LEGISLATIVE ANALYSIS AND PUBLIC POLICY ASSOCIATION

DRUG TAKE BACK AND DISPOAL 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. In the last several years, states, in coordination with the U.S. Drug Enforcement Administration (DEA) have enacted legislation or promulgated administrative regulations to authorize drug take-back programs where expired, unwanted or unused pharmaceuticals can be collected from the public by authorized individuals and disposed of in a safe manner. The findings are listed in alphabetic order by state below.

Some states have enacted drug repository programs or donation programs. Drug repository programs authorize the collection of specific unused medications that are redistributed to qualifying individuals. These programs are beyond the purview of this summary. However, if a state does not have a drug take-back program authorized by statute or administrative regulation, the summary provides information on drug repository programs in the miscellaneous provision section for the applicable jurisdictions.²

OVERVIEW

Expired, unused, or unwanted medications pose a significant public health risk. This is particularly true for medications classified as a controlled substance.³ Expired, unused, or unwanted prescription medication can lead to accidental poisoning, misuse, or overdose. According to the 2019 National Survey on Drug Use and Health, in 2019, 9.7 million people misused prescription pain relievers,⁴ 4.9 million people misused prescription stimulants,⁵ and 5.9 million people misused prescription sedatives.⁶ The consequences of prescription misuse can be fatal. The ongoing drug epidemic is at catastrophic levels across the nation, and its impact is devastating, causing approximately 108,000 deaths in 2021.⁷ In an effort to combat the very real public health danger that expired, unwanted, and unused prescription medications can pose, the DEA began coordinating a semi-annual National Prescription Take-back Day (Take-back Day)

¹ State Prescription Drug Repository Programs, NCSL.ORG, (accessed October 1, 2021), https://www.ncsl.org/research/health/state-prescription-drug-return-reuse-and-recycling.aspx.

² The goal of this research document is to provide accurate and complete information that is free of omissions or errors. If you believe that this document contains misinformation, omissions, or errors, please email LAPPA at info@thelappa.org.

³ DEA Holds National Prescription Drug Take-back Day to Turn the Tide Against the U.S. Opioid Epidemic, DEPT. JUSTICE, (accessed October 20, 2021) https://www.justice.gov/usao-ndal/pr/dea-holds-national-prescription-drug-take-back-day-turn-tide-against-us-opioid-epidemic.

⁴ SAMHSA, *Key Substance Use and Mental Health Indicators In The United States: Results From The 2019 National Survey On Drug Use and Health*, U.S. DEP'T OF HEALTH AND HUMAN SVC. 2 (Sept. 2020), https://www.samhsa.gov/data/sites/default/files/reports/rpt29393/2019NSDUHFFRPDFWHTML/2019NSDUHFFR1PDFW090120.pdf.

⁵ *Id*.

⁶ *Id*.

⁷ F.B. Ahmad, et al., *Provisional Drug Overdose Death Counts*, NAT'L CTR. HEALTH STATISTICS (March 16, 2022), https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm.

on September 25, 2010.⁸ Take-back Day serves a vital public safety role for a variety of reasons, including encouraging the proper disposal of controlled substance medications; decreasing prescription medication diversion, abuse, accidental poisonings; and decreasing environmental hazards resulting from improper medication disposal.⁹ Since the inception of Take-back Day, public and private health and safety officials have collected 14,524,391 pounds of medication.¹⁰

Four days after the first Take-back Day was held in 2010, Congress passed the Secure and Responsible Drug Disposal Act of 2010 (Disposal Act), an amendment to the Controlled Substance Act (CSA). The goal of the Disposal Act is ". . . to encourage the Attorney General [through the DEA] to set controlled substance diversion prevention parameters that will allow public and private entities to develop a variety of methods of collection and disposal of controlled substances, including some pharmaceuticals, in a secure, convenient, and responsible manner." The Disposal Act amended the CSA to give the DEA authority to promulgate new regulations, within the framework of the CSA, that allow "ultimate users" to deliver unused pharmaceutical controlled substances to appropriate entities for disposal in a safe and effective manner, consistent with effective controls against diversion.

Crucially, after passage of the Disposal Act, the DEA established regulations that explicitly authorizes drug manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with on-site pharmacies, and retail pharmacies to voluntarily administer mail-back programs and maintain collection receptacles on-site for the disposal of prescription controlled substances without the need for state authorization. ¹⁵ In addition, pursuant to the regulations promulgated under the Disposal Act, retail pharmacies or a hospital/clinic with an on-site pharmacy may also install, manage, and maintain collection receptacles at long-term care facilities. ¹⁶

⁸ OFF. OF PUB. AFF., *DEA Heads First-ever Nationwide Prescription Drug Take-back Day*, DEP'T. OF JUST. (published Aug. 19, 2010), https://www.justice.gov/opa/pr/dea-heads-first-ever-nationwide-prescription-drug-take-back-day.

⁹ 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.

¹⁰ DEA and Partners Announce Results of 20th National Prescription Drug Take-back Day, DEA.GOV (accessed October 1, 2021).

¹¹ Secure and Responsible Drug Disposal Act of 2010, PL 111-273, 124 Stat 2858 (West)(2010).

¹² Id. at 2859.

¹³ The CSA defines an "ultimate user" as "a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or a member of his household." Controlled Substances Act, 21 U.S.C.A. § 802(27)(West)(2018).

¹⁴ Secure and Responsible Drug Disposal Act of 2010.

¹⁵ Executive Summary, 79 C.F.R. § 53519 (West)(2014); 21 C.F.R. §§ 1300 -1317 (West)(2014); *see also* Scope, 21 C.F.R. § 1317.01(West)(2014).

¹⁶ Id.; see also Collection Receptacles at Long-term Care Facilities, 21 C.F.R. § 1317.80 (West)(2014).

The Disposal Act only provides for the collection of controlled substances. By law, the DEA must provide regulatory guidance for the collection and disposal of controlled substances. However, states regain the authority to regulate collection and disposed of non-controlled medications through state-run drug take-back programs and events which are often more expansive and allow the public to dispose of a variety of pharmaceuticals, including non-controlled prescription drugs and over-the-counter medications. ¹⁸

As of August 2022, 27 states have enacted legislation that authorize a drug take-back program or provides mechanisms for the collection of prescription medication disposal. These states are Arizona, California, Colorado, Connecticut, Illinois, Indiana, Kentucky, Maine, Maryland, Massachusetts, Minnesota, Missouri, Montana, New Hampshire, New Jersey, New York, Ohio, Oregon, Rhode Islands, South Carolina, Tennessee, Utah, Vermont, Virginia, Washington, Wisconsin, and Wyoming.¹⁹ Four states, Alabama, Alaska, Louisiana, and West Virginia, have promulgated administrative regulations that authorize or establish a drug take-back program or provide mechanisms for the collection of prescription medication disposal.²⁰ Any state-run drug take-back program or event that accepts controlled substances must operate in coordination with a collector who is authorized by the DEA, such as local law enforcement.²¹ Typically, DEA registrants can obtain authorization to take-back controlled substances if they are retail pharmacies, drug manufacturers, distributors, reverse distributors, narcotic treatment programs, clinics, or hospitals.²² Individuals may only dispose of medications they are lawfully permitted to possess. This includes drugs that are prescribed to them or their dependents or if they are in possession of a deceased person's medications over which they had responsibility.²³

¹⁷ Secure and Responsible Drug Disposal Act of 2010.

¹⁸ For example, Ohio law allows authorized collectors to dispose of needles or syringes if they can provide the proper disposal equipment to do so. Ohio ADMIN. CODE 4729:10-1 - 4729:10-1-04(West)(2021).

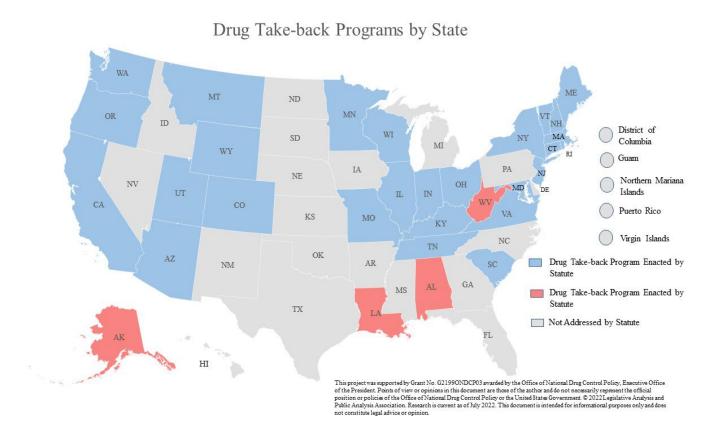
¹⁹Ariz. Rev. Stat. Ann. § 36-123.01 (West)(2018); Cal. Civ. Code § 1714.24 (West)(2017); Cal. Code Regs. tit. 16, §§ 1776-1776.6 (2017); Colo. Rev. Stat. Ann. § 25-15-328 (West)(2019); Colo. Rev. Stat. Ann. § 25-15-328 (West)(eff. Oct. 1, 2019); Conn. Gen. Stat. Ann. § 20-576a (West)(2017); 20 Ill. Comp. Stat. Ann. 3930/9.3 (West)(2015); Ind. Code Ann. §§ 25-26-23-1-25-26-23-9 (West)(2019); 856 Ind. Admin. Code 7-1-1 – 7-9-1 (West)(2017); Ky. Rev. Stat. Ann. § 218A.170 (3)(West)(2018); Me. Rev. Stat. Ann. tit 22, § 2700 (West)(2021); Md. Code Ann. Health-Gen. §§ 15-601 to -609 (West)(2021); Mass. Gen. Laws Ann. ch.94H § 1(West)(2017); Minn. Stat. Ann. § 152.105 (West)(2019); Mo. Ann. Stat. § 195.265 (West)(2018); Mont. Code Ann. § 1-1-232 (West)(2019); N.H. Rev. Stat. Ann. §§ 318-E:1(West)(2016); n.H. code Admin. R. Jus. 1603.01(West)(2021); N.J. Stat. Ann. § 45:9-22.11a(West)(2016); N.Y. Pub. Health Law § 3343-b (McKinney)(2019); N.Y. Comp. Codes R. & Regs. tit. 10, § 60-4.4 (2021); OHIO REV. Code Ann. § 4729.69 (West)(2019); OR. Rev. Stat. Ann. §§ 459A.200 – 459a.266 (West)(2019); 23 R.I. Gen. Laws Ann. §§ 23-25.5-1 - 23-25.5-4(West)(2013); S.C. Code Ann. § 44-53-362 (West)(2017); TENn. Code Ann. § 63-10-703 (West)(2017); Utah Code Ann. 1953 § 67-5-36 (West)(2020); Vt. Stat. Ann. tit.,§ 4224 (West)(2016); Vt. Stat. Ann. tit. 33, § 2004 (West)(2019); Wash. Rev. Code Ann. §§ 69-48.010 – 69.48.200 (West)(2018); Wis. Stat. Ann. § 165.65 (West)(2015); and Wyo. Stat. Ann. §§ 35-7-1601 – 35-7-1606 (West)(2005

²⁰ Ala. Admin. Code r. 680-X-2-.42 (West)(2013); La. Admin Code. tit. 46 § 2749 (West)(2020); Ohio Admin. Code 4729:10-1 - 4729:10-1-04(West)(2021); and W. Va. Code St. R. § 11-5-8 (West)(2021).

²¹ Collection by Law Enforcement, 21 C.F.R. § 1317.35(b).

²² Registrants Authorized to Collect and Authorized Collection Activities, 21 C.F.R. § 1317.40.

²³ Authorization to Collect from Non-Registrants 21 C.F.R. § 1317.30(b).



As of August 2022, California, Illinois, Maine, Oregon, Vermont, and Washington require drug manufacturers to fund programs for the collection and ultimate disposal of unused or unwanted medications. ²⁴ These programs are premised on the idea of product stewardship or extended product responsibility. Product stewardship is the ". . . act of minimizing the health, safety, environmental, and social impacts of a product and its packaging throughout all lifecycle stages, while also maximizing economic benefits. The manufacturer, or producer, of the product has the greatest ability to minimize adverse impacts, but other stakeholders, such as suppliers, retailers, and consumers, also play a role. Stewardship can be either voluntary or required by law." ²⁵ Similarly, "extended product responsibility" is a type of product stewardship. However extended producer responsibility is always mandatory and requires, at a minimum, that the manufacturer responsibility includes post-consumer management of its product and packaging. ²⁶

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²⁴ CAL. CODE REGS. tit. 16, §§ 1776-1776.6 (2017); OR. REV. STAT. ANN. §§ 459A.200 – 459a.266 (West)(2019); VT. STAT. ANN. tit. 33, § 2004 (West)(2019); and WASH. REV. CODE ANN. §§ 69.48.010– 69.48.200 (West)(2018). Previously Massachusetts law also required drug manufacturers to help fund drug take-back programs. Under Massachusetts drug take-back and disposal law in 2017 (the first year that the state's drug take-back program went into effect) all manufacturers who produced or sold Schedule II or Schedule III drugs within the state were previously required to participate in the state's drug take-back program. However, after January 1, 2018, manufacturers are allowed to work with the state to produce an alternative to participation in state's drug take-back program. MASS. GEN. LAWS ANN. ch.94H § 1(West)(2017).

²⁵ What is Product Stewardship? PRODUCTSTEWARDSHIP.US, (accessed Nov. 18, 2021), https://www.productstewardship.us/page/Definitions.

²⁶ Id.

Both product stewardship and extended producer responsibility can encompass a wide variety of products including pharmaceuticals, medical waste, medication, used electronics, mattresses, and paint.²⁷

There have been legal challenges to pharmaceutical product stewardship laws. The seminal case on this subject is *Pharm. Rsch. & Mfrs. of Am. v. Ctv. of Alameda.* In 2013, the county of Alameda, California created, what was at the time, a first in the nation approach to disposing of unused prescription drugs.²⁹ The county's Alameda Health and Safety Code Section 6.53.010³⁰ or "Safe Drug Disposal Ordinance" required manufacturers who sell, offer for sale, or distribute prescription drugs within the county to fund the entire cost of the drug disposal program.³¹ The ordinance exempted retail pharmacies and forbade drug producers from passing on the cost of the program by adding a fee at the point of sale. 32 Members of a pharmaceutical industry association that produced prescription drugs within the county brought suit against the county.³³ The plaintiffs argued that the ordinance was an unconstitutional burden on interstate commerce under the Commerce Clause.³⁴ Subsequently, the lower court granted summary judgment for the county, and the association appealed.³⁵ In 2014, the Ninth Circuit Court of Appeals upheld the lower court's ruling, finding that the ordinance did not directly regulate or discriminate against interstate commerce.³⁶ In holding for the county, the court found that the ordinance did not control conduct outside the boundaries of the county and did not discriminate against interstate commerce.³⁷ Further, the court held that the burden imposed by the ordinance was not clearly excessive to the local benefits.³⁸

²⁷ *Product Stewardship*, NCSL.ORG (updated Mar. 18, 2020), https://www.ncsl.org/research/environment-and-natural-resources/product-stewardship.aspx.

²⁸ Pharm. Rsch. & Mfrs. of Am. v. Cty. of Alameda, 967 F. Supp. 2d 1339 (N.D. Cal. 2013), aff'd sub nom., Pharm. Rsch. & Mfrs. of Am. v. Cty. of Alameda, 768 F.3d 1037 (9th Cir. 2014).

²⁹ Id.

³⁰ ALAMEDA, CA. HEALTH AND SAFETY CODE § 6.53.010 (2013), https://library.municode.com/ca/alameda_county/codes/code_of_ordinances/276242?nodeId=TIT6HESA_CH6.53A_LCOSADRDIOR_6.53.110EN.

³¹ *Id*. at 1340.

³² *Id*.

³³ Id

³⁴ *Id.* If a state law either discriminates against or directly regulates interstate commerce, it violates the Commerce Clause per se, and a court must strike it down without further inquiry. U.S.C.A. Const. Art. 1, § 8, cl. 3.

³⁵ PHARM. RSCH. & MFRS. OF AM. V. CTY. OF ALAMEDA, 768 F.3d 1037 (9th Cir. 2014).

³⁶ *Id*.

³⁷ *Id.* at 1043.

³⁸ *Id.* at 1045-1046.

ADDITIONAL FINDINGS

- ➤ While the DEA works with states to promote Drug Take-back Day to the public, some states, like Arizona, Missouri, New York, Ohio, Oregon, South Carolina, Vermont, and Washington, have also enacted laws that require the jurisdiction to promote public awareness of drug take-back and disposal programs.³⁹
- ➤ The State of Connecticut has promulgated administrative regulations that provide guidelines for the disposable of usable marijuana by a patient or caregiver. ⁴⁰
- ➤ The Eastern Band of Cherokee Indian's Code provides that when a person is convicted of an offense involving a controlled substance, the court must order him or her to make restitution for the cost of storage, testing, and disposal of controlled substances or immediate precursor chemicals.⁴¹

³⁹ Where and How to Dispose of Unused Medicines, FDA.GoV, (updated April 21, 2021), https://www.fda.gov/consumers/consumer-updates/where-and-how-dispose-unused-medicines; ARIZ. REV. STAT. ANN. § 36-123.01 (West)(2018); Mo. ANN. STAT. § 195.265 (West)(2018); N.Y. PUB. HEALTH LAW § 3343-b (McKinney)(2019); N.Y. COMP. CODES R. & REGS. tit. 10, § 60-4.4 (2021); S.C. CODE ANN. § 44-53-362 (West)(2017); VT. STAT. ANN. tit. 33, § 2004 (West)(2019)

⁴⁰ CONN. AGENCIES REGS. § 21A-408-11 (West)(2018).

