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dhfs.wisconsin.gov**Date:** November 3, 2006**OQA Memo 06-022****To:** Nursing Homes

NH 12

From: Otis Woods, Director, Office of Quality Assurance**Medication Return, Donation, and Disposal**

This memo provides guidance on situations where removal of medication from a Nursing Home facility is required. This memo also waives a portion of section HFS 132.65(6)(c) (see <http://www.legis.state.wi.us/rsb/code/dhs/dhs132.pdf>), Wis. Admin. Code, related to medication destruction.

Background

Many situations in nursing homes may require medications to be removed from the premises, e.g., medication order changes, expired medications, adulterated or contaminated medications, resident discharge, resident death, etc. The amount of medications, the options for removing these medications, and environmental concerns have increased, and have led nursing homes to ask how medications should be removed. Some nursing homes have asked about outside sources picking up medications for removal and how that should be handled. Although not comprehensive, this memo provides some information and options relating to removal of medications from nursing homes.

Rule and Waiver

Section HFS 132.65(6)(c) (see <http://www.legis.state.wi.us/rsb/code/dhs/dhs132.pdf>), Wis. Admin. Code, is the current State nursing home rule relating to medication destruction and removal.

HFS 132.65(6)(c) Destruction of medications. 1. 'Time limit.' Unless otherwise ordered by a physician, a resident's medication not returned to the pharmacy for credit shall be destroyed within 72 hours of a physician's order discontinuing its use, the resident's discharge, the resident's death or passage of its expiration date. No resident's medication may be held in the facility for more than 30 days unless an order is written every 30 days to hold the medication.

2. 'Procedure.' Records shall be kept of all medication returned for credit. Any medication not returned for credit shall be destroyed in the facility and a record of the

destruction shall be witnessed, signed and dated by 2 or more personnel licensed or registered in the health field.

Pursuant to this memo, for nursing homes that contract with companies to remove medications for the purpose of credit, donation, or destruction; the requirement at HFS 132.65(6)(c)1 (see <http://www.legis.state.wi.us/rsb/code/dhs/dhs132.pdf>) to destroy medications within 72 hours is being waived, subject to the following specific conditions. The nursing home must assure that medications that will be removed by the contracted company are:

- Physically separated from medications being used in the facility;
- Locked with access limited; and
- In an area with a system to reconcile, audit or monitor them to prevent diversion.

Removal

Medications requiring removal fall into three categories: 1) Medications that can potentially be used or returned; 2) Medications that cannot be used or returned; and 3) Controlled substances.

Medications That Can Be Used or Returned

Physician Order: Physician orders are used to hold resident medications that are temporarily stopped, and may potentially be restarted for the same resident. This practice can eliminate some medication destruction or returns. Facilities can hold these medications in facility storage as indicated at HFS 132.65(6)(c)2 (see <http://www.legis.state.wi.us/rsb/code/dhs/dhs132.pdf>).

Return to pharmacy: Wisconsin pharmacy regulations under section Phar 7.04, (see <http://www.legis.state.wi.us/rsb/code/phar/phar007.pdf>), Wis. Admin. Code, allow medications to be returned from a nursing home to a pharmacy for use by other residents under certain circumstances (see attachment section A for a summary of Phar 7.04). This return practice can eliminate some medication waste.

Return to Pharmacy Exceptions/Issues:

- Controlled substances, per Federal Drug Enforcement Administration (DEA) regulations, in general cannot be returned to a pharmacy to be used for other residents. See controlled substance discussion below.
- Many private insurance companies (and now Medicare Part D) do not have a mechanism for pharmacies to credit the insurance plan for medications that have been returned and will be used for other residents. Therefore, these medications need to be removed from the facility through another mechanism. (Medicaid continues to have a mechanism to accept returns and credit.)

Cancer/Chronic Disease Drug Repository: Newly promulgated Wisconsin Administrative Code, Chapter HFS 148, created a mechanism for usable medications to be donated to participating pharmacies. These medications may be used by individuals who do not have the means to pay for medications. Information on the repository, including participating providers, can be accessed at: <http://dhfs.wisconsin.gov/bqaconsumer/cancerdrugrepsy.htm>.

In general, a nursing home that has medications in a tamper-evident, unit dose package, e.g. blister or bubble pack, can contact one of the participating pharmacies to determine if it will accept the medication. If a participating pharmacy will accept the medication, the nursing home can fill out a donation form and send the medication to that pharmacy.

Use of a Reverse Distributor: Although rare, a nursing home and a pharmacy may have the ability for some medications to be returned through a reverse distributor. This will involve medications that were not dispensed to a specific resident and typically involve contingency supply and emergency kit medications. Nursing homes will typically send the medications back to the pharmacy, and the pharmacy will then work with the reverse distributor.

