New Options for Disposal of Controlled Substances

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Live UAN# 0175-0000-14-073-L03-P,T
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Learning assessment quiz and evaluation must be completed to receive credit for this activity.

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• Please type questions into the panel box at the right of your screen
• You may also “raise your hand” within GoToWebinar to ask a question

Disclosures

• No conflicts of interest to report
• PSW’s analysis of the Final Rule should not be considered a legal analysis. Individuals and organizations should review the final rule in its entirety prior to planning for a disposal program and prior to making policy changes.

Learning Objectives

• According to the new DEA Final Rule for the disposal of controlled substances, define "collector" and “ultimate user”
• Outline the process for DEA registrants to modify their registration to include collection of controlled substances
• Describe the role of law enforcement, pharmacies, hospitals/clinics, and long term care facilities in the collection of controlled substances for the purposes of disposal

Learning Objectives

• Outline requirements for the collection of controlled substances through take-back events, mail-back programs, and collection receptacles
• Discuss specific requirements for pharmacies, hospitals/clinics, and long term care facilities in the management of collection receptacles
• Describe opportunities and remaining challenges in the disposal of controlled substances
Audience Participation
• Which of the following best describes you
  A. I work in a long-term care facility
  B. I work in a hospital setting
  C. I work in a retail pharmacy setting
  D. I work in environmental policy

Audience Participation
• Why are you attending today’s webinar?
  A. I plan to participate in future take-back events
  B. I plan to place a receptacle in my facility
  C. I want to be a resource for patients
  D. I plan to change policies related to drug disposal in my facility

Disposal Opportunities
• Voluntary
• Patient service
• Enhanced efficiencies
• Process for long term care facilities
• Provides clarity?

Disposal Challenges
• No monies appropriated or allocated
• LTCF not clearly defined
• Implications for hospitals related to “destruction”
• “Employee” definition
• Vendors uncertain

The Issue
• Wisconsin Medication Statistics
  ▪ 120 Million Rx / 13 million pounds
  ▪ 4.4 Million pounds unused
  ▪ 95,500 lbs collected through disposal efforts
    • Permanent (44%), One day (53%), Mail back (3%)
• Public health and environmental statistics
  ▪ Risk of abuse and misuse, poisoning hazard, water pollution
  ▪ Pharmaceuticals and personal care products in WI’s wastewater and freshwater

Barriers to Success
• Barriers to Medication Disposal Efforts
  ▪ Awareness
  ▪ Lack of sustainable funding
  ▪ Inconvenience
  ▪ Regulation
  ▪ Limited capacity for storage and destruction
Drug Disposal: Multi-Level Policies

- Federal Legislation
  - Secure and Responsible Drug Disposal Act of 2010
- Federal Regulation
  - DEA Final Rule, Oct 9, 2014
- State Legislation
  - 2013 Act 198
- State Regulation
  - Department of Justice
  - DNR
  - DATCP
- Local Policy
  - Permanent Receptacles
- Practice Policy
  - Institutional handling
  - Pharmacists' role
  - Patient questions

Drug Disposal Act: Timeline

May, 2010: S.3397 Secure and Responsible Drug Disposal Act of 2010 introduced
October, 2010: Signed by President Obama
December, 2012: DEA publishes proposed rule
February, 2013: PSW submits comments
September, 2014: DEA publishes final rule
October 9, 2014: Rule Effective

2010 Drug Disposal Act

- Introduced by Senator Amy Klobuchar (D-MN)
  - 10 bipartisan cosponsors including Senators Feingold and Kohl
  - Amends Controlled Substance Act to allow, through regulatory changes, patients to deliver unused controlled substances to appropriate entities
  - Authorizes controlled substance disposal by long-term health care facilities

Definitions

- Ultimate user: a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or a member of his household
- Collection: receipt of a controlled substance for the purpose of destruction
- Retail pharmacy: includes any entity registered with DEA as a retail pharmacy vs. those registered as hospital/clinic. Closed door pharmacies, long term care pharmacies, specialty pharmacies are likely registered with DEA as a “retail pharmacy”
- Onsite: located on or at the physical premises of the registrant’s registered location

Definitions

- Reverse distributor: person registered to acquire controlled substances from another registrant or law enforcement for the purpose of return or destruction
- Non-retrievable: standard for destruction which alters a substance so that it cannot be transformed to a physical or chemical condition or state as a controlled substance or controlled substance analogue
  - Renders the substance as unavailable and unusable
  - Most common: incineration
Definitions

- **Employee:** DEA considers the following when determining if a person is an “employee” of a registrant:
  - Direct payment by registrant
  - Direct oversight by registrant
  - Required to follow registrant’s procedures and guidelines pertaining to handling controlled substances
  - Receive performance rating/evaluation regularly from registrant
  - Subject to disciplinary action by registrant
  - Render services at registrant’s location

