

LEGISLATIVE ANALYSIS AND PUBLIC POLICY ASSOCIATION

# MODEL DRUG TAKE-BACK AND DISPOSAL PROGRAM ACT

JUNE 2023



This project was supported by Grant No. G21990NDCP03A awarded by the Office of National Drug Control Policy. Points of view or opinions in this document are those of the author and do not necessarily represent the official position or policies of the Office of National Drug Control Policy or the United States Government. Research current as of January 2023.

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## *ACKNOWLEDGMENTS*

The Legislative Analysis and Public Policy Association (LAPPA) is grateful to the Office of National Drug Control Policy for its support in funding, enabling, and contributing to this Model Act.

This Model Act could not have been developed without the valuable input of the Model Drug Take-back and Disposal Program Act working group. LAPPA wishes to thank its distinguished members, many of whom are listed below, for providing their expertise, guidance, and suggestions that contributed to the model's development. The individuals and organizations that participated in the working group have not adopted, endorsed, or otherwise approved the contents of this document.

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# MODEL DRUG TAKE-BACK AND DISPOSAL PROGRAM ACT

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## SECTION I. SHORT TITLE.

This Act may be cited as the “Model Drug Take-back and Disposal Program Act,” “Model Act,” or “the Act.”

## SECTION II. LEGISLATIVE FINDINGS AND PURPOSE.

(a) Legislative findings.—The [legislature]<sup>1</sup> finds that:

- (1) The United States is in the midst of an unprecedented drug epidemic;
- (2) An estimated 109,179 Americans died from a fatal drug overdose during 2021, an increase of roughly 16 percent from the 93,655 deaths estimated in 2020;<sup>2</sup>
- (3) Access to unused, expired, and unwanted drugs, particularly controlled substances, by individuals to whom they are not prescribed provides an opportunity for the misuse of these medications;
- (4) The specific quantity of unused, expired, and unwanted drugs that are within American homes is unknown; however, research indicates that the number of unused drugs is substantial, with two-thirds of the nearly four billion prescription drugs in the United States going unused and becoming waste;<sup>3</sup>
- (5) The U.S. Drug Enforcement Administration (DEA) estimates that at its October 2022 National Prescription Drug Take-back Day, it collected just under 650,000 pounds of unneeded drugs at approximately 5,000 collection sites nationwide.<sup>4</sup> Since the inception of the semiannual Take-back Day events, the agency has collected nearly 16,000,000 pounds of drugs for disposal in collaboration with government, community, public health, and law enforcement partners;<sup>5</sup>

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<sup>1</sup> This Act contains certain bracketed words and phrases (e.g., “[legislature]”). Brackets indicate instances where state lawmakers may need to insert state-specific terminology or facts.

<sup>2</sup> *Provisional Drug Overdose Death Counts*, CTRS. FOR DISEASE CONTROL & PREVENTION, [Products - Vital Statistics Rapid Release - Provisional Drug Overdose Data \(cdc.gov\)](https://www.cdc.gov/products-vital-statistics/rapid-release-provisional-drug-overdose-data) (last reviewed April 12, 2023).

<sup>3</sup> See *The Dangers of Leftover Medication*, PROD. STEWARDSHIP INST. (accessed Feb. 3, 2022), [https://www.productstewardship.us/page/Dangers\\_Leftover\\_Med](https://www.productstewardship.us/page/Dangers_Leftover_Med); and Anandi V. Law et al., *Taking Stock of Medication Wastage: Unused Medications in US households*, 4 RES. SOC. ADM. PHARM. 571-578 (2014), <https://pubmed.ncbi.nlm.nih.gov/25487420/>.

<sup>4</sup> *DEA Teams up with more than 4,300 Partners to Remove Unneeded Prescription Medications from Communities*, <https://www.dea.gov/press-releases/2022/11/14/dea-teams-more-4300-partners-remove-unneeded-prescription-medications>, DRUG ENF’T ADMIN. (Nov. 14, 2022),

<sup>5</sup>*Id.*

- (6) According to the National Survey on Drug Use and Health, 9.3 million people misused prescription pain relievers in 2020;<sup>6</sup>
- (7) Unused, expired, and unwanted drugs that are improperly disposed of can end up in ecosystems, public waterways, and sources of drinking water and potentially harm humans and marine and animal life;<sup>7</sup> and
- (8) Per the U.S. Food and Drug Administration, the best way to dispose of unused, expired, and unwanted drugs is drug take-back and disposal programs.<sup>8</sup>

(b) Purpose.—It is the intent of the Legislature through this Act to:

- (1) Establish a comprehensive and uniform statewide system for the safe and convenient collection and disposal of unused, expired, and unwanted drugs;
- (2) Require that covered manufacturers implement drug take-back and disposal programs within the state;
- (3) Designate [state agency or department] to oversee a statewide system of drug take-back programs;
- (4) Require that covered manufacturers that sell their product into and within the state pay an annual fee to the [designated agency or department] to help cover costs related to implementing the provisions of this Act and overseeing drug take-back programs within the state for safety and compliance;
- (5) Promote public outreach that educates residents on the inherent risks of unused, expired, and unwanted drugs; the potential harm to the environment posed by improper drug disposal; and the options for collection and disposal of drugs available within the state; and
- (6) Ensure that state drug take-back and disposal programs operate in an efficient manner that prioritizes the safe and secure disposal of drugs.

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<sup>6</sup> *Highlights for the 2020 National Survey on Drug Use and Health*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS. (November 11, 2022), [https://www.samhsa.gov/data/sites/default/files/2021-10/2020\\_NSDUH\\_Highlights.pdf](https://www.samhsa.gov/data/sites/default/files/2021-10/2020_NSDUH_Highlights.pdf).

<sup>7</sup> U.S. ENV'T PROT. AGENCY, CONTAMINANTS OF EMERGING CONCERN INCLUDING PHARMACEUTICALS AND PERSONAL CARE PRODUCTS (2020).

<sup>8</sup> *Where and How to Dispose of Unused Medicines*, U.S. FOOD & DRUG ADMIN. (last updated April 21, 2021), <https://www.fda.gov/consumers/consumer-updates/where-and-how-dispose-unused-medicines>.

## Commentary

Unused, expired, and unwanted drugs are a danger to public health. While research cannot ascertain the amount of these drugs that are in U.S. homes, research does indicate that proximity to these drugs creates opportunities for misuse.<sup>9</sup> In a study of the *2015 National Survey on Drug Use and Health*, researchers found that almost half of all prescription drug misuse began when the individual consumed drugs not prescribed to him or her.<sup>10</sup> Usually, the drugs were prescribed to a friend or family member.<sup>11</sup> Children and adolescents are also vulnerable to the availability of unused, expired, and unwanted drugs.<sup>12</sup> The impact of unused, expired, and unwanted drugs reaches beyond the drug epidemic, as improperly disposed of drugs can also be dangerous to the environment. Research indicates that continuous exposure to even trace amounts of drugs from drinking water and other environmental sources can have a harmful impact on humans and marine and animal life.<sup>13</sup>

This Act provides state legislators and policymakers with a framework for the implementation and administration of drug take-back and disposal programs that provides a safe way for residents of the state to dispose of their unused, expired, and unwanted drugs. This Act also requires covered manufacturers, as defined in the Act, to fund and operate drug take-back programs statewide to collect and dispose of controlled substances, prescription drugs, non-prescription drugs, and veterinary drugs for household pets and livestock.

This Model Act is intended to serve as a legislative guide and is based on the principles of product stewardship. Product stewardship is a concept that the manufacturer has the greatest ability to minimize adverse impacts caused by its products and product disposal.<sup>14</sup> Other stakeholders, such as suppliers, retailers, and consumers, also play important roles under the product stewardship system.<sup>15</sup> Stewardship can be either voluntary or required by law.<sup>16</sup> In essence, “[p]roduct 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.”<sup>17</sup> Legislators have enacted product stewardship laws that establish systems for disposal, or recycling and disposal, of electronics and other consumer products.<sup>18</sup> In addition, as of October 2022, California, Illinois, Massachusetts, Maine, New

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<sup>9</sup> Beth Han et al., *Prescription Opioid Use, Misuse, and Use Disorders in U.S. Adults: 2015 National Survey on Drug Use and Health*, 167 ANNALS INTERNAL MED. 5, 293-301 (Sept. 2017), <https://www.doh.wa.gov/Portals/1/Documents/2300/2017/AnnalsInternalMed.pdf>.

<sup>10</sup> *Id.*

<sup>11</sup> *Id.*, see also Julia Gaither, Veronika Shabanova, & John Leventhal, *US National Trends in Pediatric Deaths from Prescription and Illicit Opioids, 1999-2016*, 1 JAMA NETWORK OPEN 8 (Dec. 2018), <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2719580>.

<sup>12</sup> Gaither, *supra* note 13.

<sup>13</sup> *Contaminants of Emerging Concern Including Pharmaceuticals and Personal Care Products*, *supra* note 9.

<sup>14</sup> *What is Product Stewardship?* PROD. STEWARDSHIP (accessed Nov. 18, 2021), <https://www.productstewardship.us/page/Definitions>.

<sup>15</sup> *Id.*

<sup>16</sup> *Id.*

<sup>17</sup> *Id.*

<sup>18</sup> *Product Stewardship*, NAT’L CONF. STATE LEGIS. (Mar. 18, 2020), <https://www.ncsl.org/research/environment-and-natural-resources/product-stewardship.aspx>.

York, Oregon, Vermont, and Washington require drug manufacturers to fund programs for the collection and ultimate disposal of unused, expired, and unwanted drugs.<sup>19</sup>

The drafters of this Act took inspiration for substantive portions of this Act from drug disposal laws in Washington State and, to a lesser extent, Oregon. Both states recently enacted legislation that requires drug manufacturers who sell drugs into and within the states to pay for and operate drug take-back and disposal programs.<sup>20</sup> Under these laws, a designated state agency is responsible for the administration and oversight of the system or network of drug take-back programs within each state. Pursuant to the provisions of this Act, a covered manufacturer may implement a drug take-back program: (1) independently; (2) as part of a group of manufacturers; or (3) through a drug take-back organization. Covered manufacturers typically join a Producer Responsibility Organization (PRO) which implements the program. The PRO assesses fees to members to cover the cost of the program, including the state's administrative costs. In the states of Oregon and Washington, the PRO acts as a drug take-back organization under the working group name Medication Education and Disposal Project (MED-Project) and is comprised of pharmaceutical manufacturers operating within the states.<sup>21</sup>

In July 2021, MED-Project released its *2020 MED-Project Annual Report for the State of Washington*, which provided information on covered activities in the jurisdiction between May 25, 2020 and December 31, 2020.<sup>22</sup> The information provided by PROs provides an opportunity to gauge the costs and fees of administering and running a drug take-back and disposal program from the perspective of program operators. The report detailed various expenditures for MED-Project which included \$1,064,000 for administrative costs, \$1,145,000 for collection and disposal costs, and \$427,000 in communication costs.<sup>23</sup> In total, MED-Project estimates that expenditures totaled \$2,636,000 for that period.<sup>24</sup> In Washington, one study found that the

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<sup>19</sup> CAL. PUB. RES. CODE § 42032.2 (West 2022); CAL. CIV. CODE § 1714.24 (West 2022); 410 ILL. COMP. STAT. ANN. 720/1 – 720/999 (West)(2022); MASS. GEN. LAWS ANN. ch. 94H, § 6 (West 2022); ME. REV. STAT. tit. 38, § 1612 (West)(2021); N.Y. COMP. CODES R. & REGS. tit. 10, § 60-4.4 (West 2022); VT. STAT. ANN. tit. 33, § 2004 (West 2022); OR. REV. STAT. ANN. § 459A.200 (West 2022); and WASH. REV. CODE ANN. § 69.48.010 (West 2022). Under Massachusetts law, for the year 2017, the first year that the state's drug take-back program was in effect, all manufacturers who produced or sold Schedule II or Schedule III drugs within the state were required to participate in the program pursuant to the provisions provided in the statute. However, beginning January 1, 2018, manufacturers are allowed to work with the state to come up with an alternative to participation in the drug take-back program pursuant to MASS. GEN. LAWS ANN. ch. 94H, § 6 (West 2022).

