

Collecting Unwanted Household Pharmaceuticals

Regulatory Guidance for Organizers of Household Pharmaceutical Collection Events

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Introduction

Household pharmaceuticals include household prescription, over-the-counter and illegal drugs. These are in the form of pills, ointments, liquids, sprays, pre-filled syringes, injection vials, etc.

The traditional ways of managing unwanted household pharmaceuticals, such as flushing them down the toilet, pouring them down the drain, or throwing them in the trash, may be harming our environment and threatening public health.

You can help reduce the potential for harm by collecting unwanted household pharmaceuticals for better management.



Collecting unwanted household pharmaceuticals requires careful planning because of the diversity of the materials and the various legal or regulatory requirements that may apply. This guidance focuses on the regulatory aspects of collecting unwanted household pharmaceuticals. For guidance on other aspects, see [Appendix A](#).

Requirements for Managing Collected Unwanted Household Pharmaceuticals

Unwanted household pharmaceuticals may be regulated by more than one set of requirements. Key considerations are below. Additional details and links to further information are included in [Appendix B](#).

Controlled Substances

These are drugs that, because of their abuse potential, are regulated by the U.S. Drug Enforcement Administration (DEA). The DEA regulations require law enforcement officers to take possession of any controlled substances you collect and to maintain possession of them at all times, including witnessing their destruction.

Collected controlled substances must be segregated from other wastes, logged, put in sealed containers, securely transported and stored, and properly destroyed. The DEA regulations do not allow a law enforcement officer to transfer custody of collected household controlled substances to a waste management contractor, even if the contractor is DEA-registered for managing controlled substances that have not been dispensed to patients.

Many local law enforcement agencies are already familiar with the DEA requirements for managing controlled substances.

If you collect controlled substances, the DEA requirement to have a law enforcement officer present at your collection will likely limit it to a special one day or several day event.

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| Type of Collected Unwanted Household Pharmaceuticals | Applicable Requirement ¹ | | | | | |
|--|-------------------------------------|--|------------------|-----------------|----------------|---------------------|
| | U.S. DEA | WI DHFS | WI DNR | | | U.S. DOT |
| | Controlled Substances | Cancer & Chronic Disease Drug Repository | Infectious Waste | Hazardous Waste | Solid Waste | Hazardous Materials |
| Controlled Substances | √ | | √ ² | √ ³ | √ ³ | √ |
| Cancer & Chronic Disease Repository Drugs & Supplies | | √ | | | | √ |
| Other Drugs | | | √ ² | √ ³ | √ ³ | √ |

¹For more information on these requirements, see [Appendix B](#).

²Only if associated with a sharp.

³A June 12, 2006 Wisconsin Department of Natural Resources (DNR) memo states the agency's intent to conditionally use discretion in enforcing hazardous waste and solid waste rules, as they apply to the management of collected household pharmaceutical waste. The conditions for the enforcement discretion are listed in [Appendix B](#).

Cancer and Chronic Disease Drug Repository

Wisconsin allows some unused cancer and chronic disease drugs and supplies to be donated to participating pharmacies or medical facilities for use by other patients. To be eligible for donation, a cancer or chronic disease drug must not be a controlled substance, must be in its original, unopened tamper-evident unit dose packaging (i.e., no bottles), and must not expire until at least six months after the donation is made.

Donated cancer and chronic disease drugs and supplies need to be managed according to the applicable Wisconsin Department of Health and Family Services (DHFS) cancer and chronic disease drug repository rules. However, as long as they are still eligible for use by others, donated cancer and chronic disease drugs and supplies are not regulated as waste.

Infectious Waste

In Wisconsin, waste sharps are presumed to be infectious waste. Sharps include medical equipment, such as hypodermic needles, syringes with needles attached, and lancets, which may cause punctures or cuts. If you accept sharps at your collection, you will need to manage them according to the applicable DNR medical waste requirements.

To be exempt from licensing and other infectious waste storage requirements, you may need to

register in advance with DNR as a sharps collection station. If you do not want the public to bring sharps to your collection site on days other than collection days, you may ask DNR to leave your location off its public list of sharps collection stations.

