



Recommendations on the Safe Collection, Transport, and Disposal of Controlled Substances

Product Stewardship Institute

January 11, 2011

The Product Stewardship Institute's Regulations Workgroup has convened for the purpose of developing options to resolve regulatory barriers that prevent clear and consistent messaging on drug disposal and hinder the sustainable collection and disposal of waste pharmaceuticals from residential and other similar sources. This multi-stakeholder group provides the following recommendations related to the development of new regulations under the Secure and Responsible Drug Disposal Act of 2010. Related issues, outside the scope of the Act, remain to be addressed. These include reducing the quantity of pharmaceutical drugs that become waste and securing sustainable funding for drug take-back programs.

We support the purpose of the Secure and Responsible Drug Disposal Act of 2010 to "allow patients to deliver unused pharmaceutical controlled substances to appropriate entities for disposal in a safe and effective manner consistent with effective controls against diversion." Effective drug take-back¹ programs encourage the public to get rid of their unwanted medications and ensure secure collection, transportation, and destruction.

Considerations for Secure Drug Disposal: Drug Take-back Programs

New regulations under the Secure and Responsible Drug Disposal Act of 2010, within the framework of the Controlled Substances Act, must make multiple collection and disposal options available to those designing and implementing drug take-back programs.

Capturing the largest possible quantity of leftover medications requires that convenient, secure collection opportunities are available when drugs are discarded due to a change of treatment or patient status. Diversity in the patient and caretaker population, as well as the multiplicity of settings, requires multiple collection options. Today's drug take-back programs are also managed by different agencies or coalitions at the local and state level. These groups may prefer different types of programs due to factors such as cost; convenience; rural vs. urban settings; and the willingness and capacity of key players such as pharmacies, clinics, or municipal facilities to participate in collection.

We believe that with government oversight and adherence to security procedures, the following options for collection, transport, and destruction of unwanted pharmaceuticals will be secure. All three options allow for tracking of packages from the point of mailing or drop-off through destruction, and should be implemented according to state

¹ This term refers to a growing number of programs around the country that collect and destroy unwanted medications from patients (including mail-back from individual homes, ongoing collections at one or more consolidation points, and collection events). For an example of on-going programs, please see: www.takebacknetwork.com.

and local environmental laws. Law enforcement agencies should have the option of implementing drug take-back programs according to their local priorities (under option “c,” below), but the regulations should not require their participation in the collection, transport, or destruction of collected drugs.

- a) **Mail-back from the home.** Pilot programs around the country, most notably in Maine, provide the opportunity for patients to mail their unwanted drugs in non-descript envelopes. Envelopes should be tamper-resistant and tamper-evident. Track and trace technology should be used through to the point of destruction.
- b) **Collection at retail pharmacies.** Not all pharmacies may choose to collect unwanted pharmaceuticals. However, many pharmacies are well-placed to provide this service in their communities if they are able to adhere to strict security procedures and have been approved by the appropriate regulating authority. We believe security protocols, such as those developed in Washington and California, provide a valuable starting point for the Drug Enforcement Administration’s consideration of security protocols applicable to collection in a pharmacy setting (where pharmacies are allowed to do so under state law).
- c) **Collection at other community facilities (including both on-going collection and collection events).** The same security procedures applied to pharmacies could be implemented in other community locations. Fire stations, clinics, and hospitals could provide a collection service under the same types of procedures. The same procedures should be applied for a one-day collection event as for an on-going collection. Law enforcement offices currently collecting pharmaceuticals could continue to do so under their existing procedures, or apply the new protocols that will be used by other types of collection sites.

Collection efforts should be able to accommodate all pharmaceutical drugs (both controlled substances and other drugs). New regulations should not preclude take-back programs from including both controlled and non-controlled drugs. The general public is not able to distinguish between these categories, and it is likely most efficient to collect all types of drugs together under the same security protocols.

Considerations for Secure Drug Disposal: Drug Take-back Programs *and* Long-term Care Facilities

New regulations should include options for long-term care facilities to dispose of drugs securely without flushing them. The following comments apply to the development of regulations applicable to both drug take-back programs (serving the public) and long-term care facilities.

