Evaluation of Home-Generated Pharmaceutical Programs in California

CalRecycle Background Paper
for July 20, 2010 Workshop

Issued July 12, 2010

Contents

I. Introduction

1. Senate Bill 966 (SB 966)

Enacted in 2007, Senate Bill 966 (Simitian, Chapter 542, Statutes of 2007) addresses improper disposal of pharmaceutical waste into sewer systems that results in pharmaceuticals entering waterways and drinking water. The goal of SB 966 is to establish a program through which the public may conveniently return drugs for safe and environmentally sound disposal.

SB 966 directed the California Integrated Waste Management Board, which is now the California Department of Resources Recycling and Recovery (CalRecycle), to:

1. Establish final criteria and procedures for model collection programs by December 2008.

   CalRecycle worked closely with numerous agencies, including the California Department of Public Health (CDPH), the Department of Toxic Substances Control, the State Water Resources Control Board, and the California State Board of Pharmacy, and considered stakeholder input to develop criteria and procedures for model pharmaceutical waste collection programs. CalRecycle adopted *Criteria and Procedures for Model Home-Generated Pharmaceutical Waste Collection and Disposal Programs*[1] (Guidelines) in November 2008, with a subsequent revision in February 2009. Programs are not required to follow these *Guidelines* but they must be consistent with them in order to be a model program under SB 966.

2. Evaluate model collection programs in California

   CalRecycle sent surveys to all known programs that collect home-generated pharmaceuticals in California. This paper presents the results of these surveys.

3. Report to the Legislature by December 2010.

   As required by SB 966, CalRecycle will include the following components:

   - An evaluation of the model programs for efficacy, safety, statewide accessibility, and cost effectiveness;
   - Consideration of the incidence of diversion of drugs for unlawful sale and use, if any; and
   - Recommendations for the potential implementation of a statewide program and statutory changes.

2. Purpose of Background Paper

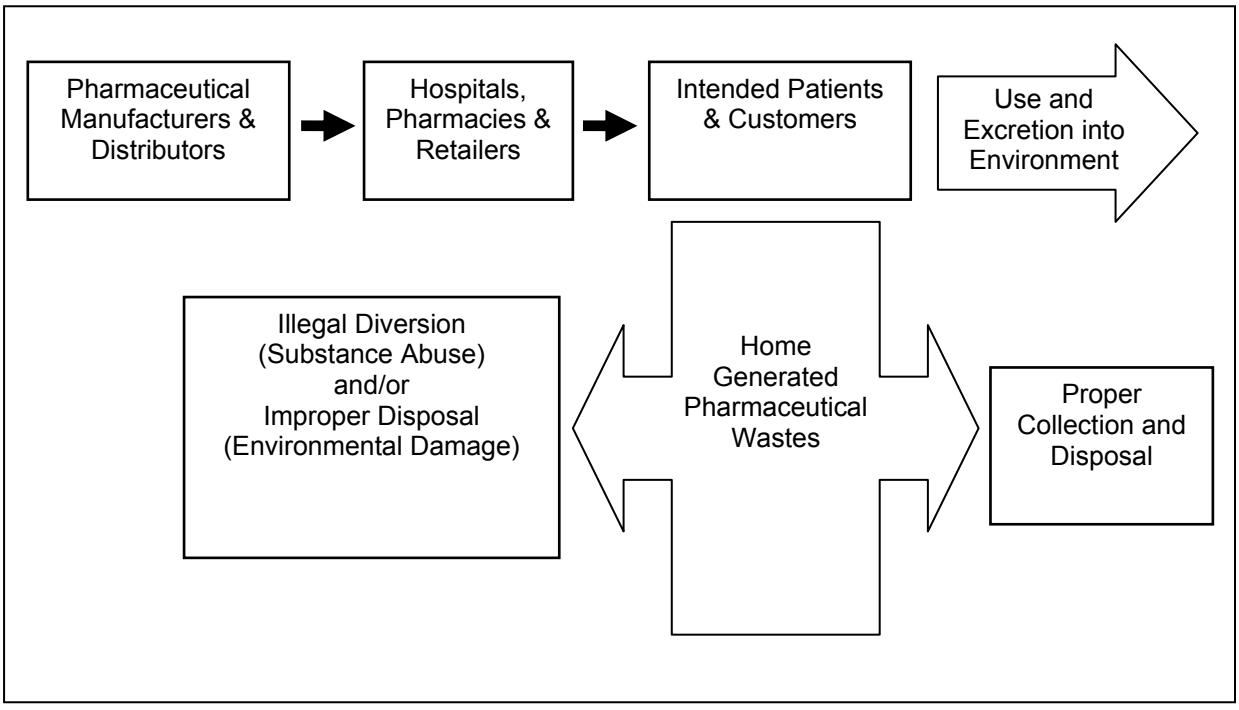
This paper will serve as a basis for discussion at the July 20, 2010, "California's Model Drug Collection Program Workshop" and it will serve as foundational material as CalRecycle prepares the required report to the Legislature. This material is intended to stimulate discussion and input from stakeholders and affected parties.

This paper includes:

- **Program Surveys and Results (Section II)**: The types and number of home-generated pharmaceutical waste collection programs in California, the number that meet the Guidelines for model programs within each type, and an evaluation of programs based on the four factors in SB 966 (safety, statewide accessibility, cost effectiveness and efficacy);
- **Challenges and Barriers (Section III):** Some of the challenges to program implementation;
- **Overview of Programs Outside of California (Section IV):** National and international programs; and,
- **Potential Options for Further State Action (Section V):** Preliminary analysis of potential options for state action.

Figure 1 shows a simplified view of the flow of pharmaceuticals, including both prescription medications and non-prescription (over-the-counter) medications. This paper only deals with one aspect of the life cycle of pharmaceuticals, specifically the post consumer fate of unused pharmaceuticals that become home-generated pharmaceutical waste. This paper discusses current efforts and future options to properly collect and dispose of this home-generated pharmaceutical waste in ways that minimize illegal diversion (potentially leading to substance abuse) and improper disposal (potentially leading to environmental damage).

Figure 1. Simplified Flow of Pharmaceuticals



Based on information available to CalRecycle, collection programs in California collect approximately 200,000 pounds of home-generated pharmaceutical waste per year. However, this is likely a small percentage of all home-generated pharmaceutical waste. There is not a definitive estimate of the amount of home-generated pharmaceutical waste in California. However, several sources suggest that a very large amount is sold and that a significant percentage subsequently becomes waste in California:

- In California pharmacies, the total retail sales for filled prescription drugs in 2009 (not including over-the-counter drugs or mail order prescriptions) reached nearly $19 billion for more than 300 million prescriptions.[2]
- The Associated Press estimated that Americans generate at least 250 million pounds of pharmaceuticals and contaminated packaging in medical facilities each year.[3] Relative to California population, that would be approximately 30 million pounds in California hospitals alone.
- Some estimates suggest that 10% to 33% of all pharmaceuticals go unused.[4] There is not universal agreement on these percentages, with some studies reporting as little as 3% unused while others report that 50% or more are unused.[5]
- In addition, the number of prescriptions per 100 people has increased between 1995 and 2008 from 0.8 to 1.2 nationwide.[6] Considering our aging population, this trend is likely to continue.

Several topics that are not within the direct scope of this analysis but which are related to the topic are listed below. The paper does not discuss some further, while others are discussed when necessary as they relate to the collection programs:

- Excretion. While human excretion is a major pathway for pharmaceuticals to reach the environment, it occurs before pharmaceuticals become home-generated wastes. The latter issue, home-generated wastes, is the focus of this background paper.
- Drug Distribution Solutions. While fewer prescriptions, reduced sales of pharmaceuticals, or changes resulting in more complete usage of medications could result in a lower amount of home-generated pharmaceuticals, these actions would occur before pharmaceuticals become home-generated wastes.
- Controlled Substances. SB 966 specifically states that it does not apply to controlled substances; however, they are mentioned in this report because their special requirements impact collection programs for other home-generated pharmaceutical wastes.
- Reverse Distributors. Reverse distributors collect unused and expired medication from hospitals and pharmacies and in return provide monetary credit or disposal of that waste. This activity occurs before pharmaceuticals become home-generated wastes. In addition, several concerns exist regarding applying this concept to home-generated wastes.[*]

[*] Once dispensed, medications may be tampered with, kept in inappropriate conditions, and become unfit for redistribution. According to the California Board of Pharmacy, a reverse distributor may not accept previously dispensed medicine & may not have sufficient safety standards to prevent illegal drug diversion.

II. Program Surveys and Results

1. Program Surveys

During April and May 2010, CalRecycle sent surveys to 67 program managers that represented all known home-generated pharmaceutical collection programs.[†] This paper includes results based on the surveys submitted by June 10, 2010.

Many program managers represented more than one program and often more than one type of program. There were three one-page surveys, each covering one of the three major program types (continuous collection programs, events, or mail-back programs, which are described below). As a result, a program manager may have filled out numerous surveys (one for each program) using the appropriate survey forms.

The survey forms (available under "Documents" at http://www.calrecycle.ca.gov/Actions/PublicNoticeDetail.aspx?id=217&aiid=217) varied by program type and included up to 25 questions that requested information on operations, funding, costs, collection amounts and security practices that related to the standards in the Guidelines. Not all of the surveys were complete and some appeared to contain contradictory, unsupported or unexplained responses. This is not unexpected when dealing with complex topics and self-directed survey instruments.

Three main types of programs collect home-generated pharmaceuticals in California: continuous collection programs, events, or mail-back programs.

For this paper:

- Continuous collection programs are defined as drop-off locations that have scheduled collection hours at least weekly throughout the year.[‡]
- Collection events are defined as programs that provide:
    - Periodic drop-off opportunities at different locations.
    - Infrequent drop-off opportunities at a single location, in comparison to continuous collection programs (e.g., an average of one or two days each month or less at the same location).
- Mail-back collection programs are defined as programs that transport drug waste through the U.S. Postal Service to an appropriate disposal location.

