BAY AREA POLLUTION PREVENTION GROUP

BAPPG

A Committee of Bay Area Clean Water Agencies

August 17, 2010

CalRecycle
1001 I Street
PO Box 4025
Sacramento, CA 95812-4025
PharmaSharps@calrecycle.ca.gov

Sent Via Email

Comments on CalRecycle Background Paper: *Evaluation of Home-Generated Pharmaceutical Programs in California*

The Bay Area Pollution Prevention Group (BAPPG) represents 43 publicly-owned wastewater treatment agencies throughout the Bay Area that work together on common pollution issues of concern. Since toilets and indoor drains have historically been a very common way for residents to dispose of unwanted medicines, we have been engaged in trying to provide a more environmentally-benign solution for the disposal of unwanted residential pharmaceuticals.

For the better part of a decade, member agencies of the BAPPG have provided residents with an easy, safe and cost effective way to dispose of their pharmaceutical waste. BAPPG members have spent many hours researching state and federal laws that impact local disposal programs, working and meeting with representatives from local and national DEA offices, Environmental Protection Agency, the US Postal Service, the California Department of Toxic Substances Control and the California Department of Public Health. In 2006, the BAPPG spearheaded the first "Safe Medicine Disposal Days," which won the EPA's 2007 Environmental Award for Outstanding Achievement.

BAPPG members were very supportive of the initial Senate Bill (SB) 966 legislation drafted by Senator Simitian, which was originally developed to provide residents with an easy disposal option for their unwanted medications. We do commend CalRecycle staff for their exhaustive efforts to gather stakeholder input and analyze and present information about pharmaceutical waste collection programs in California, across the country and outside the US. However, in reviewing CalRecycle's draft Background Paper "Evaluation of Home Generated Pharmaceutical Programs in California," we are concerned that CalRecycle staff has not addressed some key regulatory changes needed to level the playing field in California with the other 50 States, in the collection of home-generated pharmaceutical waste.

In all of our work and experience in trying to demonstrate a cost-effective and convenient method of disposal for unwanted residential pharmaceuticals, while navigating the various applicable regulations, we have found that the California Medical Waste Management Act makes the collection and disposal more difficult than in any other state – regardless of the constraints caused by the Federal DEA requirements for the handling of controlled substances. In particular, there are two issues:

1. The California Medical Waste Management Act needs to clarify that collected and consolidated residential pharmaceutical waste can be transported for proper disposal via common carrier. The current requirement that consolidated residential pharmaceutical waste be transported by a medical waste hauler adds tremendous cost to disposal programs for no real added benefit.

2. Analogous to the recent amendment that allows the collection of home-generated sharps, the California Medical Waste Management Act needs to be amended to state that California pharmacies may collect home-generated pharmaceutical waste for proper disposal. The Act is currently silent on the matter, as is the Board of Pharmacy's Business & Professions code, and Board of Pharmacy has therefore been resistant to encourage pharmacies to join in the collection efforts.

In the hope of being of assistance to CalRecycle staff, we have summarized our suggested changes to the California Medical Waste Management Act in the attached document.

Thank you for the opportunity to provide our input. Feel free to contact me at (650) 494-7629 or Karin.North@cityofpaloalto.org, if you have any questions or need clarification or additional details on our comments.

Sincerely,

Karin D. North
BAPPG Pharmaceutical Committee Chair

Suggested Changes to the California Medical Waste Management Act

The BAPPG's suggested changes to the California Medical Waste Management Act are included below. Please note that our suggested edits are underlined.

117642 – Common Carrier

"Common Carrier" means a company that hauls for hire, but who is not a Hazardous waste hauler.

117670.1 – Home-generated Pharmaceutical Waste

"Home-generated pharmaceutical waste" means prescribed and over-the-counter drugs derived from a household, including single family and multifamily residences.

117700 – Not Medical Waste

(e) Hazardous waste, radioactive waste, or household waste, including, but not limited to, home-generated sharps waste and home-generated pharmaceutical waste, as defined in Sections 117671 and 117670.1, respectively.

117748 – Pharmaceutical Waste

(a) "Pharmaceutical Waste" means any pharmaceutical that for any reason may no longer be sold or dispensed for use as a drug.

(b) For purposes of this part, "pharmaceutical" does not include any pharmaceutical that is regulated pursuant to either of the following:

(1) The federal Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C.A. Sec. 6901 et seq.).

(2) The Radiation Control Law (Chapter 8 (commencing with Section 114960) of Part 9).

