



Home-Generated Sharps and Pharmaceutical Waste

By Designating a Lead Agency, the State Could
Increase Proper Disposal

Report 2016-127

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May 9, 2017

2016-127

The Governor of California
President pro Tempore of the Senate
Speaker of the Assembly
State Capitol
Sacramento, California 95814

Dear Governor and Legislative Leaders:

As requested by the Joint Legislative Audit Committee, the California State Auditor presents this audit report concerning home-generated sharps and pharmaceutical waste. This report concludes that the lack of a lead state agency to oversee home-generated sharps and pharmaceuticals waste disposal has left California consumers with conflicting guidance and a lack of adequate information about collection sites. Because it already has oversight of state-managed solid waste handling programs, the California Department of Resources Recycling and Recovery (CalRecycle) may be best positioned to manage this oversight. In fact, one of the four options for statewide pharmaceutical waste collection that CalRecycle provided in a 2010 report generally aligns with our recommendation to assign oversight responsibility to a single state agency.

Improper disposal of sharps and pharmaceutical waste can pose risks to the public and to the environment. While our analysis suggests that more than 89 percent of Californians have access to free collection sites, the State does not maintain an accurate and accessible list of these collection sites. Further, about four million Californians may not live within 20 minutes of a collection site. By designating a lead state agency to coordinate messages, educate consumers, maintain an accurate collection site list, and implement disposal options for consumers who do not live near a collection site, the State could increase the proper disposal of this waste. California has sufficient capacity to process increased amounts of home-generated sharps and pharmaceutical waste, but pharmaceutical waste is mostly disposed of out of state because government recommendations and legal requirements discourage in-state incinerators from accepting it.

California could improve its collection and disposal of home-generated sharps and pharmaceutical waste by adopting parts of programs and practices that other states and countries use. However, some programs, including those that assign the cost for disposal to manufacturers—known as extended producer responsibility (EPR) programs—are likely to pass on costs to consumers. Several California counties have begun implementing EPR programs, but some manufacturers have resisted, in part, because counties may adopt different requirements that manufacturers believe create inefficiencies and add to costs. To ensure consistency throughout the State and to minimize the cost to consumers, the Legislature should adopt standard requirements for counties to follow when implementing EPR programs.

Respectfully submitted,



DOUG CORDINER, CGFM
Chief Deputy State Auditor

Selected Abbreviations Used in This Report

CalRecycle	California Department of Resources Recycling and Recovery
DEA	U.S. Drug Enforcement Administration
EPA	U.S. Environmental Protection Agency
EPR	extended producer responsibility
FacIT	Facility Information Toolbox
FDA	U.S. Food and Drug Administration
Pharmacy Board	California State Board of Pharmacy
Public Health	California Department of Public Health

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Summary

Results in Brief

When consumers improperly dispose of home-generated sharps and pharmaceutical waste, the waste can pose an unnecessary risk to others and to the environment. Sharps waste—which consists of used needles, lancets, and other medical devices with sharp points or edges—can potentially result in disease transmission. On the other hand, pharmaceutical waste—which consists of prescription and over-the-counter medications—can harm water quality or be misused. Agencies that provide advice offer consumers different, and sometimes conflicting, guidance about how and where to dispose of these types of waste. For example, some agencies recommend that consumers use official collection programs to dispose of pharmaceutical waste, but others recommend placing it in the trash or flushing it down the toilet. Similarly, state agencies generally recommend that consumers dispose of home-generated sharps waste in approved disposal containers, but some federal agencies recommend putting this waste in heavy plastic containers, making it illegal to transport in California if the local enforcement agency has not approved the container. These inconsistencies may confuse consumers, increasing the likelihood that they will dispose of home-generated sharps and pharmaceutical waste in unsafe or environmentally harmful ways.

Conflicting guidance regarding the disposal of sharps and pharmaceutical waste is in part the result of the fact that the State has not assigned oversight of this issue to a specific state agency. Rather, a number of different agencies have related responsibilities depending on how the waste is collected and processed. Specifically, the California Department of Resources Recycling and Recovery (CalRecycle), the California Department of Public Health (Public Health), the California State Board of Pharmacy, and the Department of Toxic Substances Control all play roles related to the processing of this waste. By placing oversight responsibility with a single agency, the State could ensure the creation of a unified educational campaign promoting consistent and proper disposal methods. We believe CalRecycle may be best-positioned to oversee household pharmaceutical and sharps waste because it already provides oversight for all state-managed solid waste-handling programs.

If the State assigned responsibility to a single agency, that agency could also help to ensure that all Californians have access to and awareness of collection sites and other means of sharps and pharmaceutical waste disposal. Although our analysis suggests that about 89 percent of consumers live within a 20-minute drive of sites for proper disposal, these consumers may not be aware of

Audit Highlights . . .

Our review concerning home-generated sharps and pharmaceutical waste highlighted the following:

- » *The State has not assigned oversight responsibility to a specific state agency for the disposal of home-generated sharps and pharmaceutical waste.*
- » *Consumers receive conflicting guidance regarding the proper disposal of sharps and pharmaceutical waste.*
- » *The State does not maintain an accurate and accessible list of collection sites for sharps and pharmaceutical waste disposal.*
- » *Because it already provides oversight for all state-managed solid waste-handling programs, CalRecycle may be best-positioned to oversee household pharmaceutical and sharps waste.*
- » *California could improve its collection and disposal of home-generated sharps and pharmaceutical waste by adopting programs and practices that other states and countries use.*

this access because no state agency maintains an accurate and comprehensive list of such sites. Both Public Health and CalRecycle maintain lists of collection sites; however, these lists are difficult to access and contain numerous errors. Further, our analysis suggests that about four million Californians may not live within 20 minutes of collection sites. An oversight entity could ensure that the State implements options to help these consumers, which might include subsidizing the use of mail-back containers to dispose of sharps and pharmaceutical waste.

California has more than sufficient capacity to process all of the State's home-generated sharps and pharmaceutical waste; however, laws and regulations discourage processing pharmaceutical waste within the State. In California, sharps are generally sterilized at one of the State's 18 medical waste facilities and then deposited in landfills. Home-generated sharps waste represents less than 1 percent of the available capacity of these facilities. If pharmaceutical waste includes controlled substances, the DEA requires collectors to ensure that such waste is rendered irretrievable, which usually means some form of incineration. Although three incinerators operate in the State that could dispose of pharmaceutical waste, government recommendations and legal requirements discourage these in-state incinerators from accepting pharmaceutical waste. Consequently, collection programs dispose of pharmaceutical waste by hauling it to out-of-state incinerators. Both the out-of-state and in-state incinerators have more than sufficient capacity to handle any future increases in the amount of the State's home-generated pharmaceutical waste.

California could improve its collection and disposal of home-generated sharps and pharmaceutical waste by adopting programs and practices that other states and countries use. For example, the state of New York requires all pharmacies to display that state's approved pharmaceutical disposal methods and requires all hospitals to accept household sharps for disposal. Canada uses extended producer responsibility programs (EPR programs) to assign the cost for disposal of pharmaceutical and sharps waste to the producers or manufacturers of the products, although in California these costs could ultimately be transferred to consumers through price increases. Several California counties have also begun implementing EPR programs but have encountered delays, mainly due to the resistance of the sharps and pharmaceutical industries.

In addition, at the Legislature's request, in 2010 CalRecycle provided options for statewide pharmaceutical waste collection programs. Although we have concerns about three of the four options CalRecycle outlined, one of its proposed models generally aligns with our audit recommendations. Specifically, this

option focuses on the Legislature's assigning oversight responsibility to a single state agency, which could then adopt regulations that might increase consumers' proper disposal of pharmaceutical waste.

Selected Recommendations

To foster consumers' proper disposal of sharps and pharmaceutical waste, the Legislature should provide CalRecycle statutory oversight responsibility for home-generated sharps and pharmaceutical waste disposal and provide CalRecycle additional resources to the extent it can justify the need. This responsibility should include the following activities:

- Developing and implementing a public education campaign about home-generated sharps and pharmaceutical waste. CalRecycle should coordinate this campaign with local, state, and, to the extent possible, federal agencies to ensure consumers receive consistent guidance regarding proper disposal methods.
- Maintaining an up-to-date, well-publicized, and accessible statewide list of free sharps and pharmaceutical waste collection sites.
- Increasing consumer access to proper disposal sites in underserved areas.

To increase in-state options for processing California's home-generated pharmaceutical waste, the Legislature should consider expressly authorizing municipal solid waste incinerators to burn limited quantities of home-generated pharmaceutical waste, but only after considering environmental impacts.

To ensure consistency throughout the State, the Legislature should adopt standard requirements for counties to follow when implementing EPR programs. These requirements should limit any additional costs the programs may impose on consumers.

Agency Comments

Although we only have recommendations directed to the Legislature, we provided a draft redacted copy of our report to CalRecycle for review and comment because we are recommending that it become the lead state agency over the disposal of sharps and pharmaceutical waste. In its response, CalRecycle took issue with certain information in our report and it also expressed significant reluctance in taking on this leadership role.

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Introduction

Background

Every year Californians use hundreds of millions of sharps—such as syringes, lancets, and other devices used to penetrate the skin for the delivery of medications—and obtain hundreds of millions of prescriptions, according to estimates by the California Department of Resources Recycling and Recovery (CalRecycle) and by the Henry J. Kaiser Family Foundation, a nonprofit organization. When consumers improperly dispose of these sharps and pharmaceuticals, the discarded items can potentially pose health, safety, and environmental risks.

If residents improperly dispose of home-generated sharps waste, that waste can represent a risk to public health. For example, if consumers dispose of sharps waste through the trash, workers who process that trash may be stuck by loose needles. A 2015 report by the University of California, Berkeley, for the Commission on Health and Safety and Workers' Compensation indicated that the risk of contracting serious diseases, such as HIV, from such injuries is low. However, because of the fear of disease contraction, needle-stick injuries can result in significant psychological stress, if not infection.

On the other hand, the risks associated with the improper disposal of pharmaceutical waste largely relate to environmental impact and inappropriate consumption.

Pharmaceutical waste consists of both prescription and over-the-counter medications. In a 2011 study, the U.S. Geological Survey found that measurable amounts of pharmaceutical compounds were present in the State's groundwater. These compounds can come from a number of different sources, including treated wastewater, landfills, septic systems, sewer lines, and animal waste. Pharmaceutical waste in waterways can cause behavioral changes in fish, according to a 2014 study published by the Royal Society, a scientific academy. A separate danger is that minors or opioid addicts may consume unused pharmaceuticals that consumers stockpile in homes or dispose of improperly.

Four state agencies are involved in overseeing or regulating the disposal of home-generated sharps and pharmaceutical waste. The text box contains short descriptions of the agencies and their regulatory responsibilities related to these types of waste.

Agencies That Have Responsibilities Related to Home-Generated Sharps and Pharmaceutical Waste

California Department of Public Health (Public Health): Regulates medical waste management programs, which encompass home-generated sharps when consolidated as medical waste.

CalRecycle: Collects information on the amount of household hazardous waste consumers dispose of, which includes home-generated sharps and pharmaceuticals.

California State Board of Pharmacy (Pharmacy Board): Licenses pharmacies, which serve as collection sites for home-generated sharps and pharmaceutical waste.

Department of Toxic Substances Control (Toxic Substances Control): Issues permits for household hazardous waste sites, which consumers can use to dispose of sharps and pharmaceuticals.

Sources: State law, Public Health staff, and CalRecycle's website.

The Disposal and Treatment of Home-Generated Sharps Waste

California law imposes a number of restrictions on the disposal of home-generated sharps. The Medical Waste Management Act (medical waste act), enacted in 1995, regulates the disposal of medical waste in California from commercial sources, such as hospitals, clinics, and other medical waste generators. Although the medical waste act specifically excludes home-generated waste from its requirements, it also states that collection sites must treat any home-generated sharps waste they receive as medical waste. Further, since September 2008, state law has specifically prohibited California residents from disposing of sharps waste in the trash.

State Law Allows Four Types of Facilities to Collect Home-Generated Sharps Waste

Household hazardous waste sites: These facilities may be operated by local government entities and collect a wide variety of hazardous waste, including paint and motor oil.

Consolidation points for home-generated sharps: Consolidation points must be approved by Public Health or other local enforcement agencies, and they can be pharmacies, police departments, or other facilities.

Medical waste generators: Businesses that generate medical waste include hospitals and clinics.

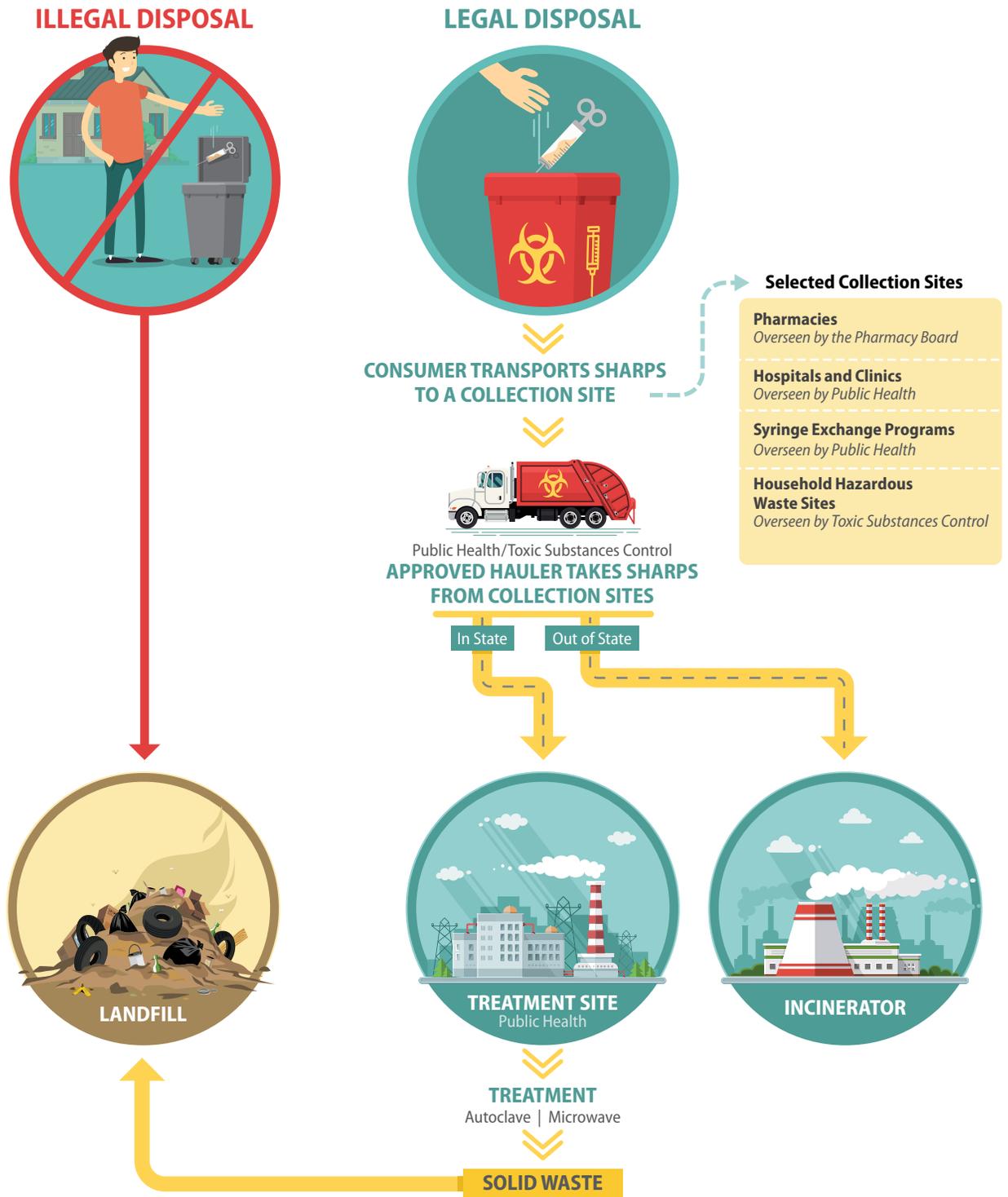
Facilities that receive sharps through mail-back containers: Generally, private waste management and medical device companies are vendors for mail-back containers, which are required to be approved by the U.S. Postal Service.

