

# Managing Pharmaceutical Waste at the **LTC Provider Pharmacy**

**Is your pharmacy compliant with all regulations related to pharmaceutical waste?**

The long-term care (LTC) industry is currently faced with the simultaneous intersection of multiple regulatory directives related to pharmaceutical waste. The Centers for Medicare & Medicaid Services (CMS), the Drug Enforcement Administration (DEA), and the Environmental Protection Agency (EPA) have all identified pharmaceutical waste management as a priority issue, yet all three federal agencies have independently addressed this issue through separate but equally impactful legislative and regulatory initiatives.

## **Current Initiatives:**

<b>Federal Agency</b>	<b>Regulation/Guidance</b>	<b>Description</b>
CMS	Short-Cycle Dispensing Regulations	Requires LTC pharmacies to utilize uniform, less than 30-day supply dispensing methods for Part D covered drugs dispensed to LTCF residents
DEA	Secure and Responsible Drug Disposal Act of 2010	New law granting the attorney general authority to develop regulations outlining disposal requirements for controlled drug waste
EPA	Best Management Practices for Unused Pharmaceuticals at Health Care Facilities	Proposed guidelines for health care facilities, including pharmacies and LTCFs, for managing and disposing unused drugs

Long-term care provider pharmacies have been actively engaged on the evolution of CMS's long-anticipated regulations mandating uniform, less than 30-day supply dispensing requirements for all Medicare Part D covered drugs bound for patients residing in a long-term care facility. The objective is to reduce costs to the Medicare program associated with already dispensed Part D covered drugs but not consumed by patients by reducing the amount of waste resulting from the discontinuation of a drug.



President Obama recently signed the Secure and Responsible Drug Disposal Act of 2010 into law, which includes a provision that may allow LTCFs to dispose of controlled drug waste through an authorized DEA registrant in the future, a practice currently prohibited by federal law since LTCFs are not DEA registrants. While the provision extends the authority to the DEA to create these regulations, they are not required to do so. In the interim, the DEA Pharmacist's Manual directs LTCFs and their provider pharmacies to consult with their local DEA Diversion Field Office (see a list at [http://bit.ly/DEA\\_Diversion](http://bit.ly/DEA_Diversion)) and state agencies for instructions on how to handle controlled drug waste.

EPA is turning its attention to the long-term care industry, both provider pharmacies and LTCFs themselves. Many in this industry are not familiar with solid and hazardous waste regulations that have been enforced in other industry sectors. To assist in your management efforts, ASCP and WM have teamed up to provide you with this brief summary.

The regulations for solid and hazardous waste disposal are driven primarily by the Resource Conservation and Recovery Act, or RCRA (pronounced "REC-rah"). About 5% of drugs in the market are hazardous wastes under these rules when discarded, and must be carefully managed, transported and disposed of. The goal is first to minimize pharmaceutical waste and then to manage the waste appropriately.

### General Considerations:

<b>Management Type:</b>	<b>Management Strategy:</b>
Return to Pharmacy stock	Appropriate for LTC provider pharmacies if payer or facility contracts mandate credit be issued for unused meds, if medications meet return guidelines, and evaluation and appropriate restocking occurs
Reverse Distribution	Appropriate for pharmacies or potentially creditable outdated drugs in original manufacturer packaging
Hazardous Waste	Must use hazardous waste incinerator
Non-Haz Pharm	Incineration at either a medical waste or waste-to-energy facility
Trace Chemo	Incineration at a medical waste facility
Medical Waste	Autoclave/microwave or medical waste incineration facility
Sewer	With permission of the local publicly-owned sewage treatment plant
Trash	In compliance with HIPAA

**COLOR KEY:** Different colored containers should be used in a facility/pharmacy to segregate and store different types of waste awaiting disposal or transfer. The colors above are suggestions, not mandated by law (except **RED** containers for Medical Waste), and represent container colors currently available on the market.

