



DRUG OVERDOSE AND HARM REDUCTION

## Issue Brief


# Mandatory Drug Stewardship Programs in States and Municipalities across the United States

## I. Introduction

Unused, expired and leftover medicines that accumulate in homes represent a significant public health problem by increasing the risk of drug misuse and preventable poisonings. According to the National Survey on Drug Use and Health, nearly 75% percent of people who reported misusing painkillers in 2013-2014 most recently got the medication not from a pharmacist but from a friend, family member, or dealer.<sup>1</sup> Improper disposal of unwanted medications also poses a heightened risk to the environment. The Environmental Protection Agency (EPA) advises the public that flushing unwanted medicines down the toilet is an inappropriate disposal practice and that wastewater treatment facilities do not have the capability to effectively remove or degrade all pharmaceutical compounds.<sup>2</sup> Trash disposal of unwanted medicines is also inappropriate. Mixed pharmaceutical wastes are considered household hazardous wastes that pose a significant risk to the environment and the public's health.<sup>3</sup>

In response to the challenge posed by unneeded drugs, Congress enacted the Secure and Responsible Drug Disposal Act of 2010, which encourages the establishment of voluntary drug take-back programs.<sup>4</sup> The law amended the Controlled Substances Act to allow an "ultimate user" of controlled substance medications to dispose of them by delivering the medications to entities authorized by the Drug Enforcement Administration (DEA) to collect controlled substances.<sup>5</sup> While the law originally only permitted law enforcement officials to be authorized to collect these substances, in 2014 the DEA amended the relevant rule to include law enforcement facilities, retail pharmacies, and hospitals and clinics with an on-site pharmacy as authorized collectors of unwanted drugs.<sup>6</sup> As a result of these federal actions, one state and several municipal governments have created voluntary drug take-back programs and encouraged persons with unwanted drugs to dispose of them at such facilities.

Despite these efforts, the reach of voluntary drug take-back programs has been limited for several reasons. First, safe disposal of drugs in voluntary programs requires individuals who possess unwanted medications to search for drop-off locations to deliver the unused drugs. With a limited number of drop-off locations, many individuals have not been able to fully participate in the program. Furthermore, the high cost of maintaining current drop-off locations and expanding to more convenient locations combined with the high cost of transporting the collected medications and safely disposing of them at hazardous waste facilities have limited the expansion of voluntary take-back initiatives.<sup>7</sup>



In response to the insufficiency of voluntary take-back programs, some local and municipal governments have enacted mandatory local drug take-back programs, also called Extended Producer Responsibility (EPR) or stewardship programs that are funded and managed by pharmaceutical companies or producers. Alameda County, California was the first local government to pass a mandatory drug stewardship ordinance in 2012. Since then, the state of Massachusetts, eight counties in California, and two counties in Washington have enacted similar legislation.

## **II. Alameda County Safe Drug Disposal Ordinance**

Alameda County passed the country's first mandatory pharmaceutical EPR program in June 2012. The County's Safe Drug Disposal Ordinance requires the creation of a drug stewardship program for the collection, transportation, and disposal of unwanted covered drugs that is financed, developed, implemented, and participated in by the producer.<sup>8</sup> The ordinance's requirements, which fall on all pharmaceutical manufacturers (producers) whose drugs are sold in Alameda County, can be grouped into four categories.


First, the ordinance requires producers to design a plan to collect unwanted medications either through drop-off kiosks placed at the place of business of entities authorized by the DEA to collect controlled substances or through other measures convenient to the public. Second, producers are required to coordinate transportation of collected drugs to a hazardous waste facility and ensure safe and appropriate disposal of the medications. Third, producers must design a plan to educate the public and to promote the program to prospective collection facilities. Finally, producers must fund the program, and are prohibited from charging a point-of-sale or point-of-collection fee to consumers.

The ordinance's first requirement requires producers to design a stewardship plan for the collection of unwanted medications. This plan may be devised and operated individually or as a joint endeavor with other producers.<sup>9</sup> Stewardship programs must provide for "collection services for unwanted products [...] that are convenient to the public and adequate to the needs of the population [...] being served."<sup>10</sup> The program must extend to all areas of Alameda County. Moreover, the program must accept all unwanted drugs regardless of whether the drugs were manufactured by the plan sponsor's producer.<sup>11</sup>

A stewardship plan will usually consist of drop-off services at retail pharmacies, hospitals/clinics with on-site pharmacies, and/or law enforcement entities. While the ordinance does not require retailers or other entities to participate as collectors,<sup>12</sup> a producer must provide a kiosk for drop-off services when requested by a prospective collector if two conditions are met.<sup>13</sup> First, the original stewardship plan prepared by the producer(s) must include having physical drop-off sites.<sup>14</sup> Second, a prospective collector must be authorized by the DEA to receive a controlled substance for the purpose of destruction.<sup>15,16</sup>