[†] CalRecycle became aware of these programs through workshops, discussions and other communications. Other programs may exist.

[‡] CalRecycle acknowledges that there is a spectrum of collection frequencies and approaches. The line between continuous collection programs and collection events is not black and white. For the purposes of this analysis, CalRecycle chose weekly collection as the threshold to distinguish between the two.

Overall, CalRecycle identified 297 collection programs and program managers returned surveys for 256 programs (86% of total). The return rate varied by collection program as shown in Figure 2. The percentage of responses in each program type adequately represents current collection efforts in California.

Figure 2. Number of Programs and Number of Survey Responses by Program Type

	Number of Known Individual Programs	Total Number of Individual Programs Represented in Survey	Percentage of Programs with Survey Responses (%)
Continuous Collection - Pharmacies	112	102	**91%**
Continuous Collection - Law Enforcement	65	63	**97%**
Continuous Collection – Household Hazardous Waste Facilities	26	18	**69%**
Continuous Collection - All Other	38	24	**63%**
Collection Events	53	46[§]	**87%**
Mail-back	3[**]	3	**100%**
Total	**297**	**256**	**86%**

Based on the survey responses, the primary locations for continuous collection programs are pharmacies (102), law enforcement sites (63), and Household Hazardous Waste (HHW) collection sites (18). Ten other location types[††] contribute another 24 continuous collection sites, but the low numbers and differences between them make it difficult to draw conclusions regarding these locations.

The remainder of this paper will focus on the top three continuous collection location types (pharmacies, law enforcement, and HHW), as well as collection events and mail-back programs.

[§] Program managers returned surveys for 50 of the known collection events. However, four surveys contained information from prior to 2009. CalRecycle became aware of two other programs after this analysis was completed. Finally, the "No Drugs Down the Drain" campaign consisted of more than 200 local one-day and ongoing pharmaceutical collection options during the week of October 4 – 11, 2008. This campaign was not included because it predated the survey period. As a result, this paper reflects 46 survey respondents.

[**] Some pharmacies use tamper-resistant cardboard "mail-back" boxes (which hold 10- or 20-gallons). Pharmacies keep these containers on site until they are full. Individual consumers do not use these boxes, so this practice is included as part of the continuous collection programs operated at pharmacies.

[††] Other locations include: clinics (6), hospitals (4), city halls (3), senior centers (3), dentists (2), door-to-door pickup (2), water districts (1), wastewater treatment plants (1), offices (1), and fire stations (1).

The responding collection events range from regular mobile collection events to limited hours at permanent household hazardous waste sites (e.g., first Saturday of each month) to highly coordinated events at multiple sites in a one-week period. Typical collection events are located in parking lots, vacant lots, pharmacies, senior centers, police substations, and household hazardous waste facilities.

The three mail-back programs all began in the Bay Area in 2009: the City of San Francisco, Teleosis (a non-profit organization in the Bay Area), and Santa Cruz County. While only a few mail-back programs currently operate in California, other states and countries utilize mail-back collection programs (as discussed below in Section IV. Overview of Programs Outside of California).

The number of surveys used in different analyses within this paper may vary because not all surveys included all the necessary information to do the necessary calculations or determinations.

The analyses in the remainder of this paper are based on the respondents not on the "known universe," because the responses are considered "confirmed" programs and have data associated with them.

2. Number of Model Programs by Type

Based on the survey responses on the 256 programs, CalRecycle determined that 89 (35%) met all the standards in the Guidelines and were model programs and 167 did not meet at least one criterion. Some of the criteria in the Guidelines, some of the questions on the survey and some of the responses to the survey contained some ambiguity, so these model program determinations contain some subjective considerations. As shown in Figures 3 and 4, there are more model programs and higher percentages of model programs in some collection program types than other program types.

Figure 3. Numbers of Model and Non-Model Programs by Type

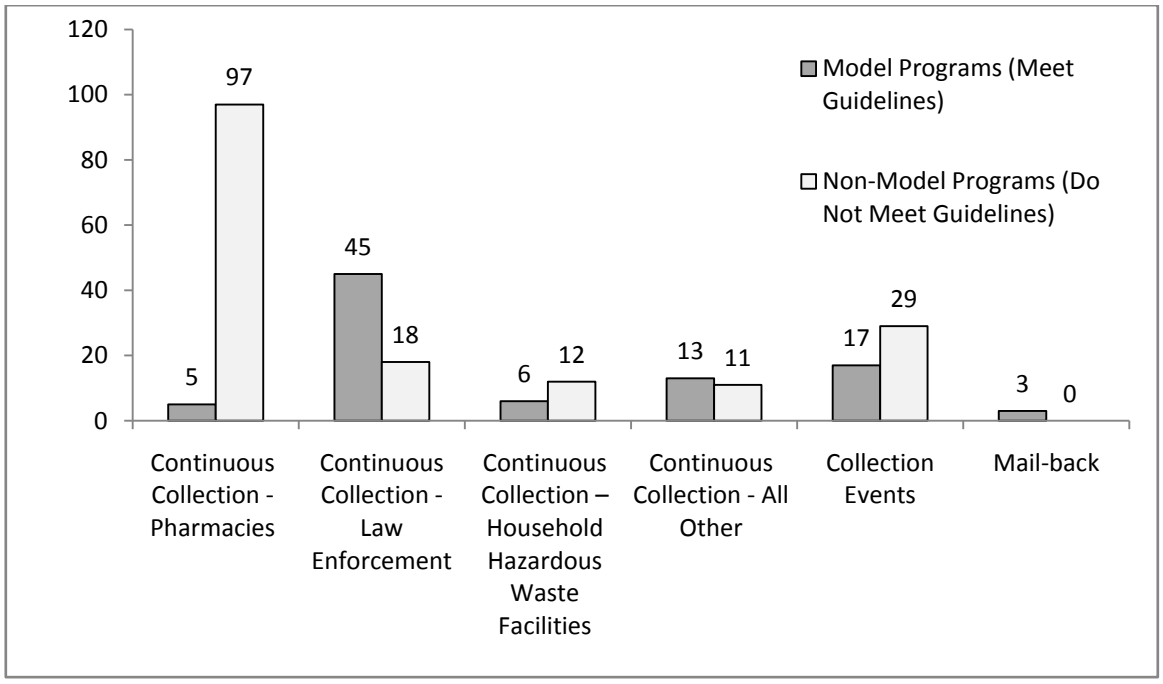


Figure 4. Numbers and Percentages of Model Programs

	Number of Model Programs (Meet Guidelines)	Number of Non-Model Programs (Do Not Meet Guidelines)	Percentage of Model Programs Within Program Type
Continuous Collection - Pharmacies	5	97	5%
Continuous Collection - Law Enforcement	45	18	71%
Continuous Collection – Household Hazardous Waste Facilities	6	12	33%
Continuous Collection - All Other	13	11	54%
Collection Events	17	29	37%
Mail-back	3	0	100%
Total	**89**	**167**	**35%**

Of the 207 continuous collection programs, 69 adequately met the Guidelines and are model programs. Five pharmacy collection programs are models (5%), 45 law enforcement collection programs are models (71%), and 6 HHW collection programs are models (33%). Of the 46 collection events, 37% (17) adequately met the Guidelines and are model programs. Of the three mail-back collection programs, 100% (3) adequately met the Guidelines and are model programs. The Guidelines emphasize the secure management of home-generated pharmaceutical wastes. To be a model, a program must meet each of the criteria in the Guidelines. The performance of programs in this area varies tremendously as discussed under "Safety (Security)" in the next section.

3. Program Evaluations for Safety, Accessibility, Cost Effectiveness and Efficacy

This section evaluates the four factors in SB 966: safety, accessibility, cost effectiveness, and efficacy. While SB 966 only calls for an evaluation of "model programs", for completeness this paper analyzes all programs that responded to the surveys. For each factor, the sections below contain:

- **Definition.** A working definition of the factor.[‡‡]
- **Limitations.** The major limitations identified by CalRecycle regarding application, interpretation, and/or comparison.
- **Numerical Results.** The data in tabular and/or chart form. The tables below contain simplified survey questions. For the complete survey questions, refer to the blank survey documents.
- **Relative Rankings.** Relative rankings of each program type for the individual factor considered.

[‡‡] CalRecycle acknowledges that each of these factors could be defined in different ways, using different metrics.

SAFETY (SECURITY)

DEFINITION

For this paper, safety pertains to the security of pharmaceutical waste collection to prevent illegal diversion. The Guidelines contain many criteria designed to prevent or deter the public and/or program employees from taking pharmaceuticals out of the collection system for abuse or sale. CalRecycle attempted to capture these criteria in the survey questions. "Safer" collection programs meet more of the criteria and the "safest" qualify as model programs.

LIMITATIONS

As mentioned above, some of the criteria and some of the questions on the survey contained some ambiguity, so model program determinations contained some subjective elements. Incomplete surveys could also result in the failure to meet the Guidelines, regardless of what the answer might have been had the response been provided.

NUMERICAL RESULTS

As shown in Figure 5 through Figure 8 below, different program types had different levels of success in meeting the criteria in the Guidelines. One unmet criterion disqualifies a program from being a model. Within each program type, different programs failed to meet different combinations of criteria so the percentages are not additive.

Continuous Collection Pharmacy Programs:

While 60% of the 102 continuous collection pharmacy programs responded that they were consistent with the Guidelines, CalRecycle determined that only 5% actually qualified as model programs.

Each line in Figure 5 shows the number and percentage of pharmacy programs that would not meet the Guidelines based on a single criterion alone. Pharmacy programs had issues with nine safety-related criteria. Issues related to collection bin access and handling were responsible for most pharmacy program disqualifications: two-key bins (93%), locking full bins (84%), and public access to bins (65%).