Medications That Cannot Be Used or Returned

This includes expired medications, adulterated or contaminated medications, and medications that cannot be accepted for return or donated for future use.

Medication waste generally falls into one of three regulatory categories: hazardous waste, infectious waste (commonly called biohazardous waste), and solid waste. All waste generators, including nursing homes, are responsible for separating their wastes into the correct regulatory categories and ensuring that the wastes are disposed of properly.

Please note:

- Destroying medications by placing them in the sink or toilet and flushing them into the waste water is highly discouraged, because waste water treatment plants do not remove medications. Drug components can harm plants and animals that live downstream. Furthermore, it may be illegal to flush certain hazardous medications.
- Mixing non-infectious waste with infectious waste is prohibited in Wisconsin. Accordingly, medications, empty medication bottles, or empty insulin or vaccine vials should not be disposed of in sharps containers or biohazard waste bags. It is no longer true that most infectious waste is incinerated; typically these wastes are disinfected and put in a landfill instead.

Use of a Waste Hauler for Medication Waste

Hazardous waste is subject to both state and federal regulations (see attachment section B). Hazardous waste involves items that are listed by name in the regulations or exhibit characteristics of hazardous waste. Common hazardous waste medications include epinephrine, Coumadin, vaccines preserved with thimerosal, and even certain shampoos and vitamin/minerals. An estimated 5-15 percent of medication waste may be hazardous. A reputable hazardous waste hauler can help you separate these wastes. State-owned facilities must use the state hazardous waste contractor for disposing of their hazardous waste. Facilities owned by local governments may also use the state contractor.

Infectious waste is regulated by the Wisconsin Department of Natural Resources (see attachment section C). This category includes sharps such as syringes and intravenous delivery devices that can cut or puncture the skin. If the needle can be detached from an IV delivery device in accordance with worker safety regulations, only the needle needs to be managed as infectious waste. In most cases, syringes are empty after use. However, when medication is left in a syringe or IV bag with a needle attached, you must determine if the medication is hazardous waste or not. In some cases you might have to manage a waste as both infectious waste and hazardous waste.

Medications that are not infectious or hazardous are considered general solid waste and may be handled like other garbage. The solid waste hauler may have specific containers and procedures for dealing with medications.

Controlled Substances

Controlled substances can only be in the possession of Drug Enforcement Administration (DEA) Registrants, law enforcement, consumers (nursing home residents) who have a prescription for the controlled substance, or the nursing home where the residents are residing. Physicians, pharmacies, and hospitals are usually DEA registrants. Most nursing homes are not DEA registrants.

Federal law currently prohibits controlled substances from being returned from a non-DEA registrant to a DEA registrant, such as a pharmacy. Accordingly, nursing homes that are not DEA registrants need to follow the destruction requirements in section HFS 132.65(6)(c)2 for all unused controlled substances.

If there are any questions related to medication removal, please contact Doug Englebert at 608-266-5388.

Attachment

Attachment

Section A Pharmacy Returns

Regulatory Practice: Phar 7.04 Summary

Medications from a nursing home can be returned to a pharmacy if:

- 1) Medications are in the original container;
- 2) The pharmacist determines that the medications are not adulterated or misbranded (not contaminated or mislabeled); or
- 3) In the judgment of the pharmacist there is a safety concern, e.g., medication was dispensed in error (medication error), medication is expired, or medication is defective.

Section B Hazardous Waste

Hazardous Waste contacts and rules can be accessed at <http://dnr.wi.gov/org/aw/wm/hazard/>. A publication regarding disposal of vaccines includes information about how to use the state contractor to dispose of hazardous wastes.

General information about hazardous waste in healthcare facilities, based on the federal regulations, is offered by Hospitals for a Healthy Environment (H2E), an environmental resource highly recommended for all healthcare facilities:

<http://www.h2e-online.org>

H2E's information about pharmaceutical disposal is at:

<http://www.h2e-online.org/hazmat/pharma.html>

Some other hazardous waste websites that may be helpful include:

<http://www.cdc.gov/niosh/docs/2004-165/pdfs/2004-165.pdf>

Section C Infectious Waste and trace chemotherapy waste

Infectious Waste information can be accessed at:

<http://dnr.wi.gov/org/aw/wm/medinf/>

Infectious waste regulations are mostly found in chapter NR 526

<http://www.legis.state.wi.us/rsb/code/nr/nr526.pdf>, Wis. Adm. Code.

One publication that includes basic information is entitled "For Generators of Small Amounts." Larger facilities should review "Medical Waste Reduction and the Annual Report."

Trace chemotherapy waste is regulated under s. NR 526.055, Wis. Adm. Code.