



NATIONAL ASSOCIATION OF  
CHAIN DRUG STORES

February 19, 2013

VIA ELECTRONIC SUBMISSION: [www.regulations.gov](http://www.regulations.gov)

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

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

Dear Sir/Madam:

The National Association of Chain Drug Stores (NACDS) thanks the Drug Enforcement Administration (DEA) for the opportunity to comment on DEA's proposed rule to govern the secure disposal of controlled substances by both DEA registrants and ultimate users.

NACDS previously commented to DEA on this subject, under the same docket number, in both March 2009 and January 2011. We are pleased to have the opportunity to engage in dialogue with DEA on this important topic.

NACDS represents traditional drug stores, supermarkets, and mass merchants with pharmacies – from regional chains with four stores to national companies. Chains operate more than 41,000 pharmacies and employ more than 3.8 million employees, including 132,000 pharmacists. They fill over 2.7 billion prescriptions annually, which is more than 72 percent of annual prescriptions in the United States. The total economic impact of all retail stores with pharmacies transcends their over \$1 trillion in annual sales. Every \$1 spent in these stores creates a ripple effect of \$1.81 in other industries, for a total economic impact of \$1.81 trillion, equal to 12 percent of GDP. For more information about NACDS, visit [www.NACDS.org](http://www.NACDS.org).

We share DEA's goal of working towards a safe and appropriate lawful means for consumers to return their unused medications to authorized entities for destruction. We appreciate that DEA has proposed three options for consumers to dispose unwanted controlled substances.

#### Mail-Back Programs

As we have commented to DEA in the past, we support providing consumers with the option to dispose unwanted controlled substances via mail-back programs. To be successful, such programs should be easy for consumers to understand and utilize. We support most of DEA's proposed requirements for mail-back programs. However, we question the need for DEA's proposed requirement for unique

identification numbers for mail-back packages. Once a consumer obtains an unused mail-back package, it will be outside the control of any regulation. It is likely that many mail-back packages will be lost or forgotten, never to be used. DEA should not consider mail-back packages not being returned to the collector as evidence of diversion. We believe that prospective collectors will be reluctant to engage in mail-back programs for fear of undue scrutiny for mail-back packages that were issued but never returned. Consequently, we believe requiring collectors to track identification numbers is an unnecessary burden, as doing so would serve no useful purpose.

Should DEA decide to retain the identification number requirement in the final rule, we request clarification that only the collectors that issue the mail-back packages are responsible for tracking identification numbers and no any other entity (or collector), such as a pharmacy, would be responsible for tracking identification numbers of packages provided to the public.

#### Collection Receptacles

We appreciate DEA's proposal to allow pharmacies voluntarily to maintain collection receptacles at their registered location or at authorized long term care facilities (LTCF). However, we have concerns that the proposed requirements are so burdensome as to discourage pharmacies from utilizing the collection receptacle option. Pharmacies should be encouraged to provide options for consumers to return their unused, unwanted medications. However, overly burdensome requirements with potentially severe penalties for unintentional noncompliance would only act to defeat the laudable goals of DEA's proposed rule.

First, we ask DEA to reconsider the need to have two authorized employees perform or supervise the removal of a receptacle's inner liner. This will serve to diminish a pharmacy's ability to provide collection receptacles, particularly in pharmacies where prescription volumes are low and there is often only one pharmacy employee on staff at a time. As potential alternatives, we ask DEA to consider allowing one authorized employee of the pharmacy perform or supervise the removal of the receptacle's inner liner, or one authorized employee of the pharmacy and one employee of the hazardous waste transporter. Moreover, with respect to LTCFs, pharmacies will be reluctant to send two authorized employees off-site just to remove and replace an inner liner. As potential alternatives, we ask DEA to consider allowing one authorized employee of the pharmacy perform or supervise the removal of the receptacle's inner liner, or one authorized employee of the pharmacy and one employee of the LTCF.

Second, we ask DEA to clarify expectations with respect to the requirement that a collection receptacle must be securely fastened to a permanent structure such as a wall, floor, or immovable countertop. Specifically, we ask DEA to provide guidance or examples of how the receptacle should be fastened. Similarly, we ask DEA to

advise on a pharmacy's liability should a receptacle become subject to diversion by someone that manages to overcome a receptacle's physical security. Pharmacies may be reluctant to provide collection receptacles if they face potential DEA fines and penalties for the actions of diverters outside of the pharmacy's control.