The ordinance's second major requirement deals with the safe transportation and disposal of collected drugs. Before being approved, a stewardship program must specify how the producers plan to track and handle the unwanted drugs from collection through disposal.<sup>17</sup> The plan must also include a description of the policies and procedures to be followed by persons handling the unwanted drugs, in order to ensure security and safety. All unwanted drugs must be disposed of by incineration at a medical waste or hazardous waste facility, which must be in possession of all required regulatory permits and licenses.<sup>18</sup> Moreover, producers are responsible for making sure that the disposal component of the stewardship program complies with all local, state, and federal regulations, including laws related to the disposal of controlled substances.<sup>19</sup>

Alameda County's ordinance's third major provision requires producers to develop a plan for promotion of their stewardship programs and for public education about the program.<sup>20</sup> Promotional material may include signage displayed at collection facilities that are visible to the public; written material for reproduction by retailers to be provided to the consumer at time of purchasing or delivery of the drug; and advertising or other promotional material related to the stewardship program.<sup>21</sup> Producers are also required to maintain a website publicizing collection locations and a toll-free telephone number where individuals can call to find nearby collection locations and be provided with an explanation of how the program works.<sup>22</sup> The ordinance also requires producers to promote their stewardship programs to pharmacists, retailers of covered drugs, health care practitioners, veterinarians, and veterinary hospitals.<sup>23</sup>



Finally, the ordinance requires producers to cover all the necessary costs associated with development, maintenance, and operation of their stewardship programs. This includes the cost of collecting, transporting, and disposing of unwanted products, and the cost of recycling or disposal (or both) of packaging collected with the unwanted drugs.<sup>24</sup> Producers must also reimburse all costs incurred by the County in the administration and enforcement of the stewardship programs<sup>25</sup> and must pay all administrative fees approved by the Department of Environmental Health.<sup>26,27</sup> The ordinance prohibits producers or other persons from charging specific point-of-sale fees to consumers to recoup the cost of the stewardship program.<sup>28</sup> Charging specific point-of-collection fees at the time the unwanted products are collected or delivered for disposal is also prohibited.<sup>29</sup>

### **III. Pharmaceutical Research and Manufacturers of America v. County of Alameda<sup>30</sup>**


In 2012, several pharmaceutical industry associations sued Alameda County in federal court challenging the constitutionality of the Safe Drug Disposal Ordinance. The plaintiffs alleged that the ordinance represented a per se violation of the dormant Commerce Clause in three ways. First, they argued that the ordinance regulated and burdened interstate commerce by shifting the costs of a local regulatory program onto interstate commerce and, by extension, onto out-of-state consumers. Second, the plaintiffs argued that the ordinance discriminated against interstate commerce by targeting drug products delivered from outside the county to finance a local program. Finally, the complaint alleged that the ordinance favored local interests over interstate interests by shifting costs away from local consumers and taxpayers and onto drug manufacturers and consumers nationwide.

In upholding the validity of the ordinance, the trial court held that the ordinance did not discriminate against out-of-state actors or otherwise place an impermissible burden on interstate commerce.<sup>31</sup> The court analyzed the plaintiffs' Commerce Clause argument under the 9th Circuit approach found in *National Collegiate Athletic Ass'n v. Miller*.<sup>32</sup> Under this approach, the court explained, "a local regulation will be found to be a per se violation of the [Commerce] Clause if it 1) directly regulates interstate commerce; 2) discriminates against interstate commerce; or 3) favors in-state economic interests over out-of-state interests."<sup>33</sup> The court found the ordinance valid under the three prongs.

In affirming the lower court's decision, the Ninth Circuit upheld Alameda's ordinance in its entirety. The court considered the Commerce Clause question under the Supreme Court's two-tier approach in *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*<sup>34</sup> Under that test, a local ordinance will be struck down if 1) the ordinance discriminates against or directly regulates interstate commerce, or 2) the burden the ordinance imposes on interstate commerce is "clearly excessive in relation to the [...] local benefits."<sup>35</sup> The court found that Alameda County's ordinance did not violate the Commerce Clause under either of the two prongs.

The court first held that the ordinance did not discriminate against interstate commerce because it treated all targeted private companies (drug producers) the same. Citing a previous Ninth Circuit opinion,<sup>36</sup> the court stated that, "a statute that treats private companies exactly the same does not discriminate against interstate commerce [...] [e]ven when only out-of-state businesses are burdened because there are no comparable in-state businesses."<sup>37</sup> In this case, the EPR ordinance required all producers who sold drugs in Alameda, irrespective of their geographic place of business, to design and operate a drug stewardship program. In so doing, the ordinance did not treat in-county businesses more favorably than out-of-county businesses because the requirement applied to all drug producers across the board. The fact that most drugs sold in Alameda came from outside the county was irrelevant to the discrimination analysis.<sup>38</sup>

The Ninth Circuit also found unpersuasive the industry associations' argument that the ordinance discriminated against interstate commerce by shifting the cost of a local program to counties outside of Alameda. First, the court stated that for an ordinance to violate the Commerce Clause under this principle, the effect must be shifted entirely to out-of-county businesses. In this case, however, while all pharmaceutical drugs travel in interstate commerce before being sold in Alameda, the fact that some of the drug producers had their headquarters in Alameda was enough to show that the burden was borne by both out-of-county and in-county producers.<sup>39</sup> Second, the court found that the cost of running the stewardship program would not be entirely shifted to out-of-county consumers because if drug prices were increased to recoup the costs of the program, both out-of-county and in-county consumers would experience higher prices.<sup>40</sup> This



across-the-board effect demonstrates that Alameda's ordinance did not discriminate against interstate commerce in favor of in-county businesses.

