

OPPORTUNITIES FOR PHARMACIES AND LONG-TERM CARE FACILITIES IN THE NEW DEA PROPOSED RULE FOR CONTROLLED SUBSTANCE DISPOSAL, BUT WHAT ABOUT HOSPITALS?

OVERVIEW AND EXECUTIVE SUMMARY

On Friday, December 21, 2012, the Drug Enforcement Administration ("DEA") released an important proposed rule governing the secure disposal of unused controlled substances. This rule (the "Proposed Rule") was developed to implement provisions of the Secure and Responsible Drug Disposal Act of 2010 ("Disposal Act") and proposes a number of new options for the disposal of unused, expired or unwanted controlled substances in accordance with applicable Federal Controlled Substances Act standards. A copy of the Proposed Rule can be found [here](#).

As we discuss in greater detail below, the DEA makes clear that the Disposal Act and Proposed Rule are intended to facilitate the safe return and disposal of controlled substances to address increasing concerns regarding the diversion and abuse of unused controlled substances. In order to support this goal, the Proposed Rule proposes (among other changes) to:

1. Increase the number of controlled substance collection and disposal methods available to both ultimate users and DEA registrants, including manufacturers, retail pharmacies, distributors and reverse distributors;
2. Implement a new drug mail-back program;
3. Permit certain DEA registrants to place drug collection receptacles at specified locations, including long-term care facilities, which will facilitate the disposal of unused resident drugs. Notably, the Proposed Rule does *not* permit such collection points by hospitals;
4. Implement various security and audit standards related to the collection and destruction of unused controlled substances; and
5. Formalize standards related to community take-back events organized by law enforcement agencies and permit community partner participation in such events.

ANALYSIS AND DISCUSSION

To implement the changes noted above, as well as others, the DEA proposes to revise current regulations and to issue new regulations that would substantially alter controlled substance disposal options currently available to ultimate users, law enforcement agencies and DEA registrants. The Proposed Rule would also clarify terms and standards related to reverse distributors who are currently responsible for receiving controlled substances from DEA registrants for manufacturer returns or destruction. In this article, we discuss in greater detail key elements of the Proposed Rule.

Controlled Substance Collectors

First, the Proposed Rule would implement a controlled substance "collector" definition. This would broaden the scope of entities able to collect unused controlled substances, which is currently limited to law enforcement agencies and reverse distributors. A "collector" could be a manufacturer, distributor, reverse distributor or retail pharmacy registered with the DEA to receive controlled substances from a patient or other DEA registrant for ultimate destruction of the drug (each a "Collector"). This would be implemented through a modification to a DEA registrant's existing registration.

Notably, while retail pharmacies co-located with a hospital could be Collectors, hospitals are *not* included on the proposed list of eligible Collectors. The DEA states that most hospitals will have on-site retail pharmacies capable of performing collection activities; however, this is typically not the case for many rural hospitals, such as critical access hospitals and sole community hospitals. Hospitals may wish to request that the DEA permit them to perform certain drug collection activities.

It is also notable that retail pharmacies would be allowed to operate collection receptacles within long-term care facilities under the

Proposed Rule. This option would enable participating long-term care facilities to dispose of controlled substances on behalf of an ultimate user that resides, or has resided, in the facility via a collection receptacle maintained by a retail pharmacy. This would address a longstanding need for disposal of controlled substances in the long-term care setting.

The DEA proposes to permit Collectors to:

1. Receive mail-back packages from ultimate users if the Collector utilizes an on-site method of destruction;
2. Maintain collection receptacles at locations for which the registrant is authorized to collect under the provisions of the Proposed Rule; and
3. Promptly dispose of sealed collection receptacle liners and their contents.

These collection activities would be allowed to occur only at the registered locations of manufacturers, distributors, reverse distributors, retail pharmacies and long-term care facilities at which registered retail pharmacies maintain an authorized collection receptacle.

Packaging and Recordkeeping Standards

With respect to Collector delivery and disposal standards, the Proposed Rule details requirements regarding mail collection packaging,¹ collection site security measures and disposal timing. For example, any Collector or law enforcement agency conducting a mail-back program must provide specified mailing packages, either at no cost or for a fee, for controlled substance collection. Also, regarding recordkeeping standards, the Proposed Rule would require that Collectors implement mechanisms that would enable auditable inventory tracking of receptacle liners and mail-back packages.

Staffing Standards

The Proposed Rule requires that individual agents or employees used by Collectors with access to, or influence over, collected controlled substances must never have: 1) been convicted of any felony offense related to controlled substances; or 2) had an application for registration with DEA denied, had a DEA registration revoked or suspended, or surrendered a DEA registration for cause.

Anti-Kickback/CMP Considerations Related to Mail-Back Programs

We note that the DEA suggests that Collectors might utilize a mail-back program as an opportunity to market items and/or services. The Proposed Rule does not, however, address the Anti-Kickback statute or Civil Monetary Penalties Law implications of this activity with respect to potential inducement of beneficiaries. As such, interested parties may want to submit a related request for comment to the DEA and may also want to consider these issues before conducting any Collector activities.

Drug Destruction Requirements

The DEA proposes a requirement that Collectors destroy controlled substances so they are "non-retrievable." Generally, "non-retrievable" is defined as permanently altering the substance's physical and/or chemical state through irreversible means in order to render the substance unavailable and unusable for practical purposes. Examples of non-retrievable methods noted in the Proposed Rule include incineration and chemical digestion. The DEA does not consider flushing or mixing controlled substances with coffee grounds or kitty litter to be non-retrievable methods. Ultimately, the Proposed Rule does not detail specific destruction requirements given the variability of the involved chemical compounds and the need for flexibility to address various processing considerations.

Collection by Law Enforcement Agencies

Finally, regarding law enforcement agency collection of unused controlled substances, the provisions of the Proposed Rule would clearly permit these agencies to collect controlled substances by utilizing:

1. Take-back events;
2. Mail-back programs; and/or
3. Collection receptacles located at the agency's physical address.

The first option (take-back events) is an option that is currently available to certain authorized law enforcement agencies or as authorized by the DEA Special Agent in Charge of the applicable area. Going forward, these events would still be conducted only by law enforcement agencies, though the DEA does propose to permit private entities and community groups to "partner" with agencies to facilitate such events.

CONCLUSION/PRACTICAL TAKEAWAY

The Proposed Rule represents the culmination of substantial efforts to affect change in the management of unused controlled substances. Retail pharmacies and long-term care facilities may have new opportunities to safely dispose of controlled substances and to notify the public of these opportunities. To the extent entities wish to request that the DEA alter the proposed regulatory provisions, comments on the Proposed Rule must be submitted electronically or postmarked no later than February 19, 2013.

If you have any questions about pharmacy issues or the Proposed Rule, please contact Todd A. Nova at 414-721-0464 or tnova@hallrender.com, Susan D. Bizzell at 317-977-1453 or sbizzell@hallrender.com or your regular Hall Render attorney.

Special thanks to Alyssa James, Law Clerk, for her assistance with the preparation of this Health Law News article.

Please visit the Hall Render Blog at <http://blogs.hallrender.com/> for more information on topics related to health care law.

1 Among other requirements, packaging must be postage-paid, tamper-evident, tamper-resistant and uniquely identifiable. Furthermore, the contents of the liners and packages may not be opened, x-rayed, handled, inventoried or otherwise discerned.