In the proposed rule, DEA seeks comment on the advisability of a "specific, uniform symbol" to indicate disposal receptacles. We are not aware of an appropriate symbol. We also question whether such a symbol to identify the receptacles would target the receptacles for diversion attempts.

#### Disposal by Another Person

In the proposed rule, DEA mentions persons that are lawfully entitled to dispose of a decedent's property. We ask DEA to clarify how DEA plans to enforce the requirement that a person is *lawfully entitled* to dispose of a decedent's property. In LTCFs, nurses should be able to dispose the remaining medications of a patient that has left the facility or has recently deceased. Also, we ask DEA to consider that one should not have to wait until death to dispose of another's unwanted controlled substances; for example, a nurse, family member, or other caregiver should be allowed to dispose the unwanted controlled substances of an individual that is infirm, homebound, or otherwise unable to do so.

#### Conflict with Other Laws and Regulations

Although we appreciate DEA's proposed rule, we have concerns that the collection receptacle provisions will conflict with myriad state and federal laws and regulations concerning pharmaceutical waste, hazardous waste, and the transport of such. We urge DEA to harmonize the proposed rules with the rules of other federal agencies including FDA, EPA, OSHA, and DOT, as well as with state requirements, to the extent possible.

Consumers may place almost anything into the collection receptacles. Commingled substances may react with each other, give off noxious fumes, and may pierce the tear-resistant inner liners. Pharmaceuticals and other chemicals can be toxic even if inhaled or absorbed through the skin. They may be carcinogenic or teratogenic. Environmental and employee safety hazards will have to be addressed.

We have concerns about storing the used inner liners, full of waste, alongside Schedule II medications. Doing so may violate the Food, Drug and Cosmetic Act, as well as state board of pharmacy regulations. It is possible that the inner liners will contain toxic and biologically hazardous substances, along with needles and other sharps. Cross contamination with prescription medications must be avoided. Storing these items in a safe or locked cabinet alongside prescription medications will be problematic and likely illegal.

We also see potential barriers with respect to environmental regulations. Authorized collectors may have to follow regulations affecting “waste generators,” including obtaining multiple licenses and permits to manage such waste. Entities that collect and transport used inner liners could be required to follow regulations affecting waste transporters.

It may be impossible for pharmacies to install and maintain collection receptacles in a manner that complies with federal and state regulations, and more importantly, in ways that protect consumers and employees from the potential hazards of substances deposited into the receptacles.

#### Clarification of Specific Rule Language

In the final rule, we ask DEA to clarify proposed rule language that we find to be unclear, as discussed below:

- §1301.51(a): Please clarify whether the term “retail pharmacies” includes institutional or closed-door pharmacies.
- §1317.50(b)(2)(iii): This section would require a registrant to record the DEA number of the collection location. However, LTCFs do not have DEA numbers. Please clarify a registrant’s requirements here.
- §1317.95: We ask DEA to clarify the language in this rule section. For example, under §1317.95(a), please clarify what is meant by “If the controlled substances are *transferred*... [emphasis added],” and how this is different from paragraph (b), in which controlled substances are “*transported* [emphasis added].” In addition, §1317.95(a) also states: “If the controlled substances are transferred to a person registered under the Act and authorized to accept the controlled substances for purposes of disposal, two authorized employees of the transferring registrant shall load and unload or observe the loading and unloading of any controlled substances until transfer is complete.” This seems to indicate that if a hazardous waste hauler is picking up a used inner liner from a pharmacy the hazardous waste hauler would need to have two employees pick it up and accompany it all the way back to the disposal facility. This would add considerable cost to the disposal process and likely discourage some haulers from offering the service.

Conclusion

NACDS appreciates the opportunity to present our views on these timely issues. We hope that we have been able to share with DEA helpful commentary as DEA finalizes the requirements for the disposal and destruction of controlled substances. In particular, we ask DEA to reconsider the overly burdensome proposed requirements for collection receptacles, and to clarify potential pharmacy penalties for unintentional noncompliance with the provisions of the proposed rule. Please feel free to contact me at [knicholson@nacds.org](mailto:knicholson@nacds.org) or 703-837-4183. Thank you for your consideration of our comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Kevin Nicholson". The signature is written in a cursive, flowing style.

Kevin N. Nicholson, R.Ph., J.D.  
Vice President  
Government Affairs and Public Policy