Local Hazardous Waste Management Program

Serving Seattle, King County, and Suburban/Other Cities in King County

King County
Solid Waste Division

King County
Water and Land
Resources Division

Public Health –
Seattle and
King County

Seattle
Public Utilities

Participating Cities:
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Beaux Arts Village
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Normandy Park
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Tukwila
Woodinville
Yarrow Point

February 14, 2013

Drug Enforcement Administration
Attention: DEA Office of Diversion Control (OD/DX)
8701 Morrissette Drive
Springfield, Virginia 22152

RE: Docket No. DEA-316, Disposal of Controlled Substances

Dear Mr. Partridge,

The Local Hazardous Waste Management Program in King County (LHWMP) is a regional partnership comprised of local government agencies, including Public Health – Seattle & King County, King County Water and Land Resources Division, King County Solid Waste Division, Seattle Public Utilities, and the 37 suburban cities of King County, Washington. We congratulate DEA on a comprehensive and historic proposed rule on the safe and secure disposal of unwanted controlled substances, and welcome this opportunity to provide comments.

LHWMP works to reduce exposures to hazardous substances and promote proper management of hazardous wastes from households and small quantity business sources. We are a partner in Take Back Your Meds (www.takebackyourmeds.org), a group of health organizations, police, pharmacies, local governments, environmental groups, and others in Washington State who support creation of secure, convenient medicine return programs for unwanted medicines from households. Medicine take-back programs reduce access to highly-addictive drugs, reduce the risk of poisonings, and reduce environmental contamination.

Enclosed are LHWMP comments on the DEA proposed rules published in the Federal Register, Volume 77, Number 246, on December 21, 2012. A few key summary comments follow:

-- The collection options DEA proposes (events, drop-boxes and mail-back envelopes) should allow sufficient flexibility for a robust take-back system for unused meds.

-- We are especially supportive of allowance for retail pharmacies to serve as hosts for collection receptacles (drop-boxes) – this is the method we have piloted here in Washington state for non-controlled substance medicines and have demonstrated protocols that have worked securely and without incident over many years.

-- Allowing co-mingling of the collected drugs (controlled substances in with non-controlled) without needing to inventory every pill will greatly support efficiency of operations and minimize diversion. Having the flexibility for co-mingling increases collection options.

-- A "non-retrievable" destruction standard, in compliance with all federal, state and local laws and regulations, allows flexibility while preventing non-secure options. DEA's statement that neither flushing nor solid waste disposal meets the non-retrievable standard is very appropriate and supportive of state and local government regulations and guidances for proper disposal of waste medicines.

-- We are supportive of the proposed rule while providing some specific comments for refinement in the attached enclosure. We encourage DEA to make the rule final as soon as possible. DEA should consider the various detailed comments it will be receiving as quickly as possible and issue a refined, final rule soon so local collection programs can integrate these new collection options to expand upon existing methods.

If you have any questions regarding LHWMP comments, contact Dave Galvin at 206-263-3085, or send a message through electronic mail to dave.galvin@kingcounty.gov .

Sincerely,

Stella Chao
Chair, Management Coordination Committee for LHWMP
Public Health - Seattle & King County

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enclosure

Comments from the Local Hazardous Waste Management Program in King County, Washington
Re: DEA's Proposed Rule for the Disposal of Controlled Substances
DEA Docket No. DEA-316
14 February 2013

The Local Hazardous Waste Management Program in King County, Washington (LHWMP) provides the following comments to the Drug Enforcement Administration (DEA) regarding DEA's proposed rule, *Disposal of Controlled Substances,* and responds to specific questions asked by DEA. LHWMP is a regional partnership comprised of local government agencies, including Public Health – Seattle & King County, King County Water and Land Resources Division, King County Solid Waste Division, Seattle Public Utilities, and the 37 suburban and other cities of King County, Washington. LHWMP has promoted safe and secure take-back of unused medicines for years and has helped to demonstrate the need as well as workable options for local collection of unused medicines.