The court also held that Alameda's EPR ordinance did not violate the Commerce Clause under the second prong of the Brown-Forman test. Under the Supreme Court's Pike decision, a local ordinance will be struck down if the burden it imposes on interstate commerce is clearly excessive in relation to the local benefits it provides. Here, the Ninth Circuit found that the burdens on interstate commerce were minimal for two reasons. First, the cost of running the disposal program was low compared to the producers' revenue.<sup>41</sup> Second, the court found no evidence that the ordinance's requirements would interrupt or decrease the flow of goods (medications) into or out of Alameda County.<sup>42</sup> The court also stated that the environmental, health, and safety benefits the ordinance would provide to the county were enough to satisfy the requirement that the burdens are not clearly excessive in relation to the benefits.

#### **IV. Other Pharmaceutical EPR Measures in the U.S.**

Alameda County's ordinance coupled with the Ninth Circuit's decision upholding the constitutionality of the mandatory pharmaceutical EPR program paved the way for other jurisdictions to enact similar requirements. As of October 2016, one state (Massachusetts) and nine additional counties or cities have passed legislation requiring drug manufacturers selling drugs within their jurisdiction to design and operate stewardship programs for the collection, transportation, and safe disposal of unwanted medications.<sup>43</sup> All of these laws and ordinances follow Alameda's lead with regard to their general requirements, with only minor differences in their particulars (see Table 1).


In all jurisdictions, producers are allowed to operate their product stewardship programs individually or jointly with other producers, but each program must be approved by the local department of health or similar entity before implementation. While most jurisdictions require producers to design their own stewardship programs, King County and Snohomish County, WA allow producers to opt to participate in a standard stewardship plan approved by the Director of the King County Department of Public Health and by the Health Officer of the Snohomish Health District, respectively.<sup>44</sup> This standard plan also serves as a benchmark plan for stewardship plans devised by the producers. Similarly, beginning January 1, 2018, Massachusetts will provide a standard alternative plan that producers can adopt.<sup>45</sup> Producers in the state must still develop their own plans to comply with the requirement during 2017.

Stewardship plans in all jurisdictions must include at least one method to collect unwanted drugs that is convenient and adequate to the public, although what exactly constitutes a convenient and adequate collection method may vary from location to location or may not be defined at all in the law or ordinance, as was the case in Alameda. For example, in King County, Washington, producers are required to establish at least one drop-off site in each city in the county and a minimum of one additional drop-off site for every 30,000 residents.<sup>46</sup> The drop-off sites must be geographically distributed to provide reasonably convenient and equitable access to county residents in different areas.<sup>47</sup> Similarly, producers selling drugs in San Francisco must provide at least five drop-off sites in every Supervisorial District in the city, geographically distributed to provide reasonably convenient and equitable access to the public.<sup>48</sup> In addition, all stewardship plans in San Francisco must provide for a jointly operated drop-off site within each city-owned pharmacy.<sup>49</sup>

Required mail-back services are one area where post-Alameda EPR requirements differ from Alameda's. All new EPR laws, except for Massachusetts's, require producers to establish mail-back programs by which people with disabilities and homebound individuals can mail their unwanted medications. These programs must be provided free of charge and producers must make them available to residents upon request through the stewardship program's toll-free telephone number and website, and through distribution of prepaid, preaddressed mailers to persons who provide services to disabled or homebound individuals.<sup>50</sup> Massachusetts's requirement is not as stringent; producers in the state need not establish a mail back program if they have established other specified methods, which may include collection kiosks, to receive unwanted medications.<sup>51</sup>

Table 1. Summary of Local EPR Laws and Ordinances

Jurisdiction	Effective Date	Producers may operate program jointly?	Jurisdiction provides benchmark plan?	Geographical Locations must be "reasonably convenient"?	Mail back services required?	Must accept all unwanted drugs?	Retail participation required?	Disposal by incineration only?	Education and outreach required?	Producers responsible for fees and costs of program?	Point-of-Sale and Point-of-Collection fee prohibited?
Alameda County, CA	7/24/12	Yes	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
Contra Costa County, CA	1/20/17	Yes	No	Yes	Yes	Yes	No	No	Yes	Yes	Yes
King County, WA	6/20/13	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes
Marin County, CA	9/11/15	Yes	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
Massachusetts	1/1/17	Yes	Yes (2018)	Yes	No	Yes	No	No	Yes	Yes	Yes
San Francisco, CA	4/17/15	Yes	No	Yes	Yes	Yes	No	No	Yes	Yes	Yes
San Mateo County, CA	5/28/15	Yes	No	Yes	Yes	Yes	No	No	Yes	Yes	Yes
Santa Barbara County, CA	7/21/16	Yes	No	Yes	Yes	Yes	No	No	Yes	Yes	Yes
Santa Clara County, CA	7/23/15	Yes	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
Santa Cruz County, CA	1/8/16	Yes	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
Santa Cruz, CA	9/9/16	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Snohomish County, WA	7/14/16	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes



Another area where post-Alameda EPR laws differ is in their definitions of “covered drugs.” While Alameda’s definition of covered drugs is broad and includes prescription and nonprescription drugs, brand name and generic drugs, drugs for veterinary use, and drugs in medical devices and combination products, most jurisdictions that have enacted similar ordinances only include prescription and nonprescription drugs, and brand name and generic drugs, but do not include drugs for veterinary use or drugs in medical devices and combination products. In fact, some municipalities, like San Francisco, have explicitly excluded medical devices and their components from their programs.<sup>52</sup> Other municipalities, like Santa Cruz County, provide a much broader definition of covered drugs, covering all drugs as defined by the Federal Food, Drug, and Cosmetic Act (FFDCA).<sup>53</sup> Also, Santa Cruz County is the only municipality that covers sharps (needles, syringes, and similar objects) as part of their drug stewardship program.<sup>54</sup> Massachusetts’s “covered drug” definition excludes “drugs approved and used primarily for medication-assisted substance use disorder treatment.”

All jurisdictions permit drop-off sites to be located at law enforcement agencies, retail pharmacies, and/or hospitals and clinics with on-site retail pharmacies. In general, drop-off locations must accept all unwanted drugs regardless of who manufactured them and must be accessible to the public during all hours that the collector entity is open for business.<sup>55</sup> Most EPR laws and ordinances follow Alameda’s lead in specifying that nothing in the law or ordinance requires any entity to host collection sites.<sup>56</sup> However, Santa Cruz County’s ordinance is unique in that it requires every retailer that provides or sells drugs or sharps in the county to establish at least one collection system, either through drop-off boxes or mail-back collection.<sup>57</sup> Other ordinances require producers to give preference to having retail pharmacies and law enforcement agencies serve as drop-off sites whenever such an entity requests to participate in the stewardship program, and most of the recently enacted ordinances require producers to accept the request of prospective collectors, if certain conditions, like being authorized by the DEA to collect controlled substances, are met.<sup>58</sup>

Stewardship programs in all jurisdictions are required to transport and dispose of all the collected drugs. In all jurisdictions, producers have the responsibility of transporting collected drugs to medical waste or hazardous waste disposal facilities, as defined by the EPA, for them to be disposed of.<sup>59</sup> However, some of the ordinances are more specific in the required disposal method. While all jurisdictions require disposal methods that are safe to the environment and to the public health, the counties of Marin, Santa Clara, and Santa Cruz, and the city of Santa Cruz all require that collected drugs be disposed of by incineration only.<sup>60</sup>

Like Alameda’s ordinance, all of the other laws require producers to develop a system of promotion, education, and public outreach regarding the stewardship program and that promotes safe storage and secure collection of unwanted drugs. Most of the ordinances follow Alameda’s lead and provide examples of what constitutes appropriate outreach mechanisms, like signage, written material, and advertising, but no law or ordinance, except Santa Cruz County’s, requires a specific mechanism of promotion and education. Santa Cruz requires retailers that provide or sell drugs and/or sharps to put in place “signage prominently displayed within five feet of every public entrance to the retailer or provider establishment and easily visible to the consumer, indicating that the retailer or provider establishment collects consumer-generated covered drugs and/or sharps waste from consumers.”<sup>61</sup> Furthermore, Santa Cruz requires retailers to provide sharps disposal containers at no additional cost to the consumer, which must be sufficient to dispose of all sharps purchased.<sup>62</sup>

All EPR laws and ordinances require producers to cover the costs of administering and operating the program but they tend to be more specific than Alameda with regard to which costs producers are responsible for. In post-Alameda legislation, these costs usually include fees associated with collection and transportation of supplies for drop-off sites; purchase of drop boxes; ongoing maintenance or replacement of drop boxes; cost of collecting unwanted drugs from disabled and/or home-bound residents; transportation of all collected drugs to final disposal; costs associated with environmentally sound disposal of all collected drugs; costs associated with promotion of the program; and costs associated with obtaining compliance with environmental regulations.<sup>63</sup> While laws and ordinances in some municipalities state that they do not seek to preclude producers from recouping the costs of their stewardship programs by raising the prices of their covered drugs,<sup>64</sup> all of the jurisdictions follow Alameda’s lead in prohibiting producers from charging a specific point-of-sale or point-of-collection fee to consumers to recoup the costs of the stewardship programs.<sup>65</sup>



## V. Cost-Effectiveness of Mandatory Stewardship Programs

When the pharmaceutical industry sued Alameda County regarding its mandatory EPR program, the industry claimed that the ordinance required drug producers to incur substantial costs to operate the program and that the ordinance's only purpose and effect was to shift costs away from local government and consumers and onto out-of-state consumers. During the trial, the pharmaceutical companies alleged that the estimated cost of establishing and operating the stewardship program ascended to \$1.2 million per year.<sup>66</sup> By contrast, Alameda County estimated that annual cost for compliance with the ordinance was significantly lower, at approximately \$330,000 per year.<sup>67</sup> During the trial, however, both parties agreed that the difference between the two estimates was not material to the outcome of the case<sup>68</sup> and, thus, there was no further discussion of the program costs.