<sup>20</sup> WASH. REV. CODE ANN. Ch. 69.48, Refs & Annos (West 2022)

<sup>21</sup> *What Should You Do with Your Unwanted and Expired Medications*, MED-PROJECT (accessed October 3, 2022), <https://med-project.org/>.

<sup>22</sup> *2020 MED-Project Annual Report: State of Washington*, MED-PROJECT WA, LLC 75 (July 1, 2021), <https://doh.wa.gov/sites/default/files/2022-02/MED-ProjectAnnualReport2020.pdf>.

<sup>23</sup> *Id.* Administrative costs included \$342,000 paid to the state of Washington in administrative fees, employee overhead, legal fees, licensing fees, local, state and federal taxes, property costs, utilities, phone, internet, and general equipment and supplies. Collection and disposal costs included the collection, transportation, and disposal of drugs, purchase, maintenance, and replacement of collection receptacles, compensation of authorized collectors, contracted and employed personnel costs associated with collection and disposal, and production, distribution, and postage of mailers. Finally, communication costs included advertising, marketing, employee costs associated with communication, and operation of a toll-free call center.

<sup>24</sup> *Id.*



estimated cost to drug manufacturers to participate in and administer drug take-back programs within the state would be 0.1 percent of annual medicine sales in the State of Washington.<sup>25</sup>

There have been legal challenges to product stewardship laws which allege that stewardship-based drug disposal laws are unconstitutional, but those challenges have been unsuccessful in court. *Pharmaceutical Research and Manufacturers of America v. County of Alameda* and *Pharmaceutical Research and Manufacturers of America v. King County* are illustrative of both the constitutional concerns raised by drug manufacturers and the current resolution by the courts on this matter.<sup>26</sup> In 2012, the County of Alameda, California created what was, at the time, a first-in-the-nation approach to the disposal of unused prescription drugs.<sup>27</sup> Alameda County's "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 county's drug disposal program.<sup>28</sup> The ordinance exempted retail pharmacies and forbade drug producers from passing on the cost of the program to consumers by adding a fee at the point of sale.<sup>29</sup> In 2013, the Board of Health of King County, Washington passed a similar ordinance which allowed consumers to return both prescription and over-the-counter drugs and also required drug manufacturers to fund the drug disposal program.<sup>30</sup>

The Pharmaceutical Research and Manufacturers of America, the Generic Pharmaceutical Association, and the Biotechnology Industry Association<sup>31</sup> filed separate lawsuits in federal court against Alameda County and King County.<sup>32</sup> In both cases, the plaintiffs argued that the ordinances presented an unconstitutional burden on interstate commerce and, thus, violated the dormant commerce clause of the U.S. Constitution.<sup>33</sup> In the case against Alameda County, the District Court of Northern California, and later the U.S. Court of Appeals for the Ninth Circuit, upheld the county's ordinance.<sup>34</sup> In its opinion affirming the district court's denial of summary judgment on behalf of the plaintiffs, the Ninth Circuit found that the ordinance did not control

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<sup>25</sup> *WA Secure Drug Take-back Act*, CMTY. ENV'T. STRATEGIES (visited Oct. 10, 2021), <https://www.cehstrategies.com/wa-drug-take-back-laws>.

<sup>26</sup> *Pharm. Rsch. & Mfrs. of Am. v. Cnty. of Alameda*, 768 F.3d 1037 (9th Cir. 2014) and *Pharm. Rsch. & Mfrs. of Am. v. King Cnty.*, No. 2:13-cv-2151 (W.D. Wash., Nov. 27, 2013).

<sup>27</sup> ALAMEDA, CAL., CODE §§ 6.53.010 to 6.53.120 (2012); see also Margaret Shield, Ph.D., *Pharmaceutical Stewardship Policy Update*, CMTY. ENV'T HEALTH STRATEGIES (Oct. 14, 2016), [https://www.cehstrategies.com/wp-content/uploads/2016/10/PharmStewardshipLawsStatus\\_CEHStrategies.pdf](https://www.cehstrategies.com/wp-content/uploads/2016/10/PharmStewardshipLawsStatus_CEHStrategies.pdf).

<sup>28</sup> ALAMEDA, CAL., CODE § 6.53.040 (2012).

<sup>29</sup> *Id.*

<sup>30</sup> *Secure Medicine Return Rule and Regulation*, KING CNTY., WASH. (Oct. 29, 2013), <http://www.kingcounty.gov/healthservices/health/BOH/MedicineTakeback.aspx>. King County's law also imposed more stringent performance standards on drug manufacturers. In 2016, Alameda County amended their drug-take back ordinance to mirror the standards enacted by King County.

<sup>31</sup> Compl. for Declaratory and Inj. Relief at 1, *Pharm. Rsch. & Mfrs. of Am. v. King Cnty.*, No. 2:13-cv-2151 (W.D. Wash. Nov. 27, 2013).

<sup>32</sup> *Pharm. Rsch. & Mfrs. of Am. v. Cnty. of Alameda*, 967 F. Supp. 2d 1339 (N.D. Cal. 2013); Compl. for Declaratory and Inf. Relief, No. 2:13-cv-2151 (W.D. Wash. Nov. 27, 2013).

<sup>33</sup> 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. CONST. art. 1, § 8, cl. 3.

<sup>34</sup> *Pharm. Rsch. & Mfrs. of Am. v. Cnty. of Alameda*, 967 F. Supp. 2d 1339 (N.D. Cal. 2013), *aff'd sub nom. Pharm. Rsch. & Mfrs. of Am. v. Cnty. of Alameda*, 768 F.3d 1037 (9th Cir. 2014).

conduct outside the boundaries of the county and, thus, did not discriminate against interstate commerce.<sup>35</sup> Further, the court held that the burden imposed by the ordinance did not clearly exceed the benefits to localities.<sup>36</sup> In response, the plaintiff, joined by the Chamber of Commerce of the United States and the Washington Legal Foundation, appealed to the Supreme Court of the United States, which declined to review the case.<sup>37</sup> Following the Supreme Court's decision to deny certiorari in the Alameda County case, the plaintiffs in the King County matter dismissed their case against the county.<sup>38</sup>

One member of the Model Act working group suggested that the drafters include an option for an alternative funding source for the state's drug take-back and disposal system. Specifically, the member suggested that the language of the Act provide the option of funding the drug take-back and disposal system using opioid settlement dollars. In the member's opinion, this would provide a viable, non-product stewardship option that could offer states the ability to expand access to permanent drug take-back programs. However, as state legislators and state policymakers allocate opioid settlement funds to various issues related to the opioid epidemic, funding for drug take-back and disposal programs may not make the cut. One of the goals of this Act is to provide for the long-term funding of statewide drug take-back and disposal programs by assigning the cost of administering and overseeing drug take-back programs to the originator, *i.e.*, covered manufacturers. Further, drug take-back and disposal programs that are funded by drug manufacturers appear to be gaining popularity, as indicated by the recent passage of product stewardship drug disposal laws in Illinois, Maine, New York, Oregon, Vermont, and Washington, all occurring in the last four years.<sup>39</sup>

Finally, this Act's drafters use the terms "drug take-back and disposal program" or "drug take-back" to describe the statewide system for the safe collection and disposal of ultimate users' prescription and non-prescription drugs. The term "drug take-back" is clear on its face, which will help laypeople understand the Act's purpose. In addition, using the term "drug take-back" mirrors the DEA's description of the various drug disposal and collection events that it oversees.<sup>40</sup> As used in the Act, drug take-back and disposal program is solely intended to encompass consumer drug take-back programs. Medications used in residential settings and other non-clinical settings and medications administered in a clinical setting are treated differently under state and federal law; thus, specifying that this Act applies solely to drugs used in the home or other non-clinical settings helps to clarify the scope of the proposed legislation.

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<sup>35</sup> 768 F.3d 1037 at 1046.

<sup>36</sup> *Id.*

<sup>37</sup> *Pharm. Rsch. & Mfrs. of Am. v. Cnty. of Alameda*, 575 U.S. 1034 (2015).

<sup>38</sup> *McDermott: Supreme Court Action Supports Safe Disposal of Unused Drugs*, KING CNTY. (June 25, 2015), <https://kingcounty.gov/council/news/2015/June/06-25-JMD-drugreturn.aspx>.

<sup>39</sup> 410 ILL. COMP. STAT. ANN. 720/1 – 720/999 (West 2022); ME. REV. STAT. ANN. tit. 38, § 1612 (West 2022); N.Y. COMP. CODES R. & REGS. tit. 10, § 60-4.4 (2021); OR. REV. STAT. ANN. § 459A.200 (West 2022); VT. STAT. ANN. tit. 33, § 2004 (West 2022); and WASH. REV. CODE ANN. § 69.48.010 (West 2022).

<sup>40</sup> *DEA Heads First-ever Nationwide Prescription Drug Take-back Day*, U.S. DEP'T OF JUST. (Aug. 29, 2010), <https://www.justice.gov/opa/pr/dea-heads-first-ever-nationwide-prescription-drug-take-back-day>.

**SECTION III. DEFINITIONS.**

*[States may already have definitions in place for some or all of the following terms. In such case, states may use the existing definitions in place of those listed below.]*

For purposes of this Act, unless the context clearly indicates otherwise, the words and phrases listed below have the meanings given to them in this section:<sup>41</sup>

- (a) Authorized collector.—“Authorized collector” has the same meaning as in 21 C.F.R. 1317.40 and includes the following persons or entities that have entered into an agreement with a program operator to collect covered drugs:
- (1) 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;
  - (2) A law enforcement agency; or
  - (3) An entity authorized by the state to provide an alternative collection mechanism for certain covered drugs that are not controlled substances as defined by [insert citation to state’s controlled substances act];<sup>42</sup>
- (b) Collection site.—“Collection site” means the location where a program operator has installed a receptacle for collecting covered drugs;<sup>43</sup>
- (c) Controlled substance.—“Controlled substance” means a drug, substance, or immediate precursor included in the federal Controlled Substances Act, 21 U.S.C. § 812 or 21 C.F.R. § 1308, or the [state] Controlled Substances Act, [insert citation to state’s controlled substances act];
- (d) Covered drug.—“Covered drug” means a drug that a covered entity discards or abandons or that a covered entity intends to discard or abandon. Covered drug includes legend drugs and nonlegend drugs, brand names and generic drugs, drugs for veterinary use including drugs for household pets and livestock, and drugs in medical devices and combination products. Covered drug shall not include:
- (1) Vitamins, minerals, or supplements;

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<sup>41</sup> Where a definition is based on, or directly pulled from, language from an enacted statute, proposed legislation, or other research material, the footnote referenced at the end of the definition provides that source.