117904 – Consolidation of home-generated sharps waste and pharmaceutical waste

(a) Consolidation of home-generated sharps waste

(2) A consolidation location approved pursuant to this section (a) shall be known as a "home-generated sharps consolidation point."

(3) A home-generated sharps consolidation point is not subject to the requirements of Chapter 9 (commencing with Section 118275), to the permit or registration requirements of this part, or to any permit or registration fees, with regard to the activity of consolidating home-generated *sharps waste pursuant to this section (a).*

(5) An operator of a home-generated sharps consolidation point approved pursuant to this section (a) shall not be considered the generator of that waste.

(b) Consolidation of home-generated pharmaceutical waste

(1) In addition to the consolidation points authorized pursuant to Section 118147, the enforcement agency may approve a location as a point of consolidation for the collection of home-generated pharmaceutical waste at, including but not limited to, pharmacies, health care facilities, veterinarian offices, clinics or hospitals, household hazardous waste programs, solid waste facilities, senior centers, or government offices.

(4) A home-generated pharmaceutical consolidation point shall comply with all of the following requirements:

(A) It shall be approved by the enforcement agency as a home generated pharmaceutical waste consolidation point.

(B) The home generated pharmaceutical waste collected and consolidated at a home generated pharmaceutical waste consolidation point (hereinafter "Take Back Waste") shall be collected in a secure manner that does not allow waste to be salvaged by unauthorized persons.

(C) Containers ready for disposal shall not be held for more than ninety days without the written approval of the enforcement agency.

(D) An operator of a home-generated pharmaceutical consolidation point may rely upon the Pharmaceutical Waste Hauling Exemption (Section 118031) to transport the Take Back Waste.

(5) An operator of a home-generated pharmaceutical consolidation point approved pursuant to this section shall not be considered the generator of that waste.

(6) The medical waste treatment facility which treats the pharmaceutical waste subject to this section shall maintain the tracking documents required by Sections 118040 or 118041, as applicable, and 118165 with regard to that pharmaceutical waste.

117930 – Treat Onsite

(f) The name and business address of the registered hazardous waste hauler used by the generator for backup treatment and disposal, for waste when the onsite treatment method is not appropriate due to the hazardous or radioactive characteristics of the waste, or the name of the registered hazardous waste hauler used by the generator to have untreated medical waste removed for treatment and disposal, and if applicable the name of the Common Carrier used by the generator to transport Pharmaceutical Waste offsite for treatment and disposal.

117945 – Information Documentation and Transportation Records

(b) Records of any medical waste transported offsite for treatment and disposal, including the quantity of waste transported, the date transported, and the name of the registered hazardous waste hauler or individual hauling the waste pursuant to Section 118030, or the Common Carrier hauling the Pharmaceutical Waste pursuant to Section 118031. The small quantity generator shall maintain these records for not less than two years.

117960 – Medical Waste Management Plan

(f) The name and business address of the registered hazardous waste hauler used by the generator to have untreated medical waste removed for treatment, if applicable and the Common Carrier hauling the Pharmaceutical Waste pursuant to Section 118031.

118000 – Transportation of Medical Waste

(a) Except as otherwise exempted pursuant to Section 118030 and 118031, all medical waste transported to an offsite medical waste treatment facility shall be transported in accordance with this chapter by a registered hazardous waste transporter issued a registration certificate pursuant to Chapter 6 (commencing with Section 118000) and Article 6.5 (commencing with Section 25167.1) of Chapter 6.5 of Division 20. A hazardous waste transporter transporting medical waste shall have a copy of the transporter's valid hazardous waste transporter registration certificate in the transporter's possession while transporting medical waste. The transporter shall show the certificate, upon demand, to any enforcement agency personnel or authorized employee of the Department of the California Highway Patrol.

(b) Except for small quantity generators transporting medical waste pursuant to Section 118030 or small quantity generators or Common Carriers transporting Pharmaceutical Waste pursuant to Section 118031, medical waste shall be transported to a permitted offsite medical waste treatment facility or a permitted transfer station in leak-resistant and fully enclosed rigid secondary containers that are then loaded into an enclosed cargo body.

118031 – Pharmaceutical Waste Hauling Exemption (PWHE)

(a) A medical waste generator or parent organization that employs health care professionals who generate Pharmaceutical Waste and an operator of a home-generated pharmaceutical consolidation point may apply to the enforcement agency for a pharmaceutical waste hauling exemption, if the generator, health care professional, or operator meets all of the following requirements:

(1) The generator, parent organization or operator has on file one of the following:

(A) If the generator or parent organization is a small quantity generator required to register pursuant to Chapter 4 (commencing with Section

117915), a medical waste management plan prepared pursuant to Section 117935.

