operator about the program;
- (4) except as otherwise provided, a drop-off site must accept all covered drugs from covered entities; and
- (5) if a drop-off site is located at a long-term care facility and allowed under applicable federal regulations, only individuals who reside, or have resided, at the facility may use the drop-off site.

A program that is unable to establish and maintain a sufficient number of drop-off sites in order to meet the requirements of the plan shall provide additional services, such as mail-back services, and hold collection events to ensure the convenience service described in the plan.

§ 459A.221 (covered drug collection events) – if a drug take-back program provides for the periodic collection of covered drugs through collection events, the collection events must be conducted in accordance with applicable federal regulations and protocols and in coordination with the local solid waste management officials who have jurisdiction over the impacted area.

§ 459A.224 (disposal of covered drugs) – covered drugs must be disposed of: (a) at a hazardous waste disposal facility; (b) at a municipal solid waste incinerator that is permitted to accept pharmaceutical waste; or (c) at a hospital, medical, and infectious waste incinerator.

§ 459A.227 (public awareness) – a program operator must promote and provide public outreach and education about the safe and secure collection of covered drugs under the drug take-back program through the use of a website and written materials provided at a the time a covered drug is delivered to a covered entity, and through the use of any signage, advertising, or other

### Program components (continued)

means of fostering public awareness. At a minimum, a program operator must:

- (1) promote the safe and secure storage of covered drugs by covered entities;
- (2) disseminate information on the inherent risks of improperly storing or disposing of opioids or opiates and other covered drugs;
- (3) discourage the disposal of covered drugs in the garbage or sewer system;
- (4) promote the disposal of covered drugs through the use of the drug take-back program;
- (5) establish a toll-free telephone number and website that a covered entity may use to contact the program operator about the program;
- (6) publicize information on the location of drop-off sites, collection processes, and any collection events;
- (7) work with authorized collectors to develop a readily recognizable and consistent design for repositories to be used at drop-off sites and to develop clear, standardized instructions to covered entities on how to use those repositories; and
- (8) conduct a biennial survey of covered entities and of pharmacists and healthcare providers who interact with covered entities.

For purposes of the survey, a program operator must submit proposed survey questions to the department for pre-approval. Surveys must measure public awareness of the program; assess the extent to which drop-off sites, mail-back service, and collection events are convenient and easy to use; and assess knowledge of and attitudes toward the risks posed by improperly storing and discarding or abandoning covered drugs.

§ 459A.230 (annual report) – a program operator must submit to the department an annual report on the development, implementation, and operation of the drug take-back program that includes:

- (1) a list of covered manufacturers participating in the program;
- (2) the total amount, by weight, of drugs collected under the program;
- (3) the amount, by weight, of drugs collected under each method of collecting drugs under the program;
- (4) the address of each drop-off site used under the program;

## Program components (continued)

- (5) the total amount, by weight, of drugs collected at each dropoff site, presented in a manner that assists the department in determining the rate of use of each site;
- (6) the date and location of each collection event held;
- (7) the method or methods used to transport drugs collected under the program;
- (8) the disposal technologies or processes used and which facilities or incinerators were used;
- (9) the total amount, by weight, of drugs dispose of by each method, presented in a manner that allows the department to conduct an audit to verify the information;
- (10) whether any safety or security problems occurred during the collection, transportation, or disposal of drugs and, if a problem occurred, a summary of the occurrence and possible resolutions;
- (11) a summary of the program's compliance;
- (12) a summary of the annual expenditures of the program, aggregated by category;
- (13) whether service was provided in compliance with the program operator's description and whether the public awareness goals have been met, including a summary of strategies and surveys used, and copies of an promotional materials developed by, the drug take-back program; and
- (14) an attestation that all covered drugs collected under the program were disposed of in compliance with applicable laws and rules.

The department shall publish approved reports on its website.

§ 459A.233 (costs of participation in a drug take-back program) – each covered manufacturer or group of covered manufacturers must pay all costs associated with participating in a program. A program operator or authorized collector may not impose a charge, including any charge imposed at the time a covered drug is sold or collected from a covered entity, against covered entities for the purpose of recouping the costs of the program.

§ 459A.236 (inspection and audit) – the Department of Environmental Quality shall ensure compliance with this act by:

- (1) entering into an agreement with the board of pharmacy whereby the board, during routine inspections of retail drug outlets inspects drop-off sites located at retail drug outlets and

# Program components (continued)

- informs the department of drop-off sites that are not in compliance with this act;
- (2) inspecting drop-off sites not located at retail drug outlets; and
- (3) auditing the records of program operators.
- § 459A.239 (enforcement; civil penalties) sets forth the requirements for enforcement of this act and the penalties to be imposed against covered manufacturers for non-compliance.
- § 459A.242 (fees) sets department fees for reviewing proposed drug take-back program plans, expenses for administering the act, and an hourly fee for any other work the department must do on behalf of a program.
- § 459A.251 (application of antitrust laws) the legislative assembly declares that program operators providing covered entities with drug take-back program services, including the safe and secure collection, transportation, and disposal of covered rugs, is in the best interest of the public. Therefore, the assembly declares its intent that participating in a program shall be exempt from state antitrust laws. The assembly further declares its intent to provide immunity for participating in programs from federal antitrust laws. This section does not authorize any person to engage in activities or to conspire to engage in activities that constitute per se violations of state or federal antitrust laws that are not authorized under this act.
- § 459A.260 (state preemption of local laws) except as expressly authorized by state law, this act supersedes and preempts any ordinance or other regulation enacted before, on, or after September 29, 2019, by the governing body of a city, county, or other political subdivision of this state that establishes or requires a program for the collection, by, or on behalf of covered manufacturers.
- 349-098-0150 (registration fees) determines manufacturer registration fees and provides the specific process for determining such fees.
- 349-098-0300 (requirements for a drug take-back program plan and updated plan) the Department of Environmental Quality may require a proposed drug take-back program plan and updated program plan to include the board of pharmacy registration number issued for each covered manufacturer participating in the proposed

# **Program components** (continued)

drug take-back program, or a statement that the manufacturer is not required to register with the board of pharmacy.

For purposes of § 459A.209, reasonably convenient and equitable access to all residents includes access for minority, lower-income, rural, and other historically underserved communities. A proposed drug take-back program plan and updated program plan must include a goal for fostering public awareness in minority, lower-income, rural, and other historically underserved communities.

340-098-0350 (services and collection events in place of a required drop-off site) – in determining whether to grant a waiver or to approve additional services and collection events in place of a drop-off site, the department will consider whether the program operator has demonstrated:

- (1) good faith efforts to solicit and enter into agreements with potential authorized collectors in the affected county or population center for which a waiver or approval is sought, such as through outreach to identify, contact, and engage with potential authorized collectors;
- (2) why a drop-off site cannot be established or maintained in the affected county or population center, including an explanation of any conditions for participation on which the program operator or any potential authorized collector could not agree;
- (3) how the proposed services and, as applicable, collection events will provide reasonably convenient and equitable access to all residents in the affected county or population center, and engagement with minority, lower-income, rural, and other historically underserved communities to help ensure this;
- (4) concurrence by the appropriate local governments in the affected population center or county with the proposed services and, as applicable, collection events, or an explanation of why the program could not obtain such concurrence despite good faith efforts; and
- (5) commitment to solicit potential authorized collectors for the affected county or population center on at least an annual basis.

340-098-0390 (fees) – each program operator must pay fees set forth in this rule, including plan review fee, the annual fee, and the hourly fee.

## **Program components** (continued)

855-041-1046 and 855-139-0460 – a pharmacy or remote dispensing site pharmacy that operates a drug take-back program or that participates in a program as an authorized collector must be registered with the DEA as an authorized collector to collect controlled and non-controlled drugs for destruction. A pharmacy that operates as a Drug Enforcement Administration authorized collector must notify the board within 30 days of initiating or terminating the program and must establish and enforce policies and procedures including, but not limited to:

- (1) provision of a secure location of the collection receptacle inside the retail drug outlet, which is accessible to the public, within view of the pharmacy counter and not located behind the pharmacy counter;
- (2) provision of adequate security measures, including proper installation and maintenance of the collection receptacle, tracking of liners, documentation, and key accountability; and
- (3) personnel training and accountability.

A pharmacy must inform consumers to directly deposit drugs into the receptacle. Pharmacy personnel must not count, sort, inventory, or otherwise handle drugs collected. A pharmacy must not dispose of drugs from pharmacy stock in a collection receptacle.

The liner must be inserted and removed from a locked collection receptacle only by or under the supervision of two employees of the pharmacy. Upon removal, the liner must be immediately sealed, and the pharmacy employees must document their participation in the insertion and removal of each liner from a receptacle on a log. Sealed liners must not be opened, analyzed, or penetrated at any time by the pharmacy or pharmacy personnel.

Liners that have been removed and immediately sealed must be directly transferred, or otherwise stored in a secured, locked location in the pharmacy for no longer than 14 days prior to being transferred, by two pharmacy personnel to a registered drug distribution agent or a reverse wholesaler registered with the DEA and the board. A pharmacy must maintain all drug disposal records for a minimum of three years.

Any tampering with a collection receptacle, liner, or theft of deposited drugs must be reported to the board in writing within one day of discovery.