**Recommended management and treatment methods for expired and waste pharmaceuticals occurring within LTC provider pharmacies:**

LTC Provider Pharmacies	Return to Pharm Stock	Reverse Distribution	Haz Waste	Non-Haz Pharm	Trace Chemo	Medical Waste	Drain	Trash
Expired drug in mfctr's package		X						
Dispensed non-controlled substances that meet return guidelines	X							
Dual Hazardous Waste & Medical Waste			X					
"Bulk" chemotherapy			X					
Pressurized aerosols			X					
Blood products, live attenuated virus vaccines						X		
*Controlled substances		X						
All other Non-Hazardous drugs				X				
Empty (as defined by RCRA) chemo containers, trace contaminated chemo paraphernalia					X			
Empty (as defined by RCRA) stock bottles, vials, IV bags, etc.								X

\*Congress enacted the "Secure and Responsible Drug Disposal Act of 2010" in October 2010 which authorizes the Drug Enforcement Administration to write regulations for consumers and LTCFs to return unused or expired controlled substances for safe disposal, and thus avoid introducing these into the sewage system.

## REFERENCES, RESOURCES, AND LINKS

- CMS Short-Cycle Dispensing Regulations - TBD
- DEA Pharmacist's Manual - [http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm\\_manual.pdf](http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf)
- EPA DRAFT Best Management Practices Guidance – <http://edocket.access.gpo.gov/2010/pdf/2010-22325.pdf>
- Practice Greenhealth 10-Step Blueprint for Managing Pharmaceutical Waste - <http://www.hercenter.org/hazmat/tenstepblueprint.pdf> (Although written for hospitals, the document provides a summary of the definitions of hazardous waste.)
- “Managing Pharmaceutical Waste - What pharmacists should know” - <http://www.pharmacology.com/pedd/pdf/Managing%20Pharmaceutical%20Waste.pdf>
- DEA Diversion Field Office Listing [http://www.deadiversion.usdoj.gov/offices\\_n\\_dirs/fielddiv/index.html](http://www.deadiversion.usdoj.gov/offices_n_dirs/fielddiv/index.html)

## EXAMPLES OF PHARMACEUTICALS CONSIDERED HAZARDOUS WHEN DEEMED “WASTE”

Drug	EPA Hazardous Waste Code
Warfarin tablets	P001
Human Insulin (m-cresol preservative)	D024
Multi-dose Adult Flu Vaccines (thimerosal preservative)	D009
Proventil Aerosols	D001

## GLOSSARY OF TERMS

- **Bulk chemotherapy:** Any container in which actual chemotherapy drug remains in more than trace amounts
- **Medical Waste:** Also known as Regulated Medical Waste or Biohazardous Waste or Potentially Infectious Waste (Includes blood products such as albumin and live attenuated virus vaccines such as FluMist)
- **Dual Hazardous Waste & Medical Waste:** Example - unused human insulin in syringe with a needle
- **RCRA:** The Resource Conservation and Recovery Act (RCRA) was enacted in 1976 to protect people and the environment from hazards of improper waste disposal.
- **RCRA-empty:** For P-listed drugs, such as warfarin and nicotine, the packaging is never RCRA-empty since it will not be triple rinsed and must be managed as a hazardous waste under the federal rules. For other hazardous waste, all the contents must be removed that can be removed and THEN no more than 3% can remain.

## DISCLAIMER

This information is solely for educational purposes and provides only a general description of various regulatory requirements. For a complete description, please consult the relevant federal and state regulatory statutes. Nothing in this information constitutes legal advice and you should not legally rely on any information provided in this presentation. We make no warranty, express or implied, with respect to such information and disclaim all liability resulting from any use or reliance of this information.

# Managing Pharmaceutical Waste at the Long-Term Care Facility

**Are your facilities compliant with all regulations related to pharmaceutical waste?**

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## Current Initiatives:

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Long-term care provider pharmacies have been actively engaged on the evolution of CMS's long-anticipated regulations mandating uniform, less than 30-day supply dispensing requirements for all Medicare Part D covered drugs bound for patients residing in a long-term care facility (LTCF). The objective is to reduce costs to the Medicare program associated with already dispensed Part D covered drugs but not consumed by patients by reducing the amount of waste resulting from the discontinuation of a drug.



