February 19, 2013

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

[Submitted online at:  www.regulations.gov]

RE:   DEA Docket No. DEA-316; Disposal of Controlled Substances; Notice of Proposed
Rulemaking

Dear Sir/Madam:

The American Pharmacists Association (APhA) appreciates the opportunity to provide feedback to the Drug Enforcement Administration (DEA) on its proposed rule on disposal of controlled substances by DEA registrations and ultimate users (i.e. patients) which outlines proposed steps to implement the Secure and Responsible Drug Disposal Act of 2010.

APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 62,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings and the uniformed services.

We appreciate DEA’s efforts to improve options to better facilitate the safe and secure disposal of controlled substances comiled with other medications. Such efforts will help to remove unused, unwanted, or expired medications that could be accessible for potential misuse, abuse, diversion and/or accidental ingestion.

APhA supports allowing the public to have access to secure medication disposal options but we do have concerns with the potential costs and logistics to implement the proposal. Our comments build on our previous disposal comments to DEA in March 2009 and at the January 2011 public meeting. We recommend DEA consider the following areas in which further clarification, guidance and revision would be helpful.

Take-Back Program Collection Receptacles: We support DEA’s option for voluntary participation in take-back programs in which the pharmacy could register as a collector to maintain a collection receptacle at the pharmacy. We anticipate that pharmacies already participating in take-back programs for non-controlled substances and additional other locations may be interesting in expanding their role in medication disposal. We expect that pharmacy participation would generally be in partnership with a third-party wholesaler or reversed distributor registered as a collector who
would have capacity to pick-up, transport and destroy the disposed medication collected at the pharmacy. APhA also supports that such receptacles are intended to comingle medications (controlled and non-controlled) and inventory would not be required. However, we do recommend DEA clarify how regulations would be reconciled with existing programs that do allow counting and inventory of collected medication for purposes of research or information gathering in collaboration with local law enforcement and academic institutions.

Related to receptacle inner liners, we are concerned with the proposed requirement for two authorized pharmacy employees to perform or supervise the removal of the liner and the logistics to store filled liners as Schedule II medications until collection by the partnering wholesaler/reverse distributor for transport. Such requirements impact pharmacy staffing, cost/space to store disposed medication, and overall logistics to comply with regulations. We are also concerned about the potential logistics for retail pharmacies to manage receptacles located at long-term care facilities (LTCFs) in which a retail pharmacy chooses to manage and be responsible for a receptacle(s). Proposed requirement may limit interest in retail pharmacy participation as a partner with LTCFs due to administrative challenges and pharmacy staff time that would be required to manage off-site locations, such as requiring two authorized pharmacy staff to perform/verify removal. If two-person verification remains in the final rule, we recommend DEA consider allowing authorized health professional staff at the LTCF to be one of the two authorized staff. We also recommend DEA clarify if the pharmacy’s partnering entity for disposal transport/destruction (wholesaler/reverse distributor) would be eligible to collect receptacles at LTCFs. In addition, we recommend DEA clarify if a LTCF that participates in an existing medication disposal process (that complies with both state and federal requirements) would be required to stop such a process or if there is a reconciliation process to continue existing activities.

Furthermore, we are concerned that pharmacies may have limited interest to voluntarily participate as a collector due to administration and logistical concerns to comply with the DEA disposal regulation regarding pharmacy collection receptacles. To provide additional information, we recommend DEA:

- Clarify tracking requirements/expectations for the pharmacy collector and/or other partner collectors who would be transporting the liner (wholesaler/reverse distributor).
- Clarify expectations of collection receptacles being “securely fastened” to a permanent structure in the location (i.e. wall, floor, immovable countertop), if there would be any flexibility in using something similar to certain existing receptacles that are one unit with the liner (for example, the unit makes inventory irretrievable and are tamper-evident), and expectations of location within the pharmacy. We recommend DEA consider more flexible options for installing/providing secure receptacles as physical permanent fixtures may be disruptive to current floor space and design within pharmacy settings.
- Provide additional guidance on a collector’s liability if a receptacle is “securely fastened” but physical security is compromised and contents may be subject to diversion. We are concerned that without clear understanding of what if any potential liability issues may be involved related to participating/compliance with the regulations that there may be limited participation by pharmacies.
  - For example, we appreciate that the proposal is focused on products legally obtained and applicable for disposal and that receptacle liners and mail-back packages are not to be opened or inventoried. However, we are concerned about potential pharmacy liability given the array of products that could be placed into a receptacle and may not be medications obtained legally as outlined in the proposal. In general, pharmacy staff would not know what is being placed into the secured receptacle, if it was legally obtained, if the individual is the ultimate user, or if the individual is “lawfully entitled”
to dispose of a decedent’s property. Trying to track or manage such information, continued uncertainties to comply, and other potential cost issues may create implementation challenges, limit voluntary pharmacy participation, and could limit public options for disposal of medications.

- We further request DEA ensure strict penalties are in place or are increased for those found guilty of pharmacy burglary/robbery crimes and attempts to tamper with, steal and/or divert collection receptacles and contents of such receptacles.