<u>OREGON</u>	
Miscellaneous provisions	None.
Recently proposed legislation	None.
Program website	Department of Environmental Quality : Drug Take-Back Program : Hazardous Waste : State of Oregon

	PENNSYLVANIA PENNSYLVANIA	
Statute(s) and regulation(s)  Effective date(s) of provision(s)	<ul> <li>• 35 PA. STAT. AND CONS. STAT. § 874.3 (West 2023) (disposal of unused prescription medication)</li> <li>• 35 PA. STAT. AND CONS. STAT. § 6029.206 (West 2023) (household hazardous waste collection program)</li> <li>• January 3, 2017 (§ 6029.206)</li> <li>• August 27, 2018 (§ 874.3)</li> </ul>	
Does the state allow drug take-back programs by statute/regulation?	Yes.	
Program components	§ 6029.206 – allows a sponsor to establish a collection event for the purpose of collecting and managing solid waste generated by households that pose a risk to the public health, safety, or the environment as part of the municipal waste stream. Programs and events conducted by the following facilities or entities are exempt from registering with the department prior to commencing operations as required:  - (1) federal, state, or local law enforcement; - (2) hospitals, assisted living facilities, home healthcare agencies, long-term care nursing facilities, hospice, domiciliary care homes, and other similar healthcare facilities; - (3) pharmacies licensed by the commonwealth; - (4) resource recovery facilities that collect expired or unwanted prescription drugs or over-the-counter pharmaceutical products; and - (5) facilities or entities similar to those listed above that the department, at its sole discretion, excludes.  The exclusion in 40 C.F.R. § 261.4(b)(1) (relating to exclusions) shall apply to unused, expired, or unwanted prescription drugs and over-the-counter pharmaceutical products generated by households if the wastes are collected as part of a registered collection event or a program or event listed above, separately managed and destroyed in a manner that renders the drugs and pharmaceutical products non-retrievable through incineration.  Expired or unwanted prescription drugs and over-the-counter pharmaceutical products generated by households and collected.	
	pharmaceutical products generated by households and collected as part of a registered collection event or a program or event listed above may be destroyed through industrial furnaces, resource recovery facilities, or any other facility that renders the drugs and pharmaceutical products non-retrievable to prevent	

<u>PENNSYLVANIA</u>	
Program components (continued)	diversion of the wastes for illicit purposes and protect the commonwealth's water, public health, and safety.
Miscellaneous provisions	§ 874.3 – a home health agency or hospice is authorized, upon the death or discharge of a patient and with the permission of the patient or the patient's family member, caregiver, or healthcare representative, to accept for disposal a patient's unused prescription medications that were prescribed, dispensed, or otherwise used by the patient while under the care of the home health agency or hospice.
	A nurse accepting the unused prescription medication under this section shall dispose of the medication in the presence of a witness at the stie where care is provided. The nurse may not transport the unused prescription medications off-site for disposal or for any other purpose. The disposal of the patient's medication shall take place during the final in-home visit by the nurse or within five business days of the death or discharge of the patient, whichever occurs first.
	A nurse who accepts and disposes of unused prescription medication under this section shall document all of the following: (a) the name and quantity of each medication surrendered; (b) the name of the person authorizing the surrender and the relationship of the person to the patient; (c) the date and method of disposal; and (d) the name of the person witnessing the disposal.
Recently proposed legislation	Yes. See Pending Federal and State Legislation.
Program website	Prescription Drug Take-Back Program

RHODE ISLAND	
Statute(s) and regulation(s)	R.I. GEN. LAWS ANN. § 21-31-24 (West 2023) (drug disposal)
Effective date(s) of provision(s)	May 22, 2012
Does the state allow drug take-back programs by statute/regulation?	Yes.
Program components	§ 21-31-24 – notwithstanding any provision of law to the contrary, any city or town may authorize the use of its police department to display a container suitable for use as a receptacle for used, expired, or unwanted drugs or drug products. The receptacle shall only permit the deposit of items, and the contents shall be locked and secured. The container shall be accessible to the public and shall have posted legible signage indicating that expired or unwanted drugs or drug products may be disposed of in the receptacle. The used, expired, or unwanted drugs or drug products disposed of under this section shall not include any controlled substance except as permitted under federal law.
Miscellaneous provisions	None.
Recently proposed legislation	None.
Program website	Prescription Drug Disposal Sites   Dept. of Behavioral Healthcare, Developmental Disabilities, and Hospitals

SOUTH CAROLINA		
Statute(s) and regulation(s)	<ul> <li>S.C. Code Ann. § 44-53-362 (2023) (controlled substance take-back events and mail-back programs; collectors)</li> <li>S.C. Code Ann. § 44-71-85 (2023) (disposal of deceased patient's unused controlled substances)</li> </ul>	
Effective date(s) of provision(s)	May 19, 2017 (all)	
Does the state allow drug	Yes.	
take-back programs by statute/regulation?		
Program components	§ 44-53-362 – a controlled substance manufacturer, distributor, or reverse distributor; a narcotic treatment program; a hospital or clinic with an onsite pharmacy; or a retail pharmacy operating in the state may apply to be registered as a collector by the federal Drug Enforcement Administration to receive Schedule II – V controlled substances from an ultimate user, or a person entitled to dispose of an ultimate user decedent's property, as part of law enforcement take-back events or collector mail-back programs. A collector must comply with any state and federal requirements to ensure the safe disposal of controlled substances and to prevent diversion of collected controlled substances.  The Department of Health and Environmental Control shall develop guidance for pharmacies and other entities qualified to register as a	
	guidance for pharmacies and other entities qualified to register as a collector to encourage participation. The department shall coordinate with law enforcement, healthcare providers, and the DEA to encourage registration as a collector and to promote public awareness of controlled substance take-back events and mail-back programs.	
Miscellaneous provisions	§ 44-71-85 – upon the death of a patient receiving outpatient services from a hospice, ownership of unused medications related to the care of the patient constituting Schedule II – V controlled substances shall transfer to the hospice for immediate disposal. Upon the death of a patient receiving outpatient services, in the presence of a witness, the hospice nurse shall record in the medical record the name and quantity of each unused controlled substance. The hospice nurse then shall conduct immediate disposal at the site of care by complying with Environmental Protection Agency and Drug Enforcement Administration guidelines for safe disposal or immediate mail-back to a collector. If conducting immediate disposal at the site of care, the nurse should perform the disposal in the presence of a witness, who shall sign a document indicating their witnessing of the disposal. If participating in immediate mail-back to a registered collector, the hospice nurse shall deposit the	

SOUTH CAROLINA	
Miscellaneous provisions (continued)	unused medications into the mail-back envelope and seal the envelope at the site of outpatient services. Hospice employees must not remove any medications from the site of outpatient services other than to conduct immediate mail-back to a registered collector. The hospice nurse shall record the method of disposal in the medical record.
Recently proposed legislation	None.
Program website	Unwanted Medications   SCDHEC

SOUTH DAKOTA	
Statute(s) and regulation(s)	None.
Effective date(s) of provision(s)	N/A
Does the state allow drug take-back programs by statute/regulation?	No.
Program components	N/A
Miscellaneous provisions	None.
Recently proposed legislation	None.
Program website	Safe Medication Disposal   Avoid Opioid SD

	MEN'S INCOME.	
	<u>TENNESSEE</u>	
Statute(s) and regulation(s)	TENN. CODE ANN. §§ 63-10-701 to 63-10-706 (West 2023) (collectively titled "Ensuring Patient Access to Pharmacy Drug Disposal Programs Act of 2015")	
Effective date(s) of provision(s)	July 1, 2015	
Does the state allow drug take-back programs by statute/regulation?	Yes.	
Program components	§ 63-10-702 (definitions) – definitions include:	
	<ul> <li>"authorized pharmacy disposal site," which means any pharmacy practice site that qualifies as a collection site under federal regulation; and</li> <li>"pharmacy drug disposal program," which means any voluntary drug disposal program located at, or implemented by, a Tennessee-licensed pharmacy located in this state, in accordance with all state and federal rules and regulations.</li> <li>§ 63-10-703 (pharmacy drug disposal program; participation) –</li> </ul>	
	any Tennessee-licensed pharmacy located within this state is authorized to participate in a pharmacy drug disposal program that meets or exceeds the minimum requirements set forth in federal rules and regulations regarding collection and destruction of prescription drugs, including controlled and non-controlled substances.	
	Participation in a drug disposal program is voluntary. The pharmacist-in-charge for the pharmacy practice site shall be responsible for deciding whether the pharmacy participates in a pharmacy drug disposal program. No person shall mandate pharmacist participation in a pharmacy drug disposal program at a pharmacy practice site.	
	§ 63-10-705 (list of participating pharmacies) – the board of pharmacy shall maintain a list of licensed pharmacies within this state that participate in pharmacy drug disposal programs as authorized by state and federal rules and regulations.	
Miscellaneous provisions	None.	
Recently proposed legislation	None.	
Program website	Safely Disposing of Unwanted Medication	

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	<u>TEXAS</u>
Statute(s) and regulation(s)	TEX. HEALTH & SAFETY CODE ANN. §§ 442A.001 to 442A.151 (West 2023) (collectively titled "Prescription Drug Safe Disposal Pilot Program")
Effective date(s) of provision(s)	September 1, 2023
Does the state allow drug take-back programs by statute/regulation?	Yes (eff. Sept. 1, 2023).
Program components	§ 442A.001 (definitions) – definitions include "board," "controlled substance," "pharmacy," "pilot program," "prescription drug," and "ultimate user."
	§ 442A.002 (prescription drug safe disposal pilot program) – the board by rule shall develop and implement a prescription drug safe disposal pilot program to increase the number of locations in this state where unused, unwanted, or expired prescription drugs are collected from the public for safe disposal.
	§ 442A.051 (pharmacy eligibility) – a pharmacy operating in this state may apply to the board to participate in the pilot program if the pharmacy:
	<ul> <li>(1) is registered as an authorized drug collection site with the U.S. Drug Enforcement Administration;</li> <li>(2) is not the subject of state or federal opioid litigation; and</li> <li>(3) meets the eligibility requirements establish by 21 C.F.R. § 1317.40 and board rules.</li> </ul>
	§ 442A.052 (application and selection processes) – the board shall adopt rules prescribing (a) the form and manner for a pharmacy to apply for participation in the program, and (b) evaluation and selection criteria and processes.
	The board shall give priority to pharmacy applicants that do not collect unused ultimate user prescription drug at the time the applicant submits the application or is located in a rural or underserved area the board designates.
	A pharmacy that operates multiple locations must submit an application for each location.