Solid Waste and Hazardous Waste

Solid and hazardous wastes are regulated by the DNR under the Wisconsin Administrative Code (NR 500 series and NR 600 series, respectively). The DNR issued a memo, dated June 12, 2006, stating the agency's intent to use discretion in enforcing solid and hazardous waste requirements applicable to collected household pharmaceuticals, provided a number of conditions are met. Conditions include managing controlled substances in accordance with DEA requirements, taking precautions to prevent theft or accidental exposure, and ensuring safe and nuisance free collection, storage, transportation and management of collected pharmaceuticals. See [Appendix B](#) for the complete list of conditions and a link to the enforcement discretion memo.

If you collect any pharmaceutical waste from other than households, this must be managed according to applicable DNR solid and hazardous waste requirements. If you collect pharmaceutical waste, which is assumed or determined to be hazardous waste, from very small quantity generators (VSQGs), you may manage it according to the DNR's reduced requirements for VSQG hazardous waste collection

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facilities. Non-households that generate more than 2.2 pounds of acute hazardous waste (e.g., unused epinephrine or coumadin drugs) per month are considered large quantity generators (LQGs). As such, there may be few non-household pharmaceutical waste generators (e.g., pharmacies and medical facilities) from which you may accept waste under the reduced requirements.

If you mix non-household and household pharmaceutical waste, the enforcement discretion does not apply to the mixture and you must manage it according to the applicable DNR hazardous waste and solid waste requirements.

Special Forms of Unwanted Household Pharmaceuticals

These include pharmaceuticals associated with sharps (e.g., pre-filled syringes including EpiPen®s) and pharmaceuticals in aerosol form (e.g., some asthma inhalers, anti-fungals and pain relievers).

Pharmaceuticals associated with sharps are also regulated as infectious waste, discussed above. Additional information on infectious waste regulation is provided in [Appendix B](#).

Because incinerators may not be allowed to, or may choose not to incinerate aerosols, pharmaceuticals in aerosol form may need to be separated from other pharmaceuticals prior to incineration.

Other Unwanted Household Healthcare Items (Non-Pharmaceuticals)

In addition to collecting unwanted household pharmaceuticals, you may want to accept other unwanted household healthcare items, such as sharps that do not contain drugs, or thermometers, which may contain mercury. As noted above, sharps are presumed to be infectious waste and must be managed accordingly.

If you accept mercury-containing thermometers, you may be able to manage them under Wisconsin's universal waste requirements, which call for you to send the thermometers to a recycler for mercury

recovery. Details regarding the universal waste requirements are included in the [DNR Wisconsin-specific universal waste guidance](http://dnr.wi.gov/org/aw/wm/publications/hazard/unv_waste204.pdf) (http://dnr.wi.gov/org/aw/wm/publications/hazard/unv_waste204.pdf).

Collection Participants

You should have pharmacists on-site during your collection to identify and sort pharmaceuticals and non-pharmaceuticals (e.g., controlled substances, cancer and chronic disease repository drugs and supplies, and other drugs).



If you accept controlled substances, you must arrange for qualified law enforcement officers to be present during your collection and to take and maintain possession of the controlled substances. Even if you do not accept controlled substances, you may still want law enforcement officers present to make household members more comfortable and to discourage theft.

You may also want to ask your waste management contractor or similarly qualified individuals to help with any other needed material sorting and to help prepare sorted materials for compliance with the applicable requirements for infectious wastes and hazardous materials.

All State of Wisconsin agencies, institutions and campuses (e.g., UW System) are required to use the [State of Wisconsin hazardous waste management contract](#). Wisconsin [municipalities](#) are also eligible to use the state contract, which may save money compared to contracting directly with a waste management company.

Unused and Expired Medicine Registry

While it is not required, you may want to voluntarily provide information to the registry on the unused and expired medicines you collect. Information on the registry is available at:

www.communityofcompetence.com/expiredmed.htm

Off-Site Transportation

Persons transporting sharps off-site may need a DNR infectious waste transportation license and may need to comply with other infectious waste transportation requirements. However, persons transporting less than 50 pounds of infectious waste per calendar month do not need an infectious waste transportation license.