General Comments

We are very supportive of the proposed regulations ("the rule") in general. We commend DEA for listening to the comments, suggestions and experience represented at the public meeting held in Washington, D.C. on January 19-20, 2011 following passage of the Secure and Responsible Drug Disposal Act of 2010. Many programs around the country have developed pilot projects to test methods for safely and securely collecting unused medicines, and many learnings from these programs appear to be incorporated into the proposed rule.

Support collection by authorized retail pharmacies and other authorized collectors: We believe that the rule offers sufficient breadth of new collectors, in addition to the continuing option for participation by law enforcement agencies, to allow for robust take-back systems for unused or otherwise left-over medicines. Coupled with the flexibility offered in many sections of the rule, we believe that DEA has developed a workable framework for the disposal of controlled substance medicines in addition to non-controlled drugs.

In particular, we support the use of retail pharmacies as collectors as an essential element of an effective take-back system, for controlled substances from ultimate users as well as for non-controlled medicines. Retail pharmacies are the most logical and convenient place for residents to bring their leftover medicines. In Washington state we have demonstrated that secure drop boxes in pharmacies are not only a viable but also a popular, well-used option by ultimate users. Detailed security and tracking protocols have been working well that mirror those proposed in the rule. Secure collection receptacles using metal, locked outer containers with a baffled opening and a removable inner container were developed through our pilot studies and have been working well in retail pharmacies for a number of years.

Authorization of other registrants as collectors – manufacturers, drug distributors, and reverse distributors – is significant and will help to build robust medicine disposal networks. It is appropriate that all these entities involved in production and distribution of medicines can be authorized collectors and should be involved in take-back systems.

Support multiple collection methods: Allowing ongoing collection by law enforcement agencies at their offices also serves to extend the network of collection sites. In addition, take-back events run by law enforcement are a good, proven method to supplement the ongoing network of retail pharmacies and law enforcement offices. A mail-back option through authorized collectors serves to expand potential services and could prove especially helpful in rural areas, and for the elderly or others with limited mobility. The rule's mix of options for disposal of controlled substance medicines is a significant improvement over current restrictions.

Support comingling of controlled drugs with other leftover medicines: We also strongly support the proposed allowance for controlled substance and non-controlled substance medicines to be co-mingled when collected. Consumers cannot discern the different between Schedule II-IV drugs and other medicines. Co-mingling will allow for significant volumes of all left-over drugs to be safely and securely collected. We support no required inventory of the collected medicines as a means to streamline the disposal process and ensure security to address diversion concerns. We comment below on the proposed rule's complete prohibition of inventorying, even for research purposes.

Support authorizing others to dispose of a decedent's unused medicines: Extending the disposal authorization for an unused controlled substance beyond ultimate users to persons lawfully entitled to dispose of an ultimate user decedent's property makes complete sense. This provision reflects the reality of many home-hospice and other end-of-life situations where the use of significant amounts of controlled substances is often required.

Support non-retrievable destruction standard: A standard requiring destruction rendering the controlled substance non-retrievable allows for flexibility in specific technology to be used now and in the future. Insisting that destruction must comply with all federal, tribal, state and local laws is important to ensure public safety as well as environmental protection. We appreciate and support the clarification that "flushing and mixing controlled substances with coffee grounds or kitty litter [i.e., trash disposal]… do not meet the non-retrievable standard." [*Federal Register* 77 (246): 75803]

These are a few of our favorite provisions in the proposed rule. We offer comments and questions below on specific issues. We want to emphasize, however, that we believe DEA has proposed a flexible set of regulations that offer a significant improvement over current restrictions regarding disposal of controlled substances. Some existing medicine take-back programs will likely have to adjust their procedures to fully comply with these rules in order to accept controlled substances along with non-controlled medicines. Some adjustments are inevitable. We believe the benefits of working within the structure outlined in the proposed rule far outweigh the challenges needed to modify existing practices.