### **TEXAS**

# **Program components** (continued)

§ 442A.053 (collection receptacle requirements) – a participating pharmacy that provides a collection receptacle for the safe disposal of prescription drugs shall ensure the receptacle:

- (1) meets federal requirements;
- (2) is accessible during the pharmacy's regular hours of operation;
- (3) allows for the anonymous deposit of unused controlled substance prescription drugs listed in Schedule II V; and
- (4) provides disposal of unused prescription drugs at no cost to the ultimate user.

Controlled substance prescription drugs and non-controlled substance prescription drugs may be collected together and comingled.

§ 442A.054 (mail-back program requirements) – a participating pharmacy that provides a collection receptacle for the safe disposal of prescription drugs may, under limited circumstances as the pharmacy determines necessary, provide at the time the pharmacy dispenses a controlled substance prescription drug to the ultimate user a vendor's mail-back envelope, at no cost to the ultimate user. The mail-back envelope must be pre-addressed and return postage paid and meet federal requirements.

A participating pharmacy may provide not more than 250 mailback envelopes during the duration of the pilot program to encourage the use of the pharmacy's collection receptacle.

§ 442A.055 (pharmacy management; records) – a participating pharmacy is responsible for the daily management and recordkeeping of the pharmacy's prescription drug safe disposal program in accordance with the pharmacy's U.S. Drug Enforcement Administration registration and board rules.

§ 442A.056 (Texas premier pharmacy designation) – the board shall designate each pharmacy participating in the pilot program as a Texas premier pharmacy provider committed to safe prescription drug disposal. A participating pharmacy may use the designation for marketing purposes.

§ 442A.101 (pilot program incentives) – the board shall assist each pharmacy participating in the pilot program, including by paying the costs of:

### **TEXAS**

# **Program components** (continued)

- (1) maintaining one collection receptacle at each participating pharmacy location and destroying through incineration of the receptacle's full inner liner the prescription drugs deposited in the receptacle;
- (2) ordering and distributing pre-addressed, return postage paid mail-back envelopes from a third-party mail-back program and destroying through incineration the returned mail-back envelopes containing the collected prescription drugs; and
- (3) other operational needs the board determines appropriate.

#### The board:

- (1) shall directly reimburse a participating pharmacy for costs the pharmacy incurs in maintaining a collection receptacle, mail-back envelopes, and other operational costs; and
- (2) may not reimburse a participating pharmacy for the cost of using a third-party incineration facility unless the facility is appropriately registered with the DEA.

Subject to money available for purposes of this chapter, the board may provide financial incentives to a pharmacy to continue providing prescription drug collection services or expand those services to accommodate controlled substance prescriptions. The board may provide financial incentives to a chain retail pharmacy for not more than 14 locations.

§ 442A.102 (community outreach) – the board shall:

- (1) develop and distribute educational outreach materials for the public about the availability of safe prescription drug disposal in this state;
- (2) post the materials on the board's website; and
- (3) provide the materials to other state agencies for those agencies to conduct the community outreach.

The educational outreach materials must be in English, Spanish, and for specific areas of this state as the board determines appropriate, another language spoken by a substantial portion of the area's residents.

§ 442A.103 (report) – not later than December 1 of each evennumbered year, the board shall submit to the governor and the legislature a report that:

<u>TEXAS</u>	
Program components (continued)	<ul> <li>(1) summarizes the results of the pilot program, including: (a) the number and geographic distribution of collection receptacles at participating pharmacies; (b) the estimated amount of prescription drugs collected by participating pharmacies under the program, measured by: (i) the number of inner liners fully filled with collected prescription drugs and sent for incineration by the pharmacies; (ii) the number of mail-back envelopes distributed by the pharmacies; and (iii) the weight, measured in pounds, of inner liners and returned mail-back envelopes filled with collected prescription drugs; (c) the amount of money distributed under the pilot program and the identity of each participating pharmacy to which money is distributed; and (d) a description of the board's educational efforts and outcomes; and</li> <li>(2) recommends whether the pilot program should continue, be expanded, or terminate, or whether the board should permanently implement a prescription drug safe disposal program.</li> </ul>
	§ 442A.151 (funding) – money contained in the opioid abatement account established under § 403.505, Government Code, may be appropriated to the board to fund the pilot program established under this chapter. The board may collect gifts, grants, and donations to fund the program.  § 442A.201 (expiration) – this chapter expires on the second anniversary of the date that all money appropriated for the pilot program has been expended.
Miscellaneous provisions	None.
Recently proposed legislation	None.
Program website	How and Where to Dispose of Unwanted Prescription Painkillers and Other Drugs

	<u>UTAH</u>
Statute(s) and regulation(s)	• UTAH CODE ANN. § 58-17b-623 (West 2023) (disposal of unused prescription drugs)
	• UTAH CODE ANN. § 67-5-36 (West 2023) (drug disposal program)
Effective date(s) of provision(s)	• May 8, 2012 (§ 58-17b-623) • May 12, 2020 (§ 67-5-36)
Does the state allow drug take-back programs by statute/regulation?	Yes.
Program components	§ 58-17b-623 – a pharmacy may accept unused prescription drugs for disposal in accordance with administrative rules adopted by the division. The division shall adopt rules regarding a pharmacy accepting unused prescription drugs for disposal as permitted by federal law and regulation relating to the disposal of unused prescription drugs.
	§ 67-5-36 – includes definitions for:
	<ul> <li>"environmentally friendly," which means a controlled substance that is rendered (a) non-retrievable, as determined by the attorney general in consultation with the department; (b) non-hazardous, as determined by the department; and (c) permissible to dispose in a landfill in a manner that does not violate state or federal law relating to surface water or groundwater; and</li> <li>"home controlled substance disposal receptacle," which means a receptacle provided by the program that can be used by an individual to render a small amount of controlled substances at an individual's residence non-retrievable and environmentally friendly.</li> </ul>
	The attorney general may, in coordination with the department and within funds available for this purpose, administer a program, known as the drug disposal program, to provide for the safe, secure, and environmentally friendly disposal of controlled substances in the state.
	The attorney general and the department, in developing and implementing the program:
	<ul> <li>(1) may work with law enforcement agencies, pharmacies, hospitals, and other entities to ensure that one or more repositories are present in each county in the state;</li> <li>(2) shall ensure that each repository renders a controlled substance placed in the repository non-retrievable and</li> </ul>

### **UTAH**

# Program components (continued)

- environmentally friendly, onsite and is secure from tampering or unauthorized removal;
- (3) may require verification that a repository complies with this section and a home controlled substance disposal receptacle renders a controlled substance non-retrievable and environmentally friendly;
- (4) shall ensure that the program operates in accordance with federal rules; and
- (5) may publish, on the websites of the attorney general's office and the department, a list of the location of each repository in the state and if home controlled substance disposal receptacles are used as part of the program, information on how to obtain a home controlled substance disposal receptacle.

The attorney general may, instead of, or in addition to, establishing a repository in a county, establish a process for residents of the county to obtain a home controlled substance disposal receptacle.

A state or local government entity, other than the attorney general's office, the department, or a designee of the department, may not:

- (1) regulate the disposal of a controlled substance rendered nonretrievable in a repository or home controlled substance disposal receptacle differently, or more strictly, than disposal of non-hazardous household waste;
- (2) regulate or restrict the location of a repository or the distribution of a home controlled substance disposal receptacle; or
- (3) otherwise take action to regulate or interfere with administration of the program.

This section does not prohibit the disposal of a controlled substance in a receptacle that does not qualify as a repository if the receptacle is located on the premises of an entity authorized by the Drug Enforcement Administration rules to accept a controlled substance for subsequent disposal and the entity ensures that the controlled substance is managed in a manner permitted by federal rule; or is disposed at a facility that has received approval under law.

Unless otherwise agreed by the attorney general, an entity that permits the placement of a repository on property owned or controlled by the entity will dispose of a controlled substance placed in the repository after the controlled substance is rendered environmentally friendly.

<u>UTAH</u>	
Miscellaneous provisions	None.
Recently proposed	None.
legislation	
Program website	Take-Back Day: Dispose of Old Prescriptions Safely - Utah
	Attorney General

VEDMONT	
	<u>VERMONT</u>
Statute(s) and regulation(s)	<ul> <li>VT. STAT. ANN. tit. 18, § 4224 (West 2023) (unused prescription drug, needle, and syringe disposal program)</li> <li>VT. STAT. ANN. tit. 33, § 2004 (West 2023) (manufacturer fee)</li> </ul>
Effective date(s) of provision(s)	June 8, 2016 (all)
Does the state allow drug take-back programs by statute/regulation?	Yes.
Program components	§ 4224 – the department of health shall establish and maintain the statewide Unused Prescription Drug, Needle, and Syringe Disposal Program to provide for the safe disposal of Vermont residents' unused and unwanted prescription drugs, needles, and syringes. The program may include establishing secure collection and disposal sites and providing medication envelopes for sending unused prescription drugs to an authorized collection facility for destruction.
	Pharmacies that operate 10 or more establishments in the United States, while concurrently conducting business in Vermont, shall enroll in a drug disposal kiosk program on or before July 1, 2023. If the physical dimensions of a pharmacy make an on-site collection receptacle impossible under state and federal law, a pharmacy shall provide a mail-back option for consumers.
Miscellaneous provisions	§ 2004 – requires that each pharmaceutical manufacturer or labeler of prescription drugs that are paid for the by Department of Vermont Health Access for individuals participating in Medicaid, Dr. Dynasaur, or VPharm shall pay a fee to the Agency of Human Services which shall be 1.75 percent of the previous calendar year's prescription drug spending by the department and shall be assessed based on manufacturer labeler codes as used in the Medicaid rebate program. Provides that fees collected under this section shall fund, among other things, statewide unused prescription drug disposal initiatives.
Recently proposed legislation	None.
Program website	Prescription Drug Disposal   Vermont Department of Health