Sources: Public Health, U.S. Postal Service regulations, and CalRecycle's website.

Both Public Health and CalRecycle encourage consumers to dispose of their sharps waste at collection sites or via approved mail-back containers. State law limits collection of home-generated sharps waste to the entities listed in the text box. As Figure 1 shows, approved collection sites can include pharmacies, hospitals, household hazardous waste sites, police stations, or sharps collection kiosks. State law requires that when residents return sharps waste to collection sites, they do so in approved sharps containers or other containers that local enforcement agencies may approve. In addition, consumers may purchase or otherwise obtain U.S. Postal Service-approved mail-back containers to dispose of sharps waste by mailing it to disposal facilities. Finally, local governments may provide a collection service through waste haulers. This service allows consumers to call their local trash haulers to request sharps collection at their residences.

The type of collection site at which consumers dispose of sharps waste will determine how the waste is processed. Because state law requires collection sites to dispose of sharps as medical waste, the sites must send sharps waste to approved medical waste treatment facilities for treatment and disposal. There are 18 medical waste treatment facilities that operate in California. These treatment facilities can sterilize sharps waste to protect against disease transmission, and then they may dispose of the waste in landfills. However, federal law imposes different requirements when consumers return sharps waste to household hazardous waste sites. Specifically, even though sharps waste may not be considered hazardous waste legally, federal law states that any mixture of solid waste and hazardous waste is a hazardous waste.

Figure 1
Collection Sites Offer Options for Legal Disposal of Home-Generated Sharps



Sources: California State Auditor's analysis of relevant laws pertaining to home-generated sharps disposal, information from Public Health as well as sharps disposal information from programs in San Luis Obispo County, Orange County, and the City and County of San Francisco.

The Disposal and Treatment of Home-Generated Pharmaceutical Waste

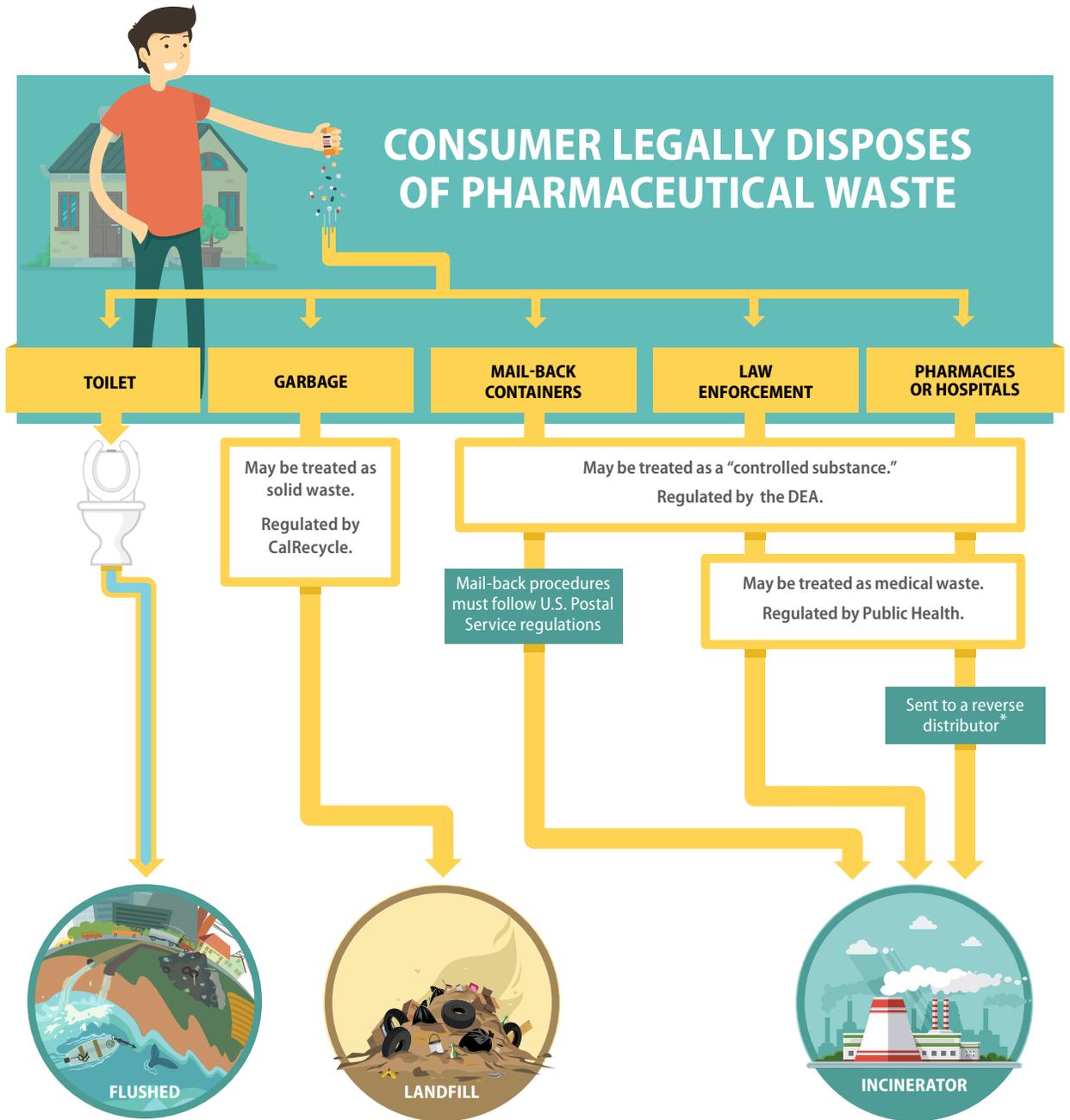
Although state law defines *pharmaceutical waste*, it does not identify or provide any specific regulatory framework for home-generated pharmaceutical waste. As household waste, home-generated pharmaceutical waste—in most circumstances—is exempt from state and federal hazardous waste laws and state medical waste laws. Thus, consumers may legally dispose of their pharmaceutical waste in their garbage. However, federal regulations do place certain restrictions on the collection of pharmaceutical waste that contains controlled substances. Specifically, federal law mandates that controlled substances can only be collected by law enforcement and certain collection sites that register with the Drug Enforcement Administration (DEA), such as hospitals and pharmacies.

Californians have several options for legally disposing of most pharmaceutical waste; however, not all of the methods are equally safe and appropriate. For example, California law does not clearly prohibit consumers from disposing of pharmaceutical waste by placing it in the trash or by flushing it down the toilet. However, localities may prohibit the flushing of home-generated pharmaceutical waste, as does the City and County of San Francisco (San Francisco), citing concerns with water quality. For the same reason, state agencies discourage the practice. Figure 2 shows that the methods consumers use to dispose of pharmaceutical waste determine the state and federal agencies with oversight authority of that waste.

In 2010 CalRecycle issued a report outlining its adopted model guidelines for home-generated pharmaceutical collection programs. Its guidelines recommended that programs allow residents to return pharmaceutical waste to designated permanent collection sites, which can include pharmacies, health care collection sites, police stations, and public health agencies, among others. Also, consumers may use approved mail-back containers to send pharmaceuticals to registered collectors of controlled substances.

CalRecycle's model guidelines recommend that collection sites should treat home-generated pharmaceutical waste as either medical or hazardous waste. Additionally, in 2012 the U.S. Environmental Protection Agency (EPA) recommended that collection sites destroy pharmaceutical waste using hazardous waste incinerators or, if these are not feasible, municipal waste incinerators. As we discuss in the Audit Results, local data suggest that most incineration of pharmaceutical waste occurs out of state, although California's in-state incinerators can and do destroy some amount of pharmaceutical waste. Figure 3 on page 10 illustrates the different recommendations that federal and state agencies have issued for how to dispose of sharps and pharmaceutical waste other than controlled substances.

Figure 2
California's Consumers Unknowingly Choose How Home-Generated Pharmaceutical Waste Is Processed



Sources: Federal and state law, interviews with agency staff, and pharmaceutical collection programs in San Luis Obispo County and in San Francisco.

* Reverse distributors act as agents for pharmacies and other entities by receiving, inventorying, managing, and disposing of outdated or unsalable dangerous drugs. DEA regulations require reverse distributors to either render controlled substances irretrievable or return them to the manufacturer.

Figure 3
State and Federal Agencies Suggest Ways to Dispose of Home-Generated Sharps and Pharmaceutical Waste



Drop off sharps waste at a syringe exchange program.



Take pharmaceutical waste to a "drug take-back" event.



Throw pharmaceutical waste in trash after mixing with an undesirable substance.



Use a mail-back program for sharps or pharmaceutical waste.



Take sharps or pharmaceutical waste to a collection site.

Sources: California State Auditor's analysis of federal and state agencies' messages about proper disposal of home-generated sharps and pharmaceutical waste.

Scope and Methodology

The Joint Legislative Audit Committee (Audit Committee) directed the California State Auditor to conduct an audit of home-generated sharps and pharmaceutical waste disposal in California. We list in Table 1 the Audit Committee's 11 separate approved objectives and the methods we used to address them.

Table 1
Audit Objectives and the Methods Used to Address Them

AUDIT OBJECTIVE	METHOD
1 Review and evaluate the laws, rules, and regulations significant to the audit objectives.	Reviewed relevant laws, rules, and regulations related to Public Health, CalRecycle, the Pharmacy Board, and Toxic Substances Control.
2 To the extent that home-generated medical waste information is available, do the following: <ul style="list-style-type: none"> <li data-bbox="349 598 820 913">a. Determine, to the extent possible, the volume of home-generated sharps and pharmaceutical waste that was disposed of statewide using approved household disposal methods over the past three years. <li data-bbox="349 913 820 1018">b. Estimate, to the extent possible, the volume of home-generated sharps and pharmaceutical waste that may have been improperly disposed of statewide over the past three years. <li data-bbox="349 1018 820 1144">c. Assess, to the extent possible, differences in home-generated sharps and pharmaceutical waste in areas with needle exchange programs versus areas without such programs. 	<ul style="list-style-type: none"> <li data-bbox="836 598 1516 682">• Searched pertinent websites to determine what data exist for the volume of home-generated sharps and pharmaceutical waste properly disposed of from fiscal years 2013–14 through 2015–16. <li data-bbox="836 682 1516 787">• Obtained and tested household hazardous waste site collection data to determine the extent of data inaccuracies. We determined whether we could use any of the data to estimate statewide sharps and pharmaceutical waste volume. <li data-bbox="836 787 1516 913">• Developed an annual statewide estimate based on data from San Francisco, as well as from other sources, because San Francisco’s large population makes its data less variable than those of cities or counties with smaller populations, and because it has multiple data sources. Searched pertinent websites to determine what data exist for the volume of home-generated sharps and pharmaceutical waste improperly disposed of from fiscal years 2013–14 through 2015–16. Reviewed syringe exchange program data from 11 syringe exchange programs, as well as from two of the counties we visited. Because these programs collect data inconsistently, we were unable to assess for collection differences.
3 Identify the methods that exist currently for free home-generated sharps and pharmaceutical waste disposal within California.	Obtained and reviewed lists that contain information regarding free home-generated sharps and pharmaceutical waste collection sites and determined the accuracy of these lists. We also used geographic information systems software to compare the availability of home-generated sharps and pharmaceutical waste collection sites to U.S. Census data for California.
4 To the extent that information is available, determine the collection rate for voluntary take-back programs that manufacturers funded in the past three years for home-generated sharps and pharmaceutical waste.	Determined whether manufacturer-funded take-back programs existed within each jurisdiction we visited. Reviewed implementation of extended producer responsibility programs and ordinances in San Francisco and in Alameda County.
5 Determine which medical waste collection models generate the best waste-collection results for both home-generated sharps and pharmaceutical waste. Consider county-based collection models, including needle exchange programs, as well as those adopted in Canada and other countries.	Performed online research on three states and four countries to understand their home-generated pharmaceutical and sharps collection models and data. In addition, we evaluated county-based collection models in San Francisco and in San Luis Obispo County. Because of these programs’ data limitations, we were unable to compare the effectiveness of their efforts.
6 Identify any existing regulatory limitations on establishing home-generated sharps or pharmaceutical waste collection sites or on methods for collecting that waste. Assess the reasonableness of any barriers that exist.	Identified limitations caused by legal requirements for various collection types. Reviewed the legal impact of classifying home-generated pharmaceutical waste as <i>hazardous waste</i> .
7 To the extent that information related to waste-processing capacity is available, do the following: <ul style="list-style-type: none"> <li data-bbox="349 1837 820 1913">a. Determine the statewide capacity for processing home-generated sharps and pharmaceutical waste in each of the last three years. 	Calculated the statewide capacity available for medical waste treatment and determined the statewide capacity for incineration.