We urge that refinements of details that we and other stakeholders identify do not prevent, nor significantly delay, adoption of a final rule. The final rule is needed as soon as possible so that procedures for collection of left-over controlled substance medicines can finally integrate with, rather than hinder, the development of robust collection networks for all unused medicines around the country. We support secure, effective medicine take-back programs as a critical part of a comprehensive strategy to reduce the epidemic of poisonings and overdoses from misuse and illicit use of medicines, and to reduce pharmaceutical pollution through proper disposal of unneeded medicines.

Specific Comments

Collectors

As noted above, we are supportive of the list of registrants eligible to be collectors: manufacturers, distributors, reverse distributors and retail pharmacies. In particular we want to emphasize the importance of retail pharmacies as collectors – these registrants are most directly connected with ultimate users and are the most logical place for ultimate users to bring back any unused medicines. People regularly stop by their nearest retail pharmacy; people do not regularly visit their nearest police or sheriff's office. We have demonstrated safe and secure take-back programs that work at retail pharmacies. The more than 60,000 potential pharmacy collection locations in the U.S. will serve as the base for a robust take-back system for all unused medicines, including controlled substances.

- **Process for designation as authorized collector**. The proposed rule states in 1301.51 that a registrant needs to request a modification of its existing registration to be designated as a collector; a limited description of the process for approval of such requests is provided. Presumably DEA will establish a procedure where registrants who wish to be collectors will provide information for DEA's review. We strongly encourage the DEA to establish a straight-forward process that can be accomplished within a short time frame to ensure that as many collectors as possible can be authorized to provide services to their communities. We are pleased that no additional fee will be required for the modification to become a collector.

- **Non-registrants cannot serve as collectors.** Many entities around the country have been involved in recent years in trying to address the problem of medicine disposal. Outside of law enforcement, many local governments have accepted left-over non-controlled substance medicines at household hazardous waste ("HHW") collection services or other facilities. The new rule includes a subset of existing DEA registrants as the only eligible entities to serve as collectors. We are supportive of this approach, but recognize that many of the existing, non-registrant drug take-back services will wish to continue to collect non-controlled substances. It would be useful for DEA to comment in its final rule about whether such continued collection of non-controlled substance medicines with careful signage and education about accepted medicines will be allowed. Please clarify whether collection of non-controlled substance medicines is within DEA's purview.

Collection by Law Enforcement Agencies

We support continued voluntary involvement by law enforcement agencies in unused medicine disposal to protect public safety, and agree with provisions in the rule to allow law enforcement agencies to run take-back events (together with community partners), mail-back services and collection receptacles at their police or sheriff offices.

- **Law enforcement officer restrictions.** We believe that the requirements that only full-time government employees with authority to carry a firearm, make arrests and serve warrants [1317.02(a)] can accept controlled substances at take-back events or mail-back services are too

restrictive. Civilian law enforcement employees who meet the same requirements as authorized employees of other collectors, such as retail pharmacies, should be allowed to handle returned materials following the agencies' secure protocols similar to their evidence room practices. As noted in the proposed rule, it is not DEA's intent to change established law enforcement agencies' procedures for handling, storage and transfer of controlled substances.

- **Officer restrictions not required for collection receptacles at law enforcement offices.** We note that the officer restriction is not included in 1317.75 for collection receptacles hosted by law enforcement agencies. We support this provision of the rule, and suggest that similar procedures and allowances can be made for handling mail-back packets and take-back events to ensure security while allowing more flexibility within the law enforcement environment.

Take-back Events

We support provisions in the rule that require law enforcement oversight of take-back events that accept controlled substance medicines. Community partners can assist with all aspects of such events except the physical handling and custody of the disposed drugs.

- As noted above, we urge more flexibility regarding the law enforcement employees authorized to maintain control and custody of controlled substances turned in by ultimate users.

Mail-back

A provision to allow mail-back services by either law enforcement agencies or collectors able to destroy the packets on-site will help to expand options for medicine disposal, and facilitate service to specific populations with more limited access to collection locations or events. Many partners can help to sponsor and distribute the pre-paid packages as part of a robust system.

- As noted above, we urge more flexibility regarding the law enforcement employees authorized to maintain control and custody of controlled substances turned in by ultimate users.