Figure 5. Safety – Continuous Collection Pharmacy Programs & Guideline Criteria

Simplified Survey Questions Representing Guideline Criteria	Number of Pharmacies Not Matching Individual Criterion	Percent that would not be Models based on each Criterion
Only police collect controlled substances?	2	2%
Secure drug waste container?	33	32%
Two-key collection bin?	95	93%
Lock bin when full?	86	84%
Bin is not publicly accessible?	66	65%
Permission to store longer than 90 days?	26	25%
Maintaining a log?	52	51%
Log accompanies controlled subs?	2	2%
CDPH-registered hauler?	11	11%

Continuous Collection Law Enforcement Programs:

While 100% of the 63 continuous collection law enforcement programs responded that they were consistent with the Guidelines, CalRecycle determined that only 71% actually qualified as model programs.

Each line in Figure 6 shows the number and percentage of law enforcement programs that would not meet the Guidelines based on a single criterion alone. Law enforcement programs had issues with five safety-related criteria. Issues related to controlled substances (29%), storage times (22%) and hauler registration (29%) were responsible for most law enforcement program disqualifications.

Figure 6. Safety – Continuous Collection Law Enforcement Programs & Guideline Criteria

Simplified Survey Questions representing Guideline Criteria	Number of Law Enforcement Not Matching Individual Criterion	Percent that would not be Models based on each Criterion
Only police collect controlled substances?	18	29%
Secure drug waste container?	1	2%
Permission to store longer than 90 days?	14	22%
Maintaining a log?	3	5%
CDPH-registered hauler?	18	29%

Continuous Collection HHW Programs:

While 78% of the 18 continuous collection HHW programs responded that they were consistent with the Guidelines, CalRecycle determined that only 33% actually qualified as model programs.

Each line in Figure 7 shows the number and percentage of HHW programs that would not meet the Guidelines based on a single criterion alone. HHW programs had issues with three safety-related criteria. Issues related to documentation (50%) and storage times (44%) were responsible for most HHW program disqualifications.

Figure 7. Safety – Continuous Collection HHW Programs & Guideline Criteria

Simplified Survey Questions representing Guideline Criteria	Number of HHW Not Matching Individual Criterion	Percent that would not be Models based on each Criterion
Permission to store longer than 90 days?	8	44%
Maintaining a log?	9	50%
CDPH-registered hauler?	2	11%

Collection Events:

While 76% of the 46 collection events responded that they were consistent with the Guidelines, CalRecycle determined that only 37% actually qualified as model programs.

Each line in Figure 8 shows the number and percentage of collection events that would not meet the Guidelines based on a single criterion alone. Issues related to documentation (46%) were responsible for most collection event disqualifications.

Figure 8. Safety – Collection Event Programs & Guideline Criteria

Simplified Survey Questions representing Guideline Criteria	Number of Collection Events Not Matching Individual Criterion	Percent that would not be Models based on each Criterion
Participants access to drugs?	7	15%
Maintaining a log?	21	46%
CDPH-registered hauler?	4	9%

Mail-back Programs:

All three mail-back programs responded that they were consistent with the Guidelines, CalRecycle determined that they all qualified as model programs. Mail-back programs had no issues with safety-related criteria.

RELATIVE RANKING

As shown in Figure 9, relative safety performance can be determined based on the number of model programs, the number of areas in which a program type fails, and/or the percentage of the programs not meeting the safety criteria.

Figure 9. Safety – Relative Performance

	Number of Model Programs (Meet Guidelines)	Number of Criteria causing Disqualifications	Percentage of Programs not meeting Safety Criteria
Continuous Collection - Pharmacies	5	9	95%
Continuous Collection - Law Enforcement	45	5	29%
Continuous Collection – Household Hazardous Waste Facilities	6	3	67%
Collection Events	17	3	63%
Mail-back	3	0	0%
Total	**76**		

Pharmacies operate the most collection programs (102), but 95% of them fail to meet safety criteria in nine different criteria areas. As a result, there are only five model pharmacy programs in California.

Law enforcement operates the second highest number of collection programs (63) in the state and has the highest number of model programs (45). However, 29% of law enforcement programs fail to meet safety criteria in five different criteria areas.

Collection events account for the third highest number of programs (46) in the state. Of that number, 63% of them fail to meet safety criteria in three different criteria areas. As a result, there are only 17 model collection events in California.

Continuous collection at HHW sites account for the fourth highest number of programs (18) in the state, and 67% of them fail to meet safety criteria in three different criteria areas. As a result, there are only six HHW model programs in California.

Mail-back programs have the smallest number of programs (3) and the highest success rate (100%) at meeting the safety criteria with three model programs in California.

STATEWIDE ACCESSIBILITY (ACCESSIBILITY)

DEFINITION

For this paper, public accessibility pertains to the ability of the public to utilize a collection program. Two factors that correlate to accessibility are the overall number of collection sites and their access hours. A tally of the returned surveys provides the number of sites for each program type, while the survey included questions regarding hours of operation per week.

LIMITATIONS

Number of sites:

An increase in the number of collection sites in the state may not correlate to a more even geographic distribution throughout the state. Some people may not consider all types of sites equally accessible (e.g., anecdotal reports suggest some people are afraid of going to law enforcement sites), so the raw number may be misleading. Additionally, events may not be the most numerous programs, but in rural areas, targeted local collection events could provide the easiest access compared to longer travel distances to continuous collection programs.

Hours of operation:

Hours of operation varied significantly within program type as well as between program types; use caution when comparing averages when this type of variability exists. For example, among continuous collection programs, hours of operation may be a meaningful comparison. However, comparing these programs to mail-back programs is difficult; e.g., should the measure of accessibility for mail-back be picking up the envelope (limited hours) or putting it in the mail (unlimited hours)? In addition, the total number of hours may be less important than the "effective hours" in which people are likely to use a program; e.g., 24-hour access may not result in 3 times the effective access or triple the collection amounts compared to access during the "right" 8 hours per day. Finally, because of their infrequent nature, collection events are not comparable regarding hours of operation but if tailored correctly to the population served could nonetheless be accessible.

NUMERICAL RESULTS

Figure 10 shows accessibility as expressed by the number of programs in California.

Figure 10. Accessibility - Number of Programs

	Total Number of Individual Programs Represented in Survey	Percentage of Respondents (%)
Continuous Collection - Pharmacies	102	40%
Continuous Collection - Law Enforcement	63	25%
Continuous Collection – Household Hazardous Waste Facilities	18	7%
Collection Events	46	18%
Mail-back	3	1%

Figure 11 shows accessibility as expressed by the number of hours per day.

Figure 11. Accessibility - Number of Access Hours per Day

	Range of Responses (hours per day)		Average (hours per day)
	Min	Max	
Continuous Collection - Pharmacies	5	12	9
Continuous Collection - Law Enforcement	3	24	19
Continuous Collection – Household Hazardous Waste Facilities	1	9	3
Collection Events (on Event Days)	3	12	7
Mail-back (to pickup mailers)	6	10	8

RELATIVE RANKING

In terms of the number of programs, pharmacies are more accessible with 102 programs represented in the survey, followed by law enforcement (63), collection events (46), HHW (18) and mail-back (3). These relative rankings reflect the total number of pharmacies in California as a whole compared to law enforcement stations (thousands compared to hundreds).

In terms of average hours of operation per site per day, law enforcement programs had the longest average operational hours (19), more than double the average hours of pharmacies (9). HHW programs followed with an average of 3 hours per day. Collection events are not directly comparable, but were available for an average of 7 hours on event days. Mail-back programs allow the public to send packages at anytime at any mailbox, but the public could obtain mail-back envelopes an average of 8 hours per day.

Accessibility is a very subjective measure. If tailored correctly to a target population, any or all of these program types could result in reasonable access for the public. Because accessibility is dependent on consumer behavior, consumer preferences will drive the actual use of collection programs. Based on a recent study of consumers in Washington and Oregon, 64% of those surveyed would be somewhat or very likely to take their home-generated pharmaceutical waste to a "convenient" drop-off location while 55% of those surveyed would be somewhat or very likely to use a mail-back program for their home-generated pharmaceutical waste.[7]

COST EFFECTIVENESS

DEFINITION

For this paper, cost effectiveness pertains to the amount of pharmaceuticals collected in comparison to the cost of the program used to collect them. There were survey questions on both quantities collected and on costs incurred. For this analysis, this metric is the average cost per pound for each program type.

LIMITATIONS

Responses that did not include both costs and pounds of pharmaceutical waste collected were not included in the cost effectiveness analysis. Errors or misreporting in either overall cost or amount collected will impact the reliability of the cost per pound calculation.

Program costs may include: 1) advertising costs; 2) a medical or hazardous waste hauler's collection, transportation, disposal, and processing fees (hauler fees); or 3) administrative/staff time. Survey respondents could choose to provide costs for any or all of these categories. This analysis uses whatever cost data was provided. For instance, many programs did not provide advertising costs because their program was mature enough that advertising was not needed, or funds were so limited that it was not an option. Also, in many cases, staff time was not tracked and was not provided. Because all costs were not included, this may be a low estimate.

The cost data varied significantly within program type as well as between program types; when this type of variability exists, use caution when comparing averages.

Most HHW programs do not track pharmaceutical weights separately from poisons they collect. Most reported estimated weights. One was excluded from the analysis as it reported a combined weight.

Many programs represented in the survey results did not encourage removing pills from pill bottles and placing them in a plastic baggie before depositing them at the collection point. In some cases, the amount collected included packaging and in some cases it did not. For more comparable numbers for cost effectiveness, the amounts were all standardized to remove the weight of packaging. The correction assumed that in mixtures of pharmaceuticals and packaging, 54% of the weight is due to the pharmaceuticals and 46% is due to the packaging (based on an average of estimates in four other reports).[8] The correction significantly impacts the cost results, as shown in Figures 12, 13 and 14.

NUMERICAL RESULTS

Figure 12 shows the cost effectiveness as expressed by the cost in dollars per pound collected without any correction for the weight of packaging.