In addition to the DNR requirements, which only apply to wastes, the DOT's hazardous materials transportation regulations may apply to any wastes and non-wastes you collect and offer for transport, or that you yourself transport away from your facility.

Recommended Best Management Practices

The recommended best management practices for collected materials are:

- donate eligible cancer and chronic disease drugs and supplies for use by other patients;
- have any mercury-containing devices such as thermometers recycled to recover the mercury; and
- hazardous waste incineration.

A less desirable alternative to hazardous waste incineration may be solid waste incineration or medical waste incineration, if the incinerator's license or permit allows incineration of the waste, and the incinerator's state exempts collected household pharmaceutical waste from regulation as hazardous waste.

Finally, the best management practice for pharmaceuticals in aerosol form, which may not be allowed to be incinerated, is to have the containers recycled as scrap metal. As with incinerators, your waste management contractor should be able to confirm whether/which facilities have the technical capabilities and are properly authorized to manage these items.

Further Information

Other collection resources and links to further information are included in the attached appendices.



This publication is available in alternative format upon request. Please call 608-266-2111 for more information or e-mail Waste.Materials@dnr.state.wi.us

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Appendix A

Other Collection Resources

The following resources are available at The Northeast Recycling Council, Inc. web site (www.nerc.org) by holding your mouse pointer over *Unwanted Medication Collections* at the bottom of the left margin and clicking any of the links in the drop-down menu, which as of August 9, 2006 were titled:

Collecting Unwanted Medications in a Mall, Rutland, VT

Franklin County Pilot Unwanted Medications Collection

In-Store Unwanted Medication Collection CVS Mill Creek, South Portland, Maine

Managing Plastic Medication Containers

Recommendations for the Disposal of Unwanted Medications Not Controlled by the U.S. DEA

Recommendation: Medications Stay in Original Containers

The Continuing Lessons of Unwanted Medication Collections: A Five-Town Event in Massachusetts

Unwanted Medication Collection in South Hadley, Massachusetts

Unwanted Medications Presentation at Michigan Recyclers Coalition Annual Meeting

Pharmaceuticals and Personal Care Products (PPCPs) as Environmental Pollutants, U.S. Environmental Protection Agency, www.epa.gov/nerlesd1/chemistry/pharma/index.htm (web site not maintained since March 2005)

Pharmwaste listserv, national pharmaceutical waste management discussion, lists.dep.state.fl.us/cgi-bin/mailman/listinfo/pharmwaste

Environment and Pharmaceuticals (including Environmentally classified pharmaceuticals), Department of the Environment and Department of Drug Management and Informatics, Stockholm County Council, Sweden, www.janusinfo.se/imcms/servlet/GetDoc?meta_id=7236

Appendix B

More Information on Management Requirements that May Apply

U.S. DEA – Controlled Substances

These substances are drugs or other substances, or immediate precursors, included in Schedule I, II, III, IV, or V of Title 21, Code of Federal Regulations (CFR), Sections 1308.11 to 1308.15. Controlled substances need to be managed according to the applicable regulations in 21 CFR Parts 1300 to 1316.

Web site: www.dea diversion.usdoj.gov

Controlled substances list: www.dea diversion.usdoj.gov/schedules/alpha/alphabetical.htm

Contact (Milwaukee): (414) 297-3395, extension 6400

Wisconsin DHFS – Cancer and Chronic Disease Drug Repository

Cancer and chronic disease repository drugs and supplies need to be managed according to the applicable rules in ch. HFS 148, Wis. Adm. Code.

Web site: dhfs.wi.gov/bgaconsumer/cancerdrugreposy.htm

Rules: www.legis.state.wi.us/rsb/code/hfs/hfs148.pdf

Wisconsin DNR –

Infectious Waste. Sharps are defined in s. NR 500.03(209), Wis. Adm. Code, and are listed in s. NR 526.05(1)(a), Wis. Adm. Code. Waste sharps are presumed to be infectious waste as defined in s. 287.07(7)(c)1.c., Wis. Stats. As infectious waste, waste sharps need to be managed according to the applicable medical waste requirements in ch. NR 526, Wis. Adm. Code. There are exemptions from licensing and some other infectious waste storage requirements in s. NR 526.09(2), Wis. Adm. Code. To be exempt, a sharps collection station needs to meet the operating requirements in s. NR 526.09(5), Wis. Adm. Code.