⁴¹ EASTERN BAND CHEROKEE INDIANS CODE SEC. 14–95.34(c)(West)(updated June 2010); see also EASTERN BAND CHEROKEE INDIANS, ORD. No. 589, ART. II, 2-8-2007 (Municode)(current through Nov. 4, 2021)

<u>ALABAMA</u>	
Statute(s) and regulation(s)	ALA. ADMIN. CODE r. 680-X-242 (West)(2013).
Does the state allow drug	Yes.
take-back programs by statute/regulation?	
Program components	(1) This Rule shall apply only 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. (2) 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/her household or an animal owned by him/her or a member of his/her household. (3) 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 (hereinafter referred to as Other Person(s)). (4) Any pharmacy which intends to receive, collect and dispose of controlled substances from an ultimate user(s) or Other Person(s) shall comply with the applicable provisions of any existing rule or regulation or any amendment or revision thereto adopted pursuant to the Secure and Responsible Drug Disposal Act of 2010. Each such pharmacy shall submit to the Board the necessary authorization to be a collector issued by the DEA within ten (10) days of the receipt thereof. In the event any such pharmacy ceases activities as a collector the Board shall be notified in the same manner as required by the applicable Federal rule or regulation. (5) Any pharmacy who also intends to receive, collect and dispose of non-controlled prescription drugs from ultimate user(s) or from Other Person(s) shall also comply with the same requirements relating to controlled substances with the exception of any requirement for authorization from the DEA. Each such pharmacy shall notify the Board at the same time of the submission of the Authorization referenced in Paragraph 3 above as well as the notification at the same time if such pharmacy ceases activities as a collector referenced in Paragraph 3 above.
Miscellaneous provisions	N/A
Recently proposed	No.
legislation	

<u>ALASKA</u>	
Statute(s) and regulation(s)	ALASKA ADMIN. CODE TIT. 12, § 52.560 (West)(2022).
Does the state allow drug take-back programs by statute/regulation?	A pharmacist may destroy noncontrolled prescription drugs if the drugs are destroyed in a way that makes the drugs unfit for human consumption. Drugs that are considered controlled substance must be disposed of in accordance with federal law.
Program components	N/A
Miscellaneous provisions	N/A.
Recently proposed legislation	No.

	ARIZONA
Statute(s) and regulation(s)	ARIZ. REV. STAT. ANN. § 36-123.01 (West)(2018).
Does the state allow drug	Yes.
take-back programs by	1 es.
statute/regulation?	
Program components	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. (e) Describes appropriate disposal methods for needles and sharps and location sites providing for disposal of needles and sharps. 2. Educational activities designed to ensure consumer awareness of the safe storage and effective disposal of prescription drugs, including controlled substances, and nonprescription drugs. B. The drug disposal education and awareness fund is established consisting of monies donated or contributed to the fund by private persons or organizations. The department shall administer the fund. Monies in the fund are continuously appropriated and are exempt from the provisions of § 35-190 relating to lapsing of appropriations. 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	N/A
Recently proposed	No.
legislation	110.

<u>ARKANSAS</u>	
Statute(s) and regulation(s)	No.
Does the state allow drug take-back programs by statute/regulation?	N/A
Program components	N/A
Miscellaneous provisions	ARK. STAT. ANN. § 17-92-1103 (West)(2005). Establishes a pilot program to determine the efficacy of redispensing prescription drugs to indigent patients. ARK. STAT. ANN. § 17-92-1104 (West)(2019). Establishes guidelines for a charitable clinic to accept redispensing prescription drugs.
Recently proposed legislation	No.

	CALIFORNIA
Statute(s) and regulation(s)	CAL. CIV. CODE § 1714.24 (West)(2017). CAL. CODE REGS. tit. 16, §§ 1776-1776.6 (West)(2017).
Does the state allow drug take-back programs by statute/regulation?	Yes.
Program components	CAL. CIV. CODE § 1714.24 (West 2021)("Collector maintaining secure drug take-back bin; civil or criminal liability; requirements for immunity.")
	(a) For purposes of this section, the following definitions shall apply: (1) "Collector" includes 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. (2) "Compensation" means reimbursement or funds received from a customer to compensate for the cost incurred in obtaining, installing, or maintaining a secure drug take-back bin. "Compensation" does not include reimbursement or funds received from any other person or entity, other than a customer, to compensate for the costs incurred in obtaining, installing, or maintaining a secure drug take-back bin. (3) "Home-generated pharmaceutical waste" means a pharmaceutical that is no longer wanted or needed by the consumer and includes any delivery system, such as pills, liquids, and inhalers. (4) "Maintains" includes owning, leasing, operating, or otherwise hosting a secure drug take-back bin on the collector's premises. (5) "Pharmaceutical" means a prescription or over-the-counter human or veterinary drug, including, but not limited to, a drug as defined in Section 109925 of the Health and Safety Code and Section 321(g)(1) of Title 21 of the United States Code. "Pharmaceutical" includes controlled substances included in Schedule II, III, IV, or V of the California Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code), but does not include a controlled substance included in Schedule I. (6) "Secure drug take-back bin" means a collection receptacle as described in Section 1317.75 of Title 21 of the Code of Federal Regulations.

CALIFORNIA

Program components (continued)

- (b) Any collector that maintains a secure drug take-back bin shall not be liable in a civil action, or be subject to criminal prosecution, for any injury or harm that results from the collector maintaining a secure drug take-back bin on its premises provided that the collector, not for compensation, acts in good faith to take all of the following steps to ensure the health and safety of consumers and employees and the proper disposal in the waste stream of the home-generated pharmaceutical waste contained in a secure drug take-back bin, unless the injury or harm results from 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 of home-generated pharmaceutical waste for disposal in secure drug take-back bins, including, but not limited to, the federal Secure and Responsible Drug Disposal Act of 2010 (Public Law 111-273).1
- (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 registered 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 secure drug take-back bin for potential tampering or diversion. Record logs of those inspections shall be maintained and retained for two years, reflecting the date and time of the inspection, and the initials of the employee inspecting the area. The logs shall be maintained in writing or electronically and may be combined with logs required by state or federal regulations. The logs may be used to demonstrate regular inspection of the area. Other records or reports mandated by federal or state regulations shall also be retained for a minimum of two years unless regulations mandate a longer period.

<u>CALIFORNIA</u>	
Program components (continued)	(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. If the collector maintains daily business hours, this notification shall be made within one calendar day. (8) Notify local law enforcement as to any decision to discontinue its voluntary collection of controlled substances and provide documentation of its written notification to the federal Drug Enforcement Administration's Registration Unit as otherwise required under federal laws and regulations. (c) Nothing in this section shall be construed to require entities that may qualify as a collector to acquire, maintain, or make available to the public a secure drug take-back bin on its premises.
	CAL. CODE REGS. tit. 16, §§ 1776-1776.6. This section provides administrative provisions for the implementation of prescription drug-take back services.
Miscellaneous provisions	Article 9.1. Prescription Drug Take-Back Services. Authorizes pharmacies, distributors, reverse distributors, and hospitals/clinics with on-site pharmacies to provide options for the public to discard prescription drugs.
Recently proposed legislation	No.

<u>COLORADO</u>	
Statute(s) and regulation(s)	Colo. Rev. Stat. Ann. § 25-15-328 (West)(2019).
Does the state allow drug take-back programs by statute/regulation?	Yes.
Program components	Colo. Rev. Stat. Ann. § 25-15-328 (West)(2019).
	Household medication take-back programcreationcollection and disposal of medication injection devicesliabilitydefinitionscash fundrules.
	(1)(a) The general assembly finds and declares that prescription drug misuse is a rampant problem in Colorado, in part due to the accidental and intentional abuse of leftover household medications. The general assembly further declares that citizen access to a disposal location to return unused household medications will reduce the availability of household medications for unintended or abusive purposes and will further protect the environment through proper disposal. (b) It is the intent of the general assembly to establish a household medication take-back program to facilitate the safe and effective collection and proper disposal of unused medications. (2) As used in this section: (a) "Approved collection site" means a site approved by the department for the collection of unused household medications. (b) "Carrier" means an entity approved by the department to transport unused household medications from approved collection sites to a disposal location. (c) "Disposal location" 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 non-retrievable state and cannot be diverted for illicit purposes. (d) "Household medications" means controlled substances approved for collection by federal law, prescription drugs, and over-the-counter medications in the possession of an individual. (3)(a) Subject to available funds, the executive director of the department shall establish a household medication take-back program to collect and dispose of unused household medications. The program must allow for individuals to dispose of unused household medications at approved collection sites and for carriers to transport unused household medications from approved collection sites to disposal locations.

COLORADO

Program components (continued)

- (b) Starting in the 2020-21 fiscal year, the executive director of the department shall use the money appropriated to the department pursuant to subsection (5)(b) of this section to implement a process for the safe collection and disposal of needles, syringes, and other devices used to inject medication. The executive director of the department shall determine the processes and locations for the safe collection and disposal of medication injection devices. (4) 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 take-back program in good faith and does not violate any applicable laws. (5)(a) The household medication take-back cash fund is created 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. The money in the fund is subject to annual appropriation by the general assembly.
- (b) For the 2020-21 fiscal year and each year thereafter, the general assembly shall appropriate money from the general fund to the department for the purpose of expanding the household medication take-back program to include the safe collection and disposal of medication injection devices pursuant to subsection (3)(b) of this section.
- (6) Nothing in this section:
- (a) Affects the authority to collect and reuse medications pursuant to section 12-280-135; or
- (b) Prohibits the operation of existing medication take-back and disposal programs regulated by the department.
- (7) The commission may promulgate rules for the implementation of this section.

Miscellaneous provisions

COLO. REV. STAT. ANN. § 18-18-607(West)(2021).

Safe stations--disposal of controlled substances--medical evaluation--definition.

Any person may go to a site designated as a "safe station" and turn in a controlled substance and request assistance in gaining access to treatment.

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<u>COLORADO</u>	
Miscellaneous provisions	COLO. REV. STAT. ANN. § 25-48-120 (West)(2016).
(continued)	A person who has custody or control of medical aid-in-dying medication may dispose of unused medication by returning to the attending doctor who prescribed the medical aid-in dying medication or in accordance with a state or federally approved medication take-back program.
Recently proposed legislation	No.

CONNECTICUT	
Statute(s) and regulation(s)	CONN. GEN. STAT. ANN. § 20-576a (West)(2017).
Does the state allow drug take-back programs by statute/regulation?	Yes.
Program components	CONN. GEN. STAT. ANN. § 20-576a (West)(2017).
	Not later than July 1, 2018, the Commissioner of consumer protection, with the advice and assistance of the commission of pharmacy, shall adopt regulations, in accordance with the provisions of Chapter 54,1 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 Chapter 400j,2 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.
Miscellaneous provisions	Conn. Gen. Stat. Ann. § 20-576a (West)(2017).
	The Commissioner of Consumer Protection, with the advice and assistance of the Commission of Pharmacy must 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 licensed pharmacies to accept and dispose of unused prescription drugs.
	CONN. GEN. STAT. ANN. § P.A. 22-81, § 19 (West)(2022).
	No later than January 1, 2023, all pharmacies must post a sign on the premises notifying consumers that they can visit the website of the Department of Consumer Protection for information on the safe storage of prescription drugs and disposal of unused and expired prescription drugs.

<u>CONNECTICUT</u>	
Miscellaneous provisions (continued)	CONN. AGENCIES REGS. § 21A-408-11 (West)(amended Aug. 28, 2018).
	Proper disposal of marijuana by patients or caregivers.
	A patient or caregiver shall dispose of all usable marijuana in the patient's or caregiver's possession no later than ten calendar days after the expiration of the patient's registration certificate, if such certificate is not renewed, or sooner should the patient no longer wish to possess marijuana for palliative use. A patient or caregiver shall complete such disposal by one of the following methods: (1) By rendering the marijuana non-recoverable in accordance with the department's proper disposal instructions, which are available on the department's Internet web site at www.ct.gov/dcp ; (2) By depositing it in a Connecticut police department medication drop-box; or (3) By disposing of the marijuana at a government-recognized drug take-back program located in Connecticut.
Recently proposed legislation	H.B. 5155, Legis. Sess. (Ct. 2022)(Passed out of the Committee on Children).
	Would require that the Department of Consumer Protection develop and distribute documents regarding the safe storage and disposal of cannabis and prescription drugs.

<u>DELAWARE</u>	
Statute(s) and regulation(s)	No.
Does the state allow drug take-back programs by statute/regulation?	N/A
Program components	N/A
Miscellaneous provisions	24 DEL. ADMIN. CODE § 2500-5.0 (5.1.14.3)(2018). 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	No.

DISTRICT OF COLUMBIA	
Statute(s) and regulation(s)	No.
Does the state allow drug	N/A
take-back programs by statute/regulation?	
Program components	N/A
Miscellaneous provisions	In 2018, the District of Columbia enacted legislation that allowed D.C. police departments, hospitals with institutional pharmacies, and retail pharmacies to collect controlled substances for disposal. Entitled the <i>Safe Disposal of Controlled Substances Act of 2018</i> , the Act was introduced in the D.C. Council and adopted and subsequently transmitted to Congress for review and went into effect on April 11, 2019. <i>Safe Disposal of Controlled Substances Act of 2018</i> , D.C. Code Ann. § 48-852.02 (West)(2019). However, the law was repealed on November 13, 2021, by 2021 District of Columbia Laws 24-45 (Acts 24-176)("An Act to Enact and Amend Provisions of Law Necessary to Support the Fiscal Year 2022 budget.") 2021 D.C. Sess. L. Serv. L24-0045(West)(2021).
Recently proposed	No.
legislation	

	<u>FLORIDA</u>	
Statute(s) and regulation(s)	No.	
Does the state allow drug	N/A	
take-back programs by		
statute/regulation?		
Program components	N/A	
Miscellaneous provisions	FLA. STAT. ANN. § 499.029 (West)(2016).	
	Cancer Drug Donation Program.	
	Authorizes a cancer drug donation program within the department for the purpose of authorizing and facilitating the donation of cancer drugs and supplies to eligible patients.	
	FLA. STAT. ANN. § 465.1902 (West)(2020).	
	Prescription Drug Donation Repository Program.	
	Authorizes the creation of a program to collect unused drugs and redistribute the drugs to qualified individuals.	
Recently proposed	2022 Florida House Bill No. 843, Florida One Hundred Twenty-	
legislation	Fourth Regular Session (Died in Professions and Public Health Subcommittee).	
	Title: At-home Drug Deactivation and Disposal Systems	
	Requires DOH, in coordination with Board of Pharmacy, to	
	establish & administer At-home Drug Deactivation & Disposal	
	System Program; provides requirements for at-home drug	
	deactivation & disposal systems; requires pharmacies to co-	
	dispense such systems with opioid prescriptions for treatment of	
	acute pain; requires DOH to develop relevant educational materials & plan for distribution of at-home drug deactivation &	
	disposal systems & educational materials.	
	disposar systems & educational materials.	
	2022 Florida Senate Bill No. 1136, Florida One Hundred Twenty-	
	Fourth Regular Session (Introduced).	
	Title: At-home Drug Deactivation and Disposal Systems	
	Substantially similar to 2022 Florida House Bill No. 843	

<u>GEORGIA</u>	
Statute(s) and regulation(s)	No.
Does the state allow drug take-back programs by statute/regulation?	N/A
Program components	N/A
Miscellaneous provisions	GA. CODE ANN. § 26-4-114 (West)(1998). Special Pharmacy Permit. Allows pharmacies located within and operated by a school or college of pharmacy to purchase, receive, possess, or dispose of drugs for educational and research purposes. GA. CODE ANN. § 31-8-301 (West)(2016). Drug Repository Program. Requires the Department of Health to establish a drug repository program to accept and dispense over the counter and prescription drugs donated for the purpose of being dispensed to eligible patients.
Recently proposed legislation	No.

<u>HAWAII</u>	
Statute(s) and regulation(s)	No.
Does the state allow drug take-back programs by statute/regulation?	N/A
Program components	N/A
Miscellaneous provisions	Haw. Rev. Stat. Ann. § 461-10.2 (West)(2019). No pharmacy may collect drugs for disposal unless the pharmacy adheres to federal and state drug laws. In addition, no pharmacy may collect drugs unless it is disposal only.
Recently proposed legislation	H.B. 386, 31st Legis. Sess. (Haw. 2021)(Referred to the Consumer Protection and Commerce Committee). Requires drug manufacturers to establish and implement a drug take-back program for the purpose of collecting and disposing both prescription and non-prescription drugs.

<u>IDAHO</u>	
Statute(s) and regulation(s)	No.
Does the state allow drug take-back programs by statute/regulation?	N/A
Program components	N/A
Miscellaneous provisions	IDAHO CODE ANN. §§ 54-1762 (West)(2019). Legend Drug Donation.
	Allows for the transfer of legend drugs (drugs approved by the U.S. Food and Drug Administration) from a donor to a donation repository for donation to medically indigent patients.
Recently proposed	No.
legislation	

<u>ILLINOIS</u>	
Statute(s) and regulation(s)	410 ILL. COMP. STAT. ANN. 720/1 – 720/999 (West)(2022).
Does the state allow drug take-back programs by statute/regulation?	Yes.
Program components	410 Ill. Comp. Stat. Ann. 720/15 (West)(2022).
	Drug Take-back Act.
	Participation in a drug take-back program. Each covered manufacturer must, beginning January 1, 2024 or six (6) 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.
Miscellaneous provisions	20 ILL. COMP. STAT. ANN. 301/5-23(a)(2)(F) Amended by 2021 Ill. Legis. Serv. P.A. 102-598 (H.B. 2589)(West)(Enrolled).
	Requires the Department of Public Health to publish a report on drug overdose prevention, including drug take-back events and mail-back programs.
Recently proposed legislation	No.

<u>INDIANA</u>	
Statute(s) and regulation(s)	IND. CODE ANN. §§ 25-26-23-1-25 - 26-23-9 (West)(2019). 856 IND. ADMIN. CODE 7-1-1 — 7-9-1 (West)(2017).
Does the state allow drug take-back programs by statute/regulation?	Yes.
Program components	Ind. Code Ann. §§ 25-26-23-1 - 25-26-23-9.
	25-26-23-1 – Provides that the Board governing the program is the Indiana Board of Pharmacy.
	25-26-23-2 – Requires that the Board adopt rules to promulgate the Chapter.
	25-26-23-3 – The Board is tasked with determining what entities may participate in a program under the Chapter.
	25-26-23-4 – Establishes guidelines for acceptance of unused medication by entities participating in the program.
	25-26-23-5 - Guidelines for the return of unused medication.
	25-26-23-6 – Requires the Board to consult with other state agencies to promulgate the guidelines of the Chapter.
	25-26-23-7 - Establishes limits on what may or may not be allowed under this Chapter.
	25-26-23-8 - Provides immunity from civil liability for an act or omissions related to operating under this Chapter.
	25-26-23-9 – Establishes requirements for acceptance of unused medication by a business or other entity.
	856 IND. ADMIN. CODE 7-1-1 – 7-9-1. Establishes standards applicable to a prescription drug take program, entities that may participate in prescription drug take-programs, and guidelines and standards for prescription drug take-back programs.
Miscellaneous provisions	No.
Recently proposed legislation	2022 Indiana House Bill No. 1057, Indiana One Hundred Twenty-Second General Assembly - Second Regular Session (Introduced). Prescription drug donation repositories. Establishes the prescription drug donation repository program.