	YWD CDW (
<u>VIRGINIA</u>	
Statute(s) and regulation(s)	<ul> <li>VA. CODE ANN. § 54.1-3411.2 (West 2023) (prescription drug disposal programs)</li> <li>VA. CODE ANN. § 54.1-3411.2 :1 (West 2023) (guidelines for disposal of unused drugs)</li> <li>18 VA. ADMIN. CODE § 110-20-211 (2023) (disposal of drugs by authorized collectors)</li> <li>18 VA. ADMIN. CODE § 110-50-51 (2023) (disposal of drugs by authorized collectors)</li> </ul>
Effective date(s) of provision(s)	<ul> <li>March 1, 2016 (§ 54.1-3411.2)</li> <li>March 24, 2016 (§§ 110-20-211 and 110-50-51)</li> <li>February 21, 2017 (§ 54.1-3411.2:1)</li> </ul>
Does the state allow drug take-back programs by statute/regulation?	Yes.
Program components	§ 54.1-3411.2 – includes definitions for:
	<ul> <li>"authorized pharmacy disposal site," which means a pharmacy that qualifies as a collection site pursuant to federal regulation; and</li> <li>"pharmacy drug disposal program," which means a voluntary drug disposal program located at or operated in accordance with state and federal law by a pharmacy.</li> <li>Provides that a pharmacy may participate in a pharmacy drug disposal program in accordance with state and federal law regarding proper collection, storage, and destruction of prescription drugs, including controlled and non-controlled substances. A pharmacy that chooses to participate in a pharmacy drug disposal program shall notify the board and the board shall maintain a list of all pharmacies in the commonwealth that have chosen to participate in a pharmacy drug disposal program on a website maintained by the board.</li> </ul>
	§ 110-20-211 – any narcotic treatment program, hospital or clinic with an on-site pharmacy, or pharmacy that accepts a previously dispensed drug for the purpose of destruction shall first be authorized by the DEA as a collector. A collector so authorized may receive drugs from an ultimate user, a person lawfully entitled to dispose of an ultimate user decedent's property, or a long-term care facility on behalf of an ultimate user who resides or has resided at the facility. The process used to collect and destroy drugs, along with any required recordkeeping, shall comply with applicable federal and state laws.

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<u>VIRGINIA</u>	
Program components (continued)	Prior to collecting drugs, an authorized collector shall submit the following in writing to the board: (a) the name, address, and license number, if applicable, of the facility; (b) the intended method or methods of collection (i.e., collection receptacle or mail-back program); and (c) signature of pharmacist in charge or medical director of a narcotic treatment program.
	If an authorized collector chooses to cease acting as a collector, the pharmacist in charge or medical director shall notify the board within 30 days.
	A narcotic treatment program that does not have an in-house pharmacy shall obtain a controlled substance registration.
	$\S$ 110-50-51 — any manufacturer, wholesale distributor, or reverse distributor wishing to accept previously dispensed Schedule II — V controlled substances for return for the purpose of destruction from an ultimate user, or a person lawfully entitled to dispose of an ultimate user decedent's property, shall first be authorized by the DEA as a collector. The process used to collect and destroy drugs, along with any required recordkeeping, shall comply with federal and state law.
	Prior to collecting drugs, an authorized collector shall submit the following in writing to the board: (a) the name, address, and license number, if applicable, of the facility; (b) the intended method or methods of collection ( <i>i.e.</i> , collection receptacle or mail-back program; and (c) signature of the responsible party.
	The authorized collector shall notify the board within 30 days of choosing to cease acting as a collector.
Miscellaneous provisions	§ 54.1-3411.2:1 – the board of pharmacy shall develop guidelines for the provision of counseling and information regarding proper disposal of unused dispensed drugs, including information about pharmacy drug disposal programs in which the pharmacy participates pursuant to § 54.1-3411.2, by pharmacists to patients for whom a prescription is dispensed.
Recently proposed legislation	None.
Program website	Drug Take Back Program

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	WASHINGTON
Statute(s) and regulation(s)	<ul> <li>WASH. REV. CODE ANN. §§ 69.48.010 to 69.48.200 (West 2023) (collectively titled "Drug Take-back Program")</li> <li>WASH. REV. CODE ANN. § 43.131.423 (West 2023) (drug take-back program—termination)</li> <li>WASH. ADMIN. CODE §§ 246-480-010 to 246-480-990 (2023) (collectively titled "Drug Take-back Program")</li> </ul>
Effective date(s) of	• June 7, 2018 (§§ 69.48.010 to 69.48.200)
provision(s)	• August 1, 2019 (§§ 246-480-010 to 246-480-990)
Does the state allow drug take-back programs by statute/regulation?	Yes.
Program components	§ 69.48.020 (definitions) – definitions include:
	<ul> <li>"authorized collector," which means any of the following persons or entities that have entered into an agreement with a program operator to collect covered drugs: (a) a person or entity registered with the U.S. Drug Enforcement Administration and that qualifies under federal law to modify its registration to collect controlled substances for the purpose of destruction; (b) a law enforcement agency; or (c) an entity authorized by the department to provide an alternative collection mechanism for certain covered drugs that are not controlled substances;</li> <li>"collection site," which means the location where an authorized collector operates a secure collection receptacle for collecting covered drugs;</li> <li>"covered drug," which means a drug from a covered entity that the covered entity no longer wants and that the covered entity has abandoned or discarded or intends to abandon or discard. "Covered drug" includes legend drugs and nonlegend drugs, brand name and general drugs, drugs for veterinary use for household pets, and drugs in medical devices and combination products. "Covered drug" does not include vitamins, minerals, or supplements; herbal-based remedies and homeopathic drugs, products, or remedies; Schedule I controlled substances; personal care products; drugs for which manufacturers provide a pharmaceutical product stewardship or drug take-back program; biological drug products; drugs administered in a clinical setting; emptied injector products or medical devices; exposed needles or sharps; or pet pesticide products;</li> <li>"covered entity," which means a state resident or other non-business entity and includes an ultimate user. "Covered entity" does not include a business generator of pharmaceutical waste</li> </ul>

# **Program components** (continued)

- such as a hospital, clinic, healthcare provider's office, veterinary clinic, pharmacy, or law enforcement agency;
- "covered manufacturer," which means a person, corporation, or other entity engaged in the manufacturer of covered drugs sold in or into Washington state. "Covered manufacturer" does not include: (a) a private label distributor or retail pharmacy that sells a drug under the retail pharmacy's store label if the manufacturer of the drug is identified under this act; (b) a repackager if the manufacturer of the drug is identified under this act; or (c) a nonprofit 501(c)(3) healthcare corporation that repackages drugs solely for the purpose of supplying a drug to facilities or retail pharmacies operated by the corporation or an affiliate of the corporation if the manufacturer is identified under this act;
- "drug take-back organization," which means an organization designated by a manufacturer or group of manufacturers to act as an agent on behalf of each manufacturer to develop and implement a drug take-back program;
- "mail-back distribution location," which means a facility, such as a town hall or library, that offers prepaid, pre-addressed mailing envelopes to covered entities; and
- "program operator," which means a drug take-back organization, covered manufacturer, or group of covered manufacturers that implements or intends to implement a drug take-back program approved by the department.

§ 69.48.030 (requirement to participate in a drug take-back program) – a covered manufacturer must establish and implement a drug take-back program that complies with the requirements of this chapter. A manufacturer that becomes a manufacturer after the effective date of this act, must, no later than six months after the date on which the manufacturer became a covered manufacturer, participate in an approved drug take-back program or establish and implement a program that complies with the requirements of this chapter. A covered manufacturer may establish and implement a drug take-back program independently, as part of a group of covered manufacturers, or through membership in a drug take-back organization.

 $\S$  69.48.040 (identification of covered manufacturers) – no later than 90 days after the effective date of this act:

- (1) a drug wholesaler that sells a drug in or into Washington must provide a list of drug manufacturers to the department in a

### Program components (continued)

form agreed upon with the department and provide an updated list to the department on January 15 each year; and

- (2) a retail pharmacy, private label distributor, or repackager must provide written notification to the department identifying the drug manufacturer from which the retail pharmacy, private label distributor, or repackager obtains a drug that it sells under its own label.

Provides that a person or entity that receives a letter of inquiry from the department regarding whether or not it is a covered manufacturer under this chapter shall respond in writing no later than 60 days after receipt of the letter. If the person or entity does not believe it is a covered manufacturer for purposes of this act, it shall: (a) state the basis for the belief; (b) provide a list of any drugs it sells, distributes, repackages, or otherwise offers for sale within the state; and (c) identify the name and contact information of the manufacturer of the drugs identified under (b).