Figure 12. Cost Effectiveness – Cost per Pound (as reported)

	Range of Responses		Number Included in Average	Average Cost per Pound
	Min	Max		
Continuous Collection - Pharmacies	$1.00	$16.67	75	$5.60
Continuous Collection - Law Enforcement	$0.38	$13.89	63	$4.56
Continuous Collection – Household Hazardous Waste Facilities	$0.13	$6.38	15	$2.86
Collection Events	$0.87	$16.67	36	$6.06
Mail-back	$6.39	$50.40	3	$33.05

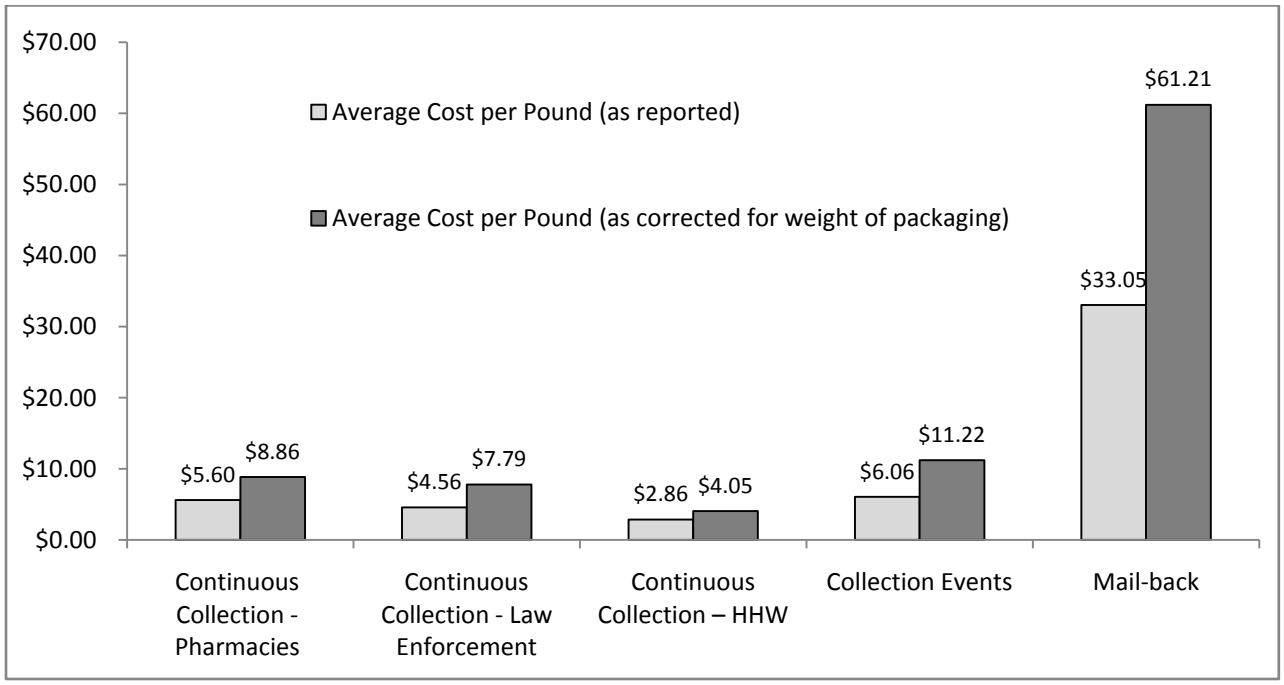
Figure 13 shows the cost effectiveness as expressed by the cost in dollars per pound collected after correction for the weight of packaging.

Figure 13. Cost Effectiveness – Cost per Pound (corrected to remove packaging)

	Range of Responses		Number Included in Average	Average Cost per Pound
	Min	Max		
Continuous Collection - Pharmacies	$1.00	$30.87	75	$8.86
Continuous Collection - Law Enforcement	$0.69	$25.72	63	$7.79
Continuous Collection – Household Hazardous Waste Facilities	$0.24	$11.82	15	$4.05
Collection Events	$1.60	$30.87	36	$11.22
Mail-back	$11.83	$93.33	3	$61.21

Figure 14 compares the costs as reported with the costs after correction for the weight of packaging.

Figure 14. Cost Effectiveness – Costs as Reported and as Corrected



RELATIVE RANKING

In terms of cost per pound after correcting for packaging, HHW programs spent the least amount per pound ($4.05), followed by law enforcement ($7.79), pharmacies ($8.86), and events ($11.22). Mail-back programs have the highest cost per pound ($61.21).

The cost per pound shown above for mail-back programs is higher because it includes the upfront cost of all the mailers purchased, not just those incinerated at the time of the survey. The percentages incinerated by the three programs at the time of the survey were 18%, 33%, and 38%. The cost per pound will go down as more envelopes are distributed and returned because the weight of home-generated pharmaceuticals collected will go up but the costs will remain the same. Additionally, the mail-back programs require that medications remain in their packaging, so correcting for removal of packaging may not be as useful. Finally, mail-back cost effectiveness can be significantly affected by the amount of pharmaceuticals included in each mailer; increasing the weight of each envelope lowers the cost per pound in cases of flat rate shipping arrangements.

Cost per pound may not be the only indicator for cost effectiveness. Collection events are often found in jurisdictions with limited resources. In situations in which the cost to open and/or operate a continuous collection program is prohibitive, collection events may allow a jurisdiction to reach all citizens with some level of collection service. Collection events appear to be more commonly utilized in areas with large dense populations such as the City of Los Angeles or the Bay Area, and also in rural jurisdictions where they provide at least some level of service to a diffuse population.

EFFICACY (COLLECTION RATE)

DEFINITION

For this paper, efficacy is measured in three ways:

- The total amount of pharmaceutical waste collected by a program divided by the number of operating days (pounds per operating day),
- The total amount collected by program type in California (total pounds per program type), and
- The average amount collected by each program type (average pounds per program).

LIMITATIONS

A common criterion is pounds collected per capita; however, this metric does not work for this analysis because the population served by a collection program (e.g., one pharmacy) is unknown.

As discussed above, both cost effectiveness and collection rate rely on weight data for collected pharmaceuticals. For this analysis, as discussed earlier, the pounds of pharmaceutical waste collected were adjusted by a 54% factor for those programs reporting they did not encourage removing pharmaceutical waste from its packaging. While these calculations were done for general comparison purposes on mail-back programs, this does not provide a direct comparison to mail-back programs since mailer instructions state that pharmaceuticals must be in their original containers.

For continuous collection programs, amount collected per day of operation equates to the amount collected at an individual site divided by the entire eight-month period. For a one-day collection event, the amount collected is divided by one day to yield the pounds collected per day of operation. As a result, comparisons between continuous collection program types may be feasible. However, comparing these programs to collection events can be problematic because the boundaries of the program are less clear (e.g. a single event, a single envelope, the entire series of events, or all envelopes).

NUMERICAL RESULTS

Figure 15 shows the efficacy as expressed by the pounds collected per day of operation without any correction for the weight of packaging.

Figure 15. Efficacy – Pounds Collected per Day of Operation (as reported)

	Range of Responses		Number Included in Average	Average Pounds per Day of Operation
	Min	Max		
Continuous Collection - Pharmacies	0.3	12.3	75	2.0
Continuous Collection - Law Enforcement	0.1	34.7	63	7.1
Continuous Collection – Household Hazardous Waste Facilities	0.4	10.3	16	2.0
Collection Events (on event days)	2.5	482.0	36	163.1
Mail-back	0.1	6.5	3	2.3

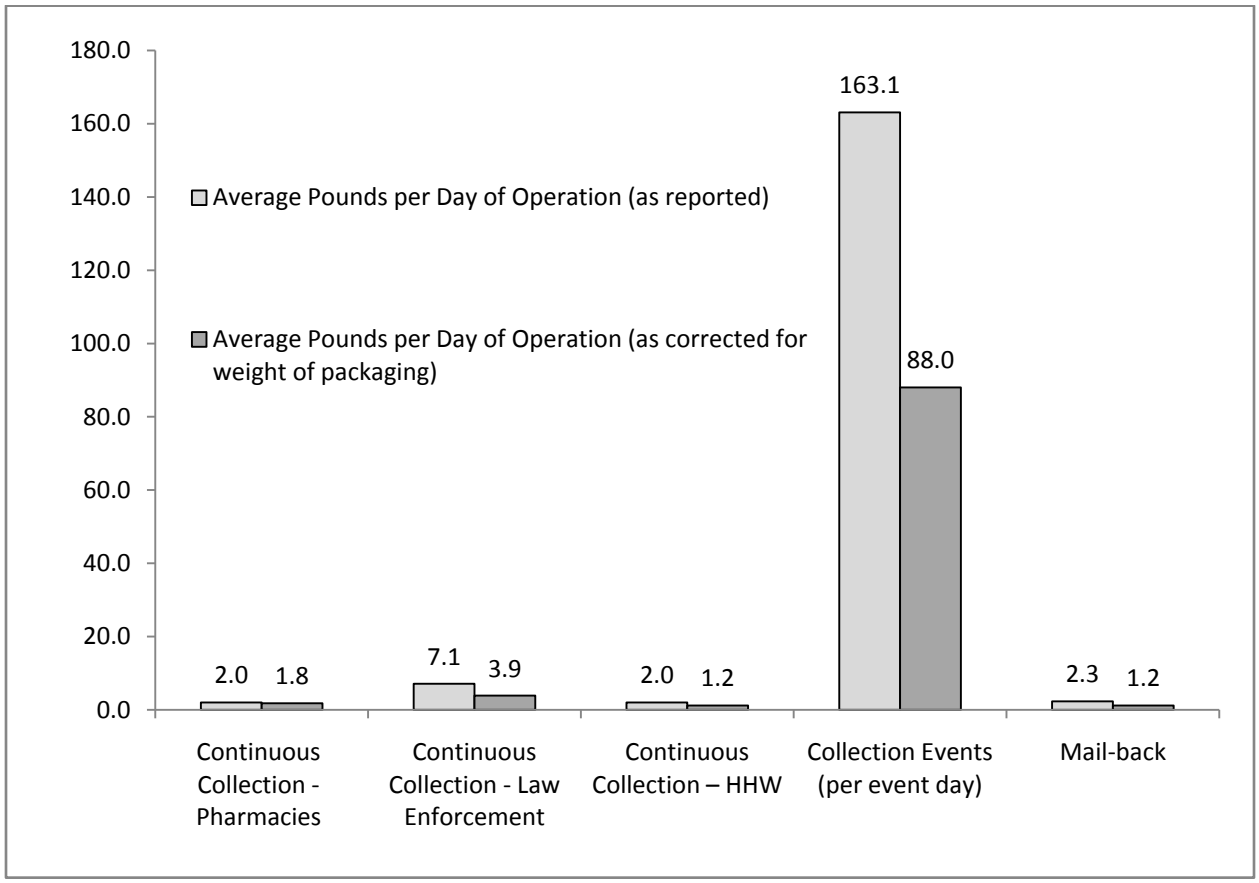
Figure 16 shows the efficacy as expressed by the pounds collected per day of operation after correction for the weight of packaging.