<sup>42</sup> WASH. REV. CODE ANN. § 69.48.020(2) (West 2022).

<sup>43</sup> WASH. REV. CODE ANN. § 69.48.020(3) (West 2022).

- (2) Herbal-based remedies and homeopathic drugs, products, or remedies;
  - (3) Controlled substances contained in Schedule I of the state’s controlled substances act as defined in subsection (c) of this section;
  - (4) 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. §§ 301 *et seq.*;
  - (5) 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. § 355-1;
  - (6) 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 of 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;
  - (7) Drugs that are administered in a clinical setting;
  - (8) Emptied injector products or emptied medical devices and their component parts or accessories;
  - (9) Exposed needles or sharps, or used drug products that are medical waste; or
  - (10) Pet pesticide products contained in pet collars, powders, shampoos, topical applications, or other forms.<sup>44</sup>
- (e) Covered entity.—“Covered entity” means a resident of the state, a nonbusiness entity located in the state, and an ultimate user as defined in 21 U.S.C. § 802(27). “Covered entity” shall not include an entity that generates pharmaceutical waste such as a hospital, healthcare provider’s office, veterinary clinic, pharmacy, or law enforcement agency that seizes drugs within the course of its work;<sup>45</sup>

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<sup>44</sup> WASH. REV. CODE ANN. § 69.48.020(4)(a) (West 2022).

<sup>45</sup> WASH. REV. CODE ANN. § 69.48.020(5) (West 2022).

- (f) Covered manufacturer.—“Covered manufacturer” means a person, corporation, or entity that manufactures covered drugs that are sold within or into the state. “Covered manufacturer” shall not include:
- (1) A private label distributor or retail pharmacy that sells a drug under that retail pharmacy’s store label, if the manufacturer is identified as such pursuant to the provisions of this Act;
  - (2) A manufacturer that solely repackages a drug; or
  - (3) A nonprofit, 501(c)(3) healthcare corporation that repackages drugs for the sole purpose of providing these drugs to facilities or retail pharmacies operated by the corporation or an affiliate of the corporation and is identified as such pursuant to the provisions of this Act;<sup>46</sup>
- (g) Department.—“Department” means the [state department of health or state department of environmental protection, whichever is chosen to have primary oversight of the system of drug take-back and disposal programs operating within the state];<sup>47</sup>
- (h) Drug.—“Drug” means:
- (1) Substances recognized as drugs in the official United States pharmacopoeia, official homeopathic pharmacopoeia of the United States, or official national formulary, or any supplement to any of them;
  - (2) Substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or animals;
  - (3) Substances other than food, minerals, or vitamins that are intended to affect the structure or any function of the body of human beings or animals; and
  - (4) Substances intended for use as a component of any item specified in paragraphs (1), (2), or (3) of this subsection;<sup>48</sup>
- (i) Drug take-back and disposal program.—“Drug take-back and disposal program,” “consumer drug take-back and disposal program,” “drug take-back program,” or

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<sup>46</sup> WASH. REV. CODE ANN. § 69.48.020(6) (West 2022).

<sup>47</sup> The State of Washington vests oversight of the drug take-back and disposal program with the Department of Health. WASH. REV. CODE ANN. § 69.48.020(7) (West 2022). By contrast, Oregon designated its Department of Environmental Quality as the department tasked with overseeing the state drug take-back program. OR. REV. STAT. ANN. § 459A.209 (West 2022).

<sup>48</sup> WASH. REV. CODE ANN. § 69.48.0209(8) (West 2022).

“program” means a program developed and implemented by a program operator for the collection, transportation, treatment, and disposal of covered drugs for which a plan has been approved;<sup>49</sup>

- (j) Drug take-back organization.—“Drug take-back organization” means an organization appointed by a covered manufacturer or a group of covered manufacturers to act as an agent of the covered manufacturer or group of covered manufacturers for the purpose of participating in or operating a drug take-back and disposal program;<sup>50</sup>
- (k) Legend drug.—“Legend drug” means a drug, including a controlled substance under the state’s controlled substance act, that is required by any applicable federal or state law or regulation to be dispensed by prescription only or that is restricted to use by practitioners only;<sup>51</sup>
- (l) Mail-back distribution location.—“Mail-back distribution location” means a facility, such as a library or community center, which offers prepaid, pre-addressed mailing packages to ultimate users for the purpose of disposing of covered drugs;<sup>52</sup>
- (m) Mail-back program.—“Mail-back program” means a method of collecting a sealed mail-back package that contains covered drugs from a covered entity by using prepaid, pre-addressed mailing packages;<sup>53</sup>
- (n) Manufacture.—“Manufacture” has the same meaning given that term in [insert citation to state law defining manufacture];<sup>54</sup>
- (o) Nonlegend drug.—“Nonlegend drug” means a drug that may be lawfully sold without a prescription;
- (p) Population center.—“Population center” encompasses a city or town and the unincorporated areas within a 10-mile radius around the center of the city or town;<sup>55</sup>
- (q) Prescription drug.—“Prescription drug” means a drug that requires a prescription to be dispensed;

<sup>49</sup> WASH. REV. CODE ANN. § 69.48.020(10) (West 2022).

<sup>50</sup> WASH. REV. CODE ANN. § 69.48.020(9) (West 2022).

<sup>51</sup> WASH. REV. CODE ANN. § 69.48.020(13) (West 2022).

<sup>52</sup> WASH. REV. CODE ANN. § 69.48.020(14) (West 2022); *see also* 21 C.F.R. § 1317.05 (West 2022).

<sup>53</sup> WASH. REV. CODE ANN. § 69.48.020(15) (West 2022).

<sup>54</sup> WASH. REV. CODE ANN. § 69.48.020(16) (West 2022).

<sup>55</sup> WASH. REV. CODE ANN. § 69.48.060(c) (West 2022).

- (r) Private label distributor.—“Private label distributor” means a company that has a valid labeler code pursuant to 21 C.F.R. § 207.17 and markets a drug product but does not manufacture the drug product;<sup>56</sup>
- (s) Program operator.—“Program operator” means a covered manufacturer, group of covered manufacturers, or a drug take-back organization which operates or proposes to operate a drug take-back program approved by the state;<sup>57</sup>
- (t) Repackager.—“Repackager” means a person or entity that repacks and relabels products containing a covered drug for sale or distribution without further transaction;<sup>58</sup>
- (u) Retail pharmacy.—“Retail pharmacy” means any place licensed as a pharmacy for the retail sale and dispensing of drugs pursuant to [insert citation to state law governing the licensure of retail pharmacies];<sup>59</sup>
- (v) Service schedule.—“Service schedule” means a predetermined time that a program operator will collect covered drugs from authorized collector sites as required by this Act; and
- (w) Wholesaler.—“Wholesaler” has the same meaning given to that term in [insert citation to state statute defining wholesaler].<sup>60</sup>

## Commentary

Individual states may have current statutory or regulatory definitions for one or more of the terms contained in this section, and lawmakers may prefer to default to that language or make other adjustments to conform to definitions used in related statutes. Nevertheless, this Act contains definitions designed to convey the intended scope of each term as it relates to the implementation, creation, and operation of a statewide drug take-back and disposal program. The definitions provided herein are primarily taken from Washington and Oregon’s drug take-back program statutes.

To encourage the safe collection and proper disposal of drugs, this Act provides that covered entities may dispose of a wide variety of drugs, including over-the-counter medications and non-controlled prescription drugs. However, there are a few notable exceptions that the drafters did not categorize as a covered drug for the reasons discussed below:

- *Schedule I drugs*. Pursuant to this Act, legal drugs that are categorized under Schedule II through V by the DEA may be collected and disposed of as a covered drug. However, drugs

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<sup>56</sup> WASH. REV. CODE ANN. § 69.48.020(19) (West 2022).

<sup>57</sup> WASH. REV. CODE ANN. § 69.48.020(20) (West 2022).

<sup>58</sup> WASH. REV. CODE ANN. § 69.48.020(21) (West 2022).

<sup>59</sup> WASH. REV. CODE ANN. § 69.48.020(22) (West 2022).

<sup>60</sup> WASH. REV. CODE ANN. § 69.48.020(11) (West 2022).

classified as a Schedule I drug may not be disposed of under this Act. Schedule I controlled substance is a drug with no currently accepted medical use and with a high potential for abuse and includes drugs such as heroin;<sup>61</sup>

- *Medical sharps.* Medical sharps are needles, syringes, lancets, or auto-injectors used by individuals outside of a healthcare setting to treat or manage conditions like cancer, diabetes, or HIV.<sup>62</sup> The drafters considered including sharps as a part of the drug take-back program. Ultimately, the drafters excluded sharps, given the nascent nature of creating, overseeing, and administering the statewide drug take-back and disposal program envisioned by the Act.<sup>63</sup> The drafters believe it is prudent to focus solely on the collection and disposal of covered drugs at this time. The drafters believe that the disposal of home-generated medical sharps, which are technically classified as untreated biohazardous medical waste, should be addressed separately and with careful consideration. The Legislative Analysis and Public Policy Association will release a model act with respect to sharps disposal in the coming months; and
- *Biological products.* Any biological drug products that, as mandated by federal law, manufacturers must administer a pharmaceutical product stewardship or drug take-back and disposal program and who provide the department with a report describing the program, including how the drug product is collected and safely disposed of 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.<sup>64</sup>

State legislators and policymakers are free to expand the types of covered drugs that state drug take-back and disposal programs can collect. For example, in states where cannabis is sold, state legislators and policymakers may want to consider including sellers and producers of cannabis as part of the statewide drug take-back and disposal program with the knowledge that cannabis is still classified as a Schedule I drug under federal law.

Section III defined “covered entity.” Essentially, almost anyone can be a covered entity, which means that the entity is permitted to take advantage of the drug take-back and disposal program and dispose of their unused, expired, or unwanted drugs. This includes any resident of the state, a nonbusiness entity, or an ultimate user as defined under federal law. The federal Controlled Substance Act defines an ultimate user as “a person who has lawfully obtained, and

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<sup>61</sup> *Drug Scheduling*, DRUG ENF’T ADMIN. (visited Dec. 7, 2022), <https://www.dea.gov/drug-information/drug-scheduling>.

<sup>62</sup> U.S. FOOD & DRUG ADMIN., SAFELY USING SHARPS (NEEDLES AND SYRINGES) AT HOME, AT WORK AND ON TRAVEL (Nov. 19, 2021).

<sup>63</sup> It is important to note that even though Washington and Oregon did not include sharps as part of the initial drug take-back and disposal programs, subsequent bills have been introduced to include or create a sharps disposal program. In addition, the State of California also includes sharps as a product that can be disposed of as a part of its drug take-back and disposal program. CAL. PUB. RES. CODE § 42032.2 (West 2022).

<sup>64</sup> 21 C.F.R. § 600.3(h).



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.”<sup>65</sup>

Subsection (f) of Section III defines a covered manufacturer as a person, corporation, or entity that manufactures covered drugs that are sold “within or into the state.” It is very important to include language that captures drug manufacturers that sell covered drugs both within and into the state. As one member of the working group aptly noted, limiting “covered manufacturers” to companies whose drugs are sold “within” the state would exclude many or most drugs sold by mail-order.