Although the costs of drug stewardship programs can vary by region, the Product Stewardship Institute, a nonprofit environmental policy group, estimates that most mandatory stewardship programs should cost drug producers approximately one cent for every \$10 in sales.<sup>69</sup> This estimate is similar to the annual cost estimated by Alameda County. In fact, during the briefings and arguments before the federal courts, Alameda repeatedly used the cost figure of "one cent in \$10," without it being disputed by the pharmaceutical industry plaintiffs.<sup>70</sup>


Mandatory programs tend to be less costly than voluntary drug disposal programs because the cost of operation, collection, and disposal is only slightly increased while the amount of collected drugs is considerably higher. While drug companies have offered little evidence to counter Alameda's estimate or to support their own estimate of \$1.2 million, Alameda's estimate is in line with estimates from similar voluntary and mandatory programs in other regions. For example, a 2012 study on the effectiveness of Wisconsin's voluntary take-back program showed that the average cost of the program was between \$0.01 and \$0.02 per prescription sold in the state.<sup>71</sup> In Santa Barbara County, California, a voluntary take-back program costs the Sheriff's department approximately \$172,000 per year, or \$5.30 per pound of drugs collected in nearly 5 years.<sup>72</sup> Similarly, in 2005, the British Columbia mandatory stewardship program collected 39,710 pounds of unwanted drugs at an annual cost of \$190,935, or about \$5.00 per pound collected.<sup>73</sup>

Besides being relatively inexpensive, drug stewardship programs are also effective in increasing the amount of unneeded medications collected for disposal. One reason for this result is that mandatory programs increase access to collection locations by increasing retail pharmacies' participation rate. For example, in British Columbia, Canada, where the government-run stewardship program is funded by producers selling medications in the province, 97.5% of pharmacies participate as collection sites.<sup>74</sup> These locations collected over 100,000 pounds of unused medications in one year alone, equivalent to 0.02 pounds of medications per resident.<sup>75</sup> For comparison, in Oregon, a state with similar population but with no mandatory stewardship program, collection sites collected only about 0.004 pounds of unused drugs per resident, a rate five times lower than British Columbia's drug disposal program.<sup>76</sup> As with the British Columbia program, the mandatory stewardship program in France has resulted in over 60% of unused medications being safely disposed of.<sup>77</sup> In fact, surveys show that 77% of French residents claimed to have disposed of unwanted medication via take-back sites, and that 70% of French residents say they always dispose of their drugs in this way.<sup>78</sup>

While the effectiveness of mandatory drug stewardship programs in reducing the effects of drug misuse and overdose has not been systematically evaluated, these programs are likely to have a positive effect on substance use disorders by reducing the availability of unneeded medications in people's homes. Medications that were not used by the person to whom they were prescribed appear to be a key source of misused opioids. Because mandatory stewardship programs have been proven effective in increasing the number of unneeded drugs collected and because their implementation costs producers only a small fraction of their total revenue, jurisdictions should consider implementing these programs to reduce the amount of opioids available for accidental ingestion and intentional misuse. At the same time, further research is required to assess the program's effectiveness in reducing the instances of drug misuse and the rate of overdoses.

## VI. Conclusion

In response to low rates of participation in voluntary drug take-back programs, several jurisdictions have enacted legislation to require drug manufacturers selling drugs in their state, counties or cities to establish and operate product



stewardship programs. Most jurisdictions have built on Alameda County’s EPR ordinance, which requires producers to develop a plan for the collection, transportation, and disposal of unwanted medications. Alameda’s ordinance also requires producers to develop plans for public education regarding safe disposal of unwanted drugs and education regarding how the stewardship programs work. Outreach efforts must also include promoting the stewardship program to prospective collectors. Moreover, Alameda’s ordinance requires producers to cover all the costs associated with the programs’ administration and operation.

After the Ninth Circuit upheld Alameda’s ordinance, a large and growing number of jurisdictions adopted laws and ordinances requiring drug producers to fund and operate drug stewardship programs, including the state of Massachusetts and large municipalities like King County and the City of San Francisco. Moreover, the first and second largest counties in the country, Cook County, Illinois and Los Angeles County, California are currently in the process of considering mandatory pharmaceutical EPR laws.<sup>79</sup> Requiring drug manufacturers to operate and cover the costs of stewardship programs might be a viable means to address the risks associated with unwanted and unused opioid pain relievers, including the risk of opioid abuse and overdose.