(B) If the generator or parent organization is a small quantity generator not required to register pursuant to Chapter 4 (commencing with Section 117915), the information document maintained pursuant to subdivision (a) of Section 117945.

(C) If the parent organization is a large quantity generator, a medical waste management plan prepared pursuant to Section 117960.

(D) An authorization from the enforcement agency to operate a home-generated pharmaceutical consolidation point.

(2) The generator or health care professional who generated the Pharmaceutical Waste or the operator of a home-generated pharmaceutical consolidation point transports the Pharmaceutical Waste or Take Back Waste, applicable, himself or herself, or directs a member of his or her staff to transport the Pharmaceutical Waste or Take Back Waste, applicable, to a parent organization or another health care facility for the purpose of consolidation before treatment and disposal, or contracts with a Common Carrier to transport the Pharmaceutical Waste or Take Back Waste, applicable, to a permitted medical waste treatment facility, or transfer station.

(3) Except as provided in paragraph (4), the generator maintains a tracking document, as specified in Section 118040.

(4)

(A) Notwithstanding paragraph (3), if a health care professional who generates Pharmaceutical Waste returns the Pharmaceutical Waste to the parent organization, a single-page form or multiple entry log may be substituted for the tracking document, if the form or log contains all of the following information:

(i) The name of the person transporting the Pharmaceutical Waste.

(ii) The number of containers of Pharmaceutical Waste. This subparagraph does not require any generator to maintain a separate medical waste container for every patient or to maintain records as to the specified source of the Pharmaceutical Waste in any container.

(iii) The date that the Pharmaceutical Waste was returned.

(B) Notwithstanding paragraph (3), if the generator or health care professional who generated the Pharmaceutical Waste or the operator of a home-generated pharmaceutical consolidation point contracts with a Common Carrier to transport the Pharmaceutical Waste or Take Back

Waste, applicable, to a permitted medical waste treatment facility, or transfer station, maintains a copy of the tracking record completed by the common carrier pursuant to Section 118041.

(C) This paragraph does not prohibit the use of a single document to verify the return of more than one container to a parent organization or another health care facility for the purpose of consolidation before treatment and disposal over a period of time, if the form or log is maintained in the files of the parent organization or another health care facility that receives the waste once the page is completed.

118040 – Tracking Records

(a) Except with regard to sharps waste and pharmaceutical waste consolidated by a home-generated sharps or pharmaceutical consolidation point approved pursuant to Section 117904 and Pharmaceutical Waste transported pursuant to 118031, a hazardous waste transporter or generator transporting medical waste shall maintain a completed tracking document of all medical waste removed for treatment or disposal. A hazardous waste transporter or generator who transports medical waste to a facility, other than the final medical waste treatment facility, shall also maintain tracking documents which show the name, address, and telephone number of the medical waste generator, for purposes of tracking the generator of medical waste when the waste is transported to the final medical waste treatment facility. At the time that the medical waste is received by a hazardous waste transporter, the transporter shall provide the medical waste generator with a copy of the tracking document for the generator's medical waste records. The transporter or generator transporting medical waste shall maintain its copy of the tracking document for three years.

118041 – Tracking Records for Pharmaceutical Waste

(a) A generator or operator of home-generated pharmaceutical consolidation point relying upon the Pharmaceutical Waste Hauling Exemption shall maintain a completed tracking document of all Pharmaceutical Waste and Take Back Waste, as applicable, removed for treatment or disposal. The generator and operator shall include a copy of the tracking document in the container with the Pharmaceutical Waste or Take Back Waste, as applicable, delivered to the Common Carrier.

(b) The tracking document shall include, but not be limited to, all of the following information:

(1) The name, address, and telephone number of the generator.

(2) That Pharmaceutical Waste or Take Back Waste, as applicable, is being transported.

(3) The name, address, and telephone number of the Common Carrier, unless

transported pursuant to Section 118030.

(4) The name, address, telephone number, permit number, of the permitted facility to whom the Pharmaceutical Waste or Take Back Waste, as applicable, is being sent.

(5) The date that the Pharmaceutical Waste or Take Back Waste, as applicable, is collected or removed from the generator or operator's facility.

(c) Any generator or operator transporting Pharmaceutical Waste or Take Back Waste, as applicable, in a vehicle shall have a tracking document in his or her possession while transporting the medical waste. The tracking document shall be shown upon demand to any enforcement agency personnel or officer of the Department of the California Highway Patrol.