Finally, the drafters have placed responsibility for the oversight and administration of the system of drug-take back and disposal programs with the state’s department of health as a default. The decision emulates that of the State of Washington, where the department of health provides oversight and the department of ecology has a consultation role.<sup>66</sup> By contrast, Oregon designated its department of environmental quality as the entity tasked with overseeing the state drug take-back program.<sup>67</sup> Both departments bring potential benefits to the role of administrator. The department of health may have experience regulating controlled substances, is typically involved in the state’s effort to combat substance misuse, and regulates entities in the pharmaceutical distribution chain. Inversely, the state’s department of environmental protection has institutional knowledge of any current state product stewardship laws and managing the environmental impacts of pharmaceutical wastes. A member of the working group raised concerns regarding the appropriate designation of responsibility for oversight and administration of the drug-take back systems. As noted by the working group member, drug disposal is essentially a waste stream, which is the “complete flow of waste from its domestic or industrial source through recovery, recycling, or final disposal.”<sup>68</sup> The Environmental Protection Agency has strict controls in place for waste stream programs. Thus, the group member recommended that the state’s environmental protection agency oversee the drug take-back program because the agency is already experienced in managing waste streams, such as household hazardous waste.

The designated department or agency is responsible for a wide variety of activities under this Act, including: (1) reviewing each proposed drug take-back plan submitted by a covered manufacturer; (2) auditing and inspecting the actions and records of drug take-back organizations and program operators; (3) determining the cost of administration and enforcement of the statewide drug take-back system; (4) setting administrative fees assessed to stewardship organizations and program operators at an appropriate level; (5) promulgating rules to establish and administer the system of statewide drug take-back programs; and (6) ensuring compliance with, and enforcing the provisions of, this Act. State legislators and policymakers should take

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<sup>65</sup> 21 U.S.C.A. § 802(27) (West 2022).

<sup>66</sup> WASH. REV. CODE ANN. § 69.48.020(7) (West 2022).

<sup>67</sup> OR. REV. STAT. ANN. § 459A.209 (West 2022).

<sup>68</sup> Didier Bourguignon, *Understanding Waste Streams: Treatment of Specific Waste*, EPRS EUR. PARLIAMENTARY RSCH. SERV. 1 (July 2015).

these responsibilities into account when making the decision as to which agency or department to designate with direct oversight of the statewide drug take-back system.

#### **SECTION IV. PARTICIPATION IN DRUG TAKE-BACK AND DISPOSAL PROGRAM.**

- (a) In general.—A person or entity that is determined to be a covered manufacturer by the department shall establish and implement a drug take-back program pursuant to the provisions of this Act.
- (b) Form of participation.—A covered manufacturer may choose to administer a drug take-back program individually, as a group of covered manufacturers, or by forming a drug take-back organization with other covered manufacturers.
- (c) Program operator.—Any covered manufacturer, group of covered manufacturers, or drug take-back organization that operates or proposes to operate a drug-take back program under the provisions of this Act shall be deemed to be a program operator.
- (d) Identification by wholesaler.—Not later than ninety (90) days after the effective date of this Act, a wholesaler that sells a covered drug in or into [state] shall provide the department with a list of all drug manufacturers operating legally within [state] of which it is aware, in a form and manner prescribed by the department, and shall update such list annually.<sup>69</sup>
- (e) Identification by other entities.—Not later than ninety (90) days after the effective date of this Act, a retail pharmacy, private label distributor, or repackager shall provide the department with the identification of the drug manufacturer from which the retail pharmacy, private label distributor, or repackager obtains covered drugs that it sells under its own label, in a form and manner prescribed by the department, and shall update such list annually.<sup>70</sup>
- (f) Inquiry.—The department shall send a written letter of inquiry to an entity identified pursuant to subsections (d) or (e) of this section that it believes meets the definition of a covered manufacturer and which is required to participate in the state’s drug take-back program pursuant to the provisions of this Act.

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<sup>69</sup> WASH. REV. CODE ANN. § 69.48.040(1) (West 2022).

<sup>70</sup> WASH. REV. CODE ANN. § 69.48.040(2) (West 2022).

- (g) Finding.—The department shall notify an entity, in writing, within thirty (30) days of receipt of the response required by subsection (h) of this section of its finding that such person or entity is determined to be a covered manufacturer required to participate in the state’s drug take-back program.
- (h) Response and appeal process.—A person or entity that receives a letter of inquiry from the department as to whether it is a covered manufacturer under this Act shall respond in writing to the department no later than sixty (60) days after receipt of the letter of inquiry. Upon receiving the letter of inquiry:
- (1) If the person or entity does not dispute that it is a covered manufacturer under this Act, it shall notify the department of its acceptance of its status as a covered manufacturer and shall take all steps necessary to comply with the provisions of this Act; or
  - (2) If the person or entity does not believe it is a covered manufacturer for purposes of this Act, it shall:
    - (A) State the basis for the belief;
    - (B) Provide a list of any drugs it sells, distributes, repackages, or otherwise offers for sale within or into the state; and
    - (C) Identify the name and contact information of the manufacturer of the drugs identified under subparagraph (B) of this paragraph.<sup>71</sup>
- (i) Compliance after the effective date.—A manufacturer that becomes a covered manufacturer after the effective date of this Act shall, no later than six (6) months after the manufacturer becomes a covered manufacturer:
- (1) Participate in an approved drug take-back program pursuant to the provisions of this Act; or
  - (2) Establish and implement a drug take-back program in compliance with this Act.

## Commentary

Under Section IV, drug wholesalers, retail pharmacies, private label distributors, and repackagers are responsible for notifying the department of potential manufacturers who are manufacturing drugs for sale within and into the state. The drafters made a conscious decision to

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<sup>71</sup> WASH. REV. CODE ANN. § 69.48.040(3) (West 2022).

put the onus of identifying covered manufacturers on the specific entities because the latter have the means and ability to access industry resources and knowledge far beyond the capabilities of the department. The U.S. Food and Drug Administration (FDA) estimates that there are more than 300,000 drugs marketed for over-the-counter usage.<sup>72</sup> There are also over 20,000 prescription drugs approved for marketing by the FDA.<sup>73</sup> Without input from wholesalers and other entities that are an integral part of the drug supply chain, it would be difficult for the department to determine whether a manufacturer is selling a covered drug into or within the state.

## **SECTION V. DRUG TAKE-BACK AND DISPOSAL PROGRAM REQUIREMENTS.**

- (a) In general.—The department shall oversee the statewide drug take-back programs established pursuant to the provisions of this Act and 21 C.F.R. Part 1317 and shall have the following duties:
- (1) Administering the provisions of this Act;
  - (2) Overseeing the program operators that administer drug take-back and disposal programs;
  - (3) Approving or denying proposals to establish drug take-back programs;
  - (4) Fostering public awareness of drug take-back programs within the state;
  - (5) Auditing and inspecting records kept by program operators;
  - (6) Resolving issues and complaints related to drug take-back programs;
  - (7) Enforcing the provisions of this Act; and
  - (8) Any other duties required by regulation.
- (b) Proposal.—In a manner determined by the department, a program operator shall submit a written proposal to the department for its drug take-back program, which shall include the following:
- (1) The identity and contact information for the program operator and each participating covered manufacturer or drug-take back organization;
  - (2) The identity and contact information for all authorized collectors, as well as the reason for excluding any potential authorized collectors from participation in the program;

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<sup>72</sup> *Over-the-Counter (OTC) Drugs Branch: The OTC Drug Review*, U.S. FOOD & DRUG ADMIN. (Feb. 2, 2015), <https://www.fda.gov/drugs/enforcement-activities-fda/over-counter-otc-drugs-branch-otc-drug-review>.

<sup>73</sup> *Fact Sheet: FDA at a Glance*, U.S. FOOD & DRUG ADMIN. (Aug. 17, 2022), <https://www.fda.gov/about-fda/fda-basics/fact-sheet-fda-glance>.

- (3) A summary of any agreements established with authorized collectors pursuant to Section VI of this Act;
  - (4) The program operator's short-term and long-term goals with respect to:
    - (A) The number of permanent collection sites;
    - (B) The weight and amount of covered drugs expected to be collected pursuant to this Act; and
    - (C) How it will foster public awareness and participation through public outreach;
  - (5) A description of how the program will provide for the collection of covered drugs as required in Section VI of this Act;
  - (6) The location and description of physical collection sites as the primary means of collection of covered drugs within the state;
  - (7) A plan for the creation and use of a mandatory mail-back program for the collection of covered drugs pursuant to the provisions of Section VI of this Act;
  - (8) Alternative collection methods for covered drugs, other than controlled substances, that cannot be accepted or commingled with other covered drugs pursuant to the provisions of Section VI of this Act;
  - (9) The identification and location of primary transporters and incinerators and other disposal means pursuant to the provisions of Section VI of this Act;
  - (10) An outline of the process for ensuring accurate record-keeping related to the collection and disposal of covered drugs as required by Section VIII of this Act; and
  - (11) An explanation of the funding mechanism for all administrative and operational costs of the program, with costs apportioned among participating covered manufacturers;<sup>74</sup> and
  - (12) The policies and procedures that will be implemented to secure patient data during the collection and disposal process.
- (c) Approval.—The department shall approve a proposal if the following requirements are met:
- (1) The program operator submits a completed application;
  - (2) The proposal meets the requirements of subsection (b) of this section; and

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<sup>74</sup> WASH. REV. CODE ANN. § 69.48.050(2) (West 2022).

- (3) The program operator pays the applicable application fee to the department as provided by Section IX of this Act.
- (d) Notice to covered manufacturer of approval or denial.—Not later than one hundred and twenty (120) days after receiving a proposal for a drug take-back program, the department shall either approve or deny the proposal in writing to the program operator.
- (e) Approval of a program operator.—A covered manufacturer shall be deemed an approved program operator upon approval of its proposal for a drug take-back program by the department pursuant to subsection (c) of this section.
- (f) Denial of proposal.—The department shall provide the reason for a denial of a proposal in writing and shall allow the program operator to appeal the denial or submit a revised proposal pursuant to subsection (n) of this section.
- (g) Extension.—The department may extend the deadline for approval or denial for good cause after written notice to the program operator that the department has extended its deadline for approval or denial of the proposal.
- (h) Appeal or submission of a revised proposal.—Not later than ninety (90) days after notice of a denial pursuant to subsection (f) of this section, the program operator may:
- (1) Appeal the denial of its proposal on a form and in a manner prescribed by the department by rule; or
  - (2) Submit a revised proposal to the department.

The department shall notify the program operator, in writing, within ninety (90) days of its decision to approve or deny the program operator's request for appeal or submission of a revised proposal. The denial must include the reason for denial of the appeal or the revised proposal, if applicable.<sup>75</sup>

- (i) Rejection of an appeal or revised proposal.—If the department rejects either an appeal or a revised proposal, the department may:
- (1) Require the applicant to submit a second revised proposal;
  - (2) Require all covered manufacturers that submitted the rejected appeal or revised proposal to participate in a previously approved drug take-back program;

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<sup>75</sup> *Id.*

- (3) Require specific changes to be made to some or all of the provisions of the rejected revised proposal; or
- (4) Deem the covered manufacturer out of compliance with this Act and take action as allowed under Section X.<sup>76</sup>
- (j) Implementation of drug take-back program after approval.—The program operator shall fully implement its drug take-back program no later than one hundred eighty (180) days after approval of the proposal by the department.
- (k) Changes to approved and implemented drug take-back program.—A program operator shall seek the department’s written approval to make modifications or changes to an ongoing drug take-back program if the change or modification would significantly alter how the program operates, including, but not limited to:
  - (1) The contact information for the program operator;
  - (2) Policies and procedures related to the handling, collection, or disposal of covered drugs;
  - (3) Policies and procedures related to securing patient information during the collection and disposal process;
  - (4) The location of collection sites;
  - (5) The location or schedule of collection events; or
  - (6) Alternative collection methods for covered drugs other than controlled substances that cannot be accepted or commingled with other covered drugs in collection receptacles.
- (l) Process for requesting changes.—A program operator shall submit a written request to the department for approval of any changes or modifications no later than thirty (30) days before the proposed effective date of the change.<sup>77</sup>
- (m) Approval or denial of request to modify an approved drug take-back program.—The department shall approve or deny a request to modify an approved drug take-back program within thirty (30) days of receipt of the request. If the department does not:
  - (1) Approve or deny the request; and

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<sup>76</sup> *Id.*

<sup>77</sup> Based on WASH. REV. CODE ANN. § 69.48.050 (West 2022).