Figure 16. Efficacy – Pounds Collected per Day of Operation (as corrected, without packaging)

	Range of Responses		Number Included in Average	Average Pounds per Day of Operation
	Min	Max		
Continuous Collection - Pharmacies	0.2	12.3	75	1.8
Continuous Collection - Law Enforcement	<0.1	18.7	63	3.9
Continuous Collection – Household Hazardous Waste Facilities	0.2	5.6	16	1.2
Collection Events (on Event Days)	1.4	260.0	36	88.0
Mail-back	<0.1	3.5	3	1.2

Figure 17 compares the efficacy as reported with the efficacy after correction for the weight of packaging.

Figure 17. Pounds Collected per Site by Program Type



Efficacy can also be demonstrated by the total amounts collected by each program type in California, and the average amounts collected by programs in each program type, as shown in Figure 18. Even though pharmacy programs outnumber law enforcement programs, the overall collection amount for law enforcement programs is considerably higher, as is the average pounds collected per law enforcement program.

Figure 18. Efficacy – Total Pounds & Average Pounds Collected by Program Type

	Pounds Collected per Program Type (as reported with packaging)	Average Pounds Collected per Program (as reported)	Pounds Collected per Program Type (as corrected for packaging)	Average Pounds Collected per Program (as corrected)
Continuous Collection - Pharmacies	18,120	178	17,543	172
Continuous Collection - Law Enforcement	194,522	3,088	105,088	1668
Continuous Collection – Household Hazardous Waste Facilities	9,349	519	5,361	298
Collection Events	5,040	110	2,722	59
Mail-back	1,678	559	906	302

RELATIVE RANKING

When efficacy is measured as the average pounds collected per day of operation (after correcting for packaging), collection events collected the most per day (88.0 pounds per event). Among the continuous collection programs, law enforcement collected the most (3.9 pounds per day of operation), followed by pharmacies (1.8 pounds per day of operation) and HHW programs (1.2 pounds per day of operation). Mail-back programs also collected an average of 1.2 pounds per day of operation.

When efficacy is measured as the total amount collected by program (after correcting for weight of packaging), law enforcement programs collected the most (105,088 pounds), followed by pharmacies (17,543 pounds), HHW (5,361 pounds), collection events (2,722 pounds) and mail-back programs (906 pounds).

When efficacy is measured as the average amount collected by each program within each program type (after correcting for weight of packaging), law enforcement programs collected the most (1668 pounds per program), followed by mail-back (302 pound per program), HHW (298 pounds per program), pharmacies (172 pounds per program) and collection events (59 pounds per program).

SUMMARY RANKING FOR ALL FOUR FACTORS BY COLLECTION PROGRAM TYPE

The relative rankings shown in this section should be used for general comparison purposes only. The rankings are merely numbers one through five (from best to worst) in each measurement. The ranking scale just shows numeric order and does not reflect the relative sizes or any linear relationship between the programs. The limitations that applied to each of the individual metrics still exist when the results are shown in rank order.

Figure 19 shows the relative summary rankings for the safety and accessibility metrics presented above.

Figure 19. Summary Rankings – Safety & Accessibility

	Safety Rankings			Accessibility Rankings		
	Number of Model Programs	Number of Problem Criteria	Percent of Programs not meeting Safety Criteria	Number of Programs	Percent of Programs in State	Average number of access hours per day
Continuous Collection - Pharmacies	4	5	5	1	1	2
Continuous Collection - Law Enforcement	1	4	2	2	2	1
Continuous Collection – Household Hazardous Waste Facilities	3	2	4	4	4	5
Collection Events	2	2	3	3	3	4
Mail-back	5	1	1	5	5	3

Figure 20 shows the relative summary rankings for the cost effectiveness and efficacy metrics presented above.

Figure 20. Summary Rankings – Cost Effectiveness & Efficacy

	Cost Effectiveness Rankings		Efficacy Rankings		
	Average Cost per Pound as reported	Average Cost per Pound as corrected	Pounds per Day	Total Pounds per Program Type as corrected	Average Pounds per Program as corrected
Continuous Collection - Pharmacies	3	3	4	2	4
Continuous Collection - Law Enforcement	2	2	2	1	1
Continuous Collection – Household Hazardous Waste Facilities	1	1	4	3	3
Collection Events	4	4	1	4	5
Mail-back	5	5	3	5	2

Figure 21 shows the totals and average ranking for all the relative rankings across the 11 metrics. The totals are just the rankings added in each row, with the minimum possible of 11 and a maximum possible of 55. The average is the total divided by the 11 metrics. A lower total number suggests a better overall fulfillment of the four factors, while a higher number suggests worse overall performance in relation to these four factors, using this set of metrics.

Figure 21. Summary Rankings – Totals

	Total of Rankings	Average Ranking (Total Divided by 11 Criteria)
Continuous Collection - Pharmacies	34	3.1
Continuous Collection - Law Enforcement	20	1.8
Continuous Collection – Household Hazardous Waste Facilities	34	3.1
Collection Events	35	3.2
Mail-back	40	3.6

The totals of the summary rankings show law enforcement continuous collection programs as best overall in satisfying the fours evaluation factors (safety, accessibility, cost effectiveness and efficacy). Pharmacy continuous collection programs and HHW continuous collection programs are next, followed extremely closely by collection events. Mail-back programs are last, but not that distant from the other program types (other than law enforcement). Law enforcement collection programs have the highest average ranking, with the others bunched somewhat closely together.

Because the rankings varied by the four factors and even by metric used within each factor, CalRecycle has no clear choice or recommendation for a program type to implement statewide. Because of local variables, differences in program implementation within each program type, and the different needs of populations to be served, there is not one best program for all locations and situations.

III. Challenges and Barriers

The survey data and survey respondent feedback revealed some challenges and barriers for current programs. This section discusses the following five challenges and barriers:

1. Safe Collection of Pharmaceuticals is Expensive
2. Lack of Public Awareness and Participation
3. Lack of Sustainable Funding
4. Lack of Goals
5. Unclear Requirements, Policies and Authorities

1. Safe Collection of Pharmaceuticals is Expensive.

Certain requirements in the Guidelines presented unique challenges to some programs. As discussed above, safety (security) issues are usually the primary reason why existing programs did not qualify as model programs. Meeting these safety issues often involve increased costs. Meeting the requirements can add more costs as specific participants are required (law enforcement personnel and registered haulers), more bins and pickups are needed (two key bins and secured containers), and special handling requirements are implemented (separate handling, weighing, and record keeping). A few of these issues are illustrated in this section.

COLLECTION OF CONTROLLED SUBSTANCES

Controlled substances represent approximately 10 percent of all prescriptions written in the United States. In the state of Maine's recent pilot mail-back program, controlled substances represented 17% of all drugs returned. Given many take back programs cannot accept controlled substances, mail back may offer convenience and privacy with these sensitive drugs.

Under Federal statute (the U.S. Controlled Substance Act), controlled substances cannot be collected unless a sworn law enforcement officer is onsite to take custody of, document, and dispose of these medications to prevent illegal diversion and abuse. Based on information available to CalRecycle, the United States is the only country that has these requirements.

Making it easier for non-law enforcement programs to collect controlled substances, and making it easier to dispose of all home-generated pharmaceutical waste within California, would decrease costs and make program implementation easier and more attractive.

Registered Waste Haulers & Disposal Facility Options

Transporting collected home-generated pharmaceutical waste using only haulers registered with CDPH may be more expensive than other options. At least nine pharmacies used the larger cardboard "mail-back" boxes described above but this method does not use a registered waste hauler.

Disposal requirements and disposal options vary depending on how the materials are collected, consolidated, mixed with other materials, and on who does the collecting. The costs of these options are very different and impact the costs of collection programs. It appears that law enforcement collection programs have the option of in-state incineration (at least for controlled substances). It also appears that HHW collection programs that mix medications and poisons may have the option of in-state hazardous waste landfills. Most other programs appear to use out-of-state incineration which is more costly. CalRecycle has requested information from CDPH and other agencies to clarify the requirements and options for disposal of home-generated pharmaceuticals.

Two Key Locking Collection Bins

To save on waste hauling expenses, employees at many pharmacies with publicly accessible bins will empty the bin and store the bin contents behind the counter to avoid extra waste hauler trips. To meet the Guidelines, bins located at pharmacies must have a two key security system so that no individual may access the drug waste alone: the pharmacy's designated responsible person would have one key and the licensed hauler would have the other key. Marin County, which began collection in 2004, would exceed its $14,000 annual budget if the county paid for a two-key collection bin for each of its 24 participating pharmacies.

Use of Secure Containers at HHW Sites

The majority of HHW facilities comingle drug waste with poisons—often in open 55-gallon drums to allow room for poisons to be easily deposited. Unfortunately, this also allows much easier access to deposited pharmaceuticals. To meet the Guidelines, an additional bin may be needed (at a cost of approximately $600 each), so that materials are not co-mingled and remain secure. However, the relatively small amounts of pharmaceutical waste compared to poisons collected at HHW sites, makes it somewhat impractical for pharmaceuticals to be managed separately from poisons; it could lead to storage times exceeding the limits and much higher disposal costs (costs rise exponentially for smaller containers).

