



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]