Law Enforcement

- **Voluntary**
- **Conduct take-back events**
- **Administer mail-back programs**
- **Maintain collection receptacles**
- **Most programs may continue unchanged**

Assessment Question

An authorized “collector” of controlled substances may include:

- A. Reverse distributor
- B. Hospital/Clinic with an onsite pharmacy
- C. Retail pharmacy
- D. All of the above

Assessment Question

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Collectors

- Registration required to become an authorized collector
  - Manufacturers
  - Distributors
  - Reverse distributors
  - Narcotic treatment programs
  - Hospitals/Clincs with an onsite pharmacy
  - Retail pharmacies
- Collectors may receive controlled substances from:
  - Ultimate users
  - Individuals lawfully entitled to dispose of deceased person’s controlled substances
  - Long Term Care Facilities on behalf of residents who reside or resided at the LTCF with a receptacle

Registering as a Collector

- Requires specification of which method(s) of collection will be used
- Portal for current DEA registrants to expand their registration as a collector of controlled substances
  - [https://www.deadiversion.usdoj.gov/disposal/spring/login](https://www.deadiversion.usdoj.gov/disposal/spring/login)
  - No fee required
- Must keep the information updated to reflect current collection role
Collection Receptacles

- Registered collectors authorized to maintain receptacles at their registered location
  - Cannot include community centers, schools, churches
  - Unique requirements for narcotic treatment programs, hospitals/clinics with an onsite pharmacy, receptacles maintained by authorized collectors in long term care facilities
  - Only ultimate users and persons lawfully entitled may deposit controlled substances
  - Once a substance has been deposited into a collection receptacle, the substance shall not be counted, sorted, inventoried, or otherwise individually handled
  - DEA registrants cannot use the collection receptacles to dispose of unused controlled substance inventory or stock

Collection Receptacle Requirements

- Securely maintained inside the collector’s registered location
- Located within the immediate proximity where controlled substances are stored and at which an employee is present (e.g., can be seen from the pharmacy counter)
- Securely fastened to permanent structure, not removable
- Be a securely locked, substantially constructed container with a permanent outer container and removable inner liner
- Prominently display a sign indicting that only non-controlled drugs and Schedule II, III, IV or V controlled substances are acceptable for collection
- Have an opening capable of being locked at times when an employee is not present (e.g., when the pharmacy department is closed) or not being regularly monitored by an LTCF employee

Assessment Question

Collection receptacle inner liners must:
A. Be waterproof, tamper-evident, and tear-resistant
B. Be opened and an inventory of controlled substances must be conducted monthly and reported to DEA
C. Once removed from a collection receptacle at a pharmacy and sealed, be securely stored at the pharmacy in either a securely locked, substantially constructed cabinet or a securely locked room with controlled access until prompt destruction can occur
D. Both A and C are true

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Receptacle Inner Liners

Linear Specifications
- Waterproof, tamper-evident, and tear-resistant
- Contents of the inner liner shall not be viewable from the outside when sealed

Linear Handling
- Removed and sealed immediately upon removal without emptying or touching the contents
- Only employees of the collector shall have access to inner liners
- Installed by at least 2 employees of authorized collector and sealed by 2 employees of authorized collector immediately upon removal

Linear Markings
- Bear a permanent, unique identification number that enables the liner to be tracked
- Size of the inner liner must be clearly marked on the outside of the liner (e.g., 5-gallon)

After Inner Liner Removal...

- Pharmacy must do one of the following:
  - Promptly destroy inner liner and contents onsite
  - Promptly deliver inner liner and contents to distributor’s or reverse distributor’s registered location by common or contract carrier pick-up or by distributor or reverse distributor pick-up at the authorized collector’s registered location
  - Request assistance from DEA
  - Securely store sealed inner liner and contents at pharmacy in either securely locked, substantially constructed cabinet or a securely locked room with controlled access until destruction can occur
Collection Receptacles

Hospitals
- Hospitals/Clinics with onsite pharmacies may maintain collection receptacles in non-urgent/emergency care areas that are regularly monitored by employees
  - "Onsite" when it has a pharmacy located on the physical premises of the registrant’s registered location
- Substance is not fully used (e.g. some of the substance remains in the vial, syringe, etc. after administration but cannot be further utilized), then the DEA registrant must destroy the remaining, unusable controlled substance in accordance with 1317.90 and 1317.95.
  - Collection receptacle may not be used

Long Term Care Facilities
- Definitions
  - DEA: “a nursing home, retirement care, mental care, or other facility or institution which provides extended health care to resident patients.”
  - Wisconsin Phar 1.02 (4m): “Long term care facility means a facility for the developmentally disabled or other nursing home”
- What about assisted living?