§ 69.48.050 (drug take-back program approval—program modifications) – sets forth the requirements for program operators to submit a proposal for approval to the department for the establishment and implementation of a drug take-back program. Provide that, to be approved, a proposed drug take-back program, independent of any other operating program, must:

- (1) identify and provide contact information for the program operator and each participating covered manufacturer;
- (2) identify and provide contact information for the authorized collectors for the program, as well as the reasons for excluding any potential collectors from participating;
- (3) provide for a collection system that complies with state law;
- (4) ensure that physical collection sites are the primary method of collection across the state. A drug take-back program's use of supplemental mail-back distribution locations or periodic collection events in any areas underserved by physical collection sites may provide collection services to no more than 15 percent of the state's residents;
- (5) provide for a handling and disposal system that complies with law;
- (6) identify any transporters and waste disposal facilities that the program will use;
- (7) adopt policies and procedures to be followed by persons handling covered drugs collected under the program to ensure

### Program components (continued)

safety, security, and compliance with federal regulations and laws;

- (8) ensure the security of patient information on drug packaging during collection, transportation, recycling, and disposal;
- (9) promote the program by providing consumers, pharmacies, and other entities with educational and informational materials;
- (10) demonstrate adequate funding for all administrative and operational costs of the drug take-back program, with costs apportioned among participating covered manufacturers;
- (11) set long-term and short-term goals with respect to collection amounts and public awareness; and
   (12) consider: (a) the use of existing providers of pharmaceutical waste transportation and disposal services; (b) separation of covered drugs from packaging to reduce transportation and disposal costs; and (c) recycling of drug packaging.

Sets forth the time deadlines for review and approval of proposed programs and requirements for rejected proposals.

Provides that proposed changes to an approved drug take-back program that substantially alter program operations must have prior written approval of the department. Proposed changes must be submitted in writing at least 15 days before the change is scheduled to occur. Changes requiring approval include changes to participating covered manufacturers, collection methods, achievement of the service convenience goal, policies and procedures for handling covered drugs, education and promotion methods, and selection of disposal facilities.

For changes that do not substantially alter program operations, program operators must notify the department at least seven days before implementing the change. Changes that do not substantially alter program operations include changes to collection site locations, methods for scheduling and locating periodic collection events, and methods for distributing prepaid, pre-addressed mailers.

By July 1, 2024, and every four years thereafter, all program operators must submit an updated proposal to the department describing any substantive changes to program elements.

If there is a single approved program at any time and that program operator intends to leave the program for any reason, participating

### Program components (continued)

manufacturers must find a new entity to take over operations of the existing program without a break in program services.

If there is more than one approved drug take-back program, and a program operator for a drug take-back program leaves the program for any reason and the covered manufacturers participating in that program fail to identify a new entity to take over operations of the existing program without a break in program services, those manufacturers must immediately join an existing approved program.

A covered manufacturer may change the approved drug take-back program it participates in but the covered manufacturer must maintain continuous participation in an established program and may not leave an approved program until it transfers participation to an approved program that has begun drug collection.

All program operators must collaborate to present a consistent statewide drug take-back system for residents to ensure that all state residents can easily identify, understand, and access services provided by an approved program.

Failure to comply with these requirements may result in enforcement action against a program operator.

§ 69.48.060 (collection system) – at least 120 days prior to submitting a program proposal, a program operator must notify potential authorized collectors of the opportunity to serve as an authorized collector for the proposed drug take-back program. A program operator must commence good faith negotiations with a potential authorized collector no later than 30 days after the potential authorized collector expresses interest in participating in a proposed program.

A person or entity may serve as an authorized collector for a program voluntarily or in exchange for compensation, but nothing in this act requires a person or entity to serve as an authorized collector. A program must include as an authorized collector any retail pharmacy, hospital or clinic with an on-site pharmacy, or law enforcement agency that offers to participate in the program without compensation and meets the requirements of this section. Such entities must be included in the program no later than 90 days after receiving the offer to participate.

### Program components (continued)

A program may also locate collection sites at: (a) a long-term care facility where a pharmacy, or a hospital or clinic with an on-site pharmacy, operates a secure collection receptacle; (b) a substance use disorder treatment program; or (c) any other authorized collector willing to participate as a collection site and able to meet the requirements of this section.

A collection site must accept all covered drugs from covered entities during the hours that the authorized collector is normally open for business with the public. A collection site located at a long-term care facility may only accept covered drugs that are in the possession of individuals who reside or have resided at the facility.

A collection site must use secure collection receptacles in compliance with state and federal law, including any applicable onsite storage and collection standards. The program operator must provide a service schedule that meets the needs of each collection site to ensure that each secure collection receptacle is serviced as often as necessary to avoid reaching capacity and that collected covered drugs are transported to final disposal in a timely manner, including a process for additional prompt collection service upon notification from the collection site. Secure collection receptacle signage must prominently display a toll-free telephone number and website for the program so that members of the public may provide feedback on collection activities. A program's collection system must be safe, secure, and convenient on an ongoing, year-round basis, and must provide equitable and reasonably convenient access for residents across the state.

In establishing and operating a collection system, a program operator must give preference to locating collection sites at retail pharmacies, hospitals or clinics with on-site pharmacies, and law enforcement agencies. Each population center must have a minimum of one collection site, plus one additional collection site for every 50,000 residents of the city or town located within the population center. Collection sites must be geographically distributed to provide reasonably convenient and equitable access to all residents of the population center. On islands and in areas outside of population centers, a collection site must be located at the site of each potential authorized collector that is regularly open to the public, unless the program operator demonstrates to the satisfaction of the department that a potential authorized collector is

# **Program components** (continued)

unqualified or unwilling to participate in the drug take-back program.

A program operator must establish mail-back distribution locations or hold periodic collection events to supplement service to any area of the state that is underserved by collection sites, as determined by the department, in consultation with the local health jurisdiction. The program operator, in consultation with the department, local law enforcement, the local health jurisdiction, and the local community, must determine the number and locations of mail-back distribution locations or the frequency and location of these collection events, to be held at least twice a year, unless otherwise determined through consultation with the local community. The program must arrange any periodic collection events in advance with local law enforcement agencies and conduct periodic collection events in compliance with federal laws and rules.

Upon request, a program must provide a mail-back program free of charge to covered entities and to retail pharmacies that offer to distribute prepaid, pre-addressed mailing envelopes for the program. Programs must permit covered entities to request mailing envelopes through the program's website, the toll-free telephone number, and a request to a pharmacist at a retail pharmacy distributing mailing envelopes.

§ 69.48.070 (drug take-back program promotion) – a program must develop and provide a system of promotion, education, and public outreach about the safe stores and secure collection of covered drugs. This system may include signage, written materials to be provided at the time of purchase or delivery of covered drugs, and advertising or other promotional materials. Requires programs to coordinate promotional activities to ensure that all state residents can easily identify, understand, and access the collection services provided by any take-back program.

The department shall conduct a survey of covered entities and a survey of pharmacists, healthcare providers, and veterinarians who interact with covered entities on the use of medicines after the first full year of operation of the drug take-back program, and again every two years thereafter. Survey questions must measure consumer awareness of the program; assess the extent to which collection sites and other collection methods are convenient and easy to use; assess knowledge and attitudes about risks of abuse, poisonings, and overdoses from drugs used in the home; and assess

### **Program components** (continued)

covered entities' practices with respect to unused, unwanted, or expired drugs, both currently and prior to implementation of the program. The department may, upon review of results of public awareness surveys, direct a program operator for an approved program to modify the program's promotion and outreach activities to better achieve widespread awareness among state residents and healthcare professionals about where and how to return covered drugs to the program.

§ 69.48.080 (disposal and handling of covered drugs) – covered drugs collected under a drug take-back program must be disposed of at a permitted hazardous waste disposal facility that meets federal requirements. If use of such a facility is unfeasible based on cost, logistics, or other considerations, the department, in consultation with the department of ecology, may grant approval for a program operator to dispose of some or all collected covered drugs at a permitted large municipal waste combustor facility.

If a program encounters a safety or security problem during collection, transportation, or disposal of covered drugs, the program operator must notify the department as soon as practicable after encountering the problem.

§ 69.48.090 (program funding) – a covered manufacturer or group of covered manufacturers must pay all administrative and operational costs associated with establishing and implementing the drug take-back program in which they participate. A program operator, covered manufacturer, authorized collector, or other person may not charge a specific point-of-sale fee to consumers to recoup the costs of a program or a specific point-of-collection fee at the time covered drugs are collected from covered entities.

§ 69.48.100 (annual program report) – by July 1 after the first full year of implementation, and each July 1 thereafter, a program operator must submit a report to the department describing implementation of the drug take-back program during the previous calendar year. The report must include:

- (1) a list of covered manufacturers participating in the program;
- (2) the amount, by weight, of covered drugs collected, including the amount by weight from each collection method used;
- (3) a list of collection sites with addresses; the number of mailers provided; locations where mailers were provided, if applicable; dates and locations of collection events held, if

### Program components (continued)

applicable; and the transporters and disposal facility or facilities used:

- (4) whether any safety or security problems occurred during collection, transportation, or disposal of covered drugs and, if so, completed and anticipated changes to policies, procedures, or tracking mechanisms to address the problem and improve safety and security;
- (5) a description of the public education, outreach, and evaluation activities implemented;
- (6) a description of how collected packaging was recycled to the extent feasible;
  - (7) a summary of the program's goals for collection amounts and public awareness, the degree of success in meeting those goals, and if any goals have not been met, what effort will be made to achieve those goals the following year; and
- (8) the program's annual expenditures, itemized by program category.

Within 30 days after each annual period of operation of an approved program, the program operator shall submit an annual collection amount report to the department that provides the total amount, by weight, of covered drugs collected from each collection site during the prior year.

§ 69.48.110 (enforcement and penalties) – provides that the department may audit or inspect the activities and records of a drug take-back program to determine compliance with this act or investigate a complaint. Sets forth the requirements for notice and warning regarding penalties for violations.

§ 69.48.120 (department to set program fees) – the department shall determine its costs for the administration, oversight, and enforcement of the requirements of this act including, but not limited to, a fee for proposal review, and the survey required by this act, and set fees at a level sufficient to recover the costs associated with administration, oversight, and enforcement, and adopt rules establishing requirements for program operator proposals.

The department shall not impose any fees in excess of its actual administrative, oversight, and enforcement costs. The annual fee set by the department shall be evenly split amongst each approved program operator.