**Mail-back Programs:** APhA supports options for voluntary participation in mail-back programs in which envelopes/packages would be available to the public at a pharmacy or other registered location. We appreciate that DEA outlined that the package content does not need to be inventoried, controlled substances can be comingled with non-controlled medications, and postage-paid envelopes/packages could be provided free of charge or for a fee. Again, we anticipate that participating pharmacies would generally partner with a third-party registered DEA collector who would be responsible for receiving and destroying the mailed package.

We are concerned with the proposed provision to have individual tracking identification numbers on each mailer and the unnecessary administrative work that may be required for such tracking. As outlined, it is unclear who is responsible for tracking the packages – the pharmacy or other registered location providing the mail-back package and/or the entity receiving the mailed package. And, it is unclear what would happen if the sequence of mailers dispensed does not match the sequence received at the entity/location managing the program – especially since once the mailer leaves the pharmacy it becomes the responsibility of the individual and there is no guarantee that the package would be mailed. If identifiers on mailers continue to be required, we recommend DEA clarify who is responsible for tracking requirements.

**Existing Pharmacy Work with Wholesalers and Reverse Distributors:** We appreciate that the proposed regulation outlined DEA expectation that a pharmacy would generally work with a partnering wholesaler/reverse distributor on disposal programs. However, we request that DEA recognize that such partnerships on disposal programs should not impact or complicate existing business relationships between pharmacies, wholesalers/reverse distributors, and manufacturers related to general management of pharmacy inventory to receive credit for returned, expired or unused inventory that has remained within the security of the pharmaceutical supply chain (registrant-to-registrant transfers) and not dispensed to patients.

**Education and Awareness:** We recommend DEA provide additional information on potential communication plans to educate the public and increase awareness of final regulations to improve options for the public to dispose of medication. Education and awareness activities will be critical to get information to: DEA registrants such as pharmacies and wholesalers/reverse distributors about participation options; the public about improved/expanded disposal options and ways to identify participating locations (such as pharmacies and law enforcement sites); and to the public about ongoing local law enforcement managed take-back days/events. APhA offers to work with DEA and other pharmacy stakeholders on potential outreach activities and communications to pharmacy and the public.

**Coordination of Federal Efforts to Address Drug Abuse:** We continue to support efforts by the White House Office of National Drug Control Policy (ONDCP) to increase coordination between various federal agencies on activities, requirements, and recommendations related to disposal of
medications as part of overall efforts to address prescription drug abuse, misuse and diversion. We encourage DEA to continue in such collaborative efforts as disposal is an important component of the key ONDCP focus areas that also include efforts related to education, prescription drug monitoring programs, and enforcement. In addition, we continue to support FDA’s efforts to clarify disposal/flush requirements outlined in the labeling for certain controlled substances.

Other Federal Regulations: We recommend that DEA consider potential implementation and compliance issues related to overlapping federal and state requirements regarding the collection, disposal, transport, and destruction of medications for different segments of the pharmaceutical supply chain. We are concerned that complying with DEA’s proposed regulations may impact compliance and navigation of other requirements and/or efforts related to medication disposal, specifically: Department of Transportation, Environmental Protection Agency, Fish and Wildlife Service (FWS), Food and Drug Administration, Occupational Safety and Health Administration, and ONDCP.

Support for Existing Programs: We encourage DEA to recognize successes of existing programs that continue to encourage disposal of medications through household trash. For example, APhA is part of a public and private partnership, the SMARxT Disposal program, with the FWS and the Pharmaceutical Research and Manufacturers of America to provide consumers with better options for medication disposal, to raise consumer awareness about disposal options, and provide environmentally friendly means to dispose of medications (for examples, tips to crush or mix unused medications with ingredients to make them unusable prior to disposing in the trash). We are also aware of other local, state and organization efforts that have been successful in improving medication disposal options for the public that may be impacted by DEA’s regulation.

Finally, we support DEA’s overall efforts to implement disposal regulations but encourage DEA to consider the concerns APhA outlined related to: implementation and management of take-back receptacles and mail-back programs, potential liability issues, cost issues, impact on existing disposal programs and pharmacy processes, and navigation of federal and state requirements related to medication disposal/transport/destruction. Again, we raise these issues because they may unfortunately limit interest in voluntary participation in take-back or mail-back programs. APhA offers our willingness to participate in further discussions with DEA and other pharmacy stakeholders to address such concerns so that revisions can be made in final regulations that ease actual and/or perceived burden to participate and answer questions as to how the programs will really work.

Thank you for the opportunity to provide comments on this important issue. If you have any questions or require additional information, please contact Marcie Bough, PharmD, Senior Director of Government Affairs, at mbough@aphanet.org or by phone at (202) 429-7538.

Sincerely,

Thomas E. Menighan, BSPharm, MBA, ScD (Hon), FAPhA
Executive Vice President and CEO

cc: Marcie Bough, PharmD, Senior Director, Government Affairs