## SUPPORTERS



Robert Wood Johnson Foundation

**The Network for Public Health Law is a national initiative of the Robert Wood Johnson Foundation with direction and technical assistance by the Public Health Law Center at William Mitchell College of Law.**

**This document was developed by Hector Hernandez-Delgado, J.D., Health Law Fellow at the National Health Law Program (NHeLP) and reviewed by Corey Davis, J.D., M.S.P.H., Deputy Director at the Network for Public Health Law — Southeastern Region. The Network for Public Health Law provides information and technical assistance on issues related to public health. The legal information and assistance provided in this document does not constitute legal advice or legal representation. For legal advice, please consult specific legal counsel.**

<sup>1</sup> SAMHSA, Results from the 2014 National Survey on Drug Use and Health: Summary of National Findings, Table 6.47B, <https://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs2014/NSDUH-DetTabs2014.htm#tab6-47b>.

<sup>2</sup> See Environmental Protection Agency, How to Dispose of Medicines Properly, April 2011, <https://archive.epa.gov/region02/capp/web/pdf/ppcpflyer.pdf>.

<sup>3</sup> For example, trash disposal of skin patches for pain relief may harm children who are exposed to the residual fentanyl they contain. See Food and Drug Admin., Medicine Disposal: Questions and Answers, <https://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/ensuringsafeuseofmedicine/safedisposalofmedicines/ucm186188.htm>. For more information on why trash disposal of medicines represents a public health hazard, see Secure Medicine Return Regulation in Snohomish County, Snohomish Health District Board of Health Ordinance No. 2016-001, Section 1: Findings.

<sup>4</sup> Pub. L. No. 111–273, 124 Stat. 2858 (2010).

<sup>5</sup> The Controlled Substances Act of 1970 defined an “ultimate user” as “a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or a member of his household.” 21 U.S.C. § 802(27) (1970). The Act restricted the dispensing of controlled substances to an ultimate user with a prescription or to persons in emergency situations. The Act only permitted ultimate users to destroy those substances themselves, surrender them to law enforcement, or seek assistance from the DEA. By definition, dispensers of controlled substances were not allowed or authorized to receive back unwanted or unused prescribed medications from ultimate users. The Secure and Responsible Drug Disposal Act of 2010 amended this provision to allow dispensers to take back unwanted medications for disposal. 21 U.S.C. § 822a (2010) provides, in relevant part:



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

<sup>6</sup> 21 C.F.R. § 1301.51(b) (2014) provides, in relevant part:

Any manufacturer, distributor, reverse distributor, narcotic treatment program, hospital/clinic with an on-site pharmacy, or retail pharmacy [...], may apply to modify its registration to become authorized as a collector [...].

<sup>7</sup> Product Stewardship Institute, Inc., Protecting our Health and the Environment: The Need for Sustainably Financed Drug Take-Back Programs, July 27, 2012, [http://c.ymcdn.com/sites/www.productstewardship.us/resource/resmgr/Resources\\_-\\_PS-Products/Pharmaceuticals\\_White\\_Paper\\_.pdf](http://c.ymcdn.com/sites/www.productstewardship.us/resource/resmgr/Resources_-_PS-Products/Pharmaceuticals_White_Paper_.pdf).

<sup>8</sup> See Alameda County Code § 6.53.030. Individual producers may design their own stewardship plans or may join the plan designed by other producers. A producer may also enter into an agreement with a stewardship organization to operate, on the producer's behalf, the product stewardship program. Each stewardship program and its components must be pre-approved by the Alameda County Department of Environmental Health before going into effect. Alameda County Code § 6.53.050(B) (2012).

<sup>9</sup> As an alternative, each producer may also enter into an agreement with a stewardship organization to operate the stewardship program on the producer's behalf.

<sup>10</sup> Alameda County Code § 6.53.050(A)(4).

<sup>11</sup> Alameda County Code § 6.53.050(A)(1).

<sup>12</sup> Alameda County Code § 6.53.050(A)(12).

<sup>13</sup> Alameda County Code § 6.53.070(E).

<sup>14</sup> If the producers seek to place drop-off kiosks at collector sites but did not include such a provision in their original stewardship plan, the producers must seek permission from the Department to amend their plan before establishing drop-off locations. Alameda County Code § 6.53.050(B)(6).

<sup>15</sup> 21 C.F.R. § 1300 (2014). Entities authorized by the federal government to collect unwanted medications include, among others, law enforcement agencies, registered manufacturers, and retail pharmacies. 21 C.F.R. § 1317.40 (2014).

<sup>16</sup> The stewardship program may include mail back services, by which people without access to physical drop-off locations can mail their unwanted medications to designated collectors. Nothing in the ordinance requires producers to maintain a system of drop-off locations, instead of only providing mail back services, but a stewardship program that consists solely of mail back services must still comply with the ordinance's adequacy requirement.

<sup>17</sup> Alameda County Code § 6.53.050(A)(7).

<sup>18</sup> Alameda County Code § 6.53.060(B).

<sup>19</sup> Alameda County Code § 6.53.060(A). A producer may use a different method of disposal if such method provides superior environmental and human health protection than the technologies contemplated in the ordinance and if the Department of Environmental Health approves their request to use a different disposal method. Alameda County Code § 6.53.060(C).

<sup>20</sup> Alameda County Code § 6.53.070

<sup>21</sup> Alameda County Code § 6.53.070(B).

<sup>22</sup> Alameda County Code § 6.53.070(C).

<sup>23</sup> Alameda County Code § 6.53.070(A).