(d) Each medical waste treatment facility and transfer station shall date and sign a copy of the tracking document upon receipt, provide data periodically and in a format as determined by the department, and maintain a copy of the tracking document for three years.

(e) Pharmaceutical Waste or Take Back Waste, as applicable, transported out of state shall be consigned to a permitted medical waste treatment facility in the receiving state. If there is no permitted medical waste treatment facility in the receiving state or if the waste is crossing an international border, the pharmaceutical waste shall be treated pursuant to Section 118222 prior to being transported out of the state.

118147 – Consolidation

Notwithstanding any other provision of this chapter, a registered medical waste generator, which is a facility specified in subdivisions (a) and (b) of Section 117705, may accept home-generated sharps and pharmaceutical waste, to be consolidated with the facility's medical waste stream, subject to all of the following conditions:

(a) The generator of the home-generated sharps or pharmaceutical waste, a member of the generator' s family, or a person authorized by the enforcement agency transports the sharps waste to the medical waste generator's facility.
(b) The home-generated sharps or pharmaceutical waste is accepted at a central location at the medical waste generator's facility.

118165 – Treatment Records

(c) Copies of the tracking documents for all medical waste it receives for treatment from offsite generators or from hazardous waste haulers or from Common Carriers pursuant to Section 118041.

BAY AREA POLLUTION PREVENTION GROUP

BAPPG

A Committee of Bay Area Clean Water Agencies

August 20, 2010

CalRecycle
1001 I Street
PO Box 4025
Sacramento, CA 95812-4025
PharmaSharps@calrecycle.ca.gov

Sent Via Email

Comments on CalRecycle Background Paper: *Evaluation of Home-Generated Pharmaceutical Programs in California*

The Bay Area Pollution Prevention Group (BAPPG) represents 43 publicly-owned wastewater treatment agencies throughout the Bay Area that work together on common pollution issues of concern. Since toilets and indoor drains have historically been a very common way for residents to dispose of unwanted medicines, we have been engaged in trying to provide a more environmentally-benign solution for the disposal of unwanted residential pharmaceuticals.

For the better part of a decade, member agencies of the BAPPG have been working to provide residents with an easy, safe and cost-effective way to dispose of their pharmaceutical waste, while complying with applicable regulations. To that end, BAPPG members have spent many hours researching state and federal laws that impact local disposal programs, working and meeting with representatives from local and national DEA offices, the US Environmental Protection Agency (EPA), the US Postal Service, the California Department of Toxic Substances Control and the California Department of Public Health. In 2006, the BAPPG spearheaded the first "Safe Medicine Disposal Days," which won the EPA's 2007 Environmental Award for Outstanding Achievement.

BAPPG members were supportive of the initial Senate Bill (SB) 966 legislation drafted by Senator Simitian, which was originally developed to provide residents with an easy disposal option for their unwanted medications. However, we are now concerned that the information presented in CalRecycle's Background Paper is misleading and is counter to the State's goal of extended producer responsibility. In hopes of making residential pharmaceutical collection available to the residents of California, we offer the following comments:

Concern with the Model Program Guidelines

Our first concern is the validity of the model program Guidelines developed by CalRecycle. It appears that these Guidelines were developed with significant input from the California Board of Pharmacy – an organization that has been resistant to having pharmacies collect unwanted residential pharmaceutical waste. Local agencies, running safe and successful pharmaceutical

collection programs for many years, were minimally consulted during the model Guidelines process and have two major issues with the current Guidelines:

1. The inclusion of a two-key system for "model" pharmacy collection programs unacceptably increases collection program costs. To our knowledge, CalRecycle's Model Program Guidelines are the first program in the world to recommend a two-key locking system, requiring the pharmacist and the waste hauler to possess keys. There are no regulatory requirements that would mandate a two-key locking system. There are other ways to ensure safe disposal mechanisms (pre- and post- weight checks, tamper-evident sealing tape, etc.) that do not require a waste hauler and a pharmacist to have simultaneous access to the collection container. The State of Washington has a two-key system, but both keys are kept on the premises and accessed by different staff. Waste haulers typically charge approximately $80 per visit; therefore, requiring a waste hauler to come every time the collection bin is full would significantly increase costs. Some examples of the increased costs that will result from the two-key, vault system for pharmacies in the Bay Area include:

   - The cost for just one of the City of Palo Alto's collection sites would increase well over $20,000 per year.
   - The cost of Union Sanitary District's pharmaceutical collection program would more than triple each year.
   - The cost of the City of Santa Rosa's Safe Medicine Program would increase 66% or almost $12,000 per year, up from $22,600. See attached summary for more details.