- (2) Provide written notice to the program operator of the department's decision within thirty (30) days of the date in which the department received the request, the proposed plan changes shall be considered approved.
- (n) Temporary implementation for cause.—If a program operator intends to make a time-sensitive proposed change to a drug take-back program but is unable to make the request at least thirty (30) days before the proposed change, the program operator shall notify the department of the proposed change as far in advance of the proposed change as is practicable. Upon receipt of notice described in this subsection, the department shall consult with the program operator regarding the proposed change and the reason for the late notification. Not later than seven (7) business days after receiving the notice, the department may temporarily approve the proposed change for good cause as determined by the department.
- (o) Required notice from program operator.—As soon as is practicable, but no later than thirty (30) days after one of the following changes occurs, a program operator shall notify the department of changes to:
- (1) The contact information for the program operator;
  - (2) The identity of a covered manufacturer participating in the program;
  - (3) The contact information of a covered manufacturer participating in the program;
  - (4) The ownership of a covered manufacturer participating in the program;
  - (5) The location or schedule of collection events; or
  - (6) The location of collection sites.<sup>78</sup>
- (p) Changes to program operator.—At any time, if there is only one (1) single statewide approved drug take-back program in which all covered manufacturers are participating, and that program operator intends to leave the program for any reason, participating manufacturers shall find a new entity to take over operation of the existing program without a break in program services. The new entity shall not make changes to the operation of the approved program, which shall be consistent with the proposal as it was approved by the department under this section, or each covered manufacturer, drug take-

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<sup>78</sup> WASH. REV. CODE ANN. § 69.48.050(5) (West 2022).



back organization, or group of covered manufacturers shall identify a new program operator to develop a new program proposal.<sup>79</sup>

- (q) New proposal based on changes to the program operator.—The department shall accept new proposals from potential program operators for a minimum of four (4) 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 (c) of this section. The department shall approve or reject proposals received using the process described in subsection (h) of this section.<sup>80</sup>
- (r) Single program operator.—If there is only one (1) single statewide approved drug take-back program in which all covered manufacturers are participating, and that program operator leaves the program and the participating manufacturers do not identify a program operator to take over the approved program as provided in subsection (p) of this section, all covered manufacturers shall participate in a new approved drug take-back program as soon as one is approved.<sup>81</sup>
- (s) Multiple program operators.—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 (p) of this section, those manufacturers shall immediately join an existing approved drug take-back program.<sup>82</sup>
- (t) Continuous participation in program.—A covered manufacturer may change the approved drug take-back program it participates in, but the covered manufacturer shall 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.<sup>83</sup>

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<sup>79</sup> WASH. REV. CODE ANN. § 69.48.050(8)(a) (West 2022).

<sup>80</sup> WASH. REV. CODE ANN. § 69.48.050(8)(b) (West 2022).

<sup>81</sup> *Id.*

<sup>82</sup> WASH. REV. CODE ANN. § 69.48.050(9) (West 2022).

<sup>83</sup> WASH. REV. CODE ANN. § 69.48.050(10) (West 2022).

- (u) Failure to comply.—Failure to comply with the requirements of this section by the applicable parties may result in enforcement actions as allowed by Section X of this Act.<sup>84</sup>

## Commentary

Section V is crucial to the establishment of statewide drug take-back programs that will operate pursuant to the provisions of this Act. The following is a framework for how the programs will operate within the state upon enactment:

- (1) A government agency or department is designated to oversee the implementation of a system of statewide drug take-back programs within the state;
- (2) The department determines which drug manufacturers meet the criteria of the Act and are required to participate in the statewide system of drug take-back programs;
- (3) Covered manufacturers that are required to administer drug take-back programs in the state can choose to participate in one of three ways, as:
  - a. An individual drug manufacturer;
  - b. Part of a group of drug manufacturers; or
  - c. A collective of drug manufacturers that form a drug take-back organization;
- (4) The covered manufacturer submits a proposal to the department that outlines how the manufacturer will administer individual drug collection sites, procedures for collecting and disposing of drugs, and plans for outreach to the public;
- (5) The department will then review the manufacturer's proposal and approve or deny the proposal;
- (6) After approval, the program operator will institute a drug take-back program based on the approved proposal; and
- (7) The department will monitor the programs for compliance with this Act, collect fees from the manufacturers to offset the cost of administering the system of drug take-back programs, and levy penalties or fines, if necessary.

Several members of the working group noted that it was important to iterate that implementation of this Act does not preclude private entities from creating or operating their own drug disposal and take-back programs. The drafters also want to make it clear that nothing in this Act prohibits or infringes upon a retail pharmacy from operating or continuing to operate

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<sup>84</sup> WASH. REV. CODE ANN. § 69.48.050(12)(b) (West 2022).

a voluntary drug disposal and take-back program. Similarly, a law enforcement agency can continue to offer a separate drug disposal and take-back program or host collection events.

## **SECTION VI. COLLECTION AND DISPOSAL REQUIREMENTS.**

- (a) In general.—A drug take-back program’s collection system shall be safe, secure, and convenient on an ongoing, year-round basis and must provide equitable and reasonably convenient access for covered entities across the state.<sup>85</sup>
- (b) Agreements.—A program operator shall establish agreements with authorized collectors for the purpose of providing no cost, convenient, and ongoing collection opportunities for covered drugs to covered entities.<sup>86</sup>
- (c) Agreement requirements.—Any agreement entered into pursuant to this section shall ensure that the authorized collector will comply with state and federal law for the collection of covered drugs.<sup>87</sup>
- (d) Status of authorized collector.—A person or entity that acts as an authorized collector may do so voluntarily or for compensation. Nothing in this Act shall require any person or entity to act as an authorized collector.<sup>88</sup>
- (e) Voluntary participation.—A program operator shall 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 drug take-back program without compensation. Such a pharmacy, hospital, clinic, or law enforcement agency shall be included as an authorized collector in the program no later than ninety (90) days after receiving the offer to participate.
- (f) Collection site location.—Each population center shall have a minimum of one (1) collection site, plus one (1) additional collection site for every fifty thousand (50,000) residents of the city or town located within the population center.<sup>89</sup>

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<sup>85</sup> WASH. REV. CODE ANN. § 69.48.060(3)(a) (West 2022).

<sup>86</sup> OR. REV. STAT. ANN. § 459A.215(1) (West 2022).

<sup>87</sup> OR. REV. STAT. ANN. § 459A.215(2) (West 2022).

<sup>88</sup> WASH. REV. CODE ANN. § 69.48.060(1) (West 2022).

<sup>89</sup> WASH. REV. CODE ANN. § 69.48.060(3) (West 2022).

- (g) Geographical distribution.—Collection sites shall be geographically distributed to provide reasonably convenient and equitable access to all covered entities in the population center.<sup>90</sup>
- (h) Areas outside of population centers.—In areas outside of population centers, a collection site shall 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 Section V of this Act.<sup>91</sup>
- (i) Collection site requirements.—Any collection site managed by a program operator pursuant to this Act shall meet the requirements of 21 C.F.R. Part 1317 and shall include the following:
- (1) Provide a regular service schedule as to when covered drugs will be collected from the collection site to ensure that the collection site is serviced as often as is necessary to avoid reaching capacity; and
  - (2) Provide a method for the authorized collector to notify the program operator if there is a need for additional collection receptacles to be placed at the collection site.
- (j) Acceptance of covered drugs.—Except as provided in subsection (p) of this section, a collection site shall accept all covered drugs from covered entities.<sup>92</sup>
- (k) Mandatory mail-back program.—A program operator shall institute a mail-back program that distributes prepaid, pre-addressed mailing envelopes at no cost to covered entities to return covered drugs for disposal and shall adhere to the requirements of 21 C.F.R. § 1317.70.
- (l) Additional distribution of mail-back materials.—A program operator shall also permit covered entities to receive prepaid, pre-addressed mailing envelopes at mail-back distribution locations or request these materials through:
- (1) The program operator’s website or toll-free number; or

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<sup>90</sup> *Id.*

<sup>91</sup> WASH. REV. CODE ANN. § 69.48.060(3)(c)(ii) (West 2022).

<sup>92</sup> OR. REV. STAT. ANN. § 459A.218(e) (West 2022).

- (2) Through a pharmacist at a retail pharmacy.
- (m) Mail-back distribution locations.—The location of mail-back distribution locations shall be determined in consultation with the department and the local health department with the goal being to provide additional supplementation to sites that are underserved by collection sites.<sup>93</sup>
- (n) Collection events.—A program operator shall conduct periodic collection events in which covered entities are encouraged to bring drugs for take-back and disposal to a designated collection site. All periodic collection events shall be conducted in compliance with federal regulations. The frequency and location of such collection events shall be determined after consultation with the department, local law enforcement, and the local health department to be held at least three (3) times per year, unless otherwise determined through consultation with the above-referenced entities.<sup>94</sup>
- (o) Disposal of covered drugs.—A drug-take back program collection site shall collect covered drugs and store them in compliance with state and federal law. All covered drugs shall be disposed of at a permitted:
- (1) Hazardous waste facility that meets the requirements under 40 C.F.R. 264 and 40 C.F.R. 265;
  - (2) Municipal waste incinerator that meets the requirements under 40 C.F.R. 50 and 40 C.F.R. 62; or
  - (3) Hospital, medical, and infectious waste incinerator that meets the requirements under subpart HHH of 40 C.F.R. part 62; an applicable state plan for existing hospital, medical, and infectious waste incinerators; or subpart Ec of 40 C.F.R. part 60 for new hospital, medical, and infectious waste incinerators.<sup>95</sup>
- (p) Alternative collection methods for certain covered drugs.—A program operator shall 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 the mail-back program required by this section, or at

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<sup>93</sup> WASH. REV. CODE ANN. § 69.48.060 (West 2022).

<sup>94</sup> WASH. REV. CODE ANN. § 69.48.060(d) (West 2022).

<sup>95</sup> 410 ILL. COMP. STAT. ANN. 720/25(g) (West 2022).

periodic collection events, to the extent permissible under applicable state and federal laws.<sup>96</sup>

- (q) Review and approval of alternative collection methods.—The department shall review and approve of any alternative collection methods prior to their implementation pursuant to Section V of this Act.
- (r) Limit on form of collection.—Any drug disposal program implemented pursuant to this Act shall ensure that collection methods used under the program are limited to:
  - (1) Mail-back options that meet the requirements of this section;
  - (2) Collection events; and
  - (3) Collection sites,and shall not include any in-home drug deactivation systems.
- (s) Privacy.—A program operator shall implement policies and to secure patient information during the collection and disposal process.