<sup>24</sup> Alameda County Code § 6.53.040(B)(1). Producers must also cover the fees associated with obtaining compliance with the California Environmental Quality Act if required of their stewardship program.

<sup>25</sup> Alameda County Code § 6.53.040(B)(4).

<sup>26</sup> Alameda County Code § 6.53.100.

<sup>27</sup> If more than one producer participates in a single plan, the program's operational cost and the fees associated with it must be distributed among each participating producer in a way that proportionally reflects the share of each producer's sales in the Alameda County market. Alameda County Code § 6.53.050(A)(13).

<sup>28</sup> Alameda County Code § 6.53.040(B)(3).

- 
- <sup>29</sup> *Id.*
- <sup>30</sup> 768 F.3d 1037 (9th Cir. 2014).
- <sup>31</sup> *Pharmaceutical Research and Manufacturers of America v. County of Alameda*, 967 F.Supp.2d 1339, 1340 (N.D. Cal. 2013).
- <sup>32</sup> 10 F.3d 633, 638 (9th Cir. 1993).
- <sup>33</sup> *Pharmaceutical Research and Manufacturers of America*, 967 F.Supp.2d 1339, 1344.
- <sup>34</sup> 476 U.S. 573, 578–79 (1986).
- <sup>35</sup> *Pike v. Bruce Church, Inc.*, 397 U.S. 137 (1970).
- <sup>36</sup> *Assoc. des Eleveurs de Canards et d'Oies du Quebec v. Harris*, 729 F.3d 937, 948 (9th Cir. 2013).
- <sup>37</sup> *Pharmaceutical Research and Manufacturers of America*, 768 F.3d 1037, 1041.
- <sup>38</sup> *Id.* at 1042.
- <sup>39</sup> *Id.*
- <sup>40</sup> *Id.* at 1043. The Ninth Circuit also held that Alameda's ordinance did not directly regulate interstate commerce because its purpose was not to control conduct beyond the boundaries of the county, but to regulate in-county conduct of an out-of-county entity that chooses to engage the county through interstate commerce. *Id.* at 1043–1044.
- <sup>41</sup> *Id.* at 1045. The cost of running the program was estimated by Alameda County to be between \$530,000 and \$1,200,000 per year, whereas the producers' revenue stream in Alameda was \$950 million per year.
- <sup>42</sup> *Id.* at 1045–1046.
- <sup>43</sup> The municipalities in California that have enacted similar mandatory stewardship programs are the counties of Contra Costa (Contra Costa County Ordinance Code § 418-16 (2017)); Marin (Marin County Code of Ordinances §§ 7.90.010–7.90.160 (2015)); San Mateo (San Mateo County Code §§ 4.116.010–4.116.190 (2015)); Santa Barbara (Santa Barbara County Code §§ 18C-12–18C-30 (2016)); Santa Clara (Santa Clara County Code §§ B11-539–B11-555 (2015)); and Santa Cruz (Santa Cruz County Code §§ 7.95.010–7.95.120 (2015)), and the cities of San Francisco (San Francisco Environment Code §§ 2200–2219, 2250–2254 (2015)) and Santa Cruz (Santa Cruz Municipal Code §§ 6.93.010–6.93.150 (2016)). King County (King County Board of Health Code §§ 11.50.010–11.50.160 (2013)) and Snohomish County (Snohomish Health District Sanitary Code §§ 15.1–15.21 (2016)) in Washington have also enacted similar local ordinances.
- <sup>44</sup> King County Board of Health Code § 11.50.040(A); Snohomish Health District Sanitary Code § 15.6(A).
- <sup>45</sup> Mass. Gen. Laws. Ann. ch. 94H, § 6 (2017). See also Department of Public Health, Circular Letter DHCQ 17-1-666, January 18, 2017, <http://www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/drug-stewardship-letter.pdf>.
- <sup>46</sup> King County Board of Health Code § 11.50.060(D)(3).
- <sup>47</sup> *Id.*
- <sup>48</sup> San Francisco Environment Code § 2205(b)(1).
- <sup>49</sup> San Francisco Environment Code § 2205(c).
- <sup>50</sup> See, for example, King County Board of Health Code § 11.50.060(F); San Francisco Environment Code § 2205(b)(5); Santa Barbara County Code § 18C-16(B)(4).
- <sup>51</sup> Mass. Gen. Laws. Ann. ch. 94H, § 3 (2017); see also Mass. Dept. of Pub. Health, Circular Letter DHCQ 17-1-666, January 18, 2017, <http://www.mass.gov/eohhs/docs/dph/quality/boards/drug-stewardship-letter.pdf>.
- <sup>52</sup> San Francisco Environment Code § 2202.
- <sup>53</sup> Santa Cruz County Code § 7.95.030.
- <sup>54</sup> See Santa Cruz County Code § 7.95.010.
- <sup>55</sup> See, for example, King County Board of Health Code § 11.50.060(E); San Francisco Environment Code § 2205(d); Santa Barbara County Code § 18C-16(D); Santa Clara County Code § B11-545(c).