   In the current economy, local agencies simply cannot afford the added expense that CalRecycle's model Guidelines would bring to pharmaceutical collection programs. This level of added expense would render most collection programs financially unsustainable and they would likely discontinue or stop offering as many collection locations.

2. The requirement to use a registered medical waste hauler to transport consolidated residential pharmaceuticals, which exists only in California, is a significant obstacle to running cost-effective take-back programs. Using non-registered haulers (common carriers, such as the US Postal Service, UPS or FedEx) would decrease disposal costs, especially if programs consolidate and ship their unwanted medications directly to a medical or hazardous waste incinerator.

The first step at easing the regulatory barriers that prevent the widespread adoption of pharmaceutical take-back programs is to modify the current Guidelines to address these two issues. The medical waste hauler issue also requires amendment of the California Medical Waste Management Act. Our August 17, 2010, comment letter addressed those suggested changes.

Suggested Changes and Edits to the Draft Background Paper

By December 2010, CalRecycle is tasked with providing the legislature a report on the different collection programs throughout California, specifically the safety, statewide accessibility, cost effectiveness and efficacy. We are concerned that CalRecycle's draft background paper

compares data that are completely different – the fabled comparing of apples with oranges. The comparison of existing collection programs with CalRecycle's Guidelines essentially finds that the majority of existing programs do not qualify as model programs, even though they have been achieving the goal of collecting unwanted residential pharmaceuticals, while complying with applicable regulations. In order to successfully evaluate the four program types, each program type should be analyzed, per SB 966, for safety, statewide accessibility, cost effectiveness and efficacy parameters. By reorganizing the background paper, a clear introduction for each program type could be added to provide the reader with the background as to why certain program types follow or do not follow the model Guidelines. See below for our suggested reorganization of the draft paper.

Suggested Restructuring of the Draft Background Paper

We suggest reorganizing and rewriting the draft background paper or, as discussed, have the Executive Summary cover the information in the following order:

a. Section 1. Programs Outside of CA

b. Section 2. Challenges and Barriers for Residential Pharmaceutical Collection in CA

    i. Include discussion on how costs associated with many of the programs would decrease significantly if legislation was passed to decrease the regulatory barriers

c. Section 3. Program Surveys and Lack of Availability of Existing Model Programs (do not compare existing programs to the Guidelines)

    i. Analyze each program type for efficacy, safety, statewide accessibility and cost effectiveness rather than trying to directly compare pharmacy, law enforcement, HHW and mail back programs to each other under the four evaluation elements. Comparing the data across program types is confusing since the programs are very different and since a combination of program types will likely be needed to capture most residential pharmaceutical waste.

        1. Pharmacy – clearly state the percentage of programs that were in existence prior to the model Guidelines. Explain that 95% of the pharmacy collection programs are not model programs, because of the two-key system that was recommended by the Board of Pharmacy. Also, include discussion that this option would provide the best geographic accessibility in terms of the number of pharmacies throughout the state outnumbering the other types of in-person collection sites (law enforcement and HHW).

        2. Law Enforcement – include discussion that under the current Federal and State regulations, law enforcement is often selected by agencies for residential pharmaceutical collection, because they are the only locations that can accept all unwanted medications, controlled and non-controlled. Point out that many law enforcement agencies are unwilling to have pharmaceutical collection, because of

limited resources – the City and County of San Francisco and the City of Oakland are both relevant Bay Area examples.

3. HHW – include discussion that HHW programs are already financially strapped from handling a number of different special household waste streams – most of which resulted from unfunded mandates. As well, HHW facilities were not designed to accept pharmaceuticals and requiring HHW facilities to follow the special handling requirements included in the model Guidelines would add significant cost to an already overburdened system. The HHW option is not financially sustainable.

4. Mail Back – recalculate the costs of mail-back to more accurately represent cost.

ii. Completely remove the section that corrects for removal of packaging. This calculation is incorrect; if you removed packaging, the disposal cost would decrease.

d. Section 4. Options for Further State Action – our suggested changes for this section were submitted in our August 17, 2010, comment letter.