## Commentary

Section VI establishes several important components of the drug take-back program. This includes providing a formula for program operators to use to determine the number of covered drug collection sites that should be established pursuant to this Act. Under this section, a population center, which is a town or city and the unincorporated area within a 10-mile radius from the center of that city or town, must have a minimum of at least one collection site. For every 50,000 residents or covered entities of a city or town located within a population center, there must be at least one additional collection site.

The language of Section VI mirrors Washington State’s definition of population center. The formula provided in this section requires program operators to determine the *minimum* number of collection sites needed based on population.<sup>97</sup> However, state legislators and policymakers may choose an alternative way to formulate the appropriate number of collection sites needed to best provide convenient drug collection and disposal services for the population of their state. However, as noted by one of the working group members, any alternative method created to equitably distribute collection sites throughout the state should be achievable, logical, measurable, and accessible to as many residents as possible.

As provided in this Act, the drug take-back laws in Washington and Oregon also have the key requirement that any retail pharmacy, hospital or clinic with an on-site pharmacy, or law enforcement agency that volunteers as a collection site must be included in the drug take-back

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<sup>96</sup> WASH. REV. CODE ANN. § 69.48.060(f) (West 2022).

<sup>97</sup> WASH. REV. CODE ANN. § 69.48.060(c) (West 2022).

program. This “opt-in” requirement is critical to ensuring a convenient program that is widely available at locations authorized by the DEA to collect unwanted medicines from consumers.

Section VI also requires that program operators operate a mandatory mail-in service to all covered entities to dispose of covered drugs by mail. Program operators must also provide mail-back distribution locations, such as libraries or community centers, with prepaid, pre-addressed mailing packages that can be picked up at these locations. A covered entity may also request a prepaid, pre-addressed mailing envelope through the program operator’s website, the program’s toll-free number, or by request to a pharmacist at a retail pharmacy. Mail-in services of covered drugs are an important component of a drug take-back system and are particularly important for vulnerable populations, such as people with disabilities or illnesses that restrict their movement, individuals experiencing geographic isolation (*e.g.*, living in a rural area), individuals in hospice care in states that do not have laws that provide for the disposal of drugs by the hospice, and people who do not have access to reliable transportation. These people may not have the ability to access a collection site to dispose of their unused, expired, and unwanted drugs.

Previous drafts of this Act allowed for the inclusion of at-home drug disposal kits or pouches to be provided as part of the program operator’s drug mail-back program. These kits are typically offered to consumers as drug deactivation systems and provide in-home means of permanent disposal of unused drugs.<sup>98</sup> However, some members of the working group expressed concern regarding language in the Act that allowed for the potential use of at-home drug disposal kits or pouches. Their concerns were centered largely on the lack of research or data on the efficacy of these at-home drug disposal kits or pouches to deactivate various drugs. One group member also noted that some drug disposal pouches or kits can take several hours for the drugs to be rendered inactive which leaves open the potential for abuse. As a result of this discussion, the drafters removed language from the Act that allowed for the use of at-home drug deactivation kits and instead provided language in subsection (r) of this section that prohibits the use of at-home treatment or disposal methods as part of the drug take-back program. In the future, as more research becomes available about at-home drug deactivation systems such as drug disposal kits or pouches, legislators may want to consider amending this section of the Act.

## **SECTION VII. PUBLIC OUTREACH.**

(a) In general.—Program operators shall engage in public outreach which shall include providing educational materials and promoting the benefits of the safe storage and collection of covered drugs to educate the public pursuant to the provisions of this section.<sup>99</sup>

(b) Program operator responsibilities.—Program operators shall:

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<sup>98</sup> See *Case Studies*, DETERRA: DRUG DEACTIVATION SYSTEM (visited April 25, 2022), <https://deterrasystem.com/resources/case-studies/>; and *Knowledge Center*, RXDESTROYER (visited April 25, 2022), <https://www.rxdestroyer.com/learn-more/>.

<sup>99</sup> WASH. REV. CODE ANN. § 69.48.070(1) (West 2022).

- (1) Publicize information on the location of collection sites, including the address of each site, the collection and disposal process, and the date and location of collection events;
  - (2) Provide a toll-free telephone number and a web resource that a covered entity may use to contact the program operator about the drug take-back program;
  - (3) Provide educational materials that fulfill the requirements of subsection (c) of this section;<sup>100</sup> and
  - (4) Annually report on its promotion, outreach, and public education activities in its annual report as required by Section VIII of this Act.
- (c) Minimum requirements.—At a minimum, program operators shall ensure that any public outreach provided pursuant to this section:
- (1) Is made available on a public website, via social media, and print;
  - (2) Is made available at or below a sixth (6th) grade reading level;
  - (3) Explains the statewide system of drug take-back programs as established by this Act;
  - (4) Promotes the safe and secure storage of covered drugs by covered entities; and
  - (5) Promotes proper drug disposal by, among other things, detailing the impact that proper disposal may have on reducing access to unused controlled substances and non-prescription drugs and avoiding environmental contamination.<sup>101</sup>
- (d) Logo and instructions.—The program operator shall work with authorized collectors to develop an easily recognizable and consistent design for use at collection sites and to develop clear standardized instructions for covered entities on how to use collection receptacles.<sup>102</sup>
- (e) Coordination with other program operators.—Program operators shall coordinate with other programs, if applicable, to ensure that covered entities can easily identify, understand, and access the services provided by all operational programs in this state.<sup>103</sup> Coordination efforts shall include:

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<sup>100</sup> WASH. REV. CODE ANN. § 69.48.070 (West 2022).

<sup>101</sup> WASH. REV. CODE ANN. § 69.48.070(e) (West 2022).

<sup>102</sup> WASH. REV. CODE ANN. § 69.48.07(g) (West 2022).

<sup>103</sup> WASH. REV. CODE ANN. § 69.48.070(h) (West 2022).



- (1) Providing covered entities with a single toll-free telephone number and single website to access information about collection services for every approved drug take-back 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
  - (2) Managing requests for prepaid, pre-addressed mailing envelopes materials.<sup>104</sup>
- (f) Department outreach responsibilities.—The department, the healthcare authority, the department of social and health services, the department of environmental protection, 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.<sup>105</sup>
- (g) Survey requirements.—The department shall conduct a survey of covered entities and a survey of pharmacists, healthcare providers, and veterinarians who interact with covered entities on drug take-back and disposal services after the first full year of operation of the drug take-back program, and every two (2) years thereafter. Survey questions shall:
- (1) Measure consumer awareness of the drug take-back program;
  - (2) Assess the extent to which collection sites and other collection methods are convenient and easy to use;
  - (3) Assess knowledge and attitudes about risks of abuse, poisonings, and overdoses from drugs used in the home; and
  - (4) Assess covered entities' practices with respect to unused, unwanted, or expired drugs, both currently and prior to implementation of the drug take-back program.
- (h) Modification of program based on survey results.—The department may, upon review of the results of public awareness surveys conducted pursuant to this section, direct a

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<sup>104</sup> WASH. REV. CODE ANN. § 69.48.070(h)(2) (West 2022).

<sup>105</sup> WASH. REV. CODE ANN. § 69.48.070 (West 2022).

program operator for an approved drug take-back program to modify the program's promotion and outreach activities to better achieve widespread awareness among state residents and healthcare professionals about where and how to return covered drugs to the drug take-back program.

- (i) Funding.—Any costs related to the department's responsibilities pursuant to this section shall be deemed administrative and paid for by drug manufacturers pursuant to Section IX of this Act.

## Commentary

The goal of public outreach is to engage the public and raise awareness about the potential dangers of unused, expired, and unwanted drugs and the solutions that the state offers its residents to address these dangers. One small cohort study found that individuals who were counseled about appropriate methods for disposal were approximately three times as likely to properly dispose of medication compared to those who received no counseling.<sup>106</sup> Section VII requires that program operators promote public awareness of the safe collection and disposal of covered drugs. The allocation of responsibility for public outreach is primarily and squarely placed on the program operators. Any outreach conducted by local or state agencies should only be to enhance the program operators' own outreach. To that end, policymakers may also consider including public service announcements and other tools tailored to share information with the community via social media, local newspapers, and radio and television stations as part of the statewide education initiative. The department can also take advantage of the wide breadth of educational materials available for free from the FDA as a part of its "Remove the Risk" campaign.<sup>107</sup> The FDA launched the campaign in 2019 in order to address the opioid crisis, decrease unnecessary exposure to opioids, and prevent substance use disorder.<sup>108</sup> As part of the campaign, the FDA launched a toolkit of materials, available in both English and Spanish.<sup>109</sup> This toolkit contains public service announcements for television, radio, print, and social media, as well as graphics and fact sheets.<sup>110</sup> The FDA has made these materials available free of charge to news media, healthcare providers, consumer groups, and any organization involved in addressing the opioid epidemic.<sup>111</sup>

## SECTION VIII. INSPECTION AND REPORTING REQUIREMENTS.

- (a) In general.—The department shall ensure compliance with the provisions of this Act by:

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<sup>106</sup> Daniel E. Buffington et al., *Understanding Factors that Contribute to the Disposal of Unused Opioid Medication*, 12 J. PAIN RSCH., 2019, 728, 725-732.

<sup>107</sup> *FDA Launches Public Education Campaign to Encourage Safe Removal of Unused Opioid Pain Medicines from Homes*, U.S. FOOD & DRUG ADMIN. (April 25, 2019), <https://www.fda.gov/news-events/press-announcements/fda-launches-public-education-campaign-encourage-safe-removal-unused-opioid-pain-medicines-homes>.

<sup>108</sup> *Id.*

<sup>109</sup> *Id.*

<sup>110</sup> *Id.*

<sup>111</sup> *Id.*

- (1) Entering into an agreement with the state board of pharmacy, whereby during discretionary inspections of retail pharmacies, the board of pharmacy shall:
    - (A) Inspect collection sites located at retail pharmacies; and
    - (B) Inform the department of any collection sites that are potentially not in compliance with the provisions of this Act;
  - (2) Inspecting collection sites not located at retail pharmacies;
  - (3) Auditing or inspecting the activities and records of program operators to determine compliance with the provisions of the Act; and
  - (4) Reviewing and approving the annual reports provided by program operators pursuant to this section.<sup>112</sup>
- (b) Annual report.—In a form and manner prescribed by the department, a program operator shall submit to the department an annual report on the development, implementation, and operation of its drug-take back program including, but not limited to:
- (1) A list of covered manufacturers participating in the drug-take back program;
  - (2) The address of each collection site;
  - (3) The method or methods used to transport covered drugs collected under the drug take-back program;
  - (4) The disposal methods used to treat covered drugs collected under the drug take-back program pursuant to Section VI of this Act;
  - (5) A summary of the annual expenditures of the drug take-back program, aggregated by category;
  - (6) Whether the program met its public outreach requirements, including a summary of the strategies and surveys used and copies of any promotional materials developed by the drug take-back program pursuant to Section VII of this Act; and
  - (7) Any other information the department may require by rule.
- (c) Publication of reports.—The department shall publish any reports submitted under this section and make them available to the public.

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<sup>112</sup> OR. REV. STAT. ANN. § 459A.236 (West 2022).

(d) Publication of proposals.—The department shall make all proposals submitted pursuant to Section V of this Act available to the public and shall provide an opportunity for written public comment on each proposal.

**[Optional]** (a) In general.—The board of pharmacy shall ensure compliance with the provisions of this Act by routinely inspecting collection sites at retail pharmacies and adhere to the additional provisions of subsection (a) of this section.