<u>IOWA</u>	
Statute(s) and regulation(s)	No.
Does the state allow drug	N/A
take-back programs by statute/regulation?	
Program components	N/A
Miscellaneous provisions	IOWA CODE ANN. §§135m.1 – 134m.7(West)(2009).
	Prescription Drug Donation Repository.
	Establishes a prescription drug donation repository for persons who have been victims of a state of disaster emergency or a public health disaster.
Recently proposed legislation	No.

<u>KANSAS</u>	
Statute(s) and regulation(s)	No.
Does the state allow drug	N/A
take-back programs by	
statute/regulation?	
Program components	N/A
Miscellaneous provisions	KAN. STAT. ANN. § 65-1671(West)(2013).
	Sets forth the criteria for acceptance of unused medication for donation.
	donation.
Recently proposed	No.
legislation	

KENTUCKY	
Statute(s) and regulation(s)	Ky. Rev. Stat. Ann. § 218A.170 (3)(West)(2018).
Does the state allow drug	Yes.
take-back programs by	
statute/regulation?	
Program components	Ky. Rev. Stat. Ann. § 218A.170(3) – (4).
	(3) A licensed pharmacist must inform patients who receive a prescription on how to dispose of unwanted, unused, or expired prescription drugs verbally, in writing, or posted signage.
	(4) A pharmacist may make available a means to dispose of a nontoxic composition for the sequestration, deactivation, destruction, and disposal of an unused or unwanted, or expired prescription of an opioid, benzodiazepine, a barbiturate, codeine, or an amphetamine or provide an on-onsite, safe, and secure medication disposal receptable or kiosk for safe disposal.
Miscellaneous provisions	Ky. Rev. Stat. Ann. § 15.291(West)(2021).
_	Kentucky Opioid Abatement Advisory Commission; membership; meetings; criteria for award of moneys from opioid abatement trust fund.
	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.
	201 KAR 2:440 (Effective July 20, 2022). Authorizes the Board of Pharmacy to promulgate administrative regulation to a create drug donation program.
Recently proposed legislation	2022 Kentucky House Bill No. 776, Kentucky 2022 Regular Session (Introduced).
	An Act Relating to Controlled Substances.
	The proposed bill would require that harm reduction centers established pursuant to the bill must dispose of or arrange for the disposal of any drug surrendered by an individual for disposal.

<u>LOUISIANA</u>		
Statute(s) and regulation(s)	La. Admin Code. Tit. 46 § 2749(West)(2020).	
Does the state allow drug take-back programs by statute/regulation?	Yes.	
Program components	La. Admin Code. tit. 46 § 2749.	
	Disposal of Controlled Substances.	
	Establishes guidelines for any person in possession of a controlled substance who desires or is required to dispose of the substance who wishes to request the assistance from the special agent in charge of the DEA in the area in which the person is located for authority and instructions to dispose of the controlled substance.	
Miscellaneous provisions	La. Stat. Ann. § 40:2191(West)(2018).	
	Disposal of deceased patient's unused controlled substances.	
	Upon death of a patient receiving hospice services, ownership of the patient's unused Schedule II, III, IV, or V controlled substances under 21 CFR 1308 may transfer to the hospice for immediate disposal.	
Recently proposed legislation	No.	

MAINE	
Statute(s) and regulation(s)	ME. REV. STAT. TIT. 38, § 1612 (West)(2021).
Does the state allow drug take-back programs by statute/regulation?	Yes.
Program components	Me. Rev. Stat. tit. 38, § 1612
	Drug Take-Back Stewardship Program.
	The law establishes a network of drug-collection kiosks and prepaid mail-back envelopes at pharmacies throughout the state and will supplement existing drug take-back events and police station drop-off sites. The law requires that drug manufacturers fund and operate the program. Pursuant to the law, drug manufacturers must also create and operate an education and outreach assessment in collaboration with the department.
Miscellaneous provisions	Me. Rev. Stat. Ann. tit 22, § 2700.
	Unused Pharmaceutical Disposal Program. Establishes that a state agency may create an unused drug disposal program 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 enforcement purposes.
Recently proposed legislation	No.

<u>MARYLAND</u>	
Statute(s) and regulation(s)	MD. CODE ANN. HEALTH-GEN. §§ 15-601 to 609 (West)(2021).
Does the state allow drug take-back programs by statute/regulation?	Yes.
Program components	Md. Code Ann. Health-Gen. §§ 15-601 to 609.
	Prescription Drug Repository Program.
	15-601. – Definitions.
	15-602 Prescription Drug Repository Program. Establishes both a donation program for unused prescriptions and establishes guidelines for the acceptance of unused prescription drugs for proper disposal (emphasis added).
	15-603 Acceptable Drugs and Medical Supplies of Program.
	15-604 Donations to The Program. Provides that any person may donate to the program.
	15-605 Board Approval of Repository. Requires Board approval of the repository for donation of donated prescription drugs.
	15-606 Eligibility of Donated Drugs or Supplies.
	§ 15-607 Immunity From Liability. Establishes immunity from liability for persons that donate prescription drugs to the program established under this section.
	15-608. – Regulations. Requires the promulgation of regulations pursuant to this Chapter.
	15-609 Maintenance of Records, Reporting Requirements. Requires the submission of periodic reports to the Board of Pharmacy related to the prescription drug repository program.
Miscellaneous provisions	N/A
Recently proposed	No.
legislation	

<u>MASSACHUSETTS</u>		
Statute(s) and regulation(s)	Mass. Gen. Laws Ann. ch.94H § 1(West)(2017).	
	Note: Under Massachusetts law, the first year that the state's drug take-back program went into effect in 2017, all manufacturers who produced or sold Schedule II or Schedule III drugs within the state were required to participate in the state's drug take-back program. However, after January 1, 2018, manufacturers are allowed to work with the state to produce an alternative to participation in the drug take program.	
Does the state allow drug	Yes.	
take-back programs by		
statute/regulation?		
Program components	MASS. GEN. LAWS ANN. 94H § 1. § 1. Definitions. [Text of section effective until December 31, 2021. Repealed by 2016, 52, Sec. 55 as amended by 2016, 351, Sec. 6. See 2016, 52, Sec. 77.] As used in this chapter, the following words shall have the following meanings unless the context clearly requires otherwise: "Covered drug", any brand name or generic opioid drug placed in Schedule II or Schedule III of section 3 of chapter 94C; provided, however, that "covered drug" shall also include benzodiazepines; provided, further, that "covered drug" shall not include: (i) drugs intended for use solely in veterinary care; (ii) substances that are regulated as cosmetic products under the United States Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq.; (iii) drugs that are compounded under a specialty license pursuant to sections 39G to 39J, inclusive, of chapter 112; (iv) hypodermic needles, lancets or other sharps products subject to collection and disposal procedures established in section 27A of chapter 94C; or (v) drugs approved and used primarily for medication-assisted substance use disorder treatment.	
	"Department," the department of public health. "Drug stewardship program," a program financed by a pharmaceutical product manufacturer or a group of manufacturers to collect, secure, transport and safely dispose of unwanted drugs." Pharmaceutical product manufacturer" or "manufacturer," an entity that manufactures a controlled substance under a United States Food and Drug Administration manufacturer's license, except for an institutional pharmacy, as defined in section 39D of chapter 112 or a wholesaler.	

Program components (continued)

"Prescription drug," any drug product which may be dispensed pursuant to chapter 94C under a written prescription by an authorized prescriber.

"Stewardship organization," 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.

"Unwanted drug", a covered drug: (i) 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 (ii) voluntarily deposited at collection points co-located with a law enforcement agency; provided, however, that "unwanted drug" shall not include: (A) 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 (B) drug products seized by law enforcement officers in the course of their law enforcement duties.

"Wholesaler" an entity licensed pursuant to section 36B of chapter 112.

Mass. Gen. Laws Ann. 94H § 2.

§ 2. Operation or Participation in Drug Stewardship Program Required; Powers and Duties of Department.

[Text of section effective until December 31, 2021. Repealed by 2016, 52, Sec. 55 as amended by 2016, 351, Sec. 6. See 2016, 52, Sec. 77.]

(a) Any pharmaceutical product manufacturer selling or distributing a covered drug to consumers in the commonwealth, whether directly or through a wholesaler, retailer or other agent, shall: (i) operate a drug stewardship program approved by the department individually or jointly with other manufacturers; (ii) enter into an agreement with a stewardship organization that shall operate a drug stewardship program approved by the department; or (iii) enter into an agreement with the department to operate an alternative plan under section 6.

Program components (continued)

- (b) The department shall establish a process to review applications for approval and renewal of a manufacturer's drug stewardship plan. The department shall consult with the Massachusetts Biotechnology Council, the Interagency Council on Substance Abuse, and other interested parties in developing the requirements of a drug stewardship program.
- (c) Each operator of a drug 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.
- (d) The department shall review for renewal each drug stewardship program at a frequency to be determined by the department.
- (e) 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. (f) The department may promulgate regulations to implement this chapter.
- § 3. Drug Stewardship Program Plan; Requirements. [Text of section effective until December 31, 2021. Repealed by 2016, 52, Sec. 55 as amended by 2016, 351, Sec. 6. See 2016, 52, Sec. 77.]

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:

(i) a collection system to provide convenient, ongoing collection services to all persons seeking to dispose of unwanted drugs; provided, however, that the collection 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 2 methods as recommended by the department, which may include, but not be limited to: (A) a mail-back program that provides prepaid and preaddressed 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 United States Drug Enforcement Administration guidelines;

- (ii) 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;
- (iii) a plan for public outreach and education about the drug stewardship program;
- (iv) 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;
- (v) an attestation that the program shall comply with all applicable state and federal requirements for the collection, security, transport, and disposal of drug products, including any requirements established by rule or regulation of either the United States Drug Enforcement Administration or the United States Environmental Protection Agency; and
- (vi) any other requirements established by the department for the safe and effective administration of a drug stewardship program.
- § 4. Notice of Requirements or of Noncompliance; Penalty; Appeal. [Text of section effective until December 31, 2021. Repealed by 2016, 52, Sec. 55 as amended by 2016, 351, Sec. 6. See 2016, 52, Sec. 77.]
- (a) 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 section 2, informing the manufacturer of the requirements to comply with this chapter. Any manufacturer in receipt of a notice shall submit an application for approval under said section 2 within 180 calendar days of receipt of such initial notice.
- (b) Upon becoming aware that a pharmaceutical product manufacturer has discontinued its drug stewardship program or has altered the program such that the program no longer fulfills the requirements of this chapter, the department shall send a notice of noncompliance to the manufacturer. A manufacturer in receipt of a notice of noncompliance shall take all required corrective steps to reestablish compliance with this chapter or submit a written appeal of the notice of noncompliance to the department within 90 days of receipt of the notice of noncompliance.

Program components (continued)

(c) If after consideration of an appeal or if the manufacturer does not appeal within 90 days of receipt of the notice of noncompliance the department determines that the manufacturer continues to be in noncompliance with this chapter, the department may assess the manufacturer a penalty in a manner to be determined by the department. If the department plans to assess a noncompliance penalty against a manufacturer pursuant to this section, the department shall send notice of the penalty and the right to appeal the penalty to the manufacturer.

Mass. Gen. Laws Ann. 94H § 5.

§ 5. Scope of Requirements; Application to Retail or Outpatient Pharmacies.

[Text of section effective until December 31, 2021. Repealed by 2016, 52, Sec. 55 as amended by 2016, 351, Sec. 6. See 2016, 52, Sec. 77.]

- (a) The requirements established by the department, in consultation with Massachusetts Biotechnology Council, the Interagency Council on Substance Abuse and other stakeholders, may exceed, but shall not conflict with, any obligations imposed on a manufacturer by a risk evaluation and mitigation strategy approved by the United States Food and Drug Administration.
- (b) 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.
- (c) 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.

	MASSACHUSETTS	
Program components (continued)		
Miscellaneous provisions	N/A	
Recently proposed legislation	2021 Mass. HB 2403, the 192nd General Court of the Commonwealth of Massachusetts ("An Act to Establish a Sharps Stewardship Program.")(Introduced). This bill amends the state's existing drug take back program to encompass the disposal of sharps or devices used to puncture or cut skin.	

	<u>MICHIGAN</u>
Statute(s) and regulation(s)	No.
Does the state allow drug	N/A
take-back programs by	
statute/regulation?	
Program components	N/A
Miscellaneous provisions	MICH. COMP. LAWS ANN. § 333.17776 (West)(2013).
	Program for Utilization of Unused Prescription Drugs.
	Establishes that a pharmacy that accepts prescriptions for
	donation must dispose of the prescription if it ultimately found to
	be ineligible for donation.
Recently proposed	No.
legislation	

<u>MINNESOTA</u>		
Statute(s) and regulation(s)	MINN. STAT. ANN. § 152.105 (West)(2019).	
Does the state allow drug	Yes.	
take-back programs by statute/regulation?		
Program components	MINN. STAT. ANN. § 152.105.	
	Disposal.	
	Subdivision 1. Disposal of controlled substances. Subdivision 2. Sheriff to maintain collection receptacle. (a) 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. For purposes of this section, "legend drug" has the meaning given in section 151.01, subdivision 17. The collection receptacle must comply with federal law. In maintaining and operating the collection receptacle, the sheriff shall follow all applicable provisions of Code of Federal Regulations, title 21, parts 1300, 1301, 1304, 1305, 1307, and 1317, as amended through May 1, 2017. (b) A sheriff may meet the requirements of paragraph (a) 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	
Miscellaneous provisions	Administration, and the Board of Pharmacy. N/A	
Recently proposed legislation	2021 Minn. Sen. File No. 1056, Minn. First Reg. Sess. of the 92nd Legis. Sess. (Referred to Health and Human Services Committee). Legend Drugs Disposal Collection Boxes Pharmacies Maintenance Requirement.	
	Would require pharmacies to maintain collection boxes for disposal of legend drugs as pharmaceutical waste.	

<u>MISSISSIPPI</u>	
Statute(s) and regulation(s)	No.
Does the state allow drug take-back programs by statute/regulation?	N/A
Program components	N/A
Miscellaneous provisions	MISS. CODE ANN. § 43-13-503 (West)(2019). Establishment of Drug Repository Program Plan.
	Provides procedures for pharmacies to dispose of drugs that are donated to the repository programs but are found to not qualify for donation.
Recently proposed legislation	No.

<u>MISSOURI</u>		
Statute(s) and regulation(s)	Mo. Ann. Stat. § 195.265 (West)(2018).	
Does the state allow drug take-back programs by statute/regulation?	Yes.	
Program components	Mo. Ann. Stat. § 195.265.	
	Disposal of Unused Controlled Substances, Permitted MethodsAwareness Program.	
	Awareness Program. 1. Unused controlled substances may be accepted from ultimate users, from hospice or home health care 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: (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 (2) drug take-back programs conducted by federal, state, tribal, or local law enforcement agencies in partnership with any person or entity. 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 the purposes of this section, the term "ultimate user" shall mean a person who has lawfully obtained and possesses a controlled 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. 2. By August 28, 2019, the Department of Health and senior services shall develop an education and awareness program	
	regarding drug disposal, including controlled substances. The education and awareness program may include, but not be limited to:	
	 a web-based resource that: Describes available drug disposal options, including take back, 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, 	

	<u>MISSOURI</u>
Program components (continued)	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 and mail-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 subsection 1 of this section; and (2) Promotional activities designed to ensure consumer awareness of proper storage and disposal of prescription drugs, including controlled substances.
Miscellaneous provisions	N/A
Recently proposed legislation	No.

	<u>MONTANA</u>
Statute(s) and regulation(s)	MONT. CODE ANN. § 1-1-232 (West)(2019).
Does the state allow drug take-back programs by statute/regulation?	Yes.
Program components	Mont. Code ann. § 1-1-232. Montana Prescription Drug Take-back Day. Designates a day in October to be a prescription drug take-back day to provide an annual day for citizens to properly dispose of unused and unneeded prescription drugs and to raise awareness about the consequences of failure to properly dispose of prescription drugs.
Miscellaneous provisions	N/A
Recently proposed legislation	No.

<u>NEBRASKA</u>		
Statute(s) and regulation(s)	No.	
Does the state allow drug take-back programs by statute/regulation?	N/A	
Program components	N/A	
Miscellaneous provisions	NEB. REV. STAT. ANN. §§71-2422 - 71-2430 (West)(2003).	
	Cancer Drug Repository Program Act.	
	Establishes a prescription drug donation program to accept, distribute, and dispense drugs for persons with cancer.	
	NEB. REV. STAT. ANN. §§71-2439 - 71-2443 (West)(2006).	
	Immunosuppressant Drug Repository Program Act.	
	Any person or entity, including, but not limited to, an immunosuppressant drug manufacturer or transplant center, may donate immunosuppressant drugs to a participant or return previously prescribed immunosuppressant drugs to the transplant center where they were originally prescribed.	
Recently proposed legislation	2021 Nebraska Legislative Bill No. 782, Nebraska One Hundred Seventh Legislature - Second Regular Session (Introduced)(January 5, 2022)	
	Budget bill includes funds for FY 2021 to contract for services for implementation of a statewide drug disposal project.	

<u>NEVADA</u>		
Statute(s) and regulation(s)	No.	
Does the state allow drug	N/A	
take-back programs by		
statute/regulation?		
Program components	N/A	
Miscellaneous provisions	NEV. REV. STAT. ANN. §§ 453.b010 - 453b.130 (West)(2010).	
	CHAPTER 453B. HIV/AIDs Drug Donation Program.	
	Establishes a prescription drug donation program to accept, distribute, and dispense drugs for persons living with HIV or AIDs.	
	NEV. REV. STAT. ANN. § 457.400 (West)(2013).	
	CHAPTER 453B. Cancer Drug Donation Program.	
	Establishes a prescription drug donation program to accept,	
	distribute, and dispense drugs for persons with cancer.	
Recently proposed legislation	L.B. 379, 107th Legis. Sess. (Neb. 2021)(Approved by the Governor on April 26, 2021).	
	State budget bill for 2021 includes funds in the amount shown in FY 2020–21 budget § 289,416 General Funds to contract for services for implementation of a statewide drug disposal project.	