President Obama recently signed the Secure and Responsible Drug Disposal Act of 2010 into law, which includes a provision that may allow LTCFs to dispose of controlled drug waste through an authorized DEA registrant in the future, a practice currently prohibited by federal law since LTCFs are not DEA registrants. While the provision extends the authority to the DEA to create these regulations, they are not required to do so. In the interim, the DEA Pharmacist's Manual directs LTCFs and their provider pharmacies to consult with their local DEA Diversion Field Office (see a list at [http://bit.ly/DEA\\_Diversion](http://bit.ly/DEA_Diversion)) and state agencies for instructions on how to handle controlled drug waste.

EPA is turning its attention to the long-term care industry, both provider pharmacies and LTCFs themselves. Many in this industry are not familiar with solid and hazardous waste regulations that have been enforced in other industry sectors. To assist in your management efforts, ASCP and WM have teamed up to provide you with this brief summary.

The regulations for solid and hazardous waste disposal are driven primarily by the Resource Conservation and Recovery Act, or RCRA (pronounced "REC-rah"). About 5% of drugs in the market are hazardous wastes under these rules, and must be carefully managed, transported and disposed of. The goal is first to minimize pharmaceutical waste and then to manage the waste appropriately.

**General Considerations:**

Management Type:	Management Strategy:
Return to Pharmacy	Appropriate if pharmacy contract allows for return of unused medications to the pharmacy, and if it meets return guidelines set forth by the pharmacy
Hazardous Waste	Must use hazardous waste incinerator
Non-Haz Pharm	Incineration at either a medical waste or waste-to-energy facility
Trace Chemo	Incineration at medical waste facility
Medical Waste	Autoclave/microwave or RMW incineration facility
Sewer	With permission of the local publicly owned sewage treatment plant
Trash	In compliance with HIPAA

**COLOR KEY:** Different colored containers should be used in a facility/pharmacy to segregate and store different types of waste awaiting disposal or transfer. The colors above are suggestions, not mandated by law (except **RED** containers for Medical Waste), and represent container colors currently available on the market.

**Recommended Management and Treatment Methods for Expired and Waste Pharmaceuticals Occurring Within LTCFs:**

Long-Term Care Facilities	Return to Provider Pharmacy	Haz Waste	Non-Haz Pharm	Trace Chemo	Medical Waste	Drain	Trash
Non-controlled that meets return guidelines, if pharmacy contract allows	X						
Dual Hazardous Waste & Medical Waste		X					
“Bulk” chemotherapy		X					
Pressurized aerosols		X					
Blood products, live attenuated virus vaccines					X		
*Controlled substances (except used patches)						X	
Used controlled substances patches			X				
All other Non-Hazardous drugs that are being discarded			X				
Electrolytes						X	
Dextrose, saline						X	
Empty (as defined by RCRA) chemo containers, trace contaminated chemo paraphernalia				X			
Empty (as defined by RCRA) OTC stock bottles, vials, IV bags, etc.							X

\*Congress enacted the “Secure and Responsible Drug Disposal Act of 2010” in October 2010 which authorizes the Drug Enforcement Administration to write regulations for consumers and LTCFs to return unused or expired controlled substances for safe disposal, and thus avoid introducing these into the sewage system.

## REFERENCES, RESOURCES, AND LINKS

- CMS Short-Cycle Dispensing Regulations - TBD
- DEA Pharmacist's Manual - [http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm\\_manual.pdf](http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf)
- EPA DRAFT Best Management Practices Guidance – <http://edocket.access.gpo.gov/2010/pdf/2010-22325.pdf>
- Practice Greenhealth 10-Step Blueprint for Managing Pharmaceutical Waste - <http://www.hercenter.org/hazmat/tenstepblueprint.pdf> (Although written for hospitals, the document provides a summary of the definitions of hazardous waste.)
- “Managing Pharmaceutical Waste - What pharmacists should know” - <http://www.pharmacology.com/pedd/pdf/Managing%20Pharmaceutical%20Waste.pdf>
- DEA Diversion Field Office Listing [http://www.deadiversion.usdoj.gov/offices\\_n\\_dirs/fielddiv/index.html](http://www.deadiversion.usdoj.gov/offices_n_dirs/fielddiv/index.html)

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