# **Program components** (continued)

§ 69.48.140 (antitrust immunity) – the activities authorized by this chapter require collaboration among covered manufacturers. These activities will enable safe and secure collection and disposal of covered drugs in Washington state and are, therefore, in the best interest of the public. The benefits of collaboration, together with active state supervision, outweigh potential adverse impacts. Therefore, the legislature intends to exempt from state antitrust laws, and provide immunity through the state action doctrine from federal antitrust laws, activities that are undertaken, reviewed, and approved by the department pursuant to this act that might otherwise be constrained by such laws. The legislature does not intend and does not authorize any person or entity to engage in activities not provided for by this act, and the legislature neither exempts nor provides immunity for such activities.

§ 69.48.160 (local ordinances—grandfathering—preemption) – for a period of 12 months after a drug take-back program begins operating, a county may enforce a grandfathered ordinance. During that 12-month period, if a county determines that a covered manufacturer is in compliance with its grandfathered ordinance, the department shall find the covered manufacturer in compliance with the requirements of this act with respect to that county.

After the effective date of this act, a political subdivision may not enact or enforce a local ordinance that requires a retail pharmacy, clinic, hospital, or local law enforcement agency to provide for collection and disposal of covered drugs from covered entities.

§ 69.48.190 (report to legislature) – no later than 30 days after the department first approves a drug take-back program, the department shall submit an update to the legislature describing rules adopted under this chapter and the approved drug take-back program.

By November 15 after the first full year of operation of an approved program and biennially thereafter, the department shall submit a report to the legislature. The report must:

- (1) describe the status of approved programs;
- (2) evaluate the secure medicine collection and disposal system and the program promotion, education, and public outreach requirements;
- (3) evaluate, in conjunction with an academic institution that is not an agency of the state, to the extent feasible, the impact of approved drug take-back programs on: awareness and

# **Program components** (continued)

compliance of residents with safe storage of medicines in the home and secure disposal of covered drugs; rates of misuse, abuse, overdoses, and poisonings from prescription and nonprescription drugs; and diversions of covered drugs from sewer, solid waste, and septic systems; and

- (4) provide any recommendations for legislation.

§ 69.48.200 (survey – expires July 1, 2026) – the department shall contract with the statewide program of poison and drug information services to conduct a survey of residents to measure whether the secure medicine collection and disposal system and the program promotion, education, and public outreach requirements established in this act have led to statistically significant changes in: (a) resident attitudes and behavior on safe storage and secure disposal of prescription and nonprescription medications used in the home; and (b) the rates of abuse or misuse of or accidental exposure to prescription and nonprescription drugs. The survey results shall be reported to the legislature and the department of health within six months of completion of the survey.

§ 43.131.423 – the authorization for drug take-back programs shall be terminated on January 1, 2029.

§ 246-480-030 (identification of covered manufacturers) – upon review of an inquiry response letter described in § 69.48.040, the department shall notify the person or entity in writing whether or not the person or entity is considered a covered manufacturer. If the department determines that the person or entity is a covered manufacturer, the written notice will include a warning regarding the penalties for violation of this chapter.

Within 30 days after the first full year of a drug take-back program's implementation, and annually thereafter, the department may provide a list of covered manufacturers potentially not participating in a program to each approved program operator. Within 30 days of receiving such a list, approved program operators may provide any comments on the list to the department. Within 30 days of receiving and considering any approved program operator comments, the department may publish on its website a list of all covered manufacturers not participating in a program.

§ 246-480-040 (drug take-back program proposal components) – sets forth the requirements for drug take-back program proposals,

# **Program components** (continued)

which includes that each proposal must be on a form provided by the department and must:

- (1) contain a table of contents clearly denoting where each component required by § 69.48.050 is located within the proposal;
- (2) provide a description of a drug collection system that includes a list of participating authorized collectors, a list of drop-off (kiosk) locations, and a detailed description of how mail-back distribution locations or periodic collection events will be used;
- (3) demonstrate that the policies and procedures to be followed by persons handling unwanted covered drugs collected under the program includes how all entities participating in the program will operate under all applicable federal and state laws and regulations and how any pharmacy collection sites will operate under applicable rules from the Washington state pharmacy quality assurance commission;
- (4) include a detailed description of the geographical distribution of collection sites that will provide equitable and reasonably convenient access to all residents;
- (5) include a budget estimate for providing the statewide program;
- (6) describe how the program operator will work with Washington state counties and the department to incorporate local programs into their proposed statewide plan; and
- (7) include an implementation plan and schedule for initiating operation of the approved program.

§ 246-480-050 (program application) – a program operator must submit its program proposal and substantial changes to an approved program on forms provided by the department.

If the department takes enforcement action as provided in § 69.48.050, the applicant through its authorized representative may request an adjudicative proceeding, which request must be in writing, state the basis for contesting the adverse action, include a copy of the adverse notice, and be served on and received by the department within 28 days of the program operator's receipt of the adverse notice.

§ 246-480-060 (collection of covered drugs—underserved areas) – to assist program operators in complying with § 69.48.060, the department will determine and locate each population center using

	WASHINGTON
Program components (continued)	geographical information systems mapping technology, and will publish updated population data to the department's website annually. The department, in consultation with the local health jurisdiction, will determine underserved areas using the following criteria: population density of counties; estimated number of participating collection sites; travel distances and times; accessible public facilities, such as libraries, town halls, and police and fire departments; and geographic features that may inhibit access to collection locations such as mountains and islands.
	§ 246-480-070 (promotion) – approved program operators must update their list of authorized collectors, collection sites, locations to receive mailers, and locations for drug take-back events at least quarterly on their website.
	§ 246-480-080 (program operator annual report) – each program operator shall submit an annual report to the department by July 1 on a form developed by the department. In addition to the elements identified and described in § 69.48.100, the report must include a summary of the program's annual expenditures organized using the same criteria as described in § 246-480-040.
	§ 246-480-990 (fees) – this section establishes the initial and annual fees for a program operator implementing a drug take-back program. By August 1, 2020, and each August 1 thereafter, the department shall notify a program operator the amount of its annual renewal fee as determined according to law. Renewal fees will reflect the department's actual administrative, oversight, enforcement, and contractual costs for that fiscal year, or not more than 10 percent of the program operator's annual expenses as reported on July 1 of each year, whichever amount is smaller. By October 1, 2020, and each October 1 thereafter, a program operator shall submit to the department the renewal fee.
Miscellaneous provisions	None.
Recently proposed legislation	Yes. See <u>Pending Federal and State Legislation</u> .
Program website	Safe Medication Return   Washington State Department of Health

	WEST VIRGINIA	
Statute(s) and regulation(s)	W. VA. CODE R. § 11-5-8 (2023) (returned or surrendered drugs; authorization and procedures for destruction; prohibition on reuse)	
Effective date(s) of provision(s)	June 1, 2022	
Does the state allow drug take-back programs by statute/regulation?	Yes.	
Program components	§ 11-5-8 – pursuant to current federal regulations, licensees of the board of medicine are prohibited from accepting unused and/or unwanted controlled substances from or on behalf of patients. A licensee may refer individuals in lawful possession of unwanted or unused controlled substances and who are seeking disposal assistance to:	
	<ul> <li>(1) entities which are registered with the DEA as authorized collectors to receive the transfer from the ultimate users of any unwanted and unused pharmaceutical controlled substances in their lawful possession for safe, secure, and responsible disposal;</li> <li>(2) local law enforcement operating federally authorized takeback events, mail-back programs, or collection receptacles; and/or</li> <li>(3) the DEA website for information regarding proper methods of disposal by the lawful possessor.</li> </ul>	
	With the exception of controlled substances, a licensee of the board may accept unused prescription drugs from or on behalf of patients for the purpose of proper disposal. The disposal of returned or surrendered prescription drugs shall occur promptly, and no later than 30 days after receipt. Until disposed of, returned or surrendered prescription drugs shall be stored in a locked or otherwise secure area to prevent access by unauthorized individuals.	
	A licensee who accepts returned or surrendered prescription drugs shall maintain a log which lists:  - (1) the name of the patient to whom the returned or surrendered	
	drug was dispensed; - (2) the strength of the drug and the quantity returned or surrendered; - (3) the date and manner of disposal; and	

WEST VIRGINIA	
Program components (continued)	- (4) the printed name and signature of the individual who actually disposed of the drug.
Miscellaneous provisions	None.
Recently proposed legislation	None.
Program website	DRoP Program - Dispose Responsibly of Prescriptions

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	WISCONSIN
Statute(s) and regulation(s)	<ul> <li>WIS. STAT. ANN. § 165.65 (West 2023) (drug disposal program)</li> <li>WIS. STAT. ANN. § 450.115 (West 2023) (drug disposal programs and authorizations)</li> <li>WIS. STAT. ANN. § 961.337 (West 2023) (drug disposal programs)</li> </ul>
Effective date(s) of	• July 1, 2015 (§§ 165.65 and 961.337)
provision(s)	• December 2, 2017 (§ 450.115)
Does the state allow drug take-back programs by statute/regulation?	Yes.
Program components	§ 165.65 – definitions include:
	<ul> <li>"drug disposal program," which means a program to receive household pharmaceutical items and to recycle, destroy, or otherwise dispose of those items. "Drug disposal program" does not include a sharps collection station operated in compliance with rules promulgated by the department of natural resources; and</li> <li>"household pharmaceutical item," which means any of the following if lawfully possessed by an individual for the individual's own use, for the use of a member of the individual's household, or for the use of an animal owned by the individual or a member of the individual's household: a drug, prescription drug, or controlled substance or controlled substance analog and a device or object used for administering a drug. "Household pharmaceutical item" does not include any item that may be contaminated with antineoplastic chemotherapy drugs and any item containing elemental mercury.</li> </ul>
	Except as otherwise provided by law, no person may receive household pharmaceutical items pursuant to a drug disposal program unless the department of justice grants written authorization for that program or the program is authorized under federal law.
	The department of justice may, without a hearing, grant written authorization to a person to operate a drug disposal program if all of the following conditions are satisfied:
	- (1) the person adopts written policies and procedures that comply with this act. The department of justice shall review and either approve or disapprove in writing those policies and procedures. The department of justice shall approve the policies

### **WISCONSIN**

# **Program components** (continued)

- and procedures if the department determines that the policies and procedures do not violate the requirements of this section or any other applicable federal or state law, and shall disapprove them otherwise;
- (2) if the drug disposal program will receive household pharmaceutical items in any manner other than the transfer of a household pharmaceutical item in person to the program by a person that lawfully possesses the household pharmaceutical item, the person demonstrates to the satisfaction of the department of justice that those transfers will comply with any federal or state law applicable to the transportation and delivery of household pharmaceutical items.