- As noted in more detail below, we support allowing all Reverse Distributors to be able to accept mail-back packages, not only those few with on-site destruction capabilities.

Collection Receptacles

We agree that substantially-constructed, locking outer containers ("shells") with removable inner liners can function safely and securely as drop-boxes for the disposal of controlled substance and non-controlled substance medicines. Since 2006, Washington retail pharmacies have demonstrated safe use of such receptacles for disposal of non-controlled substance medicines while following protocols sufficiently strict to meet safety and security considerations for controlled substances.

- **Uniform symbol?** On page 75796 of *Federal Register* 77(246), DEA seeks comment on the value and utility of requiring that a specific, uniform symbol be placed on each collection receptacle. We don't think this is essential as long as receptacles are clearly marked and labeled as to what is acceptable and what is not. A uniform symbol might help to promote proper medicine

disposal systems, so we are not opposed to the idea, but don't think it is necessary for such systems to function.

- **Signage**. DEA proposed signage on collection receptacles "indicating that only non-controlled drugs and Schedule II, III, IV, or V are acceptable" [*Federal Register 77*(246): 75796 and 75816]. Signs intended for the general public need to be in plain English, such as "only prescription or over-the-counter medicines are accepted" or "legal drugs only". Ultimate users cannot identify controlled substances from the prescription container label, nor can they identify which Schedule would apply to the medicine. Employees at the site need to know and understand the acceptance criteria as described by DEA, such as through training and written procedures.

- **Consistent terms for receptacles.** In the proposed rule, DEA sometimes refers to the outer part of the collection receptacle as a "container," and other times as a "shell." We suggest that it would be helpful to change the sentences as follows, to be consistent with the description of the outer shell used in 1317.75(e)(3)(i)
  - (ii) "The outer ~~container~~ shell shall include a small opening that allows contents…"
  - (iii) "The outer ~~container~~ shell shall prominently display a sign…"
  - "The outer ~~container~~ shell shall…"

Long-Term Care Facilities

It is important for DEA to address safe and secure disposal of controlled substance medicines from Long-Term Care Facilities ("LTCFs") because significant amounts of controlled substances and other medications are commonly used in such settings. We applaud DEA's proposal to allow retail pharmacy registrant collectors to voluntarily operate collection receptacles at LTCFs.

- **More delineation of LTCFs allowed to use the rule is needed.** Long-term care facilities include a wide range of institutions, from large nursing homes with skilled nursing professionals that function similarly to hospitals, large assisted living facilities with limited skilled nursing care that function similarly to residences, to small family-homes and other small assisted-living facilities without skilled nursing care. Residents may receive hospice services at any of these LTCFs. There is much variety state-by-state as to how these LTCFs are regulated.

  It would be helpful for DEA to clarify which types of LTCFs are allowed to be served by the proposed rule. Variations in state regulatory environments should be factored into protocols to implement LTCF disposal systems. For example, in Washington state, "adult family homes" are long-term care facilities licensed for no more than six residents. The scale of the adult family home is too small for a receptacle managed by a retail pharmacy. Mail-back service could be more appropriate. We generally agree with the implied intent of DEA's explanation on page 75787 that describes these LTCFs as facilities where the controlled substances and other medicines are owned by the ultimate user resident, as this situation has presented a significant dilemma for safe and legal disposal of leftover drugs. However, LTCFs may be reluctant to hand over controlled substances to family members because of the potential for mismanagement or abuse. More options are needed to address this important, complex LTCF environment.

- **Flushing/sewering does not meet non-retrievable standard**. Without options such as the proposed collection receptacles operated by retail pharmacy collectors, many LTCFs currently

dispose of unused medicines down the drain; a practice we view as harmful. In the narrative portion of the *Federal Register* notice, DEA makes clear that neither flushing nor municipal solid waste disposal meet the "non-retrievable" destruction standard [*Federal Register 77* (246): 75803]. DEA should make this clear in the rule itself so as to close out those inappropriate disposal options for LTCFs uniformly across the country.