AUDIT OBJECTIVE	METHOD
b. Determine the existing waste-processing capacity in California that could accommodate growth in proper disposal of home-generated sharps and, if applicable, of pharmaceutical waste.	Calculated the existing statewide processing capacity to accommodate both sharps and pharmaceutical waste disposal and compared total available capacity to our estimate of current sharps and pharmaceutical waste collection.
8 Determine where home-generated sharps and pharmaceutical waste is processed and the methods used to process the waste.	<ul style="list-style-type: none"> • Determined methods with which California home-generated sharps and pharmaceuticals is treated and processed and where this information is documented. • Analyzed local tracking documents, medical waste treatment permits, and waste-to-energy facility reports to determine how medical waste is processed in California, and where waste goes after it is treated.
9 To the extent possible, compare processing rates for home-generated sharps and, if applicable, home-generated pharmaceutical waste, in a selection of jurisdictions Public Health oversees to a comparable selection of jurisdictions with local oversight. Determine what differences exist among the jurisdictions that may affect California's processing rates.	Obtained processing rates for home-generated sharps and home-generated pharmaceutical waste, for the three counties we visited, of which one, San Luis Obispo, was under Public Health's oversight. However, because of differences in data collection methods, we were unable to compare their efforts.
10 Identify the recommendations CalRecycle and Public Health have made regarding home-generated sharps and pharmaceutical waste collection and disposal. Assess whether the recommendations reflect best practices.	<ul style="list-style-type: none"> • Reviewed CalRecycle's 2010 <i>Report to the Legislature—Recommendations for Home-Generated Pharmaceutical Collection Programs in California</i> (recommendations report). • Assessed the feasibility of the options CalRecycle identified in the report based on four criteria specified in state law: safety, accessibility, cost-effectiveness, and efficacy.
11 Review and assess any other issues that are significant to the audit.	<ul style="list-style-type: none"> • Reviewed federal and state entities websites for messages to consumers regarding the disposal of home-generated sharps and pharmaceutical waste. • Analyzed messages to identify trends and conflicts.

Sources: California State Auditor's analysis of the Audit Committee's audit request number 2016-127, state law, planning documents, and analysis of information and documentation identified in the column titled *Method*.

Assessment of Data Reliability

The U.S. Government Accountability Office (GAO), whose standards we are statutorily required to follow, requires us to assess the sufficiency and appropriateness of the computer-processed information that we use to support our findings, conclusions, or recommendations. Table 2 describes the analyses we conducted using the data from the information systems we used, our methods for testing them, and the results of our assessments.

Table 2
Methods Used to Assess Data Reliability

INFORMATION SYSTEM	PURPOSE	METHOD AND RESULT	CONCLUSION
CalRecycle's Facility Information Toolbox (FacIT)	To develop a combined list of free home-generated sharps and pharmaceutical waste collection sites for our analysis of access in California.	To test the completeness of combined list, we compared the pharmacies on these lists to the Pharmacy Board's list of active pharmacies and identified several errors, which we corrected.	Not sufficiently reliable for the purpose of this audit. Although this determination may affect the precision and completeness of the collection site locations we present, there is sufficient evidence in total to support our findings, conclusions, and recommendations.
Public Health list of consolidation sites		To test the accuracy of the information, we contacted a random sample of collection sites from the combined list and identified several inconsistencies, which we corrected.	
Pharmacy Board list of active pharmacies			
DEA online search locator			
Walgreen Co.'s (Walgreens) pharmacy list			
CalRecycle's Form 303 reporting file	To accurately determine the volume of home-generated sharps and pharmaceutical waste collected at household hazardous waste sites.	To test the accuracy and completeness of this data we analyzed the data and identified missing entries, reporting inconsistencies, and other obvious errors.	Not sufficiently reliable for the purpose of this audit. Although this determination may affect the precision of the numbers we present, there is sufficient evidence in total to support our findings, conclusions, and recommendations.

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Audit Results

The State Provides Fragmented Oversight and Inconsistent Guidance Related to the Disposal of Home-Generated Sharps and Pharmaceutical Waste

The State does not assign oversight responsibility to a specific agency for the disposal of home-generated sharps and pharmaceutical waste, resulting in consumers' receiving a patchwork of inconsistent messages regarding proper disposal methods. In fact, when we reviewed relevant consumer guidance from federal, state, and local agencies, we identified a number of messages that directly contradict one another. These inconsistent messages increase the risk that consumers will dispose of home-generated sharps and pharmaceutical waste in illegal, unsafe, or environmentally harmful ways. Further, these mixed messages emphasize the need for a single oversight agency in California to unify the differing guidance on how to dispose of home-generated sharps and pharmaceutical waste.

Several government agencies have oversight of sharps disposal, depending on the disposal method. Since September 2008, state law has specifically prohibited California residents from disposing of sharps waste in the trash. As the Introduction discusses, the medical waste act outlines four types of facilities that may collect home-generated sharps waste: household hazardous waste facilities, home-generated sharps consolidation points, medical waste generator facilities, or facilities that receive the sharps through mail-back containers. The authority to approve each of these facilities varies, and different entities can have authority over the same facilities. For example, three entities oversee household hazardous waste sites: counties and city governments establish the sites; under state law, Toxic Substances Control issues permits to the sites; and CalRecycle requires that the sites report their collection data to it. These different levels of authority create complexity in the disposal process.

Adding to this administrative complexity, state law classifies sharps waste differently depending on where consumers dispose of it. For example, the medical waste act specifically excludes home-generated sharps waste from its definition of *medical waste*. However, it grants Public Health the authority to approve consolidation points, which are locations—such as police stations and pharmacies—that collect home-generated sharps waste. Further, the medical waste act states that waste these consolidation points collect must be treated as medical waste, which means that, unless certain exceptions apply, the entities that haul it must be registered with Toxic Substances Control and listed with

Public Health, which must approve any entities that haul and treat this waste. After processing, the sharps waste becomes solid waste and, as a result, oversight for it transfers to CalRecycle.

In contrast to the State's complex rules regulating the disposal of sharps, a defined regulatory framework for home-generated pharmaceutical waste in California does not exist. Because home-generated pharmaceutical waste is generally exempt from federal hazardous waste and state medical waste regulations, residents may legally dispose of it in the trash in most cases. However, federal regulation does restrict the collection of pharmaceutical waste that contains controlled substances to law enforcement and DEA registrants, such as hospitals and pharmacies. Further, since distinguishing controlled substances from other types of drugs in pharmaceutical waste can be difficult, collection receptacles often must follow the federal restrictions as a standard practice for all pharmaceutical waste.

In part because of the lack of clear regulations and oversight, the State does not provide a unified statewide message for the disposal of home-generated sharps or pharmaceutical waste.

In part because of the lack of clear regulations and oversight, the State does not provide a unified statewide message for the disposal of home-generated sharps or pharmaceutical waste, increasing the likelihood of improper disposal. When we reviewed federal and state agencies' websites to determine the nature of the guidance they provide, we found that the guidance varies significantly. In fact, certain agencies provide guidance that directly contradicts the guidance offered by other agencies. Further, in some instances, federal guidance conflicts with state guidance.

As Figure 4 shows, state and federal agencies provide a number of different messages regarding the disposal of pharmaceutical waste. For instance, most state agencies recommend that consumers use official collection programs for pharmaceutical disposal. Alternatively, some federal and state agencies recommend disposing of pharmaceuticals in the trash after mixing them with an undesirable substance and sealing them in a plastic bag. Because neither state law nor federal regulation differentiates home-generated pharmaceutical waste from solid waste, consumers' disposing of their personal pharmaceuticals in their trash is legal. However, a risk exists that the pharmaceuticals in landfills will leach into groundwater. Additionally, when a disposal site is not available, the U.S. Food and Drug Administration (FDA) recommends that consumers flush unused medications that contain controlled substances to avoid the possibility that individuals other than the patients will take the medications. This guidance directly contradicts guidance from Public Health and the federal Centers for Disease Control and Prevention, which states that consumers should not flush medications. CalRecycle says consumers should not flush unused medications except for those on the FDA's list because waste treatment plants are not designed to remove pharmaceutical compounds.

Figure 4
 State and Federal Agencies Offer Conflicting Guidance About Proper Disposal Methods for Home-Generated Pharmaceutical Waste



Messages come from ...

STATE AGENCIES	FEDERAL AGENCIES
1 Public Health	A Centers for Disease Control and Prevention
2 CalRecycle	B U.S. Fish and Wildlife Services
3 Pharmacy Board	C U.S. Environmental Protection Agency
4 University of California, San Francisco	D FDA

Sources: California State Auditor's analysis of federal and state agencies' messages about home-generated pharmaceutical waste disposal.

Federal and state agencies send mixed messages about the disposal of home-generated sharps waste as well. CalRecycle and Public Health both recommend that consumers dispose of sharps waste in approved sharps containers at approved collection sites to reduce risks of disease transmission and needle sticks. However, when consumers do not have access to approved sharps containers, the FDA recommends putting sharps in heavy plastic containers, such as empty laundry soap containers, but transporting sharps in those containers is illegal in California, if the local enforcement agency has not approved the container. Conflicting and inconsistent messages among federal and state agencies may create confusion for consumers and thus increase the risk that they will not dispose of their sharps in a safe and environmentally responsible manner.

If the State placed with a single oversight agency the responsibility for guiding consumers' disposal of sharps and pharmaceutical waste, that agency could work with federal and state agencies to create a unified educational campaign promoting consistent and proper disposal methods. Nonprofit organizations, local government agencies, and other states have developed public information campaigns regarding the proper disposal of home-generated sharps and pharmaceutical waste, but California has not yet employed such a strategy. We discuss sharps and pharmaceutical disposal programs from other states and countries later in this report.

Because CalRecycle already oversees all of California's state-managed, solid waste-handling programs as well as its specialized recycling programs, it may be best-positioned to oversee household pharmaceutical and sharps waste disposal.

Because CalRecycle already oversees all of California's state-managed, solid waste-handling programs as well as its specialized recycling programs, it may be best-positioned to oversee household pharmaceutical and sharps waste disposal. Although other agencies currently oversee home-generated sharps and pharmaceutical waste in certain situations, CalRecycle has a role in nearly every disposal method because it has oversight of landfills, incinerators, and processing stations. The chief of CalRecycle's Statewide Analytical Resources Branch of its Materials Management and Local Assistance Division (analysis branch chief) does not believe CalRecycle is the best agency to oversee sharps and pharmaceutical waste disposal because it has no expertise in proper medical waste disposal or the enforcement of laws requiring proper disposal. However, the amount of medical expertise required to operate a collection program for sharps and pharmaceuticals seems minimal because the program would focus on disposal rather than consumption. In addition, CalRecycle already has oversight of sharps when they are sent to landfills after being sterilized, and it has oversight of the three incinerators in the State that can destroy pharmaceutical waste.

In addition, we noted a number of reasons why other state agencies are not as well-suited as CalRecycle to provide oversight and management of collection and disposal programs for home-generated sharps and pharmaceuticals. For example, CalRecycle's analysis branch chief suggested either Public Health or the Pharmacy Board as alternatives because these two agencies do possess medical expertise. However, Public Health is not well-suited for this role because it lacks CalRecycle's experience in managing waste collection and disposal programs. Further, the Pharmacy Board is

not a suitable option because it exists to ensure quality pharmacist care and the appropriate use of pharmaceuticals. Additionally, the Pharmacy Board regulates and licenses pharmacies. Toxic Substances Control is also an inappropriate choice because it performs only permitting functions for just one type of collection site—household hazardous waste facilities. In addition, Toxic Substances Control’s mission is to restore contaminated resources and reduce hazardous waste generation—not to collect or dispose of home-generated sharps and pharmaceutical waste.

Although Most Consumers Have Reasonable Access to Free Collection Sites for Sharps and Pharmaceutical Waste, They May Not Be Aware of the Sites’ Locations

Eighty-nine percent of Californians—almost 34 million people—live within a 20-minute drive of free collection sites for both home-generated sharps and pharmaceutical waste. According to our analysis of California’s census data and collection site addresses, access to free collection sites is broadest in the State’s metropolitan areas. However, because the State does not communicate accessible, reliable information, many consumers may not be aware of available collection sites. A primary problem is that no state agency maintains accurate and complete information on collection sites. To address this problem, the Legislature should task CalRecycle with creating, maintaining, and publicizing an accurate list of collection sites in California.

The remaining four million Californians may lack reasonable access to either sharps waste collection sites, pharmaceutical waste collection sites, or to both. In particular, access to disposal sites is often limited in more rural or isolated parts of the State. To ensure that consumers in these areas have the ability to properly dispose of sharps and pharmaceutical waste, the State could subsidize these consumers’ use of prepaid mail-back envelopes, among other options.

Most Consumers in Urban Areas Have Access to Disposal Sites for Home-Generated Sharps and Pharmaceutical Waste

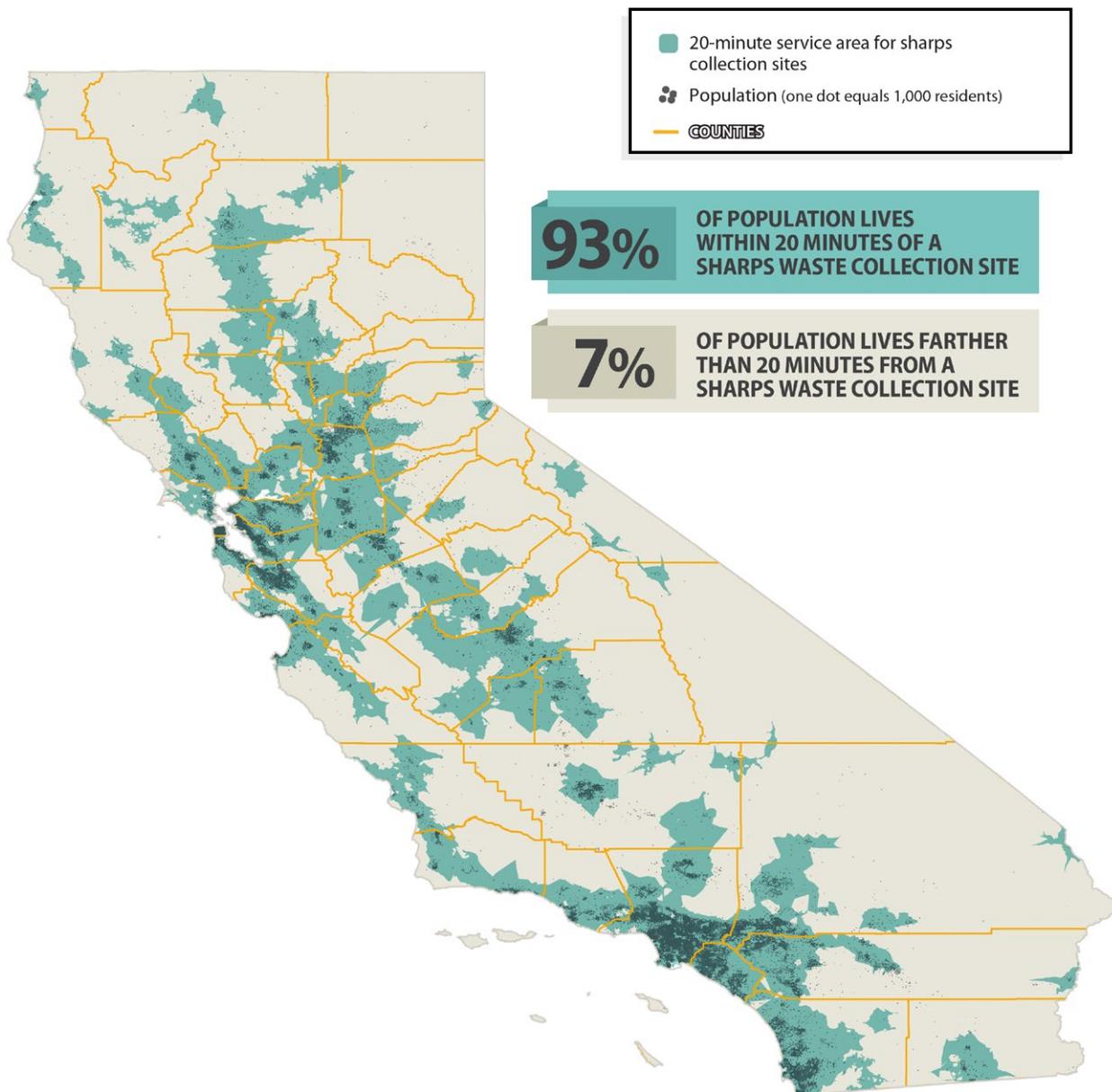
As Figure 5 on the following page shows, nearly 35.4 million Californians, or 93 percent of all residents, live within a 20-minute drive of free sharps collection sites. We refer to this proximity to collection sites as *reasonable access*, though we recognize that consumers use varying types of transportation.¹ In particular, consumers who live in urban areas of the State generally have reasonable access to sharps collection sites. For example, as Figure 6 on page 21 demonstrates, nearly the entire population of Los Angeles County lives within a 20-minute drive of sharps collection sites. Figure 6 also shows that the San Francisco Bay Area also has broadly