RECORD KEEPING AND DATA COLLECTION

Weighing, logging and tracking drug waste before and after transport is meant to prevent illegal diversion, and can also be useful in performance measures. Most survey respondents for HHW facilities reported they comingled pharmaceutical waste with poisons, which may make it more difficult to weigh, log and track pharmaceuticals separately. As discussed above, if HHW sites must treat poisons and pharmaceuticals differently their costs will be higher.

2. Lack of Public Awareness and Participation

A common challenge with any type of collection program is achieving high public awareness and participation. Given that program costs increase with more collection and that local governments fund most collection programs and face significant budget shortfalls, local governments are in one sense penalized as participation increases.

There is not enough data from programs outside of California to draw any conclusions about types of programs associated with high public participation, but anecdotally, public outreach and convenience play an important role.

3. Lack of Sustainable Funding

Local governments currently fund approximately 83% of collection programs. Of that amount, most of the funding is from counties, local waste and water agencies, and to a lesser extent cities. Pharmacies provide funding for 15% of collection programs. The other two percent comes from various other sources, such as non-profit and waste companies. Although SB 966 encourages a cooperative relationship with all stakeholders, CalRecycle is not aware of any funding from pharmaceutical manufacturers for collection programs in California. According to a recent survey of consumers in Washington and Oregon, 64% of those who responded agreed (strongly or somewhat) that pharmaceutical companies should be responsible for creating a take-back program for safe disposal of unused medicines.

This contrasts significantly with other countries (See Section IV. Overview of Programs Outside of California), where private sector manufacturers and retailers play a significant role in funding and managing pharmaceutical collection programs, many through product stewardship programs. Product stewardship programs use a private-sector approach to managing discards.[9] Producers are generally able to implement programs either individually or by joining together with other producers through a Product Stewardship Organization that collects, properly manages, and interacts with the state oversight agency on its behalf.

4. Lack of Goals

SB 966 does not provide any performance goals to measure success. Performance goals similar to CalRecycle's goal of 50% waste diversion in California by the year 2000 could drive the creation of programs and help set realistic standards for pharmaceutical waste collection throughout California. Goals accompanied with incentives can be particularly effective in driving program activity. To be effective,

measures would require some knowledge of the amounts of pharmaceuticals sold/prescribed in California, the amounts that become home-generated waste, and the amounts that are eventually collected.

5. Unclear Requirements, Policies & Authority

The Guidelines state, "Any participating entity must determine what permits or approvals are needed for home-generated pharmaceutical waste collection." However, the current patchwork of laws, regulations, and policies can be a challenge for any collection program. Entities may be discouraged from starting collection programs due to concerns and uncertainty about the applicable definitions, requirements and legal options for collecting, handling and disposing of home-generated pharmaceutical waste. In terms of potential recommendations to the Legislature, the following agencies and their respective laws, regulations, and policies may need to more directly address home-generated pharmaceutical waste collection programs.

U.S. Drug Enforcement Administration (DEA)

There are no DEA regulations specific to home-generated drug collection, but under the U.S. Controlled Substances Act, DEA governs controlled substances (Title 21, Chapter 13, Drug Abuse Prevention and Control). These regulations oversee the manufacture and distribution of narcotics, stimulants, depressants, hallucinogens, anabolic steroids, and chemicals used in the illicit production of controlled substances and define who may possess controlled substances, which impacts disposal of a controlled substance. Two proposed national bills, HR 1191 and HR 1359 (See Section IV. Overview of Programs Outside of California), would amend the Controlled Substances Act to allow for the safe and effective destruction of controlled substances.

California Board of Pharmacy

Pharmacies lack provisions for pharmaceutical collection recently granted for sharps collection. Technically, California law currently does not authorize pharmacies to accept the return of home-generated pharmaceutical waste. SB 966 states programs consistent with the Guidelines are "…in compliance with state law and regulation…" The California Board of Pharmacy's March 2010 newsletter stated, "The Board expects all pharmacies to use the [CalRecycle] Guidelines for any 'Take Back' program they offer the public."

Likewise, California law did not authorize pharmacies to accept the return of sharps from the public until Senate Bill 821 added appropriate language to the Business and Professions Code in October 2009. Until that time, the California Board of Pharmacy had a stated policy that it did not anticipate intervening in sharps collection programs unless necessitated by a complaint or public safety issue. A similar provision in California law would clarify the requirements for home-generated pharmaceutical waste.

Department of Toxic Substances Control (DTSC)

DTSC regulates hazardous waste including some pharmaceutical waste, but does not regulate home-generated pharmaceutical waste. DTSC's website states, "Pharmaceutical waste produced by a household is exempt from classification as hazardous waste or medical waste. This means that a household may legally dispose of their waste pharmaceuticals and personal care products in the solid waste stream or into

the sanitary sewer ("down the drain"). While these practices are legal, they may not be the environmentally preferred ways for a household to dispose of unwanted pharmaceuticals."

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH (CDPH)

The Medical Waste Management Program of the CDPH does not have statutory authority to regulate home-generated pharmaceutical waste. Instead, CDPH applies a best waste management policy consistent with current, existing waste collection models for home-generated pharmaceutical waste. This current policy monitors home-generated pharmaceutical waste at registered consolidation points to ensure proper containment, storage, and treatment. CDPH's policy is similar to its current regulation of home-generated sharps waste, which it defines as medical waste, when the sharps are collected at a consolidation point.

IV. Overview of Programs Outside of California

Other countries and states face similar challenges with managing unwanted pharmaceuticals. CalRecycle found examples of pharmaceutical collection programs in other countries and states and analyzed them for additional findings. Basic information about many of these programs is captured in the table in Appendix I (available under "Documents" at http://www.calrecycle.ca.gov/Actions/PublicNoticeDetail.aspx?id=217&aiid=217). Listed below are several programs that stand out for reasons noted. This is followed by discussion on common themes.[10]

1. International Guidelines and Programs

WORLD HEALTH ORGANIZATION (WHO)

- **World Health Organization**[11] issued guidelines for pharmaceuticals management in and after emergencies. These guidelines state that if take-back programs are not available and pharmaceuticals are treated prior to disposal by waste immobilization, it is acceptable to dispose of controlled substances in engineered or permitted landfills.[12] Immobilization refers to either encapsulation or inertization (removing the packaging materials from the pharmaceuticals, grinding pharmaceuticals and mixing them with water, cement, and lime).

EUROPEAN UNION

- **France: Cyclamed Program.** This national program allows consumers to return pharmaceuticals to local pharmacies for safe disposal. As the program is funded and managed by the private sector (industry, pharmacies and wholesalers), it can be described as a product stewardship program. It stands out for having relatively high per capita collection and participation rate as noted in Appendix I. Also, the amount of pharmaceuticals collected, reported in terms of with and without packaging, indicates that it is very important to understand to what extent packaging is included in measurements as it can

significantly impact the collection rates. This program offers more information on its performance than many other programs.

- **Portugal: Valormed Program**. This national program allows consumers to return unused pharmaceuticals to local pharmacies for safe disposal. As it is funded by members of pharmaceutical associations, including local pharmacies, manufacturers, distributors and chemical and pharmaceutical importers, it is a product stewardship program. This particular product stewardship program places an eco-fee of 0.00504 Euros on each package placed in the market. The program stands out as having a fairly high per capita collection as compared to other programs in this section. Significant information gaps include costs and to what extent the collection includes packaging.

- **Spain SIGRE Program**. This national program allows consumers to return unused pharmaceuticals to local pharmacies for recycling or safe disposal. As it is managed by SIGRE, a non-profit, and SIGRE is funded by members of pharmaceutical industry based on volume of sales, it is a product stewardship program. The program stands out as having fairly high per capita collection and is a product stewardship model that uses a stewardship organization. Significant information gaps include costs, to what extent the collection metrics include packaging, and to what extent recycling occurs.

- **Sweden Apoteket AB Program.** This national program allows consumers, along with other types of facilities such as care centers, dentists, hospitals, veterinarians, and farmers, to return leftover pharmaceuticals to the state-owned, non-profit retail pharmaceutical chain. The program stands out for being government managed and financed, and for having higher reported costs and lower collection rates. Significant information gaps include how the collection rate is calculated given the broader scope of the program and to what extent collection metrics include packaging.

CANADA

- **Alberta ENVIRx Program.** This province-wide program allows consumers to return pharmaceuticals to a majority of local pharmacies for safe disposal. It is mainly funded by industry, but also by small grants from the provincial government, so it could be considered a quasi-product stewardship program. The program stands out for being voluntary. Significant information gaps include costs and to what extent collection metrics include packaging.

- **British Columbia PCPSA Program.** This province-wide program allows consumers to return pharmaceuticals to a majority of local pharmacies for safe disposal. As the program is managed by a stewardship organization, PCPSA , and is funded by industry; it is a product stewardship program. The program stands out for having more complete reporting and cost information, and relatively low collection rates and high costs for a product stewardship program. Significant information gaps include to what extent collection metrics includes packaging, which can affect per capita costs and collection rates.

CalRecycle observed some common themes among these programs: All programs reviewed by CalRecycle seek to provide a secure system for pharmaceuticals and all programs in other countries use pharmacies as the collection point. It appears that other countries do not have laws on par with the U.S.

Controlled Substance Act, which only allows law enforcement officials to handle controlled substances (e.g., narcotics), and this means that in other countries, pharmacies can serve as convenient consumer drop-off locations for all types of pharmaceuticals Also, most countries with collection programs have significant industry participation, including at least some industry funding, with the exception of Sweden, which operates collection through non-profit, state-run pharmacies.