- **Hazardous waste regulations at LTCFs**. Currently, the Environmental Protection Agency (EPA) does not apply the household hazardous waste exemption to nursing homes (i.e., skilled nursing care facilities), but would apply it to other types of LTCF such as assisted living or boarding homes. When a nursing home has hazardous waste pharmaceuticals and/or controlled substances, existing EPA regulations would apply to on-site collection, transportation to a retail pharmacy, and transportation from the retail pharmacy to the disposal facility. In these situations, EPA regulations could entail hazardous waste permits and duplicate recordkeeping systems, making the disposal process more complicated.

  In 2013, EPA is developing a new proposal to establish appropriate standards for the management and disposal of hazardous waste pharmaceuticals generated by healthcare facilities. We encourage ongoing collaboration between DEA and EPA to address the specific dilemma of disposal of waste pharmaceuticals from nursing homes. We hope that EPA's new proposal (a continuation of the Universal Waste Program) can assure environmentally safe disposal while allowing DEA's secure transportation and tracking systems as an alternative to standard hazardous waste requirements. For more information see: http://www.epa.gov/wastes/hazard/generation/pharmaceuticals.htm

Handling of Collected Medicines and Inner Liners

We support provisions in the rule for safe and secure handling of the medicines collected by take-back events, mail-back packets or collection receptacles.

- **Comingling of controlled substance medicines with non-controlled medicines for all collection methods.** As mentioned above, we strongly support the proposed allowance for controlled substance and non-controlled substance medicines to be collected together. This is a key provision to allow medicine take-back programs to be convenient for consumers and cost effective for operators by avoiding unnecessary staff effort to identify and separate medicines. Ultimate users cannot discern from the label whether or not a medicine is a controlled substance; an expert is required to identify them.

- **No allowance for inventorying or research studies on returned medicines.** We support provisions in the rule that prohibit inventorying of the medicines collected for destruction. This will help to streamline handling procedures while ensuring security from diversion. However, we strongly recommend that DEA include an exception provision in the rule to allow for carefully-regulated studies to characterize and quantify the medicines returned through statistically-valid sampling of returned medicines. Using the same type of authorizations allowed for research on Schedule I controlled substances, safe and secure protocols can be developed to allow research studies on the kinds and quantities of medicines disposed – providing important data for prescribers, health care systems and environmental interests.

- **Visual pre-screening of disposed materials.** While the rule is appropriately silent on this issue, we mention this issue to promote best practice protocols that require visual pre-screening of materials disposed in collection receptacles or at take-back events. Visual pre-screening can be done by retail pharmacy staff or law enforcement agencies without the need to physically handle the materials from ultimate users that are dropped in collection receptacles or received at take-back events. Best practice protocols for mail-back programs should require clear instructions and educational materials on accepted medicines and excluded materials. Such best practice protocols will serve to prevent inadvertent contamination of the medicines collected with problematic materials such as mercury-containing fever thermometers, iodine-containing drugs, medicine-delivery devices and trash not appropriate for destruction with collected medicines. Such best, proactive protocols are essential for the unopened mail-back packets and inner liners to be transported and received for destruction at hazardous waste incinerators, and other incinerators depending on applicable regulations and state or local permits.

- **Loose pills vs. packaging.** While the rule is appropriately silent on this issue, we want to promote best practice protocols that allow ultimate users to remove pills from the container, whenever feasible and appropriate, prior to disposal. Liquids, creams, powders or other problematic medicine forms must remain in their packaging. Some programs wish to encourage separation and recycling of plastic packaging and, by doing so, minimize the weight and volume of collected medicines and minimize the burning of these plastics during destruction of medicines via high-temperature incineration. Provisions can be made to ensure compliance with HIPAA as part of recycling of prescription medicine packaging.

- **Streamline recordkeeping of inner liners.** Several recordkeeping requirements defined in 1317.50 are not necessary for a collector to adequately track collected medicines. We request that the following requirements be eliminated: tracking unused inner liners on hand, the date acquired, the date of installation and two witnesses of installed empty liners.