NEW HAMPSHIRE			
Statute(s) and regulation(s)	N.H. REV. STAT. ANN. §§ 318-E:1 (West)(2016).		
	N.H. CODE ADMIN. R. Jus. 1603.01 (West)(2021).		
Does the state allow drug	Yes.		
take-back programs by			
statute/regulation?			
Program components	N.H. REV. STAT. ANN. §§ 318-E:1.		
	Pharmaceutical Drug Take-Back Programs Authorized.		
	I. 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 as defined in this Chapter. I-a. A registered pharmacy may establish a controlled and noncontrolled pharmaceutical drug take-back program provided it complies with the United States Drug Enforcement Administration regulations, 21 C.F.R. part 1300 et seq. II. A pharmaceutical drug take-back program established by a local, county, regional, state, or other governmental entity or private entity 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. III. The Department of Justice, in consultation with the pharmacy Board, the Department of Safety, and the Department of Environmental Services shall establish rules, pursuant to RSA 541-A, for the collection, storage, and disposal of collected drugs in accordance with applicable state and federal statutes and regulations. IV. 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.		

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<u>NEW HAMPSHIRE</u>		
Program components	V. Nothing in the implementation of a pharmaceutical drug take-	
(continued)	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. VI. 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 purpose and a fee	
	from participating individuals returning unused pharmaceuticals.	
Miscellaneous provisions	N/A	
Recently proposed	No.	
legislation		

NEW MEXICO	
Statute(s) and regulation(s)	No.
Does the state allow drug take-back programs by statute/regulation?	N/A
Program components	N/A
Miscellaneous provisions	N/A
Recently proposed legislation	No.

	NEW JERSEY
Statute(s) and regulation(s)	N.J. STAT. ANN. § 45:9-22.11a (West)(2016).
	N.J. STAT. ANN. § 45:14-67.6 (West)(2020).
Does the state allow drug take-back programs by statute/regulation?	Yes.
Program components	N.J. STAT. ANN. § 45:9-22.11A.
	Pharmacy Practice Sites; Distribution of Notice Regarding Disposal of Controlled Dangerous Substances.
	A. A pharmacy practice site that dispenses prescription drugs, other than a long-term care pharmacy, shall distribute, with each prescription drug which is a controlled dangerous substance that it dispenses to an individual located in this state, a copy of the notice prepared pursuant to subsection b. of this section. For the purposes of this subsection, "pharmacy practice site" includes only those pharmacy practice sites that are located inside the state. B. The division of consumer affairs in the Department of Law and Public Safety shall prepare and post on its website a notice, for use by a prescriber pursuant to section 46 of p.l.1991, c. 187 (c.45:9-22.11), and which a pharmacy practice site shall utilize for the purposes of subsection a. of this section, to advise customers and patients about: (1) the availability of drug take-back programs sponsored by a local, state, or federal government agency; and (2) how to obtain information from the website for those programs concerning where unused prescription drugs may be dropped off for the purpose of ensuring their safe, secure, efficient, and environmentally sound disposal.
	N.J. STAT. ANN. § 45:14-67.6
	Advising patients on the proper disposal of unused prescription drugs and controlled dangerous substances; dispensing prescription drugs.
	A pharmacy practice site that dispenses prescription drugs, other than a long-term care pharmacy, that dispenses a prescription drug or medication must also include the patient with written informational materials advising of the dangers of unused, unwanted, or expired drugs.

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<u>NEW JERSEY</u>	
Miscellaneous provisions	N.J. STAT. ANN. § 26:2H-81.1 (West)(2020).
	Acceptance of unused prescription medications for disposal by hospice care program; surrender of unused prescription medications; liability
	The law allows hospice facilities to accept unused medications.
Recently proposed	No.
legislation	

NEW YORK	
Statute(s) and regulation(s)	N.Y. Pub. Health law § 3343-b (McKinney)(2019).
	N.Y. COMP. CODES R. & REGS. tit. 10, § 60-4.4 (West) (2021).
	2021 Ny Reg Text 535458(West)(2021).
Does the state allow drug	Yes.
take-back programs by statute/regulation?	
Program components	N.Y. Pub. Health Law § 3343-b.
110gram components	11.1.1 ob. HEALIII LAW § 3343-0.
	Safe Disposal of Unused Controlled Substances.
	1. The department shall oversee a program for the safe disposal of
	unused controlled substances by consumers in accordance with
	federal law and article two-B of this Chapter. Individual members of the public shall be authorized to voluntarily surrender
	controlled substances listed on schedule II, III, IV or V of section
	thirty-three hundred six of this article in a secure manner, without
	identifying themselves. Safe disposal methods shall be publicized
	consistent with the prescription pain medication awareness
	program established pursuant to section thirty-three hundred ninea of this article and article two-B of this Chapter.
	2. 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.
	3. Except as provided in article two-B of this Chapter, 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.
	N.Y. COMP. CODES R. & REGS. tit. 10, § 60-4.4
	Provides required guidelines for any pharmacy that voluntarily participates in an authorized drug take-back program.
	2021 NY REG TEXT 535458 (March 10, 2021).
	Drug Take-back. Regulations related to the implementation of the state's drug take
	Regulations related to the implementation of the state's drug takeback program.

<u>NEW YORK</u>	
Miscellaneous provisions	N/A
Recently proposed legislation	S.B. 7324, 244th Legis. Sess. (N.Y. 2021)(Introduced) Amend Public Health Law, In Relation to the Establishment and Operation of Drug Take back Collection Systems in Certain Pharmacies.
	S.B. 7605, 244th Legis. Sess. (N.Y. 2021)(Introduced) Requires a personal use pharmaceutical disposal system be provided at the time of dispensing an opioid prescription.

NORTH CAROLINA	
Statute(s) and regulation(s)	No.
Does the state allow drug take-back programs by statute/regulation?	N/A
Program components	N/A
Miscellaneous provisions	N.C. GEN. STAT. ANN. § 90-106.3 (West)(2017).
	Disposal of Residual Pain Prescriptions Following Death of Hospice or Palliative Care Patient.
	Any hospice or palliative care provider who prescribes a targeted controlled substance to be administered to a patient in his or her home for the treatment of pain as part of in-home hospice or palliative care shall, at the commencement of treatment, provide oral and written information to the patient and his or her family regarding the proper disposal of such targeted controlled substances. This information shall include the availability of permanent drop boxes or periodic "drug take-back" events that allow for the safe disposal of controlled substances such as those permanent drop boxes and events that may be identified through North Carolina Operation Medicine Drop.
Recently proposed legislation	H.B. 683, 2021 Legis. Sess. (N.C. 2021)(Referred to Committee on Rules and Operations of the Senate).
	Requires pharmacies to provide patients with written informational materials on prescription drug disposal and to make available on-site at least one consumer method for prescription drug disposal.

<u>NORTH DAKOTA</u>	
Statute(s) and regulation(s)	No.
Does the state allow drug take-back programs by statute/regulation?	N/A
Program components	N/A
Miscellaneous provisions	N.D. CENT. CODE ANN. § 43-15.2-05 (West)(2007). Chapter 43–15.2. Legend Drug Donation and Repository Program. Sets the requirements for the creation of a drug donation and repository program to allow for the donation of certain drugs for re-distribution.
Recently proposed legislation	No.

	<u>OHIO</u>	
Statute(s) and regulation(s)	OHIO REV. CODE ANN. § 4729.69 (West)(2019).	
(2)	Оню Admin. Code 4729:10-1 - 4729:10-1-04 (West)(2021).	
Does the state allow drug take-back programs by statute/regulation?	Yes.	
Program components	Ohio Rev. Code Ann. § 4729.69	
	Drug Take-Back Program; Establishment And Administration	
	The state board of pharmacy, in collaboration with the director of mental health and addiction services and attorney general, shall 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.	
	Оніо Admin. Code 4729:10-1 — 4729:10-1-04	
	4729:10-1-01 - Definitions - Prescription Drug Collection.	
	4729:10-1-02- Authorized Collectors.	
	Establishes who is considered an authorized collector for the purpose of operating a drug collection and take back program.	
	4729:10-1-03 - Law Enforcement Agencies. (A) Law enforcement agencies may operate a drug collection receptacle if all the following apply: (1) The receptacle is located inside the premises of the law enforcement agency.	
	(2) The receptacle is placed in a location that is accessible to the public during posted hours.	
	(3) The receptacle is placed within reasonable view of law enforcement personnel or under continuous video surveillance. (4) The receptacle is securely fastened to a permanent structure so that it cannot be removed and must be locked to prevent the	
	unauthorized retrieval of its contents. (5) The receptacle is clearly marked indicating the following information:	
	(a) No needles, syringes, or lancets shall be placed in the receptacle (b) No iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers) shall be placed in the receptacle	

OHIO

- (6) 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.
- (7) The law enforcement agency shall check the drug collection receptacle regularly and remove deposits to prevent the receptacle from reaching capacity.
- (8) The law enforcement agency shall maintain the confidentiality of the ultimate user disposing of the drugs pursuant to all applicable state and federal laws, rules, and regulations.
- (9) The drugs collected 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.
- (10) The law enforcement agency shall maintain custody and control of the contents deposited in the drug collection receptacle until the drugs are destroyed pursuant to rule 4729:10-1-04 of the Administrative Code.
- (11) The law enforcement 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.
- (B) Law enforcement agencies may conduct a mail-back program if all 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 made available meet the following specifications:
- (a) The package must be nondescript and shall not include any markings or other information that might indicate that the package contains pharmaceutical drugs.
- (b) The package must be water- and spill-proof, tamper-evident, tear-resistant, and sealable.
- (c) The package must be preaddressed with and delivered to the participating law enforcement's physical address.
- (d) The cost of shipping the package shall be postage paid.
- (e) 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 (the fifty states, the District of Columbia, and Puerto Rico), and notice that only packages provided by the collector will be accepted for destruction.

OHIO

- (f) The instructions for the package shall indicate the following information: No medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers) shall be placed in the package.
- (g) If a law enforcement agency chooses to limit the types of drugs that are acceptable for return, such limitations shall be clearly stated on the package instructions.
- (3) The law enforcement agency shall maintain custody and control of the sealed packages until the packages are destroyed pursuant to rule 4729:10-1-04 of the Administrative Code.
- (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, rules, and regulations.
- (5) 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.
- (6) The law enforcement 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.
- (C) Law enforcement agencies may operate a take-back event if all the following apply:
- (1) A law enforcement agency 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 collected drugs from the time the drugs are collected from the ultimate user until secure transfer, storage, or destruction of the drugs has occurred.
- (2) Each take-back event shall have at least one receptacle for the collection of drugs. The collection receptacle should be a securely locked, substantially constructed container with an outer container and a removable inner liner.
- (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.
- (4) No needles, syringes or lancets shall be collected unless a bulk sharps disposal container is provided at each take-back event for the disposal of sharps.

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Program components (continued)	(5) No iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (e.g., cancer chemotherapy drugs, cytotoxic drugs), compressed cylinders or aerosols (e.g., asthma inhalers) shall be collected. (6) At the conclusion of the collection event, the drugs shall be removed from the event location and either: (a) Stored in a manner that prevents the diversion of the collected drugs and is consistent with the agency's standard procedures for storing illicit controlled substances collected as evidence; or (b) Destroyed pursuant to rule 4729:10-1-04 of the Administrative Code. (7) The law enforcement 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. (D) The law enforcement agency shall ensure that the confidentiality of the ultimate user is maintained pursuant to applicable state and federal laws, rules, and regulations. 4729:10-1-04. Procedure for Destruction of Collected Drugs. Requires that any drug collected under this rule must be destroyed in compliance with applicable federal, state, tribal, and local laws and regulations.
Miscellaneous provisions	N/A
Recently proposed legislation	No.

<u>OKLAHOMA</u>	
Statute(s) and regulation(s)	N/A.
Does the state allow drug take-back programs by statute/regulation?	No.
Program components	N/A.
Miscellaneous provisions	OKLA. STAT. ANN. tit. 59, § 367.3.
	Program for Utilization of Unused Prescription Drugs.
	A. The Board of Pharmacy shall implement statewide a program consistent with public health and safety through which unused prescription drugs, other than prescription drugs defined as controlled dangerous substances in Section 2-101 of Title 63 of the Oklahoma Statutes, may be transferred from residential care homes, nursing facilities, assisted living centers, public intermediate care facilities for individuals with intellectual disabilities (ICFs/IID) or pharmaceutical manufacturers to pharmacies operated by a county. If no county pharmacy exists, or if a county pharmacy chooses not to participate, such unused prescription medications may be transferred to a pharmacy operated by a city-county health department or a pharmacy under contract with a city-county health department, a pharmacy operated by the Department of Mental Health and Substance Abuse Services or a charitable clinic for the purpose of distributing the unused prescription medications to Oklahoma residents who are medically indigent. B. The Board of Pharmacy shall promulgate rules and establish procedures necessary to implement the program established by the Utilization of Unused Prescription Medications Act. C. The Board of Pharmacy shall provide technical assistance to entities who may wish to participate in the program.
Recently proposed	S.B. 638, 58th Legis. Sess. (Okla. 2021)((Introduced).
legislation	Would amend existing law to provide for the return of drugs to the pharmacy for credit or reimbursement.

<u>OREGON</u>	
Statute(s) and regulation(s)	OR. REV. STAT. ANN. §§ 459A.200 – 459a.266 (West)(2019).
Does the state allow drug take-back programs by statute/regulation?	Yes.
Program components	OR. REV. STAT. ANN. §§ 459A.200 – 459a.266.
	459A.200. Definitions.
	As used in ORS. 459A.200 to 459A.266: (1) "Analogous product" means: (a) With regard to a virus, a product prepared from or with a virus or agent that is actually or potentially infectious, regardless of the degree of virulence or toxigenicity of the specific virus strain used. (b) With regard to a therapeutic serum, a product composed of whole blood or plasma, or that contains some organic constituent or product that is not a hormone or amino acid derived from whole blood, plasma or serum. (c) With regard to an antitoxin or toxin, a product, regardless of its origin source, that is intended to be applicable to the prevention, treatment or cure of a disease or human injury through a specific immune process. (2) "Antitoxin" means a product containing the soluble substance in serum or other bodily fluid of an immunized animal that specifically neutralizes the toxin to which the animal is immune. (3) "Authorized collector" 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. (4) "Biologics" means a virus, therapeutic serum, toxin, antitoxin or analogous product applicable to the prevention, treatment or cure of human diseases or injuries. (5)(a) "Covered drug" means a drug that a covered entity has discarded or abandoned or that a covered entity intends to discard or abandon. (b) "Covered drug" includes: (A) Prescription drugs, as defined in ORs 689.005; (B) Nonprescription drugs, as defined in ORs 689.005; (C) Drugs marketed under a brand name, as defined in ORs 689.515; (D) Drugs marketed under a generic name, as defined in ORs 689.515; and (E) Combination products.

- (c) "Covered drug" does not include:
- (A) Vitamins or supplements;
- (B) Herbal-based remedies or homeopathic drugs, products or remedies;
- (C) Products that are regulated as both cosmetics and nonprescription drugs by the federal Food and Drug Administration;
- (D) Drugs and biological products for which a covered manufacturer administers a drug take-back program as part of a risk evaluation and mitigation strategy under the oversight of the federal Food and Drug Administration;
- (E) Drugs administered in a clinical setting;
- (F) Drugs that are used for animal medicines, including but not limited to parasiticide drugs for animals;
- (G) Exposed sharps, as defined in ORS 459.386, or other used drug products that are medical waste;
- (H) Emptied injector products or medical devices and their components;
- (I) Dialysis concentrates and solutions used for kidney dialysis in a patient's home; or
- (J) Biologics.
- (6)(a) "Covered entity" means:
- (A) A resident of this state;
- (B) A nonbusiness entity located in this state; or
- (C) An ultimate user as defined by 21 U.S.C. 802(27).
- (b) "Covered entity" does not include a law enforcement agency or an entity that generates pharmaceutical waste, such as a hospital, health care clinic, office of a health care provider, veterinary clinic or pharmacy.
- (7)(a) "Covered manufacturer" means a person that manufactures covered drugs that are sold within this state, including, but not limited to, a person that manufactures covered drugs for another manufacturer pursuant to an agreement.
- (b) "Covered manufacturer" does not include:
- (A) A person that:
- (i)(I) Packages covered drugs that are sold within this state or that labels the containers of covered drugs that are sold within this state; or
- (II) Repackages covered drugs that are sold within this state or that relabels the containers of covered drugs that are sold within this state, if the person informs the Department of Environmental

Program components (continued)

Quality of the name of the original manufacturer of the covered drug; and

- (ii) Does not produce, prepare, propagate, compound, convert or process drugs that are sold within this state; or
- (B) A prepaid group practice described in ORS 441.229.

459A.203 - Requirement to Participate In Drug Take-Back Program; Rules; Fines.

- (1) Except as provided in subsection (2) of this section, each covered manufacturer shall participate in a drug take-back program that complies with the requirements of ORS 459A.200 to 459A.266. A covered manufacturer may participate in a drug take-back program independently, as part of a group of covered manufacturers or by delegating the covered manufacturer's duties under ORS 459A.200 to 459A.266 take-back organization.
- (2)(a) A covered manufacturer is not required to participate in a drug take-back program as described in subsection (1) of this section 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.
- (b) The Environmental Quality Commission may adopt rules regarding this subsection.
- (3) If a covered manufacturer does not participate in a drug take-back program as described in subsection (1) of this section and does not qualify for exemption under subsection (2) of this section, the State 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.206 - Organization of Program Operator.

A program operator of a drug take-back program must be organized as an entity that is exempt from income taxes under section 501(c)(3) of the Internal Revenue Code, as amended and in effect on September 29, 2019.

Program components (continued)

459A.209 - Plan for Drug Take-Back Program; Requirements; Approval; Updated Plans.