Suggested Edits to the Draft Background Paper's Content

If CalRecycle staff declines our suggestion to reorganize the background paper, below are our suggested edits to the various sections of the draft background paper's content, in its current format:

1. Section II, Figure 2 (page 8): add a column listing the percentage of survey respondents' programs that were in operation prior to the release of CalRecycle's model Guidelines.
2. Section II, 3, Safety, Definition (page 11): suggest modifying the definition as follows: "The safety criteria of the Guidelines conservatively assume that controlled substances will be collected by all programs, even those that specifically state that they do not accept controlled substances."
3. Section II, 3, Safety, Definition (page 11): suggest modifying the definition as follows: "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, "and *the Guidelines require only pharmacies to have a two-key collection bin."*
4. Section II, 3, Numerical Results, Continuous Collection Pharmacy Programs (page 11): include a statement that the majority of the continuous collection programs at pharmacies were developed well before the Guidelines were developed. The primary reason a majority of the existing pharmacy collection programs do not meet CalRecycle's security guidelines is the onerous two-key locking vault requirement which costs approximately $600 per container, requires precious retail space and requires a hauler to come every time the collection bin is full. The majority of the existing collection programs have secure containers behind the counter that are not double locked. Yet, to our knowledge, there have not been any diversion linked to the Bay Area's take-back programs. It is

more likely that diversion will occur at the home prior to disposal at a safe collection program.

5. Section II, 3, Numerical Results, Law Enforcement (page 12): it needs to be stated that many communities chose to have law enforcement run and operate their collection programs due to the current regulatory barriers.

6. Section II, 3, Safety, Relative Ranking (page 13): include a discussion that certain program types have low compliance with the Guidelines due to structural considerations that are extremely difficult to overcome. Specifically, at pharmacies, the need for a double-locking vault that has to be frequently serviced by a hauler. Continuous collection programs and events have relatively low compliance with the Guidelines due to rather simple administrative issues, such as storing longer than 90 days and not keeping a log. It is important to make the point that pharmacies are the only type of program that cannot meet the Guidelines with relative ease.

7. Section II, 3, Statewide Accessibility (page 14, 15, 16): the attempt to compare accessibility across the various types of collection programs results is misleading. For example, while law enforcement may be open 24 hours/day, it is irrational to treat each open hour (e.g. 12 noon vs. 12 midnight) as equally convenient. Furthermore, law enforcement in several jurisdictions, including the City and County of San Francisco and the City of Oakland, cannot expend the resources, nor is it a priority for them, to serve as residential pharmaceutical waste collection sites.

   In addition, the analysis of accessibility should not be based solely on what is currently available, but should also consider the potential that each program type has to provide convenience for the public. Viewed from this perspective, pharmacy collection (due to the large number of them) and mail-in programs (if envelopes are easy to obtain) are likely to be far more convenient than law enforcement collection.

   Furthermore, public expectation is another critical factor left out of consideration in evaluating accessibility/convenience in this background paper. In San Francisco, for example, 9 out of 10 residents contacting the local waste and water agencies or local waste hauler are referred to these entities from a pharmacist. This implies a strong correlation between pharmacies and convenience to the public, given that this is the first place residents turn to for pharmaceutical disposal and information.

8. Section II, 3, Cost Effectiveness (page 17): we suggest separately showing the cost for the model programs and the typical cost charged by haulers. We believe that the few pharmacies that meet the Guidelines will be the ones with a very high disposal cost per pound, since disposal costs almost always drops as the waste volume increases.

9. Section II, 3, Cost Effectiveness (page 17): the packaging analysis included in this section is incorrect; many programs' costs would decrease if packaging was removed since many programs are charged on container size or price per pound. Packaging takes up a significant amount of space in collection bins and also adds weight. We suggest that this analysis be removed, and a sentence added stating that costs would decrease if packaging was removed.