Eighty-nine percent of Californians—almost 34 million people—live within a 20-minute drive of free collection sites for both home-generated sharps and pharmaceutical waste.

¹ Our Appendix provides information on access using different driving times to sharps and pharmaceutical waste collection sites.

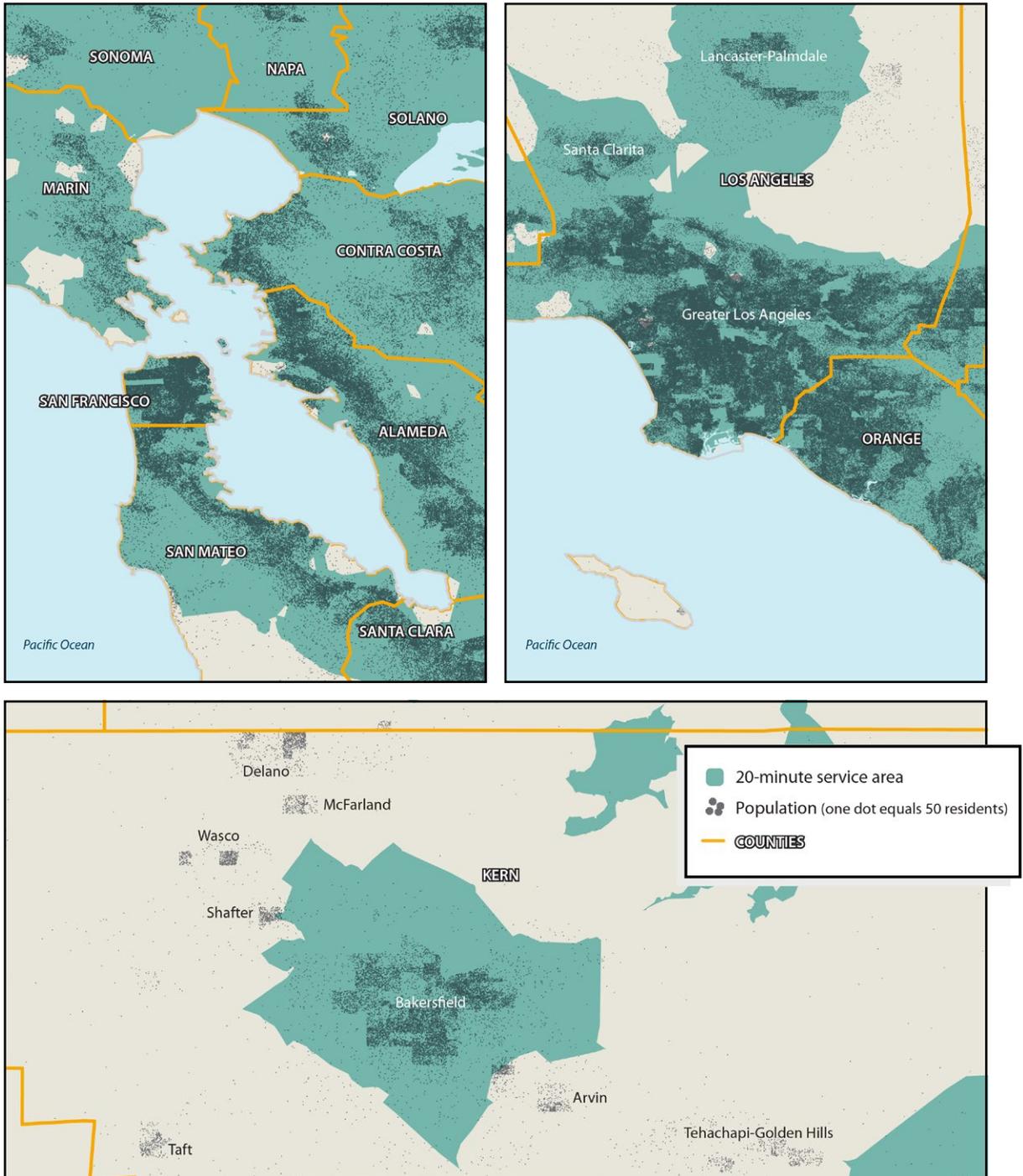
accessible sharps collection sites: in fact, 99.6 percent of the population in San Francisco lives within a 20-minute drive of sites. This high level of reasonable access is likely the result of the San Francisco Safe Needle Disposal Program, which San Francisco established in 1991 to provide free disposal of home-generated sharps at every Walgreen Co. (Walgreens) pharmacy—and at certain other locations—in the city.

Figure 5
Most Californians Live Within a 20-Minute Drive of Collection Sites for Home-Generated Sharps Waste



Sources: California State Auditor’s analysis of collection site locations as well as information from CalRecycle, Pharmacy Board, Public Health, U.S. Census Bureau, and Walgreens.

Figure 6
Access to Home-Generated Sharps Waste Collection Sites Varies Among Different Regions



Sources: California State Auditor's analysis of collection site locations as well as information from CalRecycle, Pharmacy Board, Public Health, U.S. Census Bureau, and Walgreens.

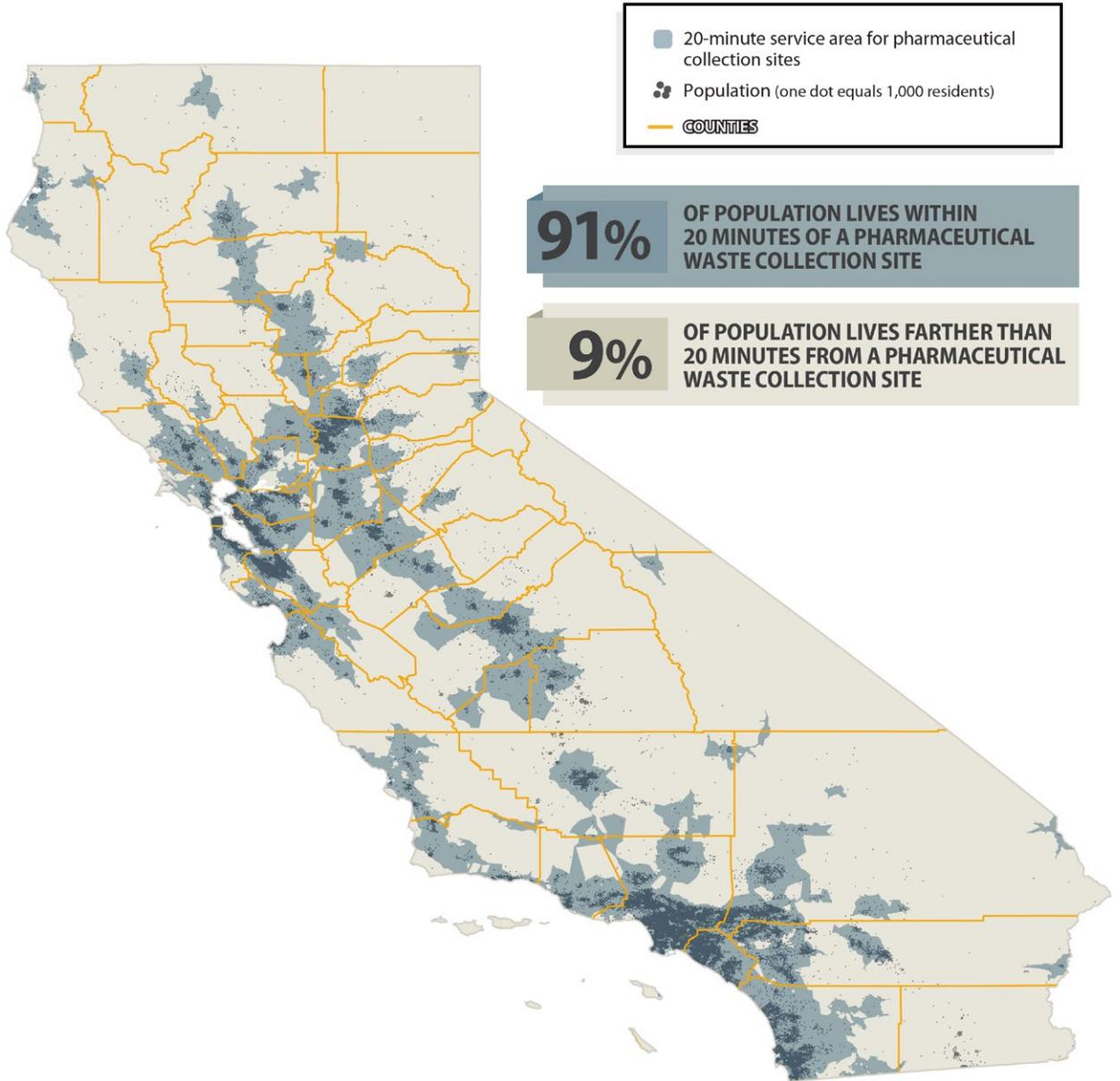
Our analysis found that around one-third of Kern residents—282,000 people—live outside a 20-minute drive from sharps collection sites.

In contrast, less populated areas of the State lack reasonable access to sharps collection sites. Rural areas with a low population density are likely to have few, if any, collection sites, and small urban areas, are also more likely to have limited access. For instance, our analysis found that around one-third of Kern County (Kern) residents—282,000 people—live outside a 20-minute drive from sharps collection sites. Figure 6 demonstrates that while Kern's largest city, Bakersfield, contains permanent collection sites, smaller urban areas like Delano, Wasco, and Taft do not. Therefore, to dispose of sharps waste, residents in these areas may have to drive long distances or rely on periodic collection events.

Although California has fewer free pharmaceutical collection sites than sharps collection sites, consumers generally have a similar level of access due to the sites' locations. As Figure 7 shows, pharmaceutical collection sites are generally spread throughout the State's major population centers. This wide distribution of the sites in major population centers means that more than 34.6 million people, or 91 percent of the State's population, have reasonable access. For example, the vast majority of Los Angeles County residents live within a 20-minute drive of pharmaceutical collection sites. Similarly, as Figure 8 on page 24 shows, most Bay Area residents also have reasonable access: most people residing in San Francisco, Alameda, and San Mateo counties need to drive 20 minutes or less to reach collection sites.

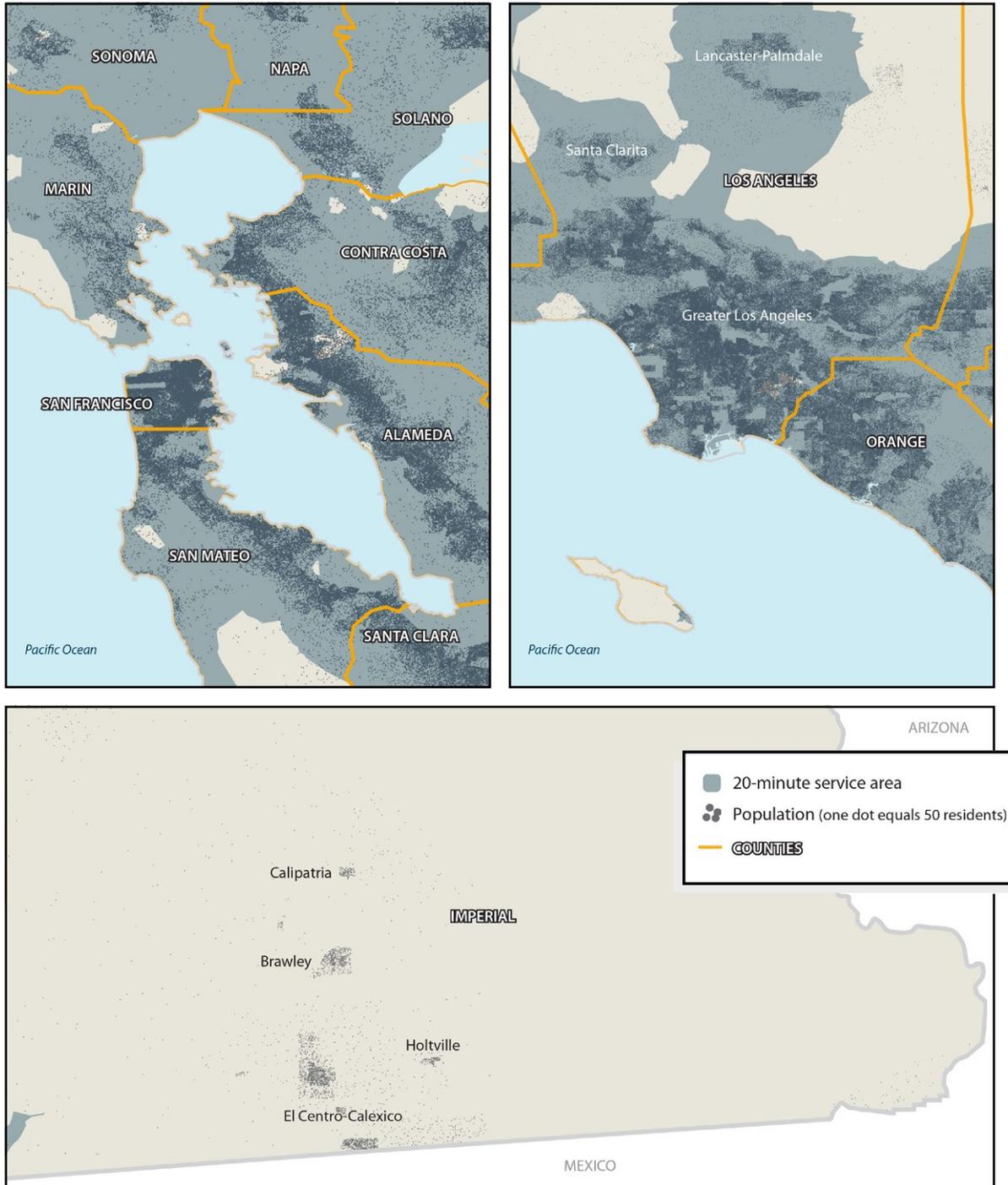
We estimate that 3.4 million people may live farther than a 20-minute drive from pharmaceutical waste collection sites, particularly in the State's areas of low population density and in less populous urban areas. For instance, Figure 8 shows that Imperial County—despite having several urbanized areas and a population greater than 177,000—does not contain any pharmaceutical collection sites that we identified in our analysis. However, our sources, and therefore our analysis, did not differentiate consistently between those pharmaceutical waste collection sites that do and do not accept controlled substances.