- (1) In a form and manner prescribed by the Department of Environmental Quality, a program operator must submit to the department a plan for participating in a drug take-back program. The department shall approve a proposed drug take-back program plan if the program operator submits a completed application, the proposed drug take-back program meets the requirements of subsections (2), (4) and (5) of this section and the program operator pays the fee established by the department under ORS 459A.242.
- (2) To be approved by the department, a proposed drug take-back program plan must:
- (a) Identify and provide contact information for the program operator and each covered manufacturer participating in the proposed drug take-back program;
- (b) Provide for a collection system that complies with ORS 459A.215, 459A.218 and 459A.221.
- (c) Provide for a disposal system that complies with ORS 459A.224;
- (d) Include policies and procedures to ensure the safe and secure handling and disposal of covered drugs;
- (e) Include policies and procedures to ensure the security of patient information that may be printed on the packaging of a covered drug and compliance with any applicable federal laws and regulations;
- (f) Set forth a plan to cover all costs associated with the proposed drug take-back program, with the costs of the proposed drug take-back program apportioned among each covered manufacturer participating in the proposed drug take-back program;
- (g) Set forth goals with respect to the amount of drugs collected under the proposed drug take-back program and with respect to fostering full public awareness of the proposed drug take-back program;
- (h) Provide public outreach and education in compliance with ORS 459A.227;
- (i) Describe how the drug take-back program will provide convenient service in every county in this state, including how under the drug take-back program the program operator will establish at least one drop-off site:
- (A) In each county in this state; and
- (B) Per population center, plus an additional drop-off site for every 50,000 residents of the city or town located within a population center;
- (j) Identify the transporters and waste disposal facilities that the program will use;

- (k) Provide upon request of a covered entity a mail-back service option that is prepaid by the program; and
- (l) Provide to a person who provides in-home hospice services, upon the person's request, mail-back service supplies to be used by the hospice services patient.
- (3) The department may waive the requirement of subsection (2)(i)(A) of this section with respect to a county if the proposed drug take-back program plan describes how the drug take-back program will provide mail-back service in the county.
- (4) Drop-off sites described in subsection (2)(i) of this section must be located throughout a population center to provide reasonably convenient and equitable access to all residents of the population center.
- (5) The drop-off site required under subsection (2)(i)(A) of this section may be the same drop-off site as the drop-off site required under subsection (2)(i)(B) of this section.
- (6)(a) A modification to the manner in which a proposed drug take-back program will provide the public outreach and education described in subsection (2)(h) of this section is not subject to the requirements of ORS 459A.212 if the modification is in response to federal, state or local regulatory changes, or to changes in industry best practices that are made in good faith to improve the quality and outcomes of the outreach and education.
- (b) A modification to the transporters and waste disposal facilities described in subsection (2)(j) of this section is not subject to ORS 459A.212 if the modification is made in response to federal, state or local regulatory changes, or to changes in industry best practices or contractors that are made in good faith and do not knowingly have a negative impact on the efficacy of the plan.
- (7)(a) Not later than 90 days after receiving a plan under subsection (1) of this section, the department shall either approve or reject the plan. If the department rejects the plan, the department shall provide the reason or reasons for the rejection.
- (b) Not later than 60 days after the department rejects a plan under paragraph (a) of this subsection, a program operator must submit to the department a revised plan for participating in a drug take-back program. Not later than 90 days after receiving a revised plan under this paragraph, the department shall either approve or reject the revised plan. If the department rejects the revised plan, the department shall provide the reason or reasons for the rejection.

Program components (continued)

- (c) If the department rejects a revised plan under paragraph (b) of this subsection, the department may:
- (A) Require the program operator to further revise the plan in accordance with the processes set forth in paragraph (b) of this subsection; or
- (B) Impose a penalty on each covered manufacturer participating in the proposed drug take-back program as described in ORS 459A.239.
- (d) Not later than four years after the department approves a plan under paragraph (a) of this subsection, a program operator must submit to the department an updated plan for the continued operation of a drug take-back program, in which the program operator describes any substantive changes to the drug take-back program that involve an element required under subsection (2) of this section. An updated plan is subject to the approval processes set forth in this subsection.
- (8) The department shall make each plan submitted under subsection (1) of this section and each revised or updated plan submitted under subsection (7) of this section available to the public.
- (9) As used in this section, "population center" means a city or town and the unincorporated area of the county that is within a 10-mile radius from the center of the city or town.

459A.215 - Authorized Collectors: Rules.

- (1) Before submitting to the Department of Environmental Quality a plan under ORS 459A.209 (1), a program operator must:
- (a) Solicit potential authorized collectors for the purpose of collecting covered drugs under the drug take-back program; and
- (b) Enter into agreements with all willing authorized collectors for the purpose of collecting covered drugs under the drug take-back program.
- (2) An agreement entered into under this section must require an authorized collector to comply with all state laws and rules and federal laws and regulations governing the keeping of covered drugs, as identified by the State Board of Pharmacy by rule.
- (3) In approving plans and updated plans under ORS 459A.209, and in preapproving changes under ORS 459A.212, the department shall, insofar as is practicable, ensure that each resident of this state has adequate access to a drop-off site.

Program components (continued)

459A.218 - Drop-off sites; rules.

- (1) 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.
- (2) For purposes of a drug take-back program:
- (a) A drop-off site must be available for use during the normal business hours of the authorized collector;
- (b) A drop-off site must use a secure repository in compliance with all state laws and rules and federal laws and regulations governing the keeping of covered drugs in repositories, as identified by the State Board of Pharmacy by rule;
- (c) The program operator must:
- (A) Ensure that each secure repository is serviced as often as necessary to avoid reaching capacity;
- (B) Ensure that collected covered drugs are transported to a location described in ORS 459A.224 in a timely manner; and
- (C) Provide a method for the authorized collector to notify the program operator of the need for additional collections at the drop-off site;
- (d) A sign must be affixed to the secure repository used at a dropoff 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 drug take-back program;
- (e) Except as provided in paragraph (f) of this subsection, a dropoff site must accept all covered drugs from covered entities; and
- (f) If a drop-off site is located at a long-term care facility, as defined in ORS 442.015, and allowed under applicable federal regulations, only individuals who reside, or have resided, at the long-term care facility may use the drop-off site.
- (3) A drug take-back program that is unable to establish and maintain a sufficient number of drop-off sites in order to meet the requirements of the plan submitted under ORS 459A.209 shall provide additional services, such as mail-back services, and hold collection events to ensure the convenient service described in the plan submitted under ORS 459A.209 subject to approval by the Department of Environmental Quality.

Program components (continued)

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:

- (1) In accordance with the applicable regulations and protocols of the Drug Enforcement Administration of the United States Department of Justice; and
- (2) 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:

- (1) At a hazardous waste disposal facility that meets the requirements of 40 C.F.R. parts 264 and 265, as in effect on September 29, 2019; or
- (2) At a municipal solid waste incinerator that is permitted to accept pharmaceutical waste.

459A.227 - Public Awareness.

- (1) 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 the time a covered drug is delivered to a covered entity, and through the use of any signage, advertising or other means of fostering public awareness. At a minimum, a program operator must:
- (a) Promote the safe and secure storage of covered drugs by covered entities;
- (b) Disseminate information on the inherent risks of improperly storing or disposing of opioids or opiates and other covered drugs;
- (c) Discourage the disposal of covered drugs in the garbage or sewer system;
- (d) Promote the disposal of covered drugs through the use of the drug take-back program;

- (e) Establish a toll-free telephone number and a website address that a covered entity may use to contact the program operator about the drug take-back program;
- (f) Publicize information on the location of drop-off sites, collection processes and any collection events;
- (g) 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
- (h) Conduct a biennial survey of covered entities and of pharmacists and health care providers who interact with covered entities
- (2) For purposes of conducting a survey under subsection (1)(h) of this section:
- (a) In a form and manner prescribed by the Department of Environmental Quality, a program operator must submit proposed survey questions to the department for preapproval.
- (b) Surveys must:
- (A) Measure public awareness of the drug take-back program;
- (B) Assess the extent to which drop-off sites, mail-back service and collection events are convenient and easy to use; and
- (C) Assess knowledge of and attitudes toward the risks posed by improperly storing covered drugs and improperly discarding or abandoning covered drugs.
- (3) A program operator shall coordinate with other program operators under this section to ensure that covered entities can easily identify, understand and access the services provided by all drug take-back programs that are operational in this state. At a minimum, all of the drug take-back programs that are operational in this state must provide a single toll-free telephone number and a single website address that a covered entity may use to contact program operators about the drug take-back programs and to acquire information about the location of the drop-off sites and the collection processes of the drug take-back programs.
- (4) Upon request by a covered entity, a retail drug outlet, hospital with an on-site pharmacy or health care clinic with an on-site pharmacy must provide a covered entity with written materials provided by a program operator for the purpose of promoting the safe and secure collection of covered drugs at the time that a covered drug is delivered to a covered entity.

<u>OREGON</u>

Program components (continued)

459A.230 - Annual Report.

- (1) In a form and manner prescribed by the Department of Environmental Quality, 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:
- (a) A list of covered manufacturers participating in the drug takeback program;
- (b) The total amount, by weight, of drugs collected under the drug take-back program;
- (c) The amount, by weight, of drugs collected under each method of collecting drugs under the drug take-back program;
- (d) The address of each drop-off site used under the drug take-back program;
- (e) The total amount, by weight, of drugs collected at each drop-off site, presented in a manner that assists the department in determining the rate of use of each drop-off site;
- (f) The date and location of each collection event held pursuant to ORS 459A.221:
- (g) The method or methods used to transport drugs collected under the drug take-back program;
- (h) The disposal technologies or processes used pursuant to ORS 459A.224 and which facilities or incinerators were used;
- (i) The total amount, by weight, of drugs disposed of by each method, presented in a manner that allows the department to conduct an audit to verify the information;
- (j) 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;
- (k) A summary of the drug take-back program's compliance with ORS 459A.227;
- (l) A summary of the annual expenditures of the drug take-back program, aggregated by category;
- (m) Whether service was provided in compliance with the program operator's description pursuant to ORS 459A.209 (2)(i) and whether the public awareness goals have been met, including a summary of strategies and surveys used, and copies of any promotional materials developed by, the drug take-back program; and

Program components (continued)

- (n) An attestation that all covered drugs collected under the drug take-back program were disposed of in compliance with applicable laws, rules and regulations.
- (2) The department shall review reports submitted under this section and approve those that comport with the requirements of this section. If the department does not approve a report under this subsection, the department shall provide the program operator with written notice of revisions necessary for approval and the timeline for resubmittal.
- (3) The department shall publish approved reports submitted under this section on a website of the department.

459A.233 - Costs of Participation in Drug Take-back Program.

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

459A.236 - Inspection and Audit.

The Department of Environmental Quality shall ensure compliance with ORS 459A.200 to 459A.266 by:

- (1) Entering into an agreement with the State Board of Pharmacy whereby the Board, during routine inspections of retail drug outlets:
- (a) Inspects drop-off sites located at retail drug outlets; and
- (b) Informs the department of drop-off sites that are not in compliance with ORS 459A.200 to 459A.266;
- (2) Inspecting drop-off sites not located at retail drug outlets; and
- (3) Auditing the records of program operators.

Program components (continued)

459A.239 - Enforcement; Civil Penalties.

- (1)(a) The Environmental Quality Commission shall send notice to a covered manufacturer if the covered manufacturer fails to participate in a drug take-back program as required by ORS 459A.200 to 459A.266. Notice sent under this subsection must explain the possible penalties that may be incurred by the covered manufacturer for committing the violation.
- (b) If, 30 days after the date on which the commission sent notice under paragraph (a) of this subsection, the covered manufacturer continues to sell drugs within this state without participating in a drug take-back program, the commission may impose a civil penalty against the covered manufacturer for an amount that does not exceed \$10,000 for each day, beginning on the 31st day, that the covered manufacturer commits the violation.
- (2)(a) The commission shall send notice to a program operator, and any covered manufacturers that participate in the program operator's drug take-back program, if the commission determines that the program operator's drug take-back program is not in compliance with ORS 459A.200 to 459A.266. Notice sent under this subsection must explain the possible penalties that may be incurred by the program operator for committing the violation.
- (b) If a drug take-back program continues to be out of compliance with ORS 459A.200 to 459A.266 30 days after the date on which the commission sent notice under paragraph (a) of this subsection, the commission may:
- (A) Impose a civil penalty against the program operator, and each covered manufacturer described in paragraph (a) of this subsection, for an amount that does not exceed \$1,000 for each entity per day, beginning on the 31st day, that the program operator commits the violation; and
- (B) If the commission determines that the violation presents a risk to public health and safety, suspend, in whole or in part, operation of the drug take-back program.
- (3) Civil penalties imposed under this section are joint and several obligations of the program operator and each covered manufacturer that participates in the program operator's drug take-back program.
- (4) The commission shall deposit moneys collected through the imposition of civil penalties under this section into the Secure Drug Take-Back Account established under ORS 459A.245,

Program components (continued)

459a.242 – Fees.

- (1) The Department of Environmental Quality shall establish the following fees for the purpose of paying the costs of administering ORS 459A. 200 to 459A.266;
- (a) A one-time fee for reviewing a drug take-back program plan submitted under ORS 459A.209.
- (b) An annual fee for expenses associated with the ongoing costs of administering ORS 459A. 200 to 459A.266.
- (c) An hourly fee for any other work that the department must do on behalf of a drug take-back program. (2) If a drug take-back program has more than one program operator, each program operator is subject to the fees established under subsection (1) of this section.
- (3) Fees established under subsection (1) of this section must be reasonably calculated to cover the costs of administering ORS 459A. 200 to 459A.266.
- (4) The department shall deposit fee moneys collected pursuant to this section into the Secure Drug Take-Back Account established under ORS 459A.245.
- 459A.245 Secure Drug Take-Back Account.
- (1) The Secure Drug Take-Back Account is established in the State Treasury, separate and distinct from the General Fund. Interest earned by the account shall be credited to the account. All moneys in the account are continuously appropriated to the Department of Environmental Quality for purposes of administering ORS 459A.200 to 459A.266.
- (2) The account shall consist of all moneys deposited into or credited to the account, including:
- (a) Moneys collected under and deposited into the account pursuant to ORS 459A.239 and 458A.242; and
- (b) Moneys appropriated or transferred to the account by the Legislative Assembly.

459A 248 – Liability.

An authorized collector, covered manufacturer, drug take-back organization, drug take-back program and program operator may not be held criminally or civilly liable for any function, duty or power performed for the purpose of complying with ORS 459A.200 to 459A.266, unless the function, duty or power was performed with gross negligence or willful and wanton misconduct.

Program components (continued)

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 drugs, is in the best interests of the public. Therefore, the Legislative Assembly declares its intent that participating in drug take-back programs as required by ORS 459A.200 to 459A.266 shall be exempt from state antitrust laws. The Legislative Assembly further declares its intent to provide immunity for participating in drug take-back programs as required by ORS 459A.200 to 459A.266 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 ORS 459A.200 to 459A.266.

459A 254 – Confidentiality.

Any proprietary information or any financial, manufacturing or sales information or data that the Department of Environmental Quality receives from a covered manufacturer or drug take-back organization under ORS 459A.200 to 459A.266 is confidential and not subject to public disclosure under ORS 192.311 to 192.478, except that the department may disclose summarized information or aggregated data if the information or data does not directly or indirectly identify the proprietary information or the financial, manufacturing or sales information or data of a specific covered manufacturer or drug take-back organization.

459A 257 – Non-applicability of Uniform Controlled Substances Act.

The provisions of the Uniform Controlled Substances Act do not apply to a program operator or authorized collector, insofar as the program operator is collecting, transporting and disposing of covered drugs pursuant to ORS 459A.200 to 459A.266.

OREGON	
Program components	459A.200 - State Preemption of Local Laws.
(continued)	437A.200 - State 1 recimption of Local Laws.
	Except as expressly authorized by state law, ORS 459A.200 to 459A.266 supersede and preempt 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, of: (1) Biologics; (2) Covered drugs; (3) Drugs for which a covered manufacturer administers a drug take-back program as part of a risk evaluation and mitigation strategy under the oversight of the federal Food and Drug Administration; (4) Drugs that are used for animal medicines, including but not limited to parasiticide drugs for animals; (5) Drugs administered in a clinical setting; or (6) Dialysis concentrates and solutions used for kidney dialysis in a patient's home.
	459A 263 - Interagency Agreements.
	The Department of Environmental Quality may enter into agreements with other state agencies for purposes including covering costs incurred in the administration of ORS 459A.200 to 459A.266.
	459A.266 – Rules.
	The Environmental Quality Commission shall adopt any rules necessary for the effective administration of ORS 459A.200 to 459A.266. Upon request, the State Board of Pharmacy shall assist the commission in adopting rules under this section.
Miscellaneous provisions	N/A
Recently proposed legislation	H.B. 2078, 81st Legis. Sess. (Or. 2021)(eff. January 1, 2022).
icgisiativii	HB 2078 amends Oregon's existing definition of a "covered manufacturer."

<u>PENNSYLVANIA</u>	
Statute(s) and regulation(s)	No.
Does the state allow drug take-back programs by statute/regulation?	N/A
Program components	N/A
Miscellaneous provisions	62 P.A. STAT. AND CONS. STAT. §§ 2921 - 2927 (West)(2008). Chapter 21. Cancer Drug Repository Program Act.
	Establishes a cancer drug repository program which sets up the requirements for donated cancer drugs to be allocated to indigent cancer patients.
Recently proposed	S.R. 149, 250th Legis. Sess. (Pa. 2021).
legislation	A resolution designating the week of July 26 through 30, 2021 as "Construction Opioid Awareness Week" to encourage drug takeback" events to combat the opioid and prescription drug abuse epidemic in Pennsylvania's construction industry.
	2021 Pennsylvania House Bill No. 752, Pennsylvania Two Hundred Fifth General Assembly - 2021-2022 (Pa. 2021)(Introduced).
	An Act amending the act of September 27, 1961 (P.L.1700, No.699), known as the Pharmacy Act, further providing for definitions; and providing for collection and disposal of drugs by pharmacies.

RHODE ISLAND	
Statute(s) and regulation(s)	23 R.I. GEN. LAWS ANN. §§ 23-25.5-1 - 23-25.5-4 (West)(2013).
Does the state allow drug take-back programs by statute/regulation?	Yes.
Program components	R.I. GEN. LAWS ANN. §§ 23-25.5-1 - 23-25.5-4.
	§ 23-25.5-1 - Short Title.
	§ 23-25.5-2 - Legislative Purpose.
	§ 23-25.5-3 – Definitions.
	§ 23-25.5-4 - Program Established.
	(a) the Department of Health and the Board of Pharmacy shall jointly develop and implement a program consistent with public health and safety through which unused prescription drugs, other than prescription drugs defined as controlled substances in § 21-28-1.02, and drugs that can only be dispensed to a patient registered with the drug's manufacturer in accordance with federal food and drug administration requirements, may be accepted by wholesalers or pharmacies, from which they were purchased, for return from nursing facilities, assisted living residences, residential care facilities, community health organizations and state correctional facilities that centrally store prescription drugs and are licensed at the M licensure level by the health, within forty-five (45) days of dispensing. (b) the program shall permit the wholesaler or pharmacy to which such medication is returned to repackage, restock, and redistribute such medication.
	 (c) the program shall include the following prescription drugs: (1) unopened sections of blister pack prescription medication, with seal intact; (2) unopened unit-dose containers of liquids with the safety seal intent.
	intact; (3) unopened unit-dose containers of powders for oral solution with safety seal intact;
	(4) unused injectables, with safety seal intact.(d) the unused prescription drug shall not be accepted, repackaged or redispersed if:
	(1) the prescription drug is expired or beyond use date; (2) the pharmacist accepting or redispensing the drug, in his or her

RHODE ISLAND	
Program components	judgment has reason to believe that the prescription drug is
(continued)	adulterated, mislabeled, or has been improperly stored; (3) the prescription drug is defined as controlled substances in § 21-28-1.02; and (4) it is a drug that can only be dispensed to a patient registered
	with the drug's manufacturer in accordance with federal food and drug administration requirements. (e) the wholesaler or pharmacy shall be required to reimburse or
	credit the purchaser for any such returned prescription drugs at original invoice price plus a restocking fee not to exceed five dollars (\$5.00).
	(f) the department and the Board of Pharmacy shall promulgate rules and regulations necessary to implement the program
	established pursuant to this Chapter within One hundred eighty days (180) of passage of this act.
Miscellaneous provisions	N/A
Recently proposed legislation	H.B. 5041, 2021 Legis. Sess. (RI 2021)(Scheduled for hearing and/or further consideration.).
	Requires drug manufacturers to establish a fund and manage state approved drug take-back programs, free of charge to the consumer and pharmacy.