When the private sector funds and manages collection programs and safe disposal of drugs, such a program is referred to as a Product Stewardship Program. As noted previously, product stewardship programs offer a private sector approach to waste management. Appendix I offers cost information on various pharmaceutical programs and this preliminary information suggests generally a lower cost per capita for those programs with greater industry funding. Overall, however, CalRecycle is not able to draw any specific conclusions about which of these programs are most effective due to data gaps and a lack of detailed information about the programs to ensure a fair comparison.

2. National Programs

No nationwide home-generated pharmaceutical waste collection programs currently exist in the United States; however, there are a few policies, laws, and regulations, along with nationally-based efforts, that address their disposal.

Federal Policy

- **White House Office of National Drug Control Policy** issued new guidelines to educate consumers on safe methods of pharmaceutical disposal in October 2009. These guidelines first recommend participating in take-back programs, if available. When that option does not exist, it recommends removing drugs from original containers and mixing them with undesirable substances, like coffee grounds or cat litter, and then sealing them in an impermeable container before throwing the unused drugs in the trash.[13]

FEDERAL LEGISLATION AND REGULATIONS

While, no national laws directly govern home-generated pharmaceutical waste, once home-generated pharmaceutical waste is collected at a consolidation point, the waste is governed by at least four national laws.

- **U.S. Controlled Substances Act** regulates the manufacture and distribution of narcotics, stimulants, depressants, hallucinogens, anabolic steroids, and chemicals used in the illicit production of controlled substances and defines who may possess controlled substances, which impacts disposal of a controlled substance. Controlled substance must be collected by sworn law enforcement officers (pharmacies may only take back uncontrolled substances).

  Program managers in California and in other states view the federal Controlled Substances Act as a barrier to collection because it limits unsorted returns of controlled substances to law enforcement, which generally is less convenient than local pharmacies. Also, consumers can't easily determine if a drug is a controlled substance or not.

- **Resource Conservation and Recovery Act (RCRA)** governs the management of hazardous wastes, including some drug waste.

- **The Health Insurance Portability and Accountability Act (HIPAA)** provides a Federal floor of privacy protections for individuals' individually identifiable health information where that information is held by a covered entity or by a business associate of the covered entity.
- **Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180)** determine how to classify and transport chemotherapeutic and pharmaceutical wastes.

PROPOSED FEDERAL LEGISLATION

Two federal laws are currently under consideration that would amend the Controlled Substances Act to make it easier to collect controlled substances, provide research and funding for pharmaceutical take-back programs, develop recommendations and educate the public on proper pharmaceutical disposal, and would educate the public on impacts from pharmaceuticals.

- **Safe Drug Disposal Act of 2009 (HR 1191 and S 1336)** Requires the DEA to design five drug disposal models for collecting controlled substances without law enforcement participation (may be used for other drugs). States would be required to pass legislation to adopt one or more of the models or propose an alternative. The second bill is more prescriptive, it does not mandate that five as opposed to only one model be developed, and no program managers or funders are specified.
- **Secure & Responsible Drug Disposal Act of 2009 (HR 1359 and S 1292)** Requires the DEA to create regulations allowing ultimate users or long-term care facilities to deliver unwanted drugs to other, authorized people for the purposes of disposal. The bill is less prescriptive than the HR 1191 and S 1336 and no program managers or funders are specified.

NATIONWIDE EFFORTS

- **Product Stewardship Institute (PSI)** works with stakeholders nation-wide to develop product stewardship approaches for the end of life management of unwanted/waste for many difficult-to-manage products, including pharmaceuticals. The main goals of the PSI multi-stakeholder dialogue are to increase awareness and to create a national, sustainable system for the end of life management of waste/unwanted pharmaceuticals. [14]
- **American Medicine Chest Challenge** is a nation-wide take-back event scheduled to occur in the US during fall of 2010.[15]

3. State Programs

At this point, several states are undertaking pilot programs, or recently finished pilot programs, to test methods for collecting home-generated pharmaceuticals. Several of these programs are listed below. These programs exclude controlled substances, unless noted:

- **Colorado:** The Colorado Department of Public Health and Environment and a consortium of concerned organizations launched a pilot program, to run through 2011. This program seeks to provide a secure and environmentally responsible way for people to dispose of unwanted medicines, excluding controlled substances. Tamper-resistant collection boxes are available at 10 locations around

the Denver metro area, including several stores, two county health department offices, and a health clinic. Funding is provided by a combination of federal, state and local government agencies (e.g., public health, water and environmental agencies), pharmaceutical and non-profit organizations.[16]

- **Iowa:** The Iowa TakeAway program aims to provide the public with a safe, easy way to properly dispose of unwanted and expired medications, excluding controlled substances. TakeAway uses community pharmacies across the state as take-back sites. Some participating pharmacies also sell TakeAway envelopes, pre-addressed, pre-postage paid large envelopes that can be taken into the home, filled with unused and expired medicine, and mailed through the United States Postal Service to the disposal facility. Funding was provided through Iowa Department of Natural Resources grants to the Iowa Board of Pharmacy, who worked closely with the Iowa Pharmacy Association, to offer the TakeAway pilot program. The $165,000 grant paid for collection in 357 pharmacies and as of May 2010, 2,550 lbs were collected and destroyed (this does not count partially filled bins).[17] [18]

- **Maine:** The Safe Medicine Disposal for ME Program (mail-back) is a statewide pilot program for the disposal of unused household medications using a mail-back return envelope system.[19] Established through state legislation and implemented in 2007 with a $150,000 grant from the U.S. Environmental Protection Agency's Aging Initiative. The program was authorized to handle both controlled and non-controlled medications. All drugs collected undergo high-heat incineration, according to the procedure already established for Maine's law enforcement drug seizures. Costs were $18.79/mailer, including both actual and in-kind costs during the start up (phase I and II); long term costs are anticipated to be $7.50 /mailer (phase III). The average weight of a mailer with drug waste is seven ounces. A report on the statewide mail-back model concludes that mail-back offers "an element of confidentiality and anonymity not found with in-person take back programs and is the least burdensome of all models in terms of consumer access and utilization." It further states that "Maine's citizen mail-back program has demonstrated that this approach is not only feasible, but effective." More recently, Maine Department of Environmental Protection reported on research that found leachate in three lined landfills that contained a large variety of pharmaceuticals and personal care products.[20]

- **Washington:** To address the need for a safe way to dispose of unwanted medicines, excluding controlled substance, a coalition of government, nonprofit, and business partners began a pilot in 2006 called Pharmaceuticals from Households: A Return Mechanism (PH:ARM) at Group Health Cooperative, a regional healthcare organization in Washington; Bartell Drug, a Western Washington retail pharmacy chain; and two boarding homes. Key findings of the PH:ARM pilot program are:

    - Medicine return programs can provide environmentally sound disposal of medicines.[21]
    - Returning medicines to a pharmacy with proper oversight and strict protocols can be safe and secure for any type of medicine, including controlled substances.
    - Medicine return programs are cost-effective to operate.
    - The Controlled Substances Act should be changed to allow collection of legally prescribed controlled substances at pharmacies.
    - A statewide program could collect a substantial amount of unwanted medicines.
    - Pharmacy-based medicine return is convenient and effective.
    - Community demand for safe disposal of medicines is high.
    - Sustainable funding is needed for a statewide medicine return program.

Additionally, many local governments and even groups of states host collection events. For example, in Maryland seven counties collect pharmaceuticals and a regional program is underway with the US EPA and four states that focuses on the Potomac watershed.[22]

Of these pilots, Washington and Maine stand out for being completed and providing fairly detailed information on costs and collections rates. Overall, among pilot programs, common themes emphasize a need for:

- Sustainable funding;
- Safe and legal disposal for home-generated pharmaceuticals;
- Convenient collection through pharmacies, other collection sites and mail back programs; and
- Controlled Substances Act should be changed to allow for the collection of prescribed controlled substances at pharmacies.

PROPOSED STATE-LEVEL LEGISLATION

Several states (Florida, Maine, Maryland, Minnesota, Oregon, Rhode Island, and Washington) have proposed product stewardship legislation for pharmaceuticals, but as of June 2010, none have passed as product stewardship legislation. An amendment to Minnesota legislation (SF 1568) narrowed its scope and enables various parties including licensed HHW facilities and county collection programs to have possession of prescription drugs for the purpose of disposal.

V. Potential Options for Further State Action

This section includes a range of potential options for further state action. These options start with continuing the status quo and are followed by three options which present possible paths forward. At the end of this section, there are "Parting Comments" which discusses the possible application of the options.

For each option, CalRecycle includes some potential impacts, arranged by the:

- Four evaluation factors in SB 966 (safety, accessibility, cost effectiveness, and efficacy),
- Challenges and barriers discussed above (Expense of Safe Collection, Lack of Public Awareness and Participation, Lack of Sustainable Funding, Lack of Goals, Unclear Requirements, Policies and Authorities), and
- Environmental impacts that SB 966 addresses.

Option 1. Continue Current Practices

Under this option, the state could encourage consumers to follow federal Office of National Drug Control Policy guidelines and also allow disposal of pharmaceuticals in landfills, if local collection options are not available. Consequently, some pharmaceutical chemicals would likely be found in landfill leachate [23] [§§] Under this option the Guidelines would continue to be optional. This option would require some tolerance of programs that do not follow the current Guidelines.