- **Storage of collected medicines as Schedule II.** The requirement to store wastes in a vault approved for Schedule II controlled substances is excessive. None of our retail pharmacy partners or distributors have sufficient space in their Schedule II areas to store the anticipated volume of collected medicines. It would be inappropriate to store wastes in the same vault used to store product. Collected medicines will be comingled, but existing storage areas for Schedule II are sized based on the volume of product, a small percentage of the total prescription and over-the-counter medicines sold. We encourage DEA to consider reasonable alternative storage methods that provide adequate security.

- **Storage of inner liners by retail pharmacy collectors.** Clarification is needed on how sealed inner liners may be stored by retail pharmacies prior to pick-up by a distributor/reverse distributor or shipment via common carrier to a distributor/reverse distributor. We recommend allowing retail pharmacies to transfer the trackable, sealed inner liner to the companies' secure warehouse facilities prior to pick-up or shipment.

- **Definition of common and contract carriers.** The rule refers to transport via "common or contract carriers" [1317.05(a)(2), 1317.05(b)(2), 1317.05(c)(2)(iii) and 1317.05(c)(2)(iv)], but it is not clear what this terminology refers to. We believe that this provision allows shipment via

U.S. Postal Service, UPS, DHS, FedEx and other appropriate carriers that utilize tracking systems. A clear reference to U.S. Department of Transportation definitions (or other) in section 1317.02 would be helpful.

- **Two persons to transport inner liners.** Transporters (carriers) normally have one person in the vehicle. Adding another person in the vehicle is a major change to the industry and doubles the labor cost. Transporting controlled substance medicines for distribution (product) does not require two people. We feel that waste management should not be held to a higher standard than drug distribution (product management).

Role of Reverse Distributors and Distributors

It makes sense for distributors and reverse distributors to play active roles as collectors for the safe disposal of controlled substance medicines.

- **Destruction timing (1).** On page 75802 of *Federal Register* 77(246), DEA invites comments on the practicability of implementing the ‘‘as soon as practicable but no later than fourteen calendar days’’ requirement while also maintaining effective controls against diversion. We support a reasonable destruction time that fits with standard practices at reverse distributors and hazardous waste incinerators, and look to those businesses to best comment on this issue.

- **Destruction timing (2).** The start date of the “fourteen days or less” standard is unclear in the proposed rule. Does this refer to pick-up date or date of receipt at a central reverse distributor’s facility? We support the DEA’s desire to keep wastes moving through the system into final disposal in order to prevent diversion or other problems, consistent with standard business practices. However, there are some challenges for reverse distributors that we are aware of. For example, wastes collected in Washington state need to be transported long distances because disposal sites such as hazardous waste incinerators are not located nearby. (The nearest hazardous waste incinerator is in Utah.) Clarification of the intent of this part of the rule would be helpful.

- **Mail-back packages.** Reverse distributors have adequate security and expertise to receive mail-back packages, even if they do not have an on-site method of destruction. Currently, incineration is a common method of destruction. With few appropriate incinerators in our region, we need the flexibility to use the capabilities of reverse distributors to consolidate small amounts into shipments to incinerators. Please revise 1317.40(c)(1) so that all reverse distributors may register as collectors and receive mail-back packages.

Destruction

We support DEA’s adoption of a “non-retrievable” standard of destruction of collected medicines to protect public health and safety. We concur with, and fully support, DEA’s position that “flushing and mixing controlled substances with coffee grounds or kitty litter [i.e., trash disposal]… do not meet the non-retrievable standard” [*Federal Register* 77 (246): 75803]. The clear intent of the Secure and Responsible Drug Disposal Act of 2010 is 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”, as well as reduce “introduction of some potentially harmful substances into the environment” (these quotes are from the “findings” of the legislation S. 3397 enacted in 2010).