10. Section II, 3, Cost Effectiveness, Figure 12 (page 17): the cost of the mail-back program is grossly incorrect. We do not believe that the cost for mail-back programs can be calculated using the same method applied to the other program types, and thus recommend deleting this cost figure. There are numerous reasons why this calculation does not make sense. We'll include an explanation of the primary one: while it's acknowledged in the text of this section that the envelopes are paid for in advance and that the cost per pound in this background paper is based on return rates ranging from 18-38% (from the three mail-back programs surveyed), there is no footnote in Figure 12 referencing this critical, result-skewing factor. Regardless, to show the cost of the mail-back program based on a snapshot in time – without considering when, or even if, the envelopes were actually distributed to users at the time of data collection – is not a valid approach. If CalRecycle staff insist on calculating the cost per pound using this method, to be fair and accurate, cost data should be included based on a range of return rates, including a 100% return rate. Otherwise, the results are not meaningful.
11. Section II, 3, Cost Effectiveness**,** Figure 13 (page 17): by attempting to correct costs by removing packaging, the cost estimates inflates program costs by creating an unrealistic scenario. Simply explained, if any program were to remove packaging in their collection process, their capacity would double and thus their disposal costs would be halved – not doubled as is concluded in Figure 13; therefore, we suggest deleting Figure 13 or correcting the analysis.
12. Section II, 3, Efficacy, Numerical Results (page 19): it appears that a broad comparison is being made between the various types of collection programs. The analysis fails to compare the actual amounts collected in the different areas. For example, data from pharmacy collection programs, where pharmaceuticals are collected at variety of locations, should not be compared to one police department's results. The summary of collection rates should be compared by monthly averages not daily and it would be even more effective to look at collection rates by County. We suggest presenting the data in Figure 15 so that it analyzes the quantity collected by geographic area and by month rather than by day. We also suggest removing Figure 16 and removing the "corrected for packaging" columns of Figure 18, because the correction for packaging is incorrect, as we discussed above in point 12.
13. Section II, 3, Summary Ranking (page 22): the relative ranking summary is confusing to the reader and does not add value since the report attempts to compare very different program types; therefore, we suggest deleting Figures 19, 20 and 21, and instead describe the conclusions in a narrative form.
14. Section III, 1, Safe Collection, Two-Key Locking Collection Bins: as mentioned previously, many of the programs were running safe and effective disposal sites before the Guidelines were created. Legislation may remove some of the barriers, created by the Board of Pharmacy interpretation of the laws. Many pharmacies do not want the vault system because it takes up too much retail floor space; others have complained the vault only holds a 5-gallon container compared to their current 18-gallon bins. The expense would cause many pharmacy programs to close down, as mentioned previously.

In summary, we applaud CalRecycle staff for their exhaustive efforts to develop this background paper. However, in its current form, we believe this document may lead to confusion, resulting in a lack of action by the legislature and ultimately sabotaging the intent of SB 966 to develop convenient, sustainable, cost-effective solutions for residential pharmaceutical waste disposal in California. Local governments, currently taking responsibility for this waste stream, strongly support the option to implement product stewardship; unfortunately, the background paper is presented in such a way that provides the pharmaceutical product chain with ammunition against the extended producer responsibility solution, since the cost of most of the model program options, pharmacies in particular, are extremely expensive.

If you have any questions regarding these comments, please contact me at (650) 494-7629 or karin.north@cityofpaloalto.org or Melody LaBella with Central Contra Costa Sanitary District at 925-229-7370 or mlabella@centralsan.org.

Regards,

Karin North, City of Palo Alto
BAPPG Pharmaceutical Committee Chair

Attachment

Model Program – City of Santa Rosa comments

The City of Santa Rosa, which operates the Subregional Wastewater Treatment Plant for Santa Rosa, Rohnert Park, Cotati and Sebastopol, has partnered with 14 local pharmacies to reduce the amount of pharmaceuticals that enter local waterways. The program began in February 2008, and to date, we have diverted 11,350 lbs of unwanted, expired, or unused pharmaceutical waste from landfills or local sewers.

The City uses Asepsis BioGroup as our medical waste hauler and the current program consists of medical waste collection bins being stored behind the counter at the pharmacies. The size of containers range from 3 – 18 gallons.

A survey was sent to all of the pharmacies in August 2010 (attachment 1), and the response from the survey has shown that all pharmacies are happy with the current program and want to continue partnering with the City and not one single respondent wants a "dual lock collection bin" in the lobby of their pharmacy. Concerns from the pharmacists included; fear that customers would use the collection bin as a trash can, lack of space in the lobby and overall desire to control the disposal (i.e. make sure pills are removed from their containers and that items being disposed of are allowable).

The City's Safe Medicine Disposal Program has recently lost two take-back locations, both Safeway Pharmacies, because our existing program does not follow the guidelines of the Model Program. These pharmacies had collected a total of 602 lbs of pharmaceuticals during their participation time. There are a total of 4 Safeway Pharmacies within the County of Sonoma that are no longer take-back locations.