- 
- <sup>56</sup> See, for example, King County Board of Health Code § 11.50.060(A); San Francisco Environment Code § 2205(a); Santa Barbara County Code § 18C-16(A); Santa Clara County Code § B11-545(a).
- <sup>57</sup> Santa Cruz County Code § 7.95.075(B)(1). Santa Cruz does require producers to pay or reimburse retailers for the cost incurred in participating in the collection program. Santa Cruz County Code § 7.95.075(E).
- <sup>58</sup> See, for example, King County Board of Health Code § 11.50.060(D)(2); San Francisco Environment Code § 2205(b)(3)–(4); Santa Barbara County Code § 18C-16(B)(3); Santa Clara County Code § B11-545(b)(3)–(4).
- <sup>59</sup> See, for example, King County Board of Health Code § 11.50.080(A); San Francisco Environment Code § 2207(a); Santa Barbara County Code § 18C-19(A).
- <sup>60</sup> Marin County Code of Ordinances § 7.90.090(B); Santa Clara County Code § B11-546(b); Santa Cruz County Code § 7.95.060(B).
- <sup>61</sup> Santa Cruz County Code § 7.95.075(B)(2).
- <sup>62</sup> Santa Cruz County Code § 7.95.075(C).
- <sup>63</sup> See, for example, King County Board of Health Code § 11.50.090(A); San Francisco Environment Code § 2208(a); Santa Barbara County Code § 18C-20(A); Santa Clara County Code § B11-549(a).
- <sup>64</sup> Snohomish Health District Sanitary Code § 15.1(I).
- <sup>65</sup> See, for example, King County Board of Health Code § 11.50.090(C); San Francisco Environment Code § 2208(b); Santa Barbara County Code § 18C-20(B); Santa Clara County Code § B11-549(b).
- <sup>66</sup> *Pharmaceutical Research and Manufacturers of America*, 967 F.Supp.2d 1339, 1343.
- <sup>67</sup> *Id.*
- <sup>68</sup> *Id.*
- <sup>69</sup> Ed Silverman, *Who should pay for disposing unused drugs? Pharma says: not us*, STAT, May 3, 2016, <https://www.statnews.com/pharmalot/2016/05/03/drug-take-back/> (last visited Feb. 28, 2017).
- <sup>70</sup> Arthur J. Shartsis & Heidi Sanborn, *The Truth about Costs of the LA County Drug Take-Back Ordinance*, Shartsis Fiese LLP, April 22, 2016, <http://www.sflaw.com/oped-truth-costs-la-county-drug-take-back-ordinance/>.
- <sup>71</sup> University of Wisconsin Extension & Product Stewardship Institute, Inc., *Wisconsin Household Pharmaceutical Waste Collection*, Oct. 15, 2012, <http://dnr.wi.gov/topic/healthwaste/documents/2012householdpharmstudy.pdf>.
- <sup>72</sup> Kelsey Brugger, *County Looks to Big Pharma to Fund Drug Take Back*, Santa Barbara Independent, May 20, 2015, <http://www.independent.com/news/2015/may/20/county-looks-big-pharma-fund-drug-take-back/>.
- <sup>73</sup> Oregon Pharmaceutical Take Back Stakeholder Group, *Final Report*, July 1, 2007, <http://www.oracwa.org/pdf/oregon-drug-takeback-report.pdf>.
- <sup>74</sup> Ed Gottlieb, *4 Reasons why EPR is the Best Solution for Safe Drug Disposal*, The PSI Blog, March 26, 2015, <https://productstewardshipinstitute.wordpress.com/2015/03/26/4-reasons-why-epr-is-the-best-solution-for-safe-drug-disposal/>.
- <sup>75</sup> *Id.*
- <sup>76</sup> *Id.*
- <sup>77</sup> For information on France's mandatory drug stewardship program, see [www.cyclamed.org/association/chiffres](http://www.cyclamed.org/association/chiffres) (in French).
- <sup>78</sup> Ed Gottlieb, *supra* note 77.
- <sup>79</sup> As of October 2016, the Cook County Safe Disposal of Pharmaceuticals Ordinance, Ordinance 16-1983, had been unanimously favored by the Legislation and Intergovernmental Relations Committee of the Cook County Board of Commissioners. For more information, see <https://cook-county.legistar.com/LegislationDetail.aspx?ID=2625841&GUID=B66B6059-470C-48BB-B629-31B3DA6CDBC0&Options=Advanced&Search>. In Los Angeles County, similar legislation was rejected on June 14, 2016 because of concerns that a mandatory stewardship program would be too costly for drug manufacturers and ineffective. Instead, the Los Angeles County Board of Supervisors adopted a measure to require county staff members to work with pharmaceutical industry groups and other stakeholders to develop a public education campaign. The county government, in partnership with drug manufacturers, will also begin hosting quarterly drug take-back events, while studying the outcomes of drop-off kiosks already in place in several retail pharmacies. For more information, see Abby Sewell, *L.A. County*



---

*supervisors roll back plans for drug take-back program*, June 14, 2016, <http://www.latimes.com/local/lanow/la-me-ln-drug-takeback-20160614-snap-story.html> (last visited Feb. 28, 2017).