A political subdivision of the state may operate or the governing body of a political subdivision may grant written authorization for a person to operate a drug disposal program only if all of the following apply: (a) the political subdivision or the authorized person operates the drug disposal program only within the boundaries of the political subdivision; (b) the applicable requirements of this act are satisfied; and (c) the drug disposal program receives household pharmaceutical items only be means of delivery in person by a person that lawfully possesses the household pharmaceutical item, unless the drug disposal program is authorized under federal law to receive household pharmaceutical items by other means.

A drug disposal program may operate within more than one political subdivision if the department of justice authorizes that program, all political subdivisions within which the program operates authorizes the program, or the program is authorized under federal law.

A person that operates a drug disposal program, except a program authorized under federal law, shall establish and promptly update as appropriate written policies and procedures that do all of the following:

- (1) describe in detail the manner in which the program operates, including an identification of the kinds of household pharmaceutical items that will be transferred by mail under the program, and the locations at which household pharmaceutical items may be transferred in person under the program;

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Program components (continued)	<ul> <li>(2) list the name, address, telephone number, and 24-hour contact information for one or more persons in this state who are responsible for the operation of the program; and</li> <li>(3) ensure compliance with federal and state laws.</li> </ul>
	The operation of a drug disposal program shall immediately cease if a law enforcement officer, a federal law enforcement officer, the department of justice, or another federal or state agency notifies a designated contact person for the program that the program is in violation of any federal or state law enforceable by the officer, department of justice, or other agency. That notification is not subject to judicial review. The program may resume operation only upon the program's receipt of written notice from the officer, department of justice, or other agency that the program is no longer in violation of the law.
	Each person that operates a drug disposal program in this state shall, within 30 days after the program begins operation, notify and provide all of the following information to the department of natural resources: (a) the location and hours of operation of the program; (b) the name, address, telephone number, and 24-hour contact information for one or more persons in this state who are responsible for the operation of the program; and (c) a description of the household pharmaceutical items the drug disposal program may receive.
Miscellaneous provisions	<ul> <li>§ 450.115 – nothing in this chapter, or rules promulgated under this chapter, prohibits:</li> <li>(1) the direct operation or implementation of a drug disposal program authorized by state or federal law; or</li> <li>(2) the transfer of a prescription drug by a person that lawfully possesses the prescription drug to a drug disposal program that accepts the prescription drug.</li> <li>Provides that a guardian may grant written authorization to an adult</li> </ul>
	who is related to the guardian's ward by blood, marriage, or

adoption within the third degree of kinship, or to a domestic partner of the ward, for the disposal of a prescription drug that belongs to the ward.

A personal representative or a trustee may grant written authorization to an adult beneficiary of the estate or trust for the disposal of a prescription drug that belongs to the estate or trust.

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	<u>WISCONSIN</u>	
Miscellaneous provisions (continued)	A person who is a competent adult may grant written authorization to that person's domestic partner or to another adult who is related to that person by blood, marriage, or adoption within the third degree of kinship for the disposal of a prescription drug that lawfully belongs to that person.	
	A personal representative, trustee, or an adult beneficiary of an estate or trust may grant written authorization to a hospice worker for the disposal of a controlled substance that belongs to the estate or trust.	
	Written authorizations under this section are valid only to the extent permitted under federal law and only if all of the following conditions are satisfied:	
	<ul> <li>(1) the authorization describes with reasonable specificity each prescription drug or controlled substance to be disposed of;</li> <li>(2) the authorization is in the physical possession of the person authorized to dispose of the prescription drug or controlled substance and each prescription drug or controlled substance described in the authorization is, within 24 hours after the authorization is signed, transferred to a drug disposal program or otherwise lawfully disposed of; and</li> <li>(3) the authorization and each prescription drug or controlled substance to be disposed of were obtained without consideration.</li> </ul>	
	§ 961.337 - nothing in this chapter, or rules promulgated under this chapter, prohibits any of the following:	
	<ul> <li>(1) the direct operation or implementation of a drug disposal program authorized under state or federal law; or</li> <li>(2) the transfer by the ultimate user, or by another person that lawfully possesses the controlled substance or controlled substance analog, of a controlled substance or controlled substance analog to a drug disposal program that has been authorized under state or federal law and that accepts the controlled substance or controlled substance analog.</li> </ul>	
Recently proposed legislation	None.	
Program website	Dose of Reality: Safe Disposal of Medications and Medical Supplies - WI Dept. of Health Services	
	<u> </u>	

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WYOMING	
Statute(s) and regulation(s)	• WYO. STAT. ANN. § 2-1-501 (West 2023) (disposal of controlled substances)
	• WYO. STAT. ANN. § 35-7-1603 (West 2023) (drug donation, redispensing and disposal program established; minimum requirements)
Effective date(s) of	• July 1, 2009(§ 35-7-1603)
provision(s)	• July 1, 2016 (§ 2-1-501)
Does the state allow drug take-back programs by statute/regulation?	Yes.
Program components	<ul> <li>§ 35-7-1603 – the department shall establish pursuant to its rules and regulations a voluntary drug donation and disposal program as provided in this section. To the extent authorized by applicable federal law, the drug drop off and disposal program shall have the following features:</li> <li>(1) drop off locations shall be located with donation sites as provided in this section or local law enforcement agencies approved by the U.S. Drug Enforcement Administration to the extent necessary under federal law;</li> <li>(2) procedures shall be maintained for the documentation of all collected unused medication;</li> <li>(3) procedures shall be maintained for the environmentally safe disposal of unused medications;</li> <li>(4) the department shall provide for public education of potential participating consumers about the availability of the drug disposal program and proper and effective disposal of unused medications; and</li> <li>(5) the department shall cooperate with law enforcement agencies to the extent required for the collection under law enforcement supervision or the secure collection, storage, transport, and destruction of controlled substances.</li> </ul>
Miscellaneous provisions	§ 2-1-501 – a person is authorized to collect any controlled substances of the decedent for purposes of disposal in accordance with federal law.
Recently proposed legislation	None.
Program website	<u>SafeMeds</u>

<u>GUAM</u>	
Statute(s) and regulation(s)	None.
Effective date(s) of provision(s)	N/A
Does the state allow drug take-back programs by statute/regulation?	No.
Program components	N/A
Miscellaneous provisions	None.
Recently proposed legislation	None.
Program website	N/A

<u>PUERTO RICO</u>	
Statute(s) and regulation(s)	None.
Effective date(s) of provision(s)	N/A
Does the state allow drug take-back programs by statute/regulation?	No.
Program components	N/A
Miscellaneous provisions	None.
Recently proposed legislation	None.
Program website	N/A

<u>U.S. VIRGIN ISLANDS</u>	
Statute(s) and regulation(s)	None.
Effective date(s) of provision(s)	N/A
Does the state allow drug take-back programs by statute/regulation?	No.
Program components	N/A
Miscellaneous provisions	None.
Recently proposed legislation	None.
Program website	N/A

PENDING FEDERAL AND STATE LEGISLATION	
State/Bill Number/ Status	Description
Connecticut H.B. 6696, Jan. Sess. (Conn. 2023) (4/25/2023 – referred to House committee	Creates new section that includes definitions for "personal opioid drug deactivation and disposal product," which means a product that is designed for personal use and enables a patient to permanently deactivate and destroy an opioid drug.
on appropriations)	The bill provides that, except as otherwise provided by law, each pharmacist who dispenses an opioid drug to a patient in this state shall provide to the patient, at the time such pharmacist dispenses such drug to the patient, a personal opioid drug deactivation and disposal product. No pharmacy or pharmacist shall charge any fee to, or impose any cost on, any patient for a personal opioid drug deactivation and disposal product that a pharmacist provides to a patient pursuant to this subdivision.
	Further provides that any pharmacy or pharmacist may seek reimbursement from the Opioid Settlement Advisory Committee for documented expenses incurred by such pharmacy or pharmacist in providing personal opioid drug deactivation and disposal products to patients. No pharmacy or pharmacist shall be required to bear any documented expense for providing personal opioid drug deactivation and disposal products to patients and, if there are insufficient funds in the Opioid Settlement Fund to cover such documented expenses or such funds are otherwise unavailable, no pharmacist shall be required to provide a personal opioid drug deactivation and disposal product.
	The bill amends § 17a-674c related to the Opioid Settlement Fund to provide that moneys in the fund shall also be spent on documented expenses incurred by pharmacies and pharmacists in providing personal opioid drug deactivation and disposal products to patients.
Nevada S.B. 183, 82 <sup>nd</sup> Leg. Sess. (Nev. 2023) (5/20/2023 –	Creates new section in Chapter 639 that provides that a collector that maintains a secure drug take-back bin for the collection and destruction of home-generated pharmaceutical waste shall:
pursuant to Joint Standing Rule No. 14.3.3, no further action allowed)	<ul> <li>(1) comply with all applicable state and federal laws and regulations relating to the collection of home-generated pharmaceutical waste for destruction in secure drug take-back bins;</li> <li>(2) ensure that the secure drug take-back bin is placed in a location that is regularly monitored by employees of the collector;</li> <li>(3) ensure that conspicuous signage is posted on the secure drug take-back bin that clearly notifies customers as to the substances that are and are not acceptable for deposit into the bin;</li> </ul>