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SOUTH CAROLINA	
Statute(s) and regulation(s)	S.C. CODE ANN. § 44-53-362 (West)(2017).
Does the state allow drug take-back programs by statute/regulation?	Yes.
Program components	S.C. CODE ANN. § 44-53-362.
	Controlled Substance Take-back Events and Mail-back Programs; Collectors.
	(A) A controlled substance manufacturer, distributer, or reverse distributer; 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, pursuant to 21 C.F.R. 1317.40, to receive Schedule II, III, IV, and 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, including as provided in 21 C.F.R. Part 1317. (B) The Department of Health and Environmental Control shall develop guidance for pharmacies and other entities qualified to register as a collector to encourage participation. The department shall coordinate with law enforcement, health care providers, and the U.S. Drug Enforcement Administration to encourage registration as a collector and to promote public awareness of controlled substance take-back events and mail-back programs.
Miscellaneous provisions	S.C. CODE ANN. § 44-71-85 (West)(2017).
	Disposal of deceased patient's unused controlled substances. Establishes requirements for the transfer of controlled substances if a patient dies while receiving outpatient services from a hospice. Ownership of the substances must be transferred to the hospice for disposal.
Recently proposed	No.
legislation	

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<u>SOUTH DAKOTA</u>	
Statute(s) and regulation(s)	No.
Does the state allow drug take-back programs by statute/regulation?	N/A
Program components	N/A
Miscellaneous provisions	N/A
Recently proposed legislation	No.

<u>TENNESSEE</u>	
Statute(s) and regulation(s)	TENN. CODE ANN. § 63-10-703 (West)(2017).
Does the state allow drug take-back programs by statute/regulation?	Yes.
Program components	§ 63-10-703. Pharmacy drug disposal program; participation Any Tennessee-licensed pharmacy located within the 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 noncontrolled substances.
Miscellaneous provisions	N/A
Recently proposed legislation	No.

<u>TEXAS</u>	
Statute(s) and regulation(s)	No.
Does the state allow drug take-back programs by statute/regulation?	N/A
Program components	N/A
Miscellaneous provisions	2020 TX REG TEXT 566534 (NS)(Effective December 10, 2020).
	Administrative code that requires any pharmacy that dispenses a controlled substance to provide written notice as to how and where a controlled substance prescription drug may be accepted for safe disposal.
	TEX. HEALTH & SAFETY CODE ANN. § 431.321- 431.325 (West)(2007).
	Drug Donation Program.
	Establishes that a drug donor may donate unused prescriptions to a charitable medical clinic, which may dispense the donated drugs.
Recently proposed legislation	No.

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<u>UTAH</u>	
Statute(s) and regulation(s)	UTAH CODE ANN. 1953 § 67-5-36 (West)(2020).
Does the state allow drug take-back programs by statute/regulation?	Yes.
Program components	Utah Code Ann. 1953 § 67-5-36.
	§ 67-5-36. Drug Disposal Program.
	(1) as used in the section:(a) "controlled substance" means the same as that term is defined in section 58-37-2.(b) "department" means the Department of Environmental Quality.
	(c) "environmentally friendly" means a controlled substance that is rendered:(i) non-retrievable, as determined by the Attorney General in consultation with the department;(ii) non-hazardous, as determined by the department; and
	(iii) permissible to dispose in a landfill in a manner that does not violate state or federal law relating to surface water or groundwater. (d) "home controlled substance disposal receptacle" 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. (e) "non-retrievable" means the same as that term is defined in 21
	C.F.R. 1300.05. (f) "program" means the drug disposal program described in this section.
	(g) "repository" means a controlled substance disposal repository described in subsection (3).
	(2) 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.
	(3) the Attorney General and the department, in developing and implementing the program:(a) 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; (b) shall ensure that each repository:
	(i) renders a controlled substance placed in the repository non-retrievable and environmentally friendly, onsite; and (ii) is secure from tampering or unauthorized removal;

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- (c) may require verification that:
- (i) a repository complies with subsection (3)(b); and
- (ii) a home-controlled substance disposal receptacle renders a controlled substance non-retrievable and environmentally friendly;
- (d) shall ensure that the program operates in accordance with drug enforcement administration rules; and
- (e) may publish, on the websites of the Attorney General 's office and the department:
- (i) a list of the location of each repository in the state; and
- (ii) if home controlled substance disposal receptacles are used as part of the program, information on how to obtain a home-controlled substance disposal receptacle.
- (4) 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.
- (5) a state or local government entity, other than the Attorney General 's office, the department, or a designee of the department, may not:
- (a) regulate the disposal of a controlled substance rendered non-retrievable in a repository or home controlled substance disposal receptacle differently, or more strictly, than disposal of non-hazardous household waste;
- (b) regulate or restrict the location of a repository or the distribution of a home-controlled substance disposal receptacle; or
- (c) otherwise take action to regulate or interfere with administration of the program.
- (6) this section does not prohibit the disposal of a controlled substance:
- (a) in a receptacle that does not qualify as a repository if:
- (i) the receptacle is located on the premises of an entity authorized by drug enforcement administration rules to accept a controlled substance for subsequent disposal; and
- (ii) the entity described in subsection (6)(a)(i) ensures that the controlled substance is managed in a manner permitted by drug enforcement administration rule; or
- (b) disposed at a facility that has received the approval required under section 19-6-108.

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Program components (continued)	(7) unless otherwise agreed by the Attorney General, an entity described in subsection (3)(a) 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. Note: section (7) of UTAH CODE ANN. § 67-5-36 provides that "unless otherwise agreed by the Attorney General" This sentence appears to contain a grammatical error and is missing the word "to" ("unless otherwise agreed [to] by the Attorney General.").
Miscellaneous provisions	UTAH CODE ANN. § 63G-1-401 (West)(2021).
	The month of April is commemorated annually as Clean Out the Medicine Cabinet Month to recognize the need to educate citizens about permanent medication disposal.
Recently proposed	2022 Utah House Bill No. 451, Utah Sixty-Fourth Legislature -
legislation	2022 General Session (Filed)
	Opioid Use Prevention and Treatment Amendments
	This bill enacts requirements for the use of funds deposited into the
	Opioid Litigation Settlement. This includes the creation of
	community programs for the disposal of drugs.

	VERMONT
Statuto(s) and nagulation(s)	
Statute(s) and regulation(s)	VT. STAT. ANN. tit. 18, § 4224 (West)(2016). VT. STAT. ANN. tit. 33, § 2004 (West)(2019).
Does the state allow drug	Yes.
take-back programs by statute/regulation?	165.
Program components	Vt. Stat. Ann. tit 18, § 4224.
	Unused Prescription Drug Disposal Program.
	The Department of Health shall establish and maintain the statewide unused prescription drug disposal program to provide for the safe disposal of Vermont residents' unused and unwanted prescription drugs. 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.
	Vt. Stat. Ann. tit. 33, § 2004
	§ 2004. Manufacturer Fee.
	(a) Annually, each pharmaceutical manufacturer or labeler of prescription drugs that are paid for by the Department of Vermont Health Access for individuals participating in Medicaid, Dr. Dynasaur, or VPharm shall pay a fee to the agency of human services. The fee 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.
	(b) Fees collected under this section shall fund collection and analysis of information on pharmaceutical marketing activities under 18 VSA §§ 4632 and 4633; analysis of prescription drug data needed by the Office of the Attorney General for enforcement activities; the Vermont Prescription Monitoring System established in 18 VSA Chapter 84a; the evidence-based education program established in 18 VSA. Chapter 91, subchapter 2; statewide unused prescription drug disposal initiatives; prevention of prescription
	drug misuse, abuse, and diversion; the substance misuse prevention oversight and advisory council established in 18 VSA § 4803; treatment of substance use disorder; exploration of nonpharmacological approaches to pain management; a hospital antimicrobial program for the purpose of reducing hospital-acquired infections; the purchase and distribution of fentanyl testing strips;

	<u>VERMONT</u>
Program components (continued)	the purchase and distribution of naloxone to emergency medical services personnel; and any opioid-antagonist education, training, and distribution program operated by the Department of Health or its agents. The fees shall be collected in the evidence-based education and advertising fund established in section 2004a of this title. (c) The secretary of human services or designee shall make rules for the implementation of this section. (d) The department shall maintain on its website a list of the manufacturers who have failed to provide timely payment as required under this section.
Miscellaneous provisions	N/A
Recently proposed legislation	2021 Vermont House Bill No. 50, Vermont 2021-2022 Legislative Session, 2021 Vermont House Bill No. 50, Vermont 2021-2022 Legislative Session (Introduced). An act relating to pharmacists providing information on the proper disposal of unused regulated drugs. Bill proposes to require pharmacists dispensing regulated drugs to provide patients with information regarding the importance of and processes for proper disposal of unused medication.
	2021 Vermont House Bill No. 462, Vermont 2021-2022 Legislative Session (Enrolled)(April 29, 2022). An act relating to miscellaneous Department of Health programs including requiring pharmacies with 10 or more outlets to host a drug disposal kiosk.

<u>VIRGINIA</u>	
Statute(s) and regulation(s)	Va. Code Ann. § 54.1-3411.2 (West)(2020).
	18 VA. ADMIN. CODE § 110-30-160 (West)(2021).
Does the state allow drug	Yes.
take-back programs by	
statute/regulation?	
Program components	VA. CODE ANN. § 54.1-3411.2.
	Prescription Drug Disposal Programs.
	A. As used in this section: "authorized pharmacy disposal site"
	means a pharmacy that qualifies as a collection site pursuant to 21 C.F.R.§ 1317.40.
	"pharmacy drug disposal program" means any voluntary drug
	disposal program located at or operated in accordance with state and federal law by a pharmacy.
	B. 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 noncontrolled 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.
	C. No person that participates in a pharmacy drug disposal program
	shall be liable for any theft, robbery, or other criminal act related to
	its participation in the pharmacy drug disposal program nor shall
	such person be liable for acts of simple negligence in the collection,
	storage, or destruction of prescription drugs collected through such
	pharmacy drug disposal program, provided that the pharmacy
	practice site is acting in good faith and in accordance with
	applicable state and federal law and regulations.
	D. In order to mitigate the risk of diversion of drugs upon the death of a patient, any hospice licensed by the department or exempt from
	licensure pursuant to § 32.1-162.2 shall develop policies and
	procedures for the disposal of drugs, including opioids, dispensed
	as part of the hospice plan of care. Such disposal shall be (i)
	performed in a manner that complies with all state and federal
	requirements for the safe disposal of drugs by a licensed nurse,
	physician assistant, or physician who is employed by or has entered
	into a contract with the hospice program; (ii) witnessed by a
	member of the patient's family or a second employee of the hospice
	program who is licensed by a health regulatory Board within the
	Department of Health professions; and (iii) documented in the
	patient's medical record.

<u>VIRGINIA</u>		
Program components	18 VA. ADMIN. CODE § 110-30-160.	
(continued)	A. If a licensee wishes to dispose of unwanted schedule ii through vi controlled substances, he shall use one of the following procedures: 1. Transfer the drugs to another person or entity authorized to possess schedule ii through vi drugs; or 2. Destroy the drugs by burning in an incinerator in compliance with all applicable local, state, and federal laws and regulations. B. If schedule ii through v drugs are to be destroyed, the following additional procedures shall apply: 1. At least 14 days prior to the destruction date, the licensee shall provide a written notice to the Board office. The notice shall state the following: A. Date, time, manner, and place of destruction; B. The names of the licensees who will witness the destruction process. 2. If the destruction date is to be changed or the destruction does not occur, a new notice stating the information required in subdivision 1 of this subsection shall be provided to the Board; 3. The actual destruction shall be witnessed by the licensee conducting the destruction and another licensee of the Board who is not employed by the licensee conducting the destruction; 4. At the conclusion of the destruction of the controlled substance stock, the DEA drug destruction form shall be fully completed and used as the record of all drugs to be destroyed. A copy of the destruction form shall be retained at the practitioner's office with other inventory records.	
Miscellaneous provisions	N/A	
Recently proposed legislation	No.	

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<u>WASHINGTON</u>		
Statute(s) and regulation(s)	WASH. REV. CODE ANN. §§ 69.48.010–69.48.200 (West)(2018). 2022 WA REG TEXT 603324 (NS)(Effective January 5, 2022).	
Does the state allow drug take-back programs by statute/regulation?	Yes.	
1 0	Wash. Rev. Code Ann. §§ 69.48.010–69.48.200. 69.48.010 – Findings. 69.48.020 – Definitions. The definitions in this section apply throughout this Chapter unless the context clearly requires otherwise. (1) "Administer" means the direct application of a legend drug whether by injection, inhalation, ingestion, or any other means, to the body of the patient or research subject by: (a) A practitioner; or (b) The patient or research subject at the direction of the practitioner. (2) "Authorized collector" 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 that is registered with the United States 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, as defined in RCW 69.50.101. (3) "Collection site" means the location where an authorized collector operates a secure collection receptacle for collecting covered drugs. (4)(a) "Covered drug" 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 generic drugs, drugs for veterinary use for household pets, and drugs in medical devices and combination products.	

- (b) "Covered drug" does not include:
- (i) Vitamins, minerals, or supplements;
- (ii) Herbal-based remedies and homeopathic drugs, products, or remedies:
- (iii) Controlled substances contained in schedule I of the uniform controlled substances act, Chapter 69.50 Rcw;
- (iv) Cosmetics, shampoos, sunscreens, lip balm, toothpaste, antiperspirants, or other personal care products that are regulated as both cosmetics and nonprescription drugs under the federal food, drug, and cosmetic act, 21 U.S.C. Sec. 301 et seq.;
- (v) Drugs for which manufacturers provide a pharmaceutical product stewardship or drug take-back program as part of a federal food and drug administration managed risk evaluation and mitigation strategy under 21 U.S.C. Sec. 355-1;
- (vi) Biological drug products, as defined by 21 C.F.R. 600.3 (h) as it exists on June 7, 2018, for which manufacturers provide a pharmaceutical product stewardship or drug take-back program and who provide the department with a report describing the program, including how the drug product is collected and safely disposed and how patients are made aware of the drug take-back program, and who updates the department on changes that substantially alter their drug take-back program;
- (vii) Drugs that are administered in a clinical setting;
- (viii) Emptied injector products or emptied medical devices and their component parts or accessories;
- (ix) Exposed needles or sharps, or used drug products that are medical wastes; or
- (x) Pet pesticide products contained in pet collars, powders, shampoos, topical applications, or other forms.
- (5) "Covered entity" means a state resident or other nonbusiness entity and includes an ultimate user, as defined by regulations adopted by the United States drug enforcement administration. "Covered entity" does not include a business generator of pharmaceutical waste, such as a hospital, clinic, health care provider's office, veterinary clinic, pharmacy, or law enforcement agency.
- (6)"Covered manufacturer" means a person, corporation, or other entity engaged in the manufacture 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 RCW 69.48.040;
- (b) A repackager if the manufacturer of the drug is identified under RCW 69.48.040; or

Program components (continued)

(c) A nonprofit, 501(c)(3) health care 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 of the drug is identified under RCW 69.48.040.

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 covered manufacturer after June 7, 2018, 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 drug take-back 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.

69.48.040 - Identification of Covered Manufacturers.

- (1) No later than ninety days after June 7, 2018, a drug wholesaler that sells a drug in or into Washington must provide a list of drug manufacturers to the department in a form agreed upon with the department. A drug wholesaler must provide an updated list to the department on January 15th of each year.
- (2) No later than ninety days after June 7, 2018, 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.
- (3) 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 sixty days after receipt of the letter. If the person or entity does not believe it is a covered manufacturer for purposes of this Chapter, 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) of this subsection.

Program components (continued)

69.48.050 - Drug Take-back Program Approval--Program Modifications.