Presently, the City estimates that hauling costs for 2010 are projected to be **$22,601.14**. Additionally, we included the projected increase in hauling costs necessary to adhere to the Model Program. If the Model Program were to be implemented the estimated cost for 2010 would be **$34,439.60**, an annual increase of **$11,838.46** (attachment 2). In addition, the City would also have to incur a one-time fee of **$13,387.64 to** purchase the double-locked chute containers (attachment 2). The estimated costs do not take into account the fact that under the Model Program there will most likely be an increase in disposal of pill bottles and containers. Currently, the City requires that the customer remove the pills from their containers prior to disposal, the pharmacists are diligent in enforcing this requirement. Once given the liberty to dispose of the medication themselves, via drop chute collection bins in the pharmacy lobby, it is projected that many of these customers will simply dispose of the pills/medications in their original bottles or containers, resulting in an increase in volume, pick-up frequency, and disposal costs. Please note that none of these costs reflect the additional 7 pharmacies that have collection take-back locations within the County of Sonoma.

Attachment 1

Survey for Safe Medicine Disposal Program participating pharmacies

Pharmacy:_____ Name of Pharmacy Staff:_____

Size of medicine collection container(s) at your pharmacy:_____

	YES	NO
1. Are you happy with the Safe Medicine Disposal Program?	⬭	⬭
Comments:		
2. Are there any improvements that you would like to see made to the program?	⬭	⬭
Comments:		
3. Are you happy with the service we have to pick up your collection bins when full?	⬭	⬭
Comments:		
4. If we stayed with the "on-call" pick-ups does your pharmacy prefer to call the Waste Hauler directly versus calling our staff for a pick-up?	⬭	⬭
Comments:		
5. Would your pharmacy be in favor of a locked collection container located in the pharmacy lobby? Customers would drop off medications without needing pharmacy staff.	⬭	⬭
Comments:		
6. Do you prefer that the collection bins stay behind the pharmacy counter?	⬭	⬭
Comments:		
7. Would your pharmacy be interested in having a sharps collection container?	⬭	⬭
Comments:		
8. Is your staff sufficiently well informed about the Safe Medicine Disposal Program?	⬭	⬭
Comments:		
9. Would you appreciate printed material about the program that could help inform your staff?	⬭	⬭
Comments:		
10. Do customers mention how they found out about the Safe Medicine Disposal Program?	⬭	⬭
Comments:		
11. Do your customers have any comments or questions about the program?	⬭	⬭
Comments:		
12. Would you appreciate printed material about the program that you could give away to customers?	⬭	⬭
Comments:		

Please return via fax by Wednesday **8/4/2010**
Fax: (707) 543-3398
Phone: (707) 543-3369

Attachment 2

Month	Gal/month 2010	Cost to date 2010	Pounds/month	Current Cost/lb	gallons converted to number of 5-gallon pick-ups	Proposed new cost	proposed cost/lb
January	82	$1,098.00	217.80	$5.04	16.4	$1,213.60	$5.57
February	113	$1,250.00	323.80	$3.86	22.6	$1,672.40	$5.16
March	237	$2,292.00	607.30	$3.77	47.4	$3,507.60	$5.78
April	179	$1,596.00	401.40	$3.98	35.8	$2,649.20	$6.60
May	153	$1,482.00	472.60	$3.14	30.6	$2,264.40	$4.79
June	259	$2,626.00	819.30	$3.21	51.8	$3,833.20	$4.68
July	334	$2,840.00	877.30	$3.24	66.8	$4,943.20	$5.63
total	**334**	**$13,184.00**	**3,719.50**	**26.23**		**$20,083.60**	
average	**194**	**$1,883.43**	**531.36**	**$3.75**		**$2,869.09**	**$5.46**
August (e)	194	$1,883.43	472.60	$3.99	38.8	$2,871.20	$6.08
September (e)	194	$1,883.43	472.60	$3.99	38.8	$2,871.20	$6.08
October (e)	194	$1,883.43	472.60	$3.99	38.8	$2,871.20	$6.08
November (e)	194	$1,883.43	472.60	$3.99	38.8	$2,871.20	$6.08
December (e)	194	$1,883.43	472.60	$3.99	38.8	$2,871.20	$6.08
Total (e)	**2327**	**$22,601.14**	**6082.50**	**$46.16**		**$34,439.60**	
Average (e)	**194**	**$1,883.43**	**506.88**	**$3.85**		**$2,869.97**	**$5.72**

(e) = estimated

Changes to hauling cost under "Model Program"	
percentage increase total cost	66%
dollar increase (projected for the year)	$11,838.46
increase in overall cost/lb hauled	$1.87

Dvault Unit Cost (includes tax & shipping)*	Number of Units Needed	Total Cost
$956.26	14	$13,387.64

*Price per unit does not include installation of units in store and cost for branding