Figure 7
Most Californians Live Within a 20-Minute Drive of Collection Sites for Home-Generated Pharmaceutical Waste



Sources: California State Auditor's analysis of collection site locations, which may or may not accept controlled substances, as well as information from CalRecycle, Pharmacy Board, Public Health, U.S. Census Bureau, and Walgreens.

Figure 8
Access to Home-Generated Pharmaceutical Waste Collection Sites Varies Among Different Regions



Sources: California State Auditor's analysis of collection site locations, which may or may not accept controlled substances, as well as information from CalRecycle, Pharmacy Board, Public Health, U.S. Census Bureau, and Walgreens.

The State Does Not Provide Reliable Information to Ensure That Consumers Are Aware of Available Collection Sites

Although the majority of residents have reasonable access to sharps and pharmaceutical waste collection sites, public information regarding those sites is scattered, inconsistent, and sometimes inaccurate. No state agency is responsible for maintaining an accurate, complete, and up-to-date list of sharps and pharmaceutical collection sites. Nonetheless, while not required to do so, two agencies—Public Health and CalRecycle—publish on their websites lists they have compiled of statewide collection sites for both sharps and pharmaceutical waste. These agencies' lists, however, have significant deficiencies that limit their usefulness.

Although Public Health maintains a list of sharps and pharmaceutical waste collection sites, it indicated to us that it chooses to make the list available as a public service and thus does not ensure that the list is accurate or complete. In fact, our analysis found that Public Health's list contains incorrect addresses, undefined abbreviations, and locations that do not collect sharps or pharmaceutical waste. For example, when we compared the pharmacies on Public Health's list to the Pharmacy Board's list of active pharmacies, we found that 36 had closed and another 11 had moved from the locations that Public Health identified.

CalRecycle also maintains a list of sharps and pharmaceutical collection sites as part of its Facility Information Toolbox (FacIT) database, which identifies solid waste and recycling facilities across the State. However, CalRecycle cautioned that it did not design FacIT to track sharps and pharmaceutical collection sites but rather to serve as an inventory of all California waste and recycling facilities for its own planning and policy purposes. We found errors in this list too, such as facilities that had closed. Further, one of CalRecycle's sources of information for FacIT is the list of sites that Public Health has collected, which as noted above contained errors. Consequently, consumers who rely on either Public Health or CalRecycle for the locations of pharmaceutical and sharps collection sites may not obtain up-to-date or reliable information.

In addition to problems with the completeness and accuracy of the information they offer, neither Public Health nor CalRecycle makes their lists readily accessible and user-friendly. Public Health's list of sharps and pharmaceutical collection sites contains detailed information on collection site practices. However, the format in which Public Health presents its list is awkward for consumers to use because the entries for disposal sites are difficult to read. Further, consumers cannot sort the list for relevant information, such as disposal sites' locations by city or county and the types of waste that the sites collect. On the other hand, CalRecycle's FacIT

CalRecycle cautioned that it did not design FacIT to track sharps and pharmaceutical collection sites but rather to serve as an inventory of all California waste and recycling facilities for its own planning and policy purposes.

If consumers can easily access accurate, searchable information about collection sites for sharps and pharmaceutical waste, they might be more likely to dispose of these products properly.

database has users navigate a detailed set of drop-down menus, which are more user-friendly than Public Health's list but require users to choose among many potentially confusing options. Finally, neither agency's list is readily designed for use on mobile devices.

State agencies could make their lists more accessible by modeling them on a website that several local agencies in the San Francisco Bay Area created. This website, Recyclewhere.org, is a collaboration between the San Francisco Department of the Environment, the Alameda County Waste Management Authority, Contra Costa County, and the cities of San Jose and Palo Alto. According to the website, its goal is to reduce many types of waste—not just sharps and pharmaceuticals—by providing accurate information about recycling, reuse, and proper disposal options for residents and businesses without regard to traditional municipal boundaries. The website's search interface allows users to enter the types of waste they are trying to dispose of and their zip codes. The website then delivers locations to the users based on their zip codes. The website also works well on mobile platforms, increasing its accessibility. A similar format would significantly improve the lists that Public Health and CalRecycle currently provide. If consumers can easily access accurate, searchable information about collection sites for sharps and pharmaceutical waste, they might be more likely to dispose of these products properly.

The State Could Implement Alternative Disposal Methods in Rural Areas

As we previously note, four million Californians may lack reasonable access to collection sites. Establishing more collection sites in rural areas may not be practical, given that the cost of hiring hazardous waste or medical waste haulers to collect waste from remote collection sites may be prohibitive. However, the State could implement alternate disposal methods for consumers who lack access to collection sites. For example, the State could subsidize these consumers' use of mail-back containers or envelopes to dispose of home-generated sharps and pharmaceutical waste. Consumers can fill the containers—which come in various sizes and can safely contain sharps or pharmaceutical waste—and mail them for disposal via DEA-registered mail-back collectors. Federal and state agencies—including the EPA, DEA, FDA, CalRecycle, and Public Health—promote mail-back systems as safe disposal methods for sharps and pharmaceutical waste.

Although mail-back options can be expensive on a small scale, they may be the most cost-effective option for rural areas. According to retail websites, the cost for a prepaid mail-back container is often \$30 or more. However, the State might be able to use its buying power to purchase these containers in bulk at lower

prices than might be available to individuals. The University of Maine ran a pilot mail-back program between 2008 and 2012 that provided Maine residents with free prepaid mail-back envelopes for disposing of their unwanted medications. The program began with funding from the EPA, and it shifted to state funding eventually to extend the program's duration by two years. In a report it published on the program, the University of Maine concluded that mail-back programs were both feasible and effective. It noted that the program had diverted a large amount of pharmaceutical waste from the water system and landfills. If California were to provide rural residents with free or subsidized mail-back containers for their sharps and pharmaceutical waste, the State could encourage proper disposal without incurring the costs of maintaining permanent collection sites in areas with low-population densities.

In addition to encouraging the use of mail-back containers, the State could also recommend that localities include collection of sharps and pharmaceutical waste, other than controlled substances, as part of local waste contracts. Waste management companies offer services that include collecting sharps directly from customers' homes, but few California communities have reported to CalRecycle that they offer these services. The State could encourage that when local entities contract for waste service, they include sharps and pharmaceutical waste services for customers. This solution could provide those living in small urban areas with a disposal option for sharps and pharmaceutical waste.

The State Lacks Data on the Volume of Sharps and Pharmaceutical Waste That Consumers Generate and the Ways in Which They Dispose of This Waste

For this audit, the Legislature asked us to estimate the volume of sharps and pharmaceutical waste that consumers properly discarded over the past three years. However, accurately estimating this amount is challenging for a number of reasons. Specifically, no state agency currently attempts to collect comprehensive and reliable data on the amount of home-generated sharps and pharmaceutical waste that consumers properly dispose of in California. Further, even if a state agency were charged with this responsibility, collecting accurate and comprehensive information would present significant challenges because of the data sources involved. CalRecycle is the only state agency that collects any data on home-generated sharps and pharmaceutical waste, but it only collects data from hazardous waste sites and does not verify the data's accuracy or completeness. The three local governments we visited also collect limited data, but there is no requirement that they report to any state agencies any information beyond their data

CalRecycle is the only state agency that collects any data on home-generated sharps and pharmaceutical waste, but it only collects data from hazardous waste sites and does not verify the data's accuracy or completeness.

for household hazardous waste sites. In addition, state law does not require California's 37 locally authorized syringe exchange programs to track the number of sharps they distribute and collect and this omission creates an additional gap in monitoring home-generated sharps and pharmaceutical waste.

Public Health, Toxic Substances Control, and the Pharmacy Board all stated that they do not collect or maintain data on amounts of home-generated sharps and pharmaceutical waste. Although state regulation requires local agencies that are responsible for household hazardous waste sites to report the amounts of waste they collect through CalRecycle's reporting database, the resulting data are neither accurate nor complete. CalRecycle does not validate the amounts of waste the household hazardous waste sites report, nor does it take any actions when sites fail to report collection data because it asserts that state law does not give it funding to enforce this reporting. Not surprisingly, our review found that CalRecycle's data had numerous errors, including repeat entries, obvious gaps in reporting, and potentially inconsistent measurements of the volume of sharps and pharmaceuticals. As a result of these problems, CalRecycle's database is not a reliable source of information for the volume of home-generated sharps and pharmaceutical waste.

Moreover, even if CalRecycle's database contained accurate and complete information, the State would still lack reliable data from other entities that collect sharps and pharmaceutical waste. The existing data we identified have significant limitations and are either insufficient or inappropriate for reasonably estimating the amount of home-generated sharps and pharmaceutical waste consumers properly dispose of in California. Some of the programs that have collected this existing data include pharmaceutical disposal sites, mail-back programs, and syringe exchanges. For example, the California Product Stewardship Council, an advocacy group, asserts that it collected nearly 5,400 pounds of unwanted medications between July 2013 and December 2015. However, it did not track or retain support for this assertion.

Most syringe exchange programs either do not collect data on waste or do not ensure the accuracy of the data they do collect.

Similarly, most syringe exchange programs either do not collect data on waste or do not ensure the accuracy of the data they do collect. The primary mission of most locally authorized syringe exchange programs is to ensure access to clean needles and to reduce the transmission of diseases such as HIV and hepatitis among people who inject drugs. Syringe exchange programs also provide a method for program participants to dispose of used sharps in a safe manner. Nonetheless, state law does not require locally authorized programs to collect data regarding the numbers of sharps they distribute and collect. Our review of programs in the counties we visited—San Luis Obispo, Orange, and San Francisco—indicated that these programs' data are often unreliable and have

significant limitations. For example, the local agencies that oversee these syringe exchange programs often do not validate the data the programs collect. Further, although state law requires local health officers to report biennially in open meetings of county boards of supervisors or city councils about local agencies' syringe exchange program activities, it does not require this reporting to include the numbers of syringes that the programs collect or distribute.

Because of the limitations of the available data sources, accurately estimating the volume of sharps and pharmaceutical waste that consumers dispose of properly is challenging. However, in an attempt to respond to the Legislature's audit request, we used the best available data to make rough estimates. As Table 3 on the following page shows, we based our estimates on many sources of varying levels of reliability, none of which we consider fully reliable. Because we were unable to determine the accuracy and completeness of these data sources, our estimates should not be used to guide policy decisions. Further, this estimate does not provide the information that might be most useful to decision makers: the amounts of these types of waste that consumers dispose of improperly. Collecting such data is probably impossible because consumers may improperly dispose of sharps and pharmaceutical waste in the sewer or trash.

Using local data from San Francisco's programs and the available statewide data, we estimated that entities statewide collect 900,000 pounds of pharmaceutical waste and 2.8 million pounds of sharps waste annually. We used San Francisco's data to generate statewide estimates of the volume of properly discarded home-generated sharps and pharmaceutical waste because San Francisco's large population makes its data less variable than that of cities or counties with smaller populations. In addition, San Francisco had more sources of data than the other two counties we visited. San Francisco's pilot program for pharmaceutical collection, the Safe Needle Disposal Program, and its household hazardous waste sites all had data available. However, our estimate for pharmaceutical waste may be high because San Francisco has a robust pharmaceutical disposal program that offers residents the opportunity to dispose of expired or unwanted medicines at 13 independent pharmacies and at all 10 of San Francisco's police stations.

Finally, we note that even if it were possible to determine the amounts of sharps and pharmaceutical waste that consumers dispose of properly, the State would still have no way of knowing the amounts of these types of waste that consumers dispose of improperly. No agency can measure accurately the amount of improperly discarded sharps and pharmaceuticals because some consumers flush their waste or throw it in the trash.

Because of the limitations of the available data sources, accurately estimating the volume of sharps and pharmaceutical waste that consumers dispose of properly is challenging.

CalRecycle's 2015 *Waste Characterization Study* attempted to quantify the types and amounts of waste generated in the State. However, it did not identify sharps and pharmaceutical waste specifically. Therefore, this study could not be used in developing estimates of the amounts of improperly disposed of sharps and pharmaceutical waste.

Table 3
The State Lacks Adequate Data to Determine the Amounts of Home-Generated Pharmaceutical and Sharps Waste That Consumers Disposed of Properly

PHARMACEUTICAL WASTE	DATA FROM SAN FRANCISCO SOURCES	STATEWIDE MULTIPLIER*	TOTAL (IN POUNDS)
San Francisco's pharmaceutical collection program, fiscal year 2015–16	18,000	x36	648,000
DEA Prescription Take-Back Day, statewide, 2016			64,000
Household hazardous waste sites, statewide, fiscal year 2015–16			168,000
Estimated pounds of properly disposed of pharmaceutical waste, annually, statewide			880,000

SHARPS WASTE	DATA FROM SAN FRANCISCO SOURCES	STATEWIDE MULTIPLIER	TOTAL (IN POUNDS)
San Francisco Safe Needle Disposal Program, fiscal year 2015–16	30,000	x36	1,080,000
Household hazardous waste sites, statewide, fiscal year 2015–16			567,000
Sharps waste from San Francisco's syringe exchange programs			
<div style="text-align: right;">July–September 2016</div> <div style="text-align: right;">772,000</div> <div style="text-align: right;">x 4</div> <hr style="width: 10%; margin-left: auto; margin-right: 0;"/> <div style="text-align: right;">Multiplied by 4 for an annual estimate</div> <div style="text-align: right;">3,088,000</div>			
<div style="text-align: right;">Divide by 100 because 100 syringes weigh about one pound.†</div> <div style="text-align: right;">3,088,000</div> <div style="text-align: right;">÷ 100</div>	31,000	x36	1,116,000
Estimated pounds of properly discarded sharps waste each year, statewide			2,763,000

Sources: U.S. Census Bureau, San Francisco's collection and disposal programs for pharmaceutical and sharps waste, CalRecycle's household hazardous waste reporting database, and San Francisco's syringe exchange programs.