### **Commentary**

Tracking, monitoring, and evaluating the efficacy and success of program operator activities under the drug-take back system is crucial to sustaining an effective program. For example, the department can use information provided by program operators to determine whether people who frequent retail pharmacies find the location of collection sites to be easily accessible. The department can also use information provided by the board of pharmacy to determine whether a pharmacy is in compliance with the provisions of this Act as it relates to collection sites.

In addition, Section VIII requires program operators to provide the department with up-to-date information on various aspects of the drug take-back program. This information can help the department determine what areas of the drug take-back program are working and what areas require improvement. This helps the department expand its research resources and ability to analyze data related to oversight of the drug take-back program and work with program operators to address any issues in a responsive and timely manner. For example, if a particular population center has ample collection sites for its population, but the program operator's annual report indicates that certain collection sites are rarely utilized, the department can potentially collaborate with the program operator to assess the best way to encourage increased collection site usage, either through additional public outreach or moving the collection sites to an alternate location.

Finally, if the board of pharmacy is the entity tasked with oversight of the drug take-back and disposal program, then the optional subsection (a) would apply.

### **SECTION IX. FEES.**

(a) In general.—The department shall assess the costs of the administration, oversight, and enforcement requirements of this Act and set fees to be paid by a covered manufacturer or a program operator at a level to recoup the costs associated with the administration, oversight, and enforcement of this Act.<sup>113</sup>

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<sup>113</sup> WASH. REV. CODE ANN. § 69.48.120(a) (West 2022).

- (b) Application fee.—The department shall impose a one (1) time application fee assessed against a covered manufacturer, group of covered manufacturers, or drug take-back organization for reviewing a drug take-back program proposal.
- (c) Annual fee.—The department shall impose an annual fee against each program operator for expenses associated with the ongoing costs of administering the provisions of this Act.<sup>114</sup>
- (d) Deadline for annual fee.—The annual fee assessed against a program operator by the department shall be paid by [insert date determined by the department in conjunction with program operators] and annually by that date thereafter.
- (e) Allocation of fees.—The annual operating fee referenced in subsection (c) shall be assessed evenly against each approved program operator.<sup>115</sup>
- (f) Calculation.—The fees referenced in subsections (b) and (c) of this section shall be calculated to cover the cost of administering the provisions of this Act.<sup>116</sup> The department shall not impose any fees in excess of its actual administrative, oversight, and enforcement costs.
- (g) Adjustments.—The department may adjust an applicable fee assessed pursuant to subsections (b) or (c) of this section on an annual basis pursuant to the requirements of this section.
- (h) Adjustments for inflation.—Any adjustment made for inflation of the fees referenced in subsections (b) or (c) of this section shall 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 (12) month period ending with June of the previous year.<sup>117</sup>
- (i) Notice of adjustment.—The department shall notify all program operators in writing of any adjustment made pursuant to this section at least ninety (90) days prior to the effective date of the adjustment.

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<sup>114</sup> *Id.*

<sup>115</sup> WASH. REV. CODE ANN. § 69.48.120(d) (West 2022).

<sup>116</sup> OR. REV. STAT. ANN. § 459A.242(3) (West 2022).

<sup>117</sup> WASH. REV. CODE ANN. § 69.48.120(c) (West 2022).

- (j) Prohibition against recouping costs.—A covered manufacturer, drug take-back organization, program operator, or authorized collector shall not impose a charge or fee against covered entities for the purpose of recouping the costs of establishing, operating, or administering a drug take-back program. This prohibition shall include any potential charge or fee imposed at the time a covered drug is sold to or collected from a covered entity.<sup>118</sup>
- (k) Secure drug-take back account.—The state treasury [or other appropriate agency or department as determined by the legislature] shall establish a “Secure Drug Take-back Account” which is separate and distinct from the state’s general fund. Interest earned by this account shall be credited to the account.<sup>119</sup>
- (l) Account.—The department shall deposit any monies collected pursuant to this section in an account established pursuant to subsection (k) of this section. The account shall hold monies deposited into or credited to the account, including penalties and fees collected by the department pursuant to this Act, and funds appropriated or transferred to the account by the legislature.<sup>120</sup>
- (m) Use of funds.—All monies in the account established pursuant to subsection (k) shall be continuously appropriated to the department, or any successor agency, for the purpose of administering the provisions of this Act.<sup>121</sup>

## Commentary

This Act requires that covered manufacturers administer their own drug take-back program and pay an annual operating fee to the department to help offset the costs of overseeing the drug take-back programs implemented throughout the state.

As referenced earlier, the drafters considered other mechanisms for both oversight and funding of the state’s role in overseeing drug take-back and disposal programs, including requiring a state agency to fully implement and oversee a statewide drug take-back program itself, and assessing the cost of running the program to drug manufacturers. However, after consideration, the drafters decided to require drug manufacturers to directly administer drug take-back and disposal programs with direct oversight by the state. Manufacturers who produce and sell a drug have the most information and knowledge about that drug and the entirety of the supply chain. Further, as noted by one of the members of the working group, other entities do

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<sup>118</sup> WASH. REV. CODE ANN. § 69.48.090 (West 2022).

<sup>119</sup> OR. REV. STAT. ANN. § 459A.245 (West 2022).

<sup>120</sup> WASH. REV. CODE ANN. § 69.48.130 (West 2022).

<sup>121</sup> OR. REV. STAT. ANN. § 459A.245 (West 2022).

share in the cost responsibility under both Washington and Oregon to some extent. Collection sites such as pharmacies, hospitals, and law enforcement agencies provide staffing to manage their collection sites and interact with covered entities who are dropping off covered drugs for collection and disposal.

The creation of a separate drug take-back program account in this section is modeled after Washington and Oregon laws.<sup>122</sup> Both states carve out a separate account for funds related to the administration of drug take-back and disposal programs in the two states.<sup>123</sup> States should consider keeping these funds separate from general funds to ensure that they are allocated solely for the administration of this Act, similar to the way funds distributed pursuant to opioid settlement funds have been allocated by some states.<sup>124</sup> For example, the Commonwealth of Massachusetts established the Opioid Recovery and Remediation Fund to ensure that funds from opioid settlement funds are used solely to “. . . mitigate the impacts of the opioid epidemic in the commonwealth . . .” and cannot be used for other purposes.<sup>125</sup> Furthermore, any remaining funds left at the end of the fiscal year do not roll over to the commonwealth’s general fund.<sup>126</sup>

## SECTION X. NOTICE AND ENFORCEMENT.

- (a) In general.—The department may audit or inspect the activities and records of a drug take-back program to determine compliance with this Act or to investigate a complaint.<sup>127</sup>
- (b) Notice of failure to participate in drug take-back program.—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 Act. The notice required by this subsection shall provide a warning regarding the penalties for violation of this Act as it relates to participation in a program as required by Sections V and VI of this Act.
- (c) Time within which to comply—covered manufacturers.—A covered manufacturer that receives a notice pursuant to subsection (b) may be assessed a penalty as set forth in subsection (i) of this section if, after sixty (60) days from receipt of the notice, the

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<sup>122</sup> See WASH. REV. CODE ANN. § 69.48.130 (West 2022); see also OR. REV. STAT. ANN. § 459A.245 (West 2022).

<sup>123</sup> *Id.*

<sup>124</sup> Opioid settlement funds are funds recovered by a state attorney general from litigation against the pharmaceutical industry, including pharmaceutical manufacturers or distributors. Katie Zezima, *Ohio Tries an Unusual Tactic toward Opioid Settlement: Working Together*, WASHINGTON POST (Feb. 4, 2020, 8:23 PM), [https://www.washingtonpost.com/national/ohio-tries-an-unusual-tactic-toward-opioid-settlement-working-together/2020/02/24/d5923faa-4c48-11ea-9b5c-eac5b16dafa\\_story.html](https://www.washingtonpost.com/national/ohio-tries-an-unusual-tactic-toward-opioid-settlement-working-together/2020/02/24/d5923faa-4c48-11ea-9b5c-eac5b16dafa_story.html).

<sup>125</sup> MASS. GEN. LAWS ANN. ch. 10, § 35000 (West 2022).

<sup>126</sup> *Id.*

<sup>127</sup> WASH. REV. CODE ANN. § 69.48.110(1) (West 2022).

covered manufacturer continues to sell a covered drug in or into the state without participating in an approved drug take-back program pursuant to this Act.<sup>128</sup>

- (d) Notice of failure to comply with requirements of this Act.—The department shall send a program operator a written notice warning of the penalties, as set forth in subsection (i), for noncompliance with this Act if the department determines that the program operator’s drug take-back program is in violation of this Act or does not conform to the proposal, and any subsequent modifications to such proposal, as approved by the department.<sup>129</sup>
- (e) Content of notice.—The written notice required by subsection (e) shall notify the program operator of the penalties for violation of this Act as set forth in this section.
- (f) Time within which to comply—program operators.—The department may assess a penalty as set forth in subsection (i) of this section against a program operator and participating covered manufacturer, group of covered manufacturers, or drug take-back organization if the program does not come into compliance within thirty (30) days after receipt of the notice sent pursuant to subsection (e) of this section.<sup>130</sup>
- (g) Suspension of drug take-back program.—The department may immediately suspend operation of a drug take-back program and assess a penalty, as set forth in subsection (i) of this section, if it determines that the program is in violation of this Act and the violation creates a condition that, in the judgment of the department, constitutes an immediate hazard to the public or the environment.<sup>131</sup>
- (h) Enforcement actions and penalties.—In enforcing the requirements of this Act, the department may:
- (1) Require that the offending program operator meet with the department for an informal administrative conference;
  - (2) Hold an administrative hearing in accordance with [insert citation to state administrative hearings act];

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<sup>128</sup> WASH. REV. CODE ANN. § 69.48.110(3) (West 2022).

<sup>129</sup> *Id.*

<sup>130</sup> WASH. REV. CODE ANN. § 69.48.110(4) (West 2022).

<sup>131</sup> WASH. REV. CODE ANN. § 69.48.110(3) and (4) (West 2022).



- (3) Require a program operator, covered manufacturer, group of covered manufacturers, drug take-back organization, wholesaler, or retail pharmacy to engage in or refrain from engaging in certain activities pertaining to this Act; or
- (4) In accordance with [insert citation to the state statute that governs the assessment of a civil fine against a person or entity by the department] assess a civil fine of up to [n dollars] per day. Each day during which a violation occurs or is permitted to continue constitutes a separate violation.<sup>132</sup>
- (i) Determination of fine.—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 that the entity would incur in remedying the violation.<sup>133</sup>
- (j) Allocation of fees.—Any fine assessed pursuant to paragraph (4) of subsection (i) of this section shall be assessed to the applicable parties pursuant to [insert citation to the state statute that governs the assessment of a civil fine against a person or entity by the department].
- (k) Failure to provide a list of drug manufacturers.—The department shall send a written notice to a wholesaler of covered drugs or a retail pharmacy that fails to provide a list of drug manufacturers to the department as required by Section IV of this Act. The notice required by this subsection shall notify the wholesaler or retail pharmacy of the penalties for violation of this Act.<sup>134</sup>
- (l) Prohibition against banning the sale of covered drugs.—The department shall not prohibit a covered manufacturer from selling a drug in or into the state based on a violation of this Act.<sup>135</sup>
- (m) Administrative regulation.—The department shall promulgate any administrative regulations necessary to enforce the provisions of this section.