- **Non-Retrievable standard (1).** On page 75803 and in Section 1317.90 of *Federal Register* 77 (246), DEA solicits comments on the proposed requirement that all destruction processes be applied in such a manner that all controlled substances are rendered "non-retrievable." The "non-retrievable" standard is essential for both goals of the Disposal Act as noted above. Collected medicines must be fully degraded by the destruction method to prevent their misuse or diversion as pharmaceutical agents, and to prevent the potential for harm to people or the environment as chemical agents. Defining the "non-retrievable" standard while not specifying a specific destruction method is the best approach in a challenging regulatory landscape for disposal of pharmaceutical wastes. This approach also allows flexibility for the use of new disposal technologies in the future that meet the "non-retrievable" standard and provide the same or enhanced environmental protection over incineration or chemical degradation.

- **Non-Retrievable standard (2).** Requiring that the method of destruction must comply with all federal, tribal, state and local laws ensures public safety as well as environmental protection. This is essential and should be retained in the final rule.

- **Non-retrievable standard (3).** Some medicines designate as RCRA hazardous wastes and many additional medicines designate as state-regulated hazardous wastes (such as in Washington state). As a result, we support proper destruction of all co-mingled waste medicines as hazardous wastes. We support the destruction of all collected medicines using methods that do not result in their disposal via flushing or municipal solid waste landfills.

- **Non-retrievable standard (4).** Various commercial entities are entering the market promising destruction via acid solutions or other "black-box" proprietary technologies. We need to guard against "easy" commercial systems that result in problematic wastes for wastewater treatment or solid waste management systems. More guidance on this issue would be helpful in the rule.

- **On-site methods.** Certain collectors are authorized to destruct controlled substance medicines via "on-site disposal." It is unclear what methods this reference refers to. We support on-site destruction via hazardous waste incineration, but we do not support various acid or other proprietary systems that could result in hazardous or other dangerous chemicals being eligible for sewering or municipal solid waste disposal. To the extent that DEA can refine its rule regarding ultimate disposal of the destructed medicines, it would support local environmental concerns and compliance with state and local environmental regulations.

- **Collaborate with EPA.** Each disposal facility permitted by EPA and state authorities has requirements to assure the safety of their operations. Destruction facilities may need to inspect inner liners to assure that the materials inside match the description and contain no unacceptable materials. We request that DEA collaborate with EPA, in a process that does not delay issuance of a final rule, to better understand these requirements and determine whether the requirement to never open sealed packages (e.g., mail-back packages or inner liners) is acceptable at destruction facilities. A reasonable approach that meets DEA's security goals as well as EPA's requirements under the Resource Conservation and Recovery Act is needed.

Economic Analysis and Information Requirements

The proposed rule for the destruction of controlled substance medicines establishes requirements for how a collection and destruction system can be set up and run, but it does not require any person to participate in such a system, as collector, law enforcement or ultimate user.

- **Economic impact.** On page 75805 of *Federal Register* 77 (246), DEA conservatively estimates that the voluntary provisions for collectors, reverse distributors, distributors, and law enforcement agencies will have a net economic impact of nearly zero, and invites comment on this estimate. We agree that the regulations as proposed do not require anyone to undertake medicine disposal activities and therefore the economic impact of the rule itself is negligible.

  However, we must point out the key challenge faced in implementation of the rule and any medicine disposal system: at the moment there is no substantial or sustainable source of funding for such systems. The costs of pilot, temporary medicine take-back approaches have been borne by local governments, law enforcement, individual pharmacies, and other stakeholders, severely limiting their scope and effectiveness. Dedicated funding through a product stewardship approach is our clear preference, with the well-crafted framework described in the proposed DEA rule funded and overseen by those companies that make and sell the medicines. We realize that financing was not considered in the Secure and Responsible Drug Disposal Act of 2010, nor in these regulations, but resolution of this issue is key to development of the robust collection and destruction systems needed for all unused medicines in this country.

- **Information Collection.** On page 75807 of *Federal Register* 77 (246), DEA solicits comments concerning the necessity, quality, utility, and clarity of the information proposed to be collected by participants in a controlled substance disposal system. The limited amount of information and tracking called for in the rule seems reasonable to us, but we defer to registrant businesses and law enforcement agencies who would potentially be involved in implementation of the proposed rule to comment on the burden imposed. We support simple data requirements that allow for efficient as well as secure medicine disposal programs.