Note: We highlight our level of confidence in each data source as follows:

■ = Moderate

■ = Uncertain

■ = Poor

* San Francisco's 400,000 households account for about 1/36 of the 14 million households statewide.

† Unit size for sharps waste varies greatly, so we based our estimate of syringes-per-pound on a commonly used brand for injecting insulin.

California Has Sufficient Capacity for Processing Sharps Waste, but It Primarily Relies on Out-of-State Incinerators for Pharmaceutical Waste

California's total collection amounts for sharps and pharmaceutical waste make up a negligible fraction of the available capacity of in-state treatment sites. Consequently, collection programs for home-generated sharps waste in the counties we visited mainly send sharps waste to in-state medical waste treatment facilities that sterilize and dispose of that waste. However, because of federal and

state regulations and recommendations related to the treatment of hazardous waste, collection sites send pharmaceutical waste to out-of-state incinerators. If California law specifically excluded household pharmaceutical waste from the definition of *hazardous waste* that applies to municipal solid waste incinerators, existing in-state incinerators might accept more pharmaceutical waste, relieving collection sites of the burden of shipping waste out of state for destruction.

Most Collection Sites Dispose of Sharps Waste in the State but Ship Pharmaceutical Waste to Out-of-State Incinerators

California law requires collection sites to treat consolidated home-generated sharps waste as medical waste, meaning that only approved medical waste treatment facilities can process it. These facilities primarily use autoclaving—a steam sterilization process involving pressure and heat—to process the sharps before disposing of them in landfills as solid waste. California has 18 medical waste treatment facilities, 16 of which use the autoclaving process.

However, if household hazardous waste sites mix home-generated sharps with other hazardous waste, these sites must treat that composite waste as hazardous rather than as medical waste. State law imposes additional requirements on the processing of hazardous waste. If sites process sharps as hazardous waste using incineration, they must send the waste out of state because there are no commercial hazardous waste incinerators within California. This situation is due in part to onerous permitting requirements and public opposition to hazardous waste incinerators. For example, Orange County collects sharps at its household hazardous waste sites, then contracts with a hazardous waste hauler to ship the sharps to out-of-state facilities for incineration.

Similarly, collection sites often send pharmaceutical waste out of state for incineration. These practices may be occurring because the model guidelines that CalRecycle outlined in its 2010 report, which we discuss in the Introduction, recommend collectors manage consolidated home-generated pharmaceutical waste as medical or hazardous waste. Furthermore, the EPA recommended in 2012 that collection sites destroy household pharmaceutical waste at hazardous waste incinerators, or, if these prove cost-prohibitive, at solid waste incinerators.

When collection programs treat pharmaceutical waste as medical or hazardous waste, they contract with waste haulers who mainly transfer the waste to incinerators in other states. Just as it lacks hazardous waste incinerators, California does not have any commercial medical waste incinerators because regulators at the state

Collection sites often send pharmaceutical waste out of state for incineration.

Because California's solid waste incinerators are not registered with the DEA, they can only destroy controlled substances under the direct supervision of DEA registrants or law enforcement personnel.

level place legal restrictions on these incinerators. For instance, the California Air Resources Board limits the amounts of dioxin emissions medical incinerators can produce. Consequently, two of the counties we visited transport pharmaceutical waste out of state for incineration. For example, San Francisco contracts with a medical waste hauler to transport out of state the waste that pharmacies collect through its pilot program for pharmaceutical collection.

In addition, if pharmaceutical waste includes controlled substances, the DEA requires collection sites to ensure that such waste is rendered irretrievable, and this process usually means some form of incineration. Although the DEA does not require that controlled substances be destroyed using a specific method, the only entities allowed to collect controlled substances for disposal are law enforcement or DEA-registered collectors, such as retail pharmacies. Because California's solid waste incinerators are not registered with the DEA, they can only destroy controlled substances under the direct supervision of DEA registrants or law enforcement personnel.

Both In-State and Out-of-State Facilities Have Sufficient Capacity to Process Significant Increases in California's Sharps or Pharmaceutical Waste

As previously mentioned, California has 18 medical waste treatment sites that can process sharps. According to facility permit applications held at Public Health, these medical waste treatment facilities have available capacity—beyond what they currently process—of 288 million pounds per year. Also discussed earlier, we estimate that California may currently collect as much as 2.8 million pounds of home-generated sharps per year, an amount that is about 1 percent of the available capacity at medical waste treatment facilities. Thus, the existing in-state capacity for medical waste treatment is more than sufficient to process significant increases in the State's home-generated sharps waste.

Similarly, hazardous waste incinerators outside of California have sufficient capacity to process future increases in the State's sharps waste. According to the EPA, eight commercial incinerators for *hazardous waste* operated in the United States in 2014. These incinerators have a combined available capacity—beyond what they currently process—to handle about 800 million pounds of home-generated sharps per year. The EPA predicts this available incineration capacity will remain stable through 2039. Thus, the eight commercial hazardous waste incinerators have more than sufficient available capacity to process any conceivable increase in sharps waste that California ships out of state.

Out-of-state incineration capacity is also sufficient to meet California's pharmaceutical disposal needs. Our estimates suggest that California may collect as much as 900,000 pounds of pharmaceutical waste per year. With 800 million pounds of available capacity annually, the eight out-of-state incinerators have ample capacity to destroy that waste. Additionally, the EPA estimates that the 10 out-of-state commercial incinerators for *medical waste* that were operating in 2013 had an annual available capacity of at least 110 million pounds. Thus, their capacity is also more than sufficient to process all of California's estimated 900,000 pounds of pharmaceutical waste per year should the State choose to process it as medical waste.

The capacity of out-of-state commercial incinerators is more than sufficient to process all of California's estimated 900,000 pounds of pharmaceutical waste per year should the State choose to process it as medical waste.

Exempting Pharmaceutical Waste From the State's Definition of Hazardous Waste Would Allow for More In-State Incineration

Despite the fact that California currently sends most of its home-generated pharmaceutical waste out of state for incineration, the State has the available capacity to incinerate it in state. Specifically, California has three active waste-to-energy incinerators for solid waste: two in Los Angeles County and one in Stanislaus County. All three California incinerators have processed home-generated pharmaceutical waste in the past or explicitly allow it in their operations documents under certain circumstances, such as when law enforcement needs to destroy controlled substances.

However, despite having the available capacity, there are barriers to incinerating pharmaceutical waste in California. Specifically, California law does not exclude home-generated pharmaceutical waste from the legal definition of *hazardous waste* that applies to solid waste incinerators. Moreover, the law requires their permits to contain procedures that prevent hazardous waste from entering the incineration process. Consequently, the operators of these in-state incinerators may put their permits at risk if they accept pharmaceutical waste.

The State could relieve collection sites of the burden of shipping home-generated pharmaceutical waste out of state for destruction by specifically excluding it from the definition of *hazardous waste*. If California law were to exempt home-generated pharmaceutical waste from its definition of *hazardous waste* for municipal waste incinerators, then these existing in-state incinerators might accept more pharmaceutical waste. The three California's waste-to-energy incinerators for solid waste have available capacity of more than 600 million pounds per year. That capacity is much greater than the State's total pharmaceutical waste collection. Thus, California's incinerators have the capacity to process all nonhazardous, noncontrolled pharmaceutical waste that collection sites currently transport out of state.

Destroying pharmaceutical waste in state could create cost savings for community collection sites.

Processing more pharmaceutical waste in state could result in savings for collection sites. According to sources we consulted, distance is a factor in medical waste disposal pricing. The farther the haulers must transport waste, the greater the cost. California's pharmaceutical waste is often shipped to other states for disposal: for instance, a contractor ships San Luis Obispo's pharmaceutical waste to Maryland, North Carolina, and Texas for destruction. Destroying such waste in state could thus create cost savings for community collection sites. In Florida, for example, in-state municipal waste combustors are allowed to incinerate or burn limited quantities of pharmaceutical waste. The Florida Department of Environmental Protection concluded that the expected impact on emissions of incinerating more pharmaceutical waste in state would be negligible—and probably undetectable.

Other States and Countries Follow Collection and Disposal Practices That Could Serve as Models for California

California could benefit by adopting some aspects of programs that other governments have implemented for disposal of home-generated sharps and pharmaceutical waste. Although other governments' programs may address different goals and target different geographic locations, one of their primary purposes is to reduce health risks associated with the disposal of sharps and pharmaceutical waste. However, comparing the performance of the programs is difficult because most of the programs do not collect data consistently, if at all. In addition, CalRecycle has outlined several model program options for pharmaceutical waste collection that California could adopt, but it is unclear who would bear the costs for those programs.

California Could Employ Elements of Programs From Other States and Countries

Other states and countries have developed and implemented a number of home-generated sharps and pharmaceutical waste disposal programs that could potentially influence California in a positive way. Some programs we identified focus on consumer education. For example, the state of New York (New York) requires all pharmacies and other retail businesses that sell pharmaceuticals to prominently display New York's approved pharmaceutical disposal methods. This law facilitates a public information campaign called Don't Flush that educates consumers on the proper disposal of home-generated pharmaceutical waste. However, New York does not collect or track data related to this campaign. Sweden also employed a month-long education campaign in 2012 to encourage consumers to dispose of their unused medications at pharmacies. After the campaign, Sweden reported that the return of unwanted medications increased 6 percent from the previous year.

Similarly, Canada has two nationwide programs that focus on raising public awareness of the benefits of proper disposal of pharmaceutical waste. Specifically, Canada uses a pharmaceutical drop-off day modeled after the U.S. National Prescription Drug Take-Back Day. In addition, a private nonprofit manages an annual, six-month-long prescription take-back campaign that encourages Canadians to dispose of expired drugs at any of the participating pharmacies throughout the country. This campaign aims to keep medications out of the hands of young people and promotes awareness and best practices for medication use and disposal.

In addition, several Canadian provinces have implemented extended producer responsibility programs (EPR programs) for sharps and pharmaceutical waste. EPR programs assign to the products' producers or manufacturers the costs, and often the design, of the disposal plans for those products. Four Canadian provinces have adopted provincewide programs for sharps collection, two of which use the EPR program model, while seven Canadian provinces have adopted provincewide programs for pharmaceutical collection, six of which use the EPR program model. Although Canada lacks accessible data on the volume of home-generated sharps and pharmaceutical waste the country as a whole collects, some of its province-level programs publish limited data on their efforts. For example, the sharps and pharmaceutical industry runs an EPR program in the province of Ontario. The program indicated in its annual report for 2016 that its collection of sharps waste had increased by 19 percent and that its collection of pharmaceutical waste had increased by 16 percent since 2015. Using these data, the executive director of the program concluded that Ontario's program was effective and efficient and that consumer awareness of it was increasing.

Unfortunately, even though the Canadian government reports some data on program collection amounts, it does not report sufficient data to compare different programs' effectiveness. For example, although Canada used as measures the sizes of containers filled when reporting Prince Edward Island's pharmaceutical collections, it used the weights of pharmaceutical waste when reporting Manitoba's collections. Thus, we could not compare the outcomes of these two programs.

As we show in Table 4 on the following page, the disposal and collection programs we identified have different policy goals that reflect the collection and disposal needs of the states or countries that implemented them. For example, Minnesota created its Take It to the Box pharmaceutical collection and disposal campaign to reduce the risks of accidental poisoning, theft, and drug abuse, while Sweden developed its education campaign for pharmaceutical waste to reduce the environmental impact of discarded medications. Before California

The disposal and collection programs we identified have different policy goals that reflect the collection and disposal needs of the states or countries that implemented them.

can implement a new collection program for home-generated sharps and pharmaceuticals, the Legislature and the responsible state oversight agency will need to identify policy goals for the program and ensure that those goals align with state and federal laws.

Table 4
Other Countries and States Have Implemented Programs That Could Be Models for California’s Disposal Program for Home-Generated Sharps and Pharmaceutical Waste

	GOAL	LOCATION	PROGRAM	PROGRAM PURPOSE	FUNDING SOURCE
SHARPS WASTE					
1	Health, Safety, and Environment	New York	Safe Sharps Collection Program	Legally requires all hospitals and nursing homes in the state to collect household sharps.	State
2	Health	New York	Syringe Exchange Program	Provides sterile syringes and collects used syringes from program participants.	State
3	Health	Maine	Syringe Exchange Program	Provides sterile syringes and collects used syringes from injection drug users.	Private
4	Health	Sweden	Syringe Exchange Program	Provides sterile syringes and collects used syringes from injection drug users.	Local government
5	Health	New York	Expanded Syringe Access Program	Allows pharmacies to sell syringes without a prescription to anyone over the age of 18.	State
6	Health	Minnesota	Syringe/Needle Access Initiative	Allows pharmacies to sell syringes to customers without prescriptions.	None needed
7	Education	Maine	Safe Sharps Disposal	Distributes 40,000 brochures regarding the safe disposal of household sharps and provides 3,000 free needle-clipping devices.	Private
8	Safety	France	DASTRI Program	Requires pharmacies to provide sharps containers to consumers, who can dispose of them at collection sites throughout the country.	Private
PHARMACEUTICAL WASTE					
1	Environment	New York	Don’t Flush Your Drugs	Requires all pharmacies and retailers that sell pharmaceuticals to display a poster outlining proper disposal methods.	None Needed
2	Health, Safety, Environment	Minnesota	Take It to the Box	Provides, through its Pollution Control Agency, free informational materials to local agencies and installs in their jurisdictions drop boxes for pharmaceutical waste.	Private
3	Safety	Canada	National Medicine Take-Back Campaign	Establishes an annual take-back campaign where pharmacies nationwide collect pharmaceutical waste from July through December.	Private
4	Health, Safety, Education	Spain	SIGRE Program	Ensures an industry-managed collection and disposal program.	Private
5	Education	Maine	Safe Medicine Disposal for ME	Provide participants with free prepaid mail-back envelopes.	Federal and State
6	Environment and Education	Sweden	Apoteket AB	Educates and encourages consumers to dispose of their unused medications at pharmacies.	Unknown
7	Environment and Health	France	Cyclamed	Allows pharmaceutical waste disposal at all pharmacies in France.	Private

Sources: Websites for government agencies, private companies, and nonprofit organizations, sometimes automatically translated into English.