Web site dnr.wi.gov/org/aw/wm/medinf

Hazardous Waste. This waste generally includes discarded material that has any of the four hazardous waste characteristics (ignitability, corrosivity, reactivity or toxicity) or is specifically listed as hazardous waste. This waste is defined in s. NR 661.03, Wis. Adm. Code, and needs to be managed according to the applicable hazardous waste requirements in chs. NR 660 to 673, Wis. Adm. Code, and ch. 291, Wis. Stats.

Web site: dnr.wi.gov/org/aw/wm/hazard

Contact information for permanent household hazardous waste collection programs & contractors: www.uwex.edu/erc/pdf/HHW/PermAddress.pdf

Contact information for one-day household hazardous waste collection programs & contractors: www.uwex.edu/erc/pdf/HHW/1DayAddress.pdf

Licensed hazardous waste transporters lists: dnr.wi.gov/org/aw/wm/faclists

Enforcement Discretion: A June 12, 2006 DNR memo states the agency's intent to use discretion in enforcing solid and hazardous waste rules applicable to the management of collected household pharmaceutical waste during a one-year evaluation period, if the following conditions are met:

1. Controlled substances must be managed according to DEA requirements.

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2. Reasonable precautions must be taken to prevent theft of, or accidental exposure to, collected household pharmaceuticals.
3. Collected household pharmaceuticals must be collected, stored, transported and managed in a safe and nuisance free manner and to prevent releases to the environment. Standards necessary to ensure this include, but are not limited to, the following:
 - a. Collected household pharmaceuticals may not be disposed in a publicly owned treatment works or other wastewater treatment facility.
 - b. To the extent possible, and with due consideration to the compatibility of the waste stream to a particular management method, pharmaceuticals should be incinerated or otherwise destroyed, so as to render them unrecoverable in the future and in order to minimize their potential impact upon the environment.
 - c. Collected household pharmaceuticals that are destined for disposal at a licensed solid waste landfill must be managed according to ch. NR 668, Land Disposal Restrictions.
 - d. Operators of household pharmaceutical collection facilities and events must ensure that the final disposition/destruction of all collected household pharmaceuticals can be ascertained.

Enforcement Discretion Memorandum:

<http://www.dnr.wi.gov/org/aw/wm/publications/hazard/EnfDiscretionPharmWaste.pdf>

Solid Waste. This waste generally includes discarded or salvageable material that is not a hazardous waste. Solid waste is defined in s. 289.01(33), Wis. Stats., and is subject to the applicable solid waste recycling and management requirements in chs. NR 500 to 524 and 544, Wis. Adm. Code, and chs. 287 and 289, Wis. Stats.

Web Sites: dnr.wi.gov/org/aw/wm/solid or dnr.wi.gov/org/aw/wm/recycle

Solid waste &/or recyclables transporters lists: dnr.wi.gov/org/aw/wm/faclists

Enforcement Discretion: The June 12, 2006 enforcement discretion memo discussed above also pertains to Solid Waste regulation.

U.S. Department of Transportation (DOT) – Hazardous Materials

These materials are substances or materials that the DOT has determined are capable of posing an unreasonable risk to health, safety, and property when transported in commerce. Hazardous material is defined in 49 CFR 171.8 and is subject to the applicable Hazardous Materials Regulations in 49 CFR Parts 171 to 180. Those regulations apply to the classification, packaging, hazard communication, incident reporting, handling and transportation of hazardous materials.

While the regulations do not apply to shipments of hazardous materials transported by a government entity in vehicles operated by government personnel for noncommercial purposes, it is a good management practice to follow the regulations. Non-government entities that offer for transport, or transport, certain types or quantities of hazardous materials in commerce may need to be registered with DOT.

Web site: hazmat.dot.gov

Hazardous Materials Registration Company Search:

<https://hazmatonline.phmsa.dot.gov/Services/companylookup.aspx>

Contacts: (608) 829-7530 (Madison) or (800) 467-4922