- **Drugs shipped via common carrier for the purpose of disposal should be tracked throughout the process using track and trace technology.** Track and trace technology that has been developed to ensure the security of valuable materials via common carrier should be used whenever drugs are shipped for disposal, whether from an individual’s home or from a long-term care facility or collection point.
- **The DEA-mandated processes and procedures for drug take-back programs and long-term care facilities should be clear and consistent throughout the country.** State and local requirements may vary, but it is important that DEA requirements be communicated clearly and consistently around the country to reduce confusion. We recommend that the regulations and corresponding guidance for complying with the regulations be posted on the DEA’s website and disseminated via the regional offices.
- **Drugs collected for disposal should not have to be inventoried.** Some take-back programs may choose to inventory drugs they collect in order to better understand the types of drugs that end up as waste (to inform waste reduction efforts) or to characterize the benefits they provide (such as the environmental benefits of capturing antibiotics or endocrine disruptors, or the safety benefits of capturing narcotics that are commonly abused). However, inventorying of drugs collected for the purpose of disposal should *not* be required. Inventorying drugs adds to the cost of drug take-back programs, and, unless conducted under certain conditions, could create opportunities for diversion due to the additional handling of the collected substances.

- **New regulations developed under an amended Controlled Substances Act should be developed in consultation with the Environmental Protection Agency (EPA). No statute related to drug disposal should preempt state and local governments' right to apply more stringent requirements regarding the ultimate disposal of collected pharmaceuticals.** Environmental concerns are one factor driving the growth in drug take-back efforts across the country. State and local governments implementing drug take-back programs should be able to design programs that adhere to the strictest possible environmental standards for the ultimate disposal of collected pharmaceuticals applicable in their own jurisdiction. The DEA should consult with the EPA to ensure the regulations are consistent with the goals and requirements of the Federal Clean Water Act, Resource Conservation and Recovery Act, and Solid Waste Disposal Act. These federal statutes allow state and local governments to impose more stringent requirements as they choose.

Endorsements

The following agencies, organizations, and companies have indicated their support for these comments by endorsing this document.

[names of agencies, organizations, and companies will be added here]



BAY AREA POLLUTION PREVENTION GROUP

A Committee of Bay Area Clean Water Agencies

January 12, 2011

Submitted electronically

Drug Enforcement Administration
Attention: DEA Federal Register Representative
ODL, 8701 Morrisette Drive
Springfield, VA 22152

Re: Docket No. DEA-316

To Whom It May Concern:

The Bay Area Pollution Prevention Group appreciates the opportunity to submit the following comments on the Procedures for the Surrender of Unwanted Controlled Substances by Ultimate Users, Docket No. DEA-316. 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. Due to the growing body of evidence that indicates the flushing of unwanted medicines threatens public health and the environment, coupled with growing public demand for convenient, secure and environmentally-sound disposal options, BAPPG member agencies have been providing residents with an environmentally-benign solution to the disposal of unwanted medications.

In 2006, the BAPPG spearheaded the first DEA-approved "Safe Medicine Disposal Days," which won the EPA's 2007 Environmental Award for Outstanding Achievement. Since 2006, BAPPG members have worked with the DEA, the Environmental Protection Agency, United States Postal Service and reverse distributors to develop a more cost effective way to dispose of all medications including controlled substances. Currently, there are over 100 permanent collection sites for unwanted pharmaceuticals in the Bay Area; unfortunately, many of these locations are unable to accept controlled substances. Therefore, we support the purpose of the Secure and Responsible Drug Disposal Act of 2010 to "allow patients to deliver unused pharmaceutical controlled substances to appropriate entities for disposal in a safe and effective manner consistent with effective controls against diversion." Effective drug take-back programs encourage the public to dispose of all unwanted medications and ensure secure collection, transportation and destruction.