In 2010 CalRecycle Provided the State With Options for Pharmaceutical Waste Collection Programs

In 2007 the Legislature passed Senate Bill 966 (SB 966) requiring CalRecycle to develop and report on recommendations for model pharmaceutical waste collection programs in the State. The bill identified minimum criteria the programs must meet, including the safe and environmentally sound collection and disposal of unused or expired home-generated pharmaceuticals at no additional cost to the consumers. It also required the model programs to include informational materials for consumers about opportunities for the proper disposal of pharmaceutical waste and the potential impacts of improper disposal. Further, SB 966 required CalRecycle to consult federal, state, and local agencies in developing model guidelines for the collection and proper disposal of pharmaceutical waste.

In response to the bill, CalRecycle submitted to the Legislature its report, *Recommendations for Home-Generated Pharmaceutical Collection Programs in California* (recommendations report), in December 2010. CalRecycle provided the Legislature four different model program options to consider. The first option involves leaving the current system in place while emphasizing the importance of following the model guidelines CalRecycle developed in response to SB 966. The second option entails clearly establishing state agencies' roles and responsibilities related to pharmaceutical waste collection, including providing an agency with enforcement authority; further, this option involves converting the model guidelines into regulations. The third option is the implementation of a statewide EPR program that—as discussed previously—would place the responsibility and costs for collecting and disposing of waste on the products' manufacturers. Finally, the fourth option is an advance disposal fee program, which would require consumers to pay a fee at the time of purchase to finance a state-managed program to collect pharmaceutical waste.

Our review of these recommended model program options suggests that the second may be the most feasible. Specifically, we believe that the first option would not result in significant change to the State's current system, which has a number of weaknesses, as we discuss in this report. Further, as Table 5 on the following page shows, either implementing a statewide EPR program or using an advanced disposal fee program would likely result in passing disposal costs onto consumers, a situation inconsistent with the criteria the Legislature established for model programs. The second option, therefore, is the only program that would address weaknesses in the current system without creating additional costs for consumers. A key element of this option is the identification of a state agency to develop regulations that would make CalRecycle's

Either implementing a statewide EPR program or using an advanced disposal fee program would likely result in passing disposal costs onto consumers, a situation inconsistent with the criteria the Legislature established for model programs.

model guidelines mandatory. This recommendation assumes that individual collection programs would not receive additional funding but acknowledges that the designated state agency would require additional resources to develop and implement regulations. As this report discussed previously, we believe that the Legislature should designate CalRecycle as the lead agency.

Table 5
In 2010 CalRecycle Proposed Four Model Program Options for Home-Generated Pharmaceutical Waste

OPTION	RECOMMENDED PROGRAM	DOES THIS PROGRAM REPRESENT CHANGE?	WOULD THIS PROGRAM REQUIRE A LEAD STATE AGENCY?	WHO WOULD MANAGE THIS PROGRAM?	WHO WOULD ABSORB COSTS?
1	Continue current use of model guidelines: the State would maintain the voluntary model guidelines and encourage consumers to follow federal guidelines.	No	No	Unclear	State agency and local governments
2	Establish clear state agency roles and responsibilities, improve model guidelines and enforcement, and convert guidelines to regulations. This option provides a state agency with authority to enforce the model guidelines.	Yes	Yes	Lead state agency and local governments	Lead state agency and local agencies
3	Implement an EPR program with private sector leadership: pharmaceutical manufacturers would design, manage, and finance a statewide program, while state government would oversee program implementation and enforcement.	Yes	Yes	Pharmaceutical producers and stewardship organizations with some state oversight	Consumers
4	Create a state collection program using an advance disposal fee and state oversight: this option would require consumers to pay a fee at the time they purchase sharps, medications, or medical devices. Funds would finance the collection program.	Yes	Yes	CalRecycle or other state agency	CalRecycle or other state agency and consumers

Sources: CalRecycle's 2010 report to the Legislature and SB 966 (Simitian, Chapter 542, Statutes of 2007).

However, CalRecycle's recommendations report ultimately proposes a combination of converting the model guidelines into regulations, making statutory changes to establish clear state agency roles and responsibilities, and developing a statewide program for disposing of home-generated pharmaceutical waste based on an EPR program model. The California Product Stewardship Council and other entities support the implementation of EPR programs by highlighting the risks of improper disposal of sharps and pharmaceutical waste. Additionally, the California Product Stewardship Council supports policies and projects in which producers share in the responsibility for managing problem products at the end of the products' lives. Similar programs already exist in California for carpet, mattresses, and paint. Nonetheless, developing a statewide EPR program would present several challenges, which CalRecycle acknowledged. For example, although the EPR program model requires manufacturers to fund collection programs, manufacturers are likely to pass on

those costs to consumers, either directly or indirectly. In addition, the implementation of a statewide EPR program would require new legislation, which CalRecycle believed would be difficult to enact. Overcoming these challenges would be necessary for making a statewide EPR program successful.

Moreover, sharps and pharmaceutical manufacturers are resistant to the implementation of a statewide EPR program. For example, the representatives with whom we spoke believe that it would be inappropriate for the sharps and pharmaceutical industry to bear the costs to dispose of sharps waste from illegal drug users. One company's representative stated that it already manages a free take-back program for its own syringes by including mail-back envelopes with its product. Further, industry representatives indicate that EPR programs place an additional cost burden on consumers and that they potentially erect market barriers for companies seeking to sell sharps products in California. Industry representatives also assert that various studies show there is minimal health risk due to improper disposal of home-generated sharps waste in consumer trash and that pharmaceutical take-back programs do not result in improved water quality. They stated that the existing problems are the result of failings in the current system for disposing of home-generated sharps and pharmaceutical waste. For example, they noted that there is insufficient education and outreach to consumers on the methods to properly dispose of sharps and pharmaceutical waste.

However, industry representatives indicated that they would prefer the establishment of uniform EPR program requirements across the State to their companies' meeting requirements that differ by county, as they currently must. Some California counties, including San Francisco and Alameda, have already adopted local EPR program ordinances. Trade associations representing manufacturers and distributors of pharmaceuticals challenged implementation of the ordinance in Alameda by arguing that it interfered with interstate commerce. Nonetheless, federal courts upheld Alameda's ordinance. According to the representatives with whom we spoke, implementing EPR programs on a county-by-county level creates inefficiencies for pharmaceutical manufacturers because each county may establish different requirements, and inconsistencies among local programs can confuse consumers. Further, the representatives indicate that implementation of various local ordinances forestalls conversations at the state and national levels around effective and equitable solutions

The counties that have already established EPR ordinances have faced additional challenges as well. For example, according to Alameda, the first county to implement a pharmaceutical

Sharps and pharmaceutical manufacturers are resistant to the implementation of a statewide EPR program.

EPR program in California, a significant barrier towards full implementation of its EPR program is reaching agreement with pharmacies to serve as collection sites. Pharmacies are logical locations to serve as pharmaceutical waste collection sites because consumers can properly dispose of unused medications when filling new prescriptions. However, Alameda's pharmaceutical waste ordinance makes pharmacies' participation voluntary, and Alameda indicates that major pharmacy chains have not yet participated.

As previously discussed, we recommend that the Legislature implement the second option that CalRecycle's recommendations report proposes and that the Legislature identify CalRecycle as the lead agency for ensuring the proper disposal of sharps and pharmaceutical waste. The Legislature could also establish an alternative to a statewide EPR program that would better enable counties to implement their own EPR programs if they desire to do so. Specifically, the Legislature could establish guidelines for counties that choose to implement their own EPR programs. Such guidelines would incorporate the Legislature's policy decisions and provide consistency among counties' EPR programs, while limiting the costs that could get passed on to consumers. For example, the guidelines could address whether the counties' EPR programs would include the collection of nonprescription medications and whether they should provide a mail-back component. This increased consistency would allow manufacturers to comply more readily with EPR programs in California.

Recommendations

To foster consumers' proper disposal of sharps and pharmaceutical waste, the Legislature should provide CalRecycle statutory oversight responsibility for home-generated sharps and pharmaceutical waste disposal and provide CalRecycle additional resources to the extent that it can justify the need. This responsibility should include the following actions:

- Developing and implementing a public education campaign about home-generated sharps and pharmaceutical waste disposal. CalRecycle should coordinate this campaign with local, state, and, to the extent possible, federal agencies to ensure consumers receive consistent guidance regarding proper disposal methods.
- Maintaining an up-to-date, well-publicized, and accessible statewide list of free sharps and pharmaceutical waste collection sites. CalRecycle should create this list by either improving its FacIT database or by establishing a new database, potentially using Recyclewhere.org as a model.

- Increasing consumers' access to proper disposal methods in underserved locations. It could increase access by subsidizing prepaid mail-back options or by encouraging municipalities to include the collection of sharps and pharmaceutical waste in their contracts with waste haulers.
- Determining the characteristics of other government programs, such as New York State's consumer education program, that might benefit California.

To increase in-state options for processing California's home-generated pharmaceutical waste, the Legislature should expressly authorize municipal solid waste incinerators to burn limited quantities of home-generated pharmaceutical waste, but only after considering environmental impacts.

To ensure consistency throughout the State, the Legislature should adopt standard requirements for counties to follow when implementing EPR programs. These requirements should limit any additional costs the programs may impose on consumers.

We conducted this audit under the authority vested in the California State Auditor by Section 8543 et seq. of the California Government Code and according to generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives specified in the Scope and Methodology section of the report. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Respectfully submitted,



DOUG CORDINER, CGFM
Chief Deputy State Auditor

Date: May 9, 2017

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For questions regarding the contents of this report, please contact Margarita Fernández, Chief of Public Affairs, at 916.445.0255.

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Appendix

ADDITIONAL INFORMATION ON DIFFERENT DRIVING TIMES TO SHARPS AND PHARMACEUTICAL WASTE COLLECTION SITES

As discussed in the Audit Results on page 19, we defined reasonable access to sharps and pharmaceutical waste collection sites as a 20-minute driving distance. We based this distance on market analyses for trading and economic areas and studies that discuss access to health care, which provide examples of a 10-minute to 30-minute drive time used as a measure of accessibility or trade areas. An example of such a study is Northern Illinois University's *Measures of Spatial Accessibility to Health Care in a GIS Environment: Synthesis and a Case Study in the Chicago Region*, which used a driving time of 30 minutes as a service area threshold. We recognize that individuals use means of transportation other than driving their own vehicles, but we believe our approach provides a reasonable basis for estimating the percentage of Californians who have reasonable access to collection sites. However, our sources, and therefore our analysis, did not differentiate consistently between those pharmaceutical waste collection sites that do and do not accept controlled substances.

Table A on the following page provides our estimates for the total population that has access to sharps and pharmaceutical waste collection sites within a driving time of between 10 minutes and 30 minutes. We based our analysis on census block groups—statistical divisions of census tracts that the U.S. Census Bureau generally defined to contain between 600 and 3,000 people. To ensure that we did not overestimate these populations, we counted the population of a census block group only when it was wholly within the service area radius covered by the driving time. Thus, we did not count the entire population of a census block group if any part of it was outside of the driving-time radius. This method of analysis is less appropriate when judging access to collection sites within very short drive times. For example, when we limit the driving time to five minutes, the service areas are disconnected and small, with the driving-time radius cutting through many urban census block groups and not fully covering larger suburban and rural blocks. As the service area increases to 10 minutes, the driving-time radius becomes larger and it is increasingly integrated because the service areas from individual collection sites merge into unified service areas. As a result, using a driving time of 10 minutes or greater reduces the margin of error for our estimates.

Table A
Access to Sharps and Pharmaceutical Waste Collection Sites Varies Based on the Driving Time Considered

SERVICE AREA RADIUS (IN MINUTES OF DRIVE TIME)	SHARPS		PHARMACEUTICAL	
	POPULATION IN SERVICE AREA	PERCENTAGE	POPULATION IN SERVICE AREA	PERCENTAGE
10	27,300,000	72%	26,000,000	68%
15	33,200,000	87	32,300,000	85
20	35,400,000	93	34,600,000	91
25	36,200,000	95	35,700,000	94
30	36,700,000	96	36,300,000	95

Sources: California State Auditor's analysis of collection site locations, which may or may not accept controlled substances, as well as information from CalRecycle, Pharmacy Board, Public Health, U.S. Census Bureau, and Walgreens.

California Environmental Protection Agency

Edmund G. Brown Jr., Governor



DEPARTMENT OF RESOURCES RECYCLING AND RECOVERY

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April 27, 2017

Doug Cordiner, CGFM*
Chief Deputy State Auditor
621 Capitol Mall, Suite 1200
Sacramento, California. 95814

Dear Mr. Cordiner:

Thank you for the opportunity to review and comment on the April 11, 2017 draft report, titled "Home Generated Sharps and Pharmaceutical Waste: By Designating a Lead Agency, the State Could Increase Proper Disposal."

CalRecycle appreciates this opportunity to provide feedback on the information contained in the report. In general, and as noted in previous discussions with audit staff, CalRecycle does deal with end of life management for a number of products. However, pharmaceuticals and sharps are particularly complicated products to manage, and their management and handling intersects multiple state and federal agencies. CalRecycle is concerned that the department does not have the resources, expertise and enforcement authority to oversee the disposal of home generated sharps and pharmaceuticals as recommended and described in this report. ① ②

CalRecycle continues to have concerns with being designated the most appropriate state agency to oversee the management of home-generate sharps and pharmaceuticals and looks forward to further conversation on how the department can be helpful in ensuring these materials are safely and effectively managed state-wide.

Please find attached the department's comments to the draft audit report.

Sincerely,

A handwritten signature in black ink that reads "Ken DaRosa".

Ken DaRosa
Chief Deputy Director

cc: Mr. John Baier, Audit Principal, State Auditor's Office
Mr. Joshua Hooper, State Auditor's Office
Ms. Christine Hironaka, Deputy Director for Legislation, California Environmental Protection Agency
Ms. Mindy McIntyre, Legislative Director, Department of Resources Recycling and Recovery
Ms. Josephine Urban, Branch Chief, Audits Office, Department of Resources Recycling and Recovery

* California State Auditor's comments begin on page 51.

CalRecycle Response to Draft Report: Home Generated Sharps and Pharmaceutical Waste: By Designating a Lead Agency, the State Could Increase Proper Disposal.