- (1) By July 1, 2019, a program operator must submit a proposal for the establishment and implementation of a drug take-back program to the department for approval. Proposals from new entities seeking to become a program operator after July 1, 2019, may be submitted as provided in subsection (7) of this section. The department shall approve a proposed program if the applicant submits a completed application, the proposed program meets the requirements of subsection (2) of this section, and the applicant pays the appropriate proposal review fee established by the department under RCW 69.48.120. The department may approve drug take-back programs proposed by one or more program operators consistent with the provisions of this section.
- (2) To be approved by the department, a proposed drug take-back program, independent of any other operating program, must:
- (a) Identify and provide contact information for the program operator and each participating covered manufacturer;
- (b) Identify and provide contact information for the authorized collectors for the proposed program, as well as the reasons for excluding any potential authorized collectors from participation in the program;
- (c) Provide for a collection system that complies with RCW 69.48.060;
- (d) Ensure that physical collection sites are the primary method of collection across the state and that methods of supplementing physical collection site service are the secondary methods for collection as required by RCW 69.48.060(3)(b) through (d). 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;
- (e) Provide for a handling and disposal system that complies with RCW 69.48.080;
- (f) Identify any transporters and waste disposal facilities that the program will use;
- (g) Adopt policies and procedures to be followed by persons handling covered drugs collected under the program to ensure safety, security, and compliance with regulations adopted by the United States drug enforcement administration, as well as any applicable laws;

- (h) Ensure the security of patient information on drug packaging during collection, transportation, recycling, and disposal;(i) Promote the program by providing consumers, pharmacies, and other entities with educational and informational materials as required by RCW 69.48.070; (j) Demonstrate adequate funding for all administrative and operational costs of the drug take-back program, with costs apportioned among participating covered manufacturers;
- (k) Set long-term and short-term goals with respect to collection amounts and public awareness; and
- (l) Consider: (i) The use of existing providers of pharmaceutical waste transportation and disposal services; (ii) separation of covered drugs from packaging to reduce transportation and disposal costs; and (iii) recycling of drug packaging. (3)(a) No later than one hundred twenty days after receipt of a drug take-back program proposal, the department shall either approve or reject the proposal in writing to the applicant. The department may extend the deadline for approval or rejection of a proposal for good cause. If the department rejects the proposal, it shall provide the reason for rejection.
- (b) No later than ninety days after receipt of a notice of rejection under (a) of this subsection, the applicant shall submit a revised proposal to the department. The department shall either approve or reject the revised proposal in writing to the applicant within ninety days after receipt of the revised proposal, including the reason for rejection, if applicable.
- (c) If the department rejects a revised proposal, the department may:
- (i) Require the program operator to submit a further revised proposal;
- (ii) Develop and impose changes to some or all of the revised proposal to address deficiencies;
- (iii) Require the covered manufacturer or covered manufacturers that proposed the rejected revised proposal to participate in a previously approved drug take-back program; or
- (iv) Find the covered manufacturer out of compliance with the requirements of this Chapter and take enforcement action as provided in RCW 69.48.110.
- (4) The program operator must fully implement an approved drug take-back program no later than one hundred eighty days after approval of the proposal by the department.
- (5)(a) Proposed changes to an approved drug take-back program that substantially alter program operations must have prior written

Program components (continued)

approval of the department. A program operator must submit to the department such a proposed change in writing at least fifteen days before the change is scheduled to occur. Changes requiring prior approval of the department include changes to participating covered manufacturers, collection methods, achievement of the service convenience goal described in RCW 69.48.060, policies and procedures for handling covered drugs, education and promotion methods, and selection of disposal facilities.

- (b) For changes to a drug take-back program that do not substantially alter program operations, a program operator 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, preaddressed mailers. (c) A program operator must notify the department of any changes to the official point of contact for the program no later than fifteen days after the change. A program operator must notify the department of any changes in ownership or contact information for participating covered manufacturers no later than ninety days after such change.
- (6) 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 described in subsection (2) of this section. The department shall approve or reject the updated proposal using the process described in subsection (3) of this section.
- (7)(a) On July 1, 2021, the department will begin the review of new proposals received by that date from entities seeking to become a program operator.
- (b) Beginning July 1, 2024, and every four years thereafter, the department will review new proposals from entities seeking to become a program operator.
- (c) The department shall approve a proposal if it meets the requirements in subsection (2) of this section and the applicant pays the appropriate fee established by the department under RCW 69.48.120. The department must approve or reject proposals received using the process provided in subsection (3) of this section.

- (8)(a) If there is a single approved drug take-back program at any time and that program operator intends to leave the program for any reason, participating manufacturers must find a new entity to take over operations of the existing program without a break in program services. The new entity may not make changes to the operations of the approved program, which must be consistent with the proposal as it was approved by the department under this section, or each covered manufacturer or group of covered manufacturers must identify a new program operator to develop a new program proposal. The department must accept new proposals from potential program operators for a minimum of four months from the date the department is notified of the program operator intending to cease operations, or until a proposal is approved by the department. The department may approve a proposal if it meets the requirements in subsection (2) of this section and the applicant pays the appropriate fee established by the department under RCW 69.48.120. The department must approve or reject proposals received using the process described in subsection (3) of this section.
- (b) If there is a single approved drug take-back program, and that program operator leaves the program and participating manufacturers do not identify a program operator to take over the approved program as provided in (a) of this subsection, all covered manufacturers must participate in a new approved drug take-back program as soon as one is approved.
- (9) 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 as described in subsection (8)(a) of this section, those manufacturers must immediately join an existing approved drug take-back program.
- (10) A covered manufacturer may change the approved drug takeback program it participates in but the covered manufacturer must maintain continuous participation in an established drug take-back program and may not leave an approved program until it transfers participation to an approved drug take-back program that has begun drug collection.
- (11) The department shall make all proposals submitted under this section available to the public and shall provide an opportunity for written public comment on each proposal.

Program components (continued)

(12)(a) 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 any approved drug take-back program. The department may identify or clarify in rule additional requirements for coordination or performance amongst program operators, if necessary, to ensure consistent operation of the drug take-back program. Requirements may include, but are not limited to: Consistent drop box appearance and signage; consistent messaging in education and outreach; and consistent metrics included in operator annual reports as required in RCW 69.48.100 to ensure the department can accurately analyze the data.

(b) Failure to comply with these requirements may result in enforcement action against a program operator as authorized under RCW 69.48.110.

69.48.060 - Collection System.

- (1)(a) At least one hundred twenty days prior to submitting a proposal under RCW 69.48.050, 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 thirty days after the potential authorized collector expresses interest in participating in a proposed program.
- (b) A person or entity may serve as an authorized collector for a drug take-back program voluntarily or in exchange for compensation, but nothing in this Chapter requires a person or entity to serve as an authorized collector.
- (c) A drug take-back 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 subsection (2) of this section. Such a pharmacy, hospital, clinic, or law enforcement agency must be included as an authorized collector in the program no later than ninety days after receiving the offer to participate.
- (d) A drug take-back program may also locate collection sites at:
- (i) A long-term care facility where a pharmacy, or a hospital or clinic with an on-site pharmacy, operates a secure collection receptacle;
- (ii) A substance use disorder treatment program, as defined in RCW 71.24.025; or

- (iii) Any other authorized collector willing to participate as a collection site and able to meet the requirements of subsection (2) of this section. (2)(a) 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.
- (b) 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.
- (c) A collection site must use secure collection receptacles in compliance with state and federal law, including any applicable onsite storage and collection standards adopted by rule pursuant to Chapter 70A.205 or 70A.300 RCW and United States drug enforcement administration regulations. 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.
- (d) An authorized collector must comply with applicable provisions of Chapters 70A.205 and 70A.300 RCW, including rules adopted pursuant to those Chapters that establish collection and transportation standards, and federal laws and regulations governing the handling of covered drugs, including United States drug enforcement administration regulations.
- (3)(a) A drug take-back 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.
- (b) 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.
- (c)(i) Each population center must have a minimum of one collection site, plus one additional collection site for every fifty thousand 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.

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- (ii) 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 unqualified or unwilling to participate in the drug take-back program, in accordance with the requirements of subsection (1) of this section.
- (iii) For purposes of this section, "population center" means a city or town and the unincorporated area within a ten-mile radius from the center of the city or town.
- (d) 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 collections 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 United States drug enforcement administration regulations and protocols and applicable state laws.
- (e) Upon request, a drug take-back program must provide a mail-back program free of charge to covered entities and to retail pharmacies that offer to distribute prepaid, preaddressed mailing envelopes for the drug take-back program. A drug take-back program must permit covered entities to request prepaid, preaddressed mailing envelopes through the program's website, the program's toll-free telephone number, and a request to a pharmacist at a retail pharmacy distributing the program's mailing envelopes.
- (f) The program operator must provide alternative collection methods for any covered drugs, other than controlled substances, that cannot be accepted or commingled with other covered drugs in secure collection receptacles, through a mail-back program, or at periodic collection events, to the extent permissible under applicable state and federal laws. The department shall review and approve of any alternative collection methods prior to their implementation.

Program components (continued)

69.48.070 - Drug Take-back Program Promotion.

- (1) A drug take-back program must develop and provide a system of promotion, education, and public outreach about the safe storage 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. At a minimum, each program must:
- (a) Promote the safe storage of legend drugs and nonlegend drugs by residents before secure disposal through a drug take-back program;
- (b) Discourage residents from disposing of covered drugs in solid waste collection, sewer, or septic systems;
- (c) Promote the use of the drug take-back program so that where and how to return covered drugs is widely understood by residents, pharmacists, retail pharmacies, health care facilities and providers, veterinarians, and veterinary hospitals;
- (d) Establish a toll-free telephone number and website publicizing collection options and collection sites and discouraging improper disposal practices for covered drugs, such as flushing them or placing them in the garbage;
- (e) Prepare educational and outreach materials that: Promote safe storage of covered drugs; discourage the disposal of covered drugs in solid waste collection, sewer, or septic systems; and describe how to return covered drugs to the drug take-back program. The materials must use plain language and explanatory images to make collection services and discouraged disposal practices readily understandable to all residents, including residents with limited English proficiency;
- (f) Disseminate the educational and outreach materials described in (e) of this subsection to pharmacies, health care facilities, and other interested parties for dissemination to covered entities;
- (g) Work with authorized collectors to develop a readily recognizable, consistent design of collection receptacles, as well as clear, standardized instructions for covered entities on the use of collection receptacles. The department may provide guidance to program operators on the development of the instructions and design; and(h) Annually report on its promotion, outreach, and public education activities in its annual report required by RCW 69.48.100.

- (2) If more than one drug take-back program is approved by the department, the programs must coordinate their promotional activities to ensure that all state residents can easily identify, understand, and access the collection services provided by any drug take-back program. Coordination efforts must include providing residents with a single toll-free telephone number and single website to access information about collection services for every approved program, including presenting all available collection sites, mail-back distribution locations, and take-back events to ensure residents are able to access the most convenient method of collection, regardless of the program operator, and must manage requests for prepaid, preaddressed mailing envelopes from covered entities and from retail pharmacies as provided in RCW 69.48.060(3)(e).
- (3) Pharmacies and other entities that sell medication in the state are encouraged to promote secure disposal of covered drugs through the use of one or more approved drug take-back programs. Upon request, a pharmacy must provide materials explaining the use of approved drug take-back programs to its customers. The program operator must provide pharmacies with these materials upon request and at no cost to the pharmacy.
- (4) The department, the Health Care authority, the Department of Social and Health Services, the Department of Ecology, and any other state agency that is responsible for health, solid waste management, and wastewater treatment shall, through their standard educational methods, promote safe storage of prescription and nonprescription drugs by covered entities, secure disposal of covered drugs through a drug take-back program, and the toll-free telephone number and website for approved drug take-back programs. Local health jurisdictions and local government agencies are encouraged to promote approved drug take-back programs.
- (5) The department:
- (a) Shall conduct a survey of covered entities and a survey of pharmacists, health care 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 drug take-back 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 covered entities' practices with respect to unused, unwanted, or expired drugs, both currently and prior to implementation of the drug take-back program; and

Program components (continued)

(b) May, upon review of results of public awareness surveys, direct a program operator for an approved drug take-back program to modify the program's promotion and outreach activities to better achieve widespread awareness among Washington state residents and health care professionals about where and how to return covered drugs to the drug take-back program.

69.48.080 - Disposal and Handling of Covered Drugs.

- (1) Covered drugs collected under a drug take-back program must be disposed of at a permitted hazardous waste disposal facility that meets the requirements of 40 C.F.R. parts 264 and 265, as they exist on June 7, 2018.
- (2) If use of a hazardous waste disposal facility described in subsection (1) of this section 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 that meets the requirements of 40 C.F.R. parts 60 and 62, as they exist on June 7, 2018.
- (3) A program operator may petition the department for approval to use final disposal technologies or processes that provide superior environmental and human health protection than that provided by the technologies described in subsections (1) and (2) of this section, or equivalent protection at less cost. In reviewing a petition under this subsection, the department shall take into consideration regulations or guidance issued by the United States environmental protection agency on the disposal of pharmaceutical waste. The department, in consultation with the Department of Ecology, shall approve a disposal petition under this section if the disposal technology or processes described in the petition provides equivalent or superior protection in each of the following areas:
- (a) Monitoring of any emissions or waste;
- (b) Worker health and safety;
- (c) Air, water, or land emissions contributing to persistent, bio-accumulative, and toxic pollution; and
- (d) Overall impact to the environment and human health.
- (4) If a drug take-back 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.

Program components (continued)

69.48.090 - Program Funding.

- (1) 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. Such administrative and operational costs include, but are not limited to: Collection and transportation supplies for each collection site; purchase of secure collection receptacles for each collection site; ongoing maintenance or replacement of secure collection receptacles when requested by authorized collectors; prepaid, preaddressed mailers; compensation of authorized collectors, if applicable; operation of periodic collection events, including the cost of law enforcement staff time; transportation of all collected covered drugs to final disposal; environmentally sound disposal of all collected covered drugs in compliance with RCW 69.48.080; and program promotion and outreach.
- (2) A program operator, covered manufacturer, authorized collector, or other person may not charge:
- (a) A specific point-of-sale fee to consumers to recoup the costs of a drug take-back program; or
- (b) A specific point-of-collection fee at the time covered drugs are collected from covered entities.
- 69.48.100 Annual Program Report.
- (1) By July 1st after the first full year of implementation, and each July 1st thereafter, a program operator must submit to the department a report describing implementation of the drug takeback program during the previous calendar year. The report must include:
- (a) A list of covered manufacturers participating in the drug takeback program;
- (b) The amount, by weight, of covered drugs collected, including the amount by weight from each collection method used;
- (c) The following details regarding the program's collection system: 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 applicable and the transporters and disposal facility or facilities used;

Program components (continued)

- (d) 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;
- (e) A description of the public education, outreach, and evaluation activities implemented; (f) A description of how collected packaging was recycled to the extent feasible;
- (g) 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
- (h) The program's annual expenditures, itemized by program category.
- (2) Within thirty days after each annual period of operation of an approved drug take-back 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.
- (3) The department shall make reports submitted under this section available to the public through the internet.

69.48.110 - Enforcement and Penalties.

- (1) The department may audit or inspect the activities and records of a drug take-back program to determine compliance with this Chapter or investigate a complaint.
- (2)(a) The department shall send a written notice to a covered manufacturer that fails to participate in a drug take-back program as required by this Chapter. The notice must provide a warning regarding the penalties for violation of this Chapter.
- (b) A covered manufacturer that receives a notice under this subsection (2) may be assessed a penalty if, sixty days after receipt of the notice, the covered manufacturer continues to sell a covered drug in or into the state without participating in a drug take-back program approved under this Chapter.
- (3)(a) The department may send a program operator a written notice warning of the penalties for noncompliance with this Chapter if it determines that the program operator's drug take-back program is in violation of this Chapter or does not conform to the proposal approved by the department. The department may assess a penalty on the program operator and participating covered manufacturers if the program does not come into compliance by thirty days after receipt of the notice.

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Program components (continued)

- (b) The department may immediately suspend operation of a drug take-back program and assess a penalty if it determines that the program is in violation of this Chapter and the violation creates a condition that, in the judgment of the department, constitutes an immediate hazard to the public or the environment.
- (4)(a) The department shall send a written notice to a drug wholesaler or a retail pharmacy that fails to provide a list of drug manufacturers to the department as required by RCW 69.48.040. The notice must provide a warning regarding the penalties for violation of this Chapter.
- (b) A drug wholesaler or retail pharmacy that receives a notice under this subsection may be assessed a penalty if, sixty days after receipt of the notice, the drug wholesaler or retail pharmacy fails to provide a list of drug manufacturers.
- (5) In enforcing the requirements of this Chapter, the department:
- (a) May require an informal administrative conference;
- (b) May require a person or entity to engage in or refrain from engaging in certain activities pertaining to this Chapter;
- (c) May, in accordance with RCW 43.70.095, assess a civil fine of up to two thousand dollars. Each day upon which a violation occurs or is permitted to continue constitutes a separate violation. In determining the appropriate amount of the fine, the department shall consider the extent of harm caused by the violation, the nature and persistence of the violation, the frequency of past violations, any action taken to mitigate the violation, and the financial burden to the entity in violation; and
- (d) May not prohibit a covered manufacturer from selling a drug in or into the state of Washington.

69.48.120 - Department to Set Program Fees.

(1)(a) The department shall: Determine its costs for the administration, oversight, and enforcement of the requirements of this Chapter, including, but not limited to, a fee for proposal review, and the survey required under RCW 69.48.200; pursuant to RCW 43.70.250, 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.

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Program components (continued)

- (b) The department shall not impose any fees in excess of its actual administrative, oversight, and enforcement costs. The fees collected from each program operator in calendar year 2020 and any subsequent year may not exceed ten percent of the program's annual expenditures as reported to the department in the annual report required by RCW 69.48.100 and determined by the department. (c) Adjustments to the department's fees may be made annually and shall not exceed actual administration, oversight, and enforcement costs. Adjustments for inflation may not exceed the percentage change in the consumer price index for all urban consumers in the United States as calculated by the United States Department of Labor as averaged by city for the twelve-month period ending with June of the previous year.
- (d) The annual fee set by the department shall be evenly split amongst each approved program operator.
- (e) The department shall collect annual operating fees from each program operator by October 1, 2019, and annually thereafter.
- (f) Between July 25, 2021, and January 1, 2024, the department shall collect a nonrefundable one-time fee of \$157,000 for review of proposals from each potential program operator applicant as provided in RCW 69.48.050.
- (2) All fees collected under this section must be deposited in the secure drug take-back program account established in RCW 69.48.130.

69.48.130 - Secure Drug Take-back Program Account.

The secure drug take-back program account is created in the state treasury. All receipts received by the department under this Chapter must be deposited in the account. Moneys in the account may be spent only after appropriation. Expenditures from the account may be used by the department only for administering and enforcing this Chapter.

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.

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Program components (continued)

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 Chapter 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 Chapter, and the legislature neither exempts nor provides immunity for such activities.

69.48.150 - Federal Law, Effect On This Chapter.

This Chapter is void if a federal law, or a combination of federal laws, takes effect that establishes a national program for the collection of covered drugs that substantially meets the intent of this Chapter, including the creation of a funding mechanism for collection, transportation, and proper disposal of all covered drugs in the United States.

69.48.160. Local Ordinances--Grandfathering--Preemption.

- (1)(a) For a period of twelve months after a drug take-back program approved under RCW 69.48.050 begins operating, a county may enforce a grandfathered ordinance. During that twelve-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 Chapter with respect to that county.
- (b) In any county enforcing a grandfathered ordinance as described in (a) of this subsection, the program operator of an approved drug take-back program must work with the county and the department to incorporate the local program into the approved drug take-back program on or before the end of the twelve-month period.
- (2) After June 7, 2018, 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.
- (3) At the end of the twelve-month period provided in subsection
- (1) of this section, this Chapter preempts all existing or future laws enacted by a county, city, town, or other political subdivision of the state regarding a drug take-back program or other program for the collection, transportation, and disposal of covered drugs, or promotion, education and public outreach relating to such a program.