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Nevada, S.B. 183 (continued)	<ul> <li>(4) ensure that public access to the bin is limited to hours during which employees of the collector are present and able to monitor the operation of the secure drug take-back bin;</li> <li>(5) regularly inspect the bin and the area surrounding the bin for potential tampering or diversion;</li> <li>(6) maintain a record of inspections conducted pursuant to paragraph (5) that must be documented in writing or electronically, include the date and time of each inspection, and include the initials of the employee who conducted each inspection;</li> <li>(7) retain each record maintained pursuant to paragraph (6) and any other record relating to the secure drug take-back bin required by state or federal laws or regulations for at least two years after the date of the event to which the record pertains; and</li> <li>(8) notify at least one local law enforcement agency of any suspected or known tampering or theft or significant loss of controlled substances that occurs while the bin is under the control of the collector not later than one business day after the date on which the tampering, theft, or significant loss is suspected or discovered.</li> <li>Provides that a collector shall not receive compensation from a customer of the collector to maintain a secure drug take-back bin or to perform any act required by this section.</li> <li>Further provides that any collector that maintains a secure drug take-back bin and complies with the provisions of this section is not subject to any: <ul> <li>(a) disciplinary action by the board for any injury or harm that directly results from the maintenance of a secure drug take-back bin on its premises, unless such harm or injury results from the gross negligence or willful and wanton misconduct of the collector, or (b) restriction established by the governing body of a county, city, or other local governmental entity that would affect the collector, transportation, treatment, or destruction of the contents of a secure drug take-back bin.</li> </ul> </li> <li>Also provides</li></ul>

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Nevada, S.B. 183 (continued)	the contents of secure drug take-back bins, unless the agreement and plan expressly provides for such collection and disposal.
	Finally provides the following definitions:
	<ul> <li>"collector," which means an entity that is authorized by and registered with the U.S. Drug Enforcement Administration to receive a controlled substance for the purpose of destruction and is in good standing with the board;</li> <li>"home-generated pharmaceutical waste," which means a</li> </ul>
	pharmaceutical that is no longer wanted or needed by the consumer including, without limitation, in the form of pills, liquids, inhalers, topical creams, suppositories, or patches; and  - "secure drug take-back bin," which means a collection receptacle as described in 21 C.F.R. § 1317.75.
New York A.B. 5086, 246 <sup>th</sup> Leg. Sess. (N.Y. 2023) (5/12/2023 – amend and recommit to health committee)	Creates Public Health Law § 3309-c, opioid personal use pharmaceutical disposal systems, which provides that no person in the state shall dispense an opioid prescription to the ultimate user of such prescribed opioid unless such person additionally provides to such ultimate user a personal use pharmaceutical disposal system at no cost to the ultimate user.
,	Defines "personal use pharmaceutical disposal system" to mean a portable product designed for personal use by the ultimate user for the purpose of allowing the ultimate user of a prescribed opioid to deactivate the prescribed opioid to a non-retrievable condition or state.
New York S.B. 5738, 246 <sup>th</sup> Leg. Sess. (N.Y. 2023) (3/15/2023 – referred to health)	Creates Public Health Law § 3309-c, controlled substance personal use pharmaceutical disposal systems, which provides that no person in the state shall dispense a controlled substance prescription to the ultimate user of such prescribed controlled substance unless such person additionally provides to such ultimate user a personal use pharmaceutical disposal system at no cost to the ultimate user.
	Further provides that each county health department shall provide personal use pharmaceutical disposal systems to each pharmacy in such county at no cost to such pharmacy to be distributed pursuant to the provisions of this section. Personal use pharmaceutical disposal systems shall either be provided to each county by the manufacturer of each controlled substance distributed in such county at no cost to the county health department, or acquired by the county health department through the use of funds made available from the state as appropriated therefor.

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Pennsylvania H.B. 818, 207 <sup>th</sup> Gen. Assemb. (Penn. 2023) (7/6/2023 – referred to Senate consumer protection and professional licensure committee)	This bill creates the Pharmaceutical Collection Sites Educational Program, established within the department of state. it provides that the program shall assist in the state board of pharmacy's efforts to educate pharmacies on pharmacies' ability to modify their registration with the U.S. Drug Enforcement Administration to receive and destroy mail-back packages and to install, manage, and maintain collection receptacles for prescription drugs.	
	Further provides that money shall be appropriated from the General Fund to the department of state to administer the program and shall be used in a manner, as determined by the department, to educate and support pharmacies on their ability to modify their registration with the DEA, to initiate a drug take-back program, to receive and destroy mail-back packages, and to install, manage, and maintain collection receptacles for prescription drugs.	
Washington Drug Take-back Program, 2023	Proposed changes to 246-480-050, program application, to provide that a potential drug take-back program operator shall submit to the department:	
Wash. Reg. Text 603324 (West 2023) (8/2/2023 – proposed	<ul> <li>(1) its proposal to be an approved program in the format provided by the department; and</li> <li>(2) the proposal review fee set forth in 246-480-990.</li> </ul>	
rules)	An approved drug take-back program operator shall submit to the department:	
	- (1) any substantial changes to an approved program in the format provided by the department;	
	<ul> <li>(2) the annual operating fee in 246-480-990; and</li> <li>(3) by July 1, 2024, and every four years thereafter, an updated proposal.</li> </ul>	
	Amends 246-480-070, promotion, education, and public outreach, to provide as follows:	
	<ul> <li>(1) program operators shall coordinate to present a consistent statewide drug take-back system;</li> <li>(2) each program operator is independently responsible for complying with all requirements of law and rule and is responsible for their own promotional material;</li> <li>(3) collection sites at long-term care facilities and substance use disorder treatment programs are not available to the general public.</li> </ul>	

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Washington, 603324 (continued)	Program operators shall exclude these collection sites from public promotional material;  (4) each program operator shall ensure their public promotional materials are easy for people to use and understand, including people with limited-English proficiency and people with disabilities, including people who are deaf or blind;  (5) each program operator shall ensure their public promotional material describes how to access all collection sites, mail-back distribution locations, and take-back events regardless of program operator;  (6) each program operator shall refer to the statewide drug take-back system as "Safe Medication Return" on all their promotional materials and shall not use any other name to refer to their program. Nothing in this section prohibits inclusion of program operator name in or on promotion, education, or outreach material;  (7) program operators shall coordinate to develop a safe medication return logo or mark and shall use the logo or mark to promote safe medication return as the statewide drug take-back system. The logo or mark must be approved by the department prior to use by any program operator and must be included on all promotional material;  (8) program operators shall ensure the single website presents a consistent statewide drug take-back system. The single website domain name must be descriptive of safe medication return, Washington's drug take-back system, and must not appear specific to any program operator. It must include information on why and how to safely store and securely dispose of medication, including discouraging disposal of medication down drains or in the garbage, what safe medication return accepts and does not accept, and the single toll-free telephone number. The website must display all collection sites and mail-back distribution locations on one map and in one table, and must display all drug take-back events for all program operators in one table and must be searchable by zip code and city and must display all options regardless of program operator. Program	
	statewide drug take-back system and include links to the single website described above;	

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Washington, 603324 (continued)	instructional inserts to inform the public how to receive support or provide comments about secure collection receptacle or mailer. Program operator specific email addresses must not be included on any other public promotional material;  - (11) program operators shall ensure the single toll-free telephone number and all call centers accessed through that number present a consistent statewide drug take-back system. The single toll-free telephone number and all call centers accessed through it must answer calls 24 hours a day, seven days a week; allow callers to access information about the statewide safe medication return system; allow callers to order mail-back supplies; and provide the department's contact information;  - (12) current program operators shall coordinate with newly approved program operators to ensure certain required provisions are met within 180 days of the department's approval of a new program operator's proposal.  The proposed rule also amends 246-480-080, program operator annual report, to provide that each program operator shall submit an annual report to the department by July 1 in the format provided by the department. provides that, in order to ensure consistency of program operator reporting and ensure the department can accurately analyze the data, the annual report must include the listed information, including, but not limited to, information regarding collections site locations, mail-back distribution locations, authorized collectors, and information regarding any safety or security problems and solutions.  The proposed rule further amends 246-480-990, fees, to provide that, until January 1, 2024, a potential program operator submitting a proposal shall submit a nonrefundable proposal review fee of \$157,000 to the department when they submit their proposal. After January 1, 2024, the fee shall be \$63,000. Approved program operators submitting updated proposals are not required to submit a proposal review fee. Also sets forth information regarding the annual operating fee.	

# ABOUT THE LEGISLATIVE ANALYSIS AND PUBLIC POLICY ASSOCIATION

Based in Washington D.C., and led by and comprised of experienced attorneys, the Legislative Analysis and Public Policy Association is a 501(c)(3) nonprofit organization whose mission is to conduct legal and legislative research and analysis and draft legislation on effective law and policy in the areas of public safety and health, substance use disorders, and the criminal justice system.

LAPPA produces timely model laws and policies that can be used by national, state, and local public health, public safety, and substance use disorder practitioners who want the latest comprehensive information on law and policy as well as up-to-theminute comparative analyses, publications, educational brochures, and other tools ranging from podcasts to fact sheets. Examples of topics on which LAPPA has assisted stakeholders include naloxone laws, law enforcement/community engagement, alternatives to incarceration for those with substance use disorders, medication-assisted treatment in correctional settings, and the involuntary commitment and guardianship of individuals with alcohol or substance use disorders.