① **Overall Management System and Authority** – The proper management for the disposal of these materials includes collection, consolidation, storage, transport, and treatment. During these stages, these materials would be considered medical and/or hazardous waste and would therefore fall under the authority of the California Department of Public Health (CDPH), Board of Pharmacy (BOP), and the Department of Toxic Substances Control (DTSC). With the exception of collection and consolidation of household hazardous waste by local government programs (which *sometimes* includes home-generated sharps and pharmaceuticals), CalRecycle is not involved with the overall management system of these materials. Furthermore, the household hazardous waste local government programs are not the entire universe of the existing overall management system nor are they necessarily convenient. As the report notes, treated sharps are currently landfilled and there is plenty of capacity for disposal of sharps. Pharmaceuticals are predominantly incinerated at out-of-state incinerators.

② **Appropriate Collection Sites** – The Board of Pharmacy (BOP) regulates reverse distributors and also regulates how pharmacists properly manage pharmaceuticals. Pharmacies can lose their license for failure to adhere. CalRecycle has no such enforcement authority and no expertise in the collection of controlled substances. As noted in the report, "...the only entities allowed to collect controlled substances for disposal are law enforcement or DEA registered collectors such as retail pharmacies." Thus, curbside collection of home-generated pharmaceutical waste is not appropriate for these materials. CalRecycle suggests that backhauling through pharmacies' reverse distribution system would be a more appropriate process to manage materials that will be considered pharmaceutical waste and potentially subject to federal and state controlled substances restrictions.

③

Even if existing state statutes are revised for disposal of home-generated sharps and pharmaceutical waste as the report suggests, there are still medical and/or hazardous waste requirements for the collection, consolidation, storage, transport, and treatment steps. Further, and notwithstanding changes to state law, federal requirements remain that specify medical and/or hazardous waste requirements.

Beyond this, CalRecycle has the following comments and questions on the information contained in the draft audit report:

- ④ ⑤ · Page 4 re: CalRecycle oversight for "all state-managed waste-handling programs"
 - This statement is incorrect. CalRecycle is responsible for solid waste management and, to some extent, has a limited role in household hazardous waste oversight. However, the department is not responsible for medical waste or hazardous waste management, such authority appropriately rests with other agencies.
- ⑥ · Page 4, paragraph 2 regarding list of collection sites
 - CDPH is required by statute to maintain a list of sharps collection locations; there are no statutory requirements for any agency to maintain a list of pharmaceutical collection locations.
- ② · Page 4, paragraph 2 regarding subsidizing use of mail-back containers
 - While the audit report discusses subsidizing this use, it does not provide recommendations on how such a program would be financed.

- Page 5, paragraph 1 regarding incinerators operating within the state that could dispose of pharmaceutical waste
 - o This would necessitate considerable permit processes across various federal, state and local agencies, including local governments, counties, air districts, CDPH, DTSC, CalRecycle, and the DEA. Additionally, this could require environmental impact review and public comment. Current solid waste facilities are not permitted to handle disposal of pharmaceutical waste except by special arrangement with law enforcement agencies that are disposing of materials that could include pharmaceuticals, e.g., contraband drugs. (7)
- Page 6 lists 3 of the key recommendations
 - o While the audit report makes recommendations regarding a public education campaign and maintaining a database, it makes no specific recommendations regarding funding sources for these activities or for authority (including enforcement) to require that information be submitted. (2)
- Page 9 regarding waste haulers
 - o Special licensing would be required for a solid waste hauler to transport household-generated pharmaceuticals and sharps. This licensing authority rests with CDPH and DTSC. (1)
- Page 11 regarding model guidelines
 - o The model guidelines expired in 2013. (8)
- Page 14 regarding “oversight for it [sharps waste] transfers to CalRecycle”
 - o Sharps are considered solid waste only after they are treated. Once treated, sharps may be disposed in a solid waste landfill, which is under the purview of CalRecycle.
- Page 16: The report indicates state and federal agencies send mixed messages for the disposal of home-generated sharps waste. The FDA’s website is consistent with state agency messages encouraging consumers to check local requirements and does not recommend putting those bottles in the trash. (5)
- Page 16 regarding unified educational campaign
 - o The audit report does not make recommendations about how such an activity would be funded. (2)
- Page 16, last paragraph regarding CalRecycle’s role
 - o The statement that CalRecycle has “oversight of landfills, incinerators, and processing stations” is true for solid waste facilities (landfills, transfer stations, compost facilities, transformation). The department does not have oversight of incinerators that process hazardous materials or medical wastes. (9)
- Page 17 top, “CalRecycle already has oversight of treated sharps”
 - o As a point of clarification, sharps are regulated by CDPH; CalRecycle has oversight of landfills where treated sharps are disposed.
- Page 17 regarding “medical expertise required to operate a collection program” (1)
 - o A medical and pharmaceutical collection program is not simply a disposal program. CalRecycle regulates solid waste disposal while BOP, CDPH, DTSC, and Department of

Transportation regulate the collection, consolidation, treatment and transportation of pharmaceuticals and sharps.

Pages 21-22 regarding lists of collection sites and FacIT

- ⑥
 - ⑩ o CDPH is required to provide the public with an accurate list of sharps collection sites throughout the state. CalRecycle provides a voluntary, detailed user-friendly database to the public mapping all solid waste facilities through FacIT. However, we also have a secondary site, <http://www.calrecycle.ca.gov/Recycle/Maps/> that provides additional locational information on collection and recycling facilities including facilities that collect medications and sharps.

- ⑪
 - o Page 24 regarding the statement of requiring that locals include sharps and pharmaceutical services when they contract out for waste services.
 - o In addition to the required statutory changes, haulers would be required to become a DEA registrant for controlled substances. This requirement may invite legal challenges by haulers.
 - o This is why San Luis Obispo County's mandatory retail pharmaceutical takeback ordinance has faced retailer challenges and DEA scrutiny and all other extended producer responsibility ordinances in the state only have voluntary retail participation.

Page 25 regarding Form 303 data

- o Home-generated sharps and pharmaceutical collection data is limited because of:
 - § Inconsistent reporting. In many cases, contractors report collection data on behalf of the local government organization. Unfortunately, some local governments have limited resources to verify whether the data is complete and correct.
 - § Incomplete reporting. Home-generated sharps are collected in airports, restaurants, large special events and are not statutorily required to be reported.

Pages 29-30: the report states CalRecycle's model guidelines "require" collectors manage consolidated HGPW as hazardous or medical waste. While following the guidelines would ensure a program complied with state law (until 2013), the recommended guidelines were only voluntary.

⑤ ⑧

Page 32: The report states, California law does not exclude HGPW from the definition of hazardous waste for solid waste incinerators. However, it's worth noting that the federal Resource Conservation and Recovery Act already does that.

⑫

Page 38 regarding "without creating additional costs for consumers"

⑬

- o It is not clear what the funding source would be for implementing an advanced disposal fee program (i.e., Option #2).

⑭

Page 39: The report discounts pursuing EPR legislation because "...manufacturers are likely to pass on those costs to consumers, either directly or indirectly..." However, EPR program fees would be more transparent and consistent with "beneficiary pays" principles.

①

Page 41: As noted, CalRecycle may not be the appropriate agency for ensuring the proper disposal of sharps and pharmaceutical waste given associated medical and/or hazardous waste requirements.

Page 42 regarding the second bullet point

②

- o Absent mandatory reporting authority from all sharps and pharmaceutical collection sites, CalRecycle could not maintain an accurate list nor could it track amounts collected for further analysis.

Page 42 regarding the third bullet point

- As noted, solid waste haulers would require special medical and/or hazardous waste permits and licensing.

⑪

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Comments

CALIFORNIA STATE AUDITOR'S COMMENTS ON THE RESPONSE FROM CALRECYCLE

To provide clarity and perspective, we are commenting on the response to our audit report from CalRecycle. Although we did not direct any recommendations to CalRecycle, we provided it an opportunity to review the draft report because we are recommending that the Legislature entrust it with statutory oversight responsibility for home-generated sharps and pharmaceutical waste disposal. The numbers below correspond to the numbers we have placed in the margin of CalRecycle's response.

We are disappointed with CalRecycle's reluctance to assume leadership responsibility for the proper disposal of home-generated sharps and pharmaceutical waste, especially given that CalRecycle itself in its recommendations report recognized that there was a pressing need for a state agency to lead these efforts for pharmaceutical waste, as we discuss on pages 37 and 38. Throughout its response, CalRecycle correctly describes some of the difficulties facing the State with these efforts because of the involvement of various government agencies and the complexities of the existing legal and regulatory structure. These difficulties are, in part, due to the absence of a lead state department to coordinate with local, state, and federal agencies to find solutions, and to propose legal and regulatory changes to streamline the disposal process. Therefore, we stand by our conclusion that CalRecycle is best positioned to take leadership responsibility over the proper disposal of home-generated sharps and pharmaceutical waste.

①

We clearly recognize that CalRecycle lacks the authority and possibly the funding to assume the lead role for the proper disposal of home-generated sharps and pharmaceutical waste. Therefore, as we recommend on page 40, if the Legislature entrusts CalRecycle with this leadership role, it should provide CalRecycle statutory oversight responsibility, which would include enforcement power, as well as additional resources to the extent that CalRecycle can demonstrate the need.

②

Our report does not suggest the use of curbside service as a collection method for disposal of pharmaceutical waste that contains controlled-substances. Rather, as indicated on page 27, the State could recommend local entities include collection of home-generated sharps and pharmaceutical waste, *other than controlled substances*, as part of local waste contracts. We also find it perplexing that CalRecycle would criticize curbside service as an option when data we obtained from its website shows that five local

③

entities reported to CalRecycle that their household hazardous waste sites operated either a curbside or door-to-door program during fiscal year 2015–16 to collect pharmaceutical waste. Similarly, this data indicated that 23 local entities also reported to CalRecycle that their household hazardous waste sites operated either a curbside or door-to-door program for home-generated sharps collection.

- ④ While preparing our draft report for publication, some page numbers shifted. Therefore, the page numbers CalRecycle cites in its response do not correspond to the page numbers in our final report.
- ⑤ This is an issue that we would have expected CalRecycle to discuss with us during its review of the draft report. Yet, despite numerous attempts to contact CalRecycle, it declined to discuss any concerns during its review of the draft report. Nevertheless, we have made a minor change to the report text to address CalRecycle's concern.
- ⑥ Senate Bill 1305 (Chapter 64, Statutes of 2006) *encouraged* the predecessors of both CalRecycle and Public Health, among other entities, to identify on their websites locations that accept home-generated sharps. As we note on page 25, Public Health has chosen to make this list available as a public service, but indicated to us that it does not ensure that the list is accurate or complete. In fact, our analysis found that the list contained errors. That is why, in recommending that the Legislature provide CalRecycle with oversight authority for the proper disposal of home-generated sharps and pharmaceutical waste, we also recommended on page 40 that one of its responsibilities be to maintain an up-to-date, well-publicized, and accessible statewide list of collection sites.
- ⑦ Contrary to CalRecycle's assertion, all three California waste-to-energy incinerators for solid waste have either processed home-generated pharmaceutical waste in the past or their operations documents explicitly allow them to accept pharmaceutical waste under certain circumstances, as we note on page 33. However, as we also state on that same page, that the operators of these incinerators may put their permits at risk if they accept pharmaceutical waste that is hazardous under state law. Therefore, to increase in-state options for processing home-generated pharmaceutical waste, we recommended on page 41 that the Legislature expressly authorize solid waste incinerators to burn limited quantities of this waste. If the Legislature adopts our recommendation, this will facilitate or eliminate many of CalRecycle's concerns.
- ⑧ CalRecycle's statement implies that the expiration of SB 966, which required CalRecycle to develop the model guidelines, diminishes their relevance. Yet, CalRecycle's website currently includes discussion of the model guidelines as well as a link to them, which indicates that CalRecycle continues to believe that the model guidelines

have applicability. Moreover, because the model guidelines are the State's most recent effort to better manage the proper disposal of home-generated pharmaceutical waste, we believe that a discussion of these guidelines is relevant and valid in the context of our audit scope.

We agree that CalRecycle does not oversee commercial hazardous waste or medical waste incinerators, because, as we indicate on pages 31 and 32, there are none of these types of incinerators operating in California. However, CalRecycle does oversee the State's three waste-to-energy incinerators for solid waste, which could incinerate pharmaceutical waste as we note on page 33.

CalRecycle overstates the usefulness of its FacIT database. As we note on page 25, the FacIT database contains inaccuracies, in part because it is based on Public Health's inaccurate database, and also because, as CalRecycle acknowledges on that same page, it did not design FacIT to track sharps and pharmaceutical collection sites. Regarding CalRecycle's claim that the FacIT database is "user-friendly," we note on pages 25 and 26 that, although it is more user-friendly than Public Health's list, users must navigate a detailed set of drop-down menus and choose among many potentially confusing options and that the database is not configured for use on mobile devices—both of which create difficulties for potential users. Further, the accuracy of CalRecycle's secondary site, <http://www.calrecycle.ca.gov/Recycle/Maps/>, is also problematic because it is based on the inaccurate data from FacIT. While we appreciate that CalRecycle has voluntarily made these lists available, until CalRecycle can improve their accuracy and accessibility, their usefulness is limited.

CalRecycle mischaracterizes our recommendation. Contrary to CalRecycle's statement, our recommendation on page 41 is, among CalRecycle's responsibilities, that it *encourage* municipalities to include sharps and pharmaceutical collection as part of local waste hauler contracts, not that it impose such a *requirement* on them. We are also fully aware that there are legal requirements that CalRecycle and municipalities will need to consider. But by taking on the oversight responsibility that we recommend, CalRecycle will be positioned to help municipalities navigate those legal requirements.

CalRecycle is correct that federal law exempts home-generated pharmaceutical waste from the definition of hazardous waste. However, California's definition is more broad and creates ambiguity over whether the State's waste-to-energy incinerators for solid waste may accept home-generated pharmaceutical waste from sources other than law enforcement. Because of this ambiguity, our recommendation on page 41 is that the Legislature should expressly

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authorize these solid waste incinerators to burn limited quantities of home-generated pharmaceutical waste after considering any environmental impacts.

- ⑬ We are puzzled as to why CalRecycle questions the funding source for the advanced disposal fee program, the fourth option in its recommendations report. As we state on page 37, this option would require consumers to pay a fee at the time of purchase to finance the waste collection program. However, this option is inconsistent with one of the criteria the Legislature established for model programs, which was that there should be no additional cost to consumers.
- ⑭ CalRecycle's statement that our report "discounts pursuing EPR legislation" is incorrect. To the contrary, we recommend on page 41 that the Legislature adopt standard requirements for counties to follow when implementing EPR programs, which would help ensure consistency and limit additional costs imposed on consumers.