Safe Disposal Options for Unwanted Controlled Substances

Capturing the largest possible quantity of leftover medications requires that convenient, secure collection opportunities are available. Diversity in the patient and caretaker population, as well as the multiplicity of settings necessitates the availability of multiple collection options. Current drug take-back programs in the Bay Area are managed by different agencies or coalitions. These groups may prefer different types of programs due to factors such as cost; convenience; rural vs. urban settings and the availability, ability, and willingness of key players such as pharmacies, clinics or municipal facilities to participate in collection.

We believe that with government oversight and adherence to security procedures, the following options for collection, transport and destruction of unwanted pharmaceuticals will be secure. All three options allow for tracking of packages from the point of mailing or drop-off through destruction, and should be implemented according to state and local environmental laws. Law enforcement agencies should have the option of implementing drug take-back programs according to their local priorities, but the regulations should not require their participation in the collection, transport or destruction of collected drugs.

1. **Collection at retail pharmacies.** Not all pharmacies may choose to collect unwanted pharmaceuticals. However, those willing and able to do so according to strict security procedures are well-placed in many communities to provide a convenient drop off location. We believe security protocols, such as those developed in Washington; provide a valuable starting point for the DEA's consideration of security protocols applicable to collection in a pharmacy setting. Some of the key security protocols are listed below:
 - All drugs should be handled together, whether controlled or not, to reduce costs as well as to reduce diversion. Comingled drugs are not as attractive as controlled substances alone.
 - Professional pharmacists must be licensed and their facilities must be inspected by State Boards of Pharmacy.
 - Inventory will not be sorted beyond representative sampling for data collection purposes. This will help ensure that no diversion occurs since comingled drugs are not as attractive as controlled substances alone.
 - Containers in the public area of the pharmacy will be locked to ensure that no member of the public can access disposed material.
2. **Mail-back from the home.** Pilot programs around the country, most notably in Maine, provide the opportunity for patients to mail their unwanted drugs in non-descript envelopes. Envelopes should be tamper-resistant and tamper-evident. Track and trace technology should be used through to the point of destruction.
3. **Collection at other community facilities (including both on-going collection and collection events).** The same security procedures applied to pharmacies could be implemented in other community locations. Many law enforcement offices currently collecting pharmaceuticals could continue to do so under these procedures. Fire stations, clinics and hospitals could provide a collection service under the same types of procedures. The same procedures should be applied for a one-day collection event as for an on-going collection.

Obstacles to the Disposal of Controlled Substances

Obstacles to the disposal of controlled substances in the San Francisco Bay Area could occur if the following options are not approved: (1) transportation and disposal options (2) flexible collection options and (3) collection of controlled substances along with all other medicines.

1. Transportation and Disposal.

Options for disposal of controlled substances by medicine take-back programs would be improved and facilitated by authorization of additional providers of pharmaceutical transport and disposal services. The new regulations need to:

- a. Provide for environmentally-sound disposal options – according to California’s Medical Waste Management Act, medical waste incinerators are the only disposal option for waste pharmaceuticals, BAPPG suggests that residential pharmaceuticals should be handled as medical r.
- b. Create a new license specifically for the disposal of unwanted household medications so that DEA-licensed Hazardous Waste Disposal Companies, DEA-licensed Reverse Distributors and commercial carriers (UPS, Federal Express, etc.) can legally transport and dispose of medicines collected in a medicine return program.
- c. Allow authorized medicine take-back programs to turn collected medicines over to DEA-registered disposal companies who can dispose of the medicines as hazardous waste.
- d. Allow for cost-effective witnessed destruction procedures at the incinerator.
- e. Allow for options in choosing a shipping company, if utilized, such as the U.S. Postal Service or common carriers such as Federal Express and UPS.

2. Flexible Collection Options. Medicine return programs need flexible options for disposal that enable them to secure the most cost-effective and safest disposal methods for their communities. These options were mentioned in page 2 of our letter (in the safe disposal options section). The Bay Area has a wide variety of communities and one size will not fit all the needs locally or throughout the nation.