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Program components (continued)

(4) For purposes of this section, "grandfathered ordinance" means a pharmaceutical product stewardship or drug take-back ordinance that: (a) Is in effect on June 7, 2018; and (b) the department determines meets or exceeds the requirements of this Chapter with respect to safe and secure collection and disposal of unwanted medicines from residents, including the types of drugs covered by the program, the convenience of the collection system for residents, and required promotion of the program.

69.48.170 - Public Disclosure.

Proprietary information submitted to the department under this Chapter is exempt from public disclosure under RCW 42.56.270. The department may use and disclose such information in summary or aggregated form that does not directly or indirectly identify financial, production, or sales data of an individual covered manufacturer or drug take-back organization.

69.48.180 - Rule making.

69.48.190 - Report to Legislature.

- (1) No later than thirty days after the department first approves a drug take-back program under RCW 69.48.050, the department shall submit an update to the legislature describing rules adopted under this Chapter and the approved drug take-back program.
- (2) By November 15th after the first full year of operation of an approved drug take-back program and biennially thereafter, the department shall submit a report to the legislature. The report must:
- (a) Describe the status of approved drug take-back programs;
- (b) Evaluate the secure medicine collection and disposal system and the program promotion, education, and public outreach requirements established by this Chapter;
- (c) Evaluate, in conjunction with an academic institution that is not an agency of the state and is qualified to conduct and evaluate research relating to prescription and nonprescription drug use and abuse and environmental impact, to the extent feasible, the impact of approved drug take-back programs on: Awareness and 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. To conduct this evaluation, the department

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Program components (continued)	and the academic institution may rely on available data sources, including the public awareness surveys required under this Chapter, and the prescription drug monitoring program and public health surveys such as the Washington state healthy youth survey. The department and the academic institution may also consult with other state and local agencies and interested stakeholders; and (d) Provide any recommendations for legislation. 69.48.200 - Survey (Expires July 1, 2026). (1)(a) The department shall contract with the statewide program of poison and drug information services identified in RCW 18.76.030 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 Chapter have led to statistically significant changes in: (i) Resident attitudes and behavior on safe storage and secure disposal of prescription and nonprescription medications used in the home; and (ii) the rates of abuse or misuse of or accidental exposure to prescription and nonprescription drugs. (b) The survey of residents must include telephone follow-up with users of the program's emergency telephone service. The survey must be conducted before the secure medicine collection and disposal system is implemented and again no earlier than four years after the system is implemented and again no earlier than four years after the system is implemented. (2) The statewide program of poison and drug information services shall report the survey results to the legislature and the Department of Health within six months of completion of the survey. (3) This section expires July 1, 2026. 2022 WA REG TEXT 603324 (NS) 2022 WA REG TEXT 603324 (NS) 2022 WA REG TEXT 603324 (NS)(Effective January 5, 2022).	
Miscellaneous provisions	N/A	
Recently proposed	No.	
legislation		

WEST VIRGINIA	
Statute(s) and regulation(s)	W. VA. CODE St. R. § 11-5-8 (West)(2021).
Does the state allow drug take-back programs by statute/regulation?	Yes.
Program components	W. VA. CODE ST. R. § 11-5-8.
	Returned or Surrendered Drugs; Authorization and Procedures for Destruction; Prohibition on Reuse.
	8.1. In accord with current federal Drug Enforcement Agency (DEA) regulations, licensees of the Board are prohibited from accepting unused and/or unwanted controlled substances from or on behalf of patients.
	8.2. A licensee may refer individuals in lawful possession of unwanted and unused controlled substances and who are seeking disposal assistance to:
	8.2.a. Entities which are registered with the Drug Enforcement Agency (DEA) as authorized collectors to receive the transfer from ultimate users of any unwanted and unused pharmaceutical controlled substances in their lawful possession for safe, secure, and responsible disposal pursuant to 21 C.F.R. § 1317.40;
	8.2.b. Local law enforcement operating federally authorized take-back events, mail-back programs, or collection receptacles; and/or 8.2.c. The DEA website for information regarding proper methods of self-disposal by the lawful possessor.
	8.3. 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.
	8.4. The disposal of returned or surrendered prescription drugs shall occur promptly, and no later than thirty days after receipt.
	8.5. Until disposed of, returned or surrendered prescription drugs shall be stored in a locked or otherwise secure area to prevent access by unauthorized individuals.
	8.6. Returned or surrendered prescription drugs may not be stored with a practitioner's office use or dispensing inventory.

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<u>WEST VIRGINIA</u>	
Program components (continued)	8.7. A licensee who accepts returned or surrendered prescription drugs shall maintain a log which lists:
	8.7.a. The name of the patient to whom the retuned or surrendered drug was dispensed;
	8.7.b. The strength of the returned or surrendered drug;
	8.7.c. The quantity returned or surrendered;
	8.7.d. The date and manner of disposal; and
	8.7.e. The printed name and signature of the individual who actually disposed of the drug.
	8.8. Logs required by subsection 8.7 must be maintained for a period of two years after disposal of the returned or surrendered prescription drug.
	8.9. A practitioner may not dispense, administer or reuse any returned or surrendered drug unless such dispensing, administering or reuse occurs pursuant to a prescription drug donation program established by this state.
Miscellaneous provisions	W. VA. CODE ANN. § 60B-1-6 (West)(2022).
	60B-1-6. Dispensing and distribution of donated drugs.
	Donated drug may be dispensed to patients pursuant to the requirements of the statute.
Recently proposed	No.
legislation	

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<u>WISCONSIN</u>	
Statute(s) and regulation(s)	WIS. STAT. ANN. § 165.65 (West)(2015).
Does the state allow drug take-back programs by statute/regulation?	Yes.
Program components	Wis. Stat. Ann. § 165.65.
	Drug Disposal Program.
	(1) Definitions. In this section: (a) "Authorized under federal law" means permitted under 21 USC 801 to 971 or 21 CFR 1300 to 1321. (am) "Controlled substance" has the meaning given in s. 961.01(4).
	["Controlled substance" means a drug, substance or immediate precursor included in schedules I to V of SUBCH. II. WIS. STAT. ANN. § 961.01(4)(West)(2021)].
	(b) "Controlled substance analog" has the meaning given in s. 961.01(4m).
	[Controlled substance analog" means a substance the chemical structure of which is substantially similar to the chemical structure of a controlled substance included in schedule I or II and: 1. Which has a stimulant, depressant, narcotic or hallucinogenic effect on the central nervous system substantially similar to the stimulant, depressant, narcotic or hallucinogenic effect on the central nervous system of a controlled substance included in
	schedule I or II; or 2. With respect to a particular individual, which the individual represents or intends to have a stimulant, depressant, narcotic or hallucinogenic effect on the central nervous system substantially similar to the stimulant, depressant, narcotic or hallucinogenic effect on the central nervous system of a controlled substance included in schedule I or II.
	 (b) "Controlled substance analog" does not include: 1. A controlled substance; 2. A substance for which there is an approved new drug application; 3. A substance with respect to which an exemption is in effect for
	investigational use by a particular person under 21 USC 355 to the extent that conduct with respect to the substance is permitted by the exemption; or

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- 4. Any substance to the extent not intended for human consumption before an exemption takes effect with respect to the substance. (c) "Drug disposal program" 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.
- (d)1. Except as provided under subd. 2., "household pharmaceutical item" 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. A drug, as defined in s. 450.01(10); a prescription drug, as defined in s. 450.01(20); or a controlled substance or controlled substance analog, if the drug, prescription drug, or controlled substance or controlled substance analog is located in or comes from a place where the individual, a member of the individual's household, an in-home hospice service, or an adult family home serving fewer than 5 adult members manages the use of the drug, prescription drug, or controlled substance or controlled substance analog.
- b. A device, as defined in s. 450.01(6), or an object used for administering a drug, if the device or object is located in or comes from a place where the individual, a member of the individual's household, an in-home hospice service, or an adult family home serving fewer than 5 adult members manages the use of the device or object.
- 2. "Household pharmaceutical item" does not include any of the following:
- a. Any item that may be contaminated with antineoplastic chemotherapy drugs, including objects used to administer drugs, gloves, and other items that have come into contact with chemotherapy drugs.
- b. Any item containing elemental mercury.
- (e) "Political subdivision" means a city, village, town, or county.
- (2) Department of Justice authorization to operate a drug disposal program. (a) Except as provided under sub. (3), no person may receive household pharmaceutical items pursuant to a drug disposal program unless the Department of Justice grants written authorization for that program under par. (b) or the program is authorized under federal law.

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- (b) 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 sub. (5). 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 and procedures if the Department of Justice 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. If the Department of Justice disapproves the policies and procedures, the Department of Justice shall state the reasons for that disapproval in writing to the person. At any time, the person may resubmit revised policies and procedures to the Department of Justice for its review and approval under this subdivision.

 2. If the drug disposal program will receive household
- 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.
- (c) A person may not revise policies and procedures approved by the Department of Justice under par. (b)1. unless the Department of Justice approves the revisions under par. (b)1.
- (d) Any determination or action by the Department of Justice under par. (b) or (c) is not subject to judicial review.
- (3) Authorization by a political subdivision to operate a drug disposal program. A political subdivision 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, except as provided under sub. (4).
- (b) The applicable requirements under sub. (5) are satisfied.
- (c) The drug disposal program receives household pharmaceutical items only by 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.

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- (4) Multijurisdictional drug disposal program. A drug disposal program may operate within more than one political subdivision if the Department of Justice authorizes that program under sub. (2), all political subdivisions within which the drug disposal program operates authorize that program under sub. (3), or the program is authorized under federal law.
- (5) Operation of a drug disposal program.
- (a) A person that operates a drug disposal program, except a drug disposal program that is 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 may be received under the program, whether the program may receive controlled substances and controlled substance analogs, whether household pharmaceutical items will be transferred by mail under the program, and the locations at which household pharmaceutical items may be transferred in person under the program.
- 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.
- 3. Ensure compliance with Chs. 450 and 961; with any applicable provision under Chs. 287, 289, and 291 and s. 299.51 relating to medical waste, solid waste, or hazardous waste; and with any other applicable federal or state law.
- (b)1. The policies and procedures for a drug disposal program authorized under sub. (2) and any changes to those policies and procedures are subject to review and approval under sub. (2)(b)1. 2. Legal counsel for the political subdivision, or, at the discretion of the political subdivision, the Department of Justice if the political subdivision's legal counsel is not an employee of the political subdivision, shall review and either approve or disapprove the policies and procedures for a drug disposal program implemented or authorized under sub. (3) and any changes to those policies and procedures. Legal counsel, or the Department of Justice if appropriate, shall approve the policies and procedures or changes if it determines that the policies and procedures or changes do not violate the requirements of this section or any other applicable federal or state law, and shall disapprove them otherwise. Any approval under this subdivision shall be in writing. The political subdivision shall provide a copy of the approval and a copy of the policies and procedures or changes to the policies and procedures to the Department of Justice.

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Program components (continued)	(c) The operation of a drug disposal program, including a drug disposal program that is authorized under federal law, shall immediately cease if a law enforcement officer, as defined in s. 165.85(2)(c), a federal law enforcement officer, as defined in s. 175.40(7)(a)1., 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 federal or state law. (d) Each person that operates a drug disposal program in this state shall, within 30 days after the drug disposal program begins operation, notify and provide all of the following information to the Department of Natural Resources: 1. The location and hours of operation of the drug disposal program. 2. 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. 3. A description of the household pharmaceutical items the drug disposal program may receive. (6) Transfer and receipt of household pharmaceutical items. (a) Notwithstanding ss. 450.03(1) and 450.11(7)(g) and (h) and (9)(b), a person that lawfully possesses a household pharmaceutical item may transfer, and it is not a crime for such a person to transfer, the household pharmaceutical item to a drug disposal program if the program is authorized under sub. (2) or (3) or is authorized under federal law. (b) Notwithstanding s. 450.11(7)(g) and (h) and (9)(b), a person may receive, and it is not a crime for a person to possess, a household pharmaceutical item pursuant to a drug disposal program if the program is authorized under sub. (2) or (3) or is authorized under federal law or, if the r
Miscellaneous provisions	N/A
Recently proposed	No.
legislation	

<u>WYOMING</u>	
Statute(s) and regulation(s)	Wyo. Stat. Ann. §§ 35-7-1601 - 35-7-1606 (West)(2005).
Does the state allow drug take-back programs by statute/regulation?	Yes.
Program components	Wyo. Stat. Ann. §§ 35-7-1601 - 35-7-1606.
	Article 16. Drug Donation Program.
	§ 35-7-1601 - Short Title.
	§ 35-7-1602 – Definitions.
	§ 35-7-1603 - Drug Donation, Redispensing and Disposal Program Established; Minimum Requirements.
	(a) The department shall establish pursuant to its rules and regulations a voluntary drug donation and disposal program as provided in this section.
	(b) The drug donation and redispensing program shall have the following features:
	(i) Any person or entity, including but not limited to a drug manufacturer, physician or health care facility, may donate drugs to the drug donation program;
	(ii) Drugs may be donated at a donation site maintained by the department, a take back event approved by the United States drug enforcement agency or at a physician's office, a pharmacy or a health care facility that elects to participate in the program and meets criteria established by the department;
	(iii) Drugs shall be redispensed under the drug donation program only if they are in their original, unopened, sealed packaging or, if the outside packaging is opened, the contents are single unit doses that are individually contained in unopened, tamper evident packaging;
	(iv) A drug shall not be redispensed within two (2) months of its expiration date or if the drug appears to be adulterated or misbranded in any way;
	(v) Drugs in the donation program may be dispensed under the Medical Assistance and Services Act; (vi) Drugs shall be delivered either to the department's central collection facility, a take back event approved by the United States drug enforcement agency or one (1) of its regional collection facilities;

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- (vii) Drugs available for redispensing shall be inventoried and posted on a list of drugs available for redispensing on the department's internet website;
- (viii) The department shall provide access to computer systems and technical assistance to aid individuals in applying for government and private prescription drug programs and discounts.
- (c) To the extent authorized by applicable federal law, the drug drop off and disposal program shall have the following features:
- (i) Drop off locations shall be located with donation sites as provided in paragraph (b)(ii) of this section or local law enforcement agencies approved by the United States drug enforcement agency to the extent necessary under federal law;
- (ii) Procedures shall be maintained for the documentation of all collected unused medication;
- (iii) Procedures shall be maintained for the environmentally safe disposal of unused medications;
- (iv) 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;
- (v) 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.
- § 35-7-1604 Program Participants.
- (a) A physician, pharmacy or health care facility that accepts donated drugs under the drug donation program shall comply with all applicable provisions of state and federal law relating to the storage, distribution and dispensing of such drugs and shall inspect all donated drugs prior to dispensing to determine if they appear to be adulterated or misbranded in any way.
- (b) Donated drugs may be distributed to another participating physician, pharmacy or health care facility for dispensing
- (c) Donated drugs shall only be dispensed to a patient pursuant to prescription as required by law.
- (d) A physician, pharmacy or health care facility may charge a handling fee for distributing or dispensing drugs under the drug donation program, as established by department rules and regulations, but shall not otherwise resell or charge for donated drugs.

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Program components (continued)	§ 35-71605 - Participant Immunity.
	 (a) In the absence of bad faith, any person who participates in donating, accepting, distributing or dispensing drugs under this act and in accordance with federal law shall be immune from civil or criminal liability or professional disciplinary action of any kind for any related injury, death or loss. No person, in the absence of bad faith, shall be liable for the bad faith of another relating to the provisions of this act. (b) The immunity provided by this section shall not decrease or increase the civil or criminal liability of a drug manufacturer, distributor or dispenser that would have existed but for the donation.
	§ 35-7-1606 - Rules and Regulations; Agency Cooperation.
	(a) The department, in cooperation with the Wyoming Board of Pharmacy, shall promulgate rules and regulations implementing the drug donation program established by this act. Initial rules shall be promulgated within ninety (90) days after the effective date of this act and shall include: (i) Eligibility criteria and other standards and procedures for participating physicians and health care facilities; (ii) Necessary forms for administration of the drug donation program, including forms for persons donating, accepting, distributing or dispensing drugs under the program; (iii) Maximum handling fees; (iv) Categories of drugs that the program will and will not accept.
Miscellaneous provisions	from approved collection sites to a disposal location. WYO. STAT. ANN. § 2-1-501 (West)(2016).
	A person is authorized to collect any controlled substances of the decedent for purposes of disposal in accordance with 21 C.F.R. part 1317.30 and 21 C.F.R. part 1317.35. WYO. STAT. ANN. § 35-7-1603 (West)(2018).
	Establishes the creation of the state's voluntary drug donation and disposal program.
Recently proposed legislation	No.

TRIBAL (EASTERN BAND OF CHEROKEE INDIANS)	
Statute(s) and regulation(s)	No.
Does the state allow drug take-back programs by statute/regulation?	N/A
Program components	N/A
Miscellaneous provisions	EASTERN BAND CHEROKEE INDIANS CODE SEC. 14–95.34(c)(West)(updated June 2010); see also EASTERN BAND CHEROKEE INDIANS, ORD. No. 589, ART. II, 2-8-2007 (Municode)(current through Nov. 4, 2021). Sec. 14-95.34 Restitution; Civil liability. (c)When any person is convicted of an offense under this Article involving the manufacture of controlled substances, the court must order the person to make restitution for the actual cost of cleanup to the law enforcement agency that cleaned up any clandestine laboratory used to manufacture the controlled substances, including personnel overtime, equipment, and supplies.
Recently proposed legislation	No.

<u>GUAM</u>	
Statute(s) and regulation(s)	No.
Does the state allow drug take-back programs by statute/regulation?	N/A
Program components	N/A
Miscellaneous provisions	G.C.A. § 5103. Updated Through P.L. 36–098 (May 13, 2022). The statute creates a medicine bank which will be a repository for the donated pharmaceuticals and health care supplies that will be distributed to community health centers and government owned medical facilities.
Recently proposed legislation	No.

NORTHERN MARIANA ISLANDS	
Statute(s) and regulation(s)	No.
Does the state allow drug take-back programs by statute/regulation?	N/A
Program components	N/A
Miscellaneous provisions	N/A
Recently proposed legislation	No.

<u>PUERTO RICO</u>	
Statute(s) and regulation(s)	No.
Does the state allow drug take-back programs by statute/regulation?	N/A
Program components	N/A
Miscellaneous provisions	N/A
Recently proposed legislation	No.

<u>VIRGIN ISLANDS</u>	
Statute(s) and regulation(s)	No.
Does the state allow drug take-back programs by statute/regulation?	N/A
Program components	N/A
Miscellaneous provisions	N/A
Recently proposed legislation	No.

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.

