



American Society of
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March 23, 2009

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

Re: Docket No. DEA-316, Disposal of Controlled Substances by Persons Not Registered with the Drug Enforcement Administration, Advance Notice of Proposed Rulemaking

Dear Sir/Madam:

The American Society of Health-System Pharmacists (ASHP) is pleased to submit written comments pertaining to the Advance Notice of Proposed Rulemaking (notice) relating to the Disposal of Controlled Substances by Persons Not Registered with the Drug Enforcement Administration (DEA). As the national professional association representing over 35,000 pharmacists who practice in hospitals and health systems, ASHP can offer unique and vital feedback on this important health care issue. Pharmacists in hospitals and health systems are experts in medication use who serve on interdisciplinary patient-care teams. They work with physicians, nurses, and other health-care professionals to ensure that medicines are used safely, effectively, and in a cost-conscious manner.

Through this notice, DEA is seeking information to provide more accessible ways to safely and responsibly dispose of dispensed controlled substances in a manner consistent with the Controlled Substances Act (CSA). ASHP commends DEA for seeking options for the disposal of controlled substances dispensed to DEA non-registrants that protect public health and safety, minimize the possibility of diversion, are consistent with the CSA and DEA regulations, and provide a sound environmental solution. ASHP understands that DEA is limited by existing law when developing any regulation related to this issue, since the CSA and its implementing regulations do not currently contemplate a situation in which an ultimate user would return a controlled substance.

ASHP has long supported the safe handling of hazardous drugs that may present an acute or chronic hazard to patients and health care practitioners. This concern extends to the impact of pharmaceutical waste products on the environment. Pharmacists are the medication experts and, together with pharmacy technicians, these individuals play a

leading role in managing the proper disposal of pharmaceutical wastes, including controlled substances.

ASHP supports the development of policies and guidelines for health-system pharmacists designed to deter drug product theft and thereby enhance both the integrity of the drug distribution chain and the safety of the workplace. Further, ASHP encourages the development of systems that limit the diversion and abuse potential of medications, including controlled substances, and thereby reduce the likelihood that these products will be targets of theft.

All drug products entering the supply chain should be thoroughly inspected and tested to establish that they have not been adulterated or misbranded, and systems should be in place to ensure patients will not receive improperly labeled and packaged, deteriorated, outdated, counterfeit, or unapproved drug products.

Methods for safely disposing of controlled substances

There are several methods that are currently being utilized in the states for consumers to dispose of unused and expired medications. The National Association of Boards of Pharmacy Report of the Task Force on Medication Collection Programs (Task Force) has reviewed several medication collection programs, including community-based drop-off programs, mail-back programs, pharmacy drop-box programs, and an educational web site. In its report, the Task Force identified the challenges and advantages associated with each, and noted that while all of the programs were beneficial since they collected unused medications, there were still challenges, particularly regarding the collection of controlled substances.

(http://www.nabp.net/ftpfiles/NABP01/08TF_Med_Collection_Programs.pdf)

ASHP encourages DEA to examine these programs as solutions for safely and responsibly disposing of controlled substances, if adapted to comply with the CSA and DEA regulations.

For Pharmacies: Mail-Back Programs

In its notice, DEA asks whether pharmacies would be willing to make postage paid envelopes available to be used by the public to mail unwanted or outdated pharmaceuticals to a reverse distributor or law enforcement agency for disposal. Pharmacies likely would be willing to make the envelopes available, as long as the pharmacy did not incur costs associated with the program.

The Safe Medication Disposal Program for Maine (discussed in the Task Force Report) provides an example of this type of program. Through the Maine program, community pharmacies provide postage-paid envelopes to consumers, who place their unused medications into the envelope and mail the envelope to a centralized Maine Drug Enforcement Agency location. The medicine is then cataloged and destroyed. This

program has proven to be convenient for patients, less expensive than other statewide programs, and allows for data analysis of the returns. Additionally, if instituted in areas where there are fewer pharmacies and health care facilities, for example rural areas, this program would provide access to a disposal program that might not be available through a community-based drop-off program.

However, the envelopes provided are small, so there are limitations on the size and quantity of medications that consumers can return through the Maine program. Additionally, while the U.S. Postal system is secure, there is a lack of accountability for returns, since there is no receipt verification. These issues should be addressed if DEA decides to institute a mail-back program for controlled substances. Additionally, DEA should be aware that programs that do not require individuals to distinguish between controlled and non-controlled substances are preferable, since consumers often find it difficult to distinguish between the two, and medical staff also find it difficult to identify medications if they are returned without their packaging. Finally, to help prevent diversion, envelopes used for mail-back programs should be nondescript, so they are not easily identifiable as potentially containing controlled substances.

For Long Term Care Facilities

As DEA notes, when patients residing in long term care facilities (LTCF) require controlled substances, their practitioner issues a prescription which is usually dispensed by a registered pharmacy. The LTCF holds the prescribed drugs in a custodial manner for the patient, and dispenses the medications on the schedule the practitioner orders. When a patient dies, or leaves the facility, or their medication is discontinued or changed, the LTCF may be left with excess controlled substances that must be disposed of to avoid diversion. LTCFs that are not DEA registrants are not permitted to transfer the controlled substances back to the pharmacy, or to a reverse distributor for disposal.

In its notice, DEA asks what the best method is for LTCFs to dispose of controlled substances. ASHP recommends that DEA consider a system where a LTCF can ship controlled substances to a DEA registrant (for example, a reverse distributor) in a sealed container, using a manifest that would document the shipment, and also require the itemization of the drugs. While itemization could increase the burden on facilities, it would have a greater likelihood of preventing diversion. The manifest would be signed by the person preparing the shipment, and an additional witness. On the receiving end, the shipment would be documented as received and destroyed, and the LTC would receive a copy of the documentation.

ASHP encourages the promulgation of regulations to permit the disposal of controlled substances by ultimate users and LTCs. As DEA develops these regulations, ASHP encourages the agency to be aware that overly-burdensome recordkeeping and reporting requirements could deter entities from participating in programs. However, ASHP does understand that requirements must be stringent enough to prevent diversion and misuse of controlled substances.

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ASHP appreciates this opportunity to present its written comments on the notice. Feel free to contact me if you have any questions regarding our comments. I can be reached by telephone at 301-664-8702, or by e-mail at jcoffey@ashp.org.

Sincerely,

A handwritten signature in cursive script that reads "Justine Coffey".

Justine Coffey, JD, LLM

Director, Federal Regulatory Affairs