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<sup>132</sup> WASH. REV. CODE ANN. § 69.48.110(4)(c) (West 2022).

<sup>133</sup> WASH. REV. CODE ANN. § 69.48.110(5) (West 2022).

<sup>134</sup> WASH. REV. CODE ANN. § 69.48.110(4) (West 2022).

<sup>135</sup> *Id.*

## Commentary

Section X provides the notice and enforcement provisions of this Act and delineates the department's responsibilities and the mechanisms for enforcement of the provisions of this Act. These include auditing or inspecting a drug take-back program for compliance with this Act, sending notices and warnings to the applicable parties (e.g., covered manufacturers or program operators), holding an informal administrative conference or administrative hearing to make a determination related to the alleged violation, suspending the drug take-back program, or assessing a fine against the applicable party. The State of Washington allows for the potential assessment of fines in the amount of \$2,000 dollars a day against parties for violations of this Act.<sup>136</sup> However, the drafters of this Act have written this section to provide legislators and policymakers with the ability to determine for themselves the appropriate amount to fine parties that are not in compliance with the Act.

As with the language of the drug take-back and disposal acts passed in Washington and Oregon, Section X is intended to avoid punitive measures and encourage the parties to work toward an equitable resolution to any issue that may arise in the drug take-back program so that the ultimate goals of this Act are met.

## SECTION XI. LIMITS ON CIVIL AND CRIMINAL LIABILITY.

- (a) In general.—Except as provided in subsection (b) of this section, an authorized collector, covered manufacturer, drug take-back organization, program operator, or drug take-back program shall not be held civilly or criminally liable for any injuries or damages resulting from a function, duty, or power performed for the purpose of complying with the provisions of this Act.<sup>137</sup>
- (b) Exception.—If an authorized collector, covered manufacturer, drug take-back organization, program operator, or drug take-back program performs a function, duty, or power with gross negligence or willful and wanton misconduct [or intentional misconduct], such entity may be held civilly or criminally liable for injury or damage resulting from such conduct.<sup>138</sup>

## Commentary

Section XI mirrors Oregon's law and exempts various parties involved in the drug take-back process from civil or criminal liability for any injury or damage that occurs as a result of a

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<sup>136</sup> WASH. REV. CODE ANN. § 69.48.110 (West 2022).

<sup>137</sup> OR. REV. STAT. ANN. § 459A.248 (West 2022).

<sup>138</sup> *Id.*

function, duty, or power performed while complying with this Act.<sup>139</sup> A party is liable if it acts with gross negligence or willful or wanton misconduct.<sup>140</sup> The drafters have exempted the parties involved in the drug take-back and disposal process as a way to encourage participation in the statewide drug take-back and disposal system.

## SECTION XII. EXEMPTION FROM ANTITRUST LAW.

- (a) In general.—Program operators shall be exempt from [insert reference to applicable state antitrust laws] solely with respect to the establishment and operation of programs pursuant to this Act.
- (b) Federal antitrust laws.—To the extent allowable by federal law, program operators are exempt from federal antitrust laws solely with respect to the establishment and operation of programs pursuant to this Act.
- (c) Limitations on application.—The provisions of this section shall not authorize any person or entity to engage in activities, or to conspire to engage in activities, which constitute per se violations of state or federal antitrust laws.<sup>141</sup>

### Commentary

Section XII exempts program operators under this Act from state and federal antitrust laws, with the caveat that the language of this section does not authorize any person to engage in activities that would be considered a per se violation of state or federal antitrust laws.<sup>142</sup> Federal antitrust laws (*i.e.*, the Sherman Act, the Federal Trade Commission Act, and the Clayton Act) are designed to prevent unreasonable restraints on trade by prohibiting certain conduct that might have an adverse impact on competition to the detriment of consumers, including through prohibiting contracts between corporations that monopolize trade, a provision that is relevant to the terms of this Act.<sup>143</sup> The language in this section is based on antitrust immunity statutes in Oregon and Washington.<sup>144</sup> Essentially, the legislatures in those states made the decision to shield program operators from state antitrust law scrutiny and to extend their own federal antitrust immunity to program operators acting within those states. Exemptions from antitrust

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<sup>139</sup> OR. REV. STAT. ANN. § 459A.248 (West 2022). The State of Washington does not provide this exemption in statute.

<sup>140</sup> Gross negligence is more serious than basic negligence and is a voluntary or conscious act or failure to act by a person who knew, at the time of his or her conduct, that the conduct was likely to cause harm to another. *See also* WASH. REV. CODE ANN. § 69.48.110 (West 2022) and OR. REV. STAT. ANN. § 459A.248 (West 2022).

<sup>141</sup> OR. REV. STAT. ANN. § 459A.251 (West 2022); *see also* WASH. REV. CODE ANN. § 69.48.140 (West 2022).

<sup>142</sup> A “per se” violation of the law is one in which the person or defendant has objectively violated a statute or acted in a way that is inherently illegal. For example, driving over the posted speed limit with a certain blood alcohol content is an act that is illegal per se. In antitrust law, anti-competitive behavior is potentially illegal per se, including activities such as price fixing or bid rigging among competitors.

<sup>143</sup> FED. TRADE COMM’N, THE ANTITRUST LAWS, [The Antitrust Laws | Federal Trade Commission \(ftc.gov\)](https://www.ftc.gov/antitrust).

<sup>144</sup> OR. REV. STAT. ANN. § 459A.251 (West 2022); *see also* WASH. REV. CODE ANN. § 69.48.140 (West 2022).

laws have historically been premised on the following policy considerations: (1) the anticompetitive conduct provides a value that is determined to be greater than the antitrust at play; (2) the exemption is necessary to protect pro-competitive behavior or behavior that on its face looks like it violates antitrust law but is actually beneficial (such as the collection and disposal of drugs); or (3) the industry has traditionally been one that is highly regulated or believed to be an industry that needs to be controlled, such as the pharmaceutical industry.<sup>145</sup>

The state’s ability to exempt itself or a non-state actor from federal antitrust laws is grounded in the state-action immunity doctrine, under which state and local authorities are immune from federal lawsuits for actions taken pursuant to a state policy that, when legislated, has foreseeable anticompetitive effects.<sup>146</sup> If the state approves and regulates certain conduct, even if such conduct is anticompetitive under federal regulatory standards, the federal government cannot punish the conduct.<sup>147</sup> The state can extend this immunity to non-state actors, here, for example, to program operators, when the non-state actor is carrying out a state regulatory program that is intended to displace competition or encourage engagement, such as in this Act where state approved program operators must collect and destroy unused, expired, and unwanted drugs within the state. As set forth in *California Retail Liquor Dealers Association v. Midcal Aluminum, Inc., et al.*, the Supreme Court has “establish[ed] two standards for antitrust immunity ... First, the challenged restraint must be ‘one clearly articulated and affirmatively expressed as state policy’; second, the policy must be ‘actively supervised’ by the State itself.”<sup>148</sup> The provisions of this Act meet both of those requirements.

### SECTION XIII. DISCLOSURE OF INFORMATION.

- (a) In general.—Except as provided in subsection (b) of this section, any proprietary, financial, manufacturing, or sales information or data that the department receives from a covered manufacturer, program operator, or drug take-back organization pursuant to the provisions of this Act shall be considered confidential and not subject to open records or freedom of information act laws pursuant to [insert reference to applicable state law(s)].<sup>149</sup>
- (b) Exception.—The department may disclose aggregate data acquired from a covered manufacturer, program operator, or drug take-back organization if the information or data does not directly or indirectly identify proprietary information or the financial,

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<sup>145</sup> John Roberti et al., *The Role and Relevance of Exemptions and Immunities in U.S. Antitrust Law*, JUST. GOV’T. 2-3 (visited November 1, 2021), <https://www.justice.gov/atr/page/file/1042806/download>.

<sup>146</sup> *Parker v. Brown*, 317 U.S. 341 (1943).

<sup>147</sup> Emily Myers, *State Action Immunity Update*, NAT’L ASS’N OF ATT’YS GEN. (Oct. 15, 2019), <https://www.naag.org/attorney-general-journal/update-state-action-immunity/>.

<sup>148</sup> *Cal. Retail Liquor Dealers Ass’n v. Midcal Aluminum, Inc. et al.*, 445 U.S. 97, 105 (1980).

<sup>149</sup> OR. REV. STAT. ANN. § 459A.254 (West 2022).

manufacturing, or sales information or data of a specific covered manufacturer, program operator, or drug take-back organization.<sup>150</sup>

#### **SECTION XIV. PREEMPTION OF LOCAL LAWS.**

- (a) In general.—For a period of twelve (12) months after a drug take-back program approved under this Act begins operating, a county may enforce a grandfathered drug take-back and disposal program ordinance.<sup>151</sup>
- (b) Compliance by the county.—During that twelve (12) month period, if a county determines that a program operator is in compliance with its grandfathered ordinance, the department shall find the covered manufacturer in compliance with the requirements of this Act with respect to that county.<sup>152</sup>
- (c) Compliance by the program operator.—In any county enforcing a grandfathered ordinance as described in subsection (a) of this section, the program operator of an approved drug take-back program shall 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 (12) month period.
- (d) Delayed effective date.—After the expiration of the twelve (12) month period provided in subsection (a) of this section, a political subdivision shall 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.
- (e) Preemption.—At the end of the twelve (12) month period provided in subsection (a) of this section, this Act shall preempt 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.<sup>153</sup>
- (f) Grandfathered ordinance.—For purposes of this section, “grandfathered ordinance” shall mean a pharmaceutical product stewardship or drug take-back ordinance that:

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<sup>150</sup> *Id.*

<sup>151</sup> WASH. REV. CODE ANN. § 69.48.160 (West 2022).

<sup>152</sup> *Id.*

<sup>153</sup> *Id.*

- (1) Is in effect on the effective date of this Act; and
- (2) The department determines meets or exceeds the requirements of this Act with respect to safe and secure collection and disposal of unwanted medicines from covered entities, including the types of drugs covered by the program, the convenience of the collection system for covered entities, and required promotion of the program.<sup>154</sup>

## **Commentary**

Initially the drafters of this Act provided that, upon the effective date of this Act, all local laws or ordinances that govern drug take-back and disposal programs would be immediately preempted. However, after discussion with some of the working group members who believe that state preemption of local regulation should be avoided because it is detrimental to community-based public health goals, this section was rewritten to reflect this belief. Section XIV now allows for a prescribed period of time for any local laws or ordinances to operate once this Act goes into effect which provides a transition period and allows time for local officials and the department to work together to incorporate the local program into the larger drug take-back and disposal program offered by drug manufacturers and administered by the state.

## **SECTION XV. RULES AND REGULATIONS.**

Within [*n*] days of the date this Act is enacted, the department shall, solely or in collaboration with [list other relevant state agencies, including the state board of pharmacy], promulgate such rules and regulations that are consistent with 21 C.F.R. Part 1317 and are necessary to effectuate this Act.

## **SECTION XVI. SEVERABILITY.**

If any provision of this Act or application thereof to any individual or circumstance is held invalid, the remaining provisions of this Act shall not be affected nor diminished.

## **SECTION XVII. EFFECTIVE DATE.**

Except as provided in Section XIV, this Act shall be effective on [specific date or reference to standard state method of determination of the effect].

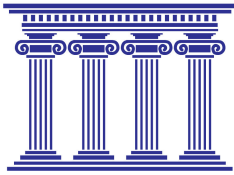
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<sup>154</sup> *Id.*

## 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-the-minute 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.



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