Collection Receptacles

Long-Term Care Facilities
- Authorized retail pharmacy or a hospital/clinic with an onsite pharmacy may install, manage, and maintain receptacles at an LTCF
- Must update DEA registration with LTCF information!
- The following may dispose of controlled substances at a LTCF:
  - Ultimate users themselves
  - Person lawfully entitled to dispose of decedent’s property
  - LTCF staff on behalf of current or previous resident
- Receptacle must be located in a secured area monitored by LTCF employees – authorized collector responsible for security procedures!

Disposal Requirements at LTCF

<table>
<thead>
<tr>
<th>Disposal Action</th>
<th>Disposal Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disposal of residents’ unwanted/unused controlled substance</td>
<td>Place in receptacle &lt; 3 days after medication discontinuation</td>
</tr>
<tr>
<td>Handling collection receptacle inner liners</td>
<td>One supervisor-level employee of the LTCF may assist in changing the collection receptacle inner liner under the supervision of one employee of the authorized collector OR two employees of the authorized collector</td>
</tr>
<tr>
<td>Storage of inner liners upon removal</td>
<td>May be stored at the LTCF for ≤ 3 business days in a securely locked, substantially constructed cabinet or a securely locked room with controlled access. May not be taken back to pharmacy!</td>
</tr>
<tr>
<td>Disposal in LTCFs without a collection receptacle</td>
<td>Utilize other disposal options (e.g. mail-back or take-back programs or otherwise discarding)</td>
</tr>
</tbody>
</table>

Record Keeping Requirements

Collection Receptacles

- Inventory
  - Receipt of liners, on-hand (unused and sealed), installed, removed, stored, transferred for destruction
- Two employee tracking
  - Names and signatures of those that witness liner installation, removal/sealing, transfer to storage, transfer for destruction
- Location tracking
  - Registration number of collector, address where liner installed or removed, information about distributor/reverse distributor who will destroy liner

Resources/Forms
- DEA Form 41
  - Used to record destruction of all controlled substance inventory, including substances collected from ultimate users
- DEA Form 106
  - Used to report theft for loss of any controlled substance, including sealed inner liners and mail-back packages
  - Required to report within one business day of discovery
Assessment Question

All of the following statements about take-back events are true EXCEPT:
A. Pharmacists, pharmacy technicians, and student pharmacists can continue to participate in take-back events.
B. Student pharmacists may collect substances from patients at their car windows and deposit them in collection barrels for analysis.
C. Law enforcement must appoint an officer to oversee the collection event.
D. Specific recommendations for collection bins are provided in the Final Rule.

Implications for Pharmacies

• Pharmacists, pharmacy technicians and student pharmacists can continue to participate in take-back events in partnership with law enforcement, but ultimate users may only transfer controlled substances directly to law enforcement.

Assessment Question

Mail-back packages must:
A. Be addressed so they are mailed to the pharmacy
B. Be nondescript, tamper-evident, tear-resistant, water- and spill-proof, and sealable
C. Contain a unique identification number
D. Both B and C are true
Mail-back Programs

- Voluntary programs may be conducted by registered manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an onsite pharmacy, or retail pharmacies that are
  1. authorized as “collectors;” AND
  2. have and utilize an “onsite” method of destruction at their registered location.
- Destruction must result in “non-retrievable” substances
  - Flushing, mixing in coffee grounds/kitty litter no longer meet non-retrievable requirement
- Collector needs to produce and provide packaging and monitor and maintain inventory

Mail-back Packages

- Postage paid and pre-addressed to the authorized mail-back location
- Nondescript, tamper-evident, tear-resistant, water- and spill-proof, and sealable
- Contain a unique identification number so that each package can be tracked
- Contain instructions for the user that indicate the process for mailing back that package, permitted substances that can be sent, notice that packages may only be mailed from within the US, and notice that only packages provided by the authorized collector will be accepted for destruction
- Patients cannot be required to provide any personally identifiable information when mailing back controlled substances to an authorized collector

Implications for Pharmacies

- Pharmacies may facilitate participation in mail-back programs in partnership with a reverse distributor, for example, but would likely not conduct the mail-back program themselves as onsite destruction of received controlled substances is required
- Pharmacies cannot receive sealed mail-back packages for disposal unless they will be destroying the sealed mail-back package onsite

Hospice

- Home hospice and homecare personnel cannot collect controlled substances from patients or their families for the purpose of disposal
- Options for disposal – Person “lawfully entitled to dispose of decedent’s property” OR a member of the deceased patient’s household may:
  - Deliver controlled substances to authorized collector (take-back event, mail-back program, collection receptacle)
  - Flush/mix with kitty litter/coffee grounds
- Hospice/Homecare organization can partner with authorized collector and provide mail-back packages

Issues/Unanswered Questions – Hospitals

- Letter to DEA from American Hospital Association, Children’s Hospital Association, Association of American Medical Colleges, etc.
- Definition of destruction – “non-retrievable”
- Definition of employee – witnessing destruction
- Recording requirements
- OSHA concerns/sharps disposal
- Delay or waiver?