3. Combined Collection and Disposal of Controlled Substances with Other Medicines. For a medicine take-back to be cost-effective and convenient for consumers, all medicines, including controlled substances, need to be collected together at the same locations. They should not have separate tracking or routes of disposal. It is not reasonable to expect residents to distinguish between medicines that are controlled and non-controlled substances. Relying on a pharmacist to sort the controlled from the non-controlled increases the demands on the pharmacist’s time and increases the costs of the collection program. If the medicines are all collected together and then sorted afterwards, this also increases costs. Controlled substances need to be collected along with non-controlled medicines and destroyed together at the same disposal facilities, without sorting or segregation at any stage.

Considerations for Secure Drug Disposal at Long-term Care Facilities

New regulations should include options for long-term care facilities to dispose of drugs securely without flushing them. The following comments apply to the development of regulations applicable long-term care facilities.

- **Drugs shipped via general carrier for the purpose of disposal should be tracked through using track and trace technology.** Track and trace technology that has been

developed to ensure the security of valuable materials via general carrier should be used whenever drugs are shipped for disposal, whether from an individual's home or from a long-term care facility or collection point.

- **The DEA-mandated processes and procedures for drug take-back programs and long-term care facilities should be clear and consistent throughout the country.** State and local requirements may vary, but it is important that DEA requirements be communicated clearly and consistently around the country to reduce confusion. We recommend that the regulations and corresponding guidance for complying with the regulations be posted on the DEA's website and disseminated via the regional offices.

BAPPG member agencies have worked for the better part of a decade to remove the current barriers that limit the safe collection and disposal of all unwanted pharmaceuticals. In the future, we hope that pharmaceutical manufacturers will lead the effort on collecting and disposing of unwanted medications, as they do in many other countries such as Canada, Europe and Australia. Currently, pharmaceutical manufacturers use the Controlled Substances Act requirements as a barrier to collect and manage the pharmaceuticals that they profit from.

Thank you for the opportunity to comment on Procedures for the Surrender of Unwanted Controlled Substances by Ultimate Users. If you have any questions, please feel free to contact, Karin North at Karin.north@cityofpaloalto.org or (650) 494-7659 or Jennifer Jackson at jacksonj@ebmud.com or (510) 287-0818.

Sincerely,



Sharon Newton, Chair
Bay Area Pollution Prevention Group

Mary Pitto

From: hhwie@yahoogroups.com on behalf of Lucy, Burke [burke.lucy@calrecycle.ca.gov]
Sent: Thursday, December 09, 2010 10:55 AM
To: 'hhwie@yahoogroups.com'
Subject: [hhwie] What S3397 means to your pharmaceutical collection program

Hi all,

I was asked to share how S.3397, the national Secure and Responsible Drug Disposal Act of 2010, might affect existing pharmaceutical waste collection programs. The key statement in the text of S.3397 (<http://thomas.loc.gov/cgi-bin/query/D?c111:6:./temp/~c111CXw7aH:>) is this:

This Act gives the Attorney General authority to promulgate new regulations, within the framework of the Controlled Substances Act, that will allow patients to deliver unused pharmaceutical controlled substances to appropriate entities for disposal in a safe and effective manner consistent with effective controls against diversion.

It goes on to specifically mention long-term care facilities and any person lawfully entitled to dispose of a decedent's property. Otherwise, there's no mention of promulgating new regulations for these substances in pharmacies, hospitals, or any other entities. It does say, "Such regulations may not require any entity to establish or operate a delivery or disposal program."

We are expecting to see an announcement next week in the Federal Register about a DEA public meeting on the rulemaking slated for January 19-20 in Washington D.C. This comment and rulemaking period can take a year or two, if not longer. So, at this point, there's no direct impact on existing collection programs except that you might expect more options for collecting controlled substances in a couple years if the comments encourage that approach and if the DEA/Attorney General agrees.

As always, I'm happy to support any sharps or pharmaceutical waste collection efforts, so please don't hesitate to contact me at any time. Also, starting tomorrow my phone number will change from 916.324-6848 to 916.341.6592.

Mr. Burke Lucy

Integrated Waste Management Specialist

Department of Resources Recycling and Recovery (CalRecycle)

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916.341.6592 (recently changed)

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