POTENTIAL IMPACTS:

- Safety: No change from current level. **Illegal diversion could still easily occur at waste disposal collection points (e.g., scavengers at trash bins, employees at materials recovery facilities). The described "treatments" in the Office of National Drug Control Policy do not appear to be a strong deterrent; e.g., mixing pharmaceutical waste with coffee grounds as the grounds are edible so drugs could still be consumable.**
- Accessibility: No change from current level. **A wide range of collection programs could continue as they currently exist, but as currently happens many consumers would be unaware of collection options or would not participate in available programs.**
- Cost effectiveness: No change from current level. **Would not reduce collection and management costs from current levels.**
- Efficacy: No change from current level. **Collection programs could continue to explore ways of providing more cost effective solutions without additional constraints or requirements. But this option would not significantly increase collection; as a consequence, pharmaceuticals would continue to be stored at home, disposed of in landfills or flushed down toilets, and eventually enter streams and groundwater. Collection levels would likely remain quite low compared to the total amount of home-generated pharmaceutical waste.**
- Expense of Safe Collection: No change from current challenge. **Because the Guidelines are voluntary, some requirements would continue to be ignored in order to reduce costs.**
- Lack of Public Awareness and Participation: No change from current challenge. **Would not address need for increased education.**
- Lack of Sustainable Funding: No change from current challenge. **Places no additional costs on state government, but would not address issue of insufficient funding or lack of sustainable funding source. Local governments would need to continue to find ways of funding these collection programs.**
- Lack of Goals: No change from current challenge.

[§§] Landfill leachate is typically gathered in leachate collection systems, although it is possible that a small amount may eventually escape containment and enter streams and rivers. Instead, most collected leachate is discharged into wastewater treatment systems. However, wastewater treatment systems are not equipped to handle pharmaceuticals and so pharmaceuticals in leachate may eventually enter streams and rivers.

- Unclear Requirements, Policies and Authorities: No change from current challenge. **Does not require new legislation. State agency roles and responsibilities would remain confusing and program managers would not have clear requirements to follow.**
- Environmental impacts: No change from current impacts. **Would not address potential impacts, such as bioaccumulation, sensitive species and/or synergistic effects, from wastewater treatment discharges (including materials originating from leachate).**

Option 2. Improve Guidelines, Enforcement, and Establish Clear State Agency Roles and Responsibilities

The Legislature could direct CalRecycle or another state agency to develop regulations based on the Guidelines which have been the leading officially-sanctioned home-generated pharmaceutical waste collection guidelines in California since November 2008. This option assumes no additional funds.

POTENTIAL IMPACTS:

- Safety: **The percentage of programs meeting the Guidelines would rise if it was mandatory.**
- Accessibility: **Because requirements will be clearer, the number of collection programs may increase and provide consumers with greater accessibility. However, the overall number of programs may not increase if the costs associated with meeting the Guidelines are too high.**
- Cost effectiveness: **Mandatory implementation of the Guidelines could result in higher costs and lower cost effectiveness. If clarification of the Guidelines identified additional options or flexibility, costs could be reduced.**
- Efficacy: **Some increase in collection is possible, but collection levels would likely remain quite low compared to the total amount of home-generated pharmaceutical waste.**
- Expense of Safe Collection: **Mandating use of the current Guidelines will likely make this challenge worse as all programs must meet all the criteria.**
- Lack of Public Awareness and Participation: No change from current challenge.
- Lack of Sustainable Funding: **Could place additional costs on state government for regulatory and enforcement activities. Would not address issue of insufficient funding or lack of sustainable funding source. Local governments would need to continue to find ways of funding these collection programs.**
- Lack of Goals: No change from current challenge.
- Unclear Requirements, Policies and Authorities: **Would provide an opportunity to update the Guidelines, set clear, consistent and enforceable standards. Could better define state agency roles and responsibilities through legislation or regulation.**

- Environmental impacts: **Significant amounts of pharmaceuticals would continue to be stored at home, disposed of in landfills or flushed down toilets, and eventually enter streams and groundwater.**

Option 3. Implement Product Stewardship

Product stewardship programs use a private-sector approach to managing discards.[24] Product stewardship is a shared responsibility approach that could provide for safe, accessible, and cost-effective end-of-life management of home-generated pharmaceuticals. Product stewardship programs are working successfully in the United States, Canada, Europe, and elsewhere for products ranging from computers to paint to pharmaceuticals.

Conceptually, this approach appropriately places the primary responsibility for pharmaceuticals management with the pharmaceutical manufacturer and the consumers who use them, rather than local governments and ratepayers. In other words, those who benefit from pharmaceuticals pay for pharmaceuticals waste management costs.

Full product stewardship programs are industry-led, giving producers or manufacturers the flexibility to design and implement their own programs, with the state or national governments' role as setting ground rules and providing oversight. Program costs are covered in the product price so those who use the product pay for its full cost. Producers are generally able to implement programs either individually or by joining together with other producers through a Product Stewardship Organization that collects, properly manages, and interacts with the state oversight agency on its behalf.

Producers (or their Product Stewardship Organization) plan and implement collection programs. For example, the producer would select the collection system that it determines to best achieve goals for the lowest cost. It could be through a willing pharmacy, or through law enforcement, at events, through mail-back, or some combination of these; and as long as goals and related laws were met, state government would not be involved, except in an oversight capacity and to ensure all producers participate.

Under this option, legislation would mandate a private-sector designed and managed producer responsibility approach for pharmaceuticals. This would provide the authority for state oversight to ensure a level playing field, and address issues of state agency roles and responsibilities so it is less confusing and more streamlined. This option would support the CalRecycle Strategic Directive on producer responsibility and it also is consistent with the Extended Producer Responsibility Framework Document adopted in January 2008.[25]

POTENTIAL IMPACTS:

- Safety: **An adequately funded and well coordinated, cooperative approach could result in safer handling of home-generated pharmaceutical waste. Better financing, consumer education, and more participation would likely increase the level of secure pharmaceutical management to prevent illegal diversion.**
- Accessibility: **Would likely result in increased consumer accessibility.**
- Cost effectiveness: **Creates an incentive for producers to more efficiently collect pharmaceuticals and considers product design changes that reduce management costs.**

- Efficacy: **Private sector programs can adapt more readily to changes in laws and market conditions and modify their program to maximize effectiveness. A more comprehensive and cooperative approach could capture significantly more home-generated pharmaceutical waste.**
- Expense of Safe Collection: **This approach may find new ways to approach the current Guidelines.**
- Lack of Public Awareness and Participation: **Efforts to increase public awareness and participation would be part of the product stewardship program.**
- Lack of Sustainable Funding: **Offers an equitable system where those who benefit from a product, pay for its full costs. Creates a new role for pharmaceutical manufacturers, who may resist additional responsibility and additional costs. Would provide sustainable funding for all program activities. Could place additional requirements on state government for oversight activities but the cost of these activities would be funded by industry through the product stewardship organization. Could reduce burden on local governments.**
- Lack of Goals: **This option would likely have goals to strive for as part of its framework.**
- Unclear Requirements, Policies and Authorities: **Requires new legislation that may be difficult to enact. Would minimize government bureaucracy, provide for clear government regulatory roles and responsibilities that can reduce program implementation costs.**
- Environmental impacts: **Less home-generated pharmaceutical waste would enter the environment.**

Option 4. Create a Statewide Collection Program Using an Advanced Disposal Fee and State Oversight

CalRecycle already manages several programs using an advanced disposal fee (ADF). Under these programs, consumers pay a fee at the time of purchase that is deposited in a fund managed by state government. Under this option, when consumers purchase pharmaceuticals they would pay a small fee that goes into an account to finance a collection program. CalRecycle, or other state agency, would establish the requirements for service providers participating in the collection program, certify or register service providers, pay service providers who collect the products covered under the program, and oversee compliance and enforcement.

POTENTIAL IMPACTS:

- Safety: **An adequately funded and well regulated program could result in safer handling of home-generated pharmaceutical waste. Better financing, consumer education, and more participation would likely increase the level of secure pharmaceutical management to prevent illegal diversion.**

- Accessibility: **An ADF option could utilize any or all of the collection program types currently used, or could mandate more specific requirements. Would likely result in increased consumer accessibility as more programs were created to tap into the funds collected through the ADF.**
- Cost effectiveness: **There would be less incentive to be innovative or to more efficiently collect pharmaceuticals if the state requires specific method(s) and/or pays a standardized processing/collection payment to service providers. ADF programs are known to achieve high collection rates, but are expensive compared to a private sector designed and managed programs, such as those using a product stewardship approach. Would increase government bureaucracy.**[***]
- Efficacy: **Private sector service providers would have an incentive (processing/collection payments) to create new programs and expand existing programs to gather more materials. A more comprehensive and regulated approach could capture significantly more home-generated pharmaceutical waste.**
- Expense of Safe Collection: **This approach could subsidize safe collection methods enough to make more programs feasible.**
- Lack of Public Awareness and Participation: **Private sector service providers would have an incentive (processing/collection payments) to educate the public about the services they provide and to compete for home-generated pharmaceutical waste.**
- Lack of Sustainable Funding: **Would provide sustainable funding for all program activities. Would place significant additional costs on state government for regulatory, fiscal and enforcement activities that would need to be funded by the ADF. Could greatly reduce burden on local governments. Would be a visible fee on consumers which may not be popular.**
- Lack of Goals: **This option would likely have goals to strive for as part of its framework.**
- Unclear Requirements, Policies and Authorities: **Requires new legislation that may be difficult to enact. Legislation would be needed to provide the authority for a state program and could result in clearer government regulatory roles and responsibilities, clearer requirements and a more uniform approach to home-generated pharmaceutical wastes.**
- Environmental impacts: **Less home-generated pharmaceutical waste would enter the environment.**

[***] For example, California's electronic waste (e-waste) program requires approximately 75 staff across state government. Among the twenty or more e-waste programs in the country, California is the only state using an ADF approach. In part, that is because it was the first program, but since then other states have opted for a product stewardship approach, which requires fewer government resources.

Parting Comments

The options above serve as starting points for further discussion and information gathering. It should be noted that some of the options may be combined.

Additionally, these options would allow multiple collection systems to co-exist, which may be necessary because CalRecycle has not found a single preferred collection system for all regions. Each system (continuous collection programs, collection events, and mail-back) has its merits when one considers programs budgets, available collection infrastructure, changing laws and regulations, and local public acceptance. Additionally, regardless of which option is implemented, much work lies ahead in finding solutions to financing, establishing clear goals, state agency responsibilities, and educating the public to meet the ultimate goal of providing safe and secure collection and management of home-generated pharmaceuticals.

